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Hepatitis C Screening

Susan Hayes

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UNIVERSITY OF NORTHERN COLORADO

Greeley, Colorado

The Graduate School

HEPATITIS C SCREENING

A Capstone Research Project Submitted in Partial Fulfillment
of the Requirements for the Degree of
Doctor of Nursing Practice

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College of Natural and Health Sciences
School of Nursing
Nursing Practice

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This Capstone Project by: Susan Hayes

Entitled: *Hepatitis C Screening*

has been approved as meeting the requirement for the Degree of Doctor of Nursing Practice in College of Natural and Health Sciences, School of Nursing, Program of Nursing Practice.

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EXECUTIVE SUMMARY

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Hepatitis C virus (HCV) is the most common blood-borne pathogen in the United States. The “Baby Boomer” population, adults born between the years 1945 and 1965, is considered a high-risk population as 75% of adults with HCV were born within this timeframe. The U. S. Preventive Services Task Force (USPSTF) made it a Grade B recommendation in 2013 for all adults born in this birth cohort to be screened for HCV even if asymptomatic. Hepatitis C virus is associated with many negative sequela including liver fibrosis, cirrhosis, hepatocellular carcinoma, and death. With successful treatment regimens available that yield a 90-100% cure rate, it is prudent and recommended to screen this birth cohort.

Eagle Ridge Medical located in Brighton, Colorado and its sister clinic located in Fort Lupton, Colorado do not currently have a standardized approach for HCV screening of this population. The researcher of this project has therefore implemented an approach for screening that includes an electronic health record (EHR) initiation of a screening alert (reminder) for the four physicians at these clinics. She also mailed an informative letter to this population that included information about the national recommendation and screening of this birth cohort in an attempt to increase screening rates at these organizations. This birth cohort includes adults born between the years 1945 and 1965.

The researcher performed a chart audit of 5% of this population that included 1,906 patients in this birth cohort ($N = 95$) both before and after implementation of this project to compare screening rates. The researcher also performed a chart audit on patients who were seen in both of these clinics six weeks prior and six weeks after project implementation; 466 patients were seen in the six weeks prior to implementation and three of them had been screened for HCV (0.6%) and 421 patients were seen in the six weeks after the project implementation and 57 of them had been screened for HCV (13.5%). The researcher anticipated screening rates would increase after this project had been implemented--they did as they rose by 4.1% using the 5% systematic sampling method and 12.9% during the six-week study period in which one positive result was noted. Many of the individuals born within this population have many years left to live if successfully treated and ultimately deserve the opportunity to be screened for HCV and treated accordingly. The effects of this study are expected to have a positive impact for the future of this birth cohort. Identifying patients who are positive for HCV will allow them the opportunity for treatment and a high potential of HCV eradication as there is a 90-100% cure rate.

DEDICATION AND ACKNOWLEDGEMENTS

I would like to dedicate this capstone project to my husband, Chad, and daughter, Emma. Their unwavering love and support has been my biggest motivator throughout these years and for that I am forever grateful.

I would also like to acknowledge and thank the members of my committee for their guidance and recommendations. To my chair, Dr. Rhonda Squires, thank you for your diligence, expertise, and quick responses to my many questions regarding this capstone project. To my co-chair, Dr. Jeanette McNeill, thank you for your support and feedback. Your advice really assisted in helping my project come together as well as it did. To my community chair, Dr. Sonya Norman, thank you for your involvement and encouragement. It has been a pleasure working with you while I implemented my capstone project at your clinic.

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LIST OF ACRONYMS

| | |
|--------|--|
| ALT | Alanine Aminotransferase |
| AST | Aspartate Aminotransferase |
| CDC | Centers for Disease Control and Prevention |
| DAA | Direct-Acting Antivirals |
| HCC | Hepatocellular carcinoma |
| HCV | Hepatitis C Virus |
| LFT | Liver Function Test |
| MDS | Micro Development Services Incorporated |
| NAT | Nucleic Acid Test |
| NHANES | National Health and Nutrition Examination Survey |
| RNA | Ribonucleic Acid |
| USPSTF | U.S. Preventive Services Task Force |
| WHO | World Health Organization |

CHAPTER I

PROBLEM STATEMENT

Introduction

Hepatitis C virus (HCV) is a blood-borne disease and a global problem that impacts multiple individuals. Hepatitis C virus was first recognized in 1974 but it was not until 1989 that it was classified by molecular means. Hepatitis C virus is a “positive-strand RNA virus that belongs to the family *Flaviviridae*” (Kesli, Polat, Terzi, Kurtoglu, & Uyar, 2011, p. 4089). Hepatitis C is either acute--with an incubation phase of about 6 to 10 weeks--or chronic in nature. In the acute phase, the individual is generally asymptomatic and rarely encounters grave diseases. Approximately 15-25% of infected individuals naturally clear Hepatitis C virus within six months of exposure without any medical management or intervention. Reasons for this spontaneous clearance of the virus are not known. The remaining 75-85% of individuals will go on to develop chronic Hepatitis C infection (Centers for Disease Control and Prevention [CDC], 2016). Chronic Hepatitis C is diagnosed when a patient is positive for the virus for longer than six months. Chronic hepatitis C causes multiple serious sequela, some can be fatal: liver fibrosis or cirrhosis, liver failure, and hepatocellular carcinoma. Hepatitis C virus is the “leading cause of death from liver disease and the most common reason for liver transplantation in the United States” (Fathauer & Meek, 2012, p. 338).

Multiple factors are involved with the risk of contracting HCV. Individuals who partake in high-risk activities such as injection drug use (either current or former and those who injected only one time if it was done many years ago) are at high risk of contracting HCV. Other individuals at risk include recipients of clotting factor concentrates made before 1987 when more progressive safe approaches of manufacturing of these concentrates were established. Recipients of solid organ transplants or blood transfusions before 1992, when universal screening measures were introduced, are also considered at high-risk. Individuals who undergo or underwent chronic hemodialysis or those with identified contact with HCV such as healthcare workers receiving a needle stick injury of someone who is positive for HCV or recipients of organs or blood from a donor who tested positive for HCV are also at high-risk. Other high-risk individuals include those who are human immunodeficiency virus (HIV)-positive and children born to mothers who are HCV-positive.

Another high-risk population is the “Baby Boomer” generation or persons born between the years 1945 and 1965. It is estimated that 75% of adults with Hepatitis C virus were born between 1945 and 1965. With this alarming percentage, it is not surprising a current recommendation by the U. S. Preventive Services Task Force (USPSTF; 2013) was for these individuals to be screened once in their lifetime even if they are asymptomatic. The USPSTF deemed this a high-risk population and a recommendation was issued in 2013, making it a Grade B recommendation to be screened. Previously, the USPSTF recommended against screening (Grade D recommendation) for adults not deemed being at a heightened risk of infection; insufficient evidence was found with regard to screening adults at high risk of infection

(Grade I recommendation). Appendix A provides Grade Definitions and Levels of Certainty Regarding Net Benefit from the USPSTF. There are various reasons why this particular population is at high risk: blood or blood product transfusions (as these products not screened for blood-borne diseases since universal screening was not implemented until 1992), intravenous drug use, and receiving unregulated tattoos. The Hepatitis C virus is transmitted through blood products (transfusions), needle stick injuries or sharing needles for various reasons including drug use, and in health care settings due to reusing items or improper sterilization of equipment consisting mostly of needles or syringes. The Hepatitis C virus can also be transmitted through sexual contact and childbirth; however, the virus is less commonly transmitted by these particular modes.

The Surgeon General, Boris Lushniak MD, provided his perspectives on testing the “Baby Boomer” population for HCV. Dr. Lushniak (2014) pointed out that over the last 15 years, limiting testing to those individuals with specific risk factors and medical symptoms has yielded limited success:

HCV is also the most common reason for liver transplantation and a leading cause of liver cancer, the fastest-rising cause of cancer-related death in the U.S. treatment for HCV is curative, however, and has been shown to reduce all-cause mortality among cured individuals. (p. 220)

The USPSTF (2015) and the CDC (2016) recommend providing a one-time screening to adults born amongst this birth cohort for HCV. With serious health complications that result from the Hepatitis C virus and a low level of diagnosis and management, it is prudent for this high-risk population, the Baby Boomers, to be tested one time in their lives. This “recommendation enables medical providers to offer HCV testing to baby boomers routinely, without the barrier of discussing stigmatized risk behaviors”

(Lushniak, 2014, p. 220). The Surgeon General urges this population be screened and tested for HCV to prevent diseases of the liver and possible death.

According to the CDC (2016), individuals in the early stages of HCV infection are typically asymptomatic but when symptoms of HCV do occur, they include fatigue, urine dark in color, fever, pale clay-colored stool, decreased appetite, abdominal pain, arthralgia, jaundice of the skin, nausea, and vomiting. If a person presents with these particular signs and symptoms, it may be advantageous to test the individual for HCV. Having an increased alanine aminotransferase (ALT), a component of the liver function test, may also be indicative of the Hepatitis C virus, or at least another type of underlying disease of the liver, and should be checked if suspicious for HCV infection.

Testing for the Hepatitis C virus is relatively simple. Initially, a serum blood draw testing for anti-HCV antibody is performed. If positive or equivocal, a serum HCV-RNA (ribonucleic acid) blood draw is performed as a positive anti-HCV antibody does not necessarily confirm the diagnosis. A positive anti-HCV only means the individual has been exposed to the Hepatitis C virus either currently or in the past. The CDC (2013) recommends “an FDA-approved NAT [Nucleic Acid Testing] assay intended for detection of HCV RNA in serum or plasma from blood of at-risk patients who test reactive for HCV antibody should be used” (Testing for HCV RNA section, para. 1). If the HCV-RNA is positive, the patient is diagnosed with active chronic Hepatitis C and may potentially receive treatment. The sensitivity and specificity of the anti-HCV antibody test are 97% and 100%, respectively. A sensitivity result of

97% indicates that the screening test will detect at least 97% of individuals who have been exposed. A specificity of 100% indicates that 100% of individuals without Hepatitis C had a negative screening test with no false-positive test results. (Joshi, 2014, p. 665)

The sensitivity of the serum HCV-RNA test varies based on which test is performed. An exact percentage could not be located; however, it is stated that “PCR [polymerase chain reaction] tests detect HCV RNA in the blood, which indicates current active infection. This type of quantitative PCR test is very sensitive and can measure as few as 5-10 IU/mL” (Franciscus & Highleyman, 2014, p. 1). The specificity of the HCV-RNA tests is 99.98% (Tillmann, 2014, p. 6702). With high sensitivity and specificity levels of the tests, it is prudent to screen individuals who are deemed at high risk in order to treat them and also decrease exposure to others who do not have HCV.

Research Question

- Q1 In adults born between the years 1945-1965 (P--Population), does a systematic population approach to Hepatitis C screening (I--Intervention) versus the provider assessing for high risk factors in the context of routine health and illness care (C--Comparison) result in increased screening (O--Outcome)?

Background and Significance of Project

The purpose of this capstone project was to implement Hepatitis C virus screening at the Eagle Ridge Medical and Fort Lupton clinics for patients born between the years 1945 and 1965--the population also known as the Baby Boomer generation (see Appendix B for Statement of Mutual Agreement). This generation has been deemed by the USPSTF (2015) as a high-risk population; therefore, it is not only prudent but also recommended to screen men and women of this population at least once in their lifetime. With successful treatment options available that currently yield a 90-100% cure rate, it is important to screen this population so they can begin a treatment regimen if warranted and not contraindicated.

Hepatitis C virus is associated with multiple negative sequela and treatment is therefore prudent and advised. Chronic “hepatitis C may eventually progress to cirrhosis, liver decompensation and hepatocellular carcinoma and many studies proved that HCV eradications reduce the risk of developing liver complications” (Calvaruso & Craxi, 2016, p. 7). Treatment methods currently exist for active chronic HCV, barring the patient does not have underlying liver disease. Furthermore, treatment therapies vary based on the six known HCV genotypes and subsequent subtypes. A gastroenterologist or hepatologist are specialty physicians who would initiate treatment therapy and monitor the effects of it. Most commonly, HCV infection is affiliated with Genotype 1. Treatment-naïve patients who express Genotype 1 are initially treated with direct-acting antivirals (DAAs) and sometimes with or without ribavirin, depending upon the medication combination. This treatment regimen is interferon-free (Chopra & Muir, 2015, Treatment-naïve Patients section, para. 1). It has been found that

HCV exhibits an extraordinarily high degree of genetic diversity--substantially greater than that of the HIV-1 pandemic--creating a major challenge for the development of both HCV vaccines and pan-genotypic drug therapies. (Messina et al., 2015, p. 78)

For this reason alone, one can see why it is important for genotype testing to be completed so the treatment may target the genotype and ensure a higher success rate of treatment. Messina et al. (2015) stated:

At present, the duration of treatment, cure rates, and the need for adjuvant interferon and ribavirin with the new DAA therapies remain dependent in part on HCV genotype and subtype. Therefore, the development of national treatment strategies using DAA therapies requires a detailed understanding of the relative HCV genotype prevalence and subtypes. (p. 78)

Direct-acting antiviral therapies generally produce more tolerable side effects than do peginterferon-alfa and ribavirin. Particularly, second generation DAA therapies such as

the protease inhibitor simeprevir are generally well tolerated and have minimal side effects such as

photosensitivity and rash [that] were reported in the simeprevir program with some serious reactions causing hospitalization. Patients should be cautioned about this risk and instructed to use sun protective measures and limit sun exposure. (Pockros, 2015, Second-generation Protease Inhibitors section, para. 5)

If the rash remains persistent or is severe in nature, it is recommended that the drug be discontinued. Transient elevations in the bilirubin level have also been noted but no reports of liver toxicity have been identified. Nausea and pruritus have also been documented as side effects of simeprevir.

In addition to medication administration, Nguyen and Hu (2014) found,

All patients with chronic HCV need education and counseling on measures which may be helpful in reducing progression of liver fibrosis. There are several studies that have reported associations between excessive alcohol use and the progression of liver fibrosis, development of HCC [hepatocellular carcinoma], and poorer response to treatment. (p. 27)

If a patient is deemed to be an alcoholic, prior treatment of the alcoholism is prudent before initiating pharmacological therapy.

In addition, if a patient does have underlying liver disease, treatment options are still available; however, they are tailored to meet the needs of the patient in an attempt to decrease the risk of causing further damage to the liver. Such treatment options include interferon-free, direct-acting antiviral medications for patients with compensated liver cirrhosis. While “interferon-free regimens appear effective and safe for such patients, treatment should generally be undertaken in consultation with an expert in managing patients with cirrhosis” (Chopra & Muir, 2015, Patients with Cirrhosis section, para. 1).

Medication options are

limited for patients with decompensated liver cirrhosis (ascites, hepatic encephalopathy, or gastroesophageal variceal hemorrhage), and antiviral treatment should only be undertaken by or in close consultation with an expert in the management of such patients, preferably at a transplant center. (Chopra & Muir, 2015, Patients with Cirrhosis section, para. 4)

This population of patients also requires frequent laboratory and clinical monitoring and observation.

According to Joshi (2014), the “universal screening recommendation is based on the finding in the National Health and Nutrition Examination Survey [NHANES] that approximately 75% of persons with a positive screening test and chronic HCV infection were born during the years 1945-1965” (p. 665). The NHANES is a chief program of the National Center for Health Statistics (NCHS) and is a part of the CDC (2014) with the responsibility of generating fundamental and health statistics for the nation (Introduction section, para. 1). With current available treatment, screening the Baby Boomer generation for the Hepatitis C virus infection is recommended and pertinent. Many individuals born within this timeframe have many years left to live if successfully treated; thus, they deserve the opportunity to be screened for HCV and treated accordingly.

National and Regional Statistics

Globally, the Hepatitis C virus infection is significant. In 2005, it was estimated that “more than 185 million people had Hepatitis C virus (HCV) antibodies (prevalence of 2.8 percent)” (Chopra, 2015, Epidemiology section, para. 1). Areas with high to low prevalence of HCV were identified. Areas with high prevalence (>3.5%) included the Middle East, central and east Asia, and North Africa. Areas with moderate prevalence (1.5 to 3.5%) included sub-Saharan Africa; south and southeast Asia; Andean, Central, and southern Latin America; Oceania; the Caribbean; western, central, and eastern

Europe; and Australasia including Australia, New Guinea, New Zealand, and nearby Pacific islands. Areas with low prevalence (<1.5%) included tropical Latin America, the Asian Pacific, and North America (Chopra, 2015).

In the United States, it is estimated that HCV is the most common blood-borne disease. With approximately 17,000 new cases of HCV infection annually in the United States, it is clear the incidence is decreasing as there were approximately 230,000 cases per year in the 1980s. The “overall incidence in 2010 was estimated to be 0.3 per 100,000. The decline relates primarily to reduced infections in injection drug users, a probable consequence of changes in injection practices motivated by a concern for HIV risk” (Chopra, 2015, United States section, para. 1). After 1985, there were almost zero cases of HCV infection due to transfusions. Deduced from analyses from the NHANES between the years 2003 and 2010 with regard to the United States, the predictable occurrence of

antibodies to HCV was 1.3 percent (reflecting an approximate 3.6 million people with past or current HCV infection), and the estimated prevalence of HCV RNA positivity was 1.0 percent (reflecting an approximate 2.7 million people with chronic HCV infection). (Chopra, 2015, United States section, para. 4)

The highest prevalence was noted in individuals born between 1945 and 1965.

With this information alone, it is prudent to identify or accept this as a current, global health problem and one that needs to be addressed. The Baby Boomer generation has a high prevalence of Hepatitis C, “sixfold the prevalence among all other adults” (Chopra, 2015, United States section, para. 7). Screening for Hepatitis C virus infection is therefore a current recommendation from the USPSTF (2015) and should be implemented in clinical practice. It is also worth noting that the researcher performed an

extensive search of the literature; however, national screening rates for HCV could not be obtained as available data did not exist.

Financial Impact

The economic burden from Hepatitis C virus infection and its affiliated sequela is discussed from a national perspective of the United States. As of 2012, the “total cost is estimated at \$6.5 (\$4.3-\$8.4) billion and it will peak in 2024 at \$9.1 (\$6.4-\$13.3) billion. The lifetime cost of an individual infected with HCV in 2011 was estimated at \$64,490” (Razavi et al., 2013, p. 2164). Yet, this cost is considerably higher amongst people who have a longer life expectancy. Appendix C provides a graph showing the total prevalence and healthcare costs with 95% Confidence Intervals. Razavi et al. (2013) stated:

The majority of peak cost will be attributable to more advanced liver diseases – decompensated cirrhosis (46%), compensated cirrhosis (20%), and HCC (16%). The maximum cost associated with mild to moderate fibrosis (F0-F3) occurred in 2007 at nearly \$780 million. The cost associated with compensated cirrhosis is expected to peak in 2022 at \$1.9 billion, while the peak cost for decompensated cirrhosis and HCC is predicted to occur in 2025, with annual costs in excess of \$4.2 billion and \$1.4 billion, respectively. (p. 2167)

It should be noted that “F0-F3” correlates with stages of fibrosis. Curry and Afdhal (2015) identified five stages:

- F0: No fibrosis
- F1: Portal fibrosis without septa
- F2: Few septa
- F3: Numerous septa without cirrhosis
- F4: Cirrhosis (Stages of Fibrosis section, para. 1).

Compensated liver disease is identified as the first two stages of liver disease wherein the individual lacks varices or ascites in Stage 1 and is positive for varices and

negative for ascites in Stage 2. Decompensated liver disease is identified as the third and fourth stages of liver disease wherein the individual might be positive or negative for varices and positive for ascites in Stage 3 and positive or negative for bleeding and positive for ascites in Stage 4 (Thornton, 2015, Approach to the Evaluation of Patients with Cirrhosis section, Figure 2).

As aforementioned, the lifetime cost of an HCV-positive person is approximately \$64,490. The lifetime cost of treating chronic hepatitis C sequela is boosted to \$205,760 (\$154,890-\$486,890) when medical cost inflation is taken into consideration (Razavi et al., 2013, p. 2167). Ultimately, it is clear to see that the Hepatitis C virus is burdensome and has a major financial impact in the United States.

Theoretical Framework

The reach, efficacy, adoption, implementation, and maintenance (RE-AIM) framework adopted by Virginia Tech (2016) was utilized for the purpose of this capstone project. The definitions of each component are discussed. *Reach* refers to the number of individuals participating in the initiative and represents the number of people the intervention will affect. *Efficacy* or effectiveness refers to the impact of the intervention on outcomes. *Adoption* refers to the number of individuals willing to partake in the intervention. *Implementation* refers to the “intervention agents’ fidelity to the various elements of an intervention’s protocol. This includes consistency of delivery as intended and the time and cost of the intervention” (Virginia Tech, 2016, Implementation section, para. 1). *Maintenance* refers to the extent of the initiative becoming routine in the practice. The goal of this framework was to encourage various individuals including evaluators and policy-makers to be aware of the importance of and pay attention to

“essential program elements including external validity that can improve the sustainable adoption and implementation of effective, generalizable, evidence-based interventions” (Virginia Tech, 2016, What is RE-AIM section, para. 1). The framework was originally devised in 1999 and is applied frequently to research and translation of evidence to practice. In their article, Glasgow, Vogt, and Boles (1999) acknowledged a need for research methods that are devised to appraise the significance of interventions:

Abrams and colleagues defined the impact of an intervention as the product of a program’s reach, or the percentage of a population receiving the intervention, and its efficacy ($I = R \times E$). We expand on this ‘RE’ (Reach X Efficacy) concept by adding 3 dimensions that apply to the settings in which research is conducted (Adoption, Implementation, and Maintenance: ‘AIM’) to more completely characterize the public health impact of an intervention. (p. 1323)

This framework is also appropriate for evaluation of other areas related to health impact including a specific population. However, there was no available research regarding application of the RE-AIM framework to HCV screening and limited available research with regard to other various diseases or disease screenings in general that were similar to this particular project.

The study conducted by Liu and Perkins (2015) was pertinent to the aim of increasing Hepatitis C virus screening rates as their study utilized the RE-AIM framework for evaluating an intervention to improve screening rates for another clinical screening recommendation. Just as HCV is the leading cause of death from liver disease and the most common reason an individual would need a liver transplantation in the United States, colorectal cancer is also a leading cause of death. The authors of this particular study included patients aged 50-74 years, which is also a USPSTF (2016) recommendation for colorectal cancer screening. The lay cancer screening navigator contacted this birth cohort by phone and by letters in the mail if contact via phone was

not achieved. Ultimately, the RE-AIM framework was utilized to evaluate the intervention and increased screening rates were identified after utilizing the lay cancer screening navigator. The results of this particular study in relation to the RE-AIM framework are discussed.

Reach: 91.9% of qualified patients were contacted by the lay cancer screening navigator; **Effectiveness:** At baseline, 28.6% of patients were already up to date on their colorectal cancer screenings and after six months, 40.5% were current and at 12 months, 42.2% were current; **Adoption:** All patients that were contacted stated they were receptive to the intervention; **Implementation:** Out of the 368 mailed fecal test kits, 41% were returned (n=151) and 17.2% were positive (n=26); **Maintenance:** There was not a significant difference amongst patients who were current at the six and 12 month marks. (Liu & Perkins, 2015, p. 280)

The RE-AIM model was expected to guide this project to achieve similar results with increased hepatitis C screening with a provider system reminder and counseling as opposed to not screening or counseling the patient at all.

In a systematic review, Compennolle et al. (2014) utilized the RE-AIM framework to explain the prospective public health impact of evidence-based multi-level interventions to enhance obesity-related behaviors in adults. This review encompassed 35 multi-level intervention studies with the following inclusion criteria:

(1) the study included at least one outcome measure assessing obesity-related behaviours (i.e. dietary, physical activity and sedentary behavior); (2) the study collected data over at least one year; and (3) the study intervention was community-based, multi-level, and targeted adults. (Compennolle et al., 2014, p. 149)

Overall, 32 intervention studies failed to report on all five components of the RE-AIM framework and one-third of the intervention studies reported on the degree of effectiveness. While most studies underreported their results within the RE-AIM framework, the framework itself was still positively evaluated.

The results of this systematic review are discussed.

- Reach--58% of the population was aware of the intervention.
- Effectiveness--89% of studies documented encouraging obesity-related behavioral (71%) or overweight and obesity-related physiological results (34%). Some of the studies reported on behavioral outcomes including physical activity or inactive behavior and other studies reported on dietary behaviors.
- Adoption--adoption of interventions was stated in all 35 studies.
- Implementation--entirety of implementation was stated in 29% of the studies ($n = 10$) and in one study, implementation percentages varied from 17% for widespread personal contacts with residents to 91% for the lending and selling of pedometers.
- Maintenance--at the individual level, eight interventions stated their health behavior at a minimum of six months after the study period. At the level of the organization, 16 interventions were continued until October of 2013.

This type of utilization of the RE-AIM framework is certainly not identical to HCV screening; however, it is significant to discuss such studies that utilize this framework to prove it does have benefit and is important in reflecting how research and evidence are translated into practice.

With regard to this capstone project, to reach the intended population (adults born between 1945 and 1965, which represents 1,906 patients), an alert in Micro Development Services Incorporated (MDS), a system utilized within the electronic health record (EHR) at Eagle Ridge Medical and Fort Lupton clinics, was created to alert the four physicians

and act as a cue to action that the patient should be informed about Hepatitis C virus screening recommendation if born between the years 1945 and 1965. The alert was a screening reminder and was generated as a task in the EHR for providers when they opened the patient's chart. Informative letters intended to notify the patient of the USPSTF's (2015) recommendation to be screened for a blood-borne disease were mailed to individuals born within this specific timeframe to give them an opportunity to be screened in case they did not have an appointment with their provider over the next several weeks.

Effectiveness was evaluated based on how many individuals born between the years 1945 and 1965 were screened for the Hepatitis C virus after the screening trigger interventions were implemented at the clinic. A chart audit was performed to establish the current screening rate of this Baby Boomer population prior to the implementation date of the screening trigger alert for the Hepatitis C virus and sending the informative postal letters to this population; the chart audits took place on 5% of the patients ($n = 95$).

Adoption of the intervention for this capstone project was achieved. Four physicians and staff members of the clinic, including the office manager, deemed this project as feasible and also valuable to the clinic. A meeting was held with regard to this capstone project and discussion ensued. The providers agreed this project was important and also agreed the clinic had not been implementing any type of standard for screening the Baby Boomer generation. The providers and staff were in agreement that the researcher could move forward with the project.

Implementation of the intervention was achieved in April of 2016 following Institutional Review Board (IRB) approval (see Appendix D). With encouragement and

support from the providers, the student anticipated adherence from the providers to ensure the patients were being screened. Dissemination of the message occurred in person as to when the providers should start screening the patients; the providers had already been educated on what the alert would look like within the EHR system. The alert cannot be turned off by the provider and appears every time the patient's chart is opened. Willingness to change provider practice and implement HCV screening was gained prior to implementation through a meeting held with the physicians. Provider compliance with the screening alert was assessed after the first week of implementation. Simply, the researcher discussed with each of the providers seven calendar days after the screening alert for HCV was created in the EHR system to gather information as to whether or not they were addressing the screening alert and subsequently screening the Baby Boomer population. All four physicians (100%) stated they had been screening this patient population and that it was helpful the EHR alert was implemented as a reminder. The researcher addressed 1,906 envelopes and worked closely with the office manager to ensure the postal letters were sent to patients born between the years 1945 and 1965. Per the office manager, the office assumed the cost of the postage and envelopes; letters were mailed in April of 2016 following IRB approval.

Maintenance of the intervention was evaluated at the initiation of the screening implementation and throughout subsequent weeks. Long-term effects of the intervention were evaluated and the researcher conveyed success of the specified intervention as screening rates increased. Discussion with the providers ensued on an as-needed basis; the researcher interviewed the providers after the screening was implemented to ensure adherence and to answer any questions as they arose.

Summary

With high prevalence of the Hepatitis C virus amongst the Baby Boomer generation (those born between the years 1945 and 1965), it was evident that screening for the infection or for the virus should be performed on this population. There are various reasons as to why this population was deemed high-risk by the USPSTF (2015) including blood or blood product transfusions prior to 1992 when universal screening was implemented, receiving unregulated tattoos, or participating in intravenous drug use. Regardless, a majority of the adults in this population might have an extended life span. With current treatment available, it was prudent for them to be screened so treatment might be initiated in a timely manner. Current treatment regimens yield an extremely high success cure rate of 90-100% and therefore should be taken advantage of if a patient is found to be HCV-positive. Overall, it is advantageous for this population to be screened in order to obtain treatment as necessary and to ensure their life expectancy is maximized.

CHAPTER II

PROJECT DESCRIPTION

Literature Review Parameters

A review of the literature was performed on articles related to Hepatitis C virus for the purpose of this capstone project. Identified databases and guideline literature included the Centers for Disease Control and Prevention, the U.S. Preventive Services Task Force, UpToDate, World Health Organization, Medline, ProQuest Nursing & Allied Health Source, and PubMed. The review of literature spanned the years from 1999-2016. Keywords included Hepatitis C virus, active Hepatitis C, chronic Hepatitis C, Hepatitis C screening, Hepatitis C treatment, Hepatitis C genotypes, Liver cirrhosis, Perinatal Hepatitis C, and Hepatitis C management. All of the researched articles and studies were credible and from well-known, evidence-based databases, journals, and websites. Types of studies included randomized controlled trials, systematic reviews, and quantitative studies. All articles, studies, and guidelines were published in English.

Summary, Critical Review, and Synthesis of Literature

The USPSTF (2015) recommended that adults born between 1945 and 1965 be screened once in their lifetime for the Hepatitis C virus. This guideline exists because most of those patients with the Hepatitis C virus are in this specific general population. Thus, it is prudent to screen this high-risk population since curative treatment is available. The USPSTF was founded in 1984 and is comprised of a

volunteer panel of national experts in prevention and evidence-based medicine. The Task Force works to improve the health of all Americans by making evidence-based recommendations about clinical preventive services such as screenings, counseling services, and preventive medications. (USPSTF, 2016, para. 1)

Such experts included those from various backgrounds including family medicine, internal medicine, behavior health, obstetrics and gynecology, nursing, and pediatrics. Their recommendations were devised after a thorough review of current peer-reviewed evidence with intentions of assisting clinicians and patients to decide together whether a preventive service was suitable for the needs of a patient (USPSTF, 2016, para. 2). The USPSTF is closely affiliated with the Agency for Healthcare Research and Quality (AHRQ) and has been since 1998. The AHRQ has been “authorized by the U.S. Congress to convene the Task Force and to provide ongoing scientific, administrative, and dissemination support to the Task Force” (USPSTF, 2016, para. 4). Annually, the Task Force reports to Congress with regard to “critical evidence gaps in research related to clinical preventive services and recommends priority areas that deserve further examination” (USPSTF, 2016, para. 5).

The CDC (2015) is another credible resource that is renowned and evidence-based:

As the nation’s health protection agency, CDC saves lives and protects people from health threats. To accomplish our mission, CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats, and responds when these arise. (CDC, 2015, CDC’s Mission section, para. 2)

This governmental resource offers clinicians up-to-date information regarding recommendations, guidelines, useful information about the diseases such as transmission patterns and risk factors, and incidence or prevalence of various diseases including the

Hepatitis C virus. A “recent CDC analysis of death certificate found that HCV-attributable deaths increased significantly between 1999-2007. CDC estimates that there were 15,106 deaths caused by HCV in 2007” (CDC, 2016, How Many Deaths Can Be Attributed to Chronic HCV Infection? section, para. 1). The CDC also reports various testing methods and recommendations on vaccinations. Overall, this resource offers a multitude of relevant and important information regarding a plethora of diseases from a national and international standpoint.

Founded in 1948, the World Health Organization (WHO; 2016) is another vital resource whose primary function is to direct and coordinate international health within the system of the United Nations. Their focal areas of work include “health systems, promoting health through the life-course, noncommunicable diseases, communicable diseases, corporate services, and preparedness, surveillance and response” (WHO, 2016, What We Do section, para. 1). The WHO understands that “early diagnosis can prevent health problems that may result from infection and prevent transmission of the virus. WHO recommends screening for people who may be at increased risk of infection” (WHO, 2015, Getting Tested section, para. 1). Recognition of high-risk populations is important to understand the magnitude of testing so individuals may be treated if warranted. The WHO goes on to mention primary, secondary, and tertiary prevention. While there is no current vaccination for the Hepatitis C virus, prevention is focused on decreasing exposure to the blood-borne virus through good hand washing, proper disposal of sharp objects including needles, proper education regarding condom use, and thorough training of health professionals (WHO, 2015, Prevention section, para. 2). Secondary and tertiary preventions include education and counseling with regard to

treatment options and the importance of immunizations against Hepatitis A and B to avoid coinfection of these viruses to protect the person's liver. These types of prevention also include prompt and appropriate medical management, including antiviral therapy if warranted, and consistent monitoring for early identification of chronic liver disease (WHO, 2015, Prevention section, para. 3).

UpToDate (2016) is another major resource that offers a wealth of information for providers:

UpToDate is an evidence-based, physician-authored clinical decision support resource which clinicians trust to make the right point-of-care decisions. More than 6,300 world-renowned physician authors, editors, and peer reviewers use a rigorous editorial process to synthesize the most recent medical information into trusted, evidence-based recommendations that are proven to improve patient care and quality. (para. 1)

The resource is unbiased as funding from pharmaceutical companies, commercial entities, and medical device manufacturers is not accepted. The resource has been utilized by more than 90% of U.S. academic medical centers and approximately 1.1 million providers in 180 countries and is affiliated with improved outcomes (UpToDate, 2016, para. 1). As aforementioned, this resource offers useful information regarding HCV.

In their article, Chopra and Pockros (2015) provided current and relevant information about various treatment options specific to the genotype and other patient factors. Multiple “studies have suggested that these regimens, even at their introductory high cost, are cost-effective for many populations, including those with genotype 1 infection or advanced fibrosis, because of their superior efficacy in clinical trials” (Chopra & Pockros, 2015, Treatment Options section, para. 2). After 12 weeks of treatment cessation, viral load should be checked to evaluate virologic response. While a

“sustained virologic response (SVR) was traditionally defined as an undetectable viral level at 24 weeks post-treatment, an undetectable level at 12 weeks post-treatment is generally maintained through week 24” (Chopra & Pockros, 2015, Assessing a Treatment Response section, para. 1). As aforementioned, management for the treatment-naïve patient with HCV Genotype 1 should include interferon-free therapies with DAAs with or without ribavirin depending on the specific combination. Chopra and Muir (2015) also included management for treatment-experienced individuals. This type of patient has

failed prior treatment with peginterferon and ribavirin and are initiating antiviral therapy now...The options are the same as for treatment-naïve patients and are ledipasvir-sofosbuvir, ombitasvir-paritaprevir-ritonavir plus dasabuvir with or without ribavirin, simeprevir plus sofosbuvir, and daclatasvir plus sofosbuvir. (Chopra & Muir, 2015, Treatment-experienced Patients section, para. 1)

In his article, Pockros (2015) provided current, evidence-based information regarding treatment of HCV. He found second generation DAAs (protease inhibitors) were proven to be better tolerated by patients, they were affiliated with more transient side effects, and they had been proven to be more effective with treating HCV genotype 1--the most common genotype in the United States. In their systematic review, Messina et al. (2015) stated, “It is important to note that the most prevalent genotype in developed economies (genotype 1) is also the most prevalent globally and should be well served by interferon-free regimens of second-generation DAA therapies with viral eradication rates of >90%” (p. 83). It is true that “treatment of chronic hepatitis C has evolved over the last two decades, with 90%-100% of individuals now being cured” (Joshi, 2014, p. 664).

Hepatitis C viral infection is prominent globally and in the United States; it is particularly prevalent amongst the Baby Boomer generation. The USPSTF (2015) recommends this population (born between 1945 and 1965) be screened for HCV at least

once in their lifetimes. The American Association for the Study of Liver Diseases/Infectious Diseases Society of America (2015) supported this recommendation with a rating of Class I, Level B (see Appendix E for classifications and descriptions). In an article for *The Journal for Nurse Practitioners*, Hande (2014) also supported the recommendation and stated,

A disproportionately high prevalence of HCV infection and HCV-related disease is associated with these adults [“Baby Boomers”]. They are at greater risk for hepatocellular carcinoma and HCV-related liver disease and comprise 73% of HCV-associated mortality. (p. 64)

The author goes on to mention that a study conducted by “Liu et al. concluded that the birth cohort screening provides nearly twice the benefit of risk-based screening alone” (p. 65).

Testing for the Hepatitis C virus includes anti-HCV antibodies and subsequent HCV-RNA if the anti-HCV antibody test is positive or equivocal. *The Ochsner Journal*, a peer-reviewed publication, has “several processes in place to ensure the *Journal’s* compliance with the Committee on Publication Ethics (COPE) and the International Committee of Medical Journal Editors ethics guidelines” (Amedee, 2015, p. 397). This journal is known to be credible and reliable and is “committed to the highest levels of professional standards and publication ethics and requires the same commitment from its authors and peer reviewers” (Amedee, 2015, p. 397). Utilized for the purpose of this capstone, this article relayed pertinent information regarding screening and testing for HCV and its cost-effectiveness.

Joshi (2014) reported:

It is often difficult to know the exact cost of medical tests because of the lack of transparency and negotiated pricing by insurance companies. Nevertheless, the screening test for hepatitis C, anti-HCV antibody, offered by testing facilities or

advertised on the internet costs \$45-\$80 for uninsured individuals and less when covered by insurance. (p. 666)

Truly, this cost is nominal when one considers the big picture of the Hepatitis C virus and its comorbidities including liver disease and hepatocellular carcinoma (HCC). With proper counseling and education, a clinician can likely assist the patient in viewing the big picture as opposed to looking at the issue from a perspective of less significance.

When one considers the cost of the disease burden of HCV itself, the cost of testing pales in comparison. The quantitative study by Razavi et al. (2013), as aforementioned, was found to be credible but did have some limitations:

The model does not explicitly account for alcohol consumption and metabolic syndrome. Frequent heavy intake of alcohol significantly increases fibrosis progression, and accelerated disease progression has been associated with metabolic syndrome. (pp. 2168-2169)

Likely, the costs associated with HCV would be even higher if these aspects were taken into account as alcohol is damaging to the liver and even more so when an individual has underlying liver disease from HCV. Razavi et al. (2013) stated:

A limitation of prevalence measures used in this analysis is that high prevalence populations may be undersampled through the NHANES. In particular, undersampling of veterans, prisoners, and the homeless would result in underestimation of the current prevalence, future disease, and cost burden. (p. 2169)

Ultimately, the costs are most likely higher than anticipated or estimated due to the sequela of HCV. Healthcare costs are projected to rise as the incidence of advanced liver disease increases. Razavi et al. (2013),

Lifetime healthcare costs for an HCV-infected person are significantly higher than for noninfected persons, and the expected cost is higher among populations with a higher life expectancy. Finally, it is possible to substantially reduce HCV infection in the US through active management (p. 2169)

Therefore, it is prudent to be screened and treated for HCV if tested positive to decrease associated costs and increase years of life.

Several studies used the RE-AIM framework to evaluate screening procedures. Glasgow, Vogt, and Boles (1999) indicated, “Public health interventions should be evaluated more comprehensively than has traditionally been done. Dimensions such as reach, adoption, and implementation are crucial in evaluating programs intended for wide-scale dissemination” (p. 1325). Evaluation of a project or implementation change is valid and necessary; often utilized is the RE-AIM framework (Virginia Tech, 2016). In their systematic review, Gaglio, Shoup, and Glasgow (2013) identified 71 articles “after excluding nonempirical articles, case studies, and commentaries” (p. e38), most of which mentioned obesity, physical activity, and disease management. The RE-AIM framework assisted in translating various types of research, including prevention and disease management, into meaningful outcomes. Gaglio et al. stated:

RE-AIM was initially designed to help evaluate interventions and public health programs, to produce a more balanced approach to internal and external validity, and to address key issues important for dissemination and generalization. Over time, it has expanded to include more diverse content areas, and is used in planning in addition to reporting reviews. More recently, it has been applied to policies and community-based multilevel interventions, as well as to reduce health disparities. (e38)

Initially, the RE-AIM framework was utilized by a group of investigators predominantly to assess research of health behaviors. Currently, it is used in the preparation stages to assess development, report outcomes, and appraise the literature in various health areas (Gaglio et al., 2013, p. e45).

A quantitative study by Liu and Perkins (2015) indicated screening rates were increased after implementation of the lay cancer screening navigator. This is not unlike

this researcher's capstone project in utilizing providers in screening patients born between 1945 and 1965 for HCV. The RE-AIM framework (Virginia Tech, 2016) was utilized for their particular study and yielded success, particularly the efficacy component. Of 1,394 qualified patients in this study, the lay cancer screening navigator communicated with 91.9% of the patients. At "baseline, 28.6% of patients were current on their colorectal screening, 40.5% at 6 months, and 42.2% at 12 months" (Liu & Perkins, 2015, p. 280). It was clear to see that implementation of this resource, the lay cancer screening navigator, increased screening rates in the population of adults between 50 and 74 years of age. Utilization of the RE-AIM framework assisted in appraisal of the significance of interventions.

A systematic review conducted by Compernelle et al. (2014) identified 35 different intervention studies and applied the RE-AIM framework (Virginia Tech, 2016) to them to ensure the authors of the studies met the components of this framework. While not all of the intervention studies were found to meet all five components, it was still deemed by the authors of this systematic review that the RE-AIM framework was positively evaluated with regard to short-term behavioral changes but would likely need more information regarding external cogency and "sustainability in order to take informed decisions on the choice of interventions that should be implemented in real-world settings to accomplish long-term changes in obesity-related behaviours" (Compernelle et al., 2014, p. 147). Although this systematic review did not identify screening rates of a particular disease and lacked positive comparison to this researcher's current project and aim of identifying increased HCV screening, it was still beneficial to observe how the RE-AIM framework was utilized amongst various studies.

The literature was limited on EHR alerts and mailing informative letters for Hepatitis C virus screening but there was pertinent literature with regard to other various screening measures. The randomized controlled trial conducted by Sequist, Zaslavsky, Marshall, Fletcher, and Ayanian (2009) provided validation for EHR alerts and mailed reminders with subsequent increases in screening rates found in their study. This study was conducted because screening for colon cancer, a leading cause of death, is a national recommendation for adults 50 years and older; it is estimated that only about 60% of eligible candidates are current on their screenings. Participants in this study “included 21,860 patients aged 50 to 80 years who were overdue for colorectal cancer screening and 110 primary care physicians” (Sequist et al., 2009, p. 364). Creating an EHR alert and mailing letters with regard to the importance of screening proved to increase rates of screenings. Sequist et al. stated:

Screening rates were higher for patients who received mailings compared with those who did not (44.0% vs 38.1%; $P < .001$). The effect increased with age: +3.7% for ages 50 to 59 years; +7.3% for ages 60 to 69 years; and +10.1% for ages 70 to 80 years ($P = .01$ for trend). Screening rates were similar among patients of physicians receiving electronic reminders and the control group (41.9% vs 40.2%; $P = .47$). However, electronic reminders tended to increase screening rates among patients with 3 or more primary care visits (59.5% vs 52.7%; $P = .07$). Detection of adenomas tended to increase with patient mailings (5.7% vs 5.2%; $P = .10$) and physician reminders (6.0% vs 4.9%; $P = .09$). (p. 364)

Overall, it was found that “mailed reminders to patients are an effective tool to promote colorectal screening, and electronic reminders to physicians may increase screening among adults who have more frequent primary care visits” (Sequist et al., 2009, p. 364).

In another randomized controlled trial, Ayanian, Sequist, Zaslavsky, and Johannes (2008) aimed to discover if mailed reminders to physicians would increase their patients' overdue colonoscopies. Not unlike an EHR alert for HCV, physicians were reminded of

important screening opportunities for their patients. This study included 141 physicians in Massachusetts in 2006 and 717 patients “who had colorectal adenomas removed during 1995 through 2000 and no follow-up colonoscopy identified via automated review of electronic records through March, 2006” (Ayanian et al., 2008, p. 762). Ayanian et al. stated:

The use of colonoscopy and detection of new adenomas or cancer were assessed at 6 months by a blinded medical record review in all patients. Among 358 patients whose physicians received reminders, 33 (9.2%) patients underwent colonoscopy within 6 months, compared with 16 (4.5%) of 359 patients whose physicians did not receive reminders ($P=0.009$). In prespecified subgroups, this effect did not differ statistically between 2 primary care networks, elderly and nonelderly patients, or women and men (all $P>0.60$ by Breslow–Day test). New adenomas or cancer were detected in 14 (3.9%) intervention patients and 6 (1.7%) control patients ($P=0.06$), representing 42.4% and 37.5% of patients who underwent colonoscopy in each group, respectively. Despite using advanced electronic health records to identify eligible patients, 22.5% of enrolled patients had a prior follow-up colonoscopy ascertained only by visual record review, and physicians reported 27.9% of intervention patients were no longer active in their practice. (p. 762)

Ultimately, for patients who were diagnosed with colorectal adenomas, mailing reminders to their physicians proved to increase colonoscopy screenings.

Summary

This extensive literature review provided evidence-based, relevant, and current information regarding the Hepatitis C virus. It is clear that HCV is a current problem both globally and nationally and a virus affiliated with six different genotypes. The HCV genotype 1 is the most prevalent in the United States and has been found to respond well to treatment with second generation DAAs. These pharmaceutical interventions generally yield more transient and therefore more tolerable side effects with a 90%-100% cure rate. Screening the identified birth cohort would be advantageous since prevalence of HCV amongst this population currently far exceeds any other birth cohort. While the

literature was limited with regard to specific increases in HCV screening rates via letters or alerts in the EHR, literature did exist for other various screenings including colorectal cancer screening, which yielded higher rates of screening when letters were mailed to patients or when a patient attended three or more visits with their primary care providers.

Project Objectives

The main objective of this project was to increase providers' awareness of the USPSTF's (2015) recommendation to screen for HCV with the focus on subsequent and projected increased screening rates measured through the EHR of the identified birth cohort (adults born between 1945 and 1965). Increasing providers' awareness of this recommendation is important so they understand the magnitude of HCV screening for the identified birth cohort as 75% of adults with HCV were born during this time frame. Eagle Ridge Medical and the Fort Lupton clinic currently do not have a standardized approach to screen for HCV. After a meeting with the providers of the clinic, it was brought to this researcher's attention that only select patients had been screened and generally only if they had physiological symptoms that warranted the screening measure. High-risk behavioral history questions of the patients such as intravenous drug or if the patient had received a blood or blood product transfusion before the year of 1992 were also not asked on a regular basis. It is important to understand the reasoning behind screening this birth cohort as adults in this particular birth cohort are "5 times more likely than other adults to be infected. In fact, 75% of adults with Hepatitis C were born in these years" (CDC, 2012, This Hepatitis C Testing Recommendation Was Made Because section, para. 1).

The objective was carried out by creating an alert reminder in the EHR for providers to screen for HCV if the patient was born in the years 1945 to 1965. Informative letters notifying the patient of the USPSTF's (2015) recommendation to be screened for a blood-borne disease were also mailed to the Baby Boomer generation in case they had not made an appointment at the clinic over the next several weeks and would not have been given the opportunity to be screened for HCV otherwise. With the high accuracy of testing results and current treatment available, screening this high-risk population is important and warranted. Identifying seropositive individuals not only gives the potential to treat and prolong a certain individual's life but also provides an opportunity for education regarding transmission and how to decrease the likelihood of spreading the virus to a loved one, friend, or stranger.

CHAPTER III

PROJECT DESIGN

Evidence-Based Project Plan

This capstone project was implemented due to the fact that the Eagle Ridge Medical and Fort Lupton clinics did not currently have a standardized implementation process of screening all adults born between 1945 and 1965 for HCV as recommended by national screening guidelines; 100% of the physicians at this clinic ($N = 4$) agreed to take part in this project by screening the specified patient population for HCV. The purpose of this project was to increase screening rates of HCV in this birth cohort by implementing an alert in the EHR (a screening reminder to act as a cue to action for the providers) for this birth cohort, which prompted providers to screen and counsel these patients on HCV. Informative postal letters indicating the patient was recommended by a group of national experts to be screened for a blood-borne disease were also mailed to this birth cohort if an appointment was not achieved during the initial project implementation to ensure this entire population of Eagle Ridge Medical and the sister clinic in Fort Lupton was being reached. The providers at Eagle Ridge (who are also affiliated with the Fort Lupton clinic as two are the same providers at both clinics) requested the letter be generic and it included the national recommendation from the USPSTF (2015) to be screened for a blood-borne disease (see Appendix F for the letter). Discussion with the office manager and providers occurred prior to implementation in the

EHR to clarify the practice change and discuss its significance. This researcher provided the background of the literature review to exemplify the evidence-based research supporting this practice change. A fact sheet (see Appendix G) from the CDC (2012) was also made available to patients who were counseled or screened for HCV. This fact sheet was available to patients in the lab of the clinic where they underwent a peripheral blood draw for testing.

The USPSTF is a government entity that guides medical practices and providers. Eagle Ridge Medical and the sister clinic in Fort Lupton are not exempt from this and are clinics with a goal to adopt standards of practice to ensure the best possible care is being delivered to their patients. Since Hepatitis C virus screening is a Grade B recommendation (USPSTF, 2013) and something not currently being done at Eagle Ridge Medical and the Fort Lupton clinics, the office manager approved this practice change and believed it to be pertinent. Other renowned resources include the CDC (2016) and the WHO (2015), which also support the screening recommendation from the USPSTF (2015). The Baby Boomer generation has been proven to be a high-risk population and a one-time screening is recommended. Current pharmacological treatment regimens exist and yield high success rates of viral eradication. Therefore, it behooves Eagle Ridge Medical and the Fort Lupton clinic to offer HCV screening to this birth cohort that utilizes their clinic for medical care and refers for treatment if warranted.

Timeline

The timeline for this capstone project was as follows:

- Meeting with office manager and four providers at Eagle Ridge Medical and the Fort Lupton clinics to increase awareness of USPSTF's (2015)

recommendation and EHR implementation of screening reminder for HCV--
February 2016

- Proposal defense/IRB approval of capstone--March 2016/April 2016
- Mail informative letters to patients (following IRB approval)--April 2016
- CDC (2012) fact sheet handouts available in the lab of the clinic--April 2016
- Chart audit prior to implementation of screening reminder in EHR and mailing of informative letters to obtain baseline screening rate--April 2016
- Chart audit after implementation of screening reminder in EHR and informative letters mailed to obtain subsequent screening rate--May 2016
- Program development--March to June 2016
- Capstone defense--June 2016

Resources, Personnel, Technology, and Budget

Personnel resources include one office manager, four physicians, and five medical assistants (MAs). The office manager is in charge of ensuring successful implementation of the screening reminder into the EHR (see Appendix H for an example of a typical screening reminder) and also ensures implementation of the flow sheet. Note that the screening reminder example in Appendix H is of a test patient and does not identify an actual patient. The screening reminder for HCV screening for the providers says “Hepatitis C Screening.” The flow sheet is a table within the EHR that informs the provider if the patient has or has not been screened or if the patient refuses screening. The physicians execute counseling and screening methods of the identified birth cohort and acknowledge the screening reminder in the EHR. The medical assistants support the

practice change by executing the standing order for the anti-HCV antibody test implemented for patients who requested testing based on the recommendations in the informative letter. In this case, the patient does not need to schedule an appointment with their provider (unless they desire to do so) and could simply come to the clinic for the blood draw. All four physicians (100%) agreed upon implementation of a standing order for the MAs to draw the anti-HCV antibody in the lab. The CDC fact sheet was also disseminated to patients in the lab per request of the office manager and physicians. Normal results will be mailed to the patients. Patients who test positive for HCV will be called and instructed to make an appointment with their provider. Positive results will not be relayed over the phone as the patient will be instructed to come to the clinic for an appointment. The administrative staff of the clinic will ensure each new patient completes the Acknowledgement of Notice of Privacy Practices and HIPAA Consent upon their initial appointment that is updated annually at the clinic by the patient (see Appendix I for a copy of the form). While there is a section on the form that identifies the patient's consent to discuss care/test results, sensitive information such as results from HCV testing are not disclosed.

Other sensitive information not disclosed included but was not limited to human immunodeficiency virus (HIV) results, sexually transmitted disease (STD) results, or pregnancy test results. A section on this form also gives the patient a "yes" or "no" option with regard to whether confidential information can be left on voice mails or answering machines. However, sensitive information or results such as the ones aforementioned are not left on a voice mail or answering machine regardless of the patient's consent on this form. To ensure the staff is speaking to the correct patient

before relaying information in general, the patient is asked his/her full name and date of birth and the staff verifies the information on the patient's chart in the EHR before any results are given. The author of this project protected identity of patients by not disclosing any protected health information (PHI) including name, date of birth, diagnosis, social security number, address, or any other sensitive information she had access to from the EHR. The utilized data for collection purposes were strictly limited to a percentage of the population screened prior to and after implementation of the EHR alert (screening reminder) and did not contain any PHI of any nature.

Additional equipment other than what was already stocked at Eagle Ridge Medical and the Fort Lupton clinics was not necessary. The labs at the clinics were already stocked with the appropriate materials needed for HCV testing including tourniquets, serum tubes, venipuncture needles, vacutainers, gauze, and tape. The clinic utilizes the EHR system; costs for creating an alert for the HCV screening reminder and the flow sheet were assumed by the clinic.

Items necessary for collecting of blood for the HCV tests were already available in the setting and further costs were not projected to increase as the clinics had a plethora of these specific supplies. The only projected cost of this project was the informative postal letters mailed to patients born between the years 1945 and 1965. The current cost of a stamp was \$0.49 and the office manager agreed to purchase these stamps with the budget from the clinic. While exact costs for these items were unavailable due to the fact that items were mailed from the main affiliated hospital, Platte Valley Medical Center, costs were estimated to be less than \$2,000 and were assumed by Eagle Ridge Medical and its sister clinic in Fort Lupton. Costs were also taken into account regarding letters

that would be mailed notifying patients of all normal HCV results. Currently, 1,906 persons born between 1945 and 1965 are patients of Eagle Ridge Medical at the Brighton and Fort Lupton locations. The Fort Lupton location is being used as well because two of the physicians at Eagle Ridge Medical in Brighton float to this clinic during the week and therefore many patients utilize both clinics. Again, while it is difficult to produce an exact cost of the anti-HCV antibody test for an insured patient, an uninsured patient would assume \$47.00. This researcher obtained the cost of the test from the billing department at Eagle Ridge Medical and the Fort Lupton clinics.

Additionally, no risks or threats were affiliated with this capstone project. Benefits of implementation of this project included increased provider awareness of the USPSTF (2015) recommendation to screen the Baby Boomer population for HCV and the significance of the screening as current treatment is available that yields a high success cure rate.

Evaluation Plan

Evaluation of the plan, which included two phases (pre- and post-intervention of the project), was assessed by first performing a chart audit of 5% of the 1,906 established patients at Eagle Ridge Medical and the Fort Lupton clinics ($n = 95$) and a chart audit of patients seen at the clinics six weeks prior to the implementation date who were born between 1945 and 1965 to establish a baseline screening rate for HCV among eligible patients. This occurred prior to implementation of the alert reminder in the EHR and mailing of informative letters to patients. This number was compared to a chart audit of 95 patients, representing 5% of the 1,906 established patients; these patients were seen at the clinics six weeks after the implementation date screened for HCV, after

implementation of the alert reminder in the EHR, and after mailing informative letters to this birth cohort. This researcher tracked absolute screening results of both the alert reminder in the EHR and mailing of letters and therefore did not discriminate between the two methods in the results section. It was this researcher's assumption that screening rates of patients for HCV would increase in this birth cohort after implementation of the alert reminder in the EHR was created and informative letters were mailed. When a patient was screened for HCV, the provider or administrative staff updated information within the EHR system to prevent duplicative screening of patients if they came to the clinic for subsequent visits after having been screened once before.

This researcher protected each patient's identity during the chart audits (prior to and after this project implementation) by ensuring the audits were done at the clinic utilizing only a clinic-approved computer and ensuring the audits were being performed in an area from which patients were restricted. The audits took place within one of the physician's offices; sensitive information such as a patient's name, birth date, home address, or phone number was not generated in the results or findings of this capstone. This researcher did not discuss any sensitive patient information with any employee or provider of the clinic who was not on a "need-to-know" basis and did not discuss any information with any individual outside of the clinic setting. The researcher adhered to the strict policies of HIPAA and fully understood the ramifications.

Summary

All four physicians involved in this study understood that the USPSTF's (2015) recommendation of screening adults born between 1945 and 1965 for HCV was useful and important. By educating the providers, this researcher successfully increased the

providers' awareness of HCV and therefore the importance of screening this birth cohort. Eagle Ridge Medical and the Fort Lupton clinics did not currently have a screening alert (reminder) established within the EHR. The four physicians admitted they had not screened this birth cohort before based on the USPSTF's recommendation and without alarming medical symptoms that might have prompted them to screen these adults in the past. The recommendation to screen this birth cohort was without regard to medical symptoms and therefore asymptomatic adults were recommended to be screened. Ultimately, this researcher anticipated that screening rates would increase once the screening alert (reminder) was implemented within the EHR and as a result of mailing informative letters to patients born between 1945 and 1965. The letter was generic based on the physicians' requests, included the USPSTF's recommendation for screening of a blood-borne disease, and informed the patient to ask about the screening at his/her next appointment. Costs affiliated with this project were projected to be less than \$2,000 and were mainly associated with envelopes and postage to mail the informative letters and normal results. The clinic utilized the EHR so further costs from support and changes within this system for the development of the screening reminder (alert) and flow sheet were not incurred. Overall, this researcher anticipated an increase in screening rates amongst this birth cohort after implementation of the screening alert (reminder) in the EHR was executed. It was also anticipated that the screening rates would increase once patients received the informative letters from the clinic and came in to have their blood drawn to test for HCV.

CHAPTER IV

RESULTS AND OUTCOMES

The objective of this capstone project was to increase screening rates of patients born in the “Baby Boomer” generation (born between the years of 1945 and 1965) at the Eagle Ridge Medical (in Brighton) and the Fort Lupton clinic. This chapter presents the results based on the planned evaluation. Two different methods were utilized for establishing baseline screening rates; they included a chart audit of 5% of the whole population of adults born between 1945 and 1965 at both clinic sites and a chart audit on all patients born in this timeframe who were seen at both of these clinic sites in the six weeks prior to informative letters being mailed and the alert reminder for HCV screening in the EHR. These two different methods were utilized to gather screening rates on active patients (patients seen in the last six weeks) and a random chart audit of all registered patients to reach less actively seen patients.

Results Linked to Problem Statement and Evaluation Plan

A chart audit was performed on 5% ($n = 95$) of the 1,906 patients of Eagle Ridge Medical and the affiliated Fort Lupton clinic as two of the physicians at Eagle Ridge Medical floated to this sister clinic a couple of days per week. The list of patients was compiled from MDS and initially, 1,933 patients were listed. Subsequently, 27 patients were excluded for various reasons: 18 were duplicate patient entries into the EHR, four

were deceased, three were discharged from the practice, and two were test patients. Data for the chart audit were collected by auditing every 10th patient in alphabetical order. Of the 95 patients audited for the purpose of this chart audit, three patients had been screened already, which resulted in 3.2% of this population. Three different physicians ordered the anti-HCV antibody tests on their patients; one of the physicians worked at Eagle Ridge Medical while the other two physicians worked at an affiliated internal medicine office in Brighton and another family practice clinic located at the Reunion site in Commerce City. All three of these patients were screened in the last two years. One of the physicians ordered the test because of an increased liver function test (LFT)--ALT of 77 (normal range: 21-72) and aspartate aminotransferase (AST) of 66 (normal range: 17-59). Another patient was tested due to a slight increase in LFTs (ALT of 59 and AST of 45) per the physician. The third patient was tested due to unknown reasons. The physician did not justify or state the reason in the affiliated progress note. All three of the patients tested from this chart audit were negative for the Hepatitis C virus.

Four hundred sixty-seven patients were seen in the six weeks before project implementation and born within the time frame of 1945 to 1965. One patient was excluded from the review due to death within the time period, which left 466 patients for the purpose of this chart audit to establish baseline screening rates. Three of the 466 patients seen in the past six weeks were screened for HCV, which meant 0.6% of this population was screened for the Hepatitis C virus prior to implementation of the screening alert in the EHR and mailing of informative letters. One patient requested the HCV testing as well as screening for HIV and STDs. The reasoning behind this request was not documented in the record. The second patient requested testing for HCV

because, per the physician's progress note, he admitted to having unprotected sexual encounters with multiple partners and was experiencing fatigue. The third patient was tested for HCV due to a rash and his significant other requesting he be tested for STDs that included blood-borne diseases. All three patients tested for HCV in the past six weeks had negative results and all three physicians who ordered the anti-HCV antibody tests worked at Eagle Ridge Medical.

An alert reminder was created in the EHR for the providers to screen for HCV if a patient was born in the years 1945 to 1965. Informative letters intended to notify the patient of the USPSTF's (2015) recommendation to be screened for a blood-borne disease were also mailed to the Baby Boomer generation in case they did not achieve an appointment at the clinic over the next several weeks and therefore would not have been given the opportunity to be screened for HCV otherwise.

The researcher met individually with all four physicians seven calendar days after initiation of this project (implementation of the alert within the EHR and mailing of informative letters). The researcher met with the physicians to ensure they were acknowledging the alert in the EHR and subsequently screening the Baby Boomer population. All four physicians (100%) stated they had been screening this population and the alert in the EHR was helpful as a reminder. All of the physicians agreed and admitted that by the end of the appointment with the patient, sometimes they would forget to screen the patient as the alert popped up immediately when the patient's chart was opened and disappeared after one acknowledged it. Regardless, all four physicians felt the screening rate for each of them had definitely increased. They denied having any questions or concerns at that time.

A chart audit was performed on 5% of the 1,906 patients ($n = 95$) of the Eagle Ridge Medical and Fort Lupton clinic at the end of the six-week mark. Results of the chart audit were collected by auditing every 10th patient in alphabetical order following the first 95 patients who were previously audited. Of the 95 patients audited, seven of them had been screened (7.3%), an increase of 4.1% in comparison to the similar chart audit completed (which was 3.2%) prior to initiation of the interventions. Of the seven patients screened, three were screened in the past six weeks due to the recommendation as they were born between the years 1945 and 1965 and the remaining four were screened for various reasons. One patient was screened because this individual worked with HIV-positive children and requested HIV testing as well as HCV testing. Another patient, a widow, was screened per request for STD testing including blood-borne diseases in case this person pursued another relationship. Per the physician's progress note, this patient denied symptoms or concerns regarding exposure. The other patient was tested due to a slightly increased AST (49) with a normal range of 14-36. The ALT was within normal limits (39) and this patient, per this physician's progress note, denied use of alcohol. All seven patients screened from this chart audit tested negative for the Hepatitis C virus. All three physicians who ordered these tests worked at Eagle Ridge Medical in Brighton and these patients were all screened within the last three years.

A chart audit was performed six weeks after implementation of the screening reminder alert in the EHR and mailing of informative letters. The chart audit was performed on 421 patients seen in the previous six weeks. Of the 421 patients seen, 57 (13.5%) were screened for HCV due to the recommendation. There was a 12.9% increase from the initial baseline screening rate of 0.6%. Of the 57 patients screened

after implementation of the alert in the EHR and mailing of informative letters, 56 patients tested negative for the Hepatitis C virus and one patient tested positive (reactive to hepatitis C) with the subsequent genotype 1a and an RNA of 14,200,000 IU/mL, which meant the patient had active, chronic Hepatitis C. Per the physician, the testing was done due to the recommendation but the patient did admit to having chronic fatigue as well. The researcher of this project investigated the patient's comprehensive metabolic panel and the patient had an ALT of 43, AST of 25, and a total bilirubin level of 0.4. All of these test results were within the normal range. Table 1 provides the screening rates prior to and after project implementation

Table 1

Screening Rates Prior to and After Project Implementation

| | Pre-Project Implementation | Post-Project Implementation |
|--|-------------------------------|--------------------------------|
| Total Clinic Population Screening Rate | | |
| Patients born between 1945-1965 | 1906 | 1906 |
| Population screened using 5% (n = 95) systematic sampling | 3 (3.2%) | 7 (7.3%) |
| Clinic Patients Seen by Provider Screening Rate | | |
| Patients seen in clinic in 6-week study period | 466 | 421 |
| Patients seen | 3 (0.6%) | 57 (13.5%) |

Extent to Which Objectives Were Achieved

It is clear to see the objectives of this capstone project were achieved. The physicians agreed they were all screening the patient population based on the USPSTF (2015) guidelines and screening rates increased. The researcher of this capstone project expected rates to increase more than 13.5%; however, perhaps with a longer timeframe, rates would have increased even more. The alert reminder in the EHR was effective in increasing the screening rate, although it had limited reach in the clinic's population. This researcher assumes the screening will continue to increase, even though the alert in the EHR for HCV screening has been deleted, because of the informative letters mailed to this patient population as this was the best method of reaching the majority of the patients. The researcher anticipates some of the patients who received the letters might not have come to the clinic yet or were waiting until a future appointment (e.g., a physical) until they asked what the screening entailed.

Key Facilitators and Barriers

Key facilitators primarily included the physicians of Eagle Ridge Medical and the Fort Lupton clinic who agreed to screen this patient population based on USPSTF's (2015) recommendations. All four physicians (100%) stated compliance with screening the patients born between 1945 and 1965 and found it was helpful to have a reminder (screening alert in the EHR) to prompt them. The researcher identified an increase in screening rates both due to the physicians screening the patients during their appointments and due to the informative letters mailed to the patients. The researcher combined results of patients being screened in the clinic and letters mailed in collecting this data; therefore, she was unable to determine which patients were screened for HCV

due to the providers doing so from the alert reminder in the EHR or from the informative letters the patients received in the mail.

The front desk staff and the Medical Assistants were also key facilitators as they received multiple phone calls with regard to the letters and answered them appropriately by telling the patients they did not need to accomplish an appointment with their provider if they simply wanted to come to the clinic for the blood draw. The Medical Assistants informed this researcher that they drew multiple patients' blood for HCV. They mailed normal results to the patients who had normal (negative) findings but for the patient who was found to be positive for HCV, they called the patient to inform this person to make an appointment with their physician. The Medical Assistants did not relay the positive result over the phone as this was the physician's responsibility. The Medical Assistants also offered the Fact Sheet from the CDC (2016; see Appendix G) that was made available in the lab of the clinic for patients.

The researcher was a key facilitator as she made multiple contacts with MDS in ensuring the EHR trigger alert (reminder) was implemented appropriately and was activated for all patients born between 1945 and 1965 at the Eagle Ridge Medical and Fort Lupton locations. She spent 45+ hours hand-addressing all 1,906 envelopes, printing the letters, stuffing the envelopes with the letters to patients born between these years, and ensuring the letters were mailed to patients. The researcher was readily available for any questions or concerns the office staff had. No significant barriers were identified with this capstone project although it would have been more cost and time efficient if the EHR could have generated letters and mailing labels for not only this informative letter but any future informative letters.

Recommendations

Overall, the researcher deemed this capstone project as beneficial and successful in increasing the screening rates for HCV of the Baby Boomer population. The physicians and office manager all agreed this project was useful and worthwhile and the physicians made great efforts in screening the patients during appointments. They relayed the importance of the EHR screening reminder alert and said it did indeed prompt them to screen patients. The Medical Assistants were an essential part of this project as they received “walk-in” patients who received letters in the mail and the front desk staff answered multiple phone calls with regard to the letters and gave patients appropriate information.

There were no unintended consequences of this capstone project but the researcher, as she anticipated, identified a significantly higher increase of screening rates for the Hepatitis C virus amongst the Baby Boomer generation in the six-week period. The researcher assumed the screening rate would increase more after implementation of the screening alert (reminder) in the EHR and mailing of informative letters and anticipates the screening rate will continue to rise over time. The researcher noted a 4.1% increase of screening rates when she did the chart audit on 5% of the 1,906 patients ($n = 95$) at the Eagle Ridge Medical and Fort Lupton sites and a 12.9% increase when she did the audits of patients seen in the six weeks prior to and six weeks after project implementation (alert reminder in the EHR and mailing of informative letters). While the physicians stated they were screening this patient population, they all admitted they sometimes forgot to screen a patient for HCV as the alert reminder in the EHR only appeared upon opening the patient’s chart. It is understandable how a provider might

forget to screen the patient or order the test at the end of the appointment. The physicians informed this researcher that many patients who were offered the screening had declined it for various reasons (such as they were already screened once before or they did not feel they were considered high-risk). However, this author was not able to capture an exact number of patients who refused screening because the physicians did not consistently annotate this in their progress notes. Per the physicians' progress notes, the researcher of this capstone noted eight documented patients who declined the screening. The reasons varied including three patients felt they were not high-risk, four patients stated they had been screened before, and one patient stated they did not have time for a blood draw that day but might return to the clinic at a later time.

CHAPTER V

RECOMMENDATIONS AND IMPLICATIONS FOR PRACTICE

The objectives of this Capstone project were to increase screening rates of patients born between 1945 and 1965 at the Eagle Ridge Medical and Fort Lupton clinic sites. These objectives were carried out by implementing an alert reminder in the EHR to act as a cue for providers to screen this high-risk population and also by mailing informative letters to the entire patient population at both of these sites ($N = 1,906$) to ensure all patients born in this timeframe were being reached. In this chapter, the researcher provides recommendations for the clinics where this project was implemented and how the project would likely prove to be beneficial in further increasing screening rates if continued. The researcher also includes recommendations regarding implementation of this project in other family practice settings as it is applicable and beneficial.

Recommendations

It is this researcher's recommendation that the project conducted on screening the Baby Boomer generation (adults born between the years 1945 and 1965) for the Hepatitis C virus at Eagle Ridge Medical and the Fort Lupton clinics be continued. The alert reminder in the EHR was turned off after the six-week mark; however, it would likely be beneficial to keep this alert in place to prompt and remind the providers to screen this patient population for HCV. This would be especially useful for new patients of the

clinic and for patients the letters did not reach. Out of the 1,906 letters mailed, 90 of them were returned (4.7%) primarily due to the patient no longer living at a specified address. Other recommendations this researcher makes include:

- The informative letter be included with each “new patient” packet made available at the clinic for patients born between the years 1945 and 1965. This way the entire Baby Boomer population at these family practice clinics will be reached including new patients as letters were already sent to established patients born in this timeframe.
- The alert reminder be generated for the Medical Assistant so the alert can be addressed and consent obtained for ordering the test to save the provider time. The provider would then see the test had been ordered and not duplicate it.
- Implement a change within the EHR so the alert reminder is generated under the “Plan” page. This is where the providers order tests and prescribe medications and would be a beneficial area within the EHR to have this alert because the provider could mention it to the patient and order it if the patient was willing to undergo the testing.

It is understandable that these types of newer national recommendations take time to integrate into practice. It is the researcher’s hope that if this screening recommendation for HCV is continued in the EHR, the providers and Medical Assistants will become accustomed to screening the Baby Boomer population without having the alert reminder prompt them. Implementing the alert in the “Plan” of the EHR is a type of automatic screening similar to colonoscopies or mammograms; these screenings seem

engrained in most providers and are generally offered without needing the EHR alert reminder. There are no ongoing evaluations needed for phases outside the scope of this DNP project at this time.

Within the framework of the organization's strategic plan, the providers and the office manager would need to be in agreement that this recommendation of screening adults born between 1945 and 1965 is useful and beneficial, especially from a long-term aspect. The office manager and providers are aware treatment is available for individuals who have active, chronic HCV and understand referrals to gastroenterologists or hepatologists are deemed warranted and necessary for a patient to begin a treatment regimen. If screening the Baby Boomer population for HCV was to continue, the office manager would need to disseminate the message to the Medical Assistants and the front desk staff to ensure everyone is aware of the screening and to require the informative letters be a part of a "new patient" packet. The Medical Assistants would likely be responsible for ensuring the lab area was always stocked with the Fact Sheet from the CDC (2016) and the lead Medical Assistant would perhaps be responsible for ensuring this Fact Sheet was updated by looking at the CDC website at least quarterly.

This capstone project would definitely be applicable in other family practice settings. It is a national recommendation from the USPSTF (2015) to screen all Baby Boomer generation patients at least once in their lifetime. As seen from the researcher's chart audits at Eagle Ridge Medical and Fort Lupton clinics, a small amount of patients had been screened prior to implementation of this project. The researcher anticipates most clinics in the nation do not have a standardized approach for screening this population for HCV, especially if the patient is asymptomatic. It is important to

understand that this population is deemed high-risk and therefore screening is warranted and recommended. Education would likely need to be delivered regarding not only the importance of the screening but also with regard to treatment availability and the high success cure rate (90-100%).

Contribution to Personal Goals

This researcher felt this capstone project contributed to her personal goals as an advanced practice nurse and as a leader. She felt she was organized and focused; she effectively disseminated the message regarding Hepatitis C screening in the Baby Boomer population by creating the alert within the EHR system and mailing letters to the entire patient population at the Eagle Ridge Medical and Fort Lupton clinic sites. Often times, education is spread by “word of mouth” and it was this researcher’s thought that patients who heard about HCV screening (either through an appointment with their provider or receiving an informative letter in the mail) would then discuss it with other people including family members or friends and, subsequently, the recommendation of this screening would be dispersed. After conducting this type of capstone project, this researcher is excited about the potential of implementing similar types of evidence-based changes amongst practices in the future. Eagle Ridge Medical is an innovative clinic that certainly seems to embody the importance of maintaining the most current recommendations and evidence in order to provide the best possible care to the patients they serve. It is this researcher’s hope that most family practice clinics are similar to Eagle Ridge Medical in this regard.

Summary

Screening this high-risk population, adults born between the years 1945 and 1965, for the Hepatitis C virus is a Grade B recommendation from the USPSTF (2015) and one worth doing. The researcher of this capstone project deemed it successful as screening rates increased after implementation of the alert reminder in the EHR, prompting the physicians to screen this high-risk population, and mailing of informative letters to capture the entire patient population at the Eagle Ridge Medical and Fort Lupton clinic sites. It is likely other family practice clinics would benefit from screening the Baby Boomer generation as well as it would allow the opportunity for treatment if patients tested positive for HCV. The researcher of this capstone project felt this project was successful even though a drastic increase of screening rates was not seen. An increase was seen overall and was particularly notable with the short, six-week timeframe. Perhaps a longer timeframe would have proven to be more successful in increasing screening rates. With that being said, however, the researcher thoroughly enjoyed working on this project and felt it enhanced her personal leadership goals by effectively implementing a beneficial change amongst a family practice setting.

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APPENDIX A
GRADE DEFINITIONS

| Grade | Definition | Suggestions for Practice |
|-----------------------|--|---|
| A | The USPSTF recommends the service. There is high certainty that the net benefit is substantial. | Offer or provide this service. |
| B | The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. | Offer or provide this service. |
| C | The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small. | Offer or provide this service for selected patients depending on individual circumstances. |
| D | The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. | Discourage the use of this service. |
| I Statement | The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined. | Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms. |

Level of Certainty

| Level of Certainty* | Description |
|---------------------|--|
| High | The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies. |
| Moderate | The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as: <ul style="list-style-type: none"> • The number, size, or quality of individual studies. • Inconsistency of findings across individual studies. • Limited generalizability of findings to routine primary care practice. • Lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion. |
| Low | The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: <ul style="list-style-type: none"> • The limited number or size of studies. • Important flaws in study design or methods. • Inconsistency of findings across individual studies. • Gaps in the chain of evidence. • Findings not generalizable to routine primary care practice. • Lack of information on important health outcomes. More information may allow estimation of effects on health outcomes. |

Source. U.S. Preventive Services Task Force (2013).

APPENDIX B
STATEMENT OF MUTUAL AGREEMENT

Statement of Mutual Agreement
University of Northern Colorado
Doctorate of Nursing Practice Capstone Project
Susan Hayes
January 10, 2016

The purpose of the "Statement of Mutual Agreement" is to describe the shared view between Eagle Ridge Medical clinic, as well as the affiliated Fort Lupton clinic, and Susan Hayes, DNP Candidate from University of Northern Colorado, concerning her proposed capstone project.

Proposed Project Title: Hepatitis C Screening

Brief Description of Proposed Project: To implement a population based intervention, a screening reminder for providers, through the use of the EHR (Electronic Health Record) to alert the provider that the patient be informed about Hepatitis C screening and mailing informative letters to patients of Eagle Ridge Medical and the Fort Lupton Clinics born between 1945 and 1965 (the Baby Boomer generation). This is a Grade B recommendation from the U. S. Preventive Services Task Force. Currently, of those people diagnosed with Hepatitis C, 75% were born in these years, and, therefore this age group is considered high-risk. A serum blood draw for anti-HCV antibody will be offered to the patient; the cost either covered by insurance or through self-pay. If positive or equivocal, a serum HCV-RNA test will be ordered. If positive, the patient is deemed to have active chronic Hepatitis C Virus and will be referred to a Gastroenterologist for treatment. Hepatitis C is affiliated with multiple, negative comorbidities including liver cirrhosis, fibrosis, or failure, and hepatocellular carcinoma. Treatment methods are currently available and it is found that 90-100% Hepatitis C positive individuals will respond to treatment if they do not already have liver disease including fibrosis, cirrhosis, or hepatocellular carcinoma. Therefore, it is prudent and recommended to screen this high-risk population. A standing order to draw the anti-HCV antibody will be implemented and the corresponding ICD-10 code is Z11.9.

Goal of Capstone Project: To implement a population-screening project that includes screening adults born between 1945 and 1965 for Hepatitis C as this is deemed a high-risk population. Patients will be educated in regards to Hepatitis C Virus and discussion of impact of positive results will ensue if appropriate. The provider will refer as deemed necessary (i.e. a positive HCV-RNA test) to a Gastroenterologist. Ultimately, it will prove to be advantageous to test for HCV in high-risk populations to decrease the prevalence of the virus as treatment options are available and successful.

Proposed On-site Activities: Implement Hepatitis C Screening tool in Greenway EHR to alert providers if the patient is born between the years, 1945 and 1965, and offer testing for HCV after discussion of the reasoning behind the screening. Also, the student will mail postal letters to patients of Eagle Ridge Medical and Fort Lupton Clinics who are born between these years as

well in case there are patients born in the specific time frame who do not come to the clinics for an appointment during the next six months.

Confidentiality of Patient Records: Patient records and personal information will be kept completely confidential to protect the patient. Patients' names will also not be identified in the written project or in the oral presentation of the report.

The designated Capstone Community/Agency member will agree to participate in the review and approval of the proposal and presentation of the final version of the project. She will attend (either on campus or remotely) the meetings for both.

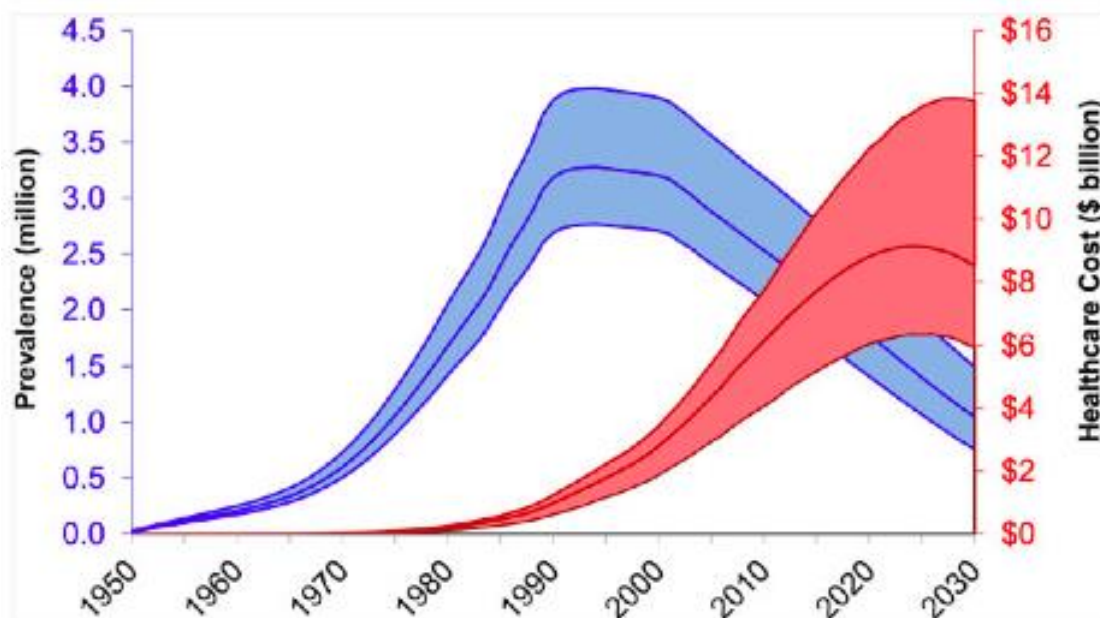
The DNP Capstone project will include a final report, an abstract, potential publication or oral presentation of the report. No personal identifiers will be included and all data will be reported in aggregate form. The author welcomes any comments or suggestions from the Agency, but reserves the right to publish findings and analysis according to professional standards and principles of academic freedom. For any work of a scholarly nature, the Author agrees to follow the Agency preferences in how it is to be named (or not) in the work.

| | |
|-----------------------------|---------|
| <i>Auson Hayes</i> | 1/26/16 |
| Signature of Student | Date |
| <i>[Signature]</i> | 1/26/16 |
| Signature of Agency Member | Date |
| <i>Rhonda D. Squires</i> | 2/2/16 |
| Signature of Capstone Chair | Date |

APPENDIX C

TOTAL PREVALENCE AND HEALTHCARE COSTS

Total Prevalence and Healthcare Costs with 95% CIs



Source. Razavi et al. (2013).

APPENDIX D
INSTITUTIONAL REVIEW BOARD APPROVAL



Institutional Review Board

DATE: April 10, 2016

TO: Susan Hayes

FROM: University of Northern Colorado (UNCO) IRB

PROJECT TITLE: [885772-2] Hepatitis C Screening

SUBMISSION TYPE: Amendment/Modification

ACTION: APPROVED

APPROVAL DATE: April 10, 2016

EXPIRATION DATE: April 10, 2017

REVIEW TYPE: Expedited Review

Thank you for your submission of Amendment/Modification materials for this project. The University of Northern Colorado (UNCO) IRB has APPROVED your submission. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on applicable federal regulations.

Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require that each participant receives a copy of the consent document.

Please note that any revision to previously approved materials must be approved by this committee prior to initiation. Please use the appropriate revision forms for this procedure.

All UNANTICIPATED PROBLEMS involving risks to subjects or others and SERIOUS and UNEXPECTED adverse events must be reported promptly to this office.

All NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this office.

Based on the risks, this project requires continuing review by this committee on an annual basis. Please use the appropriate forms for this procedure. Your documentation for continuing review must be received with sufficient time for review and continued approval before the expiration date of April 10, 2017.

Please note that all research records must be retained for a minimum of three years after the completion of the project.

If you have any questions, please contact Sherry May at 970-351-1910 or Sherry.May@unco.edu. Please include your project title and reference number in all correspondence with this committee.

Susan -

Hello and thank you very much for all your patience and willingness to work to conform to the IRB requirements with your capstone project.

Dr. Collins, the first reviewer, provided her approval based on the revisions and feedback provided.

I've subsequently reviewed all original, revised and additional information associated with this project and also approve.

You may proceed with your protocols. Be sure to use those that were provided in the revision and modifications. Best wishes with your work.

Sincerely,

Dr. Megan Stellino, UNC IRB Co-Chair

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Northern Colorado (UNCO) IRB's records.

APPENDIX E
RECOMMENDATIONS FOR TESTING, MANAGING,
AND TREATING HEPATITIS C

Rating System Used to Rate the Level of the Evidence and Strength of the Recommendation for Each Recommendation

| Classification | Description |
|--------------------------|---|
| Class I | Conditions for which there is evidence and/or general agreement that a given diagnostic evaluation, procedure, or treatment is beneficial, useful, and effective |
| Class II | Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness and efficacy of a diagnostic evaluation, procedure, or treatment |
| Class IIa | Weight of evidence and/or opinion is in favor of usefulness and efficacy |
| Class IIb | Usefulness and efficacy are less well established by evidence and/or opinion |
| Class III | Conditions for which there is evidence and/or general agreement that a diagnostic evaluation, procedure, or treatment is not useful and effective or if it in some cases may be harmful |
| Level of Evidence | Description |
| Level A* | Data derived from multiple randomized clinical trials, meta-analyses, or equivalent |
| Level B* | Data derived from a single randomized trial, nonrandomized studies, or equivalent |
| Level C | Consensus opinion of experts, case studies, or standard of care |

Source. American Association for the Study of Liver Diseases/Infectious Diseases Society of America (2015).

APPENDIX F
LETTER TO PATIENTS

Eagle Ridge Medical Clinic
1606 Prairie Center Pkwy #240
Brighton, CO 80601
303-659-1152

To whom it may concern,

You are receiving this letter because you are born between the years 1945-1965. The United States Preventive Services Task Force (USPSTF), a group of national experts in evidence-based medicine that focus on keeping people well, recommends screening adults born between these years for a blood-borne disease.

Please ask about the details of this screening at your next appointment with your provider or contact the clinic at 303-659-1152 if you wish to learn more. The testing includes checking your blood.

Sincerely,

Eagle Ridge Medical Staff

APPENDIX G
FACT SHEET

HEPATITIS C



Why Baby Boomers Should Get Tested

Why should baby boomers get tested for Hepatitis C?

While anyone can get Hepatitis C, more than 75% of adults infected are baby boomers, people born from 1945 through 1965. Most people with Hepatitis C don't know they are infected.

- Baby boomers are five times more likely to have Hepatitis C.
- Liver disease, liver cancer, and deaths from Hepatitis C are on the rise.
- The longer people live with Hepatitis C, the more likely they are to develop serious, life-threatening liver disease.
- Getting tested can help people learn if they are infected and get them into lifesaving care and treatment.
- For many people, treatments are available that can cure Hepatitis C and prevent liver damage, cirrhosis, and even liver cancer.



CDC recommends that anyone born from 1945 through 1965 get tested for Hepatitis C.

Why do baby boomers have such high rates of Hepatitis C?

The reason that baby boomers have high rates of Hepatitis C is not completely understood. Most boomers are believed to have become infected in the 1970s and 1980s when rates of Hepatitis C were the highest. Since people with Hepatitis C can live for decades without symptoms, many baby boomers are unknowingly living with an infection they got many years ago.

Hepatitis C is primarily spread through contact with blood from an infected person. Many baby boomers could have gotten infected from contaminated blood and blood products before widespread screening of the blood supply in 1992 and universal precautions were adopted. Others may have become infected from injecting drugs, even if only once in the past. Still, many baby boomers do not know how or when they were infected.

What should baby boomers know about Hepatitis C?

Hepatitis C is a serious liver disease that results from infection with the Hepatitis C virus. Some people who get infected with Hepatitis C are able to clear, or get rid of, the virus, but most people who get infected develop a chronic, or lifelong, infection. Over time, chronic Hepatitis C can cause serious health problems including liver damage, cirrhosis, liver cancer and even death. In fact, Hepatitis C is a leading cause of liver cancer and the leading cause of liver transplants.

People with Hepatitis C:

- Often have no symptoms
- Can live with an infection for decades without feeling sick
- Can be successfully treated with medications

Continued on next page



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

How would someone know they have Hepatitis C?

The only way to know if someone has Hepatitis C is to get tested. Doctors use a blood test, called a Hepatitis C Antibody Test, to find out if a person has ever been infected with Hepatitis C. The Hepatitis C Antibody Test looks for antibodies to the Hepatitis C virus. Antibodies are chemicals released into the bloodstream when someone gets infected.

Hepatitis C Antibody Test results

When getting tested for Hepatitis C, ask when and how test results will be shared. The test results can take anywhere from half an hour to several days or weeks to come back.

Non-reactive or a negative Hepatitis C Antibody Test

- A **non-reactive**, or negative, antibody test means that a person does not have Hepatitis C.
- However, if a person has been recently exposed to the Hepatitis C virus, he or she will need to be tested again.

Reactive or a positive Hepatitis C Antibody Test

- A **reactive**, or positive, antibody test means that Hepatitis C antibodies were found in the blood and a person has been infected with the Hepatitis C virus at some point in time.
- A reactive antibody test **does not** necessarily mean a person still has Hepatitis C.
- Once people have been infected, they will always have antibodies in their blood. This is true if even if they have cleared the Hepatitis C virus.
- A reactive antibody test requires an additional, follow-up test to determine if a person is currently infected with Hepatitis C.

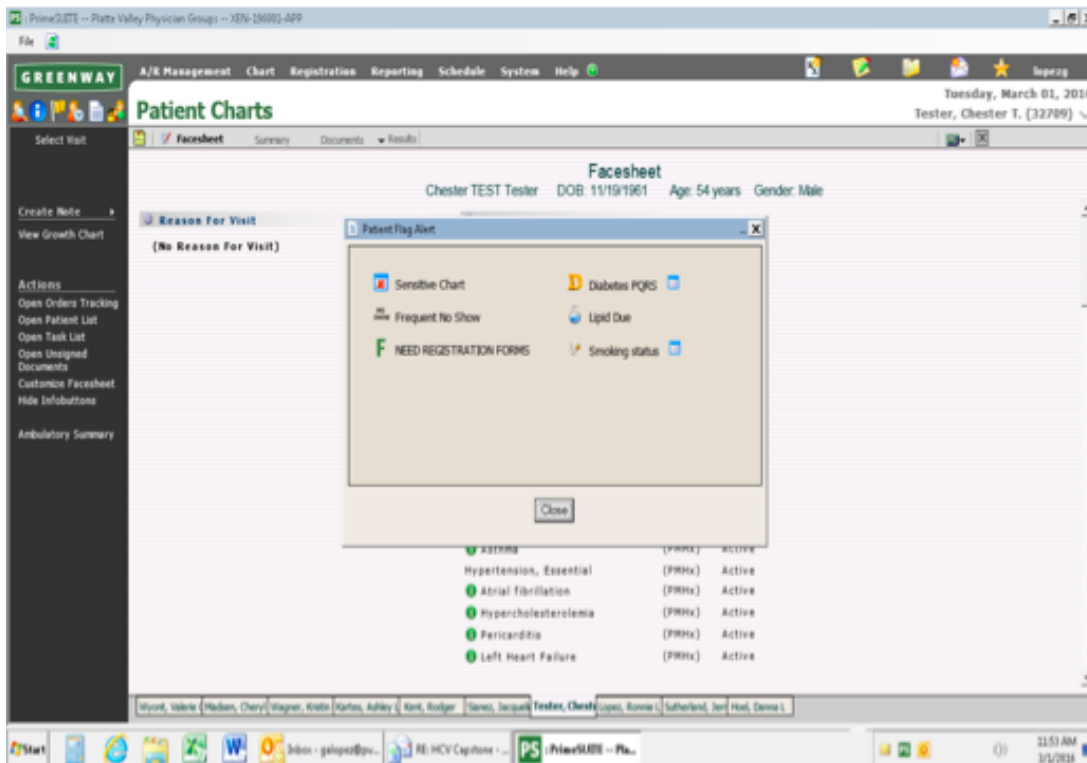


For more information

Talk to a health professional, call the health department, or visit www.cdc.gov/knowmorehepatitis.

APPENDIX H

**SCREEN REMINDER WITHIN ELECTRONIC HEALTH
RECORD AT EAGLE RIDGE MEDICAL**



APPENDIX I

**ACKNOWLEDGEMENT OF NOTICE OF PRIVACY PRACTICES
AND HEALTH INSURANCE PORTABILITY AND
ACCOUNTABILITY CONSENT**



ACKNOWLEDGEMENT OF NOTICE OF PRIVACY PRACTICES AND HIPAA CONSENT

I hereby acknowledge that I received Eagle Ridge Medical's Notice of Privacy Practices and HIPAA Notice:

PATIENT NAME (PLEASE PRINT)

DATE OF BIRTH

SIGNATURE OF PATIENT (OR
PATIENT REPRESENTATIVE)

TODAY'S DATE

CONTACT PERSONS WITH WHOM WE MAY DISCUSS YOUR CARE AND GIVE TEST RESULTS. PLEASE NOTE IF YOU WANT SPOUSE, SIGNIFICANT OTHER, AND/OR CHILDREN TO BE INCLUDED YOU MUST LIST THEM BELOW.

NAME

RELATIONSHIP

PHONE NUMBER

NAME

RELATIONSHIP

PHONE NUMBER

NAME

RELATIONSHIP

PHONE NUMBER

NAME

RELATIONSHIP

PHONE NUMBER

MAY WE LEAVE CONFIDENTIAL INFORMATION OR VOICE MAILS OR ANSWERING MACHINES LISTED BELOW:

HOME PHONE: _____ YES NO

WORK VOICE MAIL: _____ YES NO

CELL VOICE MAIL: _____ YES NO

E-MAIL: _____ YES NO

(IF YOU CHECKED "YES", YOU MUST PROVIDE US WITH AN E-MAIL ADDRESS.

THIS IS A SECURE WEBSITE FOR SENDING PATIENT RESULTS.)

I'm aware that this consent will remain in effect until such time that I provide written notification to end this agreement. I'm aware that no other person than those listed above, will be allowed to discuss my care, be given financial information, or be allowed to make or cancel appointments on my behalf.