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Virginia M. Selanik

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A Quality Improvement Project to Increase Hepatitis A and B Vaccination
in Adults with Hepatitis C in a Federally Qualified Health Center

Virginia M. Selanik, APRN, FNP-BC

Doctoral Capstone Project submitted to the School of Nursing
at West Virginia University in partial fulfillment of the requirements
for the Doctor of Nursing Practice Degree ©

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Keywords: hepatitis, hepatitis C, immunization, vaccination, provider adherence, quality
improvement

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ABSTRACT

A Quality Improvement Project to Increase Hepatitis A and B Vaccination in Adults with Hepatitis C in a Federally Qualified Health Center

Virginia M. Selanik

Problem Statement Despite long-standing recommendations for vaccination against hepatitis A virus (HAV) and hepatitis B (HBV) in persons with chronic liver disease and hepatitis C virus (HCV) infection and the life-threatening complications suffered from cirrhosis and hepatocellular cancer (HCC), vaccination rates for HAV and HBV in adults are suboptimal in clinical practice.

Theoretical Framework Based upon published clinical guidelines and performance measures for optimal care of HCV-infected persons, a quality improvement project was implemented guided by Kotter's eight-step change model. Strategies adopted from the 4 Pillars™ Practice Transformation Program, including staff/provider education, standing orders, immunization champions, open access/walk-in vaccination during office hours, posters promoting vaccination electronic medical record (EMR) reminders, patient post card reminders, and weekly charts to track progress were used.

Project Description Retrospective EMR reviews from patients with a detectable HCV viral load (HCV RNA) were conducted at the start of the project and three months following the intervention. Demographic data along with HCV RNA, HAV total antibody (HAV Ab), HBV surface antibody (HBsAb), and vaccination against HAV and HBV were derived from EMR reports, comparing vaccination rates before and after the intervention. A secondary goal included increasing provider and staff knowledge related to hepatitis and clinical guideline recommendations for immunization against HAV and HBV in persons with chronic liver disease and HCV infection. Using a quasi-experimental, one group pretest-posttest design, health care providers' and staff members' knowledge related to hepatitis and clinical guideline recommendations for immunization against HAV and HBV were evaluated before and after the educational intervention using 20-items from a pretest-posttest questionnaire.

Findings and Implications The educational intervention significantly increased the providers' and staff knowledge about hepatitis C. There was an average gain of 16.76 points (95% confidence interval, 13.32, 20.20) on a knowledge test after the educational presentation. This gain was statistically significant at $p \leq .05$ by the paired t -test (two-tailed). Improvements were seen for Havrix (16.9% pre-intervention, 19.7% post-intervention); Engerix-B (2.3% pre-intervention, 3.5% post-intervention); and Twinrix (20.8% pre-intervention, 21.4% post-intervention). Overall vaccination rates were increased by 4.6% in a predominantly publicly insured patient population. The goal of increasing vaccination rates by 20% was not met. However, multi-strategy, evidence-based interventions were an effective means of increasing HAV and HBV vaccinations in a community health center and led to increased access to vaccination services, increased community demand for vaccines, and improved system-based performance.

Dedication

I dedicate this work to my patients, without whom this project would not have been possible and to my mother, Virginia E. Selanik, who taught me the value of lifelong learning, just because... you can and want to.

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Table of Contents

Abstract	
Dedication	iii.
Acknowledgements	iv.
Table of Contents	v.
Introduction	1
Background	2
Epidemiology of the Problem	2
Hepatitis C	3
Hepatitis B	4
Hepatitis A	5
Significance	6
Description of the Population	6
Setting	7
Unique Factors Contributing to the Problem	8
Literature review and Synthesis	9
Search Strategy	9
Literature Review	9
Synthesis	22
Theoretical Framework	24
Strategies From the 4 Pillars™ Practice Transformation Program.....	24
Kotter's Eight Stages of Change Management	24
Project Design	29
Guidelines and Benchmarks for CHC Care	30
Congruence of Organization's Strategic Plan to Project	31
Procedure	32
Timeline of Project Phases	34

Resources, Personnel, Technology, and Budget	35
Measurable Project Outcomes	37
Evaluation	37
Results	38
Provider and Staff Demographics	38
Provider and Staff Knowledge	39
Patient Demographics	40
Vaccinations	42
Program Cost and Sustainability	44
Discussion and Recommendations	44
Conclusion	46
Attainment of DNP Essentials	46
References	48

List of Tables and Figures

Table 1 – Provider and Staff Demographics	39
Table 2 – Paired Samples Test	40
Table 3 – Pre-intervention and Post-Intervention Ages	41
Table 4 – Pre-intervention and Post-Intervention Gender	41
Table 5 – Pre-intervention and Post-Intervention Payor	42
Table 6 – Pre-intervention and Post-Intervention Vaccinations	43
Figure 1 – Project Model	29
Figure 2 – Timeline of Project Phases	35

Appendix

Appendix A – Definition of Terms	56
Appendix B – Patient Reminder Postcard	57
Appendix C – Authorization	58
Appendix D – Curriculum Outline	61
Appendix E – Power Point Presentation for Provider and Staff Education	62
Appendix F – Education Poster for Staff Break Rooms	67
Appendix G – Pretest-Posttest for Providers and Staff.....	68
Appendix H – Poster for Exam Rooms.....	76
Appendix I – Weekly Progress Charts.....	77
Appendix J – Project Budget	78
Appendix K – Letter of Support.....	79

HEPATITIS VACCINATION IN ADULTS WITH HEPATITIS C

Introduction

A Quality Improvement Project to Increase Hepatitis A and B Vaccination in Adults with Hepatitis C in a Federally Qualified Health Center

The global trends and adverse health impacts of hepatitis C (HCV) infection are among the major urgent public health challenges of our time. Superinfection with hepatitis A virus (HAV) or hepatitis B virus (HBV) in patients with chronic hepatitis C (CHC) infection is associated with the development of cirrhosis and hepatocellular carcinoma (HCC), which is the fastest rising cause of cancer-related death in the United States (Ward, Lok, Thomas, El-Serag, & Kim, 2012). HAV and HBV are both vaccine-preventable diseases and vaccines have been shown to be safe and effective in patients infected with HCV. Unfortunately, HCV vaccine development has been especially challenging due to the vast diversity among the genetic sequence of the seven different known genotypes of HCV, and there is no available vaccine for HCV (Ogholikhan & Schwarz, 2016). However, preventing viral hepatitis through immunization is the most effective way to prevent HCC due to chronic HBV and HCV infections (Wright, 2007).

These deficiencies highlight the need for a systematic assessment in the quality of vaccination care related to patients with HCV. This project sought to determine the effectiveness of an evidence-based intervention to increase hepatitis A and B vaccination in adults with HCV in a Federally Qualified Health Center and increase providers' and staff members' knowledge of hepatitis immunizations. Guided by Kotter's eight stages of change model (Kotter, 1995), it included using strategies from the 4 Pillars™ Practice Transformation Program (Nowalk, et al., 2016), immunization champions, and staff/provider education.

Background

Statement of the Problem

Superinfection with HAV or HBV in patients with HCV is associated with an accelerated, natural history of liver disease and a higher risk of morbidity and mortality compared to those without underlying liver disease (Keeffe, 2006; Felson, Fishbein, & Litwin, 2010; Thudi, Yadav, Sweeney & Behari, 2013). Optimal care of HCV-infected persons includes providing preventive health measures as outlined in published clinical guidelines and performance measures, including HAV and HBV vaccination. Despite long-standing recommendations for vaccination against HAV and HBV in persons with CHC and the poor outcomes associated with the complications of cirrhosis and HCC, vaccination rates for HAV and HBV in adults are suboptimal in clinical practice (Hachem, Kramer, Kanwals, and El-Serag, 2008; Tenner, Herzog, Chadhari, Bini, and Weishel, 2012). Therefore the question is: Does use of a multipronged approach (staff/provider education, standing orders, immunization champions, open-access/walk-in vaccination during office hours, posters promoting immunization, EMR reminders, patient post card reminders, and weekly charts to track progress) for primary care providers and their staff in an FQHC increase hepatitis A and B immunization rates and provider /staff knowledge related to hepatitis immunizations for adults with hepatitis C?

Epidemiology of the Problem

According to the US Centers for Disease Control and Prevention (CDC), HBV and HCV together kill more people than all other infectious diseases combined, including human immunodeficiency virus (HIV) (Klevens, Hu, Jiles, & Holmberg, 2012; National Academy of Sciences, 2017). HBV and HCV cause between 500,000 and 700,000 deaths in the world each year from chronic infection-related cirrhosis and HCC (Lavanchy, 2012). The Institute of

Medicine (IOM) issued a report on hepatitis and liver cancer in January 2010 and found that lack of knowledge and awareness about chronic viral hepatitis on the part of health care providers impedes current efforts to prevent and control HBV and HCV (Ward, et al., 2012). As the pool of persons with chronic liver disease is increasing, and HBV and HCV infections continue to rise, it is certain that a greater number of individuals with chronic liver disease will be at risk for superinfection with acute and chronic hepatitis. The role of immunization is critical, and vaccines against HAV and HBV are safe, well tolerated, and highly effective (Waghray, Waghray, Khallafi, & Menon, 2016). Because HAV and HBV vaccination is less effective in patients with advanced liver disease, it is recommended that patients undergo HAV and HBV vaccination early in the natural history of their chronic liver disease (Keefe, 2006).

Hepatitis C

HCV infection is a leading cause of chronic liver disease and the primary indication for liver transplantation in the United States (US) (Tenner, et al., 2012). Estimated to affect 130 to 185 million of the world's population, nearly 500,000 people die of HCV-related conditions each year (Denniston et al., 2014). HCV becomes chronic in approximately 75-85% of cases, with an estimated 3 million to 4 million of the non-institutionalized civilian population in the US having chronic infection (CDC, 2017). With inclusion of the homeless, veterans, the incarcerated, nursing home residents, hospitalized patients, and immigrants, the true prevalence of HCV in the US is approximately 2% or 5.2 million persons (Chak, Talal, Sherman, Schiff, & Saab, 2011). It is transmitted primarily through percutaneous exposure that can result from injection-drug use, needle stick injuries, and inadequate infection control in health care settings (CDC, 2017). Highly effective new treatments are rapidly being approved, and the number of individuals who progress to advanced liver disease and HCC may be lowered with these treatments. However, studies have

suggested that mortality associated with HCV infection from liver failure or HCC will increase over the next two decades (Ghany, Strader, Thomas, & Seeff, 2009). This is consistent with a recent study by Denniston et al. (2014) which suggested that decreases in HCV prevalence were probably a reflection of increasing mortality from HCV-related conditions. Unfortunately, since 2010, after years of declining rates, the incidence of HCV infection has increased by 75% (Dan, Moses-Einstein, & Valdiserri, 2015). The abrupt increase is likely due to the opioid and heroin epidemic and injectable drug use that has swiftly increased the transmission of HCV infection (Tsui, Evans, Lum, Hahn & Page, 2014).). HCV, in addition to causing substantial morbidity and mortality, has damaging economic consequences. When evaluating the lifetime health care costs associated with HCV infection and end-stage treatments such as liver transplants, costs can reach high into hundreds of thousands of dollars (U.S. DHHS, 2011). The U.S. Department of Health & Human Services Action Plan for the Prevention, Care, & Treatment of Viral Hepatitis (2011) reported, compared with other patients of similar age and sex, managed-care enrollees with HCV infection are hospitalized more frequently and have higher annual health-care expenses (\$21,000) exceeding the per-person costs associated with diabetes (\$10,000).

Hepatitis B

HBV remains a public health challenge with the CDC estimating approximately 850,000 persons living with HBV in the US, and an estimated 21,900 new cases of HBV in 2015 (CDC, 2016). The number of reported cases of acute HBV increased by 20.7% to 3,370 cases in 2015. It is transmitted by percutaneous or mucosal exposure to blood or body fluids of an infected person, such as from an infected mother to her newborn during childbirth, through close personal contact within households, through unsafe injections in health care settings, through injection drug use, and from sexual contact with an infected person (CDC, 2016). HBV vaccine can provide

protection against infection and associated chronic complications. HBV vaccine is the first vaccine against a cancer, such as HCC, the first vaccine protecting persons from a sexually transmitted disease, and the first vaccine to ever be licensed against a chronic disease (Lavanchy, 2012). The annual medical care costs of HBV infection have been estimated to be as high as 1.1 billion dollars (Ward et al., 2012).

Hepatitis A

Hepatitis A infection accounts for up to half of the reported cases of acute viral hepatitis in the US (Reiss & Keffe, 2004), with the estimated number of new HAV infections in 2015 reported to be 2,800 (CDC, 2016). It is transmitted through the fecal oral route and acquired in the US primarily through close contact with an infected person and during foodborne outbreaks. Infection with HAV confers life-long immunity and does not cause chronic infection. Although HAV infection is a self-limiting illness, a small subset of persons will progress to fulminant hepatic failure and death or transplantation (Reiss & Keffe, 2004). According to recent studies, the incidence of HAV has declined primarily due to implementation of immunization policies and improvement in environmental hygiene (Samandari, Bell, & Armstrong, 2004; Wasley, Samandari, & Bell, 2005). However, there is an emergence of a new cohort of persons who lack immunity to HAV and are at risk for HAV infection (Keffe, 2006), with injection drug use as the predominant risk factor for this group (Quaglio, Lugoboni, Mezzelani, Des Jarlais, & Lechi, 2006). HAV vaccination has been available since 1995 and has been shown to be safe and effective, with few adverse events (Reiss & Keffe, 2004), but it wasn't until 2006 that the Advisory Committee on Immunization Practices of the Centers of Disease Control and Prevention (ACIP) expanded immunization recommendations to include the routine vaccination of children aged ≥ 1 year in all 50 states (Dan, Eisenstein, & Valdiseri, 2015).

Significance

In West Virginia, the incidence of acute HBV and acute HCV has increased 213% and 209%, respectively as noted in the WV HBV and HCV Disease Surveillance Report 2012-2015. The WV-State Health Profile reported cases of acute HAV did not increase between 2011 and 2015, rates of acute HBV increased by 146%, and cases of HCV increased by 36% (CDC, 2015). In comparison to national rates, West Virginia reported the highest incidence of acute HBV infection at 14.7 per 100,000 population and the second highest rate of HCV infection at 3.4 per 100,000 population in the US in 2015, which is five times the national average (CDC, 2015). Injection drug use is the most common risk factor for HCV infection in the US and is the key driving force in perpetuating the epidemic of HCV infection and opioid-related deaths (Tsui et al., Evans, Lum, Hahn, & Page, 2014). A rise in new HCV infections has been noted among white adolescents and young adults with a history of injection drug use and prescription opioid use (Hagan & Schinazi, 2013). The Centers for Disease Control and Prevention estimates that nearly 20,000 deaths were associated with HCV in 2014, making it one of the deadliest diseases in the US (CDC, 2016).

Description of the Population

FamilyCare Health Centers serves over 30,000 people in four counties in south-central West Virginia, a state that lies entirely within the Appalachian region. The region is burdened with high rates of chronic illnesses (e.g., diabetes, heart disease, cancer, HCV) and poor health habits (e.g., sedentary lifestyle, tobacco use, prescription drug abuse). The target population is those people living in FamilyCare's Service Area with incomes under 200% of the Federal Poverty Guidelines in Putnam, Boone, and certain census tracts in Kanawha and Mason counties. FamilyCare's Service Area includes small towns and rural areas in addition to the cities of Charleston and Madison, West Virginia.

Setting

The study took place in a Federally Qualified Health Center (FQHC) in West Virginia where primary care services for over 500 people with substance related disorders other than tobacco or alcohol were provided in 2016. The organization was a recipient of a Substance Abuse Service Expansion award in 2016. Through that funding, the organization was able to expand its integrated primary care/behavioral health model to add substance abuse services at four clinic sites. The increased number of patients with health-center funded Medical Assisted Treatment (MAT) made evident the alarming trend of increased numbers of patients with chronic HCV infection within the organization. At the project site in 2016, an estimated 310 (62%) of those patients with substance use disorders had a diagnosis of HCV. This is consistent with current published studies that have found certain vulnerable populations are disproportionately affected, such as in inner-city ambulatory primary care and Veteran's Administration populations, where the rate of HCV infection is as high as 8%, and up to 80% among intravenous drug users (Alfandre, Gardenier, Federman, & McGinn, 2009). The need to develop and implement a change in service delivery at the clinical site based on the increasing HCV patient population made a compelling case for implementing an innovative multi-strategy, evidence-based intervention to increase HAV and HBV vaccination efforts within the organization.

Unique Factors Contributing to the Problem

Left untreated, HCV can cause the liver to develop fibrosis, a structural change in the liver as a result of chronic injury with resultant increase in liver stiffness (Rockey, 2006). Increased stiffness in the liver occurs as liver fibrosis progresses causing resistance to liver blood flow. Lack of blood flow to the liver will eventually result in liver failure which results in cirrhosis over time. Progression of liver fibrosis is a sign of worsening chronic HCV infection which can lead to

cirrhosis and complications of end-stage liver disease including liver failure, ascites, bleeding from varices, hepatic encephalopathy, and HCC. The METAVIR system is commonly used for grading activity and staging fibrosis (Bedossa & Poynard, 1996). Serum markers used to predict fibrosis in hepatitis C patients are compared to biopsy results obtained with the five point scale METAVIR system, where fibrosis is described as follows: chronic hepatitis without fibrosis (F0); portal fibrosis without septae (F1); portal fibrosis with a few septae (F2); septal fibrosis without cirrhosis (F3) and complete cirrhosis (F4) (Rossi, Adams, Bursara, & Jeffrey, 2007). The current West Virginia Medicaid Office of Pharmacy Services Prior Authorization Criteria for Chronic Hepatitis C Treatment (WV DHHS, 2017) restricts access to HCV treatment requiring that beneficiaries have a fibrosis score of F2 before they can access curative medical treatments. Up to 20% of chronic HCV patients are cirrhotic when first presenting into care, and between 20% and 30% of patients without cirrhosis will develop cirrhosis within one or more decades (Benvegnu, Gios, Buccato, & Alberti, 2004). Due to the high cost associated with medication regimens for treating HCV infection, many patients have been forced to delay treatment if liver histology displays minimal to moderate fibrosis. The need for protecting the health of the liver in patients with CHC is paramount in an era where criteria for treatment requires an F2 fibrosis score. Fewer than 11% of persons referred to care are treated (Dan et al., 2015), and there are many patients in West Virginia that are not getting treated, despite having infection and likelihood of disease progression. Many patients are young injection drug users, who have F0 fibrosis scores, and do not meet the criteria for accessing the medication for treatment. As liver disease progresses, many immunizations lose their effectiveness (Leise & Talwalkar, 2012). It is therefore important to address immunization needs in patients with CHC early on when immunizations are most effective. A greater risk of infection, coupled with a likely worse outcome, warrants vaccinating

these CHC patients against HAV and HBV, preferably as early as possible in the natural course of their illness (Reiss & Keeffe, 2004).

Literature Review and Synthesis

Search Strategy

To identify the best evidence regarding increasing HAV and HBV vaccination rates in adults with hepatitis C, an in-depth search of the literature was performed. Inclusion criteria for the search were studies that addressed hepatitis, hepatitis C, vaccination, immunizations, quality improvement, or provider adherence. Databases searched included Academic Search Complete, Medline, CINAHL, and the Cochrane Library. Keywords used in the search were combinations of hepatitis, hepatitis C, vaccination, immunization, provider adherence, and quality improvement. The initial search of all databases yielded 22,939 hits. The search was narrowed to 368 articles by limiting it to articles from 2005-2017, English language, systematic reviews, clinical practice guidelines, randomized controlled trials, cohort studies, and peer-reviewed journals. The evidence base was narrowed further by excluding articles that did not contain the search terms of vaccination, immunization, or did not include information related to quality improvement. Snowballing technique was used to identify additional articles that met initial inclusion criteria. Twenty final articles were identified for review.

Literature Review

The 4 Pillars™ Practice Transformation Program model was used in 4 studies to test its effectiveness in increasing adult immunization rates in primary care. In a triangulated mixed methods study done by Nowalk et al. (2014), a standing order program toolkit from the 4 Pillars™ Program was pilot-tested, evaluating changes in influenza and pneumococcal vaccination rates. Qualitative evaluation using on-site observation and interviews of practice staff

were used along with vaccination rates derived from the EMR between June 2011 and through the end of June 2012 in 4 primary care practices. Although response to the 4 Pillars™ standing orders toolkit may have differed in sites whose rates were initially higher, influenza rates increased significantly in 3 of the 4 sites. In a randomized controlled cluster trial, Nowalk et al. (2016) used the 4 Pillars™ Practice Transformation Program as the foundation of a 2- year study to increase adult immunization rates for influenza, pneumococcal and Tdap among patients of primary care practices in two cities. The purpose of the study was to report on changes in adult Tdap immunization rates and factors related to the likelihood of receipt of this vaccine. In the first year, cumulative Tdap vaccination increased significantly in both intervention and control groups. The percentage point increases in the intervention groups (7.7 PP in Pittsburgh and 9.9 PP in Houston) were significantly higher ($P < 0.001$) than in the control groups (6.4 PP in Pittsburgh and 7.6 PP in Houston). In the Year 2 pre-post study, in both cities, active intervention groups increased rates significantly more (6.2 PP for both) than maintenance groups (2.2 PP in Pittsburgh and 4.1 PP in Houston; $P < 0.001$). The study reported both clinically and statistically significant improvements in Tdap vaccination rates in diverse primary care practices using the 4 Pillars™ Practice Transformation Program and these changes were maintained in the post-intervention period. Zimmerman et al. (2017) completed a 20-month randomized controlled cluster trial in 25 primary care practices stratified according to metropolitan area (Houston, Pittsburgh), location (rural, urban, suburban), and type (family medicine, internal medicine). The aim was to test the effectiveness of the 4 Pillars™ Practice Transformation Program, to increase pneumococcal vaccination in individuals aged 65 and older. Using the 4 Pillars™ program and one-on-one coaching of practice-based immunization champions, pneumococcal vaccination rates increased significantly in all intervention and control groups, with average increases ranging from 6.5 to 8.7

PP ($P < .001$). The likelihood of pneumococcal vaccination in the Year 2 pre-post study was significantly higher in the active intervention sites than the maintenance sites in Pittsburgh, but not in Houston. The strengths of this study included its randomized design, large diverse sample size, diverse practice settings, and two intervention years of vaccination reporting. Weaknesses: delivery of EMR data was delayed in Year 1 intervention, which prevented the researchers from providing feedback about their progress to the sites in both cities. In another randomized controlled cluster trial by Zimmerman et al. (2017) that took place during 2013-2015, strategies from the 4 Pillars™ Practice Transformation Program were used to increase HPV vaccination uptake in primary care sites among 10,862 adolescents in 9 intervention and 11 control sites. The strategies included improving patient notification about needed vaccines, increasing convenience of vaccines, implementing standing order protocols, creating an immunization champion role, supporting the use of site-specific immunization strategies via conference calls, an on-line dashboard to track progress, and motivating staff by sharing progress towards goals via progress charts. The intervention sites increased HPV initiation 10.2 PP compared with 7.3 PP in control sites ($P < 0.001$). Completion rates for the HPV series did not differ between groups. Strengths of this study was the randomized design and the large sample size. The modest length of the intervention limited its ability to observe differences in HPV series completion between the groups.

Campbell et al., (2006) completed a 32- month randomized controlled trial with a sample of 3,181 young urban injection drug users in five US cities to assess whether convenience and monetary incentives influenced uptake of vaccinations. The purpose of the study was to describe antibody to HAV (anti-HAV) and total antibody to hepatitis B core antigen (anti-HBc) seroprevalence self-reported prior vaccination, and acceptance of free HAV and HBV vaccine by

18-30 year old injection drug users. It also assessed structural and individual factors associated with vaccine uptake. Anti-HAV and anti-HBc seroprevalence was 19% and 23%, respectively. Lack of awareness was the most common reason for no previous HAV or HBV vaccination. Only 36% received > than 1 dose, even though 83% of participants were willing to be vaccinated. Participation was highest when vaccine was immediately available and lowest when offered only after receiving results. Strength of the study: uniform procedures used for counseling and testing across 5 study sites. Weaknesses were that the study only recruited young urban IDUs, and the sample may not be representative of older IDU populations. This study was unable to determine the validity of self-reported HAV and HBV vaccination history. Considering anti-HAV and anti-HBs wane with time, serologic testing results might not have correlated with true vaccination history and true immunity.

Felson et al. (2010) conducted a retrospective review of a random sample of 207 medical records of patients enrolled in an academically affiliated, urban methadone maintenance program providing on-site primary care services. The aims of the study were to examine the rates of testing for HAV, HBV, and HCV, as well as rates of vaccination against HAV and HBV in patients with CHC infection in the program. The study found almost all patients reviewed were tested for HAV, HBV, and HCV. There were 111 patients chronically infected with HCV. Of those patients, 53 (48.6%) and 68 (63%) were found to lack immunity to HAV and HBV respectively. Of those lacking immunity, 29 (54.7%) and 2 (2.9%) were then vaccinated for HAV and HBV respectively. It was not clear why rates of vaccination were low in comparison to the high rates of clinic visits. These visits may represent missed opportunities for vaccination. Strengths of this study included the high rates of screening for HAV, HBV, and HCV. Because of the retrospective chart review, some data may have been missed if a patient was vaccinated outside of the clinic,

causing the researchers to underestimate the proportion of eligible patients who were ultimately vaccinated.

In a prospective cohort study of 68 participants from 20 primary care practices, each with a team of 4 members, Gannon et al. (2012) studied the effect of using a team approach on improving adult immunization practices in the primary care setting. Each practice designed their own practice team. Participants were given access to an on-line educational program after a baseline physician practice pattern survey and 35 random patient chart abstractions were completed. Data also revealed an increase in the number of physicians who discussed herpes zoster and pneumococcal immunizations with their patients (23.2% pre-intervention, 43.4% post-intervention; $P \leq .01$) as well as an increase in physicians using the CDC immunization schedule (52.9% pre-intervention, 88.2% post-intervention; $P \leq .02$). Knowledge scores did not differ significantly between before and after intervention showing that knowledge is necessary, but not sufficient to increase immunization rates. The information bias of physician self-report via the survey data was a limitation of this study as they might have under-reported or over-reported behavior.

Hachem et al. (2008) conducted a retrospective cohort study of 243 HCV-infected patients after calculating predictive values for hepatitis vaccination codes in a validation set of 168 patients. The purpose of the study was to validate Current Terminology (CPT) codes and drug codes for hepatitis vaccination in administrative databases and determine vaccination rates in HCV-infected patients in a single large veterans Administration Medical Center. Among patients diagnosed with HCV between 2000 and 2005, receipt of hepatitis vaccination was documented in approximately 8% overall. Of the 3,009 patients diagnosed with HCV during 2000-2005, 7.9% had a HAV vaccination and 8.6% had a HBV vaccination. Of the 57 HCV-infected patients who

received HAV vaccination, 100% had HAV serology testing and the majority (89%) had negative HAV serology. Approximately 70% of patients who received a HAV vaccination did receive a full series. Pre-vaccination serology indicated positive immune status prior to HAV vaccination in two (3.5%) of these patients. All 49 patients who received HBV vaccination had testing for HBV serology. Six of these patients (12%) had positive serology prior to receiving HBV vaccination. In patients who did not receive hepatitis vaccinations, chart review indicated that 66-96% had HAV or HBV serology checked and approximately one-third had negative HAV or HBV serology indicating susceptibility to co-infection and potential missed opportunities for vaccination. The initiatives coincided with an observed increase in vaccinations and demonstrated the potential for facility determinants in improving outcomes of care to this high-risk population. These findings have limited generalizability to the VA system as they were derived from a single VA center and may not reflect the coding practices of other VA sites.

A retrospective cohort study conducted by Hechter et al. (2014) examined HBV testing and vaccination practices in adults infected with chlamydia, gonorrhea, or syphilis seeking care in non-STD clinics of a large managed care organization in 2008-2011. The study revealed that < 30% of subjects were screened for active HBV infection (HBsAg) within 90 days following a STI diagnosis, although the testing rate did increase slightly each year, from 24.7% in 2008 to 30.3% in 2011. Only 8.8% of the subjects received both HBsAg and HBsAb testing for evaluation for vaccination need. Among those who were susceptible to HBV infection, only about 11% initiated the HBV vaccine series. This finding suggests that healthcare providers do not frequently identify candidates for HBV vaccination as part of routine clinical services, even though HBV vaccination is recommended for persons seeking STI evaluation or care. Avoiding the problem of potential selection bias and high attrition through the efficient use of an EMR database to identify

a large cohort of adults who were diagnosed with STIs and followed up on their HBV testing and vaccination status was a strength of the study. One limitation was the inability to ascertain complete history of HBV vaccination and chronic HBV infection that occurred before a person's enrollment in the managed care organization.

Hernandez et al. (2009) conducted a retrospective cohort study that included 2,968 CHC patients examining HAV and HBV serology data and immunization records between 2000 and 2007 using a hospital EMR system. All patients were veterans receiving care from a multi-campus tertiary referral teaching hospital affiliated with Stanford University. The primary purpose of the study was to determine the percent of patients with CHC who met the recently adopted performance measure on vaccination against both HAV and HBV and were either tested for antibody to HAV and HBV and subsequently immunized with HAV and/or HBV vaccine, if they received the vaccine without antibody testing. Secondary objectives were to determine the immunity to HAV and HBV, adherence rate with completing the vaccination series, and the reasons for non-adherence to the recommendation. The researchers found overall adherence to the performance measure to vaccinate all HCV-positive patients for both HAV and HBV was 62%. There were 1,834 patients found to either have documented immunity to or have received vaccination for both HAV and HBV. Only 261 (9%) were adherent to the HAV performance measure and 231 (8%) adherent to the HBV performance measure. Of the 964 patients vaccinated for HAV, only 684 (71%) completed vaccination series. There were 1,283 patients vaccinated for HBV and 654 (51%) completed the series. There were 231 patients who did not have documented immunity or receive vaccination for HAV, 261 patients with no documented immunity to HBV, and 641 patients who had no documented immunity to both HAV and HBV. Reasons for non-adherence included: missed opportunity (41%), patient did not return after diagnosis of HCV

(31%), documentation of vaccination outside of clinic (22%), and newly diagnosed within 3 months from the end of the study period, with no clinic visit since the diagnosis (4%). Strengths of the study included the large sample size with long-term follow up, and accurate data capture with EMR. The retrospective design was a limitation of the study and those vaccinated outside of the clinic were not counted as vaccinated.

Kanwal et al. (2010) completed a retrospective cohort study to evaluate the quality of health care that patients with HCV receive and the factors associated with receipt of quality care in response to the quality-of-care indicators proposed by Medicare for HCV infection. The study cohort of 10,385 patients was drawn from the research database of a large commercial health insurance carrier enrolled in the database between 2003 and 2006. Quality of care was measured by 7 explicit quality indicators included in Medicare's 2009 Physician Quality Reporting Initiative. Performance for vaccination was lowest with few (21%) receiving HAV vaccination and 26% receiving HBV vaccination. Most of the indicators were relatively insensitive to coding errors due to billing requirements and there were 99% of HCV viral load test results derived from the laboratory results file that had matching claims in the claims file. The retrospective observational design using a convenience sample was a limitation to the study.

A follow up study by Koenig et al. (2016) assessed recent changes in HAV and HBV vaccination rates with chronic liver disease and type II diabetes in the US using population data from NHANES cycles 2009-2012 and 2012-2013 and compared those to previous cycles from 1999-2004 and 2005-2008. There were 29,404 participants. The researchers measured serologic immunity or history of vaccination. In the US population, the rates of quality measure (QM serologic immunity or history of vaccination) for HBV increased from 31.9% in 1999-2004 to 49.5% in 2013-2014 ($P < 0.001$). A similar increase was noted for HAV: 12.0% in 1999-2004 to

33.4% in 2013-2014 in vaccination, 44.0% to 52.4% in HAV QM (all $P < 0.0001$). Greater increases were found in non-HBV chronic liver disease patients: 34.7% to 56.8% in HBV QM and 22.7% to 51.1% in HBV vaccination (all $P < 0.0001$). In this study, both HAV and HBV vaccination rates in the US and in subpopulations with chronic liver disease were steadily increasing. However, the majority of the US population remained susceptible to HAV and HBV throughout the study years, and it was only in the most recent years from 2013-2014 that both quality measures approached the 50% value. The researchers suggested that linking people with diabetes and chronic liver disease to accessible, affordable preventive care may be necessary to improve vaccination rates for HAV and HBV in these vulnerable groups. Weaknesses of the study included self-reported vaccination history which may have recall bias and the NHANES sample may be biased as it did not include incarcerated, institutionalized, or homeless persons.

Kramer et al. (2011) used a retrospective cohort design to determine the proportions of patients who met the Medicare quality measure for vaccination for HAV and HBV in a national cohort of 88,456 HCV-infected patients who received care in VA facilities. The overall vaccination rates of 20.7% for HAV and 21.9% for HBV were low. The quality measure rates were 57.0% and 45.5% for HBV and HAV, respectively. Factors related to HCV care were also determinants of meeting the HBV quality measure. These factors included receiving a specialist consult, genotype testing, or HCV treatment. Patients who were older, had psychosis, and had a higher comorbidity score were less likely to meet the HBV quality measure. Similar variables were related to meeting the HAV quality measure with few exceptions. Incidence of superinfection with acute HAV and HBV was significantly lower in patients who received vaccination than in those who did not. Validity concerns were alleviated by the fact that laboratory values and ICD-10 codes from the clinical case registry were highly accurate.

A retrospective review was conducted by Loy, Kwiatt, Dodda, Martin, Dua, & Saeian (2016) to identify adherence to quality measures for cirrhosis which included HAV and HBV immunization. Prospectively, they measured compliance with quality measures at 1-month, 2-month, 1-year, and 3-year follow-up after performance feedback. Baseline HAV and HBV immunization was 51% and 47%, respectively. After performance feedback, HAV and HBV vaccination rates improved to rates ranging from 92% to 100% and remained statistically significant ($P < .0001$) over a 3-year time period. Weaknesses of this study included reliance on chart review and that the performance feedback was provided to a group of health care providers as opposed to individual providers.

In a retrospective pre-post study, Petroll et al. (2014) compared rates of preventive health delivery to HIV patients at an outpatient clinic during the use of paper medical records (PMR) and implementation of an EMR. The study sought to determine the impact that an EMR had on the provision of preventive health measures that included obtaining serologies for viral hepatitis and administering vaccinations to non-immune HIV patients. The sample consisted of 160 active patients whose charts were randomly selected for review at two time points: 12-16 months prior to and 24 months following EMR implementation. There was no difference between the PMR and the EMR with regard to proportion of patients who had HAV (83% in PMR group and 77% in EMR group) and HCV (94% in both groups) serologies measured or the proportion of eligible patients who were given hepatitis vaccinations. Slightly fewer had serology for HBV measured. EMR had no effect on vaccination administration. A strength of the study was the random selection of charts. The pre-post comparison was a weakness as some of the patients could have received vaccinations that were not documented prior to the study.

Ramirez et al. (2016) conducted a before and after cohort study to review HAV and HBV antibody testing and vaccination status of patients with chronic liver disease in a liver clinic. They attempted to improve vaccination rates by using a pre-printed order set with reminder check boxes to order serum antibody testing and HAV and HBV vaccinations for patients with chronic liver disease who had negative results. Patient records from a 2005 cohort before the intervention were compared with patient records from a 2008 cohort after the intervention. Among the chronic liver disease patients, those with HCV infection were the most likely to be screened for immunity to HAV and HBV. The raw number of patients screened increased from 157 to 440 for HAV and 156 to 447 for HBV as well as the percentage of those who completed vaccinations. However, the percentage of completed vaccination was less in HBV immunization compared with HAV, most likely due to the multiple visits required to complete the HBV series (3 for HBV and 2 for HAV). A weakness of this study was that some patients in the 2008 cohort were likely the same patients from the cohort, so there was potential for overlap. Also, patients were classified by diagnosis with no account for severity of disease, which might have caused a pre-selection bias.

Rowe, Parker, Armstrong, Houlihan, and Mutimer (2012) completed a meta-analysis of 10 studies that included a total of 22,371 persons with HCV infection. The aim of the study was to determine the mortality risk of HAV superinfection in CHC infection, and to define the utility of HAV vaccination using incidence and mortality data. The studies reported the outcomes of cohort studies, population surveillance studies, and the outcomes of HAV outbreaks. The researchers estimated that 814,849 patients need to be vaccinated (at a cost of \$80.1 million) to prevent one death per year from HAV in HCV-infected persons. Using the pooled estimate of increased mortality risk of HAV superinfection, the researchers estimated that two to three deaths per year are attributable to HAV superinfection in HCV-infected persons, or one in every 2,190 deaths

(0.05%) attributable to HCV infection. The study concluded that vaccination is unlikely to lead to a significant improvement in mortality in this population and that persons with HCV infection are at low risk from mortality due to HAV superinfection in low incidence areas such as the US. In this meta-analysis of observational studies, significant heterogeneity between studies may have publication bias as CHC measured by polymerase chain reaction was only reported in one study. A strength of the study was the sensitivity to changes in incidence of HAV in analyzing cost-effectiveness.

In a large retrospective cohort study of 1,193 patients diagnosed with CHC infection conducted at a New York Veterans Affairs healthcare system, Shim et al. (2005) found that despite multiple visits to their primary care physicians or to the Gastroenterology Clinic, only 54% of the patients in the study who had CHC had been tested for HAV. Slightly more than half of those who were tested were susceptible to HAV but only 27% received at least one dose of the HAV vaccine. There were 323 patients (0.9%) who were already immune to HAV, and 1.1% of the 553 subjects who were never tested. Among the 94 vaccinated patients, 45 received only one dose of the vaccine. Three of the unvaccinated patients developed acute HAV infection during follow up and 1 of them died of acute liver failure. The large sample size, the availability of long-term follow up data, and the use of the computerized record system and pharmacy database to obtain detailed demographic and clinical data were strengths of the study. The retrospective design, the single center health system, and most patients being male were weaknesses of the study as findings may not be generalizable to other VA medical centers, non-VA settings, or women. Reasons for low HAV testing and vaccination rates in the patients could not be determined.

A 2-page questionnaire was mailed to 3,000 primary care and internal medicine physicians randomly selected from the AMA Physician Masterfile in 2006 for a study conducted by Tenner et al., (2012). The purpose of the study was to determine primary care physician knowledge, attitudes, and barriers to vaccination against HAV and HBV in patients with chronic liver disease due to HCV, and to evaluate whether these differ between family medicine and internal medicine physicians. Completed surveys were returned by 1,209 (42.2%) of 2,862 eligible physicians. There were 557 family medicine physicians and 652 internal medicine physicians in the sample. Family physicians were less likely to see more +HCV patients per week than internal medicine physicians (29.3% vs. 34.8%, $p < 0.04$). Fewer family medicine physicians compared with internal medicine physicians knew that HCV-infected patients who were HCV PCR positive should receive the HAV vaccine ((62.7% vs. 76.5%, $p < 0.006$) and the HBV vaccine (65.4% vs. 79.6%, $p < 0.001$). Compared with internal medicine physicians, a consistent, significantly lower percentage of family medicine physicians felt that the HAV and HBV vaccines were safe and effective and that HCV patients should be vaccinated for HAV and HBV. A low proportion of both groups of physicians reported that HAV/HBV testing should be done prior to vaccinating. The survey was pre-tested prior to mailing by both gastroenterologists and primary care physicians for clarity and consistency. The relatively large, randomly selected sample of physicians from a comprehensive physician database was anonymous and geographically diverse, which were strengths of the study. A weakness of the study was due to the self-reported nature of the survey, which may not have reflected actual practice patterns of the respondents.

During a 12-month retrospective cohort study in 2008 conducted at the Center for Liver Diseases of the UPMC-Presbyterian Hospital, Thudi et al. (2013) reviewed the records of 705 patients who had chronic liver disease meeting criteria for vaccination for HAV and HBV and had

a minimum of 2 follow-up visits during the study period. The objectives of the study were to evaluate adherence to hepatitis vaccination guidelines in patients with chronic liver disease at a tertiary hepatology clinic, to identify barriers to vaccinations in patients with chronic liver disease, and to determine physician variability in adherence to vaccination guidelines. HAV antibody was tested in 619/705 patients (87.7%) and of those, 29.5% tested positive for HAV antibody (immunity). There were 637/705 patients tested for HBsAg (90.4%), 596/705 (84.5%) tested for HBsAb, and 591/705 (83.8%) tested for HBcAb. Of those patients, 29.5% tested positive for HBsAb (immunity due to previous vaccination or past infection). Vaccination for HAV was recommended to 63% of the patients and 177 (68.3%) underwent vaccination. HBV vaccination was recommended to 59.7% of the patients. Significant variability was observed in vaccination recommendation amongst individual providers (30-98.6%). There were no differences in vaccination rates for Medicare patients with HCV infection for whom a vaccination reminder was automatically generated by the EMR. Insurance was a barrier in a minority of patients. This study showed that vaccination rates for hepatitis were low even in an academic, sub-specialty clinic. This retrospective study was performed at a single center and did not record differences between physicians and advanced practice providers that might have explained the individual variability in vaccination recommendation rates. Also, the EMR-based reminders were only required during the study period for Medicare patients with HCV, so results on the automated computerized reminders may not be generalizable to other groups of patients.

Synthesis

The evidence collected through the evaluation of 20 documents including four randomized controlled studies (Campbell et al., 2007; Nowalk et al., 2016; Zimmerman, et al., 2016; and

Zimmerman et al., 2017), one meta-analysis (Rowe, Parker, Armstrong, Houlihan, and Mutimer, 2012); 11 retrospective cohort studies (Felson et al., 2010; Hachem et al., 2008; Hechter et al., 2014; Hernandez et al., 2009; Kanwal et al., 2010; Kramer et al., 2011; Loy et al., 2016; Petroll et al., 2014; Ramirez et al., 2016; Shim et al., 2005; Thudi et al., 2013), one mixed methods study (Nowalk et al., 2014), one follow up study (Koenig et al., 2016), one prospective cohort study (Gannon et al., 2012) and one survey (Tenner et al., 2012) support the need for multi-strategy interventions to increase hepatitis A and B vaccination rates in HCV-infected persons. Only one study, the meta-analysis by Rowe et al., 2012, challenged the use of routine HAV vaccination in HCV-infected persons, and found the number needed to vaccinate to prevent one death per year would be costly at \$80.1 million, which the researchers believed would likely expose many individuals to an intervention of no direct benefit. Thirteen of the 20 studies used retrospective EMR reports to gather data, which is an efficient way to identify a cohort of study subjects and avoids the problem of potential selection bias. However, although an EMR allows detailed and accurate data capture, the data were dependent on documentation that a vaccination was given and some of the patients that were vaccinated outside of the study sites were not counted as vaccinated. The research suggests that interventions aimed at systems rather than the patient have better success. Four of the studies used the 4 Pillars™ Program and practices that used more strategies from the program demonstrated larger increases in adult immunizations. Based on the review of the literature, these studies support the finding that vaccination rates for HAV and HBV in adults with HCV are low and that delays in or lack of vaccination increases the morbidity and mortality of these patients.

Theoretical Framework

A combination of evidence-based HCV recommendations, along with strategies adopted from the 4 Pillars™ Practice Transformation Program and Kotter's eight step change model facilitated the design for this high-priority HCV practice change.

Strategies From the 4 Pillars™ Practice Transformation Program

Focusing on barriers and facilitators of adult immunizations from the provider and patient perspectives, the 4 Pillars™ Practice Transformation Program model provided a good fit for this project as it is an evidence-based compilation of best practices and step-by step guide for increasing adult immunizations in primary care settings, (Nowalk, et al., 2016). Developed by a team in the Department of Family Medicine, University of Pittsburgh School of Medicine, it is founded on four key domains: Pillar 1- Convenient vaccination services; pillar 2- Communication with patients about the importance of immunization and the availability of vaccines; Pillar 3- Enhanced office systems to facilitate immunization; and Pillar 4- Motivation through immunization champions (Nowalk, et al., 2016). This program was being considered for commercialization at the time of this project and so permission was requested and granted to use the concepts from the program (Appendix C).

Kotter's Eight Stages of Change Management

Following Kotter's (Kotter,1995) eight steps for successful change management helped to guide the organization and clarify the communication plan for the project. John Kotter, a professor of leadership at Harvard University during the 1990's, studied over 100 companies and their organizational change efforts. He determined more than half of all major organizational changes fail due to a lack of interest or too much energy spent on resisting the change (Kotter, International, 2012). According to Kotter, the key to facilitating change is identifying why the organization resists change and then determining what process to use to overcome the resistance.

He developed eight stages to facilitate the change process and help leaders to understand their role in driving change. These eight stages include:

1. Creating Urgency. The first step involves helping others to feel the determination to take action and is driven by a belief that there are great opportunities as well as great hazards in the world. Kotter stressed that to initiate change, it is important to create a sense of urgency in order to overcome complacency. The sense of urgency for the need to develop and implement a change in service delivery was based on the alarming trends of increased patients within the organization with chronic HCV and made a compelling case for the organization to assemble a team of leaders within the organization who could spread the model to multiple clinic sites. Within this study site, the urgency came with the increased numbers of patients with HCV infection seen in the MAT programs needing immunized. The problem of low rates of HAV and HBV vaccination in adults with CHC described in the literature needed to be addressed within the organization along with the knowledge that performance measures needed to be met for the care of patients infected with HCV. Data obtained from baseline reports were used to strengthen the sense of urgency for the change. Providers and staff within the practice were expected to be motivated to improve vaccination rates by knowing the percentage of adult patients with CHC within the practice who were not fully immunized.

2. Forming a Coalition. The second step calls for putting together a group with position, power, credibility, expertise, and leadership skills to lead the change. This was created through buy-in of the administrative staff after the project manager presented the quality improvement project to them according to the organization's policy for research evaluation. The change project was explained and presented as an educational offering to the support staff and the provider team during their regularly scheduled meetings. Nurse managers trained in motivational interviewing

were recruited as immunization champions from each of the 5 primary care sites within the organization due to their knowledge of vaccine administration and their ability to share current evidence-based immunization guidelines and recommendations. Enlisting the expertise of the nurse managers of the clinical sites facilitated learning and change. They championed the cause of immunizing patients with CHC against HAV and HBV and organized pre-visit planning activities to help avoid missed opportunities for vaccinating patients.

3. Creating a Vision. A clear vision is developed to guide the change is the third step. The project facility has a mission statement, “To improve the lives of people in the communities we serve by treating their illness and helping them stay healthy”. This quality improvement project helped improve the lives of adult patients with CHC within the organization by providing preventive treatment with HAV and HBV vaccinations to protect the health of their livers.

4. Communicating the Vision. Using strategies from the 4 Pillars™ Practice Transformation Program for the change project enabled the project manager to communicate the vision using a clear, simple model. The staff and providers were advised of the important role they play in the success of the project. There was an open line of communication with the project manager and the staff was encouraged to ask questions at any point in the intervention. An in-house educational presentation created by the project manager included a review of the current recommendations for immunizing patients with CHC against HAV and HBV, interpretation of laboratory results for HAV, HBV, and HCV, vaccine schedule for HAV and HBV, vaccine administration guidelines, and frequently asked immunization questions. The project manager was able to communicate the vision of this new model and encourage providers and staff to act by presenting educational materials and strategies to support immunization of adult HCV infected patients at the FQHC clinic sites. Reporting the organization’s status on meeting performance

measures were clearly communicated through email communication with the facility staff and verbally at staff, administration, and board meetings.

5. Short-Term Wins. The immediate improvement in the overall vaccination rate of the patient population was a short-term win for the FQHC. Small successes were celebrated each week during morning huddle meetings of the support staff, and the staff felt rewarded for their efforts when a patient with HCV infection had initiated the series of vaccinations and lessened the risk of developing the serious life-threatening complications of cirrhosis or HCC. A gourmet cupcake celebration occurred halfway through the project to keep motivation high and providers and staff focused on completion of the project.

6. Removing Obstacles. According to Kotter (Harvard Business Review, 2012), ensuring that the organization removes barriers will accelerate movement toward the vision and the opportunity. Encouraging staff to use the standing orders that are in place for immunizations expedited the process of preventive care and decreased missed opportunities. Standing orders have been shown to significantly improve adult vaccination by eliminating barriers such as the time required for the provider to assess vaccination status and issue a verbal or written order to vaccinate (Yonas, Nowalk, Zimmerman, Ahmed, & Albert, 2012). Having immunization champions to maintain sufficient vaccine stock within the clinic sites was an important part of avoiding missed opportunities for vaccinating patients. Open-access, walk-in appointments for immunizations were also good strategies to facilitate completion of vaccine series.

7. Continuing Change. In step seven of Kotter's eight stages of change, the leader builds on successes and identifies areas to improve. During the project intervention, the immunization champions and project manager highlighted progress in increasing HAV and HBV vaccinations at morning huddle meetings and on charts placed on the refrigerators where the vaccines were

stored. Data was shared at the organization's monthly quality improvement meetings. At the end of the intervention period, results and final statistical analysis was shared with the organizations' leadership, quality improvement committee, staff, and the board of directors. Input was requested from the staff regarding program weaknesses and areas that can be built upon for continued development and improvement of the process of care for adult patients with HCV at the FQHC.

8. Maintaining the Change. In the last step of Kotter's change model, the change is solidified into the organizational culture. At the completion of the project, after review of the change process, the organizational leadership examined ways to incorporate improvement of vaccination rates as part of practice standards of care for adult patients with HCV, with a plan for succession. With the high number of HCV-infected patients seen in the FQHC, HCV protocols will be updated using EMR decision support to increase testing for HVC. Anti-HCV testing will be added to routine lab testing, such as cholesterol screening to help identify seropositive baby boomer patients. The project manager, an HCV champion, must continue to address barriers to implement EMR prompts for HCV testing, including system barriers: inability to make any IT programming demands due to large proprietary EMR limitations; clinician barriers: "Prompt burn-out"; and patient barriers: lack of insurance coverage for testing. Quality measurement in HCV care has the potential to affect clinical practice, and maintain the improved rates of immunizations, especially when quality measures for immunizations will eventually affect reimbursement rates for the FQHC (Kanawal, 2012).

Project Design

Evidenced Based Project Intervention Plan

The primary intervention employed to change current practice and improve HAV and HBV vaccination rates in adult patients with HCV at the sites used evidence-based strategies from

the 4 Pillars™ Practice Transformation Program (Appendix C). Strategies included: open-access nurse visits, using all visits to vaccinate, standing orders, posters, patient reminder postcards (Appendix D), use of EMR patient alerts, immunization champions, progress charts and staff/provider education (see Figure 1).

Figure 1. Project model. Adapted from the University of Pittsburgh's 4 Pillars™ Practice Transformation Program. Retrieved from <http://www.4pillarstoolkit.pitt.edu/> and Kotter International. (2012). *The 8-step process for leading change*. Retrieved from <http://www.kotterinternational.com/our-principals/changesteps>

The primary goal of this project was to determine the effectiveness of an intervention to increase hepatitis A and B vaccination in adults with HCV that included using strategies from the 4 Pillars™ Program, and staff/provider education. Based upon published clinical guidelines and performance measures for optimal care of HCV-infected persons, a quality improvement project was implemented guided by Kotter's eight-step change model. Strategies adopted from the 4 Pillars™ Practice Transformation Program, including staff/provider education, vaccination, EMR reminders, patient post card reminders, and weekly charts to track progress standing orders,

immunization champions, open access/walk-in vaccination during office hours, posters promoting were used. Retrospective EMR reviews from CHC patients with detectable HCV RNA were conducted at the start of the project and three months following the intervention. Demographic data along with HCV viral load (HCV RNA), HAV total antibody (HAV Ab), HBV surface antibody (HBsAb), and vaccination against HAV and HBV were derived from EMR reports, comparing vaccination rates before and after the intervention. Secondary goals included increasing provider/staff knowledge related to CHC infection and clinical guideline recommendations for immunization against HAV and HBV.

Guidelines and Benchmarks for CHC Care

Strong evidence supports HAV and HBV vaccination in patients with chronic liver disease, and is endorsed by the clinical guidelines set forth by the American Association for the Study of Liver Diseases and the Infectious Diseases Society (AASLD-IDSA, 20017) in addition to: the ACIP, the World Health Organization, the National Institute of Health, the American Liver Foundation, the American College of Gastroenterology, and the Department of Veterans Affairs Hepatitis C Resource Center Program (Fiore, Wasley, & Bell, 2006; Yee, Currie, Darling, & Wright, 2006). The Centers for Medicare and Medicaid Services adopted vaccination against HAV and HBV in patients with CHC infection as a quality measure in 2008 (Waghray, et. al., 2016). In 2012, the CDC expanded its guidelines originally issued in 1998 for risk-based HCV testing with a recommendation to offer a one-time HCV test to all persons born from 1945 through 1965, without prior ascertainment of HCV risk factors (AASLD-IDSA). Healthy People 2020 includes objectives to increase HBV vaccine coverage among high-risk populations, increase HBV vaccine coverage among injection drug users, increase the proportion of persons who have been tested for HBV within minority communities experiencing health disparities, and

increase the proportion of persons aware they have a HCV infection (Healthy People, 2020). The proposed 2020 goals of the US National Viral Hepatitis Action Plan for 2017-2020 has four goals: increasing from 33% to 66% the persons who are aware of their HBV infection, increasing from 45% to 66% the proportion of persons who are aware of their HCV infection, reducing by 25% the number of new HCV infections, and eliminating mother-to-child HBV transmission (US DHHS, 2017). To achieve these goals, the plan specifically targets education of providers and communities. It is unclear to what extent patients with HCV meet these recommendations. Overall, vaccination for viral hepatitis has been reported to be poor with less than 60% of patients with HCV meeting quality measures for vaccination (Kramer, Hachem, Kanwal, Mei, & El-Serag, 2011). With the advent of these proposed goals, the importance of understanding the current processes of care for HCV-infected patients and assessing quality gaps for immunization is warranted.

Congruence of Organization's Strategic Plan to Project

This project supports the mission, values, goals and strategic plan of FamilyCare Health Centers. The mission of FamilyCare is "to improve the lives of people in the communities we serve by treating their illness and helping them stay healthy". The intervention aimed to improve the health status of adult patients with CHC through vaccination against HAV and HBV. Hepatitis C services were identified as a strategic priority by FamilyCare's administration and Board of Directors in 2014. With the basic infrastructure for this project currently in place, this project fit entirely within the framework FamilyCare has created through their Behavioral Health Integration funding. (See Appendix K Letter of Support).

The clinical change project was constructed as a quasi-experimental, one group pre-test/post-test design, with a convenience sample of family medicine providers and staff members

from five primary care sites within a large FQHC in West Virginia who were attending their monthly staff meeting on January 3, 2018. During the provider/staff education phase, an evidence-based educational curriculum on The Role of Vaccinating Adult Patients with HCV against HAV and HBV in the Prevention of Cirrhosis and HCC was developed by the project manager according to evidence-based recommendations from the CDC, to assist providers and staff members in ordering appropriate laboratory testing, interpreting laboratory test results, and ordering hepatitis vaccinations for adults with HCV. Strategies from the 4 Pillars™ Practice Transformation Program were presented (Appendix E). The pretest-posttest was developed based on the review of the literature and evidence-based guidelines.

Procedure

Following the IRB review and approval in December 2017, the educational program was presented in a power point session at a monthly family medicine provider/staff member meeting to physicians, nurse practitioners, physician assistants, and staff members on January 3, 2018. (Appendix E). Use of educational posters placed in each of the break rooms at five clinic locations, provided easy access to providers and staff, and was an efficient way for the immunization champions to present the strategies (Appendix F).

Data on effectiveness of education for the diagnosis of HCV and the role of HAV and HBV vaccination in preventing cirrhosis and HCC was evaluated using a pre/posttest questionnaire, “Hepatitis Knowledge Assessment” (Appendix G).

Patients ages 18 years and older with a detectable HCV RNA, defined as a measurable quantifiable viral load were included in the retrospective chart review. Because immunization is a dynamic, measurable area of healthcare and the patient population was already involved in the immunization process, the abbreviated timeframe of three months was used for the

implementation and evaluation of the project, looking at vaccination rates at two points in time: at the start of the project before the educational intervention, and at the end of the three-month project. The accessible population of persons in the FamilyCare Hepatitis C EMR report included a total of 278 patients. All patients who were anti-HCV-positive only but did not have HCV RNA testing or a negative HCV RNA result were excluded which resulted in a sample of 130 patients from the pre-intervention data and 229 patients from the post-intervention data. The FQHC used an EMR system that included clinic visit notes, diagnostic codes of the clinic encounter, all prescriptions, and laboratory data in searchable form. Descriptive statistics were used to describe baseline vaccination rates for HAV, HBV, and HAV/HBV, with the goal of a 20% increase in the post-intervention data gathered. Demographic data such as age, gender, and insurance were reported. HCV viral load (HCV RNA), HAV (HAVab), HBV surface antibody (HBsAb), and vaccination against HAV and HBV were derived from EMR reports, comparing vaccination rates before and after the quality improvement project with the assistance of the IT staff at FamilyCare. All personal health information was de-identified before data analysis was completed.

Nurse managers in each of the five family medicine sites were recruited as immunization champions. Health coaches were an initial consideration for serving as immunization champions, however, there were not health coaches at each of the sites. The nurse managers were chosen as they are most often responsible for ordering immunizations and are the lead clinicians for educating the support staff. The immunization champions placed awareness posters in each of the examination rooms, (Appendix H) and posted weekly progress charts on each of the clinic refrigerators where vaccines were stored (Appendix I). Immunization champions kept track of vaccine stock and made sure there were vaccines available in the clinics in order to avoid missed

opportunities. They reported progress in Monday morning huddle meetings, and led the staff in pre-visit planning activities, another strategy that may help to avoid missed opportunities.

Timeline of Project Phases

As depicted in Figure 2., Project Timeline, the entire project from selecting a capstone committee in March of 2017, to IRB submission, and then to completion spanned over 12 months. Dates in the projected timeline were adjusted as needed based on unforeseen circumstances that might have occurred for the project manager. In this project, the timeline for beginning the project had to be delayed until the beginning of 2018, as the IRB approval was not received until December. Because staff meetings are only held once a month, it was imperative that the project began at the beginning of January at the first monthly staff meeting of the year in order to gather three months of data. The timeline for the project was divided into three phases: Phase 1-Summer Semester 2017, Phase 2-Fall Semester 2017, and Phase 3-Spring Semester 2018. The development phase of the intervention began with completion of a draft of the proposal paper at the end Summer Semester 2017. The development phase was completed after final revisions from the full capstone committee were reviewed and all materials to be used for the project were finalized. The project was approved by the Institutional Review Board of West Virginia University on December 19, 2017 during Phase 2-Fall Semester. Project implementation began in January at the beginning of Spring Semester 2018. The project was implemented during the months of January, February, and March with data analysis and write up occurring at the end of March of 2018. A formal oral defense presentation of the results was on April 2, 2018 prior to graduation in May of 2018 (See Figure 2).

Figure 2.

Resources: Personnel, Technology, and Budget

The cost of the project was difficult to actually determine, as the largest cost was the salaries/wages of the staff and providers. FamilyCare was responsible for the respective employees' salaries, and thus they participated in the intervention at no cost to the project manager. Additional costs to the organization were minimal. The staff was already in place and working in the five primary care sites where the project took place, providing reimbursable care for the clinic visits. There may be some additional payer reimbursement for immunizations provided to patients with private insurance. However, most of the HCV patient population is covered by Medicaid and the cost for the vaccines was wrapped into a set fee for each visit. Although it is not likely there would be a significant return on investment for the health center in terms of revenue generated, completing the series of vaccinations requires returning to the clinic for follow up after initial testing to determine immune status. This involves additional visits

which could provide some additional income for the organization. There was no cost to the project director for classroom space, and audiovisual equipment. Another cost was the time the project director spent gathering pre- and post-data, implementing the intervention, and disseminating the data collected, which will be free.

There were projected to be 10 physicians, 11 advanced practice clinicians, 6 registered nurses, 5 LPNs, and 30 medical assistants participating in the project. The investigator estimated the cost of nursing salaries to be \$420.00 dollars by taking an average of \$20.00 dollars per hour for registered nurses, \$12.00 dollars per hour for the LPNs, and \$8.00 dollars per hour for the medical assistants. Cost for the participation of the advanced practice clinicians was estimated at \$495.00 dollars by allowing \$45.00 dollars per hour. Physician salaries were estimated to be \$1,250.00 dollars by allowing \$125.00 dollars per hour. In order to provide an educational intervention lasting approximately one hour at the beginning of the project and manage the quality improvement project over the course of the project, the nurse practitioner investigator will be needed for five hours per week for 12 weeks at a cost of \$2,700.00 dollars. The total cost for time to participate was projected to be \$4,829.00 dollars (Appendix J).

The investigator estimated the cost of the operating budget to be as follows: posters for exam rooms \$100.00 dollars, patient reminder cards \$250.00 dollars, badges for immunization champions \$50.00 dollars, posters for nursing staff break rooms \$ 125.00 dollars, hospitality \$200.00 dollars. The total cost of the operating budget was projected to cost \$725.00 dollars. The overall total cost of the intervention was projected to cost \$5,554.00 dollars. (Appendix M).

Long-term healthcare cost savings will be generated by reducing morbidity and mortality associated with the high burden of disease from CHC expected over the next 10-15 years, including the life-threatening hepatic complications of cirrhosis and HCC. With a growing need

for advanced practice registered nurses to serve patients in rural and underserved areas, the project, “Improving Nursing Scholarship, Practice, Innovation, Research, and Education to Care for WV (INSPIRE to Care for WV)” was implemented by a team of faculty from the West Virginia School of Nursing through a three-year, \$1.2 million grant from the Health Resources and Services Administration. Grant funds were anticipated from the INSPIRE project at West Virginia University to help cover the cost of the project but were not needed to complete the project.

Measurable Project Objectives

Specific outcomes to be achieved/evaluated as part of this capstone were:

1. Provider/staff knowledge regarding hepatitis A and B immunizations for adult patients with HCV diagnosis would improve after one educational session as evidenced by a change from pretest to posttest knowledge score.
2. By the end of the project, immunization rates for HAV (Havrix), HBV (Engerix-B), and HAV/HBV (Twinrix) would improve following the quality improvement project as evidenced by a 20% overall increase in rates using retrospective data analysis from EMR reports.

Evaluation

To meet objective 1, the health care providers’ and staff members’ knowledge related to CHC infection and clinical guideline recommendations for immunization against HAV and HBV were evaluated before and after an educational presentation using 20 items from a pretest-posttest questionnaire (Appendix I). The pretest, educational presentation, and post-test

was administered to providers by the project manager at their monthly staff meeting, and the pretest, educational presentation, and posttest was administered to the staff members at their monthly staff meetings by nurse managers at each of the sites. A change in knowledge from pretest to post-test was measured with a paired t- test.

To evaluate objective 2, descriptive statistics were used to describe baseline vaccination rates for HAV, HBV, and HAV/HBV, with the goal of a 20% increase from baseline. De-identified retrospective EMR reports from CHC patients with detectable HCV RNA were conducted at two time points: prior to and threemonths following the provider/staff education intervention. Demographic data along with HCV viral load (HCV RNA), HAV total antibody (HAV Ab), HBV surface antibody (HBsAb), and vaccination against HAV, HBV, and HAV/HBV were derived from the de-identified EMR reports, comparing vaccination rates prior to the implementation and three months after the implementation. Because HAV (Havrix) is given as a 2-dose series, at 0 and 6 months, and HBV (Engerix B) and HAV/HBV (Twinrix) are given as a 3-dose series at 0, 1 and 6 months, the primary outcome measures were the percentage of patients who were eligible to receive HAV and HBV vaccination (+HCV RNA) and actually received a vaccination for each of the vaccines at baseline and at the end of the active project.

Results

Provider/Staff and Patient Demographics

A total of 50 people, 14 providers, mostly physicians and nurse practitioners and 36 staff members, mostly medical assistants attended the one-hour, educational session (see Table 1.)

Table 1

Provider Demographics

Characteristic	Providers Freq (%) N=50
Clinical Title	
Nurse Practitioner	4
Physician	9
Physician's Assistant	1
RN	2
LPN	14
Medical Assistant	20
Years in Practice	
Nurse Practitioner	2-17 yrs.
Physician	5-25 yrs.
Physician's Assistant	8yrs.
RN	2-23 yrs.
LPN	1-22 yrs.
Medical Assistant	1-36 yrs.

Provider/Staff Knowledge

The educational intervention significantly increased the providers' and staffs' knowledge about hepatitis C. There was an average gain of 16.76 points (95% confidence interval, 13.32, 20.20) on a knowledge test after the educational presentation. This gain was statistically significant at $p \leq .05$ by the paired t -Test (see table 2)

Table 2

Paired Samples Test

		Paired Samples Test							
		Paired Differences							
					95% Confidence Interval of the Difference				
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper	t	df	Sig. (2-tailed)
Pair 1	Postknow - Preknow	16.80000	12.36189	1.74824	13.28679	20.31321	9.610	49	.000

There was concern for validity of results as there was a low degree of implementation fidelity. One nurse manager allowed the participants in her group to have access to the educational presentation during the posttest which may have increased their scores. Several participants did not put their names on the questionnaires and so these could not be included in the evaluation. A typographical error was discovered when the project manager was scoring the pretests and posttests which required discarding several questions and re-numbering the remaining questions in order to have the same 20 questions on each of the tests.

Patient Demographics

The pre-intervention sample included 130 patients. Ages ranged from 19 to 75 with the mean age 41.03 (see Table 3). The mean age for the post-intervention sample was 40.30. Women accounted for 55.4% of the population in the pre-intervention group and 53.7% in the post-intervention group which is consistent with the general patient population at FamilyCare where 61.1% are women (UDS reporting, 2017). The FQHC recently began providing urgent care and chronic care services to a local long-term addiction treatment center for women which could also have increased the number of women patients in the sample. The majority of patients were insured by Medicaid (79.2%). Medicare accounted for 19.2% of patients' health insurance. There were 2 patients who were uninsured (1.5%). Although FamilyCare does see patients with commercial insurance, there were no patients in this study who were commercially insured.

Table 3

Pre-intervention Ages

	N	Minimum	Maximum	Mean	Std. Deviation
age	130	19.00	75.00	41.0308	12.98296
Valid N (listwise)	130				

Post-intervention Ages

	N	Minimum	Maximum	Mean	Std. Deviation
age	229	20..00	75.00	40.3013	12.54574
Valid N (listwise)	229				

Table 4

Pre-intervention Gender

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Male	58	44.6	44.6	44.6
	Female	72	55.4	55.4	100.0
	Total	130	100.0	100.0	

Post-intervention Gender

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	male	106	46.3	46.3	46.3
	female	123	53.7	53.7	100.0
	Total	229	100.0	100.0	

Table 5

Pre-intervention Payor

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Medicaid	103	79.2	79.2	79.2
	Medicare	25	19.2	19.2	98.5
	Other	2	1.5	1.5	100.0
	Total	130	100.0	100.0	

Post-intervention Payor

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Medicaid	173	75.5	75.5	75.5
	Medicare	32	14.0	14.0	89.5
	Other	24	10.5	10.5	100.0
	Total	229	100.0	100.0	

Vaccinations

Pre-intervention baseline rates of Havrix, Engerix-B, and Twinrix vaccinations were established from the retrospective review of 130 patients with HCV (see Table 6). Post-intervention rates of these vaccinations were collected from retrospective chart reviews of 229 patients with HCV at the end of the three- month quality improvement project to evaluate the percentage of patients with HCV who had vaccinations. Due to prior immunity from previous exposure to HBV or vaccination outside of the clinic, only 2.3% of patients met the performance measure for HBV vaccination in the pre-intervention group. Improvements were seen for Havrix (16.9% pre-intervention, 19.7% post-intervention); Engerix-B (2.3% pre-intervention, 3.5% post-intervention); and Twinrix (20.8% pre-intervention, 21.4% post-intervention). Compared with the baseline sample (n=130), there was an overall 4.6% increase in vaccination rates in the post-intervention group. The project manager found overall adherence to the performance measure to vaccinate all HCV-positive patients for HAV and HBV was 40.0% in the pre-intervention group and 44.6% in the post-intervention group. This is considerably lower than a previous Veterans Administration study that demonstrated combined rates for HAV and HBV at 62% (Thudi, et al.,

2013). Of the 127 patients who received no vaccinations, 21 were immune to both hepatitis A and hepatitis B.

Table 6

Pre-intervention Vaccinations

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Havrix	22	16.9	16.9	16.9
	Engerix B	3	2.3	2.3	19.2
	Twinrix	27	20.8	20.8	40.0
	No vaccine	78	60.0	60.0	100.0
	Total	130	100.0	100.0	

Post-intervention Vaccinations

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Havrix	45	19.7	19.7	19.7
	Engerix-B	8	3.5	3.5	23.1
	Twinrix	49	21.4	21.4	44.5
	no vaccine	127	55.5	55.5	100.0
	Total	229	100.0	100.0	

Program Cost and Sustainability

The project came in under budget as outlined in Appendix M (\$ 1,084.88 vs. \$5,480.00) with the additional cost for postage that was not included in the projected budget. Two of the strategies from the 4 Pillars™ Practice Transformation Program were already in use at the sites, including walk-in immunizations and standing orders which allow non-physician personnel to

assess patients' immunization status and administer vaccines without an individual physician order. Standing order programs are a proven method of increasing adult immunizations (Nowalk, et al., 2014), and hopefully will be utilized more often since the educational intervention, which was intended to enhance staff effectiveness with managing hepatitis immunizations for adult patients with HCV. The patient alert in the EMR is an existing tool as well that can be employed specifically for alerting staff/providers when the next immunization is due and the patient's immune status.

Discussion and Recommendations

Successful implementation of this change project improved quality of care by expediting the application of an evidence-based model to improve HAV and HBV vaccination rates in adult patients with CH across five FamilyCare sites. The project increased awareness of hepatitis C as a serious health problem. There was an increase in the number of patients who asked about being tested for hepatitis. With increased knowledge, providers and staff encouraged patients to get tested which is evidenced by the increased number of patients in the post-intervention sample. This project had several limitations. One of the limitations is that the project was conducted within a single FQHC system, which serves a majority of patients that are publicly insured and therefore may limit the generalizability of the results. Other weaknesses included reliance on a retrospective manual chart review for data collection. The small sample size with no long-term follow-up did not allow for observation of completion of the vaccine series.

These findings suggest that healthcare providers do not frequently identify candidates for HAV and HBV vaccination as part of routine clinical services, even though HAV and HBV vaccination is recommended for persons with CHC. Continued focus on increasing provider/staff knowledge related to hepatitis A, B and C virus is recommended to ensure the vaccination rates

will improve as lack of adequate counseling and patient education may be a factor in patient compliance with vaccine recommendations. More emphasis needs to be placed on routine viral hepatitis screening, vaccination, and follow up for post-vaccination testing to check for immune status. Gaps in the literature show that future studies on interventions to increase immunization rates should include adequate follow up time to capture completion of the vaccination series and testing for immunity following vaccination, which supports the findings from this study. In addition, studies that examine the determinants for non-adherence for both patients and providers will be valuable information to help increase hepatitis immunization rates in persons with chronic hepatitis C, in any healthcare setting.

Conclusion

Rapid development of new HCV treatments along with increasing numbers of people being identified with HCV has increased the need for updated expert clinical guidance. The DNP will play a critical role in building health care provider capacity to diagnose and treat HCV. Accurate testing to identify current infection is important to help clinicians and other providers correctly identify patients with HCV so that preventive services can be offered. The ability of patients to improve their health is directly related to the quality of the prevention and care services offered (Quaglio et al.,2006). Notifying tested persons of their infection status, enabling them to make informed decisions about medical care and options for treatment, along with taking measures to limit HCV-associated disease progression by vaccination against HAV and HBV is paramount to improving the health of adult patients with HCV. Multi-strategy, evidence-based interventions were an effective means of increasing hepatitis A and B vaccinations in a community health center and led to increased access to vaccination services, increased community demand for vaccines, and

improved system-based performance. However, vaccination rates were only increased by 4.6% in a predominantly publicly insured patient population.

Attainment of DNP Essentials

Nurses play a significant role in preventing viral hepatitis. As educators, nurses teach healthcare providers and communities to reduce health disparities. Leveraging the expertise of advanced practice nurses' ability to provide accurate education and information regarding screening, testing, surveillance, and evaluation of the impact of strategies to immunize and prevent new hepatitis infections is integral to achieving the current goals for the care of patients with viral hepatitis. Completing this quality improvement project has given the project manager the experience needed to fulfill the Essentials of Doctoral Education for Advanced Nursing Practice. The DNP candidate utilized Kotter's evidence-based change model as a theoretical framework. Borrowing strategies used in the 4 Pillars Practice Transformation program helped her to lead a primary care team in increasing hepatitis A and B vaccinations in adults with HCV in a community health center across 5 sites based on a foundation in clinical prevention and population health. The project manager gained clinical expertise in current hepatitis A and B vaccination recommendations that improved patient outcomes. The project manager was able to demonstrate advanced nursing practice and specialization by developing and implementing an educational presentation for primary care providers and staff and applying clinical scholarship and analytical methods to design and direct quality improvement. Information systems technology was utilized to manage population level data and disseminate new information to the organization on the quality of care provided to patients with hepatitis C.

References

- Bedossa, P., & Poynard, T. (1996). An algorithm for the grading of activity in chronic hepatitis C. The METAVIR Cooperative Study Group. *Hepatology* 24, 289-93.
- Benvegna, L., Gios, M., Buccato, S., & Alberti, A. (2004). Natural history of compensated viral cirrhosis: a prospective study on the incidence and hierarchy of major complications. *Gut*, 53(5), 744-749.
- Campbell, J.V., Garfein, R.S., Thiede, H., Hagan, H., Ouellet, L.J., Golub, E.T., Hudson, S.M., Ompad, D.C., Weinbaum, C. (2007). Convenience is the key to hepatitis A and B vaccination uptake among young adult injection drug users. *Drug and Alcohol Dependence* (91S), S64-S72.
- Centers for Disease Control and Prevention (July 13, 2016), *Hepatitis A Questions and Answers for Health Professionals*. Retrieved from <https://www.cdc.gov/hepatitis/hav/havfaq.htm>
- Centers for Disease Control and Prevention (August 4, 2016). *Hepatitis B FAQs for Health Professionals*. Retrieved from <https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm>
- Centers for Disease Control and Prevention (January 27, 2017). *Hepatitis C FAQs for Health Professionals*. Retrieved from <https://www.cdc.gov/hepatitis/hcv/index.htm>
- Centers for Disease Control and Prevention, *Hepatitis C Kills More Americans than Any Other Infectious Disease*. Retrieved from <http://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html>
- Centers for Disease Control and Prevention (2015). *West Virginia-State Health Profile*. Retrieved from www.cdc.gov/nchhstp/stateprofiles/pdf/west_virginia_profile.pdf
- Chak, E., Talal, A. H., Sherman, K. E., Schiff, E. R., & Saab, S. (2011). Hepatitis C virus Infection in USA: an estimate of true prevalence. *Liver International*, 1090-1101.

Colosi, L., and Dunifon, R. (2006). What's the difference? "Post then Pre" & Pre then Post".

Cornell Cooperative Extension, 1-6.

Dan, C., Moses-Eisenstein, M., Valdiserri, R. (2015). CE: Viral hepatitis: New U.S. screening recommendations, assessment tools, and treatments. *American Journal of Nursing* (115)7, 26-35.

Denniston, M. M., Jiles, R. B., Drobeniuc, J., Klevens, M., Ward, J. W., McQuillan, G.M. & Holmberg, S.D. (2014). Chronic hepatitis C virus infection in the United States, National health and Nutrition Examination Survey 2003-2010. *Annals of Internal Medicine*, 160(5), 293-301.

Fiore, A.E., Wasley, A., Bell, B.P. (2006). Prevention of hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices. *MMWR*, 2006, (55) RR-7, 1.

Felson, U.R., Fishbein, D.A., & Litwin, A.H. (2010). Low rates of hepatitis A and B vaccination In patients with chronic hepatitis C at an urban methadone maintenance program. *Journal of Addictive Diseases*, 29(4), 461-465.

Gannon, M., Qaseem, A., Snooks, Q., Snow, V. (2012). Improving adult immunization practices in the primary care setting. *American Journal of Public Health*, 102(7), e46-52.

Ghany, M. G., Strader, D. B., Thomas, D. L., & Seeff, L. B. (2009). Diagnosis, management, and treatment of hepatitis C: an update. *Hepatology*, 49(4), 1335-1374.

Hachem, C.Y., Kramer, J.R., Kanwals, F., & El-Serag, H.B. (2008). Hepatitis vaccination in patients with hepatitis C: practice and validation of codes at a large veterans administration centre. *Alimentary Pharmacology & Therapeutics*, 28, 1078-1087.

- Hagan, L.M., & Schinazi, R.F. (2013). Best strategies for global HCV eradication. *Liver International*, 33 (suppl 1): 68-79.
- Harvard Business Review. (2012). *Accelerate!* Retrieved from <https://hbr.org/2012/11/accelerate>.
- Hecher, R.C., Jacobsen, S.J., Luo, Y., Nomura, J.H., Towner, W.J., Tartof, S.Y., & Tseng, H.F. (2014). Hepatitis B testing and vaccination among adults with sexually transmitted infections in a large managed care organization. *Viral Hepatitis*, 58, 1739-1745.
- Hernandez, B., Hasson, N.K., & Cheung, R. (2009). Hepatitis C performance measure on hepatitis A and B vaccination: missed opportunities? *The American Journal of Gastroenterology*, 104, 1961-1967.
- Hina-Syeda, H., Kimbrough, C., Murdoch, W., & Markova, T. (2013). Improving immunization rates using lean six sigma processes: alliance of independent academic medical centers national initiative III project. *The Ochsner Journal*, 13(3), 310-318.
- Kanwal, F., Hoang, T., Kramer, J., Chrusciel, T., El-Serag, H., Dominitz, J., & Asch, S.M. (2012). The performance of process measures in hepatitis C. *The American Journal of Gastroenterology*, 107, 1512-1521.
- Kanwal, F., Schnitzler, M., Bacon, B.R., Hoang, T., Buchanan, P.M., & Asch, S. (2010). Quality of care in patients with hepatitis C virus infection. *Annals of Internal Medicine*, 153(4), 231-239, W78-W84.
- Keeffe, E.B. (2006). Hepatitis A and B superimposed on chronic liver disease: vaccine-preventable diseases. *Transactions of the American Clinical and Climatological Association*, 117, 227-233.

- Klevens, R.M., Hu, D.J., Jiles, R., & Holmberg, S.D. (2012). Evolving epidemiology of Hepatitis c virus in the United States. *Clinical Infectious Diseases*, 55(S1), S3-9.
- Koenig, A., Stepanova, M., Felix, S., Kalwaney, S., Clement, S., & Younossi, Z.M. (2016). Vaccination against hepatitis A and B in patients with chronic liver disease and type 2 diabetes: has anything changed? *Liver International*. 1096-1100.
- Kotter International. (2012). *The 8-step process for leading change*. Retrieved from: <http://www.kotterinternational.com/our-principles/changesteps>
- Kotter, J. (1995). Leading change: Why transformation efforts fail. *Harvard Business Review*, March-April, 59-67.
- Kramer, J.R., Hachem, C.Y., Kanwal, F., & El-Serag, H.B. (2011). Meeting vaccination quality measures for hepatitis A and B virus in patients with chronic hepatitis C infection. *Hepatology*. 53(1), 42-51.
- Lavanchy, D. (2012). Viral hepatitis: global goals for vaccination. *Journal of Clinical Virology*, 55, 296-302.
- Loy, V., Kwiatt, J., Dodda, A., Martin, E., Dua, A., & Saeian, K. (2016). Performance feedback improves compliance with quality measures. *American Journal of Medical Quality*, 31(2), 118-124.
- Nowalk, M.P., Lin, C.J., Pavlik, V.N., Brown, A.E., Zhang, S., Moehling, K.K., Raviotta, J.M., South-Paul, J.E., Hawk, M. Ricci, E.M., Middleton, D.B. (2016). Using the 4 Pillars™ Practice transformation program to increase adult Tdap immunization in a randomized controlled cluster trial. *Vaccine*. 34, 5026-5033.

Nowalk, M. P., Nolan, B.A.D., Nutini, J., Ahmed, F., Albert, S.M., & Susick, M. (2014).

Success of the 4 pillars toolkit for influenza and pneumococcal vaccination in adults.

Journal for Healthcare Quality. 36(6), 5-15.

Nowalk, M.P., Nutini, J., Raymund, M., Ahmed, F., Albert, S.M., & Zimmerman, R.K. (2012).

Evaluation of a toolkit to introduce standing orders for influenza and pneumococcal vaccination in adults: A multimodal pilot project. *Vaccine*, 30, 5978-5982.

Ogholikhan, S. & Schwarz, K.B. (2016). Hepatitis vaccines. *Vaccines*, 4(6), 1-17.

Petroll, A.E., Phelps, J.K., & Fletcher, K.E. (2014). Implementation of an electronic medical record does not change delivery of preventive care for HIV-positive patients.

International Journal of Medical Informatics, 83(4), 1-9.

Quaglio, G., Lugoboni, F., Mezzelani, P., Jarlais, D.C., & Lechi, A. (2006). Hepatitis

vaccination among drug users, *Vaccine*, 24, 2702-2709.

Ramirez, J.C., Ackerman, K., Strain, S. C., Ahmed, S.T., de los Santos, M., & Sears, D. (2016).

Hepatitis A and B screening and vaccination rates among patients with chronic liver disease.

Reiss, Keeffe, E.B. (2004). Review article: hepatitis vaccination in patients with chronic liver disease. *Alimentary Pharmacology & Therapeutics*, 19, 715-727.

Rockey, D. C., & Bissell, D. M. (2006). Noninvasive measures of liver fibrosis. *Hepatology*, 43(2, Supp, 1), S113-S120.

Rossi, E., Adams, L.A., Bulsara, M., & Jeffrey, G.P. (2007). Assessing liver fibrosis with serum marker models. *The Clinical Biochemist Reviews*, 28(1), 3-10.

- Rowe, I.A., Parker, R., Armstrong, M.J., Houlihan, D.D., & Mutimer, D.J. (2012). Hepatitis A Vaccination in persons with hepatitis C infection: Consequences of quality measure Implementation. *Hepatology*, 56,501-506.
- Samandari, T., Bell, B.P., & Armstrong, G.L. (2004). Quantifying the impact of hepatitis A immunization in the United States 1995-2001. *Vaccine*,22, 4342-4350.
- Shaffer, M., & Ahuja, D. (2017). Hepatitis C: screening changes, treatment advances. *The Journal of Family Practice*, 66(3),136-14
- Shim, M., Khaykis, I., Park, J., & Bini, E.J. (2005). Susceptibility to hepatitis A in patients with chronic liver disease due to hepatitis C infection: missed opportunities for vaccination. *Hepatology*. 42(3), 688-695.
- Shippee, N.D., Mullan, R. J., Nabhan, M., Kermott, C.A., Hagen, T., Rhodes, D.J., Montori, V.M., & Murad, M.H. (2012). Adherence to preventive recommendation: experience of a cohort presenting for executive health care. *Population Health Management*, 15(2), 65-70.
- State of West Virginia Department of Health and Human Resources, Bureau for Medical Services, Office of Pharmacy Services, Prior Authorization Criteria for Chronic Hepatitis C Treatment, 3/09/3017. Retrieved from <http://www.dhhr.wv.gov/bms/BMS%20Pharmacy/Documents/Drug%20PA%20Criteria/Hepatitis%20C%20Criteria%20v2017.1f.pdf>

- Tenner, C.T., Herzog, K., Chaundhari, S., Bini, E.J., & Weinshel, E.H. (2012). Knowledge, attitudes and barriers regarding vaccination against hepatitis A and B in patients with chronic hepatitis C virus infection: a survey of family medicine and internal medicine physicians in the United States. *The International Journal of Clinical Practice*. 66(10), 1009-1013.
- Thudi, K., Yadav, D., Sweeney, K., & Behari, J. (2013). Physicians infrequently adhere to hepatitis vaccination guidelines for chronic liver disease. *PLOS ONE*, 8(7), 1-7.
- Tsui, J. I., Evans, J. L., Lum, P. J., Hahn, J. A., & Page, K. (2014). Opioid Agonist therapy is associated with lower incidence of hepatitis C virus infection in young adult persons who inject drugs. *JAMA Internal Medicine*, 174(12), 1974-1981.
- Volkow, N.D., Frieden, T.R., Hyde, P.S., & Cha, S.S. (2014). Medication-assisted therapies- tackling the opioid overdose epidemic. *The new England Journal of Medicine*, 370(22), 2063-2066.
- Waghray, A., Waghray, N., Khallafi, H., & Menon, K.V. (2016). Vaccinating adult patients with cirrhosis: trends over a decade in the United States. *Gastroenterology Research and Practice*, 2016, 1-7.
- Ward, J.W., Lok, A. S.F., Thomas, D.L., El-Serag, H.B., & Kim, W.R. (2012). Report on a single-topic conference on “Chronic viral hepatitis – strategies to improve effectiveness of screening and treatment. *Hepatology*, 55, 307-315.
- Ward, J.W. & Mermin, J.H. (2015). Simple, effective, but out of reach? Public health implications of HCV drugs. *New England Journal of Medicine*, 373, 2678-26

Wasley, A., Samandari, T., & Bell. (2005). Incidence of hepatitis A in the United States in the Era of vaccination, *The Journal of the American Medical Association*, 294, 194-201.

Wright, T. L., (2007). Antiviral therapy and primary and secondary prevention of Hepatocellular carcinoma. *Hepatology Research*, 37, (Suppl. 2): S294-S298.

Yee, H.S., Currie, S.L., Darling, J.M., & Wright, T.L. vc(2006). Management and treatment of hepatitis C viral infection: recommendations from the Department of Veterans Affairs Hepatitis C Resource Center Program and the National Hepatitis C Program Office. *American Journal of Gastroenterology*, 101, 2360-2378.

Younas, M.A., Nowalk, M.P., Zimmerman, R.K., Ahmed, F., & Albert, S.M. (2012). Examining structural and clinical factors associated with implementation of standing orders for adult immunization. *Journal for Healthcare Quality*, 34(3), 34-42.

Zimmerman,R.K., Brown, A. E., Pavlick, V.N., Moehling, K.K., Raviotta, J.M., Lin, C.J., Zhang, S., Hawk, M., Kyle, S., Patel, S., Ahmed, F., & Nowalk, M.P. (2017). Using the 4 Pillars™ Practice Transformation Program to increase pneumococcal immunizations for older adults: a cluster -randomized trial. *Journal of the American Geriatrics Society*, 65, 114-122.

Zimmerman R. K., Moehling, K.K., Lin, C. J., Zhang, S., Raviotta, J.M., Reis, E.C., Humiston, S.G., & Nowalk, M.P. (2016). Improving adolescent HPV vaccination in a randomized controlled cluster trial using the 4 Pillars™ Practice Transformation Program. (2016). *Vaccine*, 35, 109-117.

Appendix A

Definition of Terms

CDC: Centers for Disease Control and Prevention

CHC: Chronic Hepatitis C

DNP: Doctor of Nursing Practice

EMR: Electronic medical record

FQHC: Federally Qualified Health Center

HAV: Hepatitis A Virus

HBV: Hepatitis B Virus

HAVab: Hepatitis A antibody

HBcAb: Hepatitis B Core Antibody

HBsAb: Hepatitis B Surface Antibody

HCC: Hepatocellular cancer

HCV: Hepatitis C virus

Appendix B**Patient Reminder Post Card**

Date:_____

Dear:_____

Thank you for coming in to FamilyCare today for your _____.

Your next immunization is due on:_____.

You may walk-in without an appointment between 830 AM and 400 PM for a nurse to give you your injection. Please call us at _____ if you are unable to come in on this date so we can advise you of another date. It is important to complete your immunization series according to the recommended schedule to protect the health of your liver.

Appendix C

Authorization

From: Virginia Selanik [<mailto:virginia.selanik@familycarewv.org>]
Sent: Thursday, June 08, 2017 1:23 PM
To: Weber, Carolyn J <cweber@innovation.pitt.edu>
Subject: Terms of Usage for the 4 Pillars Practice Transformation Program

Dear Carolyn,

I respectfully request your permission to use the 4 Pillars™ Practice Transformation Program developed at the University of Pittsburgh as an intervention model for my doctoral project.

I am requesting permission to use the 4 Pillars Transformation Program concepts to guide my DNP capstone project, a quality improvement evaluation on increasing Hep A and B vaccination rates in adult patients with HCV in a Federally Qualified Health Center. I would not be using the step-by-step registered program, just the concepts and some of the intervention strategies, so I am not sure if I am understanding the terms of usage. It is my intention to publish the results of the project and if you grant permission for use, I will state that it is used with your permission.

I sincerely appreciate your consideration of this matter. Please advise me of your decision and I will gratefully forward it to my committee chair, Emily Barnes, DNP, FNP-BC.

Thank you, and I hope you will consider accepting this request.

Sincerely,

Virginia M. Selanik, APRN, FNP-BC
Email: vmseelanik@mix.wvu.edu
Phone: [\(304\)444-3324](tel:(304)444-3324)

Virginia M Selanik, APRN, FNP-BC
FamilyCare Health Centers
116 Hills Plaza
Charleston, WV 25387
[\(304\)720-4466](tel:(304)720-4466) ext. 8169

From: Weber, Carolyn J
Sent: Thursday, June 08, 2017 2:42 PM
To: Virginia Selanik <virginia.selanik@familycarewv.org>
Cc: Raviotta, Jonathan Marc <jraviotta@pitt.edu>
Subject: RE: Terms of Usage for the 4 Pillars Practice Transformation Program

Dear Virginia,

Thank you for your interest in using the 4 Pillars™ Practice Transformation Program developed here at the University of Pittsburgh. Currently, this program is being considered for commercialization and the step by step registration is not available. You indicate that you would not be using this feature. Perhaps if you need to track this, it will be available for research and/or educational purposes in the future.

You are free to use any of the publically available information on the website to improve or increase vaccination rates. You will need to cite the source of information in your publication.

I am copying the lead innovator on this program to provide any additional information on the usage of the site at this time should you require it.

Thank you again,

Carolyn

*Carolyn J. Weber, MBA
Licensing Associate*

1st Floor Gardner Steel Conference Center (GSCC)
130 Thackeray Avenue
Pittsburgh, PA 15260

(412) 383-7670- Innovation Institute
[\(412\) 383-7140](tel:(412)383-7140)-direct dial
cweber@innovation.pitt.edu

From: Raviotta, Jonathan Marc [mailto:jraviotta@pitt.edu]
Sent: Thursday, June 08, 2017 3:30 PM
To: Weber, Carolyn J; Virginia Selanik
Cc: Zimmerman, Richard (zimmrk@UPMC.EDU)
Subject: RE: Terms of Usage for the 4 Pillars Practice Transformation Program

Virginia,

We appreciate your interest in the 4 Pillars content as well as your commitment to immunization. As Carolyn mentioned, we are hoping to bring the program to a national audience in a sustainable way so some of the interactivity of the program is invisible to anonymous users. We do hope that you find the public information helpful and would welcome any feedback or suggestions as you work to implement change in your practice.

I have attached our project snapshot which has a list of publications about the program. You may find those references and their bibliographies helpful as you prepare your capstone project. Good luck!

In health,
Jonathan

Appendix D

Curriculum Outline

The Role of Vaccinating Adults with HCV Against HAV and HBV in the Prevention of Cirrhosis and Hepatocellular Carcinoma

1. Introduction

- a. Purpose of presentation**
- b. Personal interest in care of patients with HCV in primary care**
- c. How project came about**
- d. Background and significance of problem**
- e. Problem Statement:**

2. Acute HAV or HBV with HCV associated with increased morbidity and mortality

- a. The role of vaccination**
- b. Literature Review**

3. Testing and Interpretation of Laboratory Results for Hepatitis A, B, and C

- a. Recommendations**

4. Practice Change Project

- a. Using multiple strategies from the 4 Pillars™ Model**

Appendix E

Power Point Presentation for Provider Education

A Quality Improvement Project to Increase Hepatitis A and
B Vaccination in Adults With Hepatitis C in a Federally
Qualified Health Center

Virginia M. Selanik, APRN, FNP-BC

Doctoral Capstone Project submitted to the
School of Nursing
at West Virginia University
in partial fulfillment of the requirements
for the Doctor of Nursing Practice Degree

Problem Statement

Super-infection with hepatitis A(HAV) or hepatitis B(HBV) in patients with hepatitis C(HCV) is associated with an accelerated natural history of liver disease and a higher risk of morbidity and mortality due to chronic infection-related cirrhosis and HCC (Lavanchy, 2012).

Optimal care of HCV-infected persons includes providing HAV and HBV immunizations as outlined in multiple guidelines, consensus panels and expert opinions (Hernandez et al., 2009; Kramer, et al., 2011; Lau & Hewlett, 2005))

Despite these long-standing recommendations, vaccination rates for HAV and HBV are low for patients with HCV in clinical practice (Shim, Khaykis, Park, and Bini, 2005).

Background

- Healthy People 2020 objectives include: To increase HBV vaccine coverage among high-risk populations, increase HBV vaccine coverage among injection drug users, increase the proportion of persons who have been tested for HBV within minority communities experiencing health disparities, and increase the proportion of persons aware they have a HCV infection.
<https://www.healthypeople.gov/2020>
- In 2012, CDC expanded its guidelines originally issued in 1998 ([CDC, 1998](#)) for risk-based HCV testing with a recommendation to offer a one-time HCV test to all persons born from 1945 through 1965, without prior ascertainment of HCV risk-factors (AASLD-IDSA.
<http://www.hcvguidelines.org>
- In 2008, the Centers for Medicare and Medicaid Services (CMS) adopted vaccination against HAV and HBV in patients with chronic HCV infection as a quality measure (Waghray, et al., 2016).
- FQHC Project Site has increased number of patients with health center-funded Medication Assisted Treatment (MAT) for opioid addiction and with it has come an alarming trend of increased patients with chronic HCV within the organization.

Background

- The incidence of HBV and HCV increased 213% and 209% respectively in WV between 2012 and 2015
- In 2015, WV reported the highest incidence of HBV infection at 14.7 per 100,000 population in the US and the second highest rate of HCV infection at 3.4 per 100,000 population, which is five times the national average (CDC, 2015).
- Left untreated, HCV can cause the liver to develop fibrosis, which in turn can lead to cirrhosis and hepatocellular cancer.
- An estimated 1.12% (310) of patients at FamilyCare had a diagnosis of HCV in 2016
- The increased number of patients with health-center funded Medication Assisted Treatment (Suboxone-Vivitrol) made evident the trend of increased numbers of patients with chronic HCV, and makes a compelling case for implementing an innovative multi-strategy, evidence-based intervention to increase HAV and HBV vaccination efforts within the organization.

Facts

- 2.7-3.9 million people with HCV in the US
- Affects 2% of the US population
- Most people with HCV do not have symptoms
- HCV can survive outside the body at room temperature for up to 3 weeks
- A person can have normal liver enzymes (e.g., ALT) and still have HCV
- HCV accounts for most of the hepatocellular cancer in the US
- Hepatitis C is treatable and can be cured
- Currently there is no effective vaccine against HCV
- People with Hepatitis A usually improve without treatment
- Hepatitis A occurs only as an active infection and does not become chronic
- Of those with HCV, only 50% have been diagnosed
- Fewer than 38% have been referred to care
- Fewer than 11% of those referred to care are treated
- 1-5 persons with HCV die
- Persons infected with HCV should NOT be restricted from school, work, childcare, play
- Approximately 6 out of 100 (4-7%) infants born to mothers with HCV become infected with HCV (vertical transmission). The risk is higher in mothers who are co-infected with HIV

<https://www.cdc.gov/hepatitis/hav/havfaq.htm>

<https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm>

<https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm>

Purpose of the Project

The purpose of this clinical change project is to evaluate the effectiveness of using multiple strategies adopted from the 4 Pillars™ Practice Transformation Program along with staff and provider education as it relates to HAV and HBV vaccination rates in adults, aged 18 years or older who are infected with HCV, receiving care in a large Federally Qualified Health Center (FQHC) system.

The project will include application of evidence-based strategies implemented into the practice setting to address a gap in care, as identified in the literature, to address the issue of low uptake of HAV and HBV vaccinations in adults infected with HCV.

The results will contribute to the growing evidence of literature by addressing utilization of multiple strategies in providing clinically-focused preventive care to individuals aged 18 years or older who are infected with HCV, in a primary care setting.

This project holds the potential to identify new elements or variables for future projects by addressing interventions in improving HAV and HBV vaccination rates in adults with HCV.

Serologic Marker						Interpretation
HAV	IgM	IgG				Immune
	-	+				
	+	-				Acutely infected
HBV	HBsAg	Anti-HBc	Anti-HBs	IgM	HBV DNA	Immune
	-	+/-	+	-	-	
	+	+	-	+	+	Acutely infected
	+	+	-	-	+/-	Chronically infected
HCV	HCVAb	HCV RNA				Immune
	N/A ^a	N/A				Acutely infected
	+/- ^b	+ ^b				Chronically infected

Anti-HBc=HBV core antibody; anti-HBs=HBV surface antibody; HBsAg=HBV surface antigen; HCVAb=HCV antibody; IgG=immunoglobulin G; IgM=immunoglobulin M; N/A = not applicable; - = test negative; +/- = test positive
^aAntibodies for HCV are not protective.
 Reinfection is possible, and infection with multiple genotypes of HCV has been documented.

^bThere is no specific test for acute HCV. If exposure to HCV within the past six months is suspected, test for HCV RNA or repeat HCV antibody test.

A Quality Improvement Project to Increase Hepatitis A and B Vaccination in Adults with Hepatitis C in a Federally Qualified Health Center
 Michele Selanik, APRN, FNP-BC
 West Virginia University School of Nursing, Morgantown, WV

BACKGROUND

- The incidence of HBV and HCV increased 213% and 209% respectively in WV between 2012 and 2015.
- In 2015, WV reported the highest incidence of HBV infection at 14.7 per 100,000 population in the US and the second highest rate of HCV infection at 3.4 per 100,000 population, which is five times the national average (CDC, 2015).
- Left untreated, HCV can cause the liver to develop fibrosis, which in turn can lead to cirrhosis and hepatocellular cancer.
- An estimated 1-15% (3-10) of patients at FamilyCare had a diagnosis of HCV in 2015.
- The increased number of patients with health-center funded Medication Assisted Treatment (Suboxone/Vivitrol) made evident the trend of increased numbers of patients with chronic HCV, and makes a compelling case for implementing an innovative multi-strategy evidence-based intervention to increase HAV and HBV vaccination efforts within the organization.

PROBLEM STATEMENT

Superinfection with hepatitis A (HAV) or hepatitis B (HBV) in patients with hepatitis C (HCV) is associated with an accelerated natural history of liver disease and a higher risk of mortality and morbidity compared to those without underlying liver disease. Optimal care of HCV-infected persons includes providing preventive health measures that are specific to HCV-infected patients as outlined in published clinical guidelines and performance measures, including HAV and HBV vaccination. Despite long-standing recommendations for vaccination against HAV and HBV in persons with chronic HCV and the poor outcomes associated with the complications of cirrhosis and hepatocellular cancer, vaccination rates for HAV and HBV in HCV-positive patients are suboptimal in clinical practice.

FACTS

- 2.7-3.3 million people with HCV in the US
- Affects 2% of the US population
- Most people with HCV do not have symptoms
- HCV can survive outside the body at room temperature for up to 3 weeks
- A person can have normal liver enzymes (e.g., ALT) and still have HCV
- HCV accounts for most of the hepatocellular cancer in the US
- Hepatitis C is treatable and can be cured
- Currently there is no effective vaccine against HCV
- People with Hepatitis A usually improve without treatment
- Hepatitis A occurs only as an acute infection and does not become chronic
- Of those with HCV, only 50% have been diagnosed
- Fewer than 10% have been referred to care
- More than 1% of those referred to care are treated
- 1-5 persons with HCV die
- Persons infected with HCV should NOT be restricted from school, work, childcare, play
- Approximately 1 out of 100 (1%) infants born to mothers with HCV become infected with HCV (vertical transmission). The risk is higher in mothers who are co-infected with HIV

4 PILLARS™ PRACTICE TRANSFORMATION PROGRAM

Adapted from the University of Michigan's 4 Pillars™ Practice Transformation Program (www.hhs.gov/ohrt/)

STRATEGIES TO USE

- Use every (long) visit to vaccinate
- Patient education as part of intake, vital signs or importance of immunizations
- Check patient alert(s) in EMR for co-managing regarding immune status, needed vaccines
- Review vaccine status in EMR
- Use Standing Orders that are in place for administering vaccinations
- Immunization Champions
- Prescribe
- Open access appointments
- Provide feedback during morning huddle meetings
- Printed progress charts
- Mail postcard reminder

	Month 0	Month 1	Month 2
Hepatitis A Vaccine		+	+
Hepatitis B Vaccine	+	+	+
Hepatitis A and B Vaccine	+	+	+

INTERPRETING LABORATORY TESTS

Serologic Marker	IgM	IgG	Anti-HBc	Anti-HBs	IgM	HBV DNA	Interpretation
HAV	-	+					Immune
	+	-					Acutely infected
HBV	HBsAg	Anti-HBc	Anti-HBs	IgM	HBV DNA		Immune
	-	+/-	+	-	-		Acutely infected
	+	+	-	+	+		Chronically infected
HCV	HCVAb	HCV RNA					Immune
	N/A ^a	N/A					Acutely infected
	+/- ^b	+ ^b					Chronically infected

Anti-HBc=HBV core antibody; anti-HBs=HBV surface antibody; HBsAg=HBV surface antigen; HCVAb=HCV antibody; IgG=immunoglobulin G; IgM=immunoglobulin M; N/A = not applicable; - = test negative; +/- = test positive
^aAntibodies for HCV are not protective. Reinfection is possible, and infection with multiple genotypes of HCV has been documented.

^bThere is no specific test for acute HCV. If exposure to HCV within the past six months is suspected, test for HCV RNA or repeat HCV antibody test.

IMMUNIZATION SCHEDULE

Antibody	Month 0	Month 1	Month 2
Anti-HAV	+	+	+
Anti-HBs	+	+	+

HAV & HBV Combination Vaccine
 HAV Vaccine
 HBV Vaccine
 No Vaccine

Recommended Vaccination Schedule

	Month 0	Month 1	Month 6
Hepatitis A vaccine*#	•		•
Hepatitis B vaccine†‡	•	•	•
Hepatitis A and B combination vaccine±α	•	•	•

VACCINATION APPROACH BASED ON SEROLOGY				
Anti-HAV*	-	-	+	+
Anti-HBs**	-	+	-	+
	HAV & HBV Combination Vaccine (Twinrix®) or Individual Vaccines	HAV Vaccine (Havrix® or Vagta®)	HBV Vaccine (Engerix-B® or Recombivax HB®)	No vaccine

If the series is delayed between doses, it is NOT necessary to restart the series. Continue from the last dose given.

<https://www.hepatitis.va.gov/pdf/HAV-HBV-vaccine-poster.pdf>

Educational Posters for Staff Break Rooms

A Quality Improvement Project to Increase Hepatitis A and B Vaccination in Adults with Hepatitis C in a Federally Qualified Health Center

Michele Selanik, APRN, FNP-BC

West Virginia University School of Nursing, Morgantown, WV

BACKGROUND

- The incidence of HAV and HCV increased 25% and 200% respectively in WV between 2002 and 2015.
- In 2015, FHV reported the highest incidence of HCV infection at 14.8 per 100 population in the US and the second highest rate of HCV infection at 14.4 per 100 population, which is five times the national average (CDC, 2015).
- Left untreated, HCV can cause liver fibrosis, cirrhosis, which in turn can lead to cirrhosis and hepatocellular carcinoma.
- An estimated ~ 10% (15%) of patients with newly diagnosed cases of HCV in the US.
- The increased number of patients with chronic liver-related liver disease (including hepatitis) has led to increased demand for treatment.
- Medication Assisted Treatment (Methadone/Vivitrol) evidence indicates the effectiveness of medication assisted treatment in reducing risk of relapse and increasing engagement in care, leading to improved outcomes.
- Evidence-based information to increase vaccination efforts within the organization.

PROBLEM STATEMENT

Superinfection with hepatitis A (HAV) or hepatitis B (HBV) in patients with Hepatitis C (HCV) is associated with an accelerated natural history of liver disease and a higher risk of mortality and morbidity compared to those without underlying liver disease. Optimal care of HCV-infected persons includes providing preventive health measures that are specific to HCV-infected patients as outlined in published clinical guidelines and performance measures, including HAV and HBV vaccination. Despite long-standing recommendations for vaccination against HAV and HBV in persons with chronic HCV and the poor outcomes associated with the complications of cirrhosis and hepatocellular carcinoma, vaccination rates for HAV and HBV in HCV-positive patients are suboptimal in clinical practice.

FACTS

- > 2.7 million people with HCV in the US
- Affects 2% of the U.S. population
- Most patients do not have symptoms
- HCV can survive outside the body at room temperature for up to 3 weeks
- A person can have normal liver enzymes (ALT and AST) even have HCV
- HCV accounts for most of the hepatocellular carcinoma in the US
- Hepatitis C is treatable and can be cured
- Cure means there is no effective vaccine against HCV
- Vaccines for hepatitis A usually are recommended to avoid
- Hepatitis A occurs only as an acute infection and does not become chronic
- Of those with HCV, only 55% have been diagnosed
- Fewer than 1% of those have received a cure
- Fewer than 1% of those referred to care are treated
- 1.5 percent with HCV die
- Patient infected with HCV should NOT be restricted from school, work, children's play
- Approximately 1 out of 100 (1%) infants born to mothers with HCV become infected with HCV (vertical transmission). The risk is higher in mothers who smoke or inject drugs with HCV.

4 PILLARS** PRACTICE TRANSFORMATION PROGRAM

4 PILLARS

```

    graph TD
      Pillar1[COMMUNITY  
ENGAGEMENT  
AND ACTION] --- Pillar2[PATIENT  
COMMUNICATION  
STRATEGIES]
      Pillar2 --- Pillar3[EMPLOYEE  
EDUCATION AND  
TRAINING]
      Pillar3 --- Pillar4[VACCINATION  
STRATEGIES]
      Pillar1 --- Pillar4
  
```

STRATEGIES TO USE

- Use every [empty] visit to vaccinate
- Patient education component of intake, vital signs or importance of immunizations
- Check patient alert in EMR for co existing regarding insurance status, needed vaccines
- Review vaccine eligibility in EMR
- Use Standing Orders that are in place for administering vaccinations
- Immunization Champions
- Presenters
- Open access appointments
- Provide feedback during morning huddle meetings
- Periodic progress checks
- Mail prompt reminder

	Hepatitis A Vaccine	Hepatitis B Vaccine	Hepatitis A + B Vaccine
Hepatitis A Vaccine	+	-	-
Hepatitis B Vaccine	-	+	-
Hepatitis A + B Vaccine	-	-	+

INTERPRETING LABORATORY TESTS

Diagnostic Test Result	Interpretation
Anti-HAV (+)	Active Infection
Anti-HBc (+)	Active Infection
Anti-HBs (-)	Not Infected
Anti-HBe (-)	Not Infected
Anti-HBc (+)	Active Infection
Anti-HBs (+)	Immunity
Anti-HBe (+)	Immunity
Anti-HBc (+)	Active Infection
Anti-HBs (+)	Immunity
Anti-HBe (+)	Immunity

*This is a simplified test for adults. HIV exposure to HIV within the past six months is positive, but for HIV risk group, HIV testing is required.

IMMUNIZATION SCHEDULE

Antibody	Anti-HAV	Anti-HBc	Anti-HBs	Anti-HBe	Anti-HBc	Anti-HBs	Anti-HBe
Initial	+	+	+	+	+	+	+
Follow-up	+	+	+	+	+	+	+
Repeat	+	+	+	+	+	+	+

Appendix G**Pre-Test for Providers/Staff****“A Hepatitis Knowledge Assessment”**

1- The most effective way to prevent hepatocellular cancer due to chronic hepatitis B and chronic

hepatitis C is to prevent viral hepatitis through immunization.

TRUE FALSE

2- Currently there is an effective vaccine against hepatitis C virus.

TRUE FALSE

3- Hepatitis C accounts for most of the hepatocellular cancer in the US.

TRUE FALSE

4- Hepatitis A and Hepatitis B vaccination is less effective in patients with advanced liver disease.

TRUE FALSE

5- Chronic hepatitis B and chronic hepatitis C co-infection are associated with:

- a. More severe laboratory abnormalities**
- b. Worse histologic disease**
- c. Higher fatality rates**
- d. More complications of cirrhosis**
- e. Higher incidence of hepatocellular cancer**
- f. All of the above**

**Hepatitis A appears only as an acute or “newly occurring” infection and does not become Chronic. Persons affected with Hepatitis A usually improve without treatment.
(Question not counted))**

TRUE FALSE

(6) 7- How prevalent is hepatitis C in the US?

- a. 2.7-3.9 million people are infected**
- b. 1.5-2.0 million people are infected**

c. Hepatitis C Affects approximately 2% of the US population

d. a. and c.

e. b. and c.

(7))8- Hepatitis C is treatable and can be cured.

TRUE

FALSE

(8)9- Hepatitis C virus can survive outside the body at room temperature for three weeks.

TRUE

FALSE

(9)10- Who is at risk for hepatitis C infection?

a. Past injection drug users who only used 1x many years ago

b. People who received a blood product for clotting problems made before

1987

c. Recipients of donated blood or solid organ transplants before 1992

d. a. and c.

e. All of the above

10)11- What is the risk of a pregnant woman passing hepatitis to her baby?

a. Hepatitis is rarely passed from a pregnant woman to her baby

b. About 6 of every 100 infants born to mothers with hepatitis C

c. Risk is increased if mother is co-infected with HIV

d. b.

e. All of the above

- Of every 100 people infected with hepatitis C, about:

(11)a. 75-85 people will develop chronic hepatitis C infection, and of those:

TRUE

FALSE

(12)b. 60-70 will go on to develop chronic liver disease

TRUE FALSE

(13). 5-20 will develop cirrhosis over a period of 20-30 years

TRUE FALSE

(14)d. 1-5 will die

TRUE FALSE

In WV, between 2011 and 2015:

(15)a. Reported rates of acute hepatitis A did not increase

TRUE FALSE

(16)b. Reported rates of acute hepatitis B increased by 146%

TRUE FALSE

(17)c. Reported rates of acute hepatitis C increased by 36%

TRUE FALSE

(18) 15- What blood tests are used to detect hepatitis C infection?

- PCR)**
- a. Screening tests for antibody to HCV (anti-HCV)**
 - b. Qualitative tests to detect presence or absence of virus (HCV RNA by PCR)**
 - c. Quantitative tests to detect amount (titer) of virus (HCV RNA by PCR)**
 - d. All of the above**

(19)16- How soon after exposure to HCV can HCV RNA be detected by PCR?

- a. 2-3 weeks after infection**
- b. 4-6 weeks after infection**
- c. 12 weeks after infection**
- d. None of the above**

(20)17- A patient can have a normal liver enzyme (e.g., ALT) and still have chronic hepatitis C.

TRUE FALSE

-

- **HCV-infected persons should be restricted from working in certain occupations or settings.**

TRUE FALSE

- **Women with HCV infection should be advised against breastfeeding if their nipples are cracked or bleeding.(Question not counted)**

TRUE FALSE

How is hepatitis B transmitted?(Question not counted)

- a. Unprotected sexual contact**
- b. Sharing drugs, needles, or “works” when using drugs**
- c. Poor infection control practices with equipment to test blood glucose**
- d. Needle sticks or sharps expose on the job**
- e. From mother to baby during birth**
- f. Contact with wound or skin sores**
- g. When an infected person bites another person**
- h. Pre-chewing food for babies**
- i. Sharing personal care items, such as clippers, razors, or toothbrushes**
- j. All of the above**

Post-Test for Providers/Staff
“A Hepatitis Knowledge Assessment”

Age _____ Gender _____ _Total years practicing as:
MD/DO: _____
PA: _____
NP: _____
RN: _____
LPN: _____
MA: _____

1- The most effective way to prevent hepatocellular cancer due to chronic hepatitis B and chronic hepatitis C is to prevent viral hepatitis through immunization.

TRUE FALSE

2- Currently there is an effective vaccine against hepatitis C virus.

TRUE FALSE

3- Hepatitis C accounts for most of the hepatocellular cancer in the US.

TRUE FALSE

4- Hepatitis A and Hepatitis B vaccination is less effective in patients with advanced liver Disease.

TRUE FALSE

5- Chronic hepatitis B and chronic hepatitis C co-infection are associated with:

- a. More severe laboratory abnormalities**
- b. Worse histologic disease**
- c. Higher fatality rates**
- d. More complications of cirrhosis**

- e. Higher incidence of hepatocellular cancer
- f. All of the above

- Hepatitis A appears only as an acute or “newly occurring” infection and does not become Chronic.

TRUE FALSE (question not counted)

- Persons infected with hepatitis A usually improve without treatment.

TRUE FALSE (question not counted)

(6) 8- How prevalent is hepatitis C in the US?

- a. 2.7-3.9 million people are infected
- b. 1.5-2.0 million people are infected
- c. Hepatitis C affects approximately 2% of the US population
- d. a. and c.
- e. b. and c.

(7) 9- Hepatitis C is treatable and can be cured.

TRUE FALSE

(8) 10- Hepatitis C can survive outside the body at room temperature for three weeks.

TRUE FALSE

(9) 11- Who is at risk for Hepatitis C infection?

- a. Past injection drug users who only used 1x many years ago
- b. People who received a blood product for clotting problems made before 1987
- c. Recipients of donated blood or solid organ transplants before 1992
- d. b.
- e. All of the above

(10) 12- What is the risk of a pregnant woman passing hepatitis C to her baby?

- a. Hepatitis is rarely passed from a pregnant woman to her baby
- b. About 6 of every 100 infants born to mothers with hepatitis C
- c. Risk is increased if mother is co-infected with HIV
- d. b.
- e. All of the above

13- Of every 100 people infected with hepatitis C, about:

(11)a. 75-85 people will develop chronic hepatitis C infection, and of those:

TRUE FALSE

(12) b. 60-70 will go on to develop chronic liver disease

TRUE FALSE

(13) c. 5-20 will develop cirrhosis over a period of 20-30 years

TRUE FALSE

(14) d. 1-5 will die

TRUE FALSE

14- In WV, between 2011 and 2015:

(15)a. Reported rates of acute hepatitis A did not increase

TRUE FALSE

(16) b. Reported rates of acute hepatitis B increased by 146%

TRUE FALSE

(17) c. Reported rates of acute hepatitis C increased by 36%

TRUE FALSE

(18)15- What blood tests are used to detect hepatitis C infection?

a. Screening tests for antibody to HCV (anti-HCV)

b. Qualitative tests to detect presence or absence of virus (HCV RNA by PCR)

c. Quantitative tests to detect amount (titre) of virus (HCV RNA by PCR)

d. All of the above

(19)16- How soon after exposure to HCV can HCV RNA be detected by PCR?

- a. 2-3 weeks after exposure**
- b. 4-6 weeks after exposure**
- c. 12 weeks after exposure**
- d. None of the above**

(20)17- A patient can have a normal liver enzyme (e.g. ALT) and still have chronic hepatitis C.

TRUE FALSE

-

**- HCV-infected persons should be restricted from working in certain occupations.
(Question not counted)**

TRUE FALSE

- Women with HCV infection should be advised against breastfeeding if their nipples are cracked or bleeding (Question not counted)

TRUE FALSE

- How is hepatitis B transmitted? (Question not counted)

- a. Unprotected sexual contact**
- b. Sharing drugs, needles, or works when using drugs**
- c. Poor infection control practices with equipment to test blood glucose**
- d. needle sticks or sharps exposure on the job**
- e. From mother to baby during birth**
- f. Contact with wound or skin sores**
- g. When an infected person bites another person**
- h. Pre-chewing food for babies**
- i. Sharing personal care items, such as clippers, toothbrushes, or razors**
- j. All of the above**

Appendix H

Poster for Exam Rooms

**If you have chronic
Hepatitis C...**

**Vaccination
against Hepatitis
A virus and
Hepatitis B virus
is recommended
for all patients
with chronic
Hepatitis C**

*AASLD-IDSA, CDC, WHO**

*American Association for the Study of Liver
Diseases-Infectious Diseases Society of
America, Centers for Disease Control and
Prevention, World Health Organization

**...You need
protected
against Hepatitis A
and Hepatitis B**

**Ask your provider
if you need
additional testing
or vaccinated**

Appendix I**Weekly Progress Charts****Week 12 Hepatitis Vaccinations**

Appendix J

Project Budget

Operating Expenses	Estimated	Actual
Nurse Salaries	\$ 420.00	n/a
Advanced Practice Clinicians Salaries	\$3,195.00	n/a
Physician salaries	\$ 1,250.00	n/a
Posters in exam rooms	\$ 100.00	\$ 300.00
Posters in break rooms	\$125.00	\$ 288.00
Patient reminder cards	\$250.00	\$ 85.00
Badges for immunization champions	\$ 50.00	0 n/a Not used
Hospitality Cupcake Celebration at halfway mark	\$200.00	\$ 165.00
Printing Services for consent forms, pre-post tests	\$250.00	\$ 244.88
	\$ 5,480.00	\$ 1082.88
Total Expenses	Estimated	Actual

Appendix K

Letter of Support

familycarewv.org

Pulnam County

97 Great Teays Boulevard
Suite 6
Scott Depot, WV 25560-9816
304-757-6999

503 Roosevelt Boulevard
P.O. Box 163
Eleanor, WV 25070-0163
304-586-0001

Women's Health & BirthCenter
3911 Teays Valley Road
Hurricane, WV 25526-9604
304-757-4845

Pulnam County
School-Based Health Services
304-380-7728
304-586-0001

Kanawha County

116 Hills Plaza
Patrick Street Plaza
Charleston, WV 25387-2438
304-770-4466

Mary C. Snow
West Side Elementary
Health Center
100 Florida Street
Charleston, WV 25302-1131
304-414-4015

12 Kanawha Terrace
St. Albans, WV 25177-2750
304-201-1130

Children's Medicine Center
800 Pennsylvania Avenue
Charleston, WV 25302-3351
304-414-1880

Boone County

515 Main Street
Madison, WV 25130-1417
304-369-0393

Cabell County

2 Chateau Lane
Barboursville, WV 25504-1626
304-736-9662

Business Office

97 Great Teays Boulevard
Suite 6
Scott Depot, WV 25560-9816
304-757-6999
Fax 304-760-6318

September 18, 2017

Virginia M. Selanik, APRN, FNP-BC
DNP Student
West Virginia University

Dear Ms. Selanik:

I have read over your proposal for a research project to be carried out at FamilyCare Health Centers. I understand that you are conducting this project as part of your requirements for the Doctor of Nursing Practice Degree at West Virginia University and will have the chance to present your research in other venues.

I understand that the Institutional Review Board for the university is concerned with protecting the Use of Human Subjects in Research (IRB) at the university and is concerned with protecting the confidentiality, privacy, and well-being of research participants. Further, it is my understanding that you will additionally be advised in this project by your committee chair and academic advisor, Emily Barnes, DNP, APRN, FNP-BC, Clinical Associate Professor at West Virginia University School of Nursing.

FamilyCare Health Centers is pleased to support your capstone project: A Quality Improvement Project to Increase Hepatitis A and B Vaccination in Adults with Hepatitis C in a Federally Qualified Health Center and approves of the project, including recruitment of participants and data collection through our agency. Given the high incidence of Hepatitis C that is seen at FamilyCare, we welcome the opportunity to assist you in this high priority project.

Sincerely,

Martha Carter, DHSc, MBA, APRN, CNM
Chief Executive Officer
FamilyCare Health Center