Identification of Nonalcoholic Fatty Liver Disease in Patients with Hepatitis C: Using Evidence Based Guidelines to Improve Diagnosis and Transition of Care from Specialty Care Provider to Primary Care Provider

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Identification of Nonalcoholic Fatty Liver Disease in Patients with Hepatitis C:
Using Evidence Based Guidelines to Improve Diagnosis and Transition of Care from Specialty Care Provider to Primary Care Provider

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Date of Submission: October 12, 2016
Abstract

Chronic liver disease is a process that involves progressive destruction and regeneration of the liver causing fibrosis, cirrhosis and hepatocellular carcinoma, and early death. Persons with chronic liver disease treated for hepatitis C with abnormal radiological imaging consistent with increased fat content in the liver (hepatic steatosis) should be evaluated for nonalcoholic fatty liver disease (NAFLD). However, individuals treated at a community hepatitis C treatment clinic are currently not being evaluated for NAFLD. In addition, if NAFLD is diagnosed, management of these co-occurring conditions is required to delay disease progression. Factors contributing to gaps in NAFLD care include: poor communication, incomplete transfer of information, inadequate education of patients, and the absence of a single point person to ensure continuity of care.

This Doctor of Nursing Practice (DNP) project involved the development and implementation of a protocol with person-centered education to assure continuity of care based on need of those with chronic liver disease, hepatitis C and NAFLD. Findings after the implementation and evaluation of the process improvement protocol at the clinic noted patients being treated for hepatitis C with hepatic steatosis: 1) were systematically evaluated for and diagnosed with NAFLD during treatment of hepatitis C infection at the clinic; 2) received NAFLD person-centered education; and 3) transitioned from specialty care after completion of hepatitis C infection treatment to primary care provider for ongoing NAFLD management.

Keywords: hepatic steatosis, nonalcoholic fatty liver disease, hepatitis C, transition of care
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Executive Summary

Chronic liver disease can alter normal liver function leading to fibrosis, cirrhosis, hepatocellular carcinoma, and early death (Kyungeh et al., 2015). Chronic liver disease is one of the ten leading causes of death worldwide effecting people of all ages, particularly, those 40 to 60 years of age (National Institute of Health, 2009). Two major causes of chronic liver disease are chronic hepatitis C infection and nonalcoholic fatty liver disease (Kyungeh et al., 2015). Nonalcoholic fatty liver disease (NAFLD) involves a spectrum of liver diseases that range from fatty infiltration of the liver (hepatic steatosis), to liver inflammation (nonalcoholic steatohepatitis [NASH]), leading to fibrosis and/or cirrhosis (McCarthy & Rinella, 2012). The Center for Disease Control’s National Vital Statistics Reports, Deaths: Final Report for 2013 (Xu, Murphy, Kochanek & Bastian, 2016) reported chronic liver diseases and cirrhosis as a leading cause of death in the United States (US). Xu et al. (2016) reported in 2013, US deaths caused by nonalcoholic related chronic liver disease and cirrhosis totaled 18,281 and malignant neoplasms of liver and intrahepatic bile ducts was 24,032.

In a clinic setting, 30% to 70% of patients with hepatitis C have hepatic steatosis (Blonsky & Harrison, 2008; Patel & Harrison, 2012; Rafiq & Younossi, 2008). An organizational assessment of a Midwestern hospital’s clinic revealed a need for individuals with hepatitis C treated at their clinic to be further evaluated for NAFLD. Records of 100 patients at the clinic revealed 34 (34%) of the patients that received treatment for hepatitis C infection had hepatic steatosis noted on radiological imaging that needed further evaluation.

Clinical practice guidelines for diagnosis and management of NAFLD recommend patients at the clinic with hepatitis C who have abnormal imaging consistent with hepatic steatosis should be evaluated for NAFLD (Chalasani et al., 2012). If NAFLD was diagnosed in
patients at the clinic, management of these co-occurring conditions was required to delay disease progression. These patients required patient education and transition of care to their PCP after treatment of hepatitis C infection was completed for ongoing NAFLD management.

The intent of the DNP student’s quality improvement project was to improve the care for patients treated for hepatitis C with hepatic steatosis at the clinic through the development and implementation of a process improvement protocol. Findings after the implementation and evaluation of the process improvement protocol at the clinic noted patients being treated for hepatitis C with hepatic steatosis: 1) were systematically evaluated for and diagnosed with NAFLD during treatment of hepatitis C infection at the clinic; 2) received NAFLD person-centered education; and 3) transitioned from specialty care after completion of hepatitis C infection treatment to primary care provider for ongoing NAFLD management.

This DNP student’s quality improvement project may be useful for clinical practice in other primary and specialty practice settings, to diagnose and manage patients with NAFLD, and improve patient care transitions. Health care providers are key in early identification of NAFLD for treatment not only in patients with hepatitis C, but other patients with risk factors for NAFLD, such as obesity and type 2 diabetes. Early identification of NAFLD and treatment could prevent the development of nonalcoholic steatohepatitis, cirrhosis, liver failure and possibly hepatocellular carcinoma (Loomba & Sanyal, 2013).
Introduction

Chronic liver disease is one of the ten leading causes of death worldwide effecting people of all ages, particularly, those 40 to 60 years of age (National Institute of Health, 2009). Chronic liver disease can alter normal liver function leading to fibrosis, cirrhosis, hepatocellular carcinoma, and early death (Kyungheh et al., 2015). Two major causes of chronic liver disease are chronic hepatitis C infection and nonalcoholic fatty liver disease (Kyungheh et al., 2015).

Hepatitis C infection is a viral, and contagious liver disease spread through contact with the blood of an infected person (Center for Disease Control [CDC], 2015). Approximately 2.7 million persons in the United States (US) are infected with hepatitis C virus (CDC, 2015). Nonalcoholic fatty liver disease (NAFLD) involves a spectrum of liver diseases that range from fatty infiltration of the liver (hepatic steatosis), to liver inflammation (nonalcoholic steatohepatitis [NASH]), leading to fibrosis and/or cirrhosis (McCarthy & Rinella, 2012). NAFLD is one of the most common causes of chronic liver disease, affecting nearly 70 million adults in the US (Loomba & Sanyal, 2013; McCarthy & Rinella, 2012).

Nearly 70% of patients with hepatitis C infection have hepatic steatosis (Blonsky & Harrison, 2008; Patel & Harrison, 2012; Rafiq & Younossi, 2008) as a result of a virus genotype such as hepatitis C – Genotype 3 or from metabolic conditions such as insulin resistance, diabetes mellitus or metabolic syndrome (Adinolfi, Durante-Mangoni, Zampino, Ruggier, 2005; Leandro et al., 2004). As a consequence, coexisting NAFLD and hepatitis C increases chronic liver disease progression, elevates risk of hepatocellular carcinoma, and decreases the response to antiviral therapy treatment (Cortez-Pinto & Machado, 2010; Sanyal et al., 2010; & Watanbe et al., 2008). The focus of this Doctor of Nursing Practice (DNP) scholarly project is on facilitating assessment, timely diagnosis and appropriate treatment of NAFLD, with appropriate transition to
primary care for patients with hepatitis C infection and comorbid hepatic steatosis in a Midwestern clinic.

**Background**

**Overview**

Patients with hepatitis C and NAFLD often require treatment to prevent liver disease progression. Clinical practice guidelines for the management of hepatitis C and NAFLD are available (American Association for the Study of Liver Disease & Infectious Diseases Society of America, 2015; Chalasani et al., 2012). However, there are no known clinical practice guidelines for the comorbid conditions of hepatitis C when NAFLD is present. Thus, there is a great need to focus on diagnosis and treatment of fatty liver disease, namely NAFLD (Balisteri, 2014).

**Literature Supporting Problem**

Nonalcoholic fatty liver disease (NAFLD) progression to nonalcoholic steatohepatitis (NASH), was first described by Ludwig, Viggiano, McGill & Ott (1980). Nonalcoholic fatty liver disease is now recognized as one of the most common causes of chronic liver disease, affecting nearly 70 million adults in the US (Loomba & Sanyal, 2013; McCarthy & Rinella, 2012). Nonalcoholic fatty liver disease is a spectrum of liver diseases that range from simple fatty infiltration of the liver (steatosis) to fat infiltration with liver inflammation (known as NASH); to cirrhosis (McCarthy & Rinella, 2012).

The diagnosis of NAFLD requires evidence of hepatic steatosis, either by imaging or by histology, not caused by secondary hepatic fat accumulation such from alcohol consumption, use of steatogenic medication, or hereditary disorders (Chalasani et al., 2012). Individuals with persistently abnormal aspartate aminotransferase (AST) or alanine aminotransferase (ALT)
levels; or with an abnormal hepatic imaging consistent with increased fat content in the liver, should be evaluated for NAFLD (Attar and Van Thiel, 2012). It is essential for healthcare providers to understand the complexity of NAFLD. A survey of 246 providers to assess understanding and practice patterns of primary care providers with respect to the diagnosis and management of NAFLD found the majority of providers did not identify NAFLD as a clinically important diagnosis (Wieland et al., 2013).

The National Health and Nutrition Examination Survey data from 1988 to 2008 found the prevalence of major causes of chronic liver disease remained unchanged, with the exception of NAFLD and metabolic conditions, which both increased (Younossi et al., 2011). Given the increasing rates of obesity in the US, NAFLD is expected to contribute substantially to the burden of chronic liver disease (Younossi et al., 2011). This is of grave concern because NAFLD left untreated can lead to the development of NASH in approximately 25 percent of patients (Temple et al., 2016 & Watanabe et al., 2008).

Nonalcoholic steatohepatitis (NASH) is a progressive form of NAFLD that can lead to cirrhosis and potentially hepatocellular carcinoma (HCC), necessitating liver transplantation, and often contributes to liver-related mortality (Loomba & Sanyal, 2013; Wong, Cheung, & Ahmed, 2014). Cirrhosis is a chronic degenerative disease in which normal liver cells are damaged and replaced by scar tissue (fibrosis) and nodules (Ferri, 2009). Hepatocellular (HCC) is a malignant tumor of the hepatocytes (Ferri, 2009). Transplantation data in the US from 2002 to 2012 showed the incidence of NASH among HCC patients has increased dramatically, and could become the top indicator for liver transplantation (Wong et al., 2014). Therefore, identification of ways to diagnose and manage NAFLD are needed.
Gaps in patient care outcomes. The DNP prepared nurse practitioner working at the Midwestern hepatitis C clinic, receives patient referrals from primary care for the treatment of hepatitis C infection. The clinic’s DNP prepared nurse practitioner saw 330 patient referrals from primary care for evaluation and treatment of hepatitis C infection in 2015. A chart review was conducted in the clinic to determine prevalence of hepatic steatosis noted on radiological imaging, among patients with hepatitis C. Records of 100 patients were randomly selected by the DNP prepared nurse practitioner and radiological imaging reports were reviewed for the presence of hepatic steatosis. There were 34 (34%) radiological imaging reports that noted the presence of hepatic steatosis; while 66 (66%) had no evidence of hepatic steatosis. Consequently, 34% of the patients with comorbid hepatitis C had hepatic steatosis at the clinic. This is consistent with the rate of occurrence of hepatic steatosis in those with hepatitis C, reported in the literature (Blonsky & Harrison, 2008; Patel & Harrison, 2012; Rafiq & Younossi, 2008).

From this chart audit and conversations with team members at the clinic, two gaps in care were identified among patients with hepatitis C who have hepatic steatosis on radiological imaging in the clinic. First, a thorough assessment is lacking in those with hepatic steatosis to determine if NAFLD is present. Second, if diagnosed with NAFLD, no transition in care to the primary care provider (PCP) is occurring after treatment of hepatitis C in the clinic is complete. At this time, the clinic focuses on their primary purpose, treatment of hepatitis C infection; leaving NAFLD undiagnosed. Timely assessment and diagnosis of NAFLD in patients with hepatitis C could potentially prevent liver disease progression (Loomba & Sanyal, 2013).
Problem Statement

The problem addressed in this scholarly project is: Would a protocol to address assessment of NAFLD, and provision of patient education and transition in care to a PCP if diagnosed, improve the quality of care for patients with hepatitis C who have hepatic steatosis? A protocol could guide the clinicians in the clinic in the following ways: (1) identification and diagnosis of NAFLD; (2) if diagnosed with NAFLD, provision of patient education about the disease by the DNP prepared nurse practitioner in the clinic at the end of their hepatitis C treatment; and (3) a transition plan to the PCP for ongoing management of NAFLD. In the next section, a summary of the organizational assessment will be presented.

Organizational Assessment

An organizational assessment was conducted to inform this scholarly project. An assessment identifies an organization’s strengths and weaknesses, and pinpoints areas needing improvement (Canadian International Developmental Agency [CIDA], 2006).

Setting

The setting for this scholarly project was a Midwestern hepatitis C clinic. The clinic is a component of a regional health system.

Population and Sample

The population of interest in this scholarly project were patients diagnosed with hepatitis C infection and comorbid hepatic steatosis. The sample included patients diagnosed with hepatitis C infection who had hepatic steatosis reported on radiological imaging at the clinic.

The number of patients receiving treatment for hepatitis C with hepatic steatosis who require evaluation of NAFLD varied by the number of referral patients from PCPs to the clinic. In a clinic setting it is estimated that at least 30 to 70 percent of patients will have hepatitis C and
NAFLD type hepatic steatosis (Blonsky & Harrison, 2008; Patel & Harrison, 2012; Rafiq & Younossi, 2008). During three months (April, May, and June of 2016), the average number of patient referrals for treatment of hepatitis C at the clinic was 20, and approximately seven or 30 percent of these patients will potentially have hepatic steatosis.

**Framework to Assess the Organization**

An organizational assessment was conducted of the clinic using the 2006 Canadian International Development Agency (CIDA) Organization Assessment Guide. The CIDA Organization Assessment Guide (2006) was designed by the Canadian International Development Agency Evaluation Division Performance and Knowledge Management Branch; and by Universalia, an international consulting firm. The CIDA approach (Appendix A) to organization assessment included an examination of the following elements: 1) organizational performance, 2) organizational motivation, 3) organizational capacity, and 4) the external environment (CIDA, 2006). This tool was chosen as it provides a framework to assess strengths, weaknesses and opportunity for improvement at the clinic (CIDA, 2006).

**Organization performance.** The effectiveness of an organization in achieving their mission depends on its ability to adapt to a changing environment and generate revenues to meet its functional requirements for sustainability (CIDA, 2006). An organization assessment was conducted on the clinic, to include the mission, finances, and services provided to the public.

The clinic is a component of a large nonprofit organization and operates for public benefit. This nonprofit organization is a regional referral hospital system for the geographic area. It is the largest health system in the geographic area and the largest employer in the region. The clinic is a component of the regional health system, thus, the clinicians are employees of this
organization. The clinic is supported by revenue from health care services provided to patients for treatment of hepatitis C infection.

**Organization motivation.** Organizational motivation, or work climate, represents beliefs, values, and norms that guide work life within an organization (CIDA, 2006). An assessment was conducted of the organization and the clinic, to include culture, mission, and values.

As a nonprofit organization, this organization is committed to public service, serving and meeting the needs of citizens, and strengthening the community. The clinic and clinician team are dedicated to treating patients with hepatitis C infection. A former DNP student, who is now a current practitioner and employee, was instrumental in the establishment of the clinic. The clinic provided specialty patient-centered, personalized care for those diagnosed with hepatitis C infection. At the time of the assessment, the clinic did not coordinate specialty services and care management for patients with hepatitis C who had been diagnosed with comorbid hepatic steatosis.

**External environment.** Organizations exist within external environments that facilitate or impede performance (CIDA, 2006). The clinic is located in a county with a population of 172,188 (Community Research Institute [CRI], 2015). The largest age group for this county is the 45 to 64 years old (27.7%), with gender distribution of 50.4% female and 49.6% male, and a racial mix of 77.3% White, 14.3% African American, and 8.4% other (CRI, 2015).

People between the ages of 51 to 71 years old make up the majority of chronic hepatitis C cases (CDC, 2015). National data demonstrate that people in this age group are five times more likely than other adults to be infected with hepatitis C (CDC, 2015). In addition, people between the ages of 51 and 71 years old account for 73% of all hepatitis C associated mortality (CDC,
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2015). This CDC information is important because the county had a large percentage of its population in this age group who may require hepatitis C screening and treatment.

The rate of poverty in the county is 18.6%, higher than the state rate of 16.1%; and the US rate of 14.3% (PHMC, n.d.). Nearly 12% of the population in this county who are less than 65 years of age are uninsured (PHMC, n.d.). The uninsured rate is important because there is a cost of up to $1000.00 a day for hepatitis C infection medications such as ledipasvir-sofosbuvir (Hepatitis C Online, 2016). Patients without insurance may need a pharmaceutical company assistance program if they cannot afford to pay for these medications.

In 2010, Michigan had the 6th highest prevalence of obesity in the US (MDCH, 2013). An estimated 31.7% of Michigan adults were obese, while approximately 35.1% of adults were overweight (MDCH, 2013). The county is one of the most obese counties in the state, with 36% of residents being obese (PHMC, n.d.). Obesity is a risk factor for NAFLD and other medical conditions such as type 2 diabetes and dyslipidemia.

**Organization capacity.** Organizational capacity exists in leadership, human resources, resources and partnerships (CIDA, 2006). The organization has a local board; executive, senior, and physician leadership teams; and several medical staff officers. The senior leadership team had a chief nursing officer, vice president of patient care services, and a patient safety officer. The clinic is part of this larger formal organization structure.

The clinic is unique in that it is the only location in the city that treats hepatitis C infection. The clinic opened in 2011 as a result of a DNP scholarly project, as mentioned earlier, in collaboration with an infectious disease physician, to provide treatment for underserved patients with hepatitis C infection. In 2012, the organization hired the DNP prepared nurse practitioner as a part time employee (24 hours per week) to provide treatment for patients with
hepatitis C infection. In 2013, as the number of patient referrals increased, the clinic required additional staff, and a part time (8 hours per week) pharmacist was hired. The pharmacist assisted the DNP prepared nurse practitioner with medication management and insurance approval of medications. The DNP prepared nurse practitioner collaborated with the clinic physician and reported to the nursing director on operations of the clinic. In 2014, the referrals continued to increase leading to the hiring of a 32 hours per week Bachelor of Science prepared registered nurse (RN) case manager for the clinic. The DNP prepared nurse practitioner work hours were also increased to 32 hours per week. A medical assistant was hired in 2016 to assist the RN case manager. Paper records are used for patient care, as there is no electronic health record available.

The clinic team members obtained the Fibroscan 502 Touch (Echosens) at the clinic in May of 2016, after the initial organizational assessment. The clinic team members received training on how to use the Fibroscan 502 Touch (Echosens) and began using it on referral patients for evaluation of fibrosis. Sasso et al. (2010) reported the Fibroscan is an ultrasound-based vibration-controlled transient elastography device used to assess liver stiffness related to fibrosis. Ledinghen et al. (2014) reported a method for non-invasive assessment of hepatic steatosis with liver stiffness is controlled attenuation parameter (CAP) evaluated with transient elastography. The Fibroscan 502 Touch (Echosens) provides an immediate non-invasive evaluation of hepatic steatosis and liver fibrosis for patients with chronic liver disease such as hepatitis C and NAFLD. The DNP prepared nurse practitioner plans to use the Fibroscan 502 Touch (Echosens) technology to evaluate for hepatic steatosis and fibrosis in all new patients referred to the clinic for treatment of hepatitis C infection. Early diagnosis of NAFLD and management can potentially delay disease progression.
Stakeholders. A stakeholder is a person or group that has interest in an organization. The clinic stakeholders included the DNP prepared nurse practitioner, RN case manager, medical assistant, and pharmacist who were team members of the clinic providing patient care. Patients with hepatitis C receiving treatment at the clinic who needed further evaluation of hepatic steatosis were stakeholders, as well as the referring primary care physician (PCP) who would be assuming care of patients diagnosed with NAFLD.

Analysis of the assessment. This organization is a financially viable nonprofit organization whose mission and core values are to advocate for and serve the poor and vulnerable in their communities. This organization is committed to public service, serving and meeting the needs of citizens, and strengthening the community. This organization is dedicated to meeting the healthcare needs of residents in the community they serve.

Residents of the county utilize this organization for their healthcare needs. Residents in need of hepatitis C infection treatment use the highly assessable clinic at the campus location. This organization chose to meet a community need and supported the establishment of the clinic in 2012. The clinic continues to provide services to residents diagnosed with hepatitis C infection. The clinic has dedicated and compassionate providers and staff who care for patients with hepatitis C infection. The DNP prepared nurse practitioner recognized an additional need for patients receiving treatment for hepatitis C infection who have comorbid hepatic steatosis.

The organization’s needs. New cases of hepatitis C infection continue to be reported in the county (PHMC, 2015). Primary care providers (PCPs) are screening for hepatitis C infection and making referrals to the clinic for evaluation and treatment. The clinic is providing critically needed services for patients with hepatitis C infection.
The DNP prepared nurse practitioner identified a patient health care need at the clinic. As some hepatitis C patients have hepatic steatosis on radiological imaging, there was a need to evaluate for the presence of NAFLD. If a diagnosis of NAFLD was found, these patients required transition of care to their PCP after treatment of hepatitis C infection was completed, for ongoing NAFLD management. The next section presents a review of the evidence supporting why there was a need to address this critical problem.

The Evidence-Based Project

Evidence Supporting the Evidence-Based Project Solution

It may be possible for hepatitis C to be cured with direct-acting antiviral agent medication use, resulting in a decrease in HCC. This decrease in HCC has great significance, as it can lead to a reduction in the need for liver transplantation for cancer caused by hepatitis C infection disease progression (Wong et al., 2014).

It is also known that hepatitis C infection can progress to cirrhosis and increased HCC (The American Association for the Study of Liver Diseases [AASLD] & Infectious Diseases Society of America [IDSA], 2015). However, progression can be prevented with earlier intervention and treatment of the hepatitis C infection (AASLD & IDSA, 2015). To provide healthcare professionals with guidance on how to treat their patients with hepatitis C infection, the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (2015) developed a web-based process at http://www.hcvguidelines.org/ for evidence-based recommendations for hepatitis C management.

The American Association for the Study of Liver Diseases, jointly with the American College of Gastroenterology and the American Gastroenterological Association, published guidelines in 2012 for the diagnosis and management of NAFLD (Chalasani et al., 2012). These
guidelines recommend hepatic steatosis, either by imaging or by histology and there are no causes for secondary hepatic fat accumulation such as significant alcohol consumption, use of steatogenic medication, or hereditary disorders for the diagnosis of NAFLD (Chalasani et al., 2012). NAFLD is often found incidentally when a patient has elevated liver enzymes or when the disease is seen on radiologic imaging.

Clinical practice guidelines for NAFLD recommend that patients with unsuspected hepatic steatosis detected by imaging should be evaluated as though they have NAFLD (Chalasani et al., 2012). Further, clinical practice guidelines for NAFLD recommend that patients who have signs attributable to liver disease, or have abnormal liver biochemistries should be evaluated as though they have suspected NAFLD (Chalasani et al., 2012). When hepatic steatosis is evident in patients with other chronic liver disease, such as in hepatitis C, it is important to assess patients for metabolic risk factors to include significant alcohol consumption, use of steatogenic medication, or hereditary disorders (Chalasani et al., 2012).

The goal of NAFLD treatment includes prevention or reversal of hepatic injury and fibrosis through diet and exercise for weight loss and management of diabetes and dyslipidemia (Schwenger & Aller, 2014; Wilkins et al., 2013). Application of these guidelines for early identification and treatment of NAFLD could help prevent the development of cirrhosis in patients diagnosed with hepatitis C who have hepatic steatosis (Loomba & Sanyal, 2013). Primary care providers may not be using the established American Association for the Study of Liver Diseases guidelines for diagnosis and management of NAFLD (Bergqvist et al., 2012; Wieland et al., 2013). Researchers using surveys to assess understanding and practice patterns of PCPs with respect to the diagnosis and management of NAFLD reported the majority of providers did not identify NAFLD as a clinically important diagnosis and do not refer to
hepatology specialty care providers (Bergqvist et al., 2012; Wieland et al., 2013). It is essential for PCPs to understand the complexity of NAFLD in order to identify risk factors, evaluate for and diagnose the disease. One opportunity to address this problem is to utilize targeted education for PCPs on the diagnosis and management of NAFLD (Bergqvist et al., 2012; Wieland et al., 2013). Another method for increasing awareness and knowledge about the management of NAFLD is communication and collaboration between providers during the transition of patient care from specialty care provider to PCP (Naylor & Keating, 2008; Rooney & Arbaje, 2013).

Feasibility of Project to Improve Organization

The DNP prepared nurse practitioner currently working in the clinic requested assistance with establishing a protocol to provide care for patients with hepatitis C who were not being diagnosed for NAFLD. The clinic members were willing to incorporate the protocol into routine care for patients, in order to better meet patient needs, based on known evidence and practice guidelines.

Potential barriers. There were several potential barriers identified that did not prohibit the project success: 1) there is only one DNP prepared nurse practitioner at the clinic, therefore, patient care cannot occur when she is not available; 2) the clinic uses paper health records for sharing of patient health information from the DNP prepared nurse practitioner to the PCPs; 3) communication among providers is often delayed without a shared electronic health record; and 4) communication between providers via fax or mail can be misplaced or not reviewed; and may not be scanned into the electronic health record impacting patient care transitions.

The clinic members implemented the protocol to better meet the needs of the patient, with potential barriers to the implementation of the protocol identified. Initiatives to change
practice patterns are often guided by conceptual models. Two conceptual models, the Transitional Care Model and the Plan-Do-Study-Act Cycle were used to guide change in clinical practice patterns.

**Conceptual Models Guiding Project**

**Framework Guiding Evidence-Based Initiative: Transitional Care Model**

The Transitional Care Model (TCM, 2014) (Appendix B), designed by Naylor and colleagues at the University of Pennsylvania, guided this scholarly project. Transitions in care are services designed to ensure healthcare continuity, avoid preventable poor outcomes, and promote the safe and timely transfer of patients from one type of setting to another (Naylor et al., 2011). The Transitional Care Model (TCM) is a nurse-led, team-based care delivery system approach designed to increase alignment of the care system with the individual and achieve higher-quality outcomes (Naylor, 2012). The TCM addresses the negative effects associated with the care of older adults as they transition from one healthcare setting to another through patient engagement, shared decision-making, shared accountability, and self-management (Naylor, et al., 2013). The TCM can also be used in a primary care setting such as the patient-centered medical homes (Naylor, et al., 2013). Further, use of TCM supports patient and healthcare team members working together to identify needs and preferences, and to implement care plans designed to improve health and quality of life (Naylor, 2012).

Care coordination has been identified by the 2001 Institute of Medicine report as one of 20 national priorities for action. Rooney and Arbaje (2013) report poorly coordinated care or transition of care makes patients responsible for their own health outcomes. Factors that contribute to gaps in care during care transitions include poor communication, incomplete transfer of information, inadequate education of patients and the absence of a single point person
to ensure continuity of care (Naylor & Keating, 2008). Under the leadership of advanced practice registered nurses, such as a DNP prepared nurse practitioner that works in this clinic, effective transition among care settings should include collaboration and communication between providers, with strategies addressing patient education and medical follow-up during transitions (Bradway et al., 2012; Rooney & Arbaje, 2013; Stefanacci, 2011).

**TCM selected components.** Selected components of TCM (Appendix C) were used for implementation of the process improvement protocol in the clinic. This included: screening, assessment, educating patients, coordination and collaboration with the PCP, and assuring continuity of care. Interventions guided by the TCM are usually performed by nurses or advanced practice registered nurses [APRNs] (Bradway et al., 2012). The APRNs perform screening to identify and target specific population of adults at risk for poor outcomes (Hirschman et al., 2015). The APRNs conduct comprehensive assessments of adult patients, as well as risk factors for poor outcomes during initial meetings with patients (Hirschman et al., 2015). Guided by individual patient unique learning styles and preferences, the APRNs utilize multiple teaching strategies, such as the use of teach-back for educating patients (Hirschman et al., 2015). The APRNs promote communication and connections between care settings, coordinating and facilitating transfer of essential information between care providers (Hirschman, 2015). The APRNs encourage collaboration about plans of care among adult patients and members of the care team, and collaborate with physicians involved in care of the patient (Hirschman et al., 2015). The TCM promotes continuity of care to prevent breakdowns in care across settings by having the same APRN deliver and coordinate care throughout the entire care episode (Hirschman et al., 2015). The DNP prepared nurse practitioner is an APRN with the capability to perform these activities in this particular clinic.
The TCM components not chosen for the project included: elders and caregivers, symptom management and maintaining relationships. The “elders and caregivers” component of the TCM was not selected as the population of interest in this project is adults of all ages without caregivers. The “symptom management” component of the TCM was not selected as the patients with NAFLD may not have symptoms to manage, and NAFLD patient care service is not provided at the clinic. The “maintaining relationships” of the TCM was not selected as the DNP prepared nurse practitioner will not be providing health care for patients after treatment of their hepatitis C infection.

**Application of the selected components of the transitional care model.** As part of the project protocol, the DNP prepared nurse practitioner at the clinic assumed the role of patient care coordinator. The DNP prepared nurse practitioner implemented the process improvement protocol to ensure patients with hepatitis C and hepatitis steatosis are evaluated for and diagnosed with comorbid NAFLD and received patient education. The RN case manager or medical assistant screened for hepatic steatosis on radiological imaging in all newly referred patients with hepatitis C. The evaluation for and diagnosis of NAFLD by the DNP prepared nurse practitioner occurred during office visits for treatment of the hepatitis C. The DNP prepared nurse practitioner provided patient education about the new NAFLD diagnosis and evaluated patient understanding using the teach-back method. The DNP prepared nurse practitioner facilitated the transition of care between specialty care and primary care for continued care of NAFLD after completion of hepatitis C treatment. The DNP prepared nurse practitioner communicated with the PCP, to transition patient care for ongoing NAFLD management.
The process improvement protocol created by the DNP student, was developed with consideration given to ease and efficiency of work flow for the clinic team members. To implement this practice improvement, the PDSA Cycle framework was used to plan, implement, and evaluate the project.

**Model Guiding Practice Change: Plan-Do-Study-Act (PDSA) Cycle**

The model guiding the practice change in this scholarly project was the plan-do-study-act (PDSA). The PDSA (Appendix D), also known as the Deming Wheel or Deming Cycle, is a “systematic series of steps for gaining valuable learning and knowledge for the continual improvement of a product or process” (The W. Edwards Deming Institute, 2016, para. 1).

The PDSA is part of the Institute for Healthcare Improvement Model for Improvement, a tool for accelerating quality improvement used in health care (Agency for Healthcare Research and Quality [AHRQ], 2013). A change is planned and implemented, results are studied, and action is taken on what is learned (AHRQ, 2013; Litaker et al., 2006; Melnyk & Fineout-Overholt, 2011). The overall objective of improving the process or outcome requires problem identification, setting goals and planning an intervention, and evaluating outcomes (AHRQ, 2013; Melnyk & Fineout-Overholt, 2011; Speroff & O’Connor, 2004). A discussion of use of PDSA in this project follows.

**Plan-Do-Study-Act (PDSA) Approach to Project**

**Overview**

The four steps of the PDSA Cycle guided the project: (1) plan the intervention; (2) implement the intervention; (3) study and analyze the results; and (4) determine what was learned. If the modifications to the plan are needed, then refinement occurs and the plan is
implemented again. These four PDSA Cycle steps guided the practice improvement in the following manner.

**Plan-Do-Study-Act (PDSA) Implementation: Planning Phase**

In the plan phase, problems are identified, data are gathered, and the plan to carry out the improvement cycle is determined (Murphy, 2013). A process improvement protocol for patients with comorbid hepatitis C and NAFLD was created to improve the quality of patient care services using established evidence based guidelines (Chalasani et al., 2012; Sheth & Chopra, 2014; World Gastroenterology Organization, 2012). The process improvement protocol was developed in collaboration with the clinic DNP prepared nurse practitioner after chart audit, observation of the patient care process, and discussion with team members at the clinic.

**Project purpose.** The overall purpose of this DNP scholarly project was to evaluate the effectiveness of the practice improvement for patients with hepatitis C and hepatic steatosis. The goal was to improve the process to appropriately screen and diagnose NAFLD in patients with hepatitis C, provide patient-centered NAFLD education, and transition care from specialty provider to PCP for continued care for NAFLD.

**Project objectives.** This scholarly project had five objectives: 1) increase the number of appropriately diagnosed patients with NAFLD by the DNP prepared nurse practitioner during treatment of hepatitis C; 2) increase the number of patients with NAFLD who received patient education during their final office visit with the DNP prepared nurse practitioner; 3) increase the number of discharge letters to PCPs with the NAFLD algorithm for transition of patient care at the end of hepatitis C treatment; 4) increase the number of referring PCPs who reported awareness of NAFLD diagnosis as evidenced by the PCP questionnaire response; and 5) obtain
PCP perceptions of the process improvement protocol as evidenced by their response to a questionnaire.

**Project design.** This process improvement project was guided by the TCM, which incorporates factors influencing patient care transitions; and the roles of the clinic team members. Opportunities for change vary at each practice, therefore, project design should consider existing conditions, practice configuration, and dynamics when a planned change is going to occur in clinical practice (Litaker et al., 2006). The personnel, office configuration, existing conditions, practice dynamics and work flow patient care were considered when developing the intervention. The clinic process and patient care routine were considered and proposed changes were incorporated into current practice using existing resources.

The process improvement project involved the development of one protocol with data collection during two phases of the protocol. The first phase of the protocol involved identification and diagnosis of NAFLD during treatment of hepatitis C. The second phase of the protocol involved patient education, communication to the PCP with discharge letter along with NAFLD algorithm and continuation of care by PCP after treatment of hepatitis C. Data were collected and separated by each phase. The number of patients who had hepatitis C and hepatic steatosis depended on the referral patients receiving treatment at the clinic during the trial period.

**Type of project.** This was a quality improvement project designed to develop and evaluate a protocol to address quality care for patients with hepatitis C and NAFLD type hepatic steatosis in a community clinic. Improving patient care services through application of existing evidence based practice guidelines will improve patient care (Moran, Burson, & Conrad, 2014).

**Project measurement.** Prior to the process improvement protocol, there was not a clinical process or protocol for evaluating and diagnosing NAFLD in patients with hepatitis C
and hepatic steatosis at the clinic. Patients were not receiving NAFLD patient education and transitioning to their PCP for continuation of care of NAFLD. The success of the process improvement protocol was determined by a change in current clinical practice.

There was no patient care services at the clinic for those with hepatitis C and comorbid NAFLD. Thus the plan as presented earlier was developed to: 1) increase in the number of appropriately diagnosed patients with NAFLD by the DNP prepared nurse practitioner during treatment of hepatitis C; 2) increase in the number of patients with NAFLD who receive patient education during their final office visit with the DNP prepared nurse practitioner; 3) increase in the number of discharge letters along with the NAFLD algorithm to PCPs for transition of patient care at the end of hepatitis C treatment; 4) increase in the number of referring PCPs who report awareness of NAFLD diagnosis as evidenced by the return of the PCP questionnaire response within seven days of receipt of the questionnaire; and 5) obtain PCP perceptions of the process improvement protocol as evidenced by the PCP questionnaire results within seven days of receipt of the questionnaire.

Sources of data. Data sources included the health records/charts of patients with hepatitis C and hepatitis steatosis and the completed PCP questionnaires. Another source of data was the clinic team members’ responses to the question regarding how to improve the process improvement protocol.

Outcome measures. Data collection occurred during the implementation of the process improvement protocol, or “do” phase. Analyses of the data occurred during the “study” phase.

A data collection tool, Project Intervention Clinic Process Data Collection Tool (Appendix E) was created to collect data on the clinic patient care process to identify and diagnose NAFLD. The first objective of this project was to increase the number of appropriately
diagnosed patients with NAFLD by the DNP prepared nurse practitioner during treatment of hepatitis C. The following data were collected using the Project Intervention Clinic Process Data Collection Tool. First, the number of charts with appropriate documentation of hepatic steatosis on pre-testing document was identified. Second, the number of charts with appropriate documentation of NAFLD diagnosis on hepatitis C treatment flow sheet were collected. Third, the number of charts with appropriate documentation of calculated NAFLD fibrosis score (Angulo et al., 2007) on pre-testing document was identified. Finally, the number of charts appropriately flagged with a green sticker on lab requisition document to send the discharge letter along with algorithms to PCP for patients with NAFLD was collected. Analyses of the data occurred to examine documentation of the protocol steps related to the diagnosis of NAFLD.

The second objective of this project was to increase the number of patients diagnosed with NAFLD who received patient education during their final office visit with the DNP prepared nurse practitioner. A second data collection tool, Project Intervention Transition Data Collection Tool (Appendix F) was created to address the second objective. Data collected for evaluating this objective included: the number of charts with documentation of patients who received NAFLD patient education and the patient is able to teach-back information on the treatment flow sheet during the final office visit were identified. Analyses of the data occurred to examine documentation of the protocol step related to patients who received NAFLD patient education and patients who are able to utilize the teach-back method.

The third objective for this project was to increase the number of discharge letters along with the NAFLD algorithm sent to PCPs for transition of patient care at the end of hepatitis C treatment. Data collected for evaluating this objective included: the number of charts with
documentation of the discharge letter along with NAFLD algorithm mailed to the PCP at the end of hepatitis C treatment on the patient treatment flow sheet was identified. Data were recorded on the Project Intervention Transition Data Collection Tool. Analyses of the data occurred to examine documentation of the protocol step related to mailed discharge letter along with the NAFLD algorithm to the PCP.

The fourth objective of this project was to increase the number of referring PCPs who reported awareness of NAFLD diagnosis as evidenced by the PCP questionnaire response within seven days of receipt of questionnaire. A third data collection tool, Primary Care Provider (PCP) Questionnaire (Appendix G) was created to collect data to address the fourth objective. Data collected for evaluating this objective included: the number of PCPs who reported receipt of the discharge letter, and the number of PCPs who reported awareness of NAFLD diagnosis with the addition of diagnosis to the patient’s health record. The questionnaire data were analyzed for the PCPs “yes or no” response to receipt of the discharge letter and addition of NAFLD diagnosis to the patient health record.

The fifth objective of this project was to evaluate the PCP perceptions of the protocol process as evidenced by the PCP questionnaire response within seven days of receipt of the questionnaire. Data were collected using the Primary Care Provider Questionnaire: the number of PCPs who reported receipt of the NAFLD algorithm; and the number of PCPs who evaluated the NAFLD algorithm for management of NAFLD. In addition, comments from the PCPs regarding the transition of care from specialty provider to PCPs for continuation of NAFLD treatment were collected. The questionnaire data from the PCPs’ response “yes or no” to receipt and usefulness of the algorithm for management of NAFLD were analyzed, and a summary of comments for themes regarding the transition of care was conducted. PCPs who did not return
the questionnaires within seven business days received a phone call to encourage return of the completed questionnaire and this data were included. The DNP student also interviewed the clinic team members during the implementation phase of the protocol.

The DNP student interviewed the clinic DNP prepared nurse practitioner and the RN case manager to evaluate the process improvement protocol, and inquired how the process improvement protocol could be improved. The clinic team members’ recommendations for patient care document changes were made the same day as recommended. The clinic team members’ recommendations for changes and additions in steps of the protocol were recorded and incorporated into the revised protocol.

**Plan-Do-Study-Act (PDSA) Implementation: Do Phase**

Prior to implementation of the project, the proposed intervention was formally approved by the project team; and the Institutional Review Boards (IRBs) of both the organization and the university. A timeline for the project was created using the PDSA framework. During the “do” phase, the plan is implemented, problems are documented, and data analysis is initiated (Murphy, 2013). The RN case manager and DNP prepared nurse practitioner used the process improvement protocol at the clinic during the implementation phase.

**Steps to implement project.** The process improvement protocol intervention consisted of the following steps. First, the RN case manager and medical assistant identified patient referrals with hepatic steatosis during chart preparation and made written notations on the chart of imaging results. Second, the DNP prepared nurse practitioner evaluated and diagnosed NAFLD during the treatment for hepatitis C. Third, the DNP prepared nurse practitioner provided NAFLD patient education and used teach-back during the final scheduled appointment at the clinic. Fourth, the discharge letter along with NAFLD algorithm was sent by the DNP
prepared nurse practitioner to the PCP at the end treatment of hepatitis C infection. Fifth, the DNP student contacted the primary care office clinical staff and faxed the PCP questionnaire to the referring provider for completion two weeks after patient completed hepatitis C treatment. Finally, the DNP student contacted the PCP office staff to check on questionnaire status, if not returned to the clinic in seven days. Data from questionnaires returned after seven days were included.

The DNP student collected data during the implementation of the protocol intervention at the clinic. The clinic team members were interviewed during the implementation phase for comments about the process improvement protocol intervention.

**Training clinic team members.** The DNP student met with the clinic team members on July 8, 2016 the week before implementation. The meeting was conducted to review the protocol, roles, documents to use during implementation; and to answer questions.

**Documents for the evidence-based project.** The DNP student generated the tools and documents used for this project. The process improvement protocol, *Patient Referral to Clinic with Hepatic Steatosis* (Appendix H) outlined a step-by-step protocol process and the *Diagram of Protocol for Patient Referral to Clinic with Hepatic Steatosis* (Appendix I) is a visual representation of the protocol.

The DNP student developed the DNP prepared nurse practitioner’s *Discharge Letter from Specialty to Primary Care Provider* (Appendix J) along with the *Hepatic Steatosis Noted on Radiological Imaging Algorithm* (Appendix K) and *NAFLD Algorithm* (Appendix L). The documents were developed to send to PCPs when patients completed hepatitis C treatment and needed follow up for NAFLD. The documents were mailed through the US Postal Service to the PCP, in the absence of an electronic health record.
Patients received NAFLD education using the DNP student generated *Nonalcoholic Fatty Liver Disease (NAFLD) Patient Education Handout* (Appendix M) during their final office visit at the end of hepatitis C treatment. The patients were expected to teach-back NAFLD patient information and follow up needed with his or her PCP, to ensure comprehension of instructions. The DNP prepared nurse practitioner asked patients to teach-back key points for NAFLD management and follow up with their PCP as noted on his or her patient NAFLD education handout and included in patient education session with provider.

**Recruitment strategies.** There was no recruitment of patients, as patients with hepatitis C infection are referred to the clinic for treatment. A proportion of the patients with hepatitis C had hepatic steatosis reported on radiological imaging. After the project proposal was approved and IRB determination, a patient chart review was performed at the clinic by the DNP student identifying patients receiving treatment for hepatitis C with hepatic steatosis reported on radiological imaging.

**Timeline for project.**

| January – June 2016 | • Organization assessment.  
|                    | • Design of protocol, protocol diagram, algorithms, patient education handout, discharge letter and PCP questionnaire, and data collection tools. |
| July – August 2016 | • Meeting with clinic team members to review project intervention;  
|                    | • RN case manager, medical assistant and DNP prepared nurse practitioner began use of protocol in patient care process;  
|                    | • DNP prepared nurse practitioner reviews patient’s health history, assessed for alcohol abuse, and reviews laboratory results to rule out differentials for diagnosis of NAFLD;  
|                    | • NAFLD patient education from the DNP prepared nurse practitioner during their final office visit for treatment of hepatitis C;  
|                    | • The discharge letter along with NAFLD algorithm mailed by the DNP prepared nurse practitioner to the PCP after their patient has completed hepatitis C treatment;  
|                    | • The DNP student faxed questionnaire to referring PCP two weeks after the discharge letter with algorithms is mailed to the PCP;  
|                    | • The DNP student contacted the clinical staff at the PCP’s office if the questionnaire was not returned in seven days; and  
|                    | • Data collection occurred during implementation of protocol. |
| September 2016     | • Analysis of data from collection tools for the clinical process – increased percentage in diagnosis of NAFLD, patient education and transition of care, and continuity of care for patients with hepatitis C and comorbid hepatic steatosis.  
|                    | • *Project Intervention Clinic Process Data Collection Tool* |
Project Intervention Transition Data Collection Tool
Primary Care Provider (PCP) Questionnaire
- Updated the protocol intervention with solutions for the identified problems in preparation for the next PDSA Cycle.
- Decision about sustainability of intervention after first PDSA completed.
- Meeting with clinic team members and nursing director to present results of the project process improvement protocol.

**Budget.** There was not a budget for the project. There were minimal costs, as the project incorporated changes to clinical practice without an increase in personnel. However, it did have an additional cost of $0.07 for a color copy of the NAFLD algorithm that accompanied the discharge letter. The DNP prepared nurse practitioner and RN case manager incorporated the assessment for and education of patients with NAFLD into the patient care routine.

Project implementation required additional time by the DNP prepared nurse practitioner to evaluate patients whose radiological imaging reports hepatic steatosis. In addition, the DNP prepared nurse practitioner required additional time to provide NAFLD education, and send the discharge letter with the NAFLD algorithm to the PCP. The patient’s last appointment encounter with the DNP prepared nurse practitioner had two diagnoses, hepatitis C and NAFLD; and was 10 minutes longer. Approximately 50 percent of the visit devoted to educating and counseling patients. The increased time for the last appointment resulted in a potential increase in revenue as a Level 4, established visit at $184.00; instead of Level 3, established visit at $152.00. The DNP student created the project documents (i.e., protocol, algorithms, discharge letter, patient education material, and PCP letter with questionnaire) used in the project at no cost to the organization. All documents were left with the clinic DNP prepared nurse practitioner for continued use.

**Human subject protection.** The human subject considerations are minimal because this is a scholarly quality improvement project establishing patient care process at the clinic. The
DNP student completed and submitted the DNP Application for Review of Determination to the Grand Valley State University Human Research Review Committee for review. Likewise, the DNP student completed and submitted an application to the organization’s Health Human Research and Review Board. The project was deemed to be a clinical quality improvement initiative and not research by both review boards (Appendix N). After approval was obtained from both review boards the project was implemented.

The data collection tools and questionnaire were de-identified to protect patient confidentiality using a numeric value instead of the patient name. The numeric de-identifier code key and data collection tools were stored in the DNP prepared nurse practitioner designated locked desk drawer in a locked office at the clinic, to protect patient confidentiality.

There was a private fax machine located within the clinic office to fax the PCP Questionnaire Letter (Appendix O) from the DNP student to the PCP using a clinic fax cover sheet (Appendix P) for transmission. The completed questionnaire from the PCP was faxed to the DNP prepared nurse practitioner using the clinic fax cover sheet (Appendix Q) to the clinic fax machine. The RN case manager at the clinic gave received faxed questionnaire to the DNP prepared nurse practitioner. The DNP student checked with the DNP prepared nurse practitioner at the clinic weekly for the completed PCP questionnaires.

**Plan-Do-Study-Act (PDSA) Implementation: Study Phase**

**Overview.** In the study phase, data analysis was completed and included a determination of whether project aims were met (Murphy, 2013). Data collected during the implementation or “do” phase was analyzed. Data from collection tools were analyzed to evaluate the effectiveness of the practice improvement for patients with hepatitis C and hepatic steatosis.
Data analysis. Descriptive statistics were used to summarize the quantitative data. A qualitative thematic analysis was used to analyze one of the responses from the PCPs. An increase in the percentage of patients with hepatitis C who were diagnosed, received patient-centered education and transitioned to their PCP for continued care of NAFLD would support the effectiveness of the protocol.

In a clinical setting, approximately 30 to 70 percent of patients with hepatitis C have hepatic steatosis (Blonsky & Harrison, 2008; Patel & Harrison, 2012; Rafiq & Younossi, 2008). Seven patients or 30 percent of the average number of monthly patient referrals to the clinic were required for evaluation of the process improvement protocol intervention, but this number was not possible within the eight week trial period. The number of patients for the PDSA cycle was determined by the patients with hepatitis C and hepatic steatosis referred to the clinic and received treatment during the trial period. It would have been ideal to receive all of the questionnaires from PCPs to analyze. However, the number of questionnaire responses for evaluation was dependent upon the number of questionnaires returned to the clinic during the trial period.

Plan-Do-Study-Act (PDSA) Implementation: Act Phase

During the final phase, “act,” decisions are made about sustainability of the process improvement protocol, and if necessary, another round of PDSA (Murphy, 2013). Clinic team members used the protocol to improve patient care process for patients with hepatitis C and hepatic steatosis. The patients with hepatitis C and hepatic steatosis were diagnosed with NAFLD, received patient-centered education, and transitioned to their PCP for continued management of NAFLD after completion of hepatitis C treatment at the clinic. The clinic team members plan to continue the process improvement protocol with recommended revisions. A
second PDSA cycle is recommended with use of revised patient care process. A discussion of the project outcomes and implications for practice follows.

**Project Outcomes**

Review of the process improvement project involved the development of one protocol with data collection during two phases of the protocol. The first phase of the protocol involved identification and diagnosis of NAFLD during treatment of hepatitis C. The second phase of the protocol involved patient education, communication to the PCP with discharge letter along with NAFLD algorithm and continuation of care by PCP after treatment of hepatitis C. Data were collected and separated by each phase. During the PDSA cycle, only six patients receiving hepatitis C treatment with hepatitis steatosis noted on radiological imaging at the clinic were included. During the trial period, there was four new patient referrals to the clinic for hepatitis C with hepatic steatosis noted on radiological imaging pending treatment, but they did not begin treatment for hepatitis C during the trial period to include in the PDSA cycle.

The trial period for the process improvement protocol occurred from July 11, 2016 to September 12, 2016 and included six patients receiving treatment for hepatitis C at the clinic (Table 1). The six patients included four male (66.7%) and two female (33.3%) with age range from 40 to 69 years. Three of the six patients reported their race as White (50%) and three as African Americans (50%). Four of the six patients had hepatitis C genotype 1A (66.7%) and two patients had hepatitis C genotype 1B (33.3%).
Table 1

Participant Information

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n=6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Male 3 (50%)</td>
</tr>
<tr>
<td>Race</td>
<td>African American 3 (50%)</td>
</tr>
<tr>
<td>Hepatitis C Genotype</td>
<td>1A 4 (66.7%)</td>
</tr>
</tbody>
</table>

Project Objectives

To review, the scholarly project had five objectives: (1) increase the number of appropriately diagnosed patients with NAFLD by the DNP prepared nurse practitioner during treatment of hepatitis C; (2) increase the number of patients with NAFLD who received patient education during their final office visit with the DNP prepared nurse practitioner; (3) increase the number of discharge letters mailed to PCPs with the NAFLD algorithm for transition of patient care at the end of hepatitis C treatment; (4) increase the number of referring PCPs who reported awareness of NAFLD diagnosis as evidenced by the PCP questionnaire response; and (5) obtain PCP perceptions of the protocol as evidenced by their response to a questionnaire.

Objective one. The objective to increase the number of appropriately diagnosed patients with NAFLD by the DNP prepared nurse practitioner during treatment of hepatitis C was achieved with all six patients or 100 percent of the patients with hepatitis C and hepatic steatosis diagnosed with NAFLD (Table 2). Data collected for hepatic steatosis noted on the clinic pretesting document occurred four out of six opportunities (66.7%). Data collected for NAFLD diagnosis noted on the clinic hepatitis C treatment flow sheet occurred six out of six opportunities (100%). Data collected for calculated NAFLD fibrosis score noted on the clinic pretesting document occurred three out of six opportunities (50%). Data collected for green
sticker on the lab requisition document to send PCP letter and NAFLD algorithm occurred six out of six opportunities (100%). Even though these six patients were not screened for and diagnosed with NAFLD at the first office visit, the DNP prepared nurse practitioner’s knowledge of the process improvement protocol and NAFLD enabled her to screen for and diagnosis NAFLD at later patient encounters during treatment of hepatitis C. The DNP prepared nurse practitioner included the NAFLD diagnosis in the final patient encounter dictation note sent to the PCP.

Table 2
Phase 1: Objective 1 Assessment and Diagnosis of NAFLD

<table>
<thead>
<tr>
<th>Protocol Step</th>
<th>Yes</th>
<th>No</th>
<th>n=6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatic steatosis noted on pretesting document</td>
<td>4 (66.7%)</td>
<td>2 (33.3%)</td>
<td></td>
</tr>
<tr>
<td>NAFLD diagnosis noted on treatment flow sheet</td>
<td>6 (100%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fibrosis score noted on pretesting document</td>
<td>3 (50%)</td>
<td>3 (50%)</td>
<td></td>
</tr>
<tr>
<td>Green sticker placed on lab requisition document</td>
<td>6 (100%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Objective two.** The objective to increase the number of patients with NAFLD who received patient education during their final office visit with the DNP prepared nurse practitioner. Data collected for NAFLD patient education with teach-back at final office visit recorded on the clinic treatment flow sheet occurred two out of six opportunities (33.3%). The DNP prepared nurse practitioner reported all of the six patients or 100 percent of patients with newly diagnosed NAFLD received patient education with the teach-back method. Patient chart review of the dictation note from the final patient encounter with the DNP prepared nurse
practitioner noted NAFLD patient education for all six patients (100%), but only three of the six dictations (50%) noted the use of teach-back method. The DNP prepared nurse practitioner reported she forgot to dictate the teach-back method with the NAFLD education in three of the patient encounters due to new process. She also reported duplication of putting information both in patient encounter dictation note and on clinic treatment flow sheet.

**Objective three.** The objective to increase the number of discharge letters mailed to PCPs with the NAFLD algorithm for transition of patient care at the end of hepatitis C treatment. Three out of six opportunities (50%) occurred with recording completion of mailed letter with NAFLD algorithm mailed to PCP noted on the clinic treatment flow sheet. The DNP prepared nurse practitioner reported she forgot to record information on the clinic treatment flow sheet for some of the patients. She reported all six patients’ PCP were mailed a discharge letter with NAFLD algorithm and noted duplication of recording information on clinic treatment flow sheet when a copy of letter was in the patient health record.

**Objective four.** The objective to increase the number of referring PCPs who report awareness of NAFLD diagnosis as evidenced by the PCP questionnaire response. Response rates or return of PCP questionnaires was low with a return rate of four (66.7%) questionnaires. If the PCP did not return the questionnaire, the DNP student called the PCP’s office and spoke with the medical assistance to encourage the PCP to complete the questionnaire and fax back to the clinic. The four (66.7%) returned PCP questionnaires were affirmative to the following questions indicating awareness of NAFLD diagnosis and usefulness of NAFLD algorithm. Two (33.3%) PCP questionnaires were not returned.

1. Did you receive the patient’s discharge letter from the clinic provider noting diagnosis of nonalcoholic fatty liver disease (NAFLD)?
   Yes 100% of returned questionnaire   No _________
2. Was the diagnosis of NAFLD added to the patient’s medical history or problem list?
   Yes 100% of returned questionnaires  No ________

   **Objective five.** The objective to obtain the PCP’s perceptions of the process improvement protocol as evidenced by their response to a questionnaire. Again the PCP response rate with return of the questionnaire was low with four (66.7%) returned questionnaires and two (33.3%) questionnaires not returned. PCPs who responded to questions three and four were affirmative indicating receipt and usefulness of NAFLD algorithm. One of the PCPs reported he did not receive the NAFLD algorithm. A NAFLD algorithm was faxed to this PCP with a request to provide a response to question four and the PCP responded.

3. Did you receive the NAFLD algorithm sent with the discharge letter from the Mercy Health Hepatitis C Clinic provider?
   Yes 75% of returned questionnaires  No 25% of returned questionnaires

4. Was the algorithm beneficial for the treatment/management of NAFLD?
   Yes 100% of returned questionnaires  No ________

5. Are there any suggestions for improvement of the process for transition of care from specialty care to primary care for the continuation of treatment for NAFLD?

   There was no suggestions for improvement of the process for transition of care from the clinic provider to the PCP in response to question five. Two questionnaires included a comment of “no” by the PCP and two questionnaires had no comments or left blank by the PCP. A telephone conversation with the nurse of one of the PCPs, informed the DNP student that the PCP had the questionnaire on her desk but was too busy to complete it due to her work load.

   **Interviews with clinic team members.** The DNP student led interviews with the DNP prepared nurse practitioner and RN case manager occurred weekly throughout the project implementation “do” phase. The clinic team members reported ease of use of the protocol and made the following recommendations during the “do” phase of the project and were changed the same day of recommendation: 1) addition of recommended weight loss of 10 percent to the
NAFLD patient education document; 2) update of new fax number on clinic fax cover sheet; and 3) revision of letter to the PCP regarding follow up lab for patient in three months to determine hepatitis C viral cure to more accurately reflect the significance of lab result.

The following recommendations made by the clinic team members during the “do” phase of the project were recorded and included in the revised protocol: 1) discontinuation of NAFLD calculated fibrosis score and replace it with the Fibroscan 502 Touch (Echosens) hepatic steatosis and fibrosis scores; 2) stop recording patient education on clinic treatment flow sheet and continue including in patient encounter dictation note to the PCP; 3) send the discharge letter to PCP with NAFLD algorithm when end of treatment lab results are obtained instead of date of lab draw; 4) continue to include a copy of the discharge letter in patient’s chart and stop recording information on the clinic treatment flow sheet; and 5) include NAFLD patient education for appropriate patients during the consultation visit as well as the last office visit with the DNP prepared nurse practitioner.

**Summary.** There was a change in clinical practice at the clinic resulting in an improved patient care process for patients with hepatitis C and hepatic steatosis. The following are results of the process improvement protocol for the clinic site, PCP clinicians and patients.

**Site.** The clinic team members reported ease of use of the process improvement protocol. The clinic team members incorporated and used the process improvement protocol in clinical practice. The clinic team members provided recommendations for improvement of the process improvement protocol resulting in the creation of a revised protocol to use for a second PDSA cycle.

**Clinicians.** Primary care providers’ responses to the questionnaire were positive for NAFLD awareness and NAFLD diagnosis added in patient health care record. The PCP
responses were positive for the usefulness of the NAFLD algorithm. There was only two comments of “no” from the PCPs regarding suggestions for improvement of transition of care process from specialty to primary care provider.

Patients. Patients were diagnosed with NAFLD, received NAFLD education with teach-back method for comprehension of information and the need for follow up with PCP. Patient were transitioned to their primary care provider for continued care of NAFLD after hepatitis C treatment.

Implications for Practice

Successes

Successes encountered in the project included: 1) the clinic team members supported the use of the process improvement protocol; 2) the clinic team members provided feedback on the process improvement protocol to improve the process; 3) all of the clinic patients with hepatitis C who had comorbid hepatic steatosis were screened and diagnosed with NAFLD; 4) the DNP prepared nurse practitioner provided patient-centered NAFLD education using the teach-back method; 5) the clinic patients transitioned care from specialty provider to their PCP for continued care for NAFLD; 6) a change in clinical practice occurred; and 7) a revised process improvement protocol (Appendix R) for patients with hepatitis C and hepatic steatosis was developed and provided to the clinic team members to use in a second PDSA cycle.

Barriers

Barriers encountered in the project included: 1) a delay in implementation of the protocol resulted in a smaller number of patients for the project trial period; 2) a delay in new referral patients to the clinic starting hepatitis C treatment due to pending patient lab results and/or prior authorization for medication resulted in a small sample size to evaluate the protocol; 3) the
medical assistant was absent from the clinic on leave during implementation of the protocol and not available to provide feedback on the protocol; 4) the RN case manager was absent from the clinic for two weeks on vacation during the implementation phase and not available for processing new referral patients’ for treatment of hepatitis C and prepping charts; 5) incomplete documentation of protocol steps by the DNP prepared nurse practitioner in the health record for several of the patients; and 6) a low return rate (66.7%) of completed questionnaires by the PCPs.

**Sustainability Plan**

The ease of use of the process improvement protocol reported by the clinic team members helped to sustain use of the intervention at the clinic during the trial period. The clinic team members plan to continue the change in clinical practice with the revised process improvement protocol for new referral patients with hepatitis C and hepatic steatosis. The questionnaire sent to the referring PCPs was discontinued at the end of the trial period when the DNP student departed from the clinic. The clinic DNP prepared nurse practitioner did not want to continue the questionnaire to the PCPs, as it was a method to collect data during the quality improvement PDSA cycle with favorable responses from PCPs who returned the questionnaire.

The clinic does not have an electronic health care record and uses paper records. In the future, when an electronic health record is available at the clinic, the process improvement protocol could become part of the electronic health record to document diagnosis of NAFLD and document NAFLD patient education. The electronic health record could also be used to document transition of patient care to referring PCP via electronic discharge letter with NAFLD information for continuation of care. The process improvement protocol may require a PDSA cycle to ensure improvement continues after a conversion to an electronic health record.
There is potential to generate revenue for reimbursement of services at the clinic as a result of using the process improvement protocol in the care of patients with comorbid hepatitis C and NAFLD. The increased time for the last patient appointment with the provider for education resulted in an increase in revenue as a Level 4, established visit at $184.00; instead of Level 3, established visit at $152.00. However, there was an additional cost of $0.07 for a color copy of the NAFLD algorithm that accompanied the discharge letter to the PCP. The additional revenue for reimbursement of services during the implementation phase of the protocol for the six patients was $31.93 per patient for a total of $191.58 (Table 3). Future potential revenue for the clinic includes the Fibroscan fee of $230.00 per patient referred to the clinic for hepatitis C treatment to evaluate patients for hepatic fibrosis and steatosis.

Table 3

<table>
<thead>
<tr>
<th>Increased Clinic Revenue for Reimbursement of Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number of Patients</td>
</tr>
<tr>
<td>--------------------------</td>
</tr>
<tr>
<td>6</td>
</tr>
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**Stakeholder support.** Key stakeholders in this project included the DNP prepared nurse practitioner, the collaborating physician, nursing director, the RN case manager, and the medical assistant. The clinic DNP prepared nurse practitioner had requested assistance to provide care for patients with hepatitis C with undiagnosed NAFLD. The clinic team members willingly incorporated the process improvement protocol into their care for patients to improve patient care. The process improvement protocol gave the clinic team members the needed evidence-based intervention to improve patient care services to address an identified gap in care.
The transition of care from specialty practice to primary care for continued care was supported by clinic team members and the referring PCPs. The PCP’s acknowledgement of NAFLD diagnosis and usefulness of the NAFLD algorithm regarding the transition process of patient care helped sustain the process improvement protocol by the clinic team members.

**Relationship to Healthcare Trends**

**Early identification and treatment of NAFLD.** Hepatitis C is an example of one chronic disease associated with NAFLD. Undiagnosed NAFLD in susceptible patients with hepatitis C may lead to disease progression of NASH, cirrhosis, liver failure and possibly HCC requiring liver transplantation (Chalasani et al., 2012; Stein, Dong, & Loomba, 2009; Wong et al., 2014).

Early identification of NAFLD and treatment could prevent the development of nonalcoholic steatohepatitis, cirrhosis, liver failure and possibly hepatocellular carcinoma (Loomba & Sanyal, 2013). Health care providers are key in early identification of NAFLD for treatment not only in patients with hepatitis C, but other patients with risk factors for NAFLD, such as obesity and type 2 diabetes. The DNP student’s process improvement protocol provided patient care services for identification of NAFLD by the DNP prepared nurse practitioner during treatment of hepatitis C. The DNP student’s process improvement protocol improved the transition of patient care to the PCP for continuation of treatment of NAFLD preventing disease progression and early death.

**Transition of care.** Patients with complex or comorbid health conditions frequently require care from multiple providers and are particularly vulnerable to poorly executed transitions from one setting to another (Jeffs, Lyons, Merkley & Bell, 2013). Van Cleave et al. (2013) reported individuals with comorbidities experiencing care transitions is a challenge to the
health care system. Poorly executed care transitions can result in negative patient outcomes such as delays in treatment and increased healthcare spending due to progression of chronic disease (Jeffs, et al., 2013). Strategies addressing patient education, appropriate medical follow-up, and communication between providers improved the quality of care during transitions (Rooney & Arbaje, 2013).

The DNP student process improvement protocol, *Identification of Nonalcoholic Fatty Liver Disease in Patients with Hepatitis C: Using Evidence Based Guidelines to Improve Diagnosis and Transition of Care from Specialty Care Provider to Primary Care Provider*, addresses quality of care during transitions using the TCM. The TCM guided the development of the protocol, utilizing screening, assessment, patient education, coordination, collaboration and continuity of care by the DNP prepared nurse practitioner at the clinic. The use of the TCM by nurse practitioners may be benefit other patients with comorbid diseases and multiple health care providers during transition among care settings in the community.

**Limitations**

There was a small number of participants during the process improvement protocol trial period. During the trial period, six patients with hepatitis C and hepatic steatosis received treatment at the clinic available for evaluation and diagnosis of NAFLD, patient education and transition to the PCP for continued management of NAFLD. Four new referral patients for treatment of hepatitis C with hepatic steatosis on radiological imaging were excluded because that did not start treatment during the process improvement protocol trial period. There was no follow up with the six patients to determine if the patient scheduled an appointment with their PCP at the end of hepatitis C treatment for continued management of NAFLD. An additional limitation was the number of PCPs who provided feedback on the transition process from the
clinics provider to the PCP. A second PDSA cycle is recommended using the revised process improvement protocol at the clinic for patients with hepatitis C and hepatic steatosis.

**Essentials of Doctoral Education for Advanced Nursing Practice**

The American Association of Colleges of Nursing (AACN) document, *The Essentials of Doctoral Education for Advanced Nursing Practice* (2006) reports the Doctor of Nursing Practice (DNP) is a practice-focused doctorate that should prepare clinicians for leadership in evidence-based practice. The DNP degree prepares clinicians to generate and translate evidence produced through research into practice to improve health care quality, patient outcomes, and organizational or health policy (Melnyk, 2013). The DNP *Essentials* (2006) document provides content areas necessary for DNP curricula and the outcome competencies for graduates of DNP programs. The AANC (2006) DNP *Essentials* curriculum standards include: 1) scientific underpinnings for practice; 2) organizational and systems for quality improvement and systems thinking; 3) clinical scholarship and analytical methods for evidence-based practice; 4) information systems and technology and patient care technology for the improvement and transformation of health care; 5) healthcare policy for advocacy in health care; 6) interprofessional collaboration for improving patient and population health outcomes; 7) clinical prevention and population health for improving the nation’s health; and 8) advanced nursing practice. The DNP student is able to translate research into practice, evaluate and change practice (Brown & Crabtree, 2013).

As a DNP student, knowledge acquisition and competencies were obtained through the DNP curricula and the DNP project or practice change in the following ways: 1) performed an extensive literature review with synthesis on the project topic and utilized three theoretical frameworks in assessment, planning, implementing and evaluating the project; 2) enacted the
organization leaderships role through applied knowledge and skills in assessment of the organization and the community where the clinic is located to promote a quality improvement patient care process; 3) applied evidence appraisal and translation of evidence for best practice to change clinical practice at the clinic; 4) utilized change theory to plan and implement a quality improvement process with evaluation at the clinic; 5) advocated for care of patients with chronic liver disease when a gap in care was discovered at the clinic to improve patient quality of care; 6) communicated and collaborated with inter-professional and intra-professional team members at the clinic and in the community to improve patient health outcomes; and 7) portrayed the advanced practice nurse leadership role in project conception, assessment, development, implementation and evaluation of the process improvement at the clinic.

Brown and Crabtree (2013) report the DNP project requires students to use their knowledge to solve practice problems and meet the needs of patient populations to improve health care quality and patient outcomes. This DNP student’s process improvement protocol for the clinic improved the patient care process for patients with hepatitis C and hepatic steatosis. Patients with hepatitis C and hepatic steatosis benefited from early identification and diagnosis of NAFLD, patient-centered NAFLD education, and transition from specialty to primary care for NAFLD management after treatment of hepatitis C.

**Dissemination Plan**

Findings from the project will be disseminated to share information that may be useful in clinical practice for patients with hepatitis C and other chronic diseases associated with NAFLD. Dissemination of the project will begin through the DNP student’s presentation of the project results to the clinic team members and nursing director on September 19, 2016. The formal defense of the project on September 26, 2016 provides another venue for dissemination. The
DNP student presented on the topics NAFLD and NASH with the clinic DNP prepared nurse practitioner, liver disease presentation at the Michigan Society of Gastroenterology Nursing and Associates Conference on September 24, 2016. Future dissemination included submission of a manuscript for publication.

**Conclusion**

The development of a process improvement protocol filled a gap in care of patients with hepatitis C and hepatic steatosis at the clinic. The recognition of risk factors and assessment for NAFLD in patients with hepatitis C and hepatic steatosis will help promote early diagnosis and management of NAFLD to prevent progression of liver disease. NAFLD information from the DNP prepared nurse practitioner to the PCP assisted with the transition of care for patients with NAFLD for ongoing management and monitoring for disease progression by their PCP. Patient education enabled the patient’s participation in self-care and follow up with their PCP.

This DNP student’s quality improvement project may be useful for clinical practice in other primary and specialty practice settings, to diagnose and manage patients with NAFLD, and facilitate patient care transitions. Health care providers are key in early identification of NAFLD for treatment not only in patients with hepatitis C, but other patients with risk factors for NAFLD, such as obesity and type 2 diabetes. Early identification of NAFLD and treatment could prevent the development of nonalcoholic steatohepatitis, cirrhosis, liver failure and possibly hepatocellular carcinoma (Loomba & Sanyal, 2013).
References


http://doi.org/10.1093/geront/gnr078


Retrieved from


*Gastroenterology, 142*, 1592-1609.


Retrieved from http://www.cdc.gov/hepatitis/hcv/hcfaq.htm#section1


Ledinghen, V., Vergniol, J, Capdepont, M., Chermak, F., Hiriart, J., Cassinotto, C., Merrouche, W., Foucher, J., & Brigitte, L. (2014). Controlled attenuation parameter (CAP) for the


Wong, R., Cheung, R., & Ahmed, A. (2014). Nonalcoholic steatohepatitis is the most rapidly growing indication for liver transplantation in patients with hepatocellular carcinoma in
the U.S. *Hepatology*, 59, 2188-95. doi:10.1002/hep.26986


Appendix A

Canadian International Developmental Agency - Universalia/IDRC Framework

Appendix B

Transitional Care Model (TCM)

Source: Reproduced with permission from the Transitional Care Model
http://www.transitionalcare.info
Appendix C

Selected Components of the Transitional Care Model (TCM)
Appendix D

Plan-Do-Study-Act (PDSA) Cycle

### Appendix E

#### Project Intervention Clinic Process Data Collection Tool

<table>
<thead>
<tr>
<th>De-identifier</th>
<th>Hepatic steatosis noted on the clinic pretesting document</th>
<th>NAFLD diagnosis noted on the clinic hepatitis C treatment flow sheet</th>
<th>NAFLD fibrosis score noted on the clinic pretesting document</th>
<th>NAFLD green sticker on the clinic lab requisition document to remind nurse practitioner to send letter and NAFLD algorithm</th>
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Appendix F

Project Intervention Transition Data Collection Tool

<table>
<thead>
<tr>
<th>De-identifier</th>
<th>NAFLD patient education with teach-back final office visit noted on the clinic treatment flow sheet</th>
<th>Yes or No</th>
<th>Discharge letter with NAFLD algorithm mailed to PCP two weeks after final office visit noted on the clinic treatment flow sheet</th>
<th>Yes or No</th>
<th>Fax questionnaire to the PCP two weeks after the letter with NAFLD algorithm mailed</th>
<th>Date:</th>
<th>Questionnaire returned from PCP</th>
<th>Yes or No</th>
<th>Date:</th>
<th>Telephone call to the PCP’s office if questionnaire is not returned in seven days.</th>
<th>Date:</th>
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Appendix G

Primary Care Provider (PCP) Questionnaire

Primary Care Provider: _________________________________   De-identifier: ___________
Phone Number: ___________________________   Fax Number: _________________________

1. Did you receive the patient’s discharge letter from the Hepatitis C Clinic provider noting diagnosis of nonalcoholic fatty liver disease (NAFLD)?
   Yes _______    No _________

2. Was the diagnosis of NAFLD added to the patient’s medical history or problem list?
   Yes _______    No _________

3. Did you receive the NAFLD algorithm sent with the discharge letter from the Hepatitis C Clinic provider?
   Yes _______    No _________

4. Was the algorithm beneficial for the treatment/management of NAFLD?
   Yes _______    No _________

5. Are there any suggestions for improvement of the process for transition of care from specialty care to primary care for the continuation of treatment for NAFLD?

Thank you for your time and assistance with completing the questionnaire.
Please use the accompanying Hepatitis C Clinic cover sheet with the questionnaire and fax back to the Hepatitis C Clinic provider.
Appendix H

Protocol Process for a Patient Referral to Hepatitis C Clinic with Hepatic Steatosis

1. Referral received from primary care provider (PCP) to the clinic for treatment hepatitis C by registered nurse (RN) case manager or medical assistant.

2. Review of referral patient’s required health history, labs and ultrasound of right upper quadrant (RUQ) in preparation of hepatitis C treatment by RN case manager or medical assistant and patient health record is prepared for first clinic visit.

3. Radiological imaging results negative for cirrhosis but hepatic steatosis noted on ultrasound imaging. RN case manager or medical assistant will add hepatic steatosis information on patient’s clinic document, Hepatitis C Pretesting during health record preparation.

4. Patient has office visit to the clinic with health history reviewed by DNP prepared nurse practitioner specialty provider for other liver disease, metabolic risk factors for NAFLD (diabetes, hyperlipidemia, obesity), and patient assessed for potential alcohol abuse past six months:
   a. Positive for men: more than 3 drinks per day and 21 drinks per week (Chalasani, 2012)
   b. Positive for women: more than 2 drinks per day and 14 drinks per week (Chalasani, 2012)

5. Negative findings for diagnosis differentials for hepatic steatosis and negative for alcohol abuse leading to diagnosis of NAFLD by DNP prepared nurse practitioner specialty provider. NAFLD fibrosis score calculated.


7. Patient has second office visit to the clinic to discuss hepatitis C treatment and signs clinic’s document, Hepatitis C Therapy Treatment Agreement. Treatment of hepatitis C infection according to evidence based guidelines by the American Association for the Study of Liver Diseases (AASLD), Infectious Diseases Society of America (IDSA), and International Antiviral Society–USA (IAS–USA).

8. Patient’s health record is flagged with NAFLD green sticker on the Hepatitis C Clinic document, Lab Requisition and Appointment to remind the DNP prepared nurse practitioner discharge letter with NAFLD algorithms needs to be sent to PCP at end of treatment (coincides with lab draw date).

9. Last office visit at the clinic with the DNP prepared nurse practitioner is two weeks before end of treatment. At this visit, patient diagnosed with NAFLD receives education on
NAFLD and instructions to follow up with PCP after discharge from the clinic. Teach-back method used to assess patient understanding of information/education. Completion of education and teach-back noted on *Hepatitis C Treatment Flow Sheet*. The DNP prepared nurse practitioner dictation of office visit encounter sent to PCP will include new NAFLD diagnosis information.

10. Two weeks after patient’s last office visit and completion of treatment, the discharge letter and algorithms for transition of care from DNP prepared nurse practitioner to PCP is mailed, this is documented on the *Hepatitis C Treatment Flow Sheet*.

11. The DNP student will contact the PCP’s office clinical staff two weeks after patient discharge letter and NAFLD algorithms are sent, to inform them a letter with a questionnaire is being faxed to the provider to answer for evaluation of the transition process from the clinic to the PCP for continuation of NAFLD treatment. A clinic fax cover sheet will be used to fax to the PCP office and for return of the questionnaire by fax to the clinic.

- Did you receive the patient’s discharge letter from the clinic provider noting diagnosis of nonalcoholic fatty liver disease (NAFLD)?
  Yes _______ No __________
- Was the diagnosis of NAFLD added to the patient’s medical history or problem list?
  Yes _______ No __________
- Did you receive the NAFLD algorithm sent with the discharge letter from the Mercy Health Hepatitis C Clinic provider?  Yes _______ No __________
- Was the algorithm beneficial for the treatment/management of NAFLD?
  Yes _______ No __________
- Are there any suggestions for improvement of the process for transition of care from specialty care to primary care for the continuation of treatment for NAFLD?

12. A follow up phone call will be made to the referring PCP clinical staff by the DNP student if the questionnaire is not returned in seven days to the clinic in care of the DNP prepared nurse practitioner specialty provider.
Appendix I

Diagram of Protocol for Patient Referral to Hepatitis C Clinic with Hepatic Steatosis

1. Referral to Hepatitis C Clinic for treatment hepatitis C
2. Review of referral required documents from primary care provider (PCP)
3. Imaging RUQ negative for cirrhosis but positive hepatic steatosis
4. Patient office visit with DNP with review of health history and referral documents
5. At the last office visit - NAFLD patient education and follow up instructions
6. Treatment of hepatitis C according to evidence based guidelines
7. Patient preparation for start of hepatitis C treatment only but has NAFLD
8. Negative for differentials of hepatic steatosis and negative for alcohol abuse
9. Discharge letter to PCP from NP with NAFLD management algorithm at the end of treatment
10. Questionnaire faxed to referring PCP 2 weeks after treatment completed
11. Follow up phone call to PCP clinical staff if questionnaire not returned
Appendix J

Discharge Letter from Specialty to Primary Care Provider

Date

Primary Care Provider Name

Address

Address

Dear Primary Care Provider:

_Name (birthdate)_ has been under our care and has completed treatment of _his/her_ hepatitis C which was started in _month/year_. _He/she_ completed _number_ weeks of treatment with _name of drug(s)_. I will order a HCV RNA lab for your patient in three months to evaluate for a viral cure.

Your patient was noted to have steatosis on radiologic imaging and meets criteria for nonalcoholic fatty liver disease (NAFLD). The NAFLD diagnosis was included in my dictation sent to you after the patient’s last clinic visit. The patient has received education on NAFLD and instructed to follow up with you for continuation of care and monitoring.

NAFLD is a spectrum of liver disease that ranges from simple fatty infiltration of the liver (steatosis) to liver inflammation, nonalcoholic steatohepatitis (NASH). NASH is the progressive form of NAFLD that can lead to cirrhosis, hepatocellular carcinoma necessitating liver transplantation and liver-related mortality.

The American Association for the Study of Liver Diseases (AASLD), jointly with the American College of Gastroenterology (ACG) and the American Gastroenterological Association (AGA), published guidelines in 2012 for the management of NAFLD and NASH. The enclosed algorithm was developed to assist you with transition of care and management of NAFLD.

Thank you for allowing me to participate in the care of this patient. Please call the Hepatitis C Clinic if you have any additional questions.

Hepatitis C Clinic Provider
Hepatitis C Clinic Address
Phone Number
Fax Number
Appendix K

Radiological Imaging Algorithm for Hepatic Steatosis

- **Imaging Results**
  - **Cirrhosis**
    - Every 6 months AFP & liver labs and imaging
  - **Hepatic Steatosis**
    - **Positive alcohol abuse**
    - Stop alcohol
    - **Negative alcohol abuse**
      - NAFLD (nonalcoholic fatty liver disease)
  - **Negative**
    - Hepatitis C
      - Treatment hepatitis C

Appendix L

Nonalcoholic Fatty Liver Disease (NAFLD) Algorithm

- **Diabetes**: Standard Treatment Guideline
- **Hyperlipidemia**: Standard Treatment Guideline
- **Obesity**: Weight loss - 3-5% minimum
  - Standard Treatment Guideline
  - Vaccinations: Hepatitis A & B, pneumococcal and age appropriate
- **Monitoring**: Every 6 months lab CBC, platelet, protime, & liver enzymes
  - Liver Ultrasound for continued elevated liver enzymes
  - Refer to Gastroenterology for abnormal labs and or imaging
### Why is the liver important?
The liver performs many jobs in your body. It processes what you eat and drink into energy and nutrients your body can use. The liver also removes harmful substances from your body.

### What is Nonalcoholic Fatty Liver Disease (NAFLD)?
NAFLD is a name that is given to a range of liver conditions that are associated with the presence of too much fat in the liver. Some patients have a mild form of fatty liver. In other patients with fatty liver, inflammation of the liver may occur. This condition can lead to liver damage with scarring and cirrhosis.

<table>
<thead>
<tr>
<th><strong>Why is the liver important?</strong></th>
<th><strong>How Common is NAFLD?</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>The liver performs many jobs in your body. It processes what you eat and drink into energy and nutrients your body can use. The liver also removes harmful substances from your body.</td>
<td>NAFLD is likely to occur in 27-34% of adults in the United States. With the current increase in obesity, these percentages continue to rise. The rate of NAFLD increases to 75-92% in adults who are grossly obese.</td>
</tr>
</tbody>
</table>

### What is the risk factors for NAFLD?
- Obesity
- Diabetes
- Insulin resistance
- High cholesterol

### What are the symptoms of NAFLD?
- Often there are no symptoms
- When symptoms occur – most common
  - Fatigue
  - Pain or fullness in the upper right abdomen
- Additional symptoms with liver inflammation
  - Weakness
  - Loss of appetite
  - Nausea
  - Yellow skin and eyes
  - Itching

### Treatment for NAFLD:
- See your primary care provider for treatment & monitoring of NAFLD
- Take medications for high blood pressure, diabetes and high cholesterol as directed by your primary care provider
- Do not drink alcohol
- Weight loss if you are overweight or obese (10 percent of current weight recommended)
  - Increase physical activity daily
  - Low calorie diet
    - Limit foods that are high in calories
    - Eat foods that have fiber (whole grains, fruit and vegetables)

### Additional Instructions/Goals:
Follow up with your primary care provider after completion of hepatitis C treatment.
Appendix N

Institutional Review Board Determination Letter-Grand Valley State University

DATE: April 28, 2016
TO: Debra Brown Bayus, MSN
FROM: Grand Valley State University Human Research Review Committee
STUDY TITLE: [901099-1] Identification of Nonalcoholic Fatty Liver Disease in Patients with Hepatitis C: Using Evidence Based Guidelines to Improve Diagnosis and Transition of Care from Specialty Care Provider to Primary Care Provider

REFERENCE #:
SUBMISSION TYPE: New Project
ACTION: NOT RESEARCH EFFECTIVE
DATE: April 28, 2016
REVIEW TYPE: Administrative Review

Thank you for your submission of materials for your planned research study. It has been determined that this project:

DOES NOT meet the definition of covered human subjects research* according to current federal regulations. The project, therefore, DOES NOT require further review and approval by the HRRC.

If you have any questions, please contact the Research Protections Program at (616) 331-3197 or rpp@gvsu.edu. The office observes all university holidays, and does not process applications during exam week or between academic terms. Please include your study title and reference number in all correspondence with our office.

*Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102 (d)).

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains: data through intervention or interaction with the individual, or identifiable private information (45 CFR 46.102 (f)).

Scholarly activities that are not covered under the Code of Federal Regulations should not be described or referred to as research in materials to participants, sponsors or in dissemination of findings.
Appendix O

PCP Letter Accompanying Questionnaire

Date:

Dear Primary Care Provider:

Your patient has completed hepatitis C treatment and this communication is in regard to the transition of patient care to you for continuation of care for nonalcoholic fatty liver disease (NAFLD) diagnosed during treatment of hepatitis C. Communication was previously sent to you regarding the patient and diagnosis requiring continuation of care. It would be helpful if you could help with evaluating our process in transition of patient care from specialty care to primary care for continuation of care. Please complete the attached questionnaire within seven days and fax back to the Hepatitis C Clinic. A Hepatitis C Clinic fax cover sheet is also included for your convenience to fax the questionnaire back to the clinic.

Thank you for your time and assistance.

Hepatitis C Clinic Provider

Address

Phone Number

Fax Number
Appendix P

Hepatitis C Clinic Fax Cover Sheet to Send Questionnaire

FAX

Hepatitis C Clinic

To: 
From: 

Fax: 
Fax: XXX-XXX-XXXX

Phone: 
Phone: XXX-XXX-XXXX

Re: 
Date: 

CC: 
Pages: 

☐ Urgent   ☐ For Review   ☐ Please Comment   ☐ Please Reply   ☐ Please Recycle

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IF YOU HAVE RECEIVED THIS FAX IN ERROR, PLEASE NOTIFY THE SENDER IMMEDIATELY OR
CONTACT OUR CORPORATE COMPLIANCE OFFICE AT (XXX) XXX-XXXX
Appendix Q

Hepatitis C Clinic Fax Cover Sheet for Return of Questionnaire

FAX

Hepatitis C Clinic

To:  
From:  
Fax:  XXX-XXX-XXXX  
Fax:  
Phone:  XXX-XXX-XXXX  
Phone:  
Re:  
Date:  
CC:  
Pages:  

☐ Urgent  ☐ For Review  ☐ Please Comment  ☐ Please Reply  ☐ Please Recycle

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Appendix R

Revised Protocol Process for a Patient Referral to Hepatitis C Clinic with Hepatic Steatosis

1. Referral received from primary care provider (PCP) to the clinic for treatment hepatitis C by registered nurse (RN) case manager or medical assistant.

2. Review of referral patient’s required health history, labs and ultrasound of right upper quadrant (RUQ) by RN case manager or medical assistant and patient’s chart is prepared for the first clinic visit for hepatitis C treatment.

3. Radiological imaging results are negative for cirrhosis but hepatic steatosis noted on radiological imaging. RN case manager or medical assistant will add hepatic steatosis information on patient’s clinic document, Hepatitis C Pretesting during chart preparation and add green sticker to the patient’s chart.

4. During the consultation visit, the patient has a Fibroscan performed by a clinic team member for hepatic steatosis and fibrosis. The results are added to the patient’s health record and reviewed by the DNP prepared nurse practitioner.

5. During the consultation visit, lab results the health history is reviewed by DNP prepared nurse practitioner specialty provider for other liver disease, metabolic risk factors for NAFLD (diabetes, hyperlipidemia, obesity), and patient assessed for potential alcohol abuse past six months:
   a. Positive for men: more than 3 drinks per day and 21 drinks per week (Chalasani, 2012)
   b. Positive for women: more than 2 drinks per day and 14 drinks per week (Chalasani, 2012)

6. Positive finding for hepatic steatosis and negative for other differential diagnoses for hepatic steatosis, and negative for alcohol abuse leading to diagnosis of NAFLD by DNP prepared nurse practitioner specialty provider. Patient diagnosed with NAFLD receive education on NAFLD and instructions to follow up with their PCP. Teach-back method used to assess patient understanding of information/education.

7. The patient’s health record includes notation of NAFLD diagnosis on clinic document, Hepatitis C Treatment Flow Sheet. The DNP prepared nurse practitioner’s dictation of patient encounter sent to the PCP will include new NAFLD diagnosis information and completion of patient education with teach-back.

8. The patient has second office visit to the clinic is to discuss hepatitis C treatment and signs Hepatitis C Clinic’s document, Hepatitis C Therapy Treatment Agreement. Treatment of hepatitis C infection according to evidence based guidelines by the American Association for the Study of Liver Diseases (AASLD), Infectious Diseases Society of America (IDSA), and International Antiviral Society–USA (IAS–USA).
9. The last office visit at the clinic with the DNP prepared nurse practitioner is two weeks before end of treatment. At this visit, patient diagnosed with NAFLD receives education on NAFLD again with instructions to follow up with PCP after discharge from the clinic. Teach-back method used to assess patient understanding of information/education. The DNP prepared nurse practitioner dictation of office visit encounter sent to the PCP will include NAFLD diagnosis information and follow up with PCP.

10. The patient’s clinic document, *Lab Requisition and Appointment* is flagged with NAFLD green sticker to remind the DNP prepared nurse practitioner that discharge letter with NAFLD algorithm needs to be sent to PCP at end of treatment when lab results are available and reviewed.

11. A copy of the discharge letter sent to the PCP from the clinic DNP prepared nurse practitioner is placed in patient’s health record.