

NEW REFERRAL HEPATITIS C PROTOCOL: THE NEW STANDARD

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New Referral Hepatitis C Protocol: The New Standard

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ABSTRACT

The Gastroenterology (GI) clinic at Sanford Health anticipates an increase in patients with hepatitis C virus (HCV) based on the 2012 Centers for Disease Control (CDC) screening recommendations. With a disproportionately high prevalence in the baby-boomer population, 75% of all documented HCV cases, the CDC recommended a “one-time testing of all persons born during 1945-1965 without prior ascertainment of HCV risk” (CDC, 2012a).

The purpose of this practice improvement project was to refine the existing workflow of the GI clinic when caring for and managing patients with HCV. The *Plan, Do, Study, Act* method was followed to improve the processes and address the clinic goals.

The project first assessed the existing referral protocol for hepatitis C to improve the quality of care for HCV patients, to increase the clinic’s efficiency, and to identify opportunities for improvement. HCV is a complicated, intense disease process, necessitating chart reviews, patient education, and depression monitoring. To meet these time commitments the department added a new role, the designated hepatitis C nurse. The hepatitis C nurse would serve as a liaison for all HCV patients and providers.

The assessment further identified an incomplete process within the referral system. During the pre-appointment chart review for new hepatitis C referrals, many required tests were incomplete. To address the gap with referrals from primary care, a brochure containing a hepatitis C screening algorithm was created.

The assessment also identified a need for depression monitoring. To provide safe, up-to-date, treatment monitoring for depression in patients, the Patient Health Questionnaire (PHQ-9) was implemented. The inclusion of PHQ-9 monitoring by the hepatitis C nurse has helped the GI clinic reach its goals for administration compliance.

Staff members and providers have reported positive impacts at the clinic after the implementation of the new change processes at the GI clinic. Patients have expressed positive satisfaction with the services, particularly the ease of communicating with the GI clinic and consistent personnel since the implementation.

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DEDICATION

To my beautiful growing family: Reid, Ryland, and Baby Redden

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CHAPTER 1. INTRODUCTION AND PROBLEM STATEMENT

Hepatitis C virus (HCV) morbidity and mortality rates in the United States are on the rise, particularly for individuals born between the years of 1945 and 1965 (Centers for Disease Control and Prevention [CDC], 2012a). This population represents the baby-boomer generation, which is currently 23% of the residents in the United States. Baby boomers account for more than 75% of all documented HCV cases in the United States. The baby boomer population has the greatest risk of developing hepatocellular carcinoma and other HCV-related liver diseases (CDC, 2012a). HCV complications account for approximately 73% of HCV-associated deaths (CDC, 2012a). In 2012, the CDC made a screening recommendation to healthcare providers and patients. The CDC suggested a “one-time testing of all persons born during 1945-1965 without prior ascertainment of HCV risk, a population with a disproportionately high prevalence of HCV infection and related diseases” (CDC, 2012a). The intent of the new guideline was not to replace testing for patients with known risk factors but to facilitate early diagnosis for a target population. With the implementation of new screening guidelines, primary-care providers expect to see an increase of newly diagnosed HCV patients in this specific population.

While completing the requirements for my doctor of nursing practice degree, I, the author, was fortunate enough to spend a portion of my time at the GI clinic. My brief specialty rotation gave me the opportunity, in conjunction with other GI staff members, to identify a needed improvement for the clinic. The identified improvement opportunities in the clinic opened avenues to provide updated information to referring providers in the surrounding communities, too. Through discussions with the nurse practitioner (NP) during my clinical experience, I learned that many primary-care providers, locally, do not typically manage the treatment of HCV. Instead, the providers refer HCV patients to a gastroenterologist or an

infectious disease (ID) specialist. The ID department at Sanford Health in Fargo, North Dakota, typically does not follow or treat acute or chronic hepatitis C patients, with the exception of co-infected patients having human immunodeficiency virus (HIV) and HCV. Currently, the ID department refers all individuals to the GI clinic for the treatment and management of HCV.

When conducting the performance improvement project the Sanford GI clinic had two providers who specialized in treating and managing HCV, one hepatologist medical doctor (MD) and one family nurse practitioner. To manage the current and anticipated HCV patients, an identifiable need for a more efficient, standardized protocol for new HCV patient referrals was crucial.

Developing a standardized protocol would improve the quality of care for HCV patients, increase the clinic's efficiency, and create a foundation for excellent communication with HCV patients.

The author was recruited to serve as a core team member to assist in developing a standardized hepatitis C protocol to implement at the GI clinic. The author's role was to collaborate on the development of a standardized referral hepatitis C protocol, to evaluate the project once it was implemented, and to provide feedback for the core team members and providers at the GI clinic about future improvements and refinements once the project was completed.

The following sections of this clinical dissertation will discuss the prevalence and scope of HCV from a worldwide view to a local perspective. An overview of the pathophysiology of hepatitis C and the complications that could arise if left untreated. A brief discussion about the evidence-based guidelines utilized at the Sanford Health GI clinic, with a focus on potential adverse reactions from the medication treatment, is given. The clinical dissertation paper will transition into the specific framework used for the performance improvement project. An in-depth discussion of the *Plan, Do, Study, and Act* phases of the framework as well as the

continued progressive cycles are explained as the goal of achieving a standardized hepatitis C referral protocol are implemented at the GI clinic.

Pathophysiology

Viral hepatitis is caused by an infection from one of five distinct viruses: hepatitis A virus (HAV), hepatitis B virus (HBV), hepatitis C virus (HCV), hepatitis D virus (HDV), and hepatitis E virus (HEV) (CDC, 2012b). HCV, primarily transmitted, through exposure to infected blood or blood products. Individuals who have participated in intravenous or nasal drug use, or have shared drug paraphernalia are at greatest risk of HCV. Healthcare workers are considered an at-risk population due to the risk of exposure via accidental needle sticks. Others at high risk for HCV infection are recipients of a blood transfusion before 1992. The implementation of a standardized screening of donated blood for hepatitis infections came after the year 1992 (CDC, 2012b). Vertical transmission from a mother to her fetus accounts for less than two percent of HCV infection (Goldberg, Chopra, & O'Donovan, 2014). HCV can be contracted through sexual intercourse with an infected person; this mode of transmission is rather rare but does pose a risk for some individuals.

HCV infection can range in severity from a mild illness, lasting a few weeks, to a serious, chronic, lifelong illness (World Health Organization [WHO], 2012). Estimations are that as many as 25% of patients with untreated HCV infection will develop hepatic failure, requiring a liver transplant during their life (Chan, 2011). Diagnosing an HCV infection can be very challenging for providers because the reality is that many patients have minimal to no complaints or vague symptoms associated with the illness. About 15% of acute infections will resolve without treatment or diagnosis; however, the individual is able to transmit the disease during the illness' acute phase (Copstead & Banasik, 2010). The majority of people infected with HCV

will progress to a chronic state. Infected patients typically present with minor flu-like symptoms, such as fatigue, abdominal pain, nausea, vomiting, and arthralgia (Chan, 2011). Unfortunately, vague complaints and symptoms that are common with several other illnesses, delay the HCV diagnosis.

Suspicion of HCV arises when there is a detected antibody; however, additional laboratory tests are needed to confirm the diagnosis. When the HCV antibody is detected, testing for hepatitis C RNA quantitative levels, also known as the “viral load,” and genotyping are needed to confirm the HCV diagnosis. A laboratory test for a specific HCV genotype is extremely useful for predicting the likelihood of therapeutic response and dictates the duration of therapy patients receive (Chan, 2011). Currently, the World Health Organization recognizes 11 genotypes (1-11) with many subtypes (WHO, 2002). Genotypes 1-3 can be found worldwide. Genotype 4 is primarily located in the Middle East, Egypt, and central Africa (WHO, 2002). Genotype 5 typically originates in South Africa while Asia reports genotypes 6-11 as most common. In the United States, the primary genotypes observed are 1-3. Rises in genotypes other than 1-3, are beginning in the United States as more immigrants relocate and receive healthcare. GI staff members in the Fargo area report, the most common genotypes identified are genotypes 1-4. Genotype 1 is the most prevalent, followed by genotypes 2-3.

Prevalence and Scope of Problem

The WHO estimates that there are currently 150-200 million individuals infected with HCV worldwide (WHO, 2012). Persons infected with HCV represent 3.3% of the world’s population (Trustee of Dartmouth College, 2013). The percentage of HCV-infected individuals has surpassed those infected with HIV. In 2011, there were an estimated 34 million people living with HIV versus the 200 million living with HCV (WHO, 2011). Annually, 350,000

people worldwide die from HCV complications (WHO, 2012). HCV is one of the most common blood-borne illnesses in the United States.

Conservatively, HCV affects 3.2 million people in the United States (CDC, 2011); 60-75% of individuals who are acutely infected will not seek screening or medical attention due to the lack of symptoms. Therefore, many years may pass between HCV exposure and diagnosis (CDC, 2011). Delayed diagnosis prevents patients from receiving education, counseling, lifestyle modification, and early initiation of treatment (CDC, 2012a). A delay in patients receiving adequate medical attention increases the risk of developing complications associated with or spreading HCV.

In 2009, the North Dakota Department of Health reported 467 cases of newly identified people testing positive for HCV (Dwelle, Kruger, Miller, & Wagendorf, 2010). Of the 467-reported cases, 45% occurred among people who were 35-54 years of age. Individuals infected with HCV ranged from 4-83 years of age, with a median age of 41 years (Dwelle et al., 2010). HCV-infected individuals were primarily Caucasian, with 57% being white; 39% were American Indian; 1% were of Asian descent; and 3% reported other. The 5-year median incidence rate among the American Indian/Alaska Native population was 155.8 per 100,000, compared to 15.7 per 100,000 for the white population (Steffens et al., 2011). Fifty-nine percent of HCV individuals were males, and 41% were females (Dwelle et al., 2010). Each year in North Dakota, an average of 3 people test positive for hepatitis A; 65 test positive for hepatitis B; and 548-test positive for hepatitis C (Dwelle et al., 2010). The prevalence of hepatitis C, almost certainly, is underestimated in North Dakota due to the lack of identified cases (Dwelle et al., 2010). Again, many patients will remain asymptomatic for many years, causing a delay in their healthcare.

At the time of this writing, Sanford Health GI clinic was managing 16 patients with HCV. Some patients were well into treatment; others were in the beginning phase of treatment. From staff reports at the GI clinic, patients were willing to travel long distances to receive specialist HCV care and treatment. North Dakota has limited access and limited funds to assist HCV-infected patients who lack financial means and have restricted access to medical services. To ensure that every appointment was used to its fullest potential and was appropriate, creating and implementing a standardized hepatitis C referral protocol was the solution for maximizing efficiency, increasing productivity, and eliminating unnecessary visits.

CHAPTER 2. LITERATURE REVIEW AND SYNTHESIS

Hepatitis C Virus Evidence-Based Treatment Guidelines

The first pharmacologic agent, interferon, was approved to treat HCV in 1991. The success rate for treating patients with HCV ranged from 5-9% for genotype 1 and was approximately 30% for genotypes 2 and 3. In 1998, ribavirin, a synthetic guanosine analogue, was approved and combined with interferon. The ribavirin and interferon combination became the new standard treatment regimen (Chan, 2011). Initially, the patients' treatment outcomes with the new medications were promising. In 2001, the Food and Drug Administration (FDA) approved pegylated interferon. Pegylated interferon prolongs the half-life of interferon, increasing the sustained viral response (SVR) to 40-50% with genotype 1 and 80% with genotypes 2 and 3 (Chan, 2011). In 2011, the FDA approved two protease inhibitor medications, boceprevir, and telaprevir. Boceprevir has the capability to inhibit viral HCV replication (Poordad et al., 2011). Telaprevir is a reversible, selective, peptidomimetic NS3/4A serine protease inhibitor that indicated for patients with genotype 1 HCV with or without a compromised liver function (Chan, 2011). The addition of new-generation medications for HCV treatment has drastically improved the effectiveness of the drug treatments and has improved the SVR of HVC genotype 1.

Extensive testing needs to take place before HCV treatment can begin. Essential testing for a new HCV-infected patient has been outlined by the American College of Gastroenterology and is followed by the Sanford Health GI clinic. Testing includes: HCV genotype, HCV RNA, hepatitis b (HB) antigen, HB surface antibody, HB core antibody, HAV total, iron saturation, ferritin, pregnancy test, serum glucose, blood urea nitrogen (BUN), serum creatinine, hepatic panel, white blood count (WBC), hemoglobin, platelet count, thyroid stimulating hormone

(TSH), total thyroxine (T4), and anti-HIV (American College of Gastroenterology, n.d.). The initial workup may also include a liver biopsy, anti-nuclear antibody, anti-smooth muscle antibody, hemoglobin-A-1-C, triglycerides, a drug and alcohol screen, and urinalysis (American College of Gastroenterology, n.d.). Depression is a common occurrence in HCV-infected patients; screening for depression at the initial workup should be included. Additionally, baseline depression screening is important because there is a potential for significant psychological side effects from the medications used to treat HCV-infected individuals. The most common psychological side effect for HCV medications is depression. HCV medication can increase the severity of pre-existing depression or anxiety (Copstead & Banasik, 2010). At times, depression can be so severe that suicidal ideations or suicide can result. Approximately 5-10% of patients will stop treatment because of the side effects (Copstead & Banasik, 2010). The pharmaceutical company that manufactures telaprevir does not recommend restarting the medication for any reason (Vertex Pharmaceuticals, 2013). For example, a patient treated with telaprevir who had to discontinue the medication because of depression would not be able to restart the medication if the depression resolved. Stopping telaprevir drastically decreases the possibility of achieving a SVR.

Depression is a well-known side effect of interferon-based therapies. Up to 70% of HCV-infected patients treated with interferon have reported mild to moderate depression while 40% of patients have reported major depressive symptoms (Schaefer et al., 2012).

Interestingly, patients with more severe symptoms of depression have a decreased SVR rate (Maddock et al., 2005). A study by Raison and colleagues examined the success rates of patients treated for hepatitis C in relation to their self-reported depression scores. Using the Zung depression scale, patients scoring 20 or more points, indicating major depression, had a

34% rate of successful treatment (Raison et al., 2005). Patients with moderate depression, or scores between 10 and 19 points, had a 59% SVR (Raison et al., 2005). Patients who scored fewer than 10 points had a 69% SVR (Raison et al., 2005).

Depression is a frequent and potentially serious complication of interferon therapy when treating HCV-infected patients. Many patients with depression suffer from longer disability periods, have a lower quality of life, require more inpatient and outpatient visits, and have an increased risk of suicidal attempts and ideation (Papfragkakis, Rao, Moehlen, Dhillon, & Martin, 2012). Early detection of and screening for depression through the HCV treatment course could improve patients' SVR and overall quality of life.

Current Approach for Depression Screening at the Sanford Health GI Clinic

Before beginning treatment for HCV, interferon manufacturers and the American Association for the Study of Liver Disease (AASLD) suggest screening all patients for depression. However, depression screening was not routinely taking place during any step of the treatment process at the Sanford Health GI clinic.

The providers at the GI clinic have mixed methods for screening and treating depression. The NP requires all patients with a history of depression to submit a letter from the provider who is managing their depression. The letter must indicate that the patient is clinically stable from a depression point, with or without antidepressant medications, prior to starting HCV treatment. There is potential for delay in HCV treatment until a patient's depression is stable. The NP chooses not to prescribe patients an antipsychotic or antidepressant medications. Instead, a referral to behavioral health, psychology, primary care, or counseling is required prior to treatment initiation. The MD feels more comfortable starting antidepressants and managing patients with a history of mild depressive symptoms during HCV treatment. If a patient is

currently receiving treatment for depression, the MD also requires a letter from the patient's primary-care provider, indicating that the patient is clinically stable from a depression standpoint, prior to the initiation of HCV treatment. Referrals for behavioral health, psychology, psychiatry, or counseling are at the MD's discretion.

Patients with HCV require extensive laboratory testing and screening that must take place prior to treatment. Having pertinent information gathered before the initial patient visit will decrease the workload for the nursing staff and healthcare providers, and will streamline the initial patient visit. An established management protocol for HCV-infected patients with depression will improve patient care and, ultimately, decrease the potential complications of HCV treatment.

Complications

HCV can cause both acute and chronic hepatitis. Acute HCV is generally self-limited, rarely is the cause of hepatic failure, yet typically leads to chronic infection. Often, chronic HCV infection is progressive over a span of many years, ultimately resulting in cirrhosis, hepatocellular carcinoma, and the need for a liver transplant.

Complications such as hepatocellular carcinoma (HCC) and cirrhosis have drastically increased among individuals with HCV and are expected to rise substantially over the next decade (Kanwal et al., 2011). From a prospective and retrospective cohort study, an estimated 20% of infected persons will progress to cirrhosis within 20 years of being infected with the hepatitis C virus (CDC, 2012a). Five percent of HCV-infected patients will die from liver complications directly related to the HCV infection (CDC, 2012a). The CDC projects that, over the next 50 years, the number of persons with untreated HCV leading to cirrhosis will reach 1.76 million (CDC, 2014). An estimated 400,000 individuals with HCV will develop HCC. The

CDC predicts a peak in the number of cases between the years of 2020 and 2030 (CDC, 2014). With alarmingly high numbers of patients with HCC and cirrhosis, it is important that patients have unrestricted access to resources, treatment, and management.

Cost of Hepatitis C

The CDC estimates that the 10-year, direct medical cost of chronic HCV infection is likely to exceed \$10.7 billion for the years 2010-2019 (CDC, 2010). The cost of premature mortality attributed to HCV infections is projected to reach \$54.2 billion, and the cost of disability associated morbidity with HCV infection is projected to be \$21.3 billion for the years 2010-2019 (CDC, 2010).

Treatment for chronic HCV infection is expensive and cost prohibitive for some patients. Bocicprevir alone costs \$1,100 per week, and telaprevir costs \$4,100 per week (Liu, Cipriano, Holodniy, Owens, & Goldhaber-Fiebert, 2012). Bocicprevir and telaprevir are needed for six months to one year, depending on the patient's genotype. A study conducted by Liu and colleagues (2012) assessed the cost-effectiveness of new protease inhibitors and interleukin genotyping assays for treating chronic HCV infection. Two separate groups: mild and advanced fibrosis divided the study cohorts. The divided groups received either a triple therapy or the standard therapy option. New triple-therapy regimens consist of boceprevir or telaprevir plus the standard therapy (pegylated interferon and ribavirin). The cohort with mild fibrosis treated with the triple therapy had a 38% decreased hepatocellular carcinoma lifetime risk, and the cohort with advanced fibrosis had a 28% decreased lifetime risk (Liu et al., 2012). For both the mild and advanced fibrosis cohorts, the triple therapy increased the quality-adjusted life expectancy (QALY) by 8% compared to standard therapy (Liu et al., 2012). If the protease inhibitor boceprevir is included with the triple therapy, the cost was \$102,600 per QALY for mild fibrosis

and \$51,500 per QALY for advanced fibrosis compared to standard therapy (Liu et al., 2012). The new triple therapies come at an increased cost; however, triple therapy has substantially increased achievement of SVR and decreased HCV complications.

The decision to treat patients with chronic HCV infection was based upon several factors, including the natural history of the disease, the stage of fibrosis, the treatment efficacy, and the adverse effects related to therapy (Chopra, 2013). The main goal of treatment is to eradicate and maintain a SVR of HCV. The secondary goal was to improve the quality of life for the patient and to decrease the direct healthcare costs associated with HCV-related complications.

CHAPTER 3. ORGANIZATION AND STRATEGIC PLAN

Stakeholders

The identified stakeholder was the Sanford Health GI clinic, which includes GI providers, a clinical supervisor, a clinical lead, staff nurses, and behavioral health staff. Informational technology (IT) department staff, referring providers, and referring facilities are stakeholders as well. These stakeholders strive to improve the physical and mental quality of life for current and future HCV-infected patients.

Team Assembly

In order for the successful implementation of a process improvement project, a well-developed team was created. The core team members identified for the new hepatitis C referral project were as follows: a clinical operation supervisor; a clinical lead for the GI clinic; one designated hepatitis C staff nurse; and myself, a doctor of nursing student. The team consulted with experts in the areas of behavioral health, IT, and hepatitis C throughout the project's duration. Expert involvement with the improvement project gave additional viewpoints and potential solutions for standardizing the new HCV protocol that included regular screening for depression via the Patient Health Questionnaire (PHQ-9). Having access to the providers at the GI clinic provided credible information about the standards of care for HCV patients and the direction the protocol should continually strive to achieve. The team members identified a framework to guide the project. The chosen framework was Plan-Do-Study-Act (PDSA).

Framework

PDSA is an interactive, four-phase, problem-solving, and process-improving model used during the performance improvement project (Tew, Sherry, Butler, & Martin, 2008). Dr. W. Edwards Deming, a statistician, college professor, and consultant, created the PDSA model. The

idea of the PDSA cycle is to turn ideas into actions and to connect the actions with learning. The PDSA is illustrated as a circle with no end. The meaning of the circle is to repeat the cycle and to improve the action with each cycle. Starting with the *Plan*, the process transitions through three additional phases: *Do*, *Study*, and *Act*. Repeating the cycle, when needed, following the same phases will provide continuous improvement (*Figure 1*).



Figure 1. PDSA model.

The American Society for Quality (ASQ, n.d.) suggests using the PDSA in the following ways:

1. As a model for continuous improvement.
2. When developing a new or improved process design, product, or service.
3. When planning data collection and analysis to verify and prioritize problems.
4. When defining a repetitive work process.

There are three fundamental questions of the PDSA (Tew et al., 2008). The questions utilized and applied for the implementation of the “New Referral Hepatitis C Protocol” were as follows:

1. What are we trying to accomplish?
2. How will we know that a change is an improvement?
3. What changes can we make that will result in improvement?

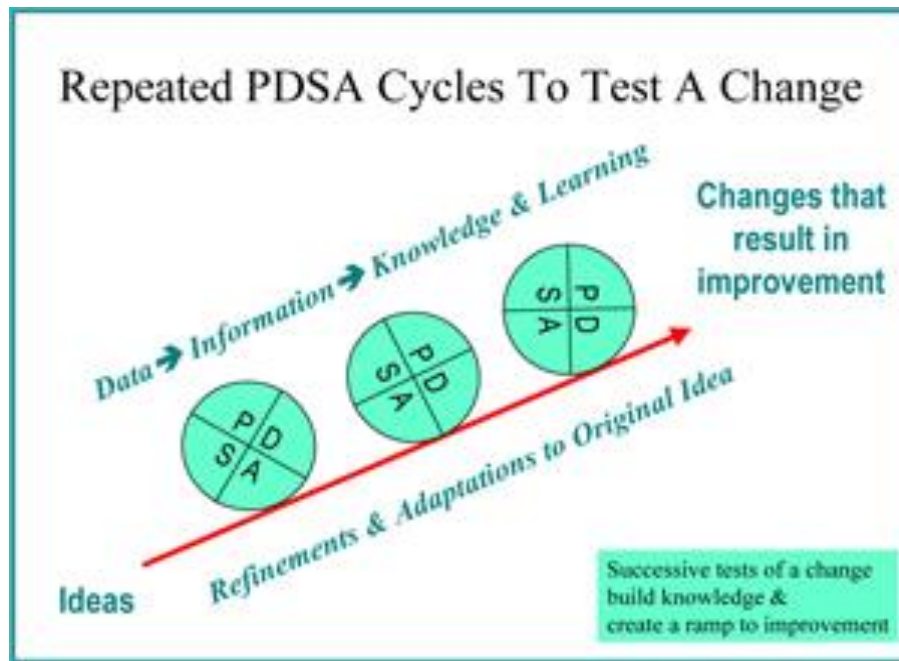


Figure 2. Repeated PDSA cycle to test a change (AAP, n.d.). As modifications to the PDSA are made, changes increase learning and improvements.

Explanation of the PDSA

The PDSA cycles provides a framework for developing, testing and implementing changes leading to improvement. To explain the PDSA model a four-step approach is used.

Step 1. *Plan*: Plan the test or observation, including a plan for collecting data. The initial stage of the PDSA cycle involves identifying an opportunity for improvement.

Once an identified opportunity for change has been identified, the planning for the improvement project can begin (Tew et al., 2008).

Step 2. *Do*: Try the test on a small scale. The purpose of the *Do* stage is to carry out the plan that was developed and to test the theory for potential improvements in a condensed version (Tew et al., 2008).

Step 3. *Study*: A sufficient amount of time should be set aside to analyze the data and study the results.

Step 4. *Act*: Implementation to a larger scale takes place when the results have met the goals. If the results fall below the expected level, the cycle is modified and repeated until reaching the desired goal (Tew et al., 2008).

CHAPTER 4. APPLICATION AND RESULTS

Utilization of PDSA

PLAN: Workflow Process

The GI clinic's staff members identified a need for improving the current HCV-patient referral process. In addition, the core team members anticipated an increase in patient referrals and patient treatment monitoring with the CDC's new hepatitis C screening recommendations for the baby-boomer population. Previous patients have voiced concerns to staff members and receptionists that access to healthcare providers has been a difficult and lengthy process. At times, provider access can take weeks to months. One goal of the clinic was to eliminate unnecessary visits, allowing more appointment availabilities for patients requiring provider visits. The core team members anticipated a decrease in time for patient access, appointments that are more meaningful, an increase in patient satisfaction, and an increase in productivity for the GI clinic staff with initiation of the standardized referral process. Having an efficient referral protocol would improve the clinic's efficiency, streamline new patient referrals, and improve the quality of patient care. A meeting for further discussion and documentation was set.

DO: Workflow Process

In the *Do* portion of the cycle, the core team members assessed the current workflow for new HCV patients and clearly defined the current system. Initially, handwritten documentation illustrated the GI clinic's current workflow. Through verbal discussion, the team concluded that a visual diagram created in a Word document would be more beneficial and would allow for easy adjustments and updates in the future. Evaluating the current referral process highlighted areas of weakness and unnecessary steps taken by staff. Providers, a receptionist, and other staff members reviewed the "New Referral Hepatitis C Protocol" for additional suggestions for

improvement to the workflow process. Suggestions and recommendations were updated in a Word document. Implementation of the “New Referral Hepatitis C Protocol” began January 2, 2013, at the GI clinic. The diagram for the “New Referral Hepatitis C Protocol” is in Appendix B.

Below is a summary of descriptive steps for the “New Referral Hepatitis C Protocol” that is utilized at the GI clinic.

1. The receptionist receives a phone call from a referring facility that is requesting an appointment for a newly confirmed hepatitis C patient.



2. A designated hepatitis C nurse begins to complete a chart review, ensuring the correct and completed laboratory results are present.

- a. If laboratory results are not present, the nursing staff will speak to a provider for further laboratory orders.



3. If the patient needs a follow-up appointment, the hepatitis C nurse sends a message to the receptionist, indicating that the patient’s appointment may be scheduled.

- a. The patient is contact by the hepatitis C nurse and encouraged to bring all copies of previously completed laboratory results done at a non-Sanford facility.



4. The patient receives a reminder letter one week prior and a reminder phone call two days prior to the scheduled appointment.



5. When the scheduled appointment takes place, the providers and patient discuss treatment plans.
 - a. Additional testing, such as a liver biopsy or ultrasound, is set up if needed.
 - b. The hepatitis C nurse begins education with the patient and pre-authorization for medication and management with insurance company.



6. At the initial visit, staff administer the PHQ-9 as a baseline measure
 - a. The provider reviews the PHQ-9 scores and makes a referral to behavioral health or a primary-care provider, if necessary.
 - b. If the patient is on medication, or in therapy for depression, the managing provider is made aware of the anticipated start date for hepatitis C treatment.
 - c. The patient is cleared for hepatitis C treatment once depression screening has been completed.



7. The patient notifies the GI clinic's hepatitis C nurse at the start date of the medication regimen.
 - a. The patient's data is entered into an electronic tracking system.
 - b. Recurring laboratory tests are recorded in the electronic medical record (EMR) based on the initial start date for the hepatitis C medication.



8. A follow-up appointment with the GI provider is scheduled four weeks after the medication start date.
 - a. The PHQ-9 scores are evaluated at the four-week appointment and at each subsequent appointment.
 - b. Additional routine office visits are scheduled for weeks 12, 24, and 48.

STUDY: Workflow Process

On January 28, 2013, the core staff members had a meeting to discuss the implementation of the “New Hepatitis C Referral Protocol.” Nursing staff and the receptionist felt that communication with new hepatitis C patients had improved. The receptionist was able to easily contact an available nurse with referral information. However, errors still occurred with nursing staff related to chart reviews, patient education, reminder calls to the patient, and laboratory tests. Miscommunication between providers and hepatitis C patients was still happening. Discussion addressed patient’s initial visit with the providers and inefficiencies that remained with locating pertinent information. At the initial visit, the provider and patient must review and discuss the viral load and genotype before an established treatment plan can begin. If the necessary viral load and genotyping had not been completed or if the results could not be located, the patient would have to return for an additional office visit or laboratory draw before further decisions about hepatitis C management could take place. This additional visit comes at an increased cost and lost time for the patient, resulting in decreased patient satisfaction and decreased provider productivity. Many times, providers were attempting to locate the results through a chart review during the patient visit. This situation wasted time for both the provider and patient. Having longer-than-necessary appointment times disrupts the provider’s workflow, and it decreases clinic efficiency, productivity, and patient satisfaction.

ACT: Workflow Process

With the new information that was discussed and gathered, the core team members concluded that a designated hepatitis C nurse should handle all aspects of care for the hepatitis C patients to ensure quality care. The hepatitis C nurse would be responsible for the initial chart review, education, and communication between the patient and providers. An additional full time equivalent FTE position was not in the department budget nor feasible at this time in the process. A current staff member with proficient background knowledge about hepatitis C who was part of the core team accepted the new role. As the PDSA cycle implies, the circle continues to repeat itself to make further improvements. The second cycle of the PDSA will start with the *Plan* of adding a hepatitis C nurse for the GI clinic.

PLAN: Hepatitis C Nurse

HCV treatment is complicated and there is a significant time commitment for both patients and healthcare providers. Patient education starts once a patient has had a positive viral load and confirmed genotype. Previously, patients received information about the treatment, side effects, insurance coverage, and required testing from numerous people. Multiple people educating patients caused confusion, inconsistency, duplication of information, and missed information. There was much confusion and misplaced documents when a new hepatitis C patient was referred to the clinic. The nursing staff had different duties and time allocations when completing chart reviews for a new hepatitis C patient. Follow-up and clarification on required information was being neglected. The GI clinic is a very fast-paced, high-volume department with limited staff members. The four full-time staff nurses are responsible for rooming, providing education, and performing screenings for approximately 60 patients per day.

The added chart review for new hepatitis C patients was beneficial, although it was causing confusion and miscommunication among staff members. Core team members and GI staff members felt that providing consistent education from one designated nurse would decrease confusion and allow the patient to develop a trusting rapport with the staff. The designated hepatitis C nurse, along with the providers, would ensure that the initial chart review, laboratory tests, PHQ-9 results, education, and other pertinent cares were documented. Having a designated hepatitis C nurse would assist in navigating the patient through the complicated process of HCV treatment.

DO: Hepatitis C Nurse

A current staff nurse with proficient knowledge about hepatitis C treatment and management transitioned into the role of the designated hepatitis C nurse. With the immense amount of patient monitoring and documentation that is required to care for an HCV-infected patient, the designated hepatitis C nurse needed a convenient and simple method. Having a clear and concise document to track results would increase provider productivity and the quality of patient care. In addition, having all the patient's results and information in one location decreases the time the hepatitis C nurse needs to complete a chart review. The providers gave their expert opinion regarding the pertinent information to be include in the reference form in the EMR system. Consultation with core team members and the providers' input resulted in the identification of key components needed for a quick-reference document. Key information included is as follows:

1. Treatment Start Date: Date field
2. Treatment Completion Date: Date field

3. Treatment Status: ongoing, completed, noncompliant, terminated, unable to locate, deceased, or other with comments (select only one option)
4. Genotype: 1, 2, 3, 4, 5, or 6 (multi-select)
5. Treatment Plan: 6 months, 6 months extended, or 12 months (select only one option)
6. Labs completed this visit: CBC with differential, ALT, Hepatitis C RNA, PCR quantitative, HCG screen, or other (multi-select)
7. Depression Management by: Behavioral Health, Gastroenterology, PCP, Non-Sanford, or Other with comments (multi-select)

Experts from the IT department assisted with building a template in the EMR. With the above-mentioned information, a snapshot of the patient's hepatitis C information was created in the EMR.

STUDY: Hepatitis C Nurse

The hepatitis C nurse believed that the transition to the new role was successful. The snapshot of the patient's hepatitis C information was useful and utilized for documenting and tracking hepatitis C patients. Patients reported to the designated hepatitis C nurse and providers that they enjoy the consistency of care and the ease of contacting the GI clinic with questions or concerns. The designated hepatitis C nurse reported a very high rate of patient compliance with follow-up labs and appointments.

During the initial chart review of potential new hepatitis C referral, the designated hepatitis C nurse continued to see a high percentage of patients referred to the GI clinic without completed laboratory tests. The most common trend was that patients had a detected hepatitis C antibody, but there was no documentation for the viral load. The viral load is confirmation that

the patient has active hepatitis C and used for tracking the response to treatment. Measurement of the patient's viral load is required before treatment and consultation can begin. Consequently, GI staff identified the need to provide an algorithm of current guidelines for hepatitis C screening to referring providers.

ACT: Hepatitis C Nurse

Establishing a designated hepatitis C nurse, with defined roles and responsibilities, has had a positive impact for the clinic and patients. One of the GI provider reports, "It has been a big help, and the nursing staff really benefit from the addition." Patients have reported to the designated hepatitis C nurse that they feel as if they are the main priority of care and are able to get quick responses from direct access to the designated hepatitis C nurse. To continue with the new standard of care, a job description was created to outline the specific requirements for the hepatitis C nurse.

The results of the PDSA cycle for adding the hepatitis C nurse laid the foundation for the job description. In addition, guidelines and recommendations for monitoring patients were collected from the manufacturer of the hepatitis C medications and the AASLD. This information provided the specifications for the job description. Discussion with the designated hepatitis C nurse and the clinical nurse specialist for recommendations to the job description were applied. The job description includes the specific roles and responsibilities for managing and monitoring HCV patients from the designated hepatitis C nurse position. The job description will be useful in the event that an additional hepatitis C nurse position is needed or with future hires.

The implementation of the third cycle of the PDSA was used to address the lack of knowledge consistently found in referrals from primary-care settings. Missing or incomplete test

results wastes staff and patient time and potentially prolongs initiation of treatment. To provide information on appropriate laboratory draws, vaccine information, and screening recommendations, a brochure containing a hepatitis C screening algorithm was created for referring providers.

PLAN: Algorithm

Two brochures containing a hepatitis C referral algorithm for primary-care providers were created to address the incomplete referrals seen at the GI clinic. Algorithms are widely used in the healthcare field and at Sanford Health. A prototype for managing back pain created by Sanford Health Neurosurgery was used as the inspiration for the hepatitis C referral algorithm. During the planning phase, the core team members discussed what information would be pertinent to primary-care providers. The team required that the hepatitis C referral algorithm include appropriate laboratory tests, screening updates, when to refer patients, and contact information for the GI clinic. In addition, an introduction to the clinic and hepatitis C services offered was to be included. The team agreed that the author would create and submit the sample brochures to core team and GI providers for evaluation and discussion.

DO: Algorithm

A literature review and a hepatitis C guideline search provided information for the two sample brochures created. The CDC screening guidelines, the United States Preventative Task Force, and the American College of Gastroenterology were the chosen sources to gather information. Core team members reviewed the two sample brochures after construction. The two sample brochures included all pertinent information discussed previously. The first page of the brochure had an introduction to the GI clinic, a brief description about the staff members, and

a list of hepatitis C services offered. The screening recommendations included information as followed:

- One-time testing for adults born between 1945 and 1965.
- Any history of intravenous drug use or tattoos done in an unsterile environment.
- Recipients of clotting-factor concentrate products before 1987.
- Patients who received a blood transfusion, blood component, or an organ transplant before July 1992.
- Patients with persistently abnormal alanine aminotransferase (ALT) or aspartate aminotransferase (AST).

The two sample brochures contained contact information in multiple places for the GI clinic, including the phone number, fax number, and hours of operation. One location for the contact information was the lower left-hand side of the brochure, when open, for easy access.

Once the brochure is fully open it starts with a decision tree that begins with the HCV antibody test. Additional actions are based on the results of the antibody test. If undetected, the provider would consider rescreening the patient in 3-6 months if the patient were at high risk from recent exposure. This recent exposure could include IV drug use, unsterile tattooing, blood contact with an individual who is known to have hepatitis C, and other forms of hepatitis C transmission. Otherwise, the provider informs the patient that the results of the hepatitis C screening are negative and that no further testing or referral is needed at this time. Detection of the HCV antibody instructs the provider to order additional tests to confirm an active hepatitis C virus. The additional testing is the HCV RNA quantitative and genotype laboratory test. If the HCV RNA quantitative is undetected, there is no active infection, and the patient does not need further treatment or referral at this time. If there is a detection of the HCV RNA quantitative

referral to the GI clinic is needed. Once the patient has been referred to GI the brochure #1 is completed. Brochure #1 can be viewed in Appendix D.

The second brochure, brochure #2 (Appendix E) instructs providers to refer to the GI clinic and to collect additional information related to vaccine status and laboratory testing. The decision tree instructs providers to update the patient's hepatitis A and hepatitis B status, if needed. Many patients may not have proof or may be unable to locate this information; at this time, antibody testing for hepatitis A and hepatitis B would need to take place and addressed accordingly. Evaluation of patient's current influenza and pneumococcal vaccines status is also included in the algorithm. An additional blood draw to test CBC with differential, ALT, and AST, if not done within the past six months, is also necessary for a thorough evaluation at the GI clinic. Female patients of childbearing age require a pregnancy test. The information gathered by the referring provider is very helpful for the initial chart review completed by the designated hepatitis C nurse and the provider. This is the completion of brochure #2. Brochure #2 can be viewed in Appendix E.

STUDY: Algorithm

The two sample brochures were used in a small, focused study. The study's objective was to evaluate which brochure containing the hepatitis C algorithm would be most beneficial to providers in a primary-care setting. The focus study took place in a clinic located 90 miles west of Fargo, ND. The participants were approached personally in the clinic setting. Each provider received a brief verbal introduction of the performance improvement project. The providers were instructed that the survey would take less than five minutes of their personal time to complete. The survey included both medical doctors and advanced practice nurses. Additional information was collected to examine the results of the survey for preference trends. The

additional information included questions related to the participants' professional title and years of experience in the family-practice setting. Participants had time to ask questions before viewing brochure #1 and brochure #2. The results of the survey concluded that, overall, 57% of the participants preferred brochure #1 and that 43% of the participants preferred brochure #2, $N=7$ (Figure 3).

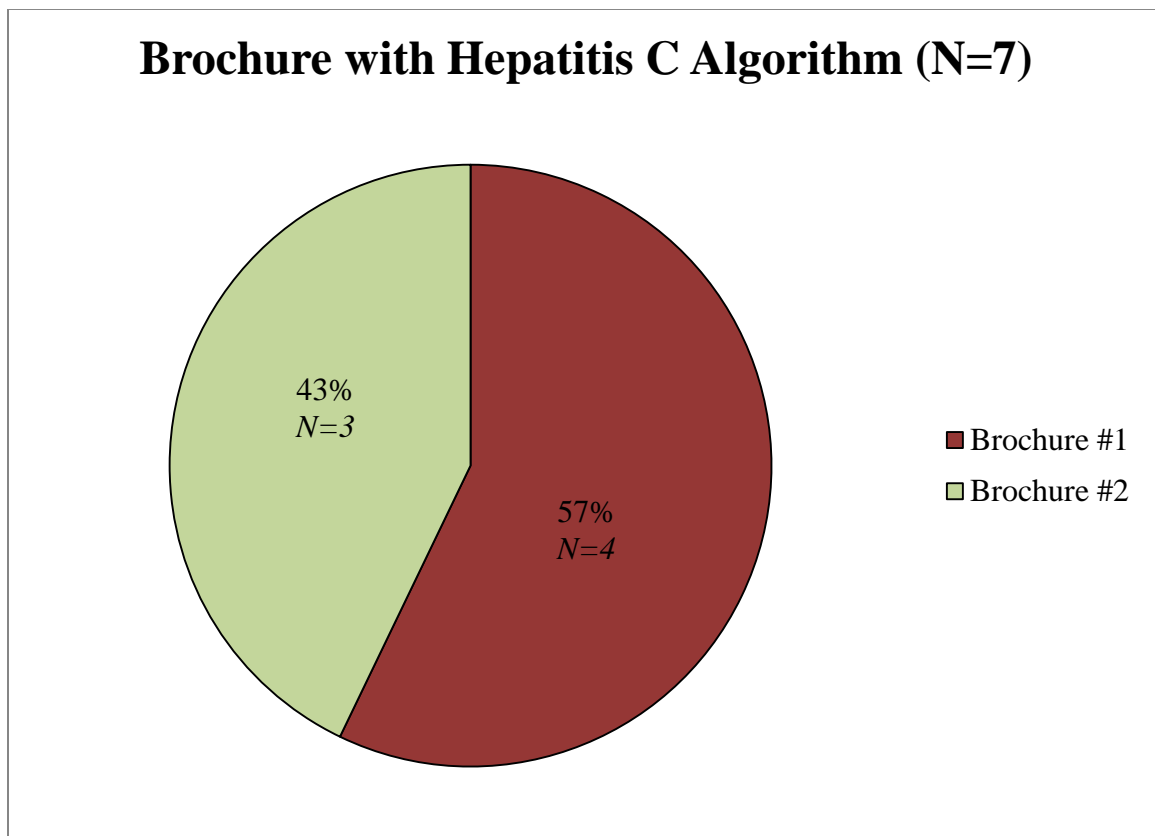


Figure 3. Results of hepatitis C recommendations and referral algorithm.

A further breakdown of the additional information collected from the participants was examined (Table 1). There were three medical doctors and four advanced practice nurses, giving a total of seven participants. Brochure #1 was selected 66.7% of the time by surveyed medical doctors while brochure #2 was selected 33.3% of the time. Fifty percent of the advanced practice nurses selected brochure #1, and 50% selected brochure #2. Due to the small sample size, no significant trends could be found.

Table 1

Descriptive information about survey participants

Job Description	Years in Primary-Care Setting	Brochure #1	Brochure #2
Medical Doctor: <i>N=3</i>	3 5 22 Average: 10 years	<i>N=2</i> 66.7%	<i>N=1</i> 33.3%
Advance Practice Nurse: <i>N=4</i>	11 11 4 7 Average: 8.25 years	<i>N=2</i> 50%	<i>N=2</i> 50%

ACT: Algorithm

The results of the survey were presented to the core team members during a team meeting. No changes were made to either brochure after the results of the survey. The core team members selected the brochure #1 to be utilized, based on the results of the survey and the input from the providers. In the future, the brochure will be sent to referring providers in the primary-care setting. At this time, the department budget does not allow for printing, processing, and mailing of the chosen brochure. To address the delay of providing information, both sample brochures have been saved on a flash drive for the clinic to use at its discretion.

To provide safe, up-to-date treatment at the GI clinic, monitoring HCV patients' depression was necessary. The last cycle at the GI clinic was implementing the PHQ-9 depression screening.

PLAN: PHQ-9

The GI clinic implemented the new HCV protocol on January 2, 2013, using the "New Referral Hepatitis C Protocol," the protocol included the administration of the PHQ-9 depression-screening tool. Throughout the Sanford Health organization, the Patient Health

Questionnaire (PHQ-9) is used for screening and monitoring depression in primary care, outpatient, and inpatient services. Providers and staff members believed that improved monitoring of and support for depression could increase the treatment completion rates and the quality of life for HCV-infected patients. Close monitoring of patients' depression would ensure that the appropriate actions were taken in a timely manner.

The GI nursing staff was to administer the PHQ-9 during the rooming process for the patient's visit for hepatitis C. The results of the PHQ-9 would be recorded in the EMR system. The provider would then view the results. Options of referring the patient to behavioral health or scheduling an appointment with the patient's primary-care provider, if needed, would be at the provider's discretion based on the patient's depression scores. Screening and reviewing the PHQ-9 score would be done for all active hepatitis C patients at the GI clinic.

During a follow-up core team meeting after the initiation of the PHQ-9 screening tool, it was identified that the GI staff and providers were not familiar with the tool. The providers and staff nurses were unsure about the indications and uses of the PHQ-9 tool. The core team members decided that the staff and providers needed additional education.

DO: PHQ-9

The core team contacted a member from Sanford Health Behavior Health department to present educational information related to the PHQ-9 to staff members. A meeting took place with the core team members and the selected behavior health member before scheduling a staff meeting. At the initial meeting with the behavioral health staff member, the core team discussed potential side effects related to depression and the goal of screening patients at every visit with the PHQ-9 tool. Once the behavioral health member understood the goals for monitoring depression in HCV patients, an educational department meeting was set. The behavioral health

staff member presented the PHQ-9 information to GI staff members on January 22, 2013. The behavioral health staff member educated the GI staff and providers about the significance of the PHQ-9 depression screening, basic treatment guidelines, and referral recommendations. The primary goal for the staff education was to demonstrate the correct use of the PHQ-9 and successful screening for depression in HCV-infected patients. The GI department's staff members started utilizing the PHQ-9 in the EMR after the January 22, 2013, staff meeting.

During the week of February 4 -8th, 2013, a report was run to see how many hepatitis C patients had the appropriate PHQ-9 documentation. The results were 0%. Friendly email reminders and communication from the clinic supervisor were discussed with the nursing staff members who were responsible for rooming patients. During the week of May 6 -10th, 2013, a report was run to check for compliance with PHQ-9 administration, the results were 50%. The core team members met again to discuss how to address the poor compliance and potential solutions to achieve the 80% goal that the GI clinic had set for itself.

STUDY: PHQ-9

With the GI clinic falling short of the 80% compliance rate, the providers were not able to have an accurate, standardized evaluation of the patient's mental well-being. The core team members conducted a meeting to discuss possible solutions to be made to meet the 80% compliance rate. The final decision made at the meeting concluded that the designated hepatitis C nurse would start rooming the hepatitis C patients. The hepatitis C nurse would preview the providers' schedule for the following day identifying patients for hepatitis C appointments. The hepatitis C nurse would provide the receptionist with paper copies of the PHQ-9. When patients checked-in for their hepatitis C appointment, they were given a form to fill out and bring back to the exam room. During the rooming process, the hepatitis C nurse would ensure that all

questions had been addressed and confirm that the patient understood the questions. The hepatitis C nurse would then enter the results into the EMR system and load the results into a progress note that the providers could easily view. The hepatitis C nurse would also leave the paper copy in the room for the provider.

Figure 4 illustrates the PHQ-9 completion rates for correct administration of the PHQ-9 screening tool. For one year the first full week of each month was examined for completed PHQ-9 percentages. The corresponding interventions are also included in the graph. The goal of 80% compliance is illustrated across the duration of the monitoring period.

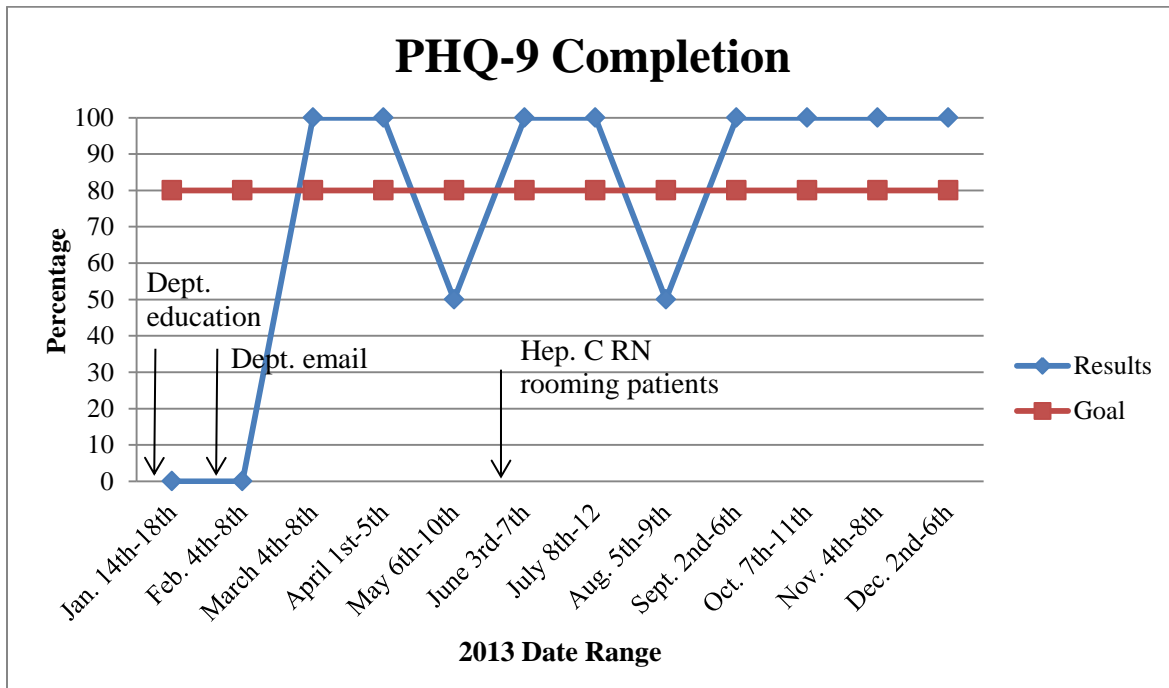


Figure 4. PHQ-9 completion percentage for the 2013 year.

Just as the PDSA model has no end, the cycle was utilized repeatedly throughout the project’s trial phase to reach the clinic’s goal of 80% compliance.

ACT: PHQ-9

The hepatitis C nurse reports that the current system for administering the PHQ-9 is working well for the GI clinic and its patients. The new job duty that the hepatitis C nurse now completes has been included in the job description.

Currently, once the patient completes the hepatitis C treatment, the PHQ-9 administration stops. Depression monitoring should continue at the patient's follow-up appointment at six months and one year post completion. Recommendations are for the GI clinic to administer the PHQ-9 at these pivot stages of the patient's treatment and to address the depression accordingly when needed.

CHAPTER 5. DISCUSSION AND CONCLUSIONS

Limitations

The focus survey to gather information about the provider's preference for the algorithms resulted in a small sample size. Conducting the study in a small rural setting offered a limited number of potential providers. Small sample size can lead to difficulties when determining the significance of relationships in the collected data. The algorithm chosen to represent the GI clinic's screening recommendations and referral guideline for hepatitis C was based partially on the study's results. However, the small sample size may not reflect the preference of providers across the state of North Dakota.

When addressing the progress of the "New Referral Hepatitis C Protocol" and the roles implemented at the GI clinic, responses were not anonymous. Directly asking through verbal and email communication may not have given respondents the opportunity to express the negative effects or their true feelings. In addition, the reported patient responses were made on a voluntary basis. Anonymous suggestion boxes would have provided more information related to the patient's perspective about the clinic changes made.

The GI clinic receives weekly reports about the compliance rate for administering the PHQ-9 to hepatitis C patients. The first full week of the month was selected to gather information for the project. The staff was unaware of which week was chosen to gather the information. The limitation was that some selected weeks could falsely represent the statistics. For instance, during the first week of June, the GI clinic could have received 100% for administering the PHQ-9; during the second and third weeks, the results could have been 0%; and the fourth week could have been 80%. Combined, the scores would have given the GI clinic an overall monthly score of 45% for June. The 45% compliance rate would be well below the

clinic's targeted percentage of 80%. Because we were only examining the first full week of the month, the information potentially was skewed.

Recommendations for Further Improvements at the GI Clinic

On January 17, 2014, core team members and other staff from the GI clinic were invited to a meeting in which a short verbal presentation about the author's final recommendations for the GI clinic was given. The author created and presented the information based on the findings and evidence gathered during study. All attendants were given a handout outlining the topic, improvement recommendations, supporting data, and corresponding handouts, when applicable.

Recommendation 1

Topic: Workflow process

Improvement recommendation:

1. The final "New Referral Hepatitis C Protocol" should continue to be followed with all new hepatitis C referrals.
2. Continue to review the "New Referral Hepatitis C Protocol" on a yearly basis for possible areas of improvement. If improvements are identified, implement them using the PDSA cycle.
3. Review the "New Referral Hepatitis C Protocol," in depth, with all new GI staff members to ensure full understanding of the process.

Supporting data: Positive verbal confirmation from staff members and providers showed that the established protocol is working in the GI clinic. Patients verbalized that they had improved access to care and communication with staff members.

A color, printed, 11x17 document illustrating the “New Referral Hepatitis C Protocol” was given to the GI core team members. The document is currently displayed at the GI clinic. Please refer to Appendix B.

Recommendation 2

Topic: Hepatitis C nurse

Improvement recommendations:

1. Keep the current hepatitis C nurse position that was created.
2. Review and update the job description on an annual basis.
3. The employee who holds the position should review the job description at least once per year.
4. Continue to administer the PHQ-9 depression screening while rooming the hepatitis C patients.

Supporting data: Implementing the “New Referral Hepatitis C Protocol” led the core team to conclude that there was a need for a designated hepatitis C nurse position. The trial of designating one specific nurse to complete initial chart reviews for the new hepatitis C referral had a positive impact on the GI clinic. One provider reported an “increase in efficiency and proficiency of the clinic.” The hepatitis C nurse was also able to provide patient education, to handle patient follow-up, and to serve as a consistent liaison between patients and providers during the complicated treatment of hepatitis C. The PHQ-9 administration goal of 80% compliance exceeded the expectation set by the clinic once the hepatitis C nurse started rooming the patients.

A document outlining the job description for the hepatitis C nurse was given to the clinic. To view the document, refer to Appendix C.

Recommendation 3

Topic: Provider brochure containing hepatitis C algorithm

Improvement recommendation:

1. Allocate a portion of the 2014 budget for printing, processing, and mailing of brochures to providers.
2. One week before sending the selected brochure #1, a generic email explaining the purpose of the brochure should be sent on behalf of the GI clinic. In addition, an informational insert should accompany the brochure.
3. A GI staff representative should attend at least two conferences or in-services that focus on primary healthcare to hand out the brochures containing the hepatitis C algorithm to providers. Two suggestions for possible distribution are as follows.
 - The 6th Annual North Dakota Nurse Practitioner Association (NDNPA) Pharmacy Conference.
 - Fargo, North Dakota
 - Tentatively scheduled for September 2014
 - <http://ndnpa.org/calendar.htm>
 - 2014 Dakota Conference on Rural and Public Health
 - Grand Forks, North Dakota
 - June 18-20, 2014
 - <http://www.ndcenterfornursing.org/events/2014-dakota-conference-on-rural-public-health/>
4. Contact Sanford Learn regarding the module titled “sc-1047 Infection Prevention”; the information presented to learners on hepatitis C screening recommendations is outdated.

Supporting data: The core team members' perspective and results from a focus group support using the hepatitis C short form as the algorithm to be sent out to referring providers. In October 2013, the author completed a module titled "Infection Control Prevention"; information presented in the module is from a 2005 CDC guideline, which does not include screening for patients born between 1945 and 1965. The updated 2012 CDC guideline should replace the 2005 guideline in the module.

The two completed and printed brochures containing the hepatitis C algorithm were presented to the clinic. They are in Appendixes D and E.

Recommendation 4

Topic: PHQ-9 depression screening tool

Improvement recommendation:

1. Continue having the hepatitis C nurse screen hepatitis C patients at every appointment.
2. Complete PHQ-9 screening at the six month and one year appointments.
3. Remain in contact with behavior health for any updates or recommendations for depression screening. Utilize behavioral health more frequently as an expert resource for questions related to depression.
4. Review depression-screening reports on a monthly basis until the 80% goal has been met for six consecutive months; then the review should be reduced to every other month.

Supporting data: Depression is a well-known side effect of interferon- (IFN) based therapies. Up to 70% of HCV-infected patients who are treated with IFN have reported mild to moderate depression while 40% of patients have reported major depressive symptoms (Schaefer et al., 2012). This information supports the fact that monitoring and managing depression is essential when receiving treatment for hepatitis C.

Utilizing the PDSA at the GI Clinic

For future improvements made at the GI clinic the *Plan, Do, Study, and Act* method should be used for trial, evaluation, and implementation. The cycle is an interactive, four-stage, problem-solving model that focuses on improvement projects.

Step 1. *Plan*: Identify an opportunity for improvement. Plan the test or observation and include a plan for collecting data.

Step 2. *Do*: Try the test on a small scale. The purpose of the *DO* stage is to carry out the plan that was developed and to test the theory for potential improvements.

Step 3. *Study*: A sufficient amount of time should be set aside to analyze the data and study the results.

Step 4. *Act*: Implementation to a larger scale takes place when the results have met the goals. If the results fall below the expected level, the cycle is modified and repeated until reaching the desired goal (Tew et al., 2008).

Future Recommendations for Practice Improvements

Before selecting which of the two brochures to send to referring providers, a study should be conducted on a larger scale and at multiple sites. Having a larger sample size with a greater variation in location will provide a better representation of which algorithm is the most useful to providers. To achieve this recommendation, a survey should be sent to the members of the North Dakota Nurse Practitioner Association (NDNPA). This group would target many advance practice nurses and graduate NP students in the state of North Dakota; however, few to no physicians would be included in the survey. To obtain physicians' perspectives, sending the same survey to the North Dakota Academy of Family Physicians would be beneficial when gathering information. This group of physicians represents over 500 family physicians, medical

students, and residents in the state. By selecting these two professional groups, the target audience will consist of providers who refer patients to the Sanford Health GI clinic in Fargo, North Dakota.

Once the selected brochure has been sent to referring providers, the GI clinic should conduct a retrospective study. That study should focus on examining the completeness of the documentation and test results for patients being referred to the GI clinic for hepatitis C evaluation, specifically comparing the frequency of needing to order additional laboratory tests for hepatitis C referral patients before and after implementing the brochure containing the hepatitis C algorithm. Gathering this information would illustrate the influence that the algorithm tool has for referring providers. The information could serve as a model for other specialized disease processes that need algorithms for referring providers.

The above-mentioned recommendations should continue to utilize the PDSA model for implementation and evaluation. The GI clinic should serve as the pilot clinic. Once the implementation has proven to be effective and meet the goals set by the GI clinic at the Fargo location, the ideas could be implemented Sanford wide.

A suggestion for more of a research-based recommendation would be looking at new FDA-cleared medication and the impact the medication has on depression monitoring and management. For instance, the GI clinic monitors patients' depression scores using the PHQ-9 screening tool as well as documenting the progression of patients' status related to hepatitis C treatment. With the hepatitis C medication manufacturers making major advancements, treatment options will continue to remain in the frontlines of healthcare providers' journals and newsfeeds. On December 9, 2013, the FDA approved a medication called Sovaldi (sofosbuvir). The drug is approved for two chronic hepatitis C indications: in combination with pegylated

interferon and ribavirin for treatment-naïve adults with genotype 1 and 4 infections, and in combination with ribavirin for adults with genotype 2 and 3 infections (Ault, 2013). The appealing notion with this medication is the advantage of not having to use it in combination with pegylated interferon and the shortened duration of the medications. Pegylated interferon is the portion of the medication regimen that has been linked to many adverse side effects, including depression. The manufacturer claims that the most common adverse events observed with Sovaldi in combination with ribavirin were fatigue and headache (Gilead Sciences, 2013). The most common adverse events observed with Sovaldi in combination with peginterferon alfa and ribavirin were fatigue, headache, nausea, insomnia, and anemia (Gilead Sciences, 2013). F At this time, there are no published studies looking at the success rate of SVR and the correlation of depression scores with the new medication, Sovaldi. One could hypothesize seeing similar results as the study conducted by Raison et al. (2005) that concluded the lower the depression scores are, the higher the sustained viral response rates will be. To further support the importance of monitoring and managing depression for hepatitis C patients, a study should be conducted to look at the correlation of PHQ-9 score and the sustained viral response rates while on Sovaldi + ribavirin and Sovaldi + ribavirin + pegylated interferon alfa. The GI clinic would not have to change any of the current processes for monitoring or rooming the patient because the PHQ-9 is part of the patients' management.

The future research recommendations at a local, system, and worldwide level have the potential to make improvements to the patients' healthcare management. The recommendations here address many aspects of hepatitis C, starting with initial screening recommendations to potential management improvement. Above all, the recommendation's main goal is to ensure that patients with hepatitis C have their health upheld to the highest standards of care.

Implications for Advanced Nursing Practice

As NPs continue to serve as frontline providers in the primary-care setting, awareness of current guidelines that affect the health of their patients is essential. Practicing in an ever-changing healthcare environment, NPs have a responsibility to provide their patients with the best available evidence-based care, incorporating that evidence into the provider-client decision-making process. Staying up to date through respectable organizations, professional groups, and attending educational forums will allow primary-care providers to deliver evidence-based practice to diverse patient populations. Hepatitis C symptoms will continue to have vague to non-existent symptoms; a clear understanding about which patient population is at a disproportionately high rate of positive HCV is important for screening recommendations. Utilizing the resources, such as an algorithm for hepatitis C screening, would keep providers current with recommendations. These resources can assist in decision-making and proper referral to specialty areas, such as the GI clinic. Keeping NPs' knowledge up to date and applying the principles of evidence-based practice have become the cornerstone strategy for NPs to translate research findings into clinical practice.

Since the creation of the NP role in the 1960s, physicians and NPs have worked together in primary care and specialties. The integrated team of NPs and physicians has positively affected the healthcare system (Clarín, 2007), yet barriers to effective collaboration and communication about a patient's healthcare continue to exist. The barriers may result in reduced level of care for patients. One of the most common reasons for ineffective patient care between providers is a lack of communication. Poor communication among medical professionals affects the quality of patient care. Strategies to avoid communication gaps should be addressed early in the collaborative and referral process. Keeping the lines of communication

open between primary-care providers and specialty-care providers will create an environment that is conducive to patient success. When primary-care providers make changes to a current hepatitis C patient's depression medication, informing the providers will ensure that the patient's safety is upheld. Encouraging the GI providers to communicate with primary care providers of hepatitis C treatment plan will allow for closer monitoring of adverse side effects and quicker interventions particularly for patients living in rural communities being cared for by NPs.

NPs provide a large amount of preventive medicine and health promotion during the annual physical exam. Many NPs take this opportunity to educate their patients about screening recommendations and updated guidelines. Having a clear understanding of the CDC's recommendations about screening for hepatitis C will allow for enhanced clinical judgment during the decision-making process. Providing patients with this type of information allows them to feel in control of their healthcare while receiving the latest evidence-based practice recommendation. Promoting early detection of HCV prevents patients from enduring further damage and possibly spreading the disease.

Dissemination Strategies

Dissemination is the targeted distribution of information and material to an identified group (Agency for Healthcare Research and Quality, 2012). Dissemination of information has broad goals: (1) to increase the reach of evidence; (2) to increase people's motivation to use and apply evidence; and (3) to increase people's ability to use and apply the evidence (Agency for Healthcare Research and Quality, 2012). To appeal to different preferred methods of learning and accepting new information, a multifaceted approach was used to disseminate the information and products identified through the performance improvement project.

In April of 2013, a poster presentation was held at NDSU to showcase the progression of graduate student's projects. My poster titled "New Referral Hepatitis C Protocol: The New Standard" was submitted and accepted to the event. The poster included a brief explanation of the problem, project objectives, framework, project design, and analysis. The event was open to the public. NPs practicing in the community were encouraged to attend through email and personal invitation from students. The event allowed for informal questioning and answering of the material being presented. A member of the public found the new CDC guidelines to be very intriguing as she was born between the years of 1945 and 1965. The member also asked numerous questions related to the signs and symptoms related to hepatitis C, I reported that they could be vague to nonexistent. Upon completion of our conversation, the public member informed me that she would be requesting screening for hepatitis C at her next scheduled wellness exam.

On April 7, 2014 the second NDSU graduate poster presentation is scheduled. I will submit my poster. Anticipating acceptance I will display my poster with the completed findings from the project. I will also display the new hepatitis C referral protocol, hepatitis C job description, and provider brochures containing the hepatitis C algorithm during the event.

Besides presenting the information during poster presentation, I will submit an abstract to a nursing journal. The intent of submitting the information to a widely published journal is to reach a large number of readers that participate in a variety of healthcare settings. Distributing the methods and framework that were implemented at the GI clinic has the potential to improve the workflow, productivity, and patient satisfaction at other facilities.

On January 17, 2014, I disseminated the finding and results performance improvement project to the GI clinic staff and core team members. The presentation followed the PDSA

framework progression of implementation at the GI clinic. The GI clinic was presented with hard copies of all final products created during the process.

Conclusion

Addressing the GI clinic's goals to improve the efficiency and productivity of the referral process for hepatitis C patients to deal with an expected patient surge revealed other opportunities for improvement. Utilizing the PDSA model allowed many areas of weakness to be identified. These areas included a lack of consistent communication, a lack of referring providers' knowledge about hepatitis C, and a lack of depression monitoring at the clinic. Each area of weakness was addressed and continuously improved until the implementations met satisfactory expectations of the GI clinic. To address these areas of weakness, a standardized, new hepatitis C referral protocol; designated hepatitis C nurse; provider reference algorithms; and PHQ-9 administration were created and implemented. Implementing the new processes at the GI clinic has created a positive performance improvement for staff members and patients.

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**APPENDIX A. PERMISSION TO USE THE REPEATED PDSA CYCLE TO TEST A
CHANGE**

From: Cozza, Amanda <acozza@aap.org>
Sent: Thursday, January 30, 2014 9:06 AM
To: Toby Redden
Subject: RE: Copyright Request

Dear Dr Redden:

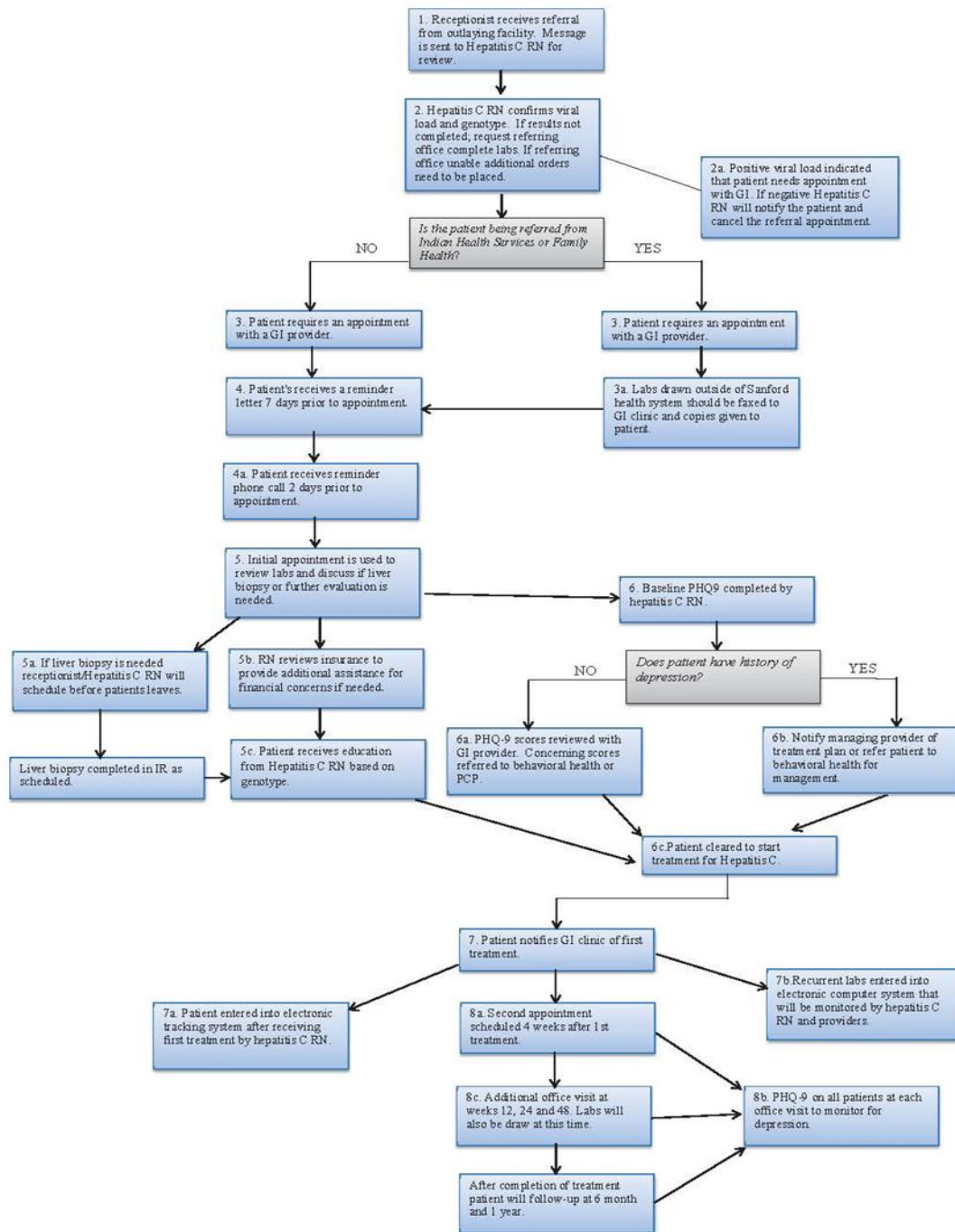
I am Amanda Cozza, Editorial Specialist for the AAP, and I handle all requests for permission to use material from AAP manuals and Web sites. Many thanks for your request, which was forwarded to my attention.

By way of this e-mail, permission is granted to use the indicated figure as you have described. This permission is granted nonexclusively for one-time use and educational purposes only. Rights granted do not apply to revised editions or foreign language editions. Near the figure, please prominently place a credit line to the AAP and the original source of the figure.

Kind regards,

Amanda
Ms Amanda Cozza
Editorial Specialist
American Academy of Pediatrics
Phone: 847/434-7133
E-mail: ACozza@aap.org

APPENDIX B. NEW REFERRAL HEPATITIS C PROTOCOL



APPENDIX C. HEPATITIS C JOB DESCRIPTION

Gastroenterology Department

Hepatitis C Nurse Manual-Monitoring and Management of Hepatitis C Patients

Approved By:		Written By:	T. Redden RN, BSN, DNP-S; Audrey Hooey RN & T. Geire RN
Original Date:	11/13	Effective Date:	1/14
Review Date:		Revised Date:	

Job Description:

The appointed hepatitis C registered nurse/license practice nurse working in the Sanford Health System shall provide initial comprehensive chart screening prior to patient's first visit with the provider. In addition the appointed hepatitis C nurse will continue to monitor the progression of the patient and laboratory values while effectively communicating results/concerns with the providers.

The remainder of the job description will refer to the hepatitis C registered nurse/license practice nurse as the *nurse*

Purpose: To provide standardized guidelines for the nurse to monitor hepatitis patients through the duration of the treatment and effectively communicate with the providers. Following the *New Hepatitis C Protocol* that has been adopted by the GI clinic, the hepatitis C nurse is responsible for the following.

Specific job requirement:

1. The nurse will complete the initial chart screening prior to the patient first scheduled appointment with one of the GI providers.
2. Chart screening protocol entail collecting information via electronic medical record (EMR), faxed or scanned documents. Information collection should include but not limited to:
 - a. Hepatitis C Virus (HCV) antibody
 - i. If undetected patient's appointment related to hepatitis C would be cancelled, following the appropriate protocol of the clinic.
 - b. HCV RNA Quantitative
 - i. If undetected patient's appointment related to hepatitis C would be cancelled, following the appropriate protocol of the department.
 - c. HCV genotype
 - d. Complete blood count with differintail, ALT, AST within last six months are applicable.
 - e. Nurse will discuss results of labs and missing labs with the provider for further laboratory orders prior to patient's initial visit if needed
 - f. Any additional testing or screening that has been made by the department following treatment guidelines or provider preference.
3. At initial patient visit nurse will be responsible for rooming the patient

- a. Collect vital signs
 - b. Update medication list
 - c. Update vaccine status
 - d. Document PHQ-9 in Doc. Flow sheet as well as progress note.
 - i. Will need to explain validity and sensitivity of PHQ-9 to patient on initial visit.
 - e. Assist in scheduling additional test outside of the department if needed.
 - f. Collect necessary documentation for pre-authorization of insurance.
 - g. Provide information to patient for financial assistance if needed.
4. Remain in contact via phone or other forms of communication with each individual patient throughout treatment duration.
 - a. Provide reminder phone calls for upcoming appointments and laboratory draws
 - b. Provide courtesy phone calls to check on status of patient during the treatment course.
 5. Provide excellent communication between other GI staff members and providers on critical laboratory values, reportable side effect of medication, depression status, and treatment concerns.

APPENDIX D. BROCHURE #1: ALGORITHM SHORTFORM

Sanford Health Gastroenterology

Providers at the gastroenterology have specialized training in providing treatment options and monitor of patient with confirmed Hepatitis C Virus.

The Sanford Health Gastroenterology department is able to deliver leading diagnostic and treatment services to their patients. The caring supportive staff at the Gastroenterology department has created an algorithm as a guide to assist referring providers.

**Sanford Health
Gastroenterology
Phone: 701-234-2525**

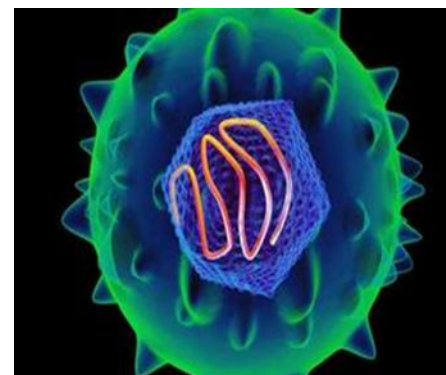
Sanford Health Gastroenterology

Sanford Broadway Clinic
Address: 801 Broadway N
Fargo, ND 58102

Phone: 701-234-2525
Fax: 701-234-2910

Office Hours: 8am-5pm
Monday-Friday

Sanford Health Gastroenterology



The Sanford Health Gastroenterology brings together dedicated caring providers and staff to offer patients with the latest evaluation, treatment methods and medications for the management and cure of Hepatitis C Virus.

Hepatitis C Virus Screening Recommendations and Referral Algorithm

Who Should Be Tested

*One-time testing for adults born 1945 and 1965.

*Any history of intravenous drug use or tattoos done in an unsterile environment

*Recipients of clotting factor produced before 1987.

*Received a blood transfusion, blood component or an organ transplant before July 1992.

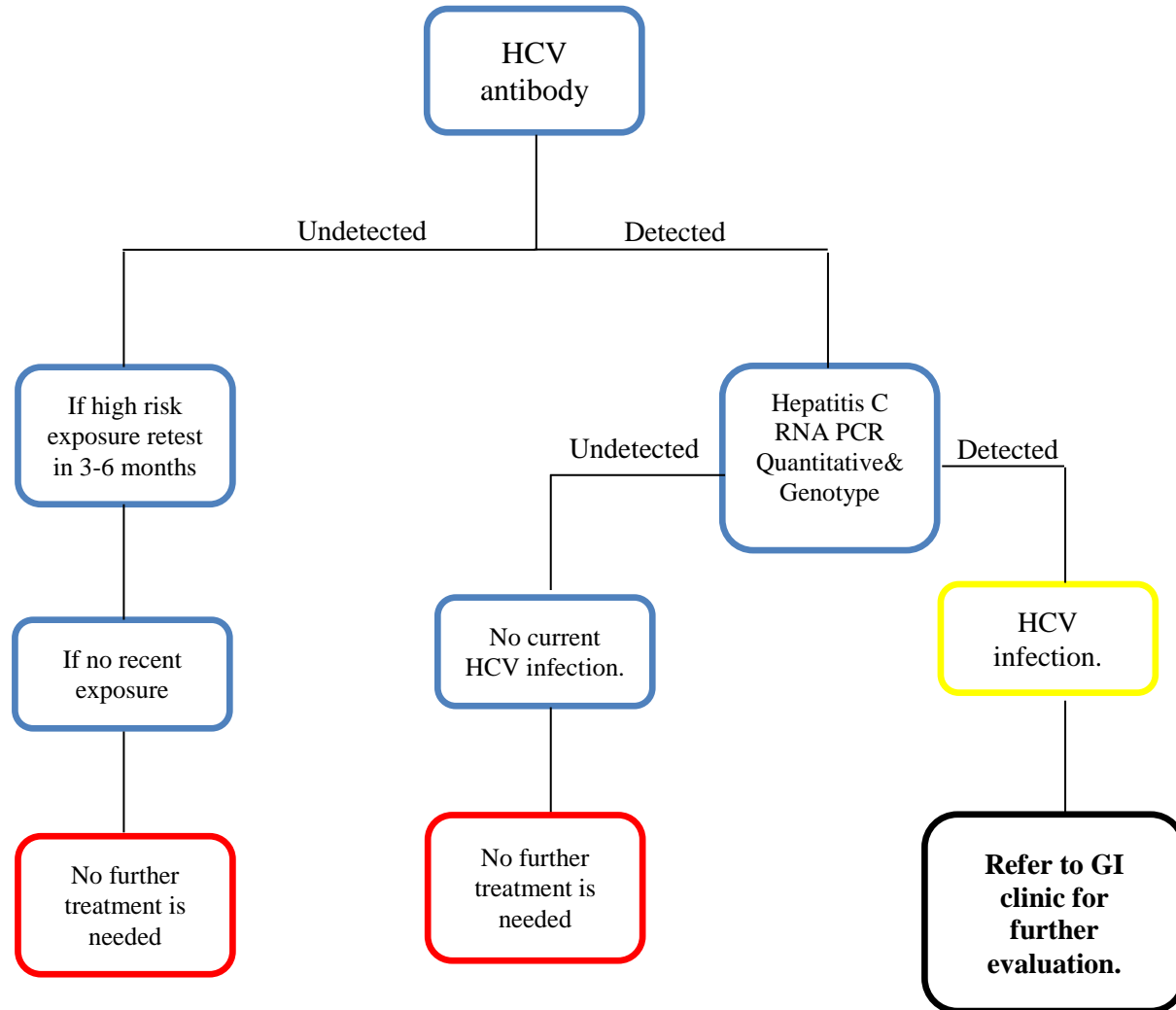
*Persistently abnormal alanine aminotransferase level (ALT) or aspartate aminotransferase (AST).

Gastroenterology Clinic

Phone: 701-234-2525

Fax: 701-234-2910

Office Hours: 8am-5pm
Monday-Friday



Sanford Health Gastroenterology

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**Sanford Health
Gastroenterology
Phone: 701-234-2525**

Sanford Health Gastroenterology

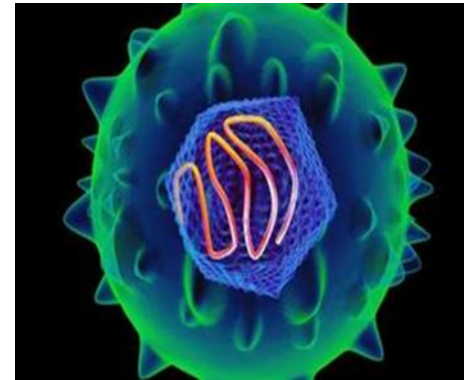
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Sanford Health Gastroenterology



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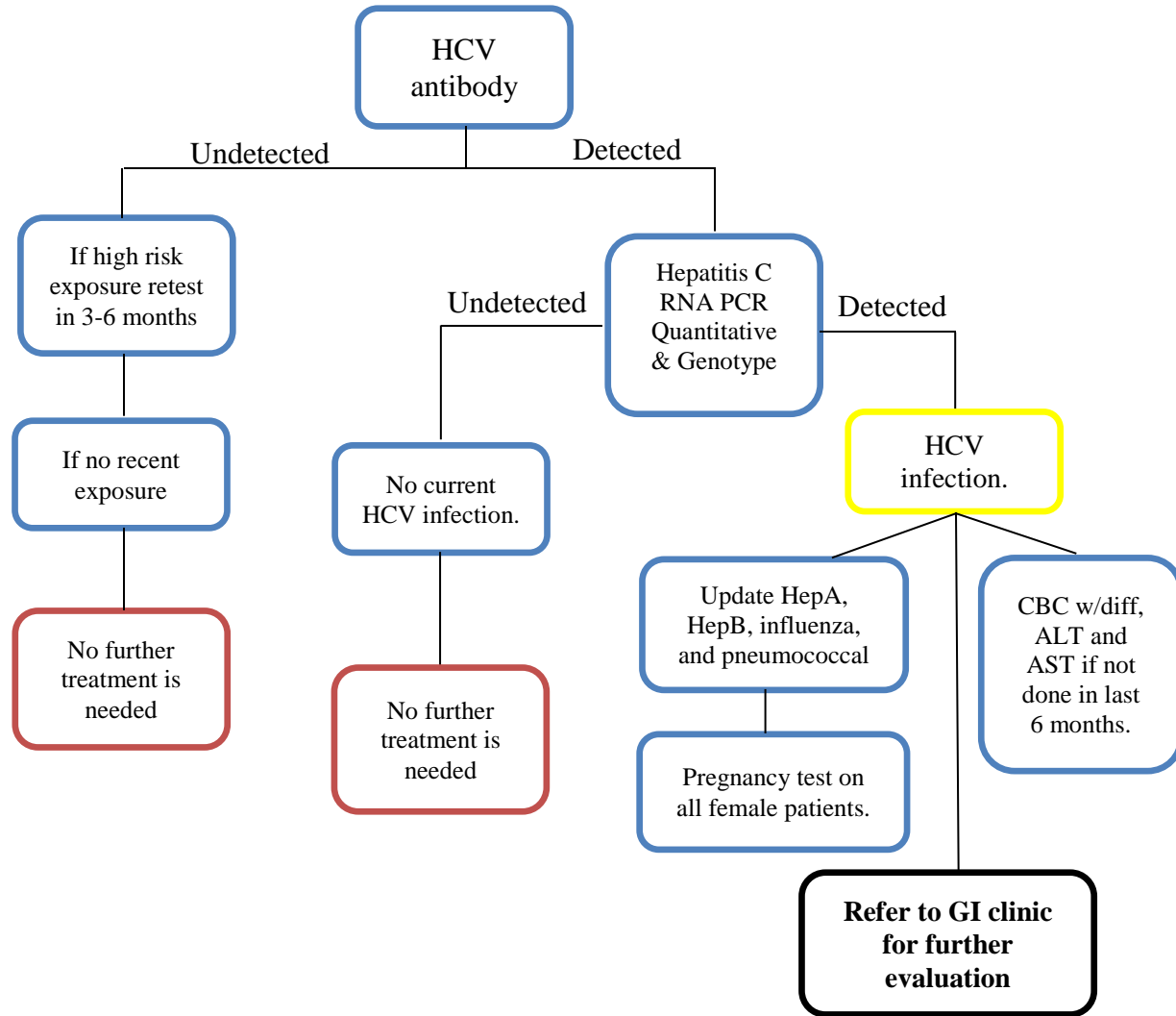
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Gastroenterology Clinic

Phone: 701-234-2525
 Fax: 701-234-2910
 Office Hours: 8am-5pm
 Monday-Friday



APPENDIX F. NDSU IRB EXEMPT



June 13, 2013

Dr. Tina Lundeen
Dept of Nursing
Sudro Hall

Re: Your submission to the IRB: "Implementation of a New Hepatitis C Referral Process at the Sanford Gastrointestinal Department: Out with the Old in with the New"

Research Team: Toby Redden

Thank you for your inquiry regarding your project. At this time, the IRB office has determined that the above-referenced protocol does not require Institutional Review Board approval or certification of exempt status because it does not fit the regulatory definition of 'research involving human subjects'.

Dept. of Health & Human Services regulations governing human subjects research (45CFR46, *Protection of Human Subjects*), defines 'research' as "... a systematic investigation, research development, testing and evaluation, designed to contribute to generalizable knowledge." These regulations also define a 'human subject' as "... a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

It was determined that your project does not require IRB approval (or certification of exempt status) because individual identifiable records are not being obtained for the research. The board makes this determination conditional on your assertions the Sanford IT department will provide data aggregated by department rather than individual patient data.

We appreciate your intention to abide by NDSU IRB policies and procedures, and thank you for your patience as the board has reviewed your study. Best wishes for a successful project!

Sincerely,

A handwritten signature in cursive script that reads "Kristy Shirley".

Kristy Shirley, CIP; Research Compliance Administrator

INSTITUTIONAL REVIEW BOARD

NDSU Dept 4000 | PO Box 6050 | Fargo ND 58108-6050 | 701.231.8995 | Fax 701.231.8098 | nds.u.edu/irb

Shipping address: Research 1, 1735 NDSU Research Park Drive, Fargo, ND 58102

NDSU is an EO/AA university.

APPENDIX G. SANFORD HEALTH IRB EXEPEMT

From: Urban,Karen [Karen.Urban@sanfordhealth.org]
Sent: Wednesday, June 19, 2013 5:37 PM
To: Toby Redden
Cc: Robinson,Karen; Langstraat,Debra; Hansen,Carla
Subject: NDSU Practice Improvement Project: Toby Redden

Toby,

Upon review of both your NDSU IRB application and the letter you received from NDSU regarding the decision that your project does not require IRB approval “because individual identifiable records are not being obtained for the research”, it has been determined that you would not need to go through the Sanford IRB process as long as all data you are collecting for your practice improvement project will be collected and shared in aggregate form. We will accept the NDSU IRB determination. According to the IRB application, data will be in the form of **“A generalized electronic medical record report with clustered information will be generated to assess the compliance of the administration of the PHQ-9. The information will not contain patient identifiers or staff members’ names.”** If at any point in your project, the data collection process changes, please contact our team to determine if additional requirements are needed.

Please do not hesitate to contact me with any questions.

Sincerely,
Karen
Karen Urban, MS, RN, ACNS-BC
Sanford Medical Center Fargo
Office of Nursing Practice
2 West - Neurology Route #196
Phone: (701) 234-5567
Pager number: 1198
karen.urban@sanfordhealth.org

APPENDIX H. EXECUTIVE SUMMARY

Introduction and Background Information

The Gastroenterology (GI) clinic at Sanford Health anticipates an increase in patients with hepatitis C virus (HCV) based on the 2012 Centers for Disease Control (CDC) screening recommendations in the baby-boomer population. Baby-boomers make up 23% of the residents in the United States and accounts for more than 75% of all documented HCV cases in the United States. With a disproportionately high prevalence in the baby-boomer population, the CDC recommended a “one-time testing of all persons born during 1945-1965 without prior ascertainment of HCV risk” (CDC, 2012a).

The purpose of this practice improvement project was to refine the existing workflow of the GI clinic when caring for and managing patients with HCV. To manage the current and anticipated HCV patients, an identifiable need for a more efficient, standardized protocol for new HCV patient referrals was needed. Developing a standardized protocol would improve the quality of care for HCV patients, increase the clinic’s efficiency, and create a foundation for excellent communication with HCV patients.

Framework

To improve the processes and address the clinic goals, the *Plan, Do, Study, Act* (PDSA) method was used. PDSA is an interactive, four-phase, problem-solving, and process-improving model that was used during the performance improvement project (Tew, Sherry, Butler, & Martin, 2008). The idea of the PDSA cycle is to turn ideas into actions and to connect the actions with learning.

Cycle 1: New Hepatitis C Referral Protocol

To improve the quality of care for HCV patients, to increase the clinic's efficiency, and to identify opportunities for improvement the existing referral protocol for hepatitis C was examined. One goal of the clinic was to eliminate unnecessary visits, allowing more appointment availabilities for patients requiring provider visits. A new standardized referral protocol was created and improved upon using the PDSA multiple times before creating the final protocol. The protocol was entered into a Word document and illustrated the department's step by step protocol for new hepatitis C referrals. The protocol started with the receptionist receiving the referral phone call from an outlying facility and ended with the 1 year follow-up appointment for the patient that had completed the treatment course. Once the final protocol was reviewed and accepted by staff and core team members of the project the "New Referral Hepatitis C Protocol" was implemented on January 2, 2013. The initial interview with nursing staff and the receptionist felt that communication with new referral hepatitis C patients had improved. However, errors still existed with nursing staff related to chart reviews, patient education, reminder calls to the patient, and laboratory tests. After further discussion core team members concluded that adding a designated hepatitis C nurse would be beneficial to the department efficiency, productivity and elimination of unnecessary appointments.

Cycle 2: Hepatitis C Nurse

HCV is a complicated, intense disease process, necessitating chart reviews, patient education, and depression monitoring. Multiple people educating patients caused confusion, inconsistency, duplication of information, and missed information. To meet these time commitments and eliminate confusion it was concluded that a designated hepatitis C nurse would be utilized. The hepatitis C nurse would serve as a liaison for all HCV patients and providers.

The designated hepatitis C nurse, along with the providers, would ensure that the initial chart review, needed laboratory draws, PHQ-9 administration, education, insurance correspondence, and other pertinent care was managed. After the hepatitis C nurse had been in the new position for some time the nurse reported that the transition was successful. The patients reported to the designated hepatitis C nurse and providers that they enjoyed the consistency of care and the ease of contacting the GI clinic with questions or concerns. To continue with this standard of care, a job description was created to outline the specific requirements for the hepatitis C nurse. The job description is intended to be reviewed by the hepatitis C nurse on an annual basis. The job description also serves as a guideline for new employee taking on the role as the hepatitis C nurse.

Cycle 3: Provider Algorithm

During the initial chart review for new hepatitis C referral, the designated hepatitis C nurse continued to see a high percentage of patients referred to the GI clinic without completed laboratory tests. The frequency of the incomplete laboratory test led to the third cycle of the PDSA of addressing the lack of knowledge that was consistently found in referrals from primary-care settings. To address this gap with referrals, a brochure containing a hepatitis C referral algorithm was created. The algorithm was created using information gathered from the CDC screening guidelines, the United States Preventative Task Force, and the American College of Gastroenterology. The hepatitis C referral algorithm included appropriate laboratory tests, screening updates, when to refer, and contact information for the GI clinic. In addition, an introduction to the clinic and hepatitis C services offered was included. The brochure printing, mailing and distribution cost will be added to the upcoming departmental budget.

Cycle 4: PHQ-9 Screening

The last PDSA cycle at the GI clinic was implementing the PHQ-9 depression screening. Before beginning treatment, the American Association for the Study of Liver Disease (AASLD) and the HCV medication manufacturers suggest that patients be screened for depression. Depression is a frequent and potentially serious complication of interferon therapy when treating HCV-infected patients. Many patients with depression suffer from longer disability periods, have a lower quality of life, require more inpatient and outpatient visits, and have an increased risk of suicidal attempts and ideation (Papfragkakis, Rao, Moehlen, Dhillon, & Martin, 2012). To provide safe, up-to-date treatment at the GI clinic, monitoring HCV patients' depression was necessary. Providers and staff members believed that improved monitoring of and support for depression could increase the treatment completion rates and the quality of life for HCV-infected patients. After multiple attempts to achieving 80% compliancy rate for administration of the PHQ-9 it was concluded that the most successful rate came from the PHQ-9 being administered by the designated hepatitis C nurse. The last report showed 100% compliancy for 3 months in a row. Recommendation have been made to the GI clinic to review depression-screening reports on a monthly basis until the 80% goal has been met for 6 consecutive months; then, the review may be reduced to every other month.

Conclusion

Utilizing the PDSA model allowed many areas of weakness to be identified. These areas included a lack of consistent communication, a lack of referring providers' knowledge about hepatitis C, and a lack of depression monitoring at the clinic. Each area of weakness was addressed and continuously improved until it met satisfactory expectations of the GI clinic. Staff members and providers have reported positive impacts at the clinic after the implementation of

the new change processes at the GI clinic. Patients verbalize excellent satisfaction with the services, particularly the ease of communicating with the GI clinic and consistent personnel since the implementation.

The process of improving a current system was the focus of the project. The approaches implemented at the GI clinic can be replicated in many other healthcare settings. Specialty areas with a high population of a specific group should consider following the project's implementation process that was completed at the GI clinic. The use of the PDSA framework serves as a logical progression of phases to follow. The PDSA allows for continued examination and improvement of an implementation until reaching satisfactory goals.