

CHRONIC PAIN MANAGEMENT: IMPLEMENTING BEST PRACTICE STRATEGIES

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ABSTRACT

The purpose of this project was to improve the monitoring of chronic pain patients at a rural primary care clinic by creating and implementing a chronic pain flow sheet and pain visit template within the electronic health record. These evidence-based tools were developed using published guidelines regarding the monitoring of chronic pain patients. The clinic has three providers, one physician and two advanced practice providers, and provides primary care along with an extensive amount of chronic pain management.

An initial survey was performed on the three providers via a questionnaire along with open discussion regarding their current chronic pain management practice. All providers reported treating chronic pain patients was difficult and the electronic health record was currently not user-friendly when monitoring chronic pain patients. The flow sheet and pain visit template was designed by the project leader (writer) and created by the Computer Information Systems (CIS) department. Once it was created, an initial chart review and flow sheet implementation was performed on a sample population of adult chronic pain patients at the clinic. Providers were educated on the available flow sheet along with the pain visit template available for use.

A six-month chart review was conducted to evaluate the project and determined how the flow sheet and template were utilized. A post-implementation survey, similar to the initial questionnaire, was also dispensed and analyzed. Results indicate providers do plan to use the designed monitoring tools but there were some barriers standing in the way of consistent use. The chart review found an increase in presence of pain contracts signed and filed within the last year, but a decrease in the presence of a pain visit within the last four months, urine drug screen within the last six months, and the prescription drug monitoring program checked within the last six months.

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CHAPTER ONE. INTRODUCTION

Opioid abuse is a prevalent problem in the United States with potentially lethal complications. Because of the medical and ethical implications of opioid therapy providers are hesitant to prescribe opioids, despite their evidence-based effectiveness in caring for chronic pain. In order to understand opioid abuse, one must define what opioid abuse is and the associated behaviors.

Definitions

Substance misuse is defined as “the use of any drug in a manner other than how it is indicated or prescribed”. Substance abuse is defined as “the use of any substance when such use is unlawful, or when such is detrimental to the user or others”. Addiction occurs when the abused substance is used out of control, compulsively, or its use continues despite potential harm (Butler, Fernandez, Benoit, Budman, & Jamison, 2008, p. 361).

Unfortunately, prescription opioids are substances that are commonly abused. Opioids act on the central nervous system as a depressant and in return, deliver an analgesic effect and a state of euphoria. Several examples of opioids exist, including heroin, morphine, codeine, fentanyl, and oxycodone. Because of their euphoric and addictive properties, a craving or desire for opioids cause aberrant drug-related behaviors. These behaviors are “any behaviors that imply misuse of prescription medications” (Butler et al., 2008, p.361). Aberrant behaviors include any behavior consistent with abuse, addiction, or diversion. Examples include stealing medications, using medications for non-prescribed reasons, or abusing opioids in conjunction with illicit substances.

Prevalence

Despite the increase in misuse behaviors, the use of therapeutic opioids continues on the rise. In fact, the supply of opioids drastically increased over the past 13 years, increasing from 96mg of morphine equivalence per person in 1997 to 710mg per person in 2010. This is enough opioid to supply every American adult with 5mg hydrocodone every 6 hours for 45 days.

Although opioids are available worldwide, America consumes 99% of the global consumption of hydrocodone and 83% of oxycodone (Manchikanti et al., 2012).

The Impact of Opioid Abuse

Substance use disorders are one of the most common psychiatric disorders in the United States, affecting 20% of the population (Moore, Jones, Browder, Daffron, & Passik, 2009).

Opioid abuse causes health hazards and has a negative economic impact on the country.

Adverse Effects of Opioids

Substance abuse leads to dependence, decreased sexual functioning, interpersonal violence, risky sexual behavior, and neurological and cognitive impairments (Moore et al., 2009). Health side effects from opioids can affect nearly every body system. Neurological side effects include hyperalgesia, sedation, and muscle rigidity. Nausea, vomiting, and constipation are common gastrointestinal side effects. Although not common or well known, cardiac dysrhythmias and sleep apnea can occur secondary to opioid use. The kidneys may be affected with the use of opioids causing decreased renal function and peripheral edema. Hypogonadism, sexual dysfunction, and immune suppression are also side effects of opioid use (Harris, 2008).

Drug overdoses are now the leading cause of injury-related deaths in the United States. Forty-four thousand people die annually from drug overdose, which has more than doubled in the past 14 years (Brooks, 2015). In 2008, deaths related to overdose exceeded deaths related to

motor vehicle accidents for the first time since 1980. Of the 36,500 drug poisoning deaths in 2008, 40% involved opioid analgesics (Warner, Chen, Makuc, Anderson, & Minino, 2011).

Economic Impact

The continued epidemic of prescription opioid abuse not only causes adverse health effects; it negatively impacts the country's economy. In 2001, the cost of opioid abuse was \$11.8 billion and 53% was attributed to lost workplace productivity, 30% to healthcare, and 17% to criminal justice. Excess costs per privately insured patient due to opioid abuse was estimated to be at \$17,768 per patient (Birnbaum et al., 2011, 657).

A research article published in 2011 in Pain Medicine examined the societal costs of opioid abuse in 2007 and compared the 2001 numbers. The study showed that opioid abuse has grown in the past six years and caused a worsening economic impact. Results showed the 2007 cost of opioid abuse is \$55.7 billion, \$25.6 billion spent on lost workplace productivity, \$25 billion on healthcare costs, and \$5.1 billion on criminal justice. Opioid abuse not only affects the individual with opioid related aberrant behaviors, but affects the entire economy, from taxpayers to employers (Birnbaum et al, 2011, 661-662). The Center for Disease Control and Prevention performed a more recent analysis showing the total economic burden of opioid abuse totals \$78.5 billion a year (Anson, 2016).

The Face of Opioid Abuse

Ingesting opioids in excess amounts, or for reasons besides therapeutic indication, is done for various reasons or motives. Personal history, life stressors, and characteristics can lead someone to be more apt to abuse opioids. In order to detect opioid abuse in patients, readers should understand the motivation and characteristics behind opioid abuse.

Motivation for Abuse

Research has shown substance abuse occurs for a variety of motives. A study performed on undergraduate psychology students involved a questionnaire regarding their use of prescription opioids and choosing the motives behind the use. Reasons for use were divided into four categories: enhancement, coping, social, and pain. Examples of specific reasons for use besides their indicated use for pain include “because it’s fun”, “because it gives you a pleasant feeling”, “because you feel more self-confident or sure of yourself”, and “because it improves parties and celebrations” (Jones, Spradlin, Robinson, & Tragesser, 2014).

Patient Characteristics of Opioid Abuse

A study was conducted in a Boston, MA hospital on medical inpatients with acute pain suspected of non-medical opioid abuse (Jamison, Butler, Edwards, & Wasan, 2010). Of the population evaluated for possible non-medical use of opioids, 77.8% had a psychiatric disorder, such as major depression or bipolar depression and 88.9% had a diagnosis of substance use disorder, such as opioids, alcohol, cocaine, or cannabis. Over sixty-six percent of the patients selected for evaluation were also prescribed a psychiatric medication, such as antidepressants, mood stabilizer, antipsychotic, benzodiazepine, and stimulants (Jamison, Butler, Edwards, & Wasan, 2010).

Gender differences also exist between male and female patients abusing opioids. Women are shown to have a higher incidence of pain and are prescribed opioids more often than men. Substance abuse behavior is more prevalent in men. A history of depression and sexual abuse are more frequent in substance misuse and are more common in women. “Gender Differences in Risk Factors for Aberrant Prescription Opioid Use” was a research study published in 2010 that interviewed chronic non-cancer pain patients from pain management centers in five different

states in the United States (Jamison, Butler, Edwards, & Wasan, 2010). Results showed “women tended to endorse items that are based more on emotional issues and affective distress compared with men. Conversely, men scored higher on opioid misuse behaviors such as associating with others who abuse drugs and alcohol and engaging in criminal behavior. Men reported less mood problems than women but were more likely to admit behavioral problems leading to abuse” (Jamison, Butler, Edwards, & Wasan, 2010, p. 316).

Opioid Craving

Craving related to substance abuse is defined as “a strong desire for or urge to imbibe psychoactive substances, such as drugs, alcohol, and tobacco” (Wasan et al., 2012, p. 146). Prescription opioid cravings are associated with an elevated rate of opioid misuse. A research article titled “Craving of Prescription Opioids in Patients with Chronic Pain: A Longitudinal Outcomes Trial” looked at 62 patients with low to high risk of opioid misuse while they were enrolled in a randomized control trial to improve prescription opioid medication adherence. Participants showed intense opioid craving correlated with urge, preoccupation, and mood. The study argued that intervening to decrease patients’ cravings will potentially reduce opioid misuse and improve adherence (Wasan et al., 2012).

Problem Statement

Opioid abuse is a growing epidemic. Deaths from overdoses are increasing in number. Healthcare costs continue to rise due to opioid abuse and inadequate chronic pain management. Primary care providers feel inexperienced and uncomfortable with managing opioid therapy safely and effectively. To address this problem, a monitoring and documentation tool was developed within the electronic health record to assist primary care providers serving chronic

pain patients in a rural primary care clinic. The purpose of this project was to implement evidence-based practices for prescribing opioids for chronic pain management and monitoring.

Project Objectives

Objective One

The first objective was to assess the providers' perception of their current chronic pain management process in regards to usability, efficiency, and overall comfort level in caring for the chronic pain patient population. This information was obtained through a developed survey (Appendix B) delivered to the clinic providers. The goal was to find a level of improvement in providers' perception of their practice of caring for chronic pain patients after the implementation of the tools mentioned below.

Objective Two

The second objective was to create and implement evidence-based chronic pain documentation and monitoring tools to be used within the electronic health record. Tools included a template to be used when documenting a pain visit along with a flow sheet to easily monitor important parameters of chronic pain patients. The goal of this objective was for providers to find the tools to be useful in practice and for the comparative data from the chronic pain patients' chart review to show improvement in chronic pain monitoring parameters. The monitoring parameters within the chronic pain flow sheet included:

- Urine drug screen performed within the past six months
- Pain visit within the last 3-4 months
- Pain agreement signed and filed within the last one year
- If a query was done on prescription drug monitoring program with the last new or refilled opioid prescription

CHAPTER TWO. LITERATURE REVIEW OF EVIDENCE-BASED PRACTICE

A literature review was performed using databases containing evidence-based articles to contribute and support the objectives of this practice improvement project. Databases that were used included EBSCO, Cinahl, and PubMed. Topics searched focused on chronic pain, safe opioid prescribing, documentation of pain visits, and monitoring chronic pain patients.

Essential Monitoring Elements in Chronic Pain Patients

Many clinicians feel a structured approach that is applied uniformly across patient groups helps meet the challenges of monitoring each patient on long-term opioid therapy. Several computerized systems are in existence but patient care can be greatly improved with systems that contain tools for collecting, analyzing, and utilizing outcomes. Tips for effective monitoring include: listening carefully and compassionately, attending to entire patient (not just the pain), referring to relevant health professionals as needed (such as pain centers or mental health professionals), adjusting pain medications, modifying functional goals, and collaborating with the patient on their treatment plan (Fisherman, 2012).

An opioids special issue was published in 2008 in the Pain Physician journal titled, “Monitoring Opioid Adherence in Chronic Pain Patients: Tools, Techniques and Utility”. The aim of the review was to address the issues of hesitancy in prescribing opioid medications due to risk of patient misuse and/or potential for professional prosecution. The authors emphasized the importance of adherence monitoring in order to avoid misuse and abuse, but also ensuring proper pain management (Manchikanti, Atluri, Trescot, & Girodano, 2008). Tools and monitoring measures include urine drug testing, prescription drug monitoring programs, and controlled substance agreements.

Urine Drug Screens

Urine drug testing in chronic pain patients is becoming more prevalent in practice and serves to test for adherence and identify presence of illicit drugs or other medications that are not prescribed to the patient. The test has relatively good specificity, sensitivity, ease of administration, and low cost. However, no urine test can test for the presence or absence of all drugs; but urine drug screens can provide useful information to the prescriber if considering whether or not to continue prescribing opioid medication (Manchikanti et al, 2008).

Interpretation of the urine drug screening needs to be done in conjunction with patient's history as each substance metabolizes differently (Manchikanti et al, 2008). For example, cocaine, codeine, and heroin are detected in the urine for 1-3 days after use but benzodiazepines can stay in the urine for up to 30 days, which is the same for chronic marijuana use. Another caveat of interpreting urine drug screens (UDS) is knowing the end product metabolite of opioid medication. An example of this is codeine, a UDS showing positive for morphine is appropriate as codeine is metabolized into morphine (Manchikanti et al, 2008).

Despite the potential limitations of urine drug screening, evidence shows that urine drug screens are beneficial in providing prescribers objective data. Also, "studies suggest that behavior monitoring alone in patients on chronic opioid treatment will fail to detect potential problems revealed by urine toxicology testing". In fact, that study showed that "one in five patients who appeared to be taking opioids as prescribed by an expert clinician had a positive urine screen for an illicit drug" (Sehgal, Manchikanti, & Smith, 2012, p. ES78). Because of the urine drug testing performed in this study's sample, 40% were referred to behavioral health and addiction specialists and 19.6% of patients were diagnosed with drug abuse and addiction. Data

from this study supports the practice of collecting urine drug screens on patients receiving opioids, regardless of signs or symptoms of drug misuse (Sehgal et al., 2012).

Schneider, a board certified physician in internal medicine, addiction medicine, and pain management, makes suggestions regarding the frequency of UDS. She points out that published guidelines do not specify a frequency but she recommends only doing random UDS since patients can plan and prepare if they know the schedule of UDS collection. In her practice, samples are obtained at random, 2-3 times a year, and additionally if there are concerns about adherence (Schneider, 2014). Fisherman, a physician who specializes in pain management, warns of “white coat compliance”. An example of white coat compliance is when an abuser diverting opioids attempts to appear compliant by taking the medication only prior to a scheduled or anticipated urine drug screen (Fisherman, 2012).

Prescription Drug Monitoring Program (PDMP)

The PDMP is a statewide electronic database that collects data on controlled substances dispensed in the state. The PDMP is housed by a specified statewide regulatory, administrative or law enforcement agency (U.S. Department of Justice, 2011). The housing agency distributes data from the database to individuals who are authorized under state law to receive the information for purposes of their profession. Data collected as of October 2011 shows 37 states with operational PDMPs and 11 states with the legislation to establish a PDMP (U.S. Department of Justice, 2011).

According to “Monitoring Opioid Adherence in Chronic Pain Patients: Tools, Techniques and Utility” (2008, p. 18-19), the majority of state PDMPs have the following goals:

- To educate and inform practitioners and the public
- To develop and advance public health initiatives

- To facilitate early identification and intervention in cases of drug misuse or abuse
- To aid in investigation and law enforcement
- To safeguard the integrity, and access to the programs' database

A report by the Office of Justice Programs found that the presence of the PDMP may reduce per capita supply of prescription pain medications (Manchikanti et al., 2008).

A research study performed using the prescription records from a Massachusetts prescription monitoring program (PMP) for Schedule II opioids over a ten-year timeframe found the number of prescriptions, doses prescribed, and individuals receiving Schedule II prescriptions steadily increased during that timeframe. They found the use of the prescription monitoring program has the ability to capture relevant data regarding opioid dispensing, including activity that may be indicative of misuse. Several variables of the PMP were found to be suggested indicators of inappropriate use, such as number of dosage units dispensed, number of prescribers, and number of pharmacies used. Researchers in this study felt that the use of the state PMP can be beneficial on many levels. The program provides individual patient data to providers regarding level of pain management, administrative problems, abuse, addiction, and diversion. Community risk data can also be obtained by looking at questionable activity and negative health outcomes and help initiate appropriate interventions. Lastly, it has the potential to help identify questionable activity at both the patient and prescriber level that may warrant further investigation (Katz et al., 2010).

In 2012, New York required prescribers to check the PDMP before prescribing painkillers, resulting in a 75 percent drop in patients seeing multiple prescribers for the same drugs. That same year in Tennessee, the same rule was introduced and the state saw a 36%

decline in patients seeing multiple prescribers for the same drugs (PDMP Center for Excellence, 2014).

The Minnesota Prescription Monitoring Program is administered by the MN Board of Pharmacy and collects prescription data on all schedule II-IV controlled substances (MN Prescription Monitoring Program, 2015). The database contains information about controlled substance prescriptions that were dispensed in or into the state of MN. A check of the PDMP reveals the recipient, name of prescription medication, quantity of prescription medication, name of prescriber, and date and location of where prescription was dispensed. Prescribers and dispensers are not required to use the database and the program is not intended to prevent patients from receiving necessary medications (MN Prescription Monitoring Program, 2015).

Controlled Substance Agreements

Controlled substance agreements are considered invaluable tools in pain management and serve to clarify parameters of treatment, explain patient and provider responsibility, inform patients of expectations, and address potential consequences if obligations and responsibilities are not upheld (Manchikanti et al., 2008). Rhode Island internal medicine residents were surveyed on their opinion of the usefulness of pain medication agreements (PMA) and 90% stated they were broadly useful and helpful in reducing multiple prescribers, reducing requests for early refills, decreasing calls and pages from patients requesting additional drugs, discussing potential problems associated with chronic opioid use, and identifying patients who are abusing pain medications. Ideally, the agreement should contain information about the risks, benefits, and possible complications of long-term opioid therapy and outline what a violation would entail and the consequence that would ensue (Manchikanti et al., 2008).

A narrative review by Sehgal, Manchikanti, and Smith (2012) discusses opioid treatment agreements and reports similar benefits as the sources mentioned above. The authors mention that the agreements may be perceived as controversial because of their intent, elements, language and tone, readability, physician responsibility, and legal risk. There is a lack of evidence showing that these agreements are effective in decreasing opioid abuse but are still widely supported and in some states, mandated (Sehgal, Manchikanti, & Smith, 2012).

As stated above, formalized agreements have not been validated to improve efficacy. They are, however, recommended by regulators and experts on treatment guidelines for long-term opioid therapy. The Veteran's Administration (VA) and the Department of Defense (DoD), which manage America's largest health systems, performed a 2-year systematic review of medical literature on the use of the opioid treatment agreements. The VA and DoD released in their evidence-based guidelines that the use of opioid treatment agreements are a standard of care when prescribing long-term opioid therapy (Fisherman, 2012).

Chronic Pain Visits and Documentation

In performing a literature review for the evidence-based recommendations on chronic pain visits and the essential documentation elements to include in those visit notes, there is a lack of standardized and detailed recommendations. This may be due to the highly individualized aspect of chronic pain management and how every patient and his/her circumstance is unique. Clinicians need to use their clinical expertise to help determine their follow-up plan for each patient and consider the patient's risk of opioid abuse, co-morbidities, and the level of effectiveness of their current treatment plan.

Schneider provides her recommendations on assessment, documentation, and follow-up visits for chronic pain patients (Schneider, 2014). Assessment of chronic pain is commonly

based on the 4 A's: analgesia (the level of pain or the level of pain relief), activities of daily living (what does the patient do on a daily basis and how does the pain interfere with those activities), adverse effects, and aberrant behaviors (requesting early refills or having a positive UDS for illicit drugs). Schneider (2014) also recommends a 5th A, affect. Depression and anxiety often exacerbate pain and many chronic pain patients are clinically depressed (Schneider, 2014).

Frequency of visits is very dependent on the rapport between the provider and the patient. A visit every 1-2 months for stable patients is recommended, and if the patient is considered to be on a relatively low dose of opioids, every 3 months is appropriate. In patients with adherence or abuse issues, these patients should be seen every 1-2 weeks and may also need additional contact via phone or electronic messaging between visits. The frequency of visits should also be considered in conjunction with whether or not a provider should prescribe without an office visit. Published guidelines do not require an office visit for every controlled substance prescription and the DEA permits writing multiple prescriptions for Schedule II drugs for up to 90 days as long as they are dated appropriately and have do not fill until x date included (Schneider, 2014).

Fisherman (2012) recommends the intensity and frequency of monitoring chronic pain patients depend on the patient's risk for abuse, diversion, or addiction. States vary on their requirements for intervals at which follow-up visits are required when controlled substances are prescribed. Patients requiring more intense monitoring include history of prior addiction, abuse, or aberrant use, occupations demanding more mental acuity, older adults, unstable or dysfunctional social environment, and comorbid psychiatric or medical conditions (Fisherman, 2012).

Prescribers should be motivated to diligently chart pain visits. Schneider (2014) points out that documentation is rarely a reason for scrutiny or prosecution in hypertension or diabetes,

but is very common with the treatment of chronic pain patients with opioids (Schneider, 2014). “A Review of Forensic Implications of Opioid Prescribing with Examples from Malpractice Cases Involving Opioid-Related Overdose” discussed malpractice lawsuits involving patients who overdosed while consuming therapeutic opioids (Rich & Webster, 2011). Physician error and non-adherence by patients were common contributory factors in prescription drug deaths. Prescriber errors included initiating doses too high for opioid-naïve patients, incorrect titration or dose conversion, and concurrent use of benzodiazepines. Physicians encountered legal problems on both ends of the pain management spectrum in prescribing opioids in patients with a clear risk of abuse and on the other hand, strictly withholding necessary pain medication for patients in need out of fear of being prosecuted. The study pointed out the obvious clinical challenge these patients create and recommend seeking education on providing competent care to pain patients and also being knowledgeable of regulatory policies and laws (Rich & Webster, 2011).

Prescribing practices that can warrant scrutiny include issuing prescriptions for large amounts of controlled substances without medical justification, failing to keep accurate records, and failing to evaluate and/or monitor patients. Another practice that may raise suspicion includes prescribing drug-dependent persons without adequate consultation, evaluation, and monitoring (United States Department of Justice, Drug Enforcement Administration, 2010).

Fisherman (2012), a leading pain medicine clinician, explains how documentation that is clear, consistent, and detailed is part of “best practice”. Proper documentation includes essential information including effectiveness of treatment regimen and the clinician’s rationale for treatment. Key elements of effective documentation include: assessment, education, treatment agreement and informed consent, action plans, outcomes, and monitoring (Fisherman, 2012).

Recommendations for Providers

Clinical guidelines in regards to the safe prescribing practices of opioid therapy are available and have similar recommendations for practice. American Society of Interventional Pain Physicians and the Center for Disease Control and Prevention have both written guidelines in regards to chronic pain management and monitoring.

American Society of Interventional Pain Physicians

The “American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain: Part 2- guidance” (2012) provides a thorough background of opioid abuse, recommendations for practice, and user-friendly materials to utilize in the clinic setting. The recommendations are organized chronologically and outline directions for use with each category. Opioid therapy begins with a comprehensive assessment that further details the chronic pain but also looks at the psychological aspect of pain, along with the medical and surgical history. This section also includes performing an addiction risk-screening tool and if necessary, checking a urine drug screen and prescription monitoring program (Manchikanti, 2012).

Establishing a diagnosis is the next step and may include a consult or diagnostic imaging. Important steps in determining if opioids are appropriate include establishing medical necessity and establishing treatment goals. Criteria for meeting medical necessity for opioid therapy includes moderate to severe pain, suspected organic problem, failure to respond to non-controlled substances, adjuvant agents, physician ordered physical therapy, structured exercise program, and interventional techniques. Every therapy needs to be evaluated for effectiveness. The guidelines suggest looking at the effectiveness and the side effects, being careful with high doses of long-acting opioids, considering trial of opioid rotation, and also looking at possible

opioid contraindications. Patients need to be aware of the risks and benefits of initiating opioid therapy (Manchikanti, 2012).

To initiate treatment, the guideline recommends performing a stratification of risk to prevent misuse or abuse and to categorize the patient into low, medium, or high risk. Patients need to be started on the lowest dose possible and titrated gradually to higher dosages, if necessary. Once therapy is started, adherence monitoring and managing side effects are important for a provider to monitor and reassess to determine if opioid treatments need to continue. Accurate and complete documentation must be performed, including all aspects of pain characteristics and management (Manchikanti, 2012).

CDC Guidelines for Prescribing Opioids for Chronic Pain

The Centers for Disease Control and Prevention (CDC) published updated guidelines for prescribing opioids for chronic pain and their recommendations are geared towards primary care providers. Twelve recommendation statements were written and addressed when to initiate or continue opioids for chronic pain, opioid selection, dosing, duration, follow-up, and discontinuation, and also assessing risk and addressing harms of opioid use. The CDC performed a systematic review of the scientific evidence to base their recommendations on in combination with input from experts and stakeholders (Centers for Disease Control and Prevention, 2016).

Statistics from the CDC further emphasize the prevalence of opioid abuse in the United States. According to the CDC published guidelines (2016), “an estimated 20% of patients presenting to physician offices with noncancer pain symptoms or pain-related diagnoses (including acute and chronic pain) receive an opioid prescription” (p. 1). Opioid prescriptions increased by 7.3% from 2007 to 2012. A study showed that 11.2% of adults report daily pain and

having chronic pain can cause clinical, psychological, and social consequences (Centers for Disease Control and Prevention, 2016).

The CDC guidelines outlined three recommendations related to the initiation and continuation of opioids for chronic pain. Nonpharmacologic therapy and nonopioid pharmacologic therapy are the preferred treatment options for chronic pain. Opioids should only be considered if the benefits outweigh the risks. If deciding to start opioid therapy, treatment goals should be established and focused on realistic pain and function levels. How the therapy will be discontinued should also be discussed at the time of initiation (Centers for Disease Control and Prevention, 2016).

Before beginning opioid therapy and periodically throughout the therapy, clinicians should discuss with patients the known risks and benefits of opioid therapy. Patients and clinicians also need to discuss each parties' responsibilities in regards to the treatment plan (Centers for Disease Control and Prevention, 2016).

The CDC wrote four recommendation statements regarding the selection of opioids, proper dosing, reasonable duration, and follow-up and discontinuation plans. In regards to opioid selection, immediate-release opioids should be used instead of extended-release or long acting opioids. The lowest effective dose should be prescribed and always be used with caution, regardless of the dose. Clinicians should avoid increasing the dose to greater than 90 morphine milligram equivalents a day (Centers for Disease Control and Prevention, 2016).

Acute pain can often lead to long-term opioid use. Clinicians treating acute pain should prescribe the lowest effective dose possible and shortest duration possible, three days is typically sufficient. For chronic opioid users, clinicians should be evaluating them at least every three

months. If benefits are not outweighing the risks, other therapies should be optimized and opioids should be tapered down (Centers for Disease Control and Prevention, 2016).

Opioid therapy has many potential risks and can be dangerous to patients, even leading to death. Before and during therapy, risk factors for opioid-related harms should be evaluated. Extra caution should be used in patients that have a history of overdose, history of substance use disorder, higher opioid dosages, or concurrent benzodiazepine use. The CDC recommends the use of the PDMP to evaluate for dangerous combinations or receiving excess opioids. The PDMP should be checked with every prescription or at least every three months (Centers for Disease Control and Prevention, 2016).

Another safety recommendation includes avoiding the concurrent use of opioids with benzodiazepines whenever possible. If patients have opioid use disorder, evidence-based treatment plans should be offered or arranged (Centers for Disease Control and Prevention, 2016).

This guideline provides evidence-based recommendations for primary care providers treating patients for chronic pain. The CDC recommends using extra caution when treating chronic pain with opioids and stresses that opioids are not first-line therapy for chronic pain. Ideally this guideline will lead to safer opioid prescribing and maybe decrease the amount of opioid prescriptions written nationwide.

CHAPTER THREE. THEORETICAL FRAMEWORK

Iowa Model of Evidence-Based Practice

Healthcare management, policies, and protocols are developed based on evidence-based practice. Evidence-based practice is defined as “the use of reliable, explicit, and judicious evidence to make decisions about the care of individual patients, combining the results of well-designed research, clinical expertise, patient concerns, and patient preferences” (Doody & Doody, 2011, p. 661). The Iowa model focuses on knowledge triggers, questions current practices, and considers improving practice through current research findings. The Iowa model involves seven steps, from selection of a topic to evaluation.

Selection of a Topic

Selection of a topic should consider the priority of the problem, apply to a variety of areas, contribute to improving care, and be supported by evidence related to the problem (Doody & Doody, 2011). Managing chronic pain patients receiving opioid pain medications requires frequent assessments and monitoring. Adequate monitoring of chronic pain can improve the care of patients and potentially prevent many complications. A thorough literature review regarding this topic produces a large amount of research articles.

Forming the Team

The team is responsible for development, implementation, and evaluation (Doody & Doody, 2011). Members possess interest in the current topic. This project’s team includes a chair, three committee members, and a graduate school appointee. The chair and three committee members on the team are all opioid-prescribing nurse practitioners and have professional experience to contribute to this topic. The graduate appointee is a member of the College of Pharmacy who has expertise in statistical analysis and economics.

Evidence Retrieval and Grading the Evidence

Based on the topic and recommendations from committee members, evidence was found using electronic databases as mentioned above. Topics searched included opioid screening tools, opioid abuse, pain management protocols, opioid abuse risk factors, and monitoring programs for patients at risk for opioid abuse. The evidence retrieved includes both qualitative and quantitative data. Criteria for evidence included date of publication being recent and from a valid and trusted source.

Developing and Implementing Evidenced-Based Practice

The goal of the project was to develop an evidence-based systematic process of monitoring patients with chronic pain. The project was designed to assist providers with patient-centered care in regards to pain management. Providing documentation tools and best practice flow sheets within the electronic health record were developed in order to provide a user-friendly tool for providers caring for chronic pain patients. Partnership is encouraged for safe pain management, such as with the use of a pain contract between patient and provider.

Implementation of the project began with collaborating with the healthcare organization's computer information systems department to create a pain visit template and chronic pain flow sheet. Once those tools were created, the project leader inputted the data based upon a chart review of known chronic pain patients to assist providers on managing these patients when they present to the clinic along with informing them of what patients are lacking identified elements of safe and effective chronic pain management.

Evaluation

Evaluation is essential to the theoretical framework in order to see the contribution of the evidence to practice and evaluation of this project involves two parts both at the initial

implementation and at the six-month follow-up. The initial phase occurred with the implementation and data entry to determine what the chronic pain patient population is lacking in regards to monitoring. The second phase was a chart review at the six-month follow-up to determine if that same patient population's chronic pain monitoring and adherence improved and also a survey of the providers to determine if they felt the pain visit templates and chronic pain flow sheets were of benefit to their practice and if they foresee use of these tools in the future.

The Trajectory Model

The theory used to guide this project is a middle-range nursing theory known as the Trajectory Model. The Trajectory Model was developed by Anselm L. Strauss, a medical sociologist, and Juliet Corbin, a nurse theorist. After over 30 years of interdisciplinary research on a variety of chronic illnesses, this model was created. The trajectory considers the course of the chronic illness along with the actions taken by health professionals and patients in managing the disease (Corbin & Strauss, 1991).

The Trajectory Model not only focuses on the work of the individual, but also suggests collaboration between the patient and provider. Goals for pain management are set collaboratively with any uncertainties being addressed and establishing a trust between the provider and patient. These steps are recommended for enhancing the aforementioned collaboration with attempts to improving the overall trajectory (Granger, Moser, Harrell, Sandelowski & Ekman, 2007).

Chronic pain is considered a chronic disease. The Trajectory Model is applicable to the chronic pain population and their adherence to their individual management plan. An individual's ability to manage their condition takes work. For example, chronic pain patients are required by the provider treating their chronic pain to fill their prescriptions, attend follow-up

appointments, provide urine drug screens, and possibly participate in other pain adjuncts, such as physical therapy or cognitive behavioral therapy. The model was utilized to improve the understanding of chronic pain patients and provide the patient’s perspective on their individual chronic disease process. Below is a visual representation of the Trajectory Model applied to chronic pain.

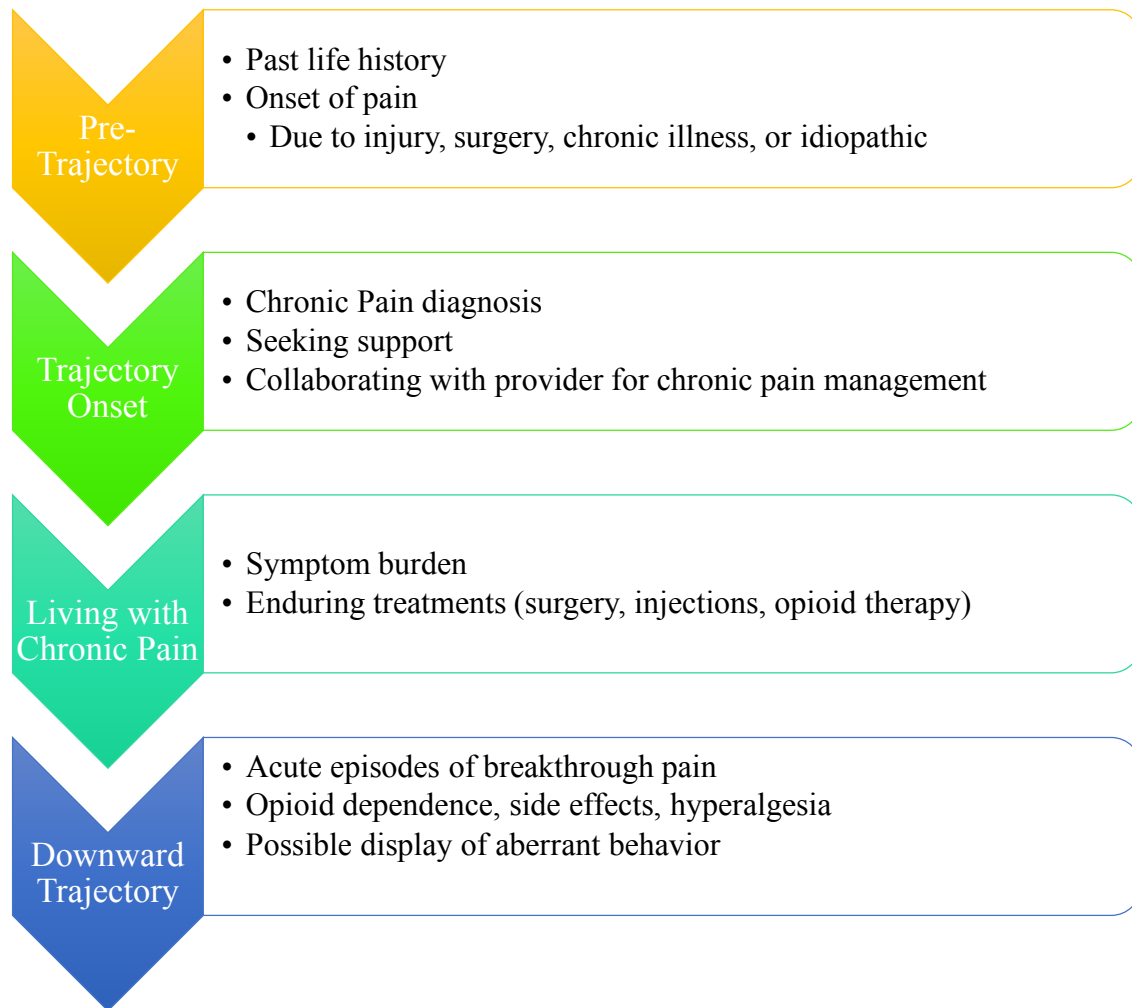


Figure 1. The Trajectory Model

Congruence of the Project to the Organization’s Strategic Plan/Goals

The regional health system values honest communication, collaboration for superior patient care and provide service to meet the emotional, spiritual, and physical needs for their

patients. The regional health system network where the project was implemented consists of several rural clinics providing comprehensive patient care; including chronic pain management. The participating clinic aims to provide chronic pain management that is safe and effective. The participating clinic hopes to better utilize the electronic health record in order to provide more efficient care to their many chronic pain patients as they do not currently possess an in-network pain clinic.

CHAPTER FOUR. PROJECT DESIGN

This practice improvement project started with determining the need of a chronic pain monitoring and documentation tool within the electronic health record in a rural primary care clinic. The project leader met with a nurse practitioner from the clinic on February 3, 2016. The nurse practitioner reports that a large percentage of the patient population seen at the clinic are chronic pain patients and himself and the other two providers, find difficulty monitoring this particular population. These patients are managed at this rural clinic, as a specialized pain clinic does not exist within network and referrals to outside facility are not always feasible based on patient's schedules, long wait-lists at the clinics, psychosocial background, and transportation issues.

The clinic and larger healthcare system the clinic falls under uses AllScripts for their electronic medical record. Based on the current desktop and available templates for charting office visit notes, the project leader in collaboration with Hohman determined that a chronic pain flow sheet along with a pain visit template had the greatest potential to provide benefit in caring for this patient population.

The flow sheet was made easily accessible from the patient's chart desktop. Elements of the flow sheet were beneficial to chronic pain patients and in congruence with evidence-based practice. These elements included dates of last pain contract signed, prescription monitoring program checked, last urine drug screen, and last pain visit. A pain visit template was added to the office visit note and contained a combination of the Brief Pain Inventory (Appendix E), a pain assessment filled out by the patient prior to the start of the visit, and the 4 A's of chronic pain, which include analgesia, activity, adverse effects, and aberrant behaviors. The tools were

created in collaboration with the computer information services (CIS) team at the healthcare organization.

The project leader sought approval and chart access through the human resources department by completing background checks and providing any requested information. The providers at the clinic were sought after for approval to use the flow sheet in a percentage of their chronic pain patients.

Following approval of the proposal and the Internal Review Board, implementation of the project began. Implementation involved surveying the three providers (including a physician, nurse practitioner, and physician's assistant) regarding their current practice of caring for chronic pain patients. The providers along with nurses received notification that the pain visit template was available along with how to update information in the flow sheet after the writer performed the initial data input.

The majority of the project implementation entailed the project leader taking the provided sample set (a percentage of chronic pain patients seeking care at the clinic) and assessing what elements the patients were lacking and inputting the dates into the created flow sheet. Specific statistical data and information regarding chronic pain patients' needs were given to the providers and nursing staff.

After a six-month timeframe, a chart review of the exact same patients in the sample was performed to assess if a greater percentage of the elements were present, if the flow sheet was manually updated, and if the pain visit template was utilized. A follow-up survey was again delivered to the three providers.

Timeline of Project Phases

February:

- Key informant interview with nurse practitioner from the clinic
- Meeting with CIS department
- Design of Pain Visit Template and Chronic Pain Flow Sheet in collaboration with CIS
- Obtain chart access through human resources department

March:

- Memo of Understanding and Agency Letter of Agreement signed by lead physician
- Proposal Meeting

April:

- IRB Approval

May:

- Provider surveys/interview with the providers
- Meeting with the CIS department

June:

- Initial chart review and data input

August:

- Halfway point check-in

December:

- Chart review and data collection

January:

- Dispensed post-implementation surveys

March 2017:

- Final dissertation written
- Dissertation defense

Resources

Resources for this project included providers, nurses, and CIS specialists from the clinic and healthcare organization. Technology resources included remote access to the electronic health record and approval to use this access from the human resources department. No financial resources or outside funding was required to implement this practice improvement project.

Protection of Human Subjects

The practice improvement project entailed virtually no risk to patients as the project did not involve any direct contact with patients. Patient medical records were accessed using a secure log in and information was not shared with any other parties. Data collection was done in a way that patients were not identifiable within the data collection record. No HIPPA violations occurred during this practice improvement project.

The potential benefits of this project largely outweigh the risks. This practice improvement project aimed to improve the safety of opioid prescribing and monitoring of chronic pain patients. Important knowledge gained from this project was identifying current gaps in chronic pain patients seeking opioids at a rural clinic and providing tools to decrease those gaps in practice.

Institutional Review Board Approval

Approval for protocol #PHI16232 was received from the North Dakota State University Institutional Review Board (Appendix D). The surveying of the providers fell under the exempt

category for IRB approval. The chart review and data input portion of the project fell under the expedited category #5.

Methods

A meeting was held with the providers at the clinic. The meeting began with the providers completing the survey (Appendix B) followed by an open discussion regarding the use of opioids and the monitoring of opioid prescriptions within their current practice.

The project leader reviewed all the current pain visit templates available within the All Scripts electronic charting system. After reviewing the templates, provider preference, and the research on the documentation requirements for chronic pain visits, a rough draft pain visit template was designed. After discussing with members of the CIS team about the capabilities of having a chronic pain flow sheet, a chronic pain flow sheet was designed. Elements of the flow sheet was determined by the published evidence-based guidelines stating the recommended parameters to monitor in chronic pain patients.

With the creation of the pain visit templates and chronic pain visit rough drafts, the project leader along with committee member, Adam Hohman, DNP, met with the CIS department. The CIS department was able to collaborate with the project leader and within one week, produce the pain visit template and chronic pain flow sheet and make it available for the clinic providers to use within the electronic medical record.

The next step of the project was performing the initial chart review and inputting the data into the flow sheet. The sample for this project included adults aged 18 years and older seeking chronic pain management from the designated clinic. The patients were selected primarily from the use of the Minnesota Prescription Drug Monitoring Program Database. The sample size totaled sixty-one patients. Patients were assigned a number in order to maintain confidentiality.

Approximately one month following the initial data input, the project leader touched base with the providers to ensure they were aware of how to make use of the flow sheet and the pain visit template. Questions and concerns were addressed at that time.

Six months after the initial chart review and data entry, a final chart review was performed of the same original sample. Monitoring parameters were compared to see if chronic pain patients were more closely monitored and recommended documentation was in place. Providers were issued another survey (Appendix C) that resembled the initial pre-implementation survey and also asked questions regarding their use of the flow sheet and pain visit template.

Data Includes: All		03 Aug 2016	27 Jun 2016
Item Name	Select	1	1
Pain contract signed and filed...	<input type="checkbox"/>		2-11-16
Last prescription drug...	<input type="checkbox"/>		6-8-16
Last urine drug screen (every...	<input type="checkbox"/>	8-3-16	7-7-15
Last pain visit (every 3-4...	<input type="checkbox"/>	8-3-16	6-8-16

Figure 2. Example of the Chronic Pain Flow Sheet

CHAPTER FIVE. EVALUATION

The evaluation plan for this project involved individually evaluating the objectives.

Evaluation of Objective One

The first objective was to assess the providers' perception of their current chronic pain management process in regards to usability, efficiency, and overall comfort level in caring for the chronic pain patient population. Objective one was evaluated based on surveys administered to the three providers at the clinic during the initial implementation of the project and at final review of the project. Comparisons of the survey were made to determine if this project improved providers' comfort level in regards to safe opioid prescribing practices and made the monitoring of their chronic pain patients easier and more comprehensive. See Appendix B and C for pre and post-implementation provider surveys.

Evaluation of Objective Two

The second objective was to create and implement evidence-based chronic pain documentation and monitoring tools to be used within the electronic health record. Tools included a template to be used when documenting a pain visit along with a flow sheet to easily monitor important parameters of chronic pain patients. Objective two was evaluated by determining the presence or absence of the elements of chronic pain management in the patient sample. These statistics were taken at the initial phase of the project implementation and compared to a six-month chart review. The project leader aimed for the final evaluation to show a higher percentage of elements were completed on the sample of chronic pain patients. The six-month chart review also revealed if the template was utilized and the flow sheet updated appropriately. Another piece of evaluating this objective was performed via a questionnaire to

the providers simply asking if the created tools were useful and beneficial to practice (see Appendix C).

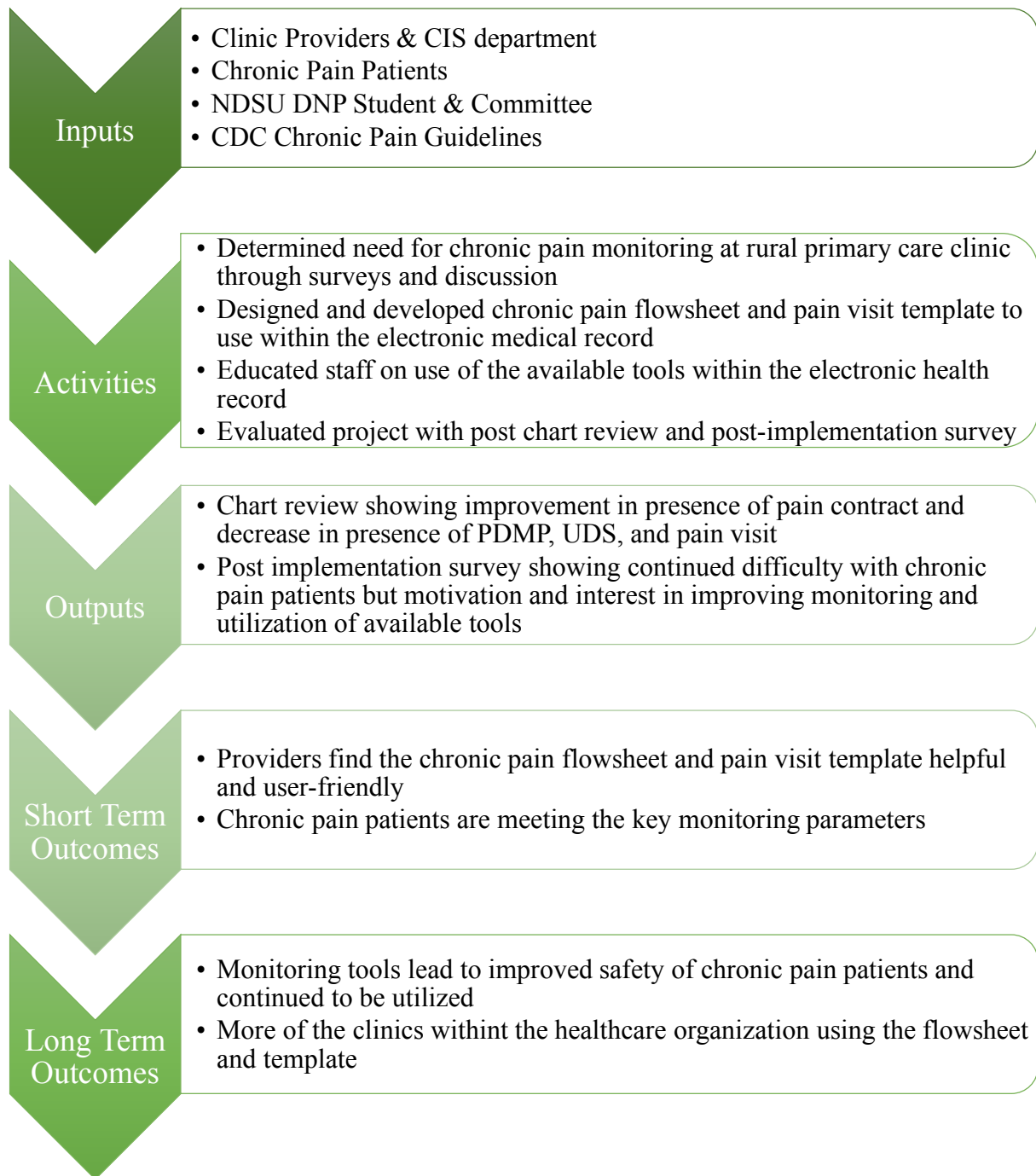


Figure 3. Logic Model

CHAPTER SIX. RESULTS

The practice improvement project involved analyzing two aspects of chronic pain monitoring in patients receiving care at the designated rural clinic. The first was collecting qualitative data regarding the providers' current perception of their chronic pain patients and the monitoring of their care and how that perception may have changed after the implementation of this project. The second part of this project was the design and implementation of a chronic pain flow sheet and pain visit template. Using evidence-based research, the project leader determined the important monitoring parameters of patients with chronic pain and performed an initial chart review and inserted the data into the flow sheet. The project leader then performed a six-month chart review to determine if the monitoring parameters were met and if there was an overall improvement in the monitoring of chronic pain patients.

Pre-Implementation Provider Survey Results

A pre-implementation survey (Appendix B) was dispensed to the three providers at the clinic on May 31, 2016. An open discussion was held after the survey portion was filled out between the project leader and the providers.

The first question of the survey asked about the current level of satisfaction with the monitoring of chronic pain patients and providers responded based on a scale from 1-5, with 5 being extremely satisfied and 1 being not at all satisfied. One provider felt slightly satisfied (score of 2) and the other two felt moderately satisfied (score of 3).

The second question was of multiple parts, asking providers to answer the questions in a form of a percentage, based on their current chronic pain patients having certain parameters in place. Two providers felt 60-80% of their patients had a signed pain contract within the last year, one provider felt only 41-60% had a contract. Two providers thought 61-80% of their chronic

pain patients had a urine drug screen performed within the last six months, and one provider felt 21-40% of his/her patients had this performed. Two providers felt that 0-20% of their patients had their pharmacy drug monitoring program checked with the last pain prescription, and one provider felt 21-40% of their patients had their PDMP checked with the last prescription. When asked if a patient had a pain visit within the last 3-4 months, two providers felt 61-80% of their patients had a pain visit within that time frame and one provider felt 81-100% of his patients met this criterion.

The third question of the survey targeted the providers' feelings regarding the electronic health record (EHR) and its usability for searching for monitoring elements of chronic pain patients. This question was answered on a scale from not at all to extremely user-friendly. One provider felt the EHR was not easy to use at all, one provider felt it was slightly user-friendly, and the last provider felt it was moderately user-friendly. The fourth question asked how the providers document pain visits and options included: free text, dictate, use a template, every patient is different, and other. Two providers chose dictate and one provider chose free text.

The fifth question of the survey asked providers about their current level of satisfaction in regards to the system's ability to allow for pain visits to be easily documented and ensure they cover all the necessary elements of pain assessments (analgesia, activities of daily living, adverse effects, aberrant behaviors, and affect). One provider felt not at all satisfied with the system and two providers felt only slightly satisfied with the current system.

The final three questions of the survey were open-ended and allowed for individual answers and opinions. Question six simply asked, "What is going well currently with your chronic pain management in your practice?". Answers included, "using forms from paper charts", "dictating notes", and "printing Rx's". One provider said, "we are decreasing the amount

of people and dosages on many of the patients” and also mentioned “using PT, massage, topicals, etc. instead”.

The seventh question of the survey inquired about the barriers and concerns providers have with chronic pain management in their practice. Providers responded with “vague structures from regulating agencies”, “EHR issues”, and “lack of consultants to review patients needs and care plan”. Other barriers or concerns mentioned were “no good tracking system here with prescriptions- Sanford has prescription monitoring where they are automatically generated monthly and tracked by a nurse”, “finding data in EHR pertaining to pain visit”, and “charts being flagged as pain contract present”.

The final question on the survey that led to open discussion was “what other comments do you have?”. Providers mentioned frustrations with having no second opinion available regarding their chronic pain patients, guidelines being difficult to follow and treat patients accordingly, and feeling that the practice of treating chronic pain is difficult. Providers also mentioned the change in practice over the past twenty years. For example, twenty years ago providers were encouraged to push medications and if a provider did not treat pain, they were considered a bad provider. Now, regulatory agencies are enforcing providers to reduce or stop opioids at all costs. One provider stated “a flow sheet would be very helpful”.

Results of Initial Chart Review

During the month of June, the project leader performed an initial chart review of 61 chronic pain patients seeking treatment at the clinic. Data collected on each patient included pain contract signed and filed within the last year, last prescription drug monitoring program checked, last urine drug screen, and last pain visit. Data analysis was performed to determine the percentage of patients that met each parameter along with determining how many patients met

multiple parameters. Patients were assigned a number that is not-identifiable and no demographic information was collected.

Data analysis on the presence of a pain contract signed and filed showed that 24.59% of patients did have a signed contract within the EHR. Of that percentage, 19.67% had a contract that was done within the last 12 months. Fifty-five point seventy-four percent of patients did not have an electronically filed pain contract but did possibly have a paper chart copy. The remaining patients either did not have a pain contract at all (11.48%) or required an updated contract (8.20%), meaning there was not a paper copy or the contract was void since it was not the most recent pain contract version.

Next, the project leader looked at whether or not the prescriber checked the prescription drug monitoring program. This statistic is limited in the fact that unless the provider charted that they checked the PDMP, the project leader assumed it was not checked. Research showed that 22.95% of patients had their PDMP checked and it had been done within the last six months. However, over three-fourths (77%) of charts showed the prescriber never checked the patient's PDMP.

Ideally, urine drug screens are completed on chronic pain patients every six months. The project leader's initial chart review revealed 36.1% of patients had a urine drug screen on record, and 26.2% of patients had a urine drug screen performed within the last six months. The majority of patients (63.9%) had no urine drug screen on file.

Pain visits were present in the majority of chronic pain patients and 72.1% were done in the last four months. However, 3.3% of chronic pain patients did not have a documented pain visit.

As stated above, guidelines and regulatory agencies recommend that all of the measured parameters be met in every chronic pain patient to ensure treatment is done safely and efficiently. Criteria used for this data analysis included: pain contract within the last 12 months, PDMP within the last six months, UDS within the last six months, and pain visit within the last four months. Data analysis revealed that only 8.2% of chronic pain patients met all four parameters, 11.5% met three parameters, 16.4% met two parameters, 44.3% met one parameter, and 19.7% did not meet any of the monitoring parameters.

Post-Implementation Provider Survey Results

A post-implementation survey (Appendix C) was distributed to the providers at the clinic on January 12, 2017. After the surveys were dispensed, an open forum discussion took place. Providers were also informed of the results of the data analysis from the chart review, as described in the next section.

The following graphs (Figures 4 and 5) show the comparison of the survey questions 1, 2, 3, and 5.

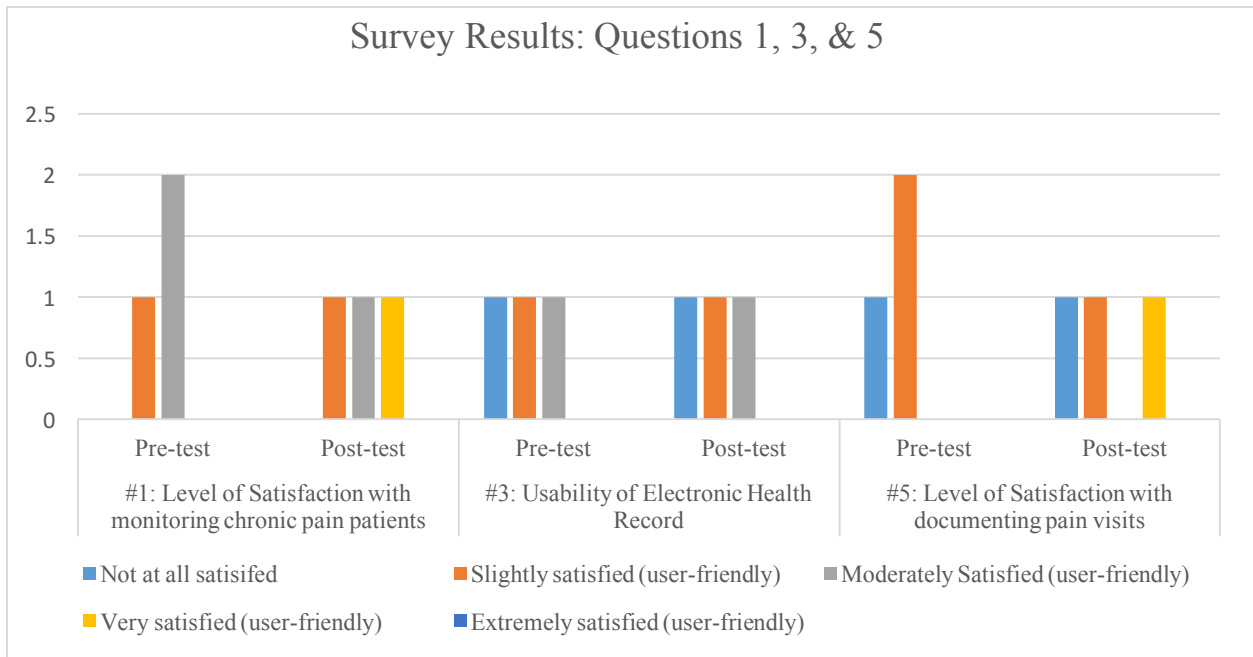


Figure 4. *Survey Results: Questions 1,3,5*

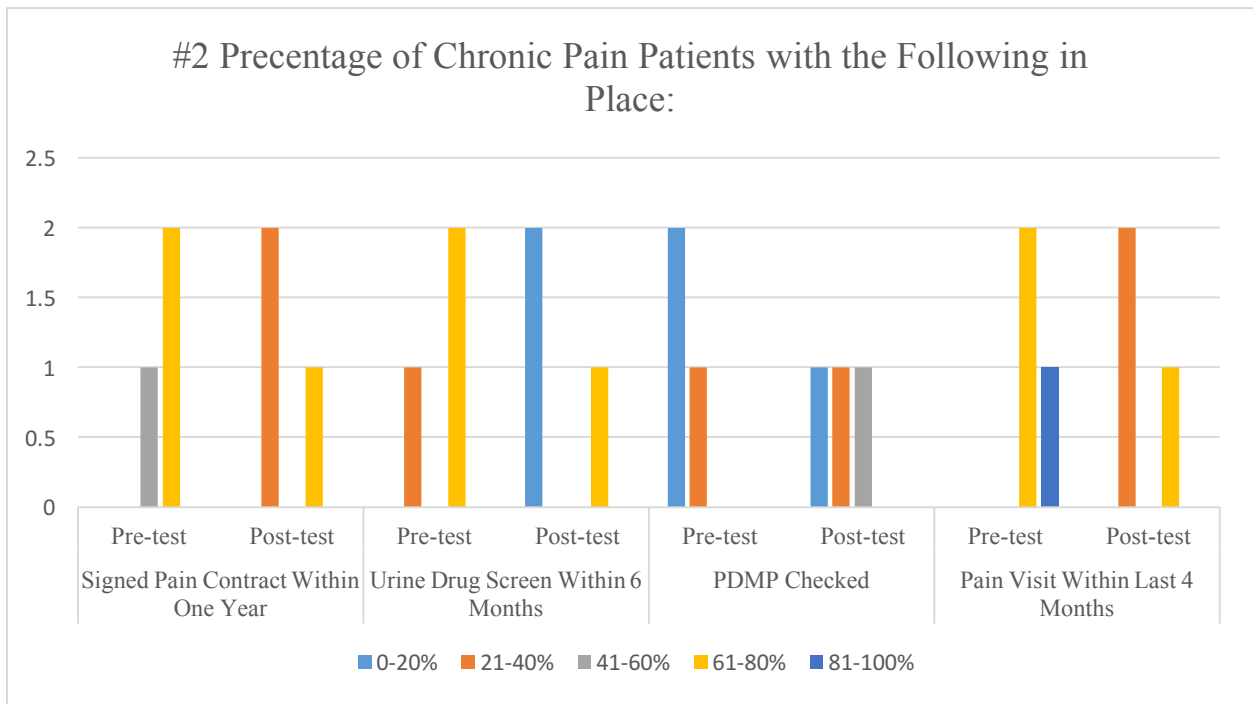


Figure 5. *Survey Results: Question 2*

The fourth question asked how the providers document pain visits and options included: free text, dictate, use a template, every patient is different, and other. One provider chose free text, one chose dictate, and the last provider chose using a template.

Question six simply asked, “What is going well currently with your chronic pain management in your practice?”. Answers included, “utilizing chronic pain flow sheet to track patients and patients’ cooperation with contract”. One provider responded with “nothing got easier with the electronic health record”. Other responses included “weaning people off”. This provider also stated “I do not have many and they have done everything I have asked and are compliant”.

The seventh question of the survey inquired about the barriers and concerns providers have with chronic pain management in their practice. Providers responded with “non-compliance, selling instead of taking”. Other barriers or concerns mentioned were “regulators” and “lack of my accountability to get patients in for appointments along with difficulty getting patients into pain clinic at times due to long visits”.

The eighth question on the survey asked about the frequency of use of the chronic pain flow sheet on a scale of never to every time. One provider selected every time, one selected never, and another selected almost never. The ninth question asked about the frequency of the use of the pain visit template. Responses included never, almost never, and almost every time (if started by nursing at the beginning of the visit). The tenth question asked about the likelihood of continuing use of the flow sheet and template on a scale of extremely unlikely (1) to extremely likely (5). Two providers were neutral in responding to this question and the third provider responded as being extremely likely to continue the use of the designed tools.

The survey asked for suggestions on how to make the flow sheet and pain visit template more efficient and user-friendly. One provider suggested, “have EHR built in to auto populate some of the info”. Another provider simply stated “big big task”. These comments suggest providers feel overwhelmed with monitoring chronic pain patients and feel their EHR could help with this task. The final question of the survey asked for any comments providers have. Comments included “need to do better job on my part of re-emphasizing to nurses to use template”, and “it is difficult to separate pain treatment from non-pain care”.

After the surveys were completed and data analysis results shared, the providers and project leader discussed chronic pain patients, the monitoring tools within the chart, and areas for improvement. One of the biggest barriers identified was seeing a patient solely for their pain visit. Often patients come in for their multiple chronic diseases and at the same time, their chronic pain is addressed. One of the providers suggested a policy change that requires patients to come in for a pain visit and patients are under the understanding that they can only discuss their chronic pain at that visit.

Ideas were discussed on ways to improve the overall monitoring process such as involving pharmacists in checking the PDMP and utilizing nursing staff more for tasks such as checking the PDMP and updating the out of date pain contracts. Also, providers mentioned changing their own habits in ensuring they are documenting when they check the PDMP and also updating the information within the flow sheet. Providers also requested printed out instructions in the room as to how to implement the flow sheet and template within their patient’s chart.

Overall, providers appeared motivated to improve the monitoring of their chronic pain patients and to take advantage of the tools available to them within the electronic health record. Time is always an issue for busy primary care providers, so working on making the

documentation of these elements a habit, along with delegating to appropriate parties for help, could increase the percentages of patients meeting all the required parameters. In the end, the providers admitted “I need to start using it, I need to get better”.

Results of Final Chart Review

Approximately six months after the initial chart review was performed and the chronic flow sheet was made available within the electronic health record, the project leader performed a final chart review using the same panel of chronic pain patients. This post chart review aimed to see that these identified chronic pain patients at the clinic possessed the recommended monitoring parameters in their medical record.

During the month of December, the project leader determined if the patients had a signed and filed pain contract within the last 12 months, the prescription drug monitoring program checked within the last six months, a urine drug screen within the last six months, and finally, if a documented pain visit was performed within the last four months.

For the initial chart review, the sample size was 61 chronic pain patients. For the final chart review, the sample size decreased to 52 chronic pain patients. The decreased sample size is due to patients' chronic pain contract (and prescription of opioids) being discontinued for various reasons. Reasons included mental health disorders, terminal illness, inappropriate urine drug screens, and safety concerns related to elderly and chronic opioid use.

Data analysis on the presence of a signed and filed pain contract within the last 12 months showed 25% of chronic pain patients met this criterion. The remaining 75% of the chronic pain patients either had an outdated pain contract or did not possess a pain contract that was visible within the electronic health record. During the initial chart review, 19.67% of chronic pain patients had a pain contract signed and filed within the last 12 months. Therefore, the clinic

saw a 5.33% increase in chronic pain patients possessing a valid pain contract within the medical record.

The next parameter measured determined if the PDMP was checked within the last six months. This data was retrieved by looking at the chronic pain flow sheet and/or looking at the last pain visit to see if the provider documented checking the PDMP. In reviewing the charts, the project leader found 11.5% of chronic pain patients had their PDMP checked within the last six months. The resulting percentage dropped from 22.95% during the initial chart review. The remaining 88.5% of patients had no documentation within their medical record that the PDMP had ever been checked or greater than six months had passed.

Guidelines recommend checking a urine drug screen every six months. To determine if this testing was done on the project sample, the project leader referred to both the chronic pain flow sheet and the lab results. The results showed 21.2% of patients completed a urine drug screen within the last six months. In comparing those results to the initial chart review, the sample showed an approximate 5% decrease in patients meeting the six months' criteria for UDS.

The final parameter determined if a pain visit was performed within the last four months. Data analysis revealed 69.2% of patients met this criterion. This data was collected by checking both the chronic pain flow sheet and looking through the medical record at previous visits. Analysis from the initial review and comparing the results to the final review show a 2.9% decrease in chronic pain patients having a pain visit within four months.

As performed in the initial chart review, the project leader again determined how many of the four identified parameters each patient met. Four of the fifty-two patients met all four parameters, or 7.7% of the sample population. Three parameters were met in 5.8% of the sample

population, 19.2% met two of the parameters, and 46.2% of the population met only one parameter. A total of 11 patients, or 21.2%, did not meet any of the monitoring parameters.

CHAPTER SEVEN. DISCUSSION AND RECOMMENDATIONS

The results of the practice improvement project show the importance and the necessity of monitoring and documenting tools in regards to care of the chronic pain patients at the rural clinic. However, based on the chart review statistical analysis of the data, the developed chronic pain flow sheet was not as effective as anticipated by the project leader. One provider was very actively involved in this project and seemed to utilize the tools created more than the other two providers. The survey does show providers feel the need to improve the monitoring of their chronic pain patients and see the potential benefit in better utilizing the flow sheet and template.

Project Limitations

After designing, implementing, and evaluating the practice improvement project, the project leader identified several limitations of the project. The pain visit template was designed to make the electronic health record more user-friendly in the documentation of pain visits and allow for the provider to easily assess and document all the areas of chronic pain management. Chart review and provider discussions revealed the pain visit template was only utilized if the nursing staff opened the note prior to the provider seeing the patient. More education with nursing staff regarding how and when to open a patient's chart with the pain visit template may have improved template utilization.

The provider dissatisfaction with the electronic health record is not unique to the healthcare organization utilized in the project. A survey of 146 primary care providers regarding the "meaningful use" of the electronic health record showed overall dissatisfaction and suboptimal use of the key functions of the EHR. The study showed large potential for improvement in regards to reliability and accuracy of the EHR and helping providers use their time more efficiently (Makam et al., 2013).

The chart review information primarily came from reviewing the chronic pain flow sheet. The data input needed to be done manually in the chronic pain flow sheet. For example, a date may not have been updated in the flow sheet for the last PDMP checked, but the check was truly done, the provider simply did not input the new date. Another consideration is that the flow sheet and the information requested may simply have been used as a reminder for providers. Although the data was not updated, it may have been queuing providers to ensure they were checking those important elements.

Another limitation for this project is the fact that all patients are unique, and chronic pain patients are no exception. It may not be possible for all patients to meet all the recommended monitoring parameters. For example, a chronic pain patient with chronic kidney disease may have difficulty providing a urine sample. Also, chronic pain patients typically have other comorbidities. So, it may appear that a pain visit was not performed, even if their chronic pain was addressed in combination with several other chronic health problems.

Providers can perform many interventions on their end to ensure safe and effective chronic pain management. However, the patients also need to take an active role in their care. Unfortunately, sometimes patients do not follow-up or comply with the recommendations to be seen frequently. Due to lack of follow-up, this may be seen as a limitation for this project and result in lower than expected data analysis results.

A final consideration for this project may be the difference in providers and possibly generational characteristics. As stated above, it was once thought that a provider was considered “bad” or “negligent” if he/she did not adequately treat their patient’s pain. What was once considered “the fifth vital sign” has turned into an area that needs careful consideration to avoid detrimental consequences. Not only do viewpoints of pain management differ among the

generations of providers, so does the comfort level with technology. Seasoned providers may not feel as comfortable with new tools within the electronic health record or take less of an initiative to change their current documentation practices.

Limitations of this project were anticipated due to the magnitude of the task at hand. Opioid abuse and chronic pain are difficult for primary care to manage, not only at the designated clinic but primary care practices around the country. A study was conducted on a select group of primary care providers in the Boston metro area to determine presence of benefits of interventions to track compliance with opioid medications prescribed to patients with non-cancer chronic pain. Patients were monitored on a monthly basis via a telephone call and providers were given questionnaires regarding their chronic pain practice (Jamison, Scanlan, Matthews, Jurcik, & Ross, 2016).

Despite these monthly monitoring interventions on patients and opioid education for providers, many primary care providers remained concerned about opioid addiction and dependence but did feel pleased their patients were closely monitored. Patients did have better compliance with their opioid medication and felt the monthly monitoring was beneficial. Overall, providers felt chronic pain patients were stressful to deal with. Results of this study, similar to those of the described practice improvement project, show need for continuing education for primary care providers and close monitoring of chronic pain patients (Jamison, Scanlan, Matthews, Jurcik, & Ross, 2016).

Recommendations for Project Site

Despite data analysis not showing improvement in chronic pain monitoring parameters, the project leader recommends this project be continued at the rural clinic and expand to the larger healthcare system. Further education needs to occur on both the nursing and provider level

to improve the usage of the pain visit template and chronic pain flow sheet. Collaboration with the CIS department may improve compliance with the chronic pain flow sheet by finding a way to allow the fields of the chronic pain flow sheet to be automatically filed. For example, any time a urine drug screen is resulted for a pain patient that has a chronic pain flow sheet open within the chart, the date of the drug screen is automatically inputted into the flow sheet. A multidisciplinary approach has the greatest potential for reaching the desired outcome of improved chronic pain monitoring.

Despite the data analysis not showing overwhelming improvement in chronic pain monitoring, the project leader does think the pain visit template and chronic pain flow sheet have the potential to help primary care providers manage their chronic pain patients. Because these tools were developed within AllScripts, the tools are available to not only the rural clinic, but the entire healthcare network. This project has the potential to positively impact the practice of several providers and may result in a network-wide improvement in the management of chronic pain patients. Considering opioid abuse and chronic pain is at the forefront of medicine and considered a national priority to reduce its negative effects, primary care providers may find it imperative and beneficial to utilize the tools created.

The project leader suggests the clinic continues this project and expand its usage through further education and guidance. The provider that was very familiar with the available tools should create “cheat sheets” for the other providers to show them how to access the available tools within the electronic records of their chronic pain patients. Also, nursing staff should be educated in these interventions and be delegated to seek out updated pain contracts for patients. Nursing staff may also be given delegate access to check the PDMP and provide open communication among nursing staff and providers.

Incentives for providers at the clinic to continue this project include mandates derived from the state level. In March of 2016, Minnesota developed the Opioid Prescribing Work Group to reduce opioid dependency and substance use by Minnesotans. Tasks set forth by this group include recommending protocols that address all phases of the opioid prescribing cycle, improving providers' education on use of opioids, and implementing quality-improvement measures in clinical practice (Minnesota Department of Human Services, 2016).

Whether continuation of this quality improvement project or implementing new quality improvement projects, future project leaders can take steps to improve health behavior interventions in a primary care setting. The following recommendations derived from a study conducted through the Robert Wood Johnson Foundation's Prescription for Health. The first step is for the project leader to have a better understanding of the practice's organization. Secondly, collaborating with the multidisciplinary team can help clinicians identify patients who need change and assist clinicians in working towards that positive change. Lastly, the project leader should include a goal of implementing long-term and sustainable quality improvements (Cohen, Tallia, Crabtree, & Young, 2005).

Implications for Practice and Future Research

Results of this practice improvement project were disseminated to multiple audiences in various forms. A poster presentation with available data analysis statistics was presented at the North Dakota Nurse Practitioner Association Pharmacology Conference in September 2016. The project leader also wrote and delivered a three-minute synopsis of the project to a non-healthcare audience during the Three Minute Thesis Competition held at North Dakota State University in February 2017. A final poster was also created by the project leader and presented at the Health Professions poster presentations in March 2017 at North Dakota State University.

Upon evaluation of this project, the project leader found areas where this could improve the primary care provider's management of chronic pain, but also areas for improvement to further enhance its use in practice. Monitoring is essential and having proper documentation of the evidence-based recommendations of chronic pain monitoring could only help providers, especially if litigation or safe practices ever came into question. However, it is also important to utilize the electronic health record to its full potential so these tools are improving efficiency and effectiveness, without increasing workload and documentation time of already stressed and overworked providers. Proper utilization of the EHR has many benefits including cost containment, error reduction, and improved compliance through clinical decision support and recommendations (Rothman, Leonard, & Vigoda, 2012).

Future research related to this practice improvement project should include continued evidence on ways to best monitor and care for the chronic pain population. Obtaining viewpoints of chronic pain patients could reveal important insight and may inspire new ways to improve compliance and cooperation. Another avenue to consider is reviewing the daily morphine equivalents of chronic pain patients to ensure providers are complying with the latest guidelines. Dangerous side effects, even death, are often related to an over-escalated dosing of opioid medications. Evidence suggests the risk for drug-related adverse events is higher in individuals prescribed opioids at doses equal to 50mg or more per day of morphine. Research has shown a direct correlation between maximum prescribed daily dose of opioids and risk for overdose death (Bohnert et al., 2011).

Application to Other Doctor of Nursing Practice Roles

The design, development, implementation, and evaluation of this project utilized all roles considered essential for the Doctor of Nursing Practice (DNP). This role required leadership in

taking initiative to improve clinical practices with the end goal of positively influencing patient care. In combination with assisting providers in caring for chronic pain patients, this project inspired the project leader to be an advocate for chronic pain patients in ensuring their right to safe and effective pain management was being met. Continued education is another essential role for the DNP and throughout this process, the project leader was constantly learning and examining new research and evidence-based guidelines. Lastly, health promotion and prevention is an area where DNPs excel. Improving chronic pain management to improve overall health and prevent poor health outcomes was the overarching goal of this entire project.

REFERENCES

- Anson, P. (2016). CDC: Prescription opioid abuse costs \$78.5 billion. *Pain News Network*. Retrieved from <https://www.painnewsnetwork.org/stories/2016/9/15/cdc-prescription-opioid-abuse-costs-785-billion-annually>.
- Birnbaum, H., White, A., Schiller, M., Waldman, T., Cleveland, J., & Roland, C. (2011). Societal costs of prescription opioid abuse, dependence, and misuse in the United States. *Pain Medicine, 12*(4), 657-667.
- Bohnert A., Valenstein, M., Bair, M., Ganoczy, D., McCarthy, J., Ilgen, M., & Blow, F. (2013). Association between opioid prescribing patterns and opioid overdose-related deaths. *Journal of American Medical Association, 305*(13), 1315-1321.
- Brooks, M. (2015). Drug overdose now leading cause of injury-related deaths. *Medscape*. Retrieved from http://www.medscape.com/viewarticle/846636_print.
- Butler, S., Fernandez, K., Benoit, C., Budman, S., & Jamison, R. (2008). Validation of the revised screener and opioid assessment for patients with pain (SOAPP-R). *The Journal of Pain, 9*(4), 360-372.
- Centers for Disease Control and Prevention. (2016). CDC guideline for prescribing opioids for chronic pain- United States, 2016. *Morbidity and Mortality Weekly Report, 65*(1), 1-49.
- Cohen, D. J., Tallia, A. F., Crabtree, B. F., & Young, D. M. (2005). Implementing Health Behavior Change in Primary Care: Lessons From Prescription for Health. *Annals of Family Medicine, 3*(Suppl 2), s12-s19.
- Corbin, J. & Strauss, A. (1991). A nursing model for chronic illness management based upon the trajectory framework. *Scholarly Inquiry for Nursing Practice, 5*, 155-174.

- Doody, C., Doody, O. (2011). Introducing evidence into nursing practice: Using the IOWA model. *British Journal of Nursing*, 20(11), 661-664.
- Fisherman, S. (2012). *Responsible opioid prescribing: A guide for Michigan clinicians*. Washington, D.C.: Waterford Life Sciences. 3
- Granger, B., Moser, D., Harrell, J., Sandelowski, M. & Ekman, I. (2007). A practical use of theory to study adherence. *Progress in Cardiovascular Nursing*, 22, 152-158.
- Harris, J. (2008). Management of expected and unexpected opioid-related side effects. *The Clinical Journal of Pain, Supplement 10*, S8-S13.
- Jamison, R., Butler, S., Budman, S., Edwards, R., & Wasan, A. (2010). Gender differences in risk factors for aberrant prescription opioid use. *The Journal of Pain*, 11(4), 312-320.
- Jamison, R. N., Scanlan, E., Matthews, M. L., Jurcik, D. C., & Ross, E. L. (2016). Attitudes of Primary Care Practitioners in Managing Chronic Pain Patients Prescribed Opioids for Pain: A Prospective Longitudinal Controlled Trial. *Pain Medicine*, 17(1), 99-113.
- Jones, R., Spradlin, A., Robinson, J., & Tragesser, S. (2014). Development and validation of the opioid prescription medication motives questionnaire: A four-factor model of reasons for use. *Psychology of Addictive Behaviors*, 28(4), 1290-1296.
- Katz et al. (2010). Usefulness of prescription monitoring programs for surveillance- analysis of Schedule II opioid prescription data in Massachusetts, 1996-2006. *Pharmacodepidemiology and Drug Safety*, 19, 115-123.
- Makam, A. N., Lanham, H. J., Batchelor, K., Samal, L., Moran, B., Howell-Stampley, T., & ... Halm, E. A. (2013). Use and satisfaction with key functions of a common commercial electronic health record: a survey of primary care providers. *BMC Medical Informatics & Decision Making*, 13(1), 1-7.



- Manchikanti, L., Abdi, S., Atluri, S., Balog, C., Benyamin, R., Boswell, M., ... Wargo, B. (2012). American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain: Part 2- Guidance. *Pain Physician, 15*, S67-S116.
- Manchikanti, L., Atluri, S., Trescot, A., & Giordano, J. (2008). Monitoring opioid adherence in chronic pain patients: Tools, techniques and utility. *Pain Physician, Special Issue 11*, 1-26.
- Minnesota Department of Human Services. (2016). Opioid Prescribing Improvement Program. Retrieved from <http://www.mn.gov/dhs-stat/images/opioid-prescribing-improvement-program.pdf>.
- Minnesota Prescription Monitoring Program. (2015). General Program FAQ's. Retrieved from www.pmp.pharmacy.state.mn.us.
- Moore, T., Jones, T., Browder, J., Daffron, S., & Passik, S. (2009). A comparison of common screening methods for predicting aberrant drug-related behavior among patients receiving opioids for chronic pain management. *Pain Medicine, 10*(8), 1426-1433.
- PDMP Center for Excellence. (2014). *Mandating PDMP participation by medical providers: Current status and experience in selected states*. Retrieved from http://www.pdmpexcellence.org/sites/all/pdfs/COE_briefing_mandates_2nd_rev.pdf.
- Rich, B. & Webster, L. (2011). A review of forensic implications of opioid prescribing with examples from malpractice cases involving opioid-related overdose. *Pain Medicine, 12*, S59-S65.
- Rothman, B., Leonard, J. C., & Vigoda, M. M. (2012). Future of Electronic Health Records: Implications for Decision Support. *Mount Sinai Journal of Medicine, 79*(6), 757-768.

- Schneider, J. (2014). Opioid prescribing part 2: Appropriate documentation of follow-up visits. *Practical Pain Management*, 36-39. Retrieved from <http://www.jenniferschneider.com/pdf/OpioidPrescribingPart2Schneider.pdf>.
- The Office for Human Research Protections. (2016). Human subjects regulations decision charts. *U.S. Department of Health & Human Services*. Retrieved from <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c2>.
- U.S. Department of Justice: Drug Enforcement Administration. (2011). State Prescription Drug Monitoring Programs. Retrieved from http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm.
- Warner, M., Chen, L., Makuc, D., Anderson, R., & Minino, A. (2011). Drug poisoning deaths in the United States, 1980-2008. *NCHS Data Brief*, 81. Retrieved from www.cdc.gov/nchs/data/databriefs/db81.pdf.
- Wasan, A., Ross, E., Michna, E., Chibnik, L., Greenfield, S., Weiss, R., & Jamison, R. (2012). Craving of prescription opioids in patients with chronic pain: A longitudinal outcomes trial. *The Journal of Pain*, 13(2), 146-154.

APPENDIX A. PERMISSION TO USE IOWA MODEL

Reply all Delete Junk

Permission to Use and/or Reproduce The Iowa Model

 Kimberly Jordan - University of Iowa Hospitals and Clinics <noreply@qemailserver.com>
To:  Jenna Wallace;

Reply all

Mon 3/2/2015 7:19 PM

PIP: Opioids

| Action Items

You have permission, as requested today, to review/use *The Iowa Model of Evidence-Based Practice to Promote Quality Care (Titler et al., 2001)*. Click the link below to open the model.

Copyright of the Iowa Model of Evidence-Based Practice to Promote Quality Care will be retained by The University of Iowa Hospitals and Clinics.

Permission is not granted for placing the Iowa Model on the internet.

[The Iowa Model](#)

In written material, please add the following statement:

- *Used/Reprinted with permission from the University of Iowa Hospitals and Clinics and Marita G. Titler, PhD, RN, FAAN. Copyright 1998. For permission to use or reproduce the model, please contact the University of Iowa Hospitals and Clinics at (319)384-9098.*

If you have questions, please contact Kimberly Jordan at 319-384-9098 or kimberly-jordan@uiowa.edu.

APPENDIX B. PRE-IMPLEMENTATION PROVIDER SURVEY

1. What is your current level of satisfaction with the monitoring of chronic pain patients?
 - 1- Not at all satisfied
 - 2- Slightly satisfied
 - 3- Moderately satisfied
 - 4- Very satisfied
 - 5- Extremely satisfied

2. To your best knowledge, what percentage of your chronic pain patients have the following in place:
 - Signed Lake Region Healthcare Pain Contract within last year
 - 0-20 %
 - 21-40%
 - 41-60%
 - 61-80%
 - 81-100%

 - Urine drug screen within last 6 months
 - 0-20 %
 - 21-40%
 - 41-60%
 - 61-80%
 - 81-100%

 - Pharmacy Drug Monitoring Program checked with last prescription refill/renewal
 - 0-20 %

- 21-40%
 - 41-60%
 - 61-80%
 - 81-100%
- Pain Visit within the last 3-4 months
 - 0-20 %
 - 21-40%
 - 41-60%
 - 61-80%
 - 81-100%

3. To what extent do you feel the electronic health record is easy to use in regards to searching for monitoring elements (last UDS, last PDMP checked, signed contract)?

- Not at all
- Slightly user-friendly
- Somewhat user-friendly
- Moderately user-friendly
- Extremely user-friendly

4. How do you currently document pain visits?

- Free text
- Dictate
- Use a template
- Every patient is different
- Other:

5. What is your current level of satisfaction in regards to your system's ability to allow you to easily document pain visits that cover all the necessary elements of pain assessments (analgesia, activities of daily living, adverse effects, aberrant behaviors, and affect)?
 - 1- Not at all satisfied
 - 2- Slightly satisfied
 - 3- Moderately satisfied
 - 4- Very satisfied
 - 5- Extremely satisfied
6. What is going well currently with your chronic pain management in your practice?
7. What barriers or concerns do you have with chronic pain management in your practice?
8. What other comments do you have?

APPENDIX C. POST-IMPLEMENTATION SURVEY

1. What is your current level of satisfaction with the monitoring of chronic pain patients?
 - 1- Not at all satisfied
 - 2- Slightly satisfied
 - 3- Moderately satisfied
 - 4- Very satisfied
 - 5- Extremely satisfied

2. To your best knowledge, what percentage of your chronic pain patients have the following in place:
 - Signed Lake Region Healthcare Pain Contract within last year
 - 0-20 %
 - 21-40%
 - 41-60%
 - 61-80%
 - 81-100%

 - Urine drug screen within last 6 months
 - 0-20 %
 - 21-40%
 - 41-60%
 - 61-80%
 - 81-100%

 - Pharmacy Drug Monitoring Program checked with last prescription refill/renewal
 - 0-20 %

- 21-40%
 - 41-60%
 - 61-80%
 - 81-100%
- Pain Visit within the last 3-4 months
 - 0-20 %
 - 21-40%
 - 41-60%
 - 61-80%
 - 81-100%

3. To what extent do you feel the electronic health record is easy to use in regards to searching for monitoring elements (last UDS, last PDMP checked, signed contract)?

- Not at all
- Slightly user-friendly
- Somewhat user-friendly
- Moderately user-friendly
- Extremely user-friendly

4. How do you currently document pain visits?

- Free text
- Dictate
- Use a template
- Every patient is different
- Other:

5. What is your current level of satisfaction in regards to your system's ability to allow you to easily document pain visits that cover all the necessary elements of pain assessments (analgesia, activities of daily living, adverse effects, aberrant behaviors, and affect)?
- 1- Not at all satisfied
 - 2- Slightly satisfied
 - 3- Moderately satisfied
 - 4- Very satisfied
 - 5- Extremely satisfied
6. What is going well currently with your chronic pain management in your practice?
7. What barriers or concerns do you have with chronic pain management in your practice?
8. When caring for a chronic pain patient, how often did you use the Chronic Pain Flow Sheet?
- Never
 - Almost Never
 - Occasionally/Sometimes
 - Almost Every Time
 - Every Time

9. When seeing a patient for chronic pain, how often do you use the Pain Visit Template?

- Never
- Almost Never
- Occasionally/Sometimes
- Almost Every Time
- Every Time

10. What is the likelihood that you will continue to use the Chronic Pain Flow Sheet and Pain Visit Template?

- 1 – Extremely unlikely
- 2 – Unlikely
- 3 – Neutral
- 4 – Likely
- 5 – Extremely likely

11. What other comments do you have?

APPENDIX D. IRB APPROVAL



April 15, 2016

Mykell Barnacle
Nursing

Re: IRB Certification of Exempt Human Subjects Research:
Protocol #PH16246, "Chronic Pain Management: Implementing Best Practice Strategies"

Co-investigator(s) and research team: Jenna Wallace

Certification Date: 4/15/2016 Expiration Date: 4/14/2019
Study site(s): Lake Region Barnesville Area Clinic
Sponsor: n/a

The above referenced human subjects research project has been certified as exempt (category # 2b) in accordance with federal regulations (Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects). This determination is based on the revised protocol and consent/information sheet (received 4/13/2016).

Please also note the following:

- If you wish to continue the research after the expiration, submit a request for recertification several weeks prior to the expiration.
- The study must be conducted as described in the approved protocol. Changes to this protocol must be approved prior to initiating, unless the changes are necessary to eliminate an immediate hazard to subjects.
- Notify the IRB promptly of any adverse events, complaints, or unanticipated problems involving risks to subjects or others related to this project.
- Report any significant new findings that may affect the risks and benefits to the participants and the IRB.

Research records may be subject to a random or directed audit at any time to verify compliance with IRB standard operating procedures.

Thank you for your cooperation with NDSU IRB procedures. Best wishes for a successful study.

Sincerely,

A handwritten signature in black ink that reads "Kristy Shirley".

Digitally signed by Kristy Shirley
DN: cn=Kristy Shirley, o=NDSU,
ou=Institutional Review Board,
email=kristy.shirley@ndsu.edu, c=US
Date: 2016.04.15 09:58:54 -0500

Kristy Shirley, CIP, Research Compliance Administrator

For more information regarding IRB Office submissions and guidelines, please consult http://www.ndsu.edu/research/integrity_compliance/irb/. This Institution has an approved FederalWide Assurance with the Department of Health and Human Services: FWA00002439.

INSTITUTIONAL REVIEW BOARD

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

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

NDSU is an EO/AA university.

April 27, 2016

Dr. Mykell Barnacle
Nursing

IRB Approval of Protocol #PH16232, "Chronic Pain Management: Implementing Best Practice Strategies (Chart Review protocol)"
Co-investigator(s) and research team: Jenna Wallace

Approval period: 4/27/2016 to 4/26/2017
Continuing Review Report Due: 3/1/2017

Research site(s): Lake Region Barnesville Area Clinic Funding Agency: n/a
Review Type: Expedited category # 5
IRB approval is based on the original protocol (received 4/4/2016) with revised anticipated end date.

Additional approval is required:

- o prior to implementation of any changes to the protocol (Protocol Amendment Request Form).
- o for continuation of the project beyond the approval period (Continuing Review/Completion Report Form). A reminder is typically sent 4-6 weeks prior to the expiration date; timely submission of the report is your responsibility. To avoid a lapse in approval, suspension of recruitment, and/or data collection, a report must be received, and the protocol reviewed and approved prior to the expiration date.

A report is required for:

- o any research-related injuries, adverse events, or other unanticipated problems involving risks to participants or others within 72 hours of known occurrence (Report of Unanticipated Problem or Serious Adverse Event Form).
- o any significant new findings that may affect risks to participants.
- o closure of the project (Continuing Review/Completion Report Form).

Research records are subject to random or directed audits at any time to verify compliance with IRB regulations and NDSU policies.

Thank you for cooperating with NDSU IRB procedures, and best wishes for a successful study.

Sincerely,



Digitally signed by Kristy Shirley
DN: cn=Kristy Shirley, o=NDSU,
ou=Institutional Review Board,
email=kristy.shirley@ndsu.edu, c=US
Date: 2016.04.27 11:08:06 -05'00'

Kristy Shirley, CIP, Research Compliance Administrator

For more information regarding IRB Office submissions and guidelines, please consult www.ndsu.edu/irb. This Institution has an approved FederalWide Assurance with the Department of Health and Human Services: FWA00002439.

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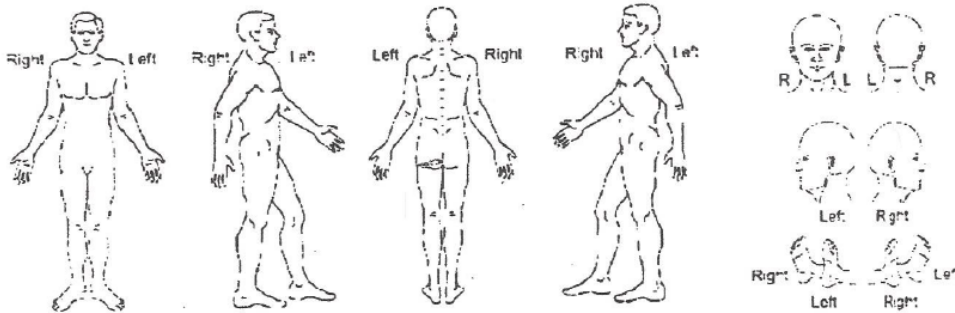
APPENDIX E. BRIEF PAIN INVENTORY

Patient : _____ BAC# _____

Patient Pain Assessment

Date: _____ Time: _____

1. Have you had pain other than everyday kinds of pain (such as minor headaches, sprains, and toothaches) today? Yes No
2. On the diagram, put an X on the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain at its **WORST** in the past 24 hours.

0 1 2 3 4 5 6 7 8 9 10
 No Pain Pain as bad as you can image

4. Please rate your pain by circling the one number that best describes your pain at its **LEAST** in the past 24 hours.

0 1 2 3 4 5 6 7 8 9 10
 No Pain Pain as bad as you can image

5. Please rate your pain by circling the one number that best describes your pain on the **AVERAGE** since your last office visit.

0 1 2 3 4 5 6 7 8 9 10
 No Pain Pain as bad as you can image

6. Please rate your pain by circling the one number that tells how much pain you have **RIGHT NOW**.

0 1 2 3 4 5 6 7 8 9 10
 No Pain Pain as bad as you can image

7. Please list current treatment or medications you are receiving for your pain.

Current Pain meds _____

Breakthrough meds _____

Side effects _____

Other treatments _____

Patient : _____ BAC# _____

8. In the **PAST 24 HOURS**, how much relief have pain treatments or medications provided?
Please circle the one percentage that most shows how much **RELIEF** you have received.
0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
No Relief Complete Relief

9. **SINCE YOUR LAST OFFICE VISIT**, on average how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much **RELIEF** you have received.
0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
No Relief Complete Relief

10. Circle the one number that describes how, since your last office visit, pain has interfered with your:

A) General Activity:

0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely interferes

B) Mood:

0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely interferes

C) Walking Ability:

0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely interferes

D) Normal work (includes both outside the home and housework):

0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely interferes

E) Relations with other people:

0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely interferes

F) Sleep:

0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely interferes

G) Enjoyment of life:

0 1 2 3 4 5 6 7 8 9 10
Does not interfere Completely interferes

APPENDIX F. EXECUTIVE SUMMARY

Background and Significance

Opioid abuse is a growing epidemic. Deaths from overdoses are increasing in number. Healthcare costs continue to rise due to opioid abuse and inadequate chronic pain management. Primary care providers feel inexperienced and uncomfortable with managing opioid therapy safely and effectively. To address this problem, a monitoring and documentation tool was developed within the electronic health record to assist primary care providers serving chronic pain patients in a rural primary care clinic. The purpose of this project was to implement evidence-based practices for prescribing opioids for chronic pain management and monitoring.

Project Summary

The chronic pain flow sheet was implemented in the charts of chronic pain patients at a rural primary care clinic and data was inputted based on four important monitoring parameters. Parameters were determined based on extensive literature review using evidence-based research. Data was collected regarding a pain visit signed and filed within the last 12 months, prescription drug monitoring program checked within the last six months, urine drug screen performed within the last six months, and a documented pain visit within the last four months.

The project leader held a meeting with the three providers at the clinic and delivered a survey regarding their current practice of caring for chronic pain patients. The providers were also educated on the presence of the chronic pain flow sheet and the availability of the pain visit template. Survey questions were answered along with open discussion to allow the project leader to collect qualitative data on the providers' view on caring and managing chronic pain patients.

Results

Initial Chart Review

Results of the initial chart review showed 19.67% of patients had a signed contract in the electronic medical record that was filed within the last 12 months. The prescription drug monitoring program was checked with the last six months in 22.95% of patients. A urine drug screen was performed within the last six months in 26.23% of the patients. A pain visit was documented within the last four months in 72.13% of patients.

Ideally, chronic pain patients meet all the parameters to ensure safe and effective chronic pain management. In the initial review, all four parameters were met in 8.2% of the patients. Three parameters were met in 11.48% of patients, two parameters met in 16.39% of patients, one parameter met in 44.26% of patients, and no parameters were met in 19.67% of patients.

Pre-Implementation Survey

The pre-implementation survey was dispersed to the three providers at the clinic. Questions were asked regarding level of satisfaction of the monitoring of chronic pain patients, the percentage of their patients that met the pain monitoring parameters, the usability of the electronic medical record for documenting pain visits, and the perception of the electronic medical record's ability to monitor chronic pain patients. The last three questions allowed for more open-ended answers regarding what is going well with chronic pain patients, barriers to managing chronic pain, and any additional comments they may have.

Survey results overall showed a moderately-slightly satisfied view on chronic pain management and providers had a higher estimate of those monitoring parameters being met in their chronic pain patients. Responses varied in regards to the usability of the EMR from not easy to use to moderately easy to use.

The fourth question asked how the providers document pain visits and options included: free text, dictate, use a template, every patient is different, and other. Two providers chose dictate and one provider chose free text.

The fifth question of the survey asked providers about their current level of satisfaction in regards to the system's ability to allow for pain visits to be easily documented and ensure they cover all the necessary elements of pain assessments (analgesia, activities of daily living, adverse effects, aberrant behaviors, and affect). One provider felt not at all satisfied with the system and two providers felt only slightly satisfied with the current system.

The final three questions of the survey were open-ended and allowed for individual answers and opinions. Question six simply asked, "What is going well currently with your chronic pain management in your practice?". Answers included, "using forms from paper charts", "dictating notes", and "printing Rx's". One provider said, "we are decreasing the amount of people and dosages on many of the patients" and also mentioned "using PT, massage, topicals, etc. instead".

The seventh question of the survey inquired about the barriers and concerns providers have with chronic pain management in their practice. Providers responded with "vague structures from regulating agencies", "EHR issues", and "lack of consultants to review patients needs and care plan". Other barriers or concerns mentioned were "no good tracking system here with prescriptions- Sanford has prescription monitoring where they are automatically generated monthly and tracked by a nurse", "finding data in EHR pertaining to pain visit", and "charts being flagged as pain contract present".

The final question on the survey that led to open discussion was "what other comments do you have?". Providers mentioned frustrations with having no second opinion available

regarding their chronic pain patients, guidelines being difficult to follow and treat patients accordingly, and feeling that the practice of treating chronic pain is difficult. Providers also mentioned the change in practice over the past twenty years. For example, twenty years ago providers were encouraged to push medications and if a provider did not treat pain, they were considered a bad provider. Now, regulatory agencies are enforcing providers to reduce or stop opioids at all costs. One provider stated “a flow sheet would be very helpful”.

Six-Month Chart Review

A six-month chart review was performed to see if the chronic pain flow sheet was being utilized and the parameters were updated and being met. In regards to presence of a pain contract within the last 12 months, 25% of patients met this parameter. In comparison to the initial chart review, there was a 5.33% increase in pain contracts. Eleven and a half percent of patients had their PDMP checked within the last six months. However, a 5% decrease was seen in checking PDMPs compared to the initial chart review. Pain visits were present in 69.2% of patients, which was down 2.9% since the initial chart review.

In regards to meeting the chronic pain monitoring parameters, all four parameters were met in 7.7% of patients. Three parameters were met in 5.8% of patients, two parameters met in 19.2% of patients, and one parameter met in 46.2% of patients. No parameters were met in 21.2% of patients.

Post-Implementation Survey

Post-implementation surveys were dispensed to the clinic providers in January 2017 and included the first seven questions from the initial survey plus additional questions. The eighth question on the survey asked about the frequency of use of the chronic pain flow sheet on a scale of never to every time. One provider selected every time, one selected never, and another

selected almost never. The ninth question asked about the frequency of the use of the pain visit template. Responses included never, almost never, and almost every time (if started by nursing at the beginning of the visit). The tenth question asked about the likelihood of continuing use of the flow sheet and template on a scale of extremely unlikely (1) to extremely likely (5). Two providers were neutral in responding to this question and the third provider responded as being extremely likely to continue the use of the designed tools.

The survey asked for suggestions on how to make the flow sheet and pain visit template more efficient and user-friendly. Providers felt chronic pain management is a difficult and time-consuming task. One suggestion was to make the flow sheet be auto-populated somehow so it requires less documentation and data entry by the user. The final question of the survey asked for any comments providers have. Comments included “need to do better job on my part of re-emphasizing to nurses to use template”, and “it is difficult to separate pain treatment from non-pain care”.

Recommendations

Despite data analysis not showing improvement in chronic pain monitoring parameters, the project leader recommends this project be continued at the clinic and expand to the other healthcare system’s clinic sites. The project leader does think the pain visit template and chronic pain flow sheet have the potential to help primary care providers manage their chronic pain patients. Because these tools were developed within AllScripts, these tools are available to not only the rural clinic but the entire healthcare network. This project has the potential to positively impact the practice of several providers and may result in a network-wide improvement in the management of chronic pain patients. Considering opioid abuse and chronic pain is at the

forefront of medicine and considered a national priority to reduce its negative effects, primary care providers may find it imperative and beneficial to utilize the tools created.