PRESCRIPTION DRUG ABUSE: IMPLEMENTING AN EVIDENCE-BASED PAIN MANAGEMENT PROTOCOL

A Dissertation
Submitted to the Graduate Faculty
of the
North Dakota State University
of Agriculture and Applied Science

By

Ginger Kathleen Parrish Warren

In Partial Fulfillment of the Requirements
for the Degree of
DOCTOR OF NURSING PRACTICE

Major Department:
Nursing

July 2016

North Dakota State University
Graduate School

Title

PRESCRIPTION DRUG ABUSE: IMPLEMENTING AN EVIDENCE-BASED PROTOCOL

By

Ginger Kathleen Parrish Warren

The Supervisory Committee certifies that this ***disquisition*** complies with North Dakota State University's regulations and meets the accepted standards for the degree of

DOCTOR OF NURSING PRACTICE

SUPERVISORY COMMITTEE:

Dr. Mykell Barnacle
Chair

Dr. Daniel Friesner

Dr. Heidi Saarinen

Dr. Mary Merrigan

Approved:

08/19/2016
Date

Dr. Carla Gross
Department Chair

ABSTRACT

Prescription drug abuse is an intentional misuse of a prescribed drug for recreational or other purposes that was not intended by the prescriber of the drug. Since 2012, fatalities from opioid overdoses have risen to approximately 17,000 per year in the United States. It is important for healthcare providers to follow a standardized guideline with patients receiving controlled substances, such as opioids, in order to prevent abuse. Within this project, a chronic pain management protocol was created, implemented, and evaluated in a selected critical access hospital's emergency department and two rural health clinics. The protocol addressed the use of an online prescription drug monitoring program (PDMP) to identify patients who have a history of obtaining multiple controlled substance prescriptions and using multiple pharmacies to fill these prescriptions. In addition to using a PDMP, providers are educated in identifying risk factors of opioid use in their patients by using an evidence-based risk assessment tool. Opioid abuse prevention strategies and best practices for opioids prescribing are within the protocol. Strategies include pain treatment contracts and a stepwise approach to prescribing based on the patient's report of pain, with opioids as the last resort. Other methods include urine drug screening, a nonjudgmental attitude from the provider towards the patient regarding abuse, and motivational interviewing methods to assist patients to stop abuse. Emphasis on other nonpharmacological methods are included, such as: physical therapy, cognitive behavioral therapy, counseling, yoga, biofeedback, and guided imagery. Evaluation of this protocol includes pre- and post-implementation surveys with the project stakeholders, including administrators and providers within the project hospital and clinics.

ACKNOWLEDGEMENTS

I would like to express my sincere appreciation to my committee chair, Dr. Mykell Barnacle for her feedback, motivation, and patience with me throughout the process of completing this project. I could not have completed this project without her. I would also like to thank my committee: Dr. Daniel Friesner, Dr. Mary O'Connor-Merrigan, and Dr. Heidi Saarinen for their valuable expertise and their input during this project.

I would like to thank Ms. Kathy R. Zahn, Program Administrator for the State of North Dakota Board of Pharmacy Prescription Drug Monitoring Program (PDMP), and Dr. Mark J. Hardy, Executive Director of the North Dakota Board of Pharmacy for their assistance and time during this project.

I would also like to thank the North Dakota State University Writing Center and the Technology Learning and Media Center for their willingness to help students strengthen their writing and formatting skills. Their assistance to me during this project has been valuable.

I appreciate my family during this time and at all times. My husband and best friend, Frank Warren, has encouraged me from the very beginning to do my very best in everything that I do. He has motivated me to persevere in all that I have desired to accomplish. I would like to thank my son, Terry, for his encouragement, and my daughter, Laura, for desiring to follow in my footsteps and become a nurse.

This clinical dissertation project is dedicated to many people that I have cared for that have had issues with prescription drug abuse and have been able to overcome their addiction. Thank you for fueling my compassion for high-risk prescription drug monitoring and prescription drug abuse prevention.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER ONE. INTRODUCTION OF PRESCRIPTION DRUG ABUSE

Prescription drug abuse is identified as the intentional misuse of a prescribed drug for recreational or other purposes that was not intended by the prescriber of the drug (National Institute on Drug Abuse [NIDA], 2011). Statistics regarding prescription drug abuse are astounding and reveal the severity of the problem. The National Institute on Drug Abuse comments that: "Prescription drug abuse remains a significant problem in the United States" (NIDA, 2011). In 2010, approximately seven million people (2.7% of the US population) in the United States were illegally using prescription drugs (NIDA, 2011). These statistics represent a significant problem of prescription drug abuse in the US. Not only are prescription drugs a significant problem in the United States, but North Dakota has also been affected with problems with prescription drug abuse. According to the North Dakota Office of the Attorney General (2014), 17.6% of North Dakota high school students admit to taking a controlled substance, such as OxyContin, Percocet, or Vicodin, without a prescription from a provider at least once. The statistic is equivalent to the national rate (North Dakota Office of the Attorney General, 2014). The 17.6% of North Dakota high school students who admit to prescription drug abuse illustrates an ongoing problem with prescription drug abuse in North Dakota. There has not been further research by the North Dakota Office of the Attorney General to include the prevalence of prescription drug abuse among North Dakota young adults and adult populations.

Therefore, the purpose of this project is to identify those populations in North Dakota who are at risk for prescription drug abuse, as well as seek to educate health care providers regarding best practices when prescribing controlled substances and preventing prescription drug abuse. The project goals were achieved through providing tools with which to identify those high-risk populations, in order to help prevent access to prescription drugs by the identified high-

risk populations. Furthermore, this project compared prescription drug abuse prevention methods used by rural primary health care providers in two clinics and one critical access hospital's emergency department in northwestern North Dakota. This project evaluated how the development and utilization of pain management protocols can help prescribers deter and prevent prescription drug abuse. This project further explored each prescriber's biases and treatment methods used for the patient. By considering common treatment methods between prescribers, a common ground was identified in order to centralize communication between prescribers to help decrease the incidence of prescription drug abuse in a northwestern North Dakota rural health clinic and a critical access hospital's emergency department.

Significance of Prescription Drug Abuse

Opioids are frequently used for a recreational purpose instead of original medical purpose, such as pain management (Green et al., 2011). Opioid use is now associated with grave concern in public health because the inappropriate use of opioids is responsible for addiction, fatal overdoses, and mixing with other drugs to make a fatal combination (Green et al., 2011). Benzodiazepines, stimulants, hypnotics, and opioids are classes of drugs that are the most addictive (Julien, Advokat, & Comaty, 2011). There are certain classes of medications that are more commonly abused than other classes. The NIDA (2011) reports these classes and the approximate number of people abusing them are: pain relievers - 5.1 million, tranquilizers - 2.2 million, stimulants - 1.1 million, and sedatives – 0.4 million.

Deaths due to prescription drug abuse exceeded motor vehicle crashes in 2009 as the number one cause of accidental death in the United States (Green et al., 2011). Prescription drug abuse has become one of the most serious substance abuse problems in the US, possibly because they are easily accessible (Green et al., 2011). The prevalence of prescription drug abuse has

reached epidemic proportions within the past two decades (Carlson et al., 2014; Kelly, Rendina, Vuolo, Wells, & Parsons, 2015; and McHugh, Nielsen, & Weiss, 2015).

In addition to statistics regarding prescription drug abuse, alcohol use with either illicit or prescription drugs is a significant problem. The dangers of combining opioids and alcohol are particularly dangerous due to both substances causing respiratory depression, which can lead to death (Phillips, 2013; Crist & Berrettini, 2014). According to Jung (2010), the incidence of people who abuse alcohol are more likely to abuse drugs as well. According to Julien et al. (2011), combinations of alcohol and benzodiazepines or other sedatives can result in significantly impaired coordination required to operate a motor vehicle, or inability to conduct other activities requiring alertness. Based on the above, it is important for providers to assess a patient's alcohol or illicit drug use, abuse, or addiction as part of the pain management protocol.

Chronic Pain

There are approximately one hundred million people in the United States that suffer from chronic pain (Katzman, Comerce, Landen, Loring, et al., 2014). Of these one hundred million people, it is estimated that "thirty-five million Americans (13.7%) adults age 12 years and older had used a pain reliever non-medically at least once in their lifetime" (Katzman et al., 2014, p. 1356). An estimated 15.7 million Americans admit to using prescription drugs for recreational purposes (Beauchamp et al., 2014). A troubling consequence of the abuse is the high number of accidental overdoses that result (Beauchamp, Winstanley, Ryan, & Lyons, 2014). Approximately 46 Americans die daily as a result of an accidental opioid overdose (Beauchamp et al., 2014). The above high statistics indicate that prescription drug abuse is now in epidemic proportions in the United States healthcare system (McHugh et al., 2015). Green, Black, Serrano, Budman, and

Butler (2011) report that controlled substances such as opioids now exceed marijuana as the substance that most first-time drug users become addicted to.

Problem Statement or Purpose

The prevalence of prescription drug abuse in our healthcare system has led many providers to take various measures in the clinical setting to help keep it under control. These measures include treatment agreements, random urine or serum drug screens, communication between providers, communication between providers and pharmacists, and communication via a prescription drug monitoring program. Many primary care providers choose not to prescribe addictive medications to their patients. Some providers focus primarily on eradicating their patient's pain or anxiety, and their prescriptive practices do not account for addictive behaviors of patients.

Furthermore, pain management education is essential for patients with and at risk for addiction issues. First, the addicted patient needs to be identified. Within the pain management protocol developed during this project, the tool included to help identify a patient with a high risk of addiction or an actual addiction is the Opioid Risk Tool. The Opioid Risk Tool was developed in 2010 by Dr. Lynn Webster and is used in many pain management clinics. Many times the best option to prevent addiction is not to prescribe an opioid, particularly for an individual at high risk for opioid abuse and dependence (Matthias et al., 2013). Alternative methods of pain management, such as physical therapy, biofeedback, psychotherapy, or yoga are effective. Frequent assessments of skin need to be completed at every visit, paying close attention to any skin ulcers that may be present due to intravenous drug use or "skin popping" (Canales, Gerhard, & Younce, 2015).

Deaths from opioid use, whether intentional as suicide or unintentional as an overdose, have been dramatically increasing in the US within the past two decades; unfortunately, the opioids were obtained from a prescriber in many cases (Haegerich, Paulozzi, Manns, & Jones, 2014). Since this is such a risk, prescribers need to be diligent with follow-up on their patients to assess that they are taking their prescriptions exactly as directed.

Prescribing practices between healthcare providers have a wide variance and there is a need for guidelines for improvement on both the provider's and the patient's accountability. Many states are monitoring providers' prescribing statistics through their prescription drug monitoring programs, ranging from "pill mills", which is considered inappropriate prescribing to minimal prescribing (Haegerich et al., 2014). Health insurance companies, such as Medicaid, Medicare, and private in conjunction with "pharmacy benefit managers", or PBMs, create alerts for providers to become aware of evidence-based prescribing practices and if any overlapping activity is occurring with their patient's prescriptions with other providers (Haegerich et al., 2014). These alerts are helpful to prescribers, but there is a need for pain management protocols in all individual clinics so each clinic may monitor providers' prescribing practices internally. Additionally, not all patients have health insurance that can monitor prescribing practices.

While overuse and abuse of controlled prescription medications is of paramount concern, many patients take less of their medications in order to avoid addiction and do not disclose such to their provider (Daughton & Ruhoy, 2013). As a result, the provider continues to prescribe the same quantity of the prescription, which creates a stockpile of medications (Daughton & Ruhoy, 2013). This stockpile of medications thus leads to more problems; such as unnecessary waste, unnecessary costs, possible diversion, and unintended overdoses either by children having access

to the medications, or someone who does not know what the medication is for (Daughton& Ruhoy, 2013).

Project Description with Purpose and Objectives

This project included a development of a pain management protocol within a critical access hospital's emergency department in North Dakota and two affiliated rural primary care clinics. A pre- and post-implementation survey was distributed to each participating administrator and provider. The data from these surveys were analyzed with comparisons to determine the effectiveness of the protocol. Each licensed staff member [registered nurses (RN) and licensed practical nurses (LPN)] was individually taught how to recognize risk factors of prescription drug abuse in patients. Each RN and LPN gained access to PDMP as a delegate under the supervision of the medical chief of staff in order to research each patient that is prescribed opioids in the critical access hospital's emergency department and two rural healthcare clinics. The hospital and clinics are where this student was employed.

Congruence of the Project to the Organization's Strategic Plans/Goals

The primary stakeholders identified in this project are employees of the two rural clinics and critical access hospital's emergency department in northwestern North Dakota, including four medical doctors, one doctor of osteopathy, and three family nurse practitioners. These employees were active participants in the planning, creating, implementation, and evaluation of the pain management protocol in these facilities.

The mission statement for the hospital and clinics "is to provide comprehensive and compassionate health care for individuals and families in cooperation with the area medical community" (Anonymous, n.d.). The content of the developed and implemented pain management protocol maintained compassion and empathy for the patient in order to remain

congruent with the organization's mission statement. In addition to compassion and empathy to the patient, the pain management protocol contained the most recent comprehensive healthcare strategies to provide pain management as well as prevention of prescription drug abuse.

Project Objectives

The project has the following objectives:

- Objective 1: Develop and implement a pain management protocol in a rural North Dakota primary care clinic and critical access hospital's emergency department.
- Objective 2: Improve, increase, and expand providers' knowledge about safe opioid prescribing practices in order to improve patient monitoring for those receiving opioid therapy for chronic pain management.
- Objective 3: Promote utilization and sustainability of the pain management protocol through integration of the protocol into daily provider and staff operations in selected clinics within four months from project implementation to evaluation.

CHAPTER TWO. LITERATURE REVIEW

There are many different methods that providers can use to monitor their patients on opioids and other controlled substances in order to prevent prescription drug abuse. Providers need to be able to recognize some of these abuse risk factors via assessment tools. Primary care providers especially need to be assessing their patients with several different methods; such as using the prescription drug monitoring program, urine drug screening, and treatment agreements. Sometimes providers need to be creative in working with their patients in initiating change as in motivational interviewing. Approaches such as providers involving themselves with continuing education about opioid pharmacology and prescribing opioids have been found to be helpful. It has been found helpful for providers being consistent with their prescribing methods, use of patient monitoring techniques to prevent prescription drug abuse, and use of pain management protocols whenever available.

The North Dakota Prescription Drug Monitoring Program, now called PDMP is a tool that prescribers can utilize to assess their patients' activity on receiving controlled substance prescriptions from other providers and the pharmacies that they have had their prescriptions filled. Kathy Zahn, director of the North Dakota PDMP, reports that as of fourth quarter of 2014, 17.9% of North Dakota physicians (e.g., medical doctors and doctors of osteopathy) and 36.4% of North Dakota advanced practice providers (e.g., nurse practitioners and physician assistants) accessed and utilized the monitoring system (telephone communication, 3/12/15).

It is unknown why the above statistics of PDMP utilization are low among providers. The top reasons are that the providers do not have access to the PDMP for various reasons; providers are unaware of the PDMP existence; and providers do not have the time to access the PDMP (Perrone, DeRoos, & Nelson, 2012). Many providers identify barriers to using the PDMP as

time-consuming from entering the patient's information to the final report, as well as inconsistent prescription and pharmacy information between states (Hildebran et al., 2014).

However, the benefits of PDMP utilization outweigh the barriers in that providers can become more aware of their patients' controlled substance prescription activity by receiving additional prescriptions from other providers, and using multiple pharmacies (Green, Mann, Bowman, Zaller, Soto, Gadea, Cordy, et al., 2012). In addition to monitoring, printed PDMP reports that are discussed between a provider and a patient can become an excellent teaching tool to make the patient aware of their own addiction (Green et al., 2012). Based on the above information, PDMP utilization by providers has the potential for many opportunities for improvement in controlled substance prescribing and prevention of prescription drug abuse.

Medications with Potential for Abuse

Opioids

The mechanism of action of opioids involves three types of receptors in the central nervous system and in the peripheral nervous system; which are *mu*, *kappa*, and *delta* (Julien et al., 2011). Mu receptors have the most significant effects in the brain, especially the thalamus, brain stem, and spinal cord (Julien et al., 2011). The mu receptors have the strongest properties for addiction, are the most effective for pain control, and are the most dangerous because of the respiratory depressive effect on the brain stem (Julien et al., 2011). The kappa receptors have minimal pain control properties and minimal to no properties for addiction (Julien et al., 2011). Delta receptors also have minimal to no properties for addiction and minimal pain control properties (Julien et al., 2011). When drugs that affect the dopamine pathways such as opioids are abused, it causes a pleasurable surge in the dopamine pathways in the brain, and with

repeated use, can lead to addiction (NIDA, 2012). Opioids such as OxyContin stimulate the same receptors as heroin (NIDA, 2012).

The physiological effects of opioids are processed in the brain; the thalamus, the periaqueductal gray matter where the serotonin pathways, enkephalin pathways, and noradrenaline pathways are located (Julien et al., 2011). In these areas, the pathways are stimulated by the opioids and inhibit pain transmission (Julien et al., 2011). With the case of chronic pain, the pathways are damaged, thus limiting the pain transmission inhibition, which is called neuroadaptation (Julien et al., 2011). For this reason, opioids are a poor choice for chronic pain maintenance (Julien et al., 2011).

The psychological effect of opioids includes euphoria that is caused from the release of endorphins from the dopamine pathways (Julien et al., 2011). Many people who abuse opioids do it for the pleasurable effects and develop a psychological obsession to continue to abuse for the relief of emotional pain regardless of the consequences (Julien et al., 2011). Julien et al. (2011) also discuss the following: "Morphine produces a pleasant euphoric state, which includes a strong feeling of contentment, well-being, and lack of concern" (p. 332). The feelings that result from habitual morphine use "is part of the affective, or reinforcing, response to the drug" (Julien et al., 2011, p. 332).

Opioids produce sedation and anxiolysis due to slowing down cognitive processes, although the patient can easily be awakened, unlike central nervous system depressants such as alcohol (Julien et al., 2011). A dangerous effect of opioids is respiratory depression ranging from sleep apnea to respiratory cessation due to "decreasing the respiratory center's sensitivity to higher levels of carbon dioxide in the blood" (Julien et al., 2011, p. 334). Julien et al. (2011) also state that, "Respiratory depression is the single most important acute side effect of morphine and

is the cause of death from acute opioid overdosage [sic]" (p. 334). A unique characteristic of opioid use is pupillary constriction, especially from "mu and kappa agonists" (Julien et al., p. 334). Julien et al. (2011) also state that "pupillary constriction in the presence of analgesia is characteristic of opioid ingestion" (p. 334). Nausea and vomiting is caused by stimulation of the "chemoreceptor trigger zone in the medulla" (Julien et al., p. 334). Constipation is a common gastrointestinal effect from opioid use due to decreased gastrointestinal motility and increased fluid absorption from fecal material, creating hardened stools (Julien et al., 2011).

Endocrine effects from opioid use include irregular menses and decreased fertility in women, and decreased sex drive and "hypogonadism" in men (Julien et al., 2011, p. 335). Opioid tolerance can develop quickly due to "glutaminergic receptors", which "regulates the mu receptor messenger (m) ribonucleic acid (RNA)", and creates "tolerance" with the opioid always being at the receptors (Julien et al., 2011, p. 336). Problems with opioid tolerance occur when the opioid is used on a regular basis, due to loss of efficacy from the original dose (Julien et al., 2011). As a result, the patient will complain of more pain and the dosage will have to be increased in order for the patient to achieve the same quality of pain control as they had when they first began using the opioid. Julien et al. (2011) commented, "The use of all mu agonist opioids is severely limited because of the development of tolerance, the presence of uncomfortable side effects, and the potential for compulsive abuse" (p. 335).

Acute withdrawal symptoms of opioids include, "pain and irritability, hyperventilation, dysphoria and depression, restlessness and insomnia, fearfulness and hostility, increased blood pressure, diarrhea, pupillary dilation, hyperthermia, lacrimation, runny nose, spontaneous ejaculation, and chilliness and 'gooseflesh'" (Julien et al., 2011, p. 337). These symptoms are

extremely unpleasant to the person experiencing them, but they are not potentially fatal (Julien et al., 2011).

Protracted abstinence syndrome is the time frame after acute withdrawal symptoms from opioids up to six months after cessation of opioid use (Julien et al., 2011; Smith & Aston-Jones, 2014; Stinus, Cador, & Caille, 2012). The hallmark symptoms of protracted abstinence syndrome include depression, dramatic responses to stress, craving the drug of choice, low self-image, and other mental health problems (Julien et al., 2011). During the time frame of protracted abstinence syndrome, there are co-occurring or dual diagnoses that can be identified in the patient; such as, "affective and personality disorders" with "antisocial personality disorders and major depression" being the most common co-occurring disorders (Julien et al., 2011, p. 338).

Benzodiazepines

Julien et al. (2011) state, "All benzodiazepines are termed pure GABA agonists because they faithfully facilitate GABA binding at GABA receptors" (p. 250). Benzodiazepines are appropriate for short-term anxiety use, but inappropriate for treatment of depression or long-term anxiety (Julien et al., 2011). They are effective for treatment of insomnia, but with risk of addiction (Julien et al., 2011). There are cases of people who develop "paradoxical agitation (anxiety, aggression, hostility, and behavioral disinhibition)" while taking benzodiazepines (Julien et al., 2011, p. 253). Alcohol combined with benzodiazepines can be especially dangerous due to decreased metabolism of both substances, leading to toxicity (Jung, 2010). There have been many fatalities due to this combination of substances (Julien et al., 2011).

Another common use of benzodiazepines is for anesthesia and conscious sedation for surgical procedures (Julien et al., 2011). Midazolam, or Versed, is the best-known short-acting benzodiazepine that is used for procedures, mainly for its amnesic effect (Julien et al., 2011).

When a benzodiazepine overdose is suspected in an emergency department, an antidote called flumazenil (Romazicon) is given intravenously to reverse the toxic effects of the benzodiazepines (Julien et al., 2011). Due to the short half-life of flumazenil, multiple doses may have to be given due to the recurrence of the benzodiazepine toxicity (Julien et al., 2011).

A working knowledge of drugs with the potential for abuse and mechanism of action of those drugs is helpful for providers who have prescriptive authority, and the knowledge can be used to further educate patients. Education is extremely important; it can mean life or death to many people. An extensive examination of the neurology, pharmacology, and the progression, diagnosis, and treatment of an opioid use disorder is not within the scope of this project.

Assessing Risk Factors for Opioid Abuse

There are known characteristics, or risk factors, for a patient to be at high risk for opioid abuse. These risk factors can be assessed by providers by using an assessment tool, such as the "Current Opioid Misuse Measure (COMM)" questionnaire that was developed by the National Institutes of Health and PainEDU@inflexxion.com (Inflexxion, 2008). The patient completes the questionnaire and the answers that are provided assists the provider to determine whether the patient is at high risk of opioid abuse or not. The questionnaire consists of 17 questions that has the patient consider a time frame of the past thirty days. The risk factors that are addressed in the questionnaire are the following according to the COMM: Evidence of physiological dependence, irrational emotions, non-therapeutic responses to opioids, evidence of psychological dependence, frequent use or abuse of healthcare, and frequent requests for early refills of opioids (Inflexxion, 2008).

In addition to the COMM assessment tool, the "Screener and Opioid Assessment for Patients with Pain (SOAPP)" was also developed by the National Institutes of Health and

PainEDU@inflexxion.com (Inflexxion, 2008). The twenty-four item questionnaire is designed in a five-point Likert scale from 0 representing "never" to 4 representing "very often" (Inflexxion, 2008). The content of the questions addresses the patient's behavior issues, illicit drug use, prescription drug abuse, family history of alcohol or drug abuse, any history of alcohol or drug treatment, problems with providers, and legal issues (Inflexxion, 2008). The content of these questions indicate the population at risk for opioid abuse.

Another risk assessment tool that is used is called the "Opioid Risk Tool" developed by Lynn R. Webster, MD in 2010. It addresses gender, family history of substance abuse, personal history of substance abuse, age range that is high risk for abuse, any history of sexual abuse, and any presence of mental health disorders (Webster, 2010). This assessment tool and the two preceding tools can give the provider an idea of the patient's prescription drug abuse risk factors. The tool that was used within this project was the "Opioid Risk Tool".

The Opioid Risk Tool is a good resource for the provider to gather data about opioid abuse risk factors, but many patients evade the truth by answering questions dishonestly for fear of rejection from the provider (Webster, n.d.). According to Dr. Webster (n.d.), the best methods of screening patients for opioid abuse is by observing the behaviors, consulting the prescription drug monitoring program which includes patients' provider and pharmacy activity, and have the patient come into the office for frequent visits. Also, it is important to validate the patient's pain and develop a trusting relationship early (Webster, n.d.). The above tools have a high validity that assists providers in safe opioid prescribing.

Prescription Drug Abuse Management in Primary Care

Within the primary care system, any pain management program involves a multi-pronged approach designed to assess risk and minimize abuse of prescription medications. Abusive

prescription medication behaviors need to be identified and the provider needs to be able to modify abusive behaviors through the use of a treatment agreement or treatment contract.

In 2005, the North Dakota Legislative Assembly, in conjunction with the North Dakota Board of Pharmacy, implemented a computerized Prescription Drug Monitoring Program (PDMP) (North Dakota Board of Pharmacy, 2012). This monitoring program is designed for prescribers, their delegates who are generally licensed nurses, and pharmacists to use and gain information on prescription drug filling habits for their patients' population.

The PDMP is an agency sponsored by state board of pharmacies, which has a website that is available for approved prescribers, their approved delegates, and pharmacists to access (North Dakota Board of Pharmacy, 2012). The information that this website reveals is: names of individuals, names of controlled substances that were prescribed to the individual, the name of the prescriber, and the name of the pharmacy where the prescription was filled. The PDMP user needs to enter the first and last name of the individual and the birth date in order to access the above information. All scheduled II, III, IV, and some V controlled substances are included in the PDMP information. As of January 1st, 2007, Tramadol (Ultram) and Carisoprodol (Soma) were added to the reported medications in PDMP (North Dakota Board of Pharmacy, 2012). The information is entered into the PDMP system by pharmacists at the time the prescriptions are filled.

The North Dakota PDMP, now called PDMP, has access to certain states, such as, West Virginia, Idaho, Wisconsin, Colorado, Minnesota, Illinois, South Dakota, New Mexico, Delaware, Kansas, Arizona, Michigan, Indiana, Mississippi, Connecticut, and South Carolina (http://northdakota.pmpaware.net).

In the northwestern North Dakota critical access hospital's emergency department and rural healthcare clinics, providers have access to the PDMP and approved treatment agreements, but neither are consistently used by all providers for every patient that receives pain management. Providers also lack a centralized system that monitors patients who seek and regularly receive prescriptions for controlled substances.

In addition to more frequent use of the PDMP, providers also want to limit the use of potentially addictive substances. The duration of pain is important to consider in order to classify the pain as acute or chronic. Educating providers to use this stepwise approach of prescribing pain medications helped to decrease addiction potential in patients.

Acute Pain Management Protocols

There was a prospective study conducted in Seoul, South Korea at Hangang Sacred Heart Hospital burn center from May 2011 through November 2011 regarding general pain management and procedural pain management with dressing changes on a population of 107 burn patients (Yang, Hur, Kwak, Yim, Cho, et al., 2013). The researchers developed a comprehensive pain management protocol including several different scales to assess pain, anxiety, depression, and post-traumatic stress disorder (Yang et al., 2013). The "numeric rating score" (0-10) was used to assess pain as well as several other scales; such as "a Clinician-Administered Post-traumatic stress disorder Scale (CAPS), a Hamilton Depression Rating Scale (HDRS), a State-Trait Anxiety Inventory Scale (STAIS), and a Holmes and Rahe Stress Scale (HRSS)" (p. 620). This pain management protocol in this study was used by the staff consistently with their patients during each assessment and revised the plan of care based on the pain management protocol and changes in the patient's condition with good results (Yang et al., 2013).

There was another study conducted in Australia by Miller, Rodger, Kipping, and Kimble in 2011 regarding a pain management protocol that was used on children with burns. This protocol involved pharmacological and non-pharmacological methods (Miller et al., 2011). The pharmacological agents that were used for pain management were paracetamol (known as acetaminophen in the United States), Pain Stop (analgesic ointment), and oxycodone (Miller et al., 2011). The non-pharmacological methods that were used for pain management was a "Multi-Modal Distraction (MMD)" device that provides distraction and preparation for a burn wound dressing change (Miller et al., 2011). There were three different MMDs that the children could choose from, which were: "MMD touch and find stories, MMD games, or the MMD *Bobby got a Burn* story" (p. 398). The MMD use involved one group of study participants. The other group of study participants did not have access to the MMDs, but did have access to "television, video games, stories, age appropriate toys, nursing staff soothing, and caregiver support throughout the change of dressing" (pp. 397-398). Pain assessments were conducted before the dressing change, during the removal of the dressing, during the application of the new dressing, and after the dressing change (Miller et al., 2011). The result of the study was that the MMD group displayed less pain than the "Standard Distraction (SD)" group because the MMD group was given specific information on burns and the SD group was given generalized distractions. The MMD group was better prepared for the burn dressing change because they were given specific information about the upcoming procedure.

Another protocol study was conducted in Shiraz, Iran by Mansouri et al. (2013) within a nine-month period of time in an Intensive Care Unit (ICU) setting. The authors wanted to improve patient outcomes by improving treatment of "pain, agitation, and delirium (PAD)" by developing a protocol for the nursing staff to assess and treat the patient as necessary (p. 918).

The ICU patients who participated in the study were separated into two groups: the PAD group and control group (Mansouri et al., 2013). The PAD group was assessed by the nursing staff using the following protocols: "Behavioural Pain Scale (BPS) or Numerical Rating Scale (NRS) when feasible, Richmond Agitation Sedation Scale (RASS), and Confusion Assessment Method in ICU (CAM-ICU)" (p. 919). The ICU nurses assessed every patient in the PAD group every hour for pain, agitation, and delirium according to these scales, and then medicated according to the score (Mansouri et al., 2013). Within both the PAD and control groups, the specific medications that were given for pain were morphine, fentanyl, sufentanyl, and acetaminophen (Mansouri et al., 2013). The medications that were given for agitation were midazolam, propofol, and haloperidol (Mansouri et al., 2013). Haloperidol alone was also given for delirium (Mansouri et al., 2013). The difference between the PAD and control groups was the method used to assess the patients. The authors concluded that implementation of a "well-designed protocol that involves regular and precise monitoring of PAD, along with appropriate and timely medical therapy" can greatly improve ICU patient outcomes (p. 921).

Chronic Pain Management Protocols

In addition to acute pain management protocols as discussed above, there are a few chronic pain management protocols that are found in the literature. Kroenke et al. (2014) conducted a study called "The Stepped Care to Optimize Pain Care Effectiveness (SCOPE) (p. 240). This was a randomized clinical trial that selected veterans from five different primary care clinics within the Veterans Administration (VA). These randomly selected participants were divided into two groups: one group received pain management via "telephone-delivered collaborative care management intervention" and another group which received face-to-face office pain management visits with a provider (Kroenke et al., 2014, p. 240). The criteria for the

selected participants were that they had to be from 18 to 65 years old; have generalized musculoskeletal pain that rated a 5 or above on a 0 to 10 scale; and the participants have had this pain at a minimum of three months or greater (Kroenke et al., 2014).

In the telecare group, the participants communicated their symptoms via an "automated symptom monitoring (ASM)" using their choice of telephone or internet (p. 242). The participants utilized the ASM on a scheduled time-frame within twelve months, while using a measuring tool designed for the participant's pain assessment, existence of anxiety or depression, and quality of life (Kroenke et al., 2014). Based on the participant's response; the pain management specialist, the primary care provider, and the nurse would create an individualized care plan for the participant to receive medication, physical therapy, or cognitive behavioral therapy (Kroenke et al., 2014). The nurse would make follow-up calls to verify the participant's automated response. The researchers concluded that the telecare group pain management "substantially increased the proportion of primary care patients with improved chronic musculoskeletal pain" (p. 247). This study illustrates the importance of frequent follow up with patients with chronic pain in order to monitor for potentially worsening co-occurring disorders.

There was another study conducted in 2007 by Gallagher, Weiz-Bosna, and Gammaitoni at the Pain Medicine Service at Philadelphia Veterans Administration (VA) Medical Center. The study prospectively assessed the frequency of "long-acting opioids" in patients with chronic non-cancer pain. The long-acting opioids that were used in the study were Oxycodone CR, Morphine CR, Methadone, and Fentanyl patches (Gallagher et al., 2007). The results of this study were that the patients were requiring more frequent dosing of the long-acting opioids that were "recommended by the manufacturer" (p. 72).

There was a literature review study conducted by Courtenay and Carey in 2008 in the United Kingdom regarding nurses leading in acute and chronic pain management. In the beginning of the article, the authors defined acute pain as occurring immediately after surgery, traumatic injuries, or life-threatening medical diagnoses such as cardiac arrests. They defined chronic pain as pain lasting greater than three months. The authors discovered that nurse-led chronic pain management services provide great educational opportunities for patients who suffer from chronic pain by using pain management protocols that include "non-pharmacological treatments", such as cognitive behavioral therapy and multiple pain assessment tools (p. 2010). These pain specialist nurses can also provide pain management education to other nurses to better assess their patients' pain through pain assessment tools; provide timely implementation of pain management, whether pharmacological or non-pharmacological; and improve on evaluation of their patients' pain relief (Courtenay & Carey, 2008). The pain specialist nurses can be in an inpatient or outpatient setting. Nurses can be instrumental in pain management assistance and education for their patients, which emphasizes the importance of including education for the patient.

In 2012, the American Pain Society (APS) and the American Academy of Pain Medicine (AAPM) created *The Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non Cancer Pain.* These guidelines recommended several different items for prescribers to adhere to regarding management of opioids in their patients; such as,

- A good history of the patient's origin and source of pain.
- Any history of illicit drug or inappropriate prescription drug abuse as well as alcohol abuse.
- Mutual goals and responsibilities between prescriber and patient.

- Requirements from the provider that the patient participate in non-pharmacological treatment modalities for pain.
- Written treatment agreement that includes strict guidelines for receiving all prescriptions exclusively from the prescriber.
- The patient filling all prescriptions from one pharmacy.
- Urine toxicology tests as determined by the prescriber.
- Guidelines for treatment from the prescriber regarding refill policy and policies for office visits (APS & AAPM, 2012).

Methods of Prescription Drug Abuse Prevention

In addition to pain management protocols to help prevent prescription drug abuse, Casty, Wieman, and Shusterman (2013), discuss in their article, "Current Topics in Opioid Therapy for Pain Management: Addressing the Problem of Abuse", several methods of preventing prescription drug abuse. The United States Food and Drug Administration (FDA) have requested pharmaceutical companies to add ingredients into opioids that make the drug inactive if it is taken in any other form than swallowed whole, such as crushed and snorted or injected (Casty et al., 2013). As a result, in the past five years the pharmaceutical companies have altered the delivery mechanism of an opioid to become inactive if the drug is taken in any other route other than the appropriate route that the drug was therapeutically designed (Casty et al., 2013).

In addition to the pharmaceutical companies changing their composition of their opioids to prevent prescription drug abuse, the FDA determined that the providers who were prescribing opioids to their patients need to monitor them frequently. According to Casty et al. (2013), the FDA also instituted requirements for pharmaceutical companies to develop a task force called "Risk Evaluation and Mitigation Strategies (REMS)". Within the REMS, there was another task

force called “Elements to Assure Safe Use (ETASU)”. The ETASU contains several items that require providers to have a certain amount of continuing education in safe opioid prescribing, patient monitoring, and frequent patient follow-up visits (Casty et al., 2013). The REMS also requires certain protocols to be in place within a healthcare setting in order to maintain safety with opioids (Casty et al., 2013).

Pain Treatment Contracts

Pain treatment contracts, or treatment agreements, are legal documents that indicate important components between a provider and a patient. The information that is included in a pain treatment contract may differ in between clinics, but it indicates responsibilities of the provider and the patient and consequences that may occur if the responsibility is not followed. Pain treatment contracts are generally used in an outpatient clinic setting.

Hariharan, Lamb, and Neuner published a “retrospective cohort study” in 2007 regarding medication treatment contracts for opioid use in a primary care setting (p. 485). The authors emphasized the importance of a thorough, methodical, and careful approach with primary care providers prescribing opioids to their patients with chronic pain. During this study, there were 330 patients who agreed to receive opioid prescriptions while using a treatment contract with their providers (Hariharan et al., 2007). Within the treatment contract, patients agreed to adhere to medication compliance and submitting to random urine drug screens (Hariharan et al., 2007). The results of the study include that of the 330 patients, 37% of the contracts were cancelled by the end of the study by either the patient or by the provider for presence of illegal drugs in the urine drug screen (Hariharan et al., 2007). The authors concluded that medication treatment contracts provide “structure, support, and monitoring for long-term chronic pain management” (p. 490).

Arnold, Han, and Seltzer (2006) discuss the usefulness of opioid contracts and the ethical dilemmas that can result from their use. They also discuss important objectives that should be included in opioid contracts. First, the primary objective of an opioid contract is to establish patient compliance within opioid treatment (Arnold et al., 2006).

Another objective that the authors discuss is the concept of "informed consent" within the opioid contract. Arnold et al. (2006) advise to use caution when the provider uses the opioid contract as a means of informed consent because all of the components of an informed consent must be present; such as "known risks, benefits, and alternatives of opioid therapy" (p. 293). Including patient education in the pain management protocol in this project could yield a more positive outcome. In order for an opioid contract to be legally sound as an informed consent, it must include all components of pain management medical standards (Arnold et al., 2006). The wording of such a document must be concise in order to be legal and not put the provider at risk for malpractice.

A third objective identified by the authors is "legal risk management". They stress the importance of spelling out the advantages and disadvantages of opioid therapy. In addition, specific goals and expectations of the provider and patient therapeutic relationship must be explained thoroughly within the opioid contract (Arnold et al., 2006). The provider should make clear what the consequences are if the patient is noncompliant with the requirements of the opioid contract.

The last objective that is discussed is that of "practice efficiency" (p. 294). The authors describe the opioid contract as a point of reference for the clinic's pain management (Arnold et al., 2006). The contract can serve as a focus point for the patient's interdisciplinary care (Arnold et al., 2006).

The authors also bring up two different viewpoints on opioid contracts. First, the opioid contract can be viewed as a positive part of opioid therapy because it is goal-oriented and establishes a therapeutic relationship between the patient and the provider. On the other hand, the opioid contract can be construed as just a risk management legal document for the provider's benefit and display a "lack of trust" in the patient. To avoid making the opioid contract a negative part of opioid therapy, the provider must word the contract carefully and avoid any personal biases and remain nonjudgmental (Arnold et al., 2006). The purpose of an opioid contract is to establish a therapeutic partnership on the patient's behalf as well as hold the patient accountable for their responsibility of prescribed opioid use.

Prescription Drug Urine Screening

Random urine drug screening that is used on patients can be an effective method that providers can use to monitor patients that are being prescribed opioids for pain management. Pergolizzi et al. (2010) identified in their article, "The Role of Urine Drug Testing for Patients on Opioid Therapy", two different indications for random urine drug screening. The practice is intended to monitor patient compliance with taking the prescribed opioid as well as to monitor for any evidence of illicit drug use or using a medication that the provider has not been made aware of by the patient. The authors of this article mention that even though most providers agree that urine drug screening is an effective method of patient monitoring, it is not ordered by providers often. They also comment that, "in one study, only 8% of chronic pain patients on opioid therapy *ever* had a urine drug test administered in this context" (p. 498). Even though urine drug screening is considered optional at this time, some states are trying to pass laws making it mandatory. The authors state that Florida made urine drug screening mandatory "at initial prescription and twice yearly thereafter and medical records that document appropriate

testing, treatment plans, informed consent, and periodic review of therapeutic objectives" (p. 498).

Unfortunately, there can be false negatives or false positives in urine drug screens. The immunoassay drug screens have certain cutoff levels and if the urine contains levels of the drug below the cutoff level, a negative reading is registered (Pergolizzi et al., 2010). False positive results can be caused by "cross-reactivity" from one form of opioid to another, for example codeine and morphine both display positive results because codeine is metabolized to morphine in the liver (Pergolizzi et al., 2010). If there is any doubt of the result, the provider may request that the local laboratory send the urine sample to a larger laboratory that can perform a confirmation test, such as gas chromatography (Pergolizzi et al., 2010). The authors advise that a provider should not make a final conclusion of opioid abuse based on one urine drug screen result until further testing is conducted using more sophisticated methods. Urine drug screening is a small, but important part of patient prescription drug monitoring.

Theoretical Framework

Within this project, the foundational theory was the Plan, Do, Study, and Act (PDSA) model. The PDSA model is important for the project in that it is congruent to the algorithm (see Appendix A) in that both are cyclical or ongoing. Within the PDSA model, there are specific actions that occur with each phase, such as planning, implementation, evaluation, and continuance of the protocol after the project has been completed.

Plan Do Study Act Model

The design of this project was utilized through the PDSA quality improvement model. It was derived from the plan, do, check, act (PDCA) that was first developed by Demming and Shewhart during World War II (Zaccagnini & White, 2014). This model is important to use in

system today and, according to, Zaccagnini & White (2014), the PDSA model is used for "*rapid cycle improvement processes"*. The PDSA quality improvement model can be used for a variety of healthcare issues that need to be researched and new evidence-based protocols developed in a quick and efficient manner, such as in errors in patient identification in computed tomography (CT) scans (Barnosky, 2014). This model was helpful in this project in that each phase (plan, do, study, act) is included in this model.

The first step of the PDSA process is to gather data from the needs assessment and create a plan to initiate change in current methods or protocols related to the problem in the healthcare system (Ragsdale & Mueller, 2005). All of the prescribers and the administrators of the clinics and hospital were interviewed individually by this student, and the common result of each interview is that there is a need for established guidelines for pain management in the form of a protocol. Providers also felt that consistent use of North Dakota PDMP by either the prescriber or a delegated user, such as the nursing staff is necessary. PDMP should be used with each opioid prescription. In order to use PDMP, the provider or delegate needs to look up the patient's number and type of controlled substance prescriptions, how many providers that this patient has seen in a certain length of time, and how many pharmacies the patient has had prescriptions filled.

With the prescription drug abuse project, the research participants, or respondents, consisted of the prescribers in the northwestern North Dakota clinics and critical access hospital's emergency department. The plan included an extensive review of literature to aid in the creation of an evidence-based pain management protocol. The protocol provided consistent management strategies for patients that are managed for chronic pain that are treated with highly

addictive substances, such as opioids; and medications that are controlled by the Drug Enforcement Agency (DEA).

The second step, or "do" step, involved creating a protocol to treat acute and chronic pain, and incorporated strategies to prevent prescription drug abuse. Some of these strategies involved utilization of the prescription drug monitoring program and the initiation of a treatment agreement with each patient as appropriate. Providers were asked to provide feedback as the protocol is being developed. Once it has been approved by providers and administrators, a clinical staff meeting was held to introduce the new protocol to the nursing staff and the support staff, and give them a chance to ask questions about the protocol and give feedback.

The third step, or "study" step, involved gathering and analyzing data from the pre- and post-implementation surveys that were administered to the providers. The data gathered from these surveys were reviewed and conclusions were made on whether a pain management protocol is effective for prescription drug abuse prevention or not.

The fourth step, or "act" step, involved making the new pain management protocol part of the standard medical practice in the clinic. After the project was completed with the appropriate conclusions met, the research was shared with the stakeholders, which were identified as the prescribers in the clinic, the hospital and clinic's board of directors, hospital administrators, which are the chief executive officer and the chief financial officer, and the North Dakota Board of Pharmacy. Recommendations for changes were made based upon the results of the pre- and post-implementation surveys (see Figure 1).

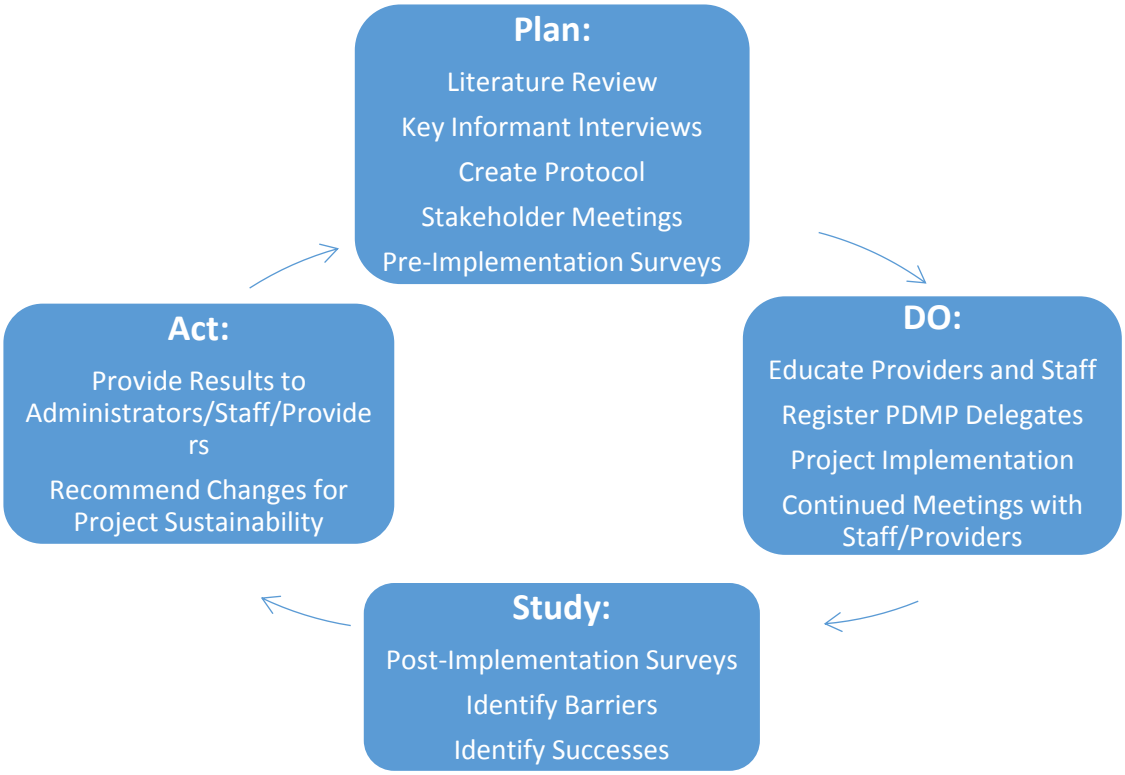


Figure 1. Plan, Do, Study, Act Model

CHAPTER THREE. PROJECT DESIGN

This project was designed within a critical access hospital's emergency department and two rural health clinics located in northwestern North Dakota. The stakeholders of this project included four administrators and nine providers. The project was a case series design because it involved the administrators' and providers' interpretations of the pain management protocol before and after it was implemented (Sullivan, 2012). Each administrator evaluated the effect of the protocol on the daily operations within the hospital and clinics. Each provider evaluated the effect of the protocol within each of their individual patients with pain management needs. There were no control or experimental patient groups.

Project Implementation

In late August of 2015, pre-implementation surveys were distributed to each participating administrator and provider. At the time each provider was approached with the surveys, education was provided about the study, signs and symptoms of patients with prescription drug abuse issues, and education about opioid prescribing best practices, including treatment agreements for patients who may have prescription drug abuse issues. In addition to the pre-implementation surveys, each provider was given a cover letter explaining the purpose of the project, a pain management protocol checklist, an algorithm of the pain management protocol, and assessment tools, including the Patient Health Questionnaire (PHQ-9) and Dr. Lynn Webster's Opioid Risk Assessment Tool.

After the surveys were returned to this student from the administrators and providers, each licensed staff member (registered nurses and licensed practical nurses) within the hospital and clinics was approached individually by this student to educate about identifying risk factors of prescription drug abuse in patients. All of the licensed staff members were able to describe

characteristics of patients with prescription drug abuse issues (i.e., asking for early refills, erratic behavior, using multiple providers to obtain prescriptions, using multiple pharmacies to fill prescriptions, drug withdrawal signs and symptoms such as diaphoresis, elevated pulse and blood pressure).

After the individualized staff education was completed, each staff member was instructed on enrolling as a delegate in the North Dakota Prescription Drug Monitoring Program or PDMP. After each delegate received approval by the North Dakota Board of Pharmacy, the pain management protocol was implemented.

NDSU IRB Approval

This project was approved by the North Dakota State University (NDSU) Institutional Review Board (IRB), under exempt status category number two. Category two includes survey procedures only with observance of human behavior by participating administrators and providers. Research was not performed directly with human subjects. The identity of the participants was kept confidential and each participant was free from risk of civil or criminal liability (NDSU IRB exempt protocol form, 2015).

Data Collection

Each of the administrators and providers were interviewed individually by this student in order to determine whether the need for a pain management protocol within the critical access hospital's emergency department and the two rural healthcare clinics existed. The outcome from these interviews unanimously supported that a pain management protocol was needed. Data were collected from a pre-implementation and post-implementation survey from the administrators and providers. The surveys were a hybrid of quantitative and qualitative data. The quantitative questions were designed in a five-point Likert scale. Examples of the qualitative questions

include asking the participant why the question was answered a certain way as well as perceived barriers and benefits of the protocol.

CHAPTER FOUR. EVALUATION

Within this project, there were three specific objectives identified, which are discussed below. The quality improvement model for this project is the Plan, Do, Study, Act model. This model is a cyclical type of model which includes four phases in order for each objective to be measured for evaluation outcomes.

Objective One

Objective one: Develop and implement a pain management protocol in a rural North Dakota primary care clinic and critical access hospital's emergency department. The utilization of treatment agreements between prescribers in the northwestern North Dakota rural healthcare clinics and prescribing controlled substances were compared before and after the implementation of the pain management protocol by a pre-implementation and a post-implementation survey. During the pre-implementation survey, questions were asked about the provider's current level of knowledge about prescription drug abuse, assessment of opioid abuse risks in patients, and the provider's anticipated feelings of benefits or barriers of implementing a pain management protocol. During the post-implementation survey, questions were asked about how the provider expresses concern to the patient if any signs of prescription drug abuse are being exhibited, how often the provider is using the PMDP, and what are the benefits or barriers of the implemented protocol.

Objective Two

Objective two: Improve, increase, and expand providers' knowledge about safe opioid prescribing practices in order to improve patient monitoring for those receiving opioid therapy for chronic pain management. This objective was evaluated by this student conducting a post-

implementation follow-up survey with all prescribers and administrators within the rural healthcare clinics and the critical access hospital's emergency department.

Objective Three

Objective three: Promote utilization and sustainability of the pain management protocol through integration of the protocol into daily provider and staff operations in selected clinics within four months from project implementation to evaluation. This objective was originally to be evaluated by the successful incorporation of the protocol within the electronic medical record. Due to the high cost, incorporation of the protocol into the electronic medical records was not approved by administration. Instead, a method was incorporated into the daily patient care operation by providers and staff within the selected hospital and clinics. This method was created by instructing all registered nurses and licensed practical nurses to access the PDMP as delegates. When their access was approved by the North Dakota Board of Pharmacy, the nurses used the PDMP to research all patients that were prescribed opioids. The report from the PDMP was printed out by the nurses and the report was placed on the chart for the provider to review before the patient was seen. In addition to available reports for patients being seen, the nurses printed out a PDMP report for all patients requesting refills for their opioids.

CHAPTER FIVE. RESULTS

Presentation of Findings

A key informant interview was conducted with each project participant to determine each individual's perception of how their patient's pain is managed effectively. The providers that were interviewed agree that the lack of a facility-wide protocol led to prescribing differences of medications with potential for abuse. While all providers have knowledge of the PDMP system, many acknowledged that the PDMP, which is the best place to search, is not searched each and every time an opioid is prescribed.

After receiving approval from the IRB, pre-implementation surveys from four administrators and seven health care providers were completed. Licensed personnel (RN and LPN) were instructed regarding how to create an account with the North Dakota Prescription Drug Monitoring Program (PDMP) as a delegate in order to research every patient that presents into either the emergency department or either clinic that has an opioid prescription. When each licensed staff received approval from the North Dakota Board of Pharmacy as a delegate, the protocol went into effect. During the month of November, a post-implementation survey was distributed to the study participants, and data from both surveys were analyzed and compared to one another.

Pre-Implementation Surveys for Administrators

The questions were in a 5-point Likert scale format developed by this student, with the content of the questions assessing the value of implementing the protocol, the anticipated ease of implementation of the protocol, the anticipated level of support from the hospital and clinic staff, and the anticipated effect of the normal hospital and clinic daily operations by the implementation of the protocol (see Table 1 on next page).

Table 1

Administrator Survey Results

N=4	Pre-Implementation	Post-Implementation
Value for daily operations	3 agree 1 strongly agree	3 agree 1 neither agree or disagree
Ease of implementation of protocol	2 easy 2 neutral	2 easy 2 neutral
Level of support from hospital and clinical staff regarding implementation	4 somewhat favor	3 somewhat favor 1 neutral
Effect of implementation of pain management protocol with hospital and clinic daily operations	4 somewhat positively	3 somewhat positively 1 neutral

Post-Implementation Survey Results from Administrators

The questions were in a 5-point Likert scale format, with the content of the questions being the value of implementing the protocol for daily operations of the organization, the ease of implementation of the protocol, the level of support from the hospital and clinic staff, and the effect of the normal hospital and clinic daily operations by the implementation of the protocol. One administrator from both the hospital and the clinics made the comment that with time, the project was successful in deterring prescription drug diversion within the clinic and the hospital (see Table 1 above).

Pre-Implementation Survey Results from Providers

The pre-implementation survey for the providers was a combination of quantitative and qualitative data. There was a total of eight pre-implementation surveys returned. The responses from the first, second, third, fifth, ninth, and tenth questions are shown in Figure 2 and Table 2.

Post-Implementation Survey Results from Providers

The post-implementation survey for the providers was a combination of quantitative and qualitative data. There was a total of eight post-implementation surveys returned. During the implementation of the pain management protocol, one medical doctor left the practice and dropped out of the project. A nurse practitioner joined the practice approximately midway into the project and agreed to participate when approached by this student. There was a total of ten questions, which first assessed current level of knowledge regarding best practices for prescribing opiates after the pain management protocol was implemented (See Figure 2 and Table 2).

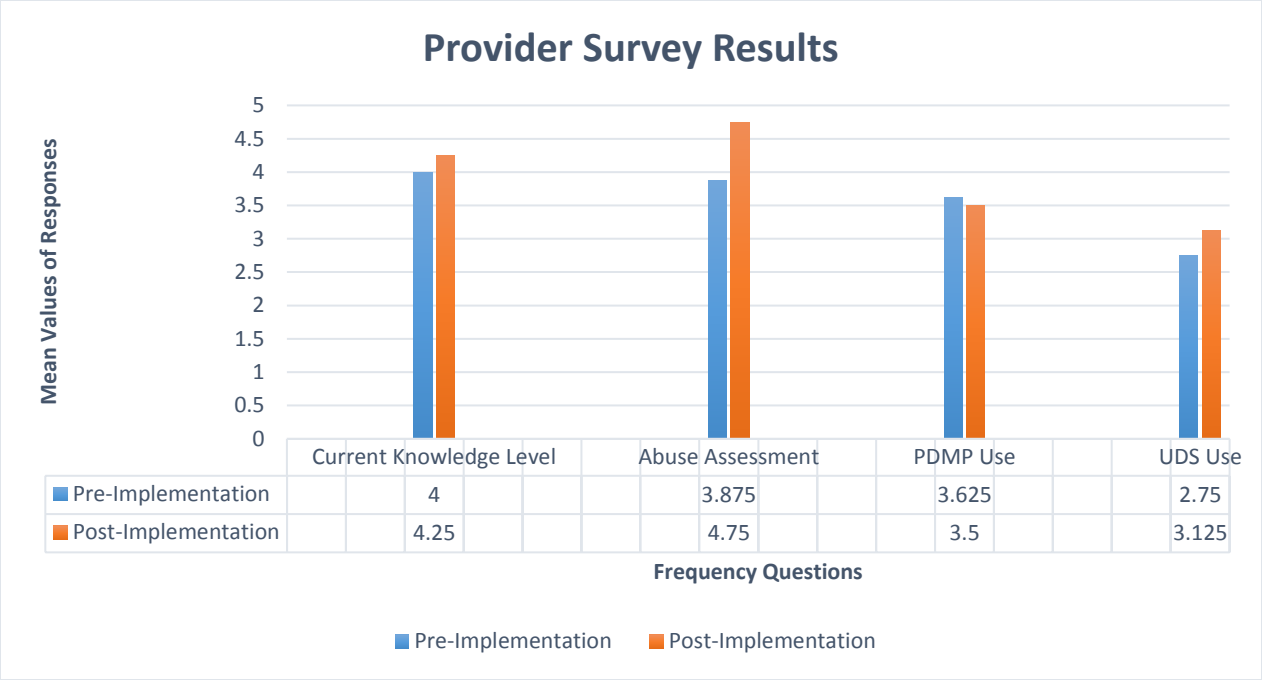


Figure 2. Provider Survey Results-Mean Values of Responses
PDMP= Prescription Drug Monitoring Program UDS= Urine Drug Screen
Legend: 1=not at all aware/never; 2=slightly aware/rarely; 3=somewhat aware/occasionally; 4=moderately aware/a moderate amount; 5=extremely aware/a great deal

Table 2

Quantitative Data from Provider Surveys

Question	Pre-Implementation (n=8)	Post-Implementation (n=8)
#1 Current level of knowledge regarding best practices for prescribing opiates.	8 moderately aware	1 somewhat aware 4 moderately aware 3 extremely aware
#2 Discussing the potential for abuse that certain medications have with the patient before prescribing	1 sometimes 5 often 2 every time	1 sometimes 2 often 5 every time/always
#3 Discussing concerns with a patient if the patient is exhibiting signs of prescription drug abuse or dependence.	1 sometimes 4 often 5 always	1 occasionally/sometimes 1 often/a moderate amount 5 always
#5 Current risk assessment of opioid abuse prior to prescribing chronic opioids to a patient.	1 rarely 3 occasionally 4 a great deal	1 occasionally 4 a moderate amount 3 a great deal
#9 Pre-implementation/#8 Post-implementation: How often are you using the PDMP?	1 never 2 sometimes 3 often 2 always	1 never 3 occasionally/sometimes 2 often/almost every time 1 always/every time
#10 Pre-implementation/#9 Post-implementation: How often do you use a urine drug screen as part of the clinical decision-making process when prescribing controlled substances?	1 never 1 almost never 5 occasionally/sometimes 1 almost every time	2 never 2 occasionally/sometimes 3 almost every time 1 every time
#10 Post-implementation: How often do you follow the protocol when you prescribe a controlled substance?	N/A	(n=7) 1 never 1 occasionally/sometimes 4 almost every time 1 every time

Based on the above findings, this student concluded that the providers' current level of knowledge varied with the post-implementation survey. The providers increased the frequency in which they discussed with their patients the potential for abuse that certain medications have before they prescribed the medication. The frequency of urine drug screen use changed minimally between the pre- and post-implementation surveys.

Qualitative Data from Pre-Implementation Provider Survey

The fourth question asked the providers about the strategies that they use to promote the health of their patient. Their responses were consistent in prioritizing the promotion of safe opioid prescribing. One provider responded: "Try not to alienate them or be accusatory but rather express concern for their long term general well-being."

The majority of the providers responded that they assessed a patient's risk of opioid abuse prior to prescribing chronic opioids by reviewing records and discussion with the patient. One provider responded that a "state search" (PDMP) of the patient is important prior to prescribing opioids.

The sixth question was about the providers' thoughts or feelings about implementation of the pain management protocol. The majority of the providers responded favorably about implementing a pain management protocol. One individual responded: "It would be nice for a clinic that has a variety of providers to have one protocol so that everyone is on the same page. That said, there is something nice about provider autonomy as we all practice differently and relate differently with certain types of patients." Most providers expressed interest in having a protocol available for guidance while maintaining autonomy.

The seventh question was about the providers' anticipation of the benefits of a pain management protocol. One individual responded: "Decreases the provider risk with prescribing controlled substances. Patient will abuse meds no matter what protocols are in place." Another individual responded: "The protocol should help prevent patients changing providers if unhappy since same protocol will be followed by all." The majority of the providers responded that the protocol would be beneficial for both the patient and the provider.

The eighth question was about the providers' anticipation of the barriers of implementing a pain management protocol. The majority of the providers expressed concern about the extra time and energy that the protocol would require. One individual commented that the protocol would affect: "Patient compliance. Risk of negative patient reviews."

The ninth and tenth questions about PDMP use and urine drug screen use, respectively, are illustrated in Figure 2 and Table 2. One of the providers' responses for the reasons why they do not use the PDMP was as follows: "Retired MD. Do not have my own patients anymore." One of the providers' responses regarding urine drug screen use was as follows: "Depends on my trust of the patient. If they are new I use it, but if they are routinely compliant, I don't use these with every visit." Another provider responded: "Inaccuracy of the test. High rate of false positives."

Qualitative Data from Post-Implementation Provider Surveys

The fourth question asks the provider to list strategies that are used to promote the health of that patient. One of the providers' responses was as follows: "I express my concerns with the patient. I explain why I am concerned. Monitor the patient more closely with more frequent visits, urine drug screens, check prescription drug monitoring program more frequently. Refer to pain management and/or addiction medicine." The majority of the providers' responses were consistent with safe opioid prescribing.

The fifth question asks if the provider currently assesses risks of opioid abuse prior to prescribing chronic opioids to a patient. This question was a hybrid of quantitative and qualitative data. One of the responses as to how they assess risks of opioid abuse prior to prescribing chronic opioids to a patient was: "Ask about history of substance abuse. Screen for depression." The rest of the providers had similar responses.

The sixth question asks the provider what thoughts or feelings that he/she has about the implementation of the pain management protocol. One provider did not answer the question. One of the other provider's responses was: "Neutral. Unchanged. Good theory behind protocol." Another provider responded: "I appreciate the additional education." The remainder of the providers responded that the protocol was helpful to prevent prescription drug abuse.

The eighth question asks the provider how often he/she uses the Prescription Drug Monitoring Program, and if not, why? One provider commented that they only provided "part-time ER coverage" and did not feel the need to use the PDMP. Another provider commented: "Sometimes it's down or it's for a few days following an ER visit. Time constraints can be inhibiting". There was a decrease in the frequency in the providers' use of the PDMP in the post-implementation survey because of the RN and LPN delegates.

The ninth question asks the provider how often a urine drug screen was used as part of the clinical decision-making process when prescribing controlled substances. One of the providers that answered "never" commented: "Unreliable results. Both false positives and false negatives". One provider commented: "Most affordable urine drug screens not accurate enough to use to make decisions about treatment".

The eleventh question asks the provider what are the barriers to consistent use of the protocol. One of the provider's answers was: "Increased time required to do things such as drug screens and check prescription drug monitoring program." The majority of the providers were concerned about time management and energy spent on the protocol.

The twelfth question asks what the advantages were with consistent use of the protocol. One of the provider's answers was: "Increased providers' comfort and ease of use. Uniform

patient expectations and care delivery." The remainder of the providers responded that the protocol improved patient care and decreased opioid abuse within the clinic.

CHAPTER SIX. DISCUSSION AND RECOMMENDATIONS

Interpretation of Results

Based on these results, the providers were supportive of the pain management protocol before and after its implementation. However, the providers continued to practice in their own methods. For example, the providers who did not believe urine drug screens were reliable before the protocol was implemented still did not believe that urine drug screens were reliable after the protocol.

Objective One

Objective one: Develop and implement a pain management protocol in a rural North Dakota primary care clinic and critical access hospital's emergency department. Pre-implementation surveys were distributed to four administrators and nine providers, which all of the surveys were returned to this student within two weeks. At the time of survey distribution, each administrator and provider was given an explanation of the pain management protocol, with a cover letter with an explanation of the research study, a copy of the algorithm, a pain management protocol checklist, and assessment tools including a Patient Health Questionnaire (PHQ-9) and an Opioid Risk Tool. There were no providers that stated that they used the PHQ-9 nor the Opioid Risk Tool in their assessment of their patients whom were prescribed opioids.

In addition to meeting with administrators and providers, this student met individually with each licensed staff member (registered nurses and licensed practical nurses (RN and LPN), in the critical access hospital's emergency department and the rural healthcare clinic. Each RN and LPN was taught and instructed to register online with the North Dakota PDMP as a delegate. Also, each staff member was educated about recognizing signs of acute withdrawal (i.e., aberrant

behavior, asking for early refills, agitation, elevated blood pressure and pulse, and excessive perspiration or diaphoresis).

The objective was partially achieved. The key facilitators that made the objective achievable were full participation from the RNs and LPNs at the rural healthcare clinic. The staff at the clinic utilized the PDMP for all patients that presented to the clinic for a pain management appointment and for all patients who called requesting an opioid refill. The clinic staff printed out a PDF file of each patient's prescription activity for the past year and had a copy on the patient's chart for the provider to review at the time the patient was seen. Also, a PDF file was available to the provider with the opioid refill request. By having these reports available to providers, time constraints for informed opioid prescribing were minimal. Also, the PDMP use by the providers decreased after the protocol was implemented because the delegates were using the PDMP on the providers' behalf.

The key barrier was minimal participation from the critical access hospital's emergency department staff. During the time the pain management protocol was initiated, a new hospital electronic medical record system was implemented. This pain management protocol was a lesser priority than the becoming proficient with the electronic health record. Extra time was given with individual explanation of the protocol to the hospital staff to minimize frustration. There were ten RNs in the critical access hospital's emergency department. All of them received the same education about the pain management protocol as the clinic staff. Four out of the ten RNs followed through with using the PDMP with each emergency department patient, each acute inpatient, and each swing bed patient. The Director of Nursing at the critical access hospital's emergency department remained neutral to the protocol after it was implemented because of the higher priority of the new electronic medical record system.

Objective Two

Objective two: Improve, increase, and expand providers' knowledge about safe opioid prescribing practices in order to improve patient monitoring for those receiving opioid therapy for chronic pain management. The objective was achieved to a great extent due to the providers responding in a similar way in both the pre- and post-implementation surveys. The responses, however, were diverse in using urine drug screens. Some providers did not feel that the urine drug screen results were reliable enough to make a clinical decision of the patient abusing prescription drugs. Others felt that urine drug screens were essential in monitoring their patients for prescription drug abuse.

Many providers stated that they had a strong knowledge base of recognizing signs of prescription drug abuse that were displayed by their patients. None of the providers verbalized that they used the PHQ-9 or the Opioid Risk Tools during their patient assessments. The key tool the providers felt was important was using PDMP in monitoring their patients for prescription drug abuse. After the protocol was implemented, a few providers expressed improvement in the frequency of assessing their patients for abuse and using urine drug screens in their post-implementation surveys. There were two providers who did not change their practice in not using urine drug screens on their patients because of their unchanged belief that they were unreliable.

The key barrier identified by the providers and administrators was time constraints in using the pain management protocol. The main barrier was taking the time to research the PDMP for prescription drug activity. One way to overcome the barrier was to have the staff perform the PDMP inquiry for the providers so they could spend time with the patient.

Objective Three

Objective three: Promote utilization and sustainability of the pain management protocol through integration of the protocol into daily provider and staff operations in selected clinics within four months from project implementation to evaluation. The objective was fully achieved within the rural healthcare clinics, and partially achieved within the critical access hospital's emergency department, mainly due to lack of participation. The key facilitators were the cooperation of the nursing staff at both the rural healthcare clinics and the critical access hospital's emergency department participating as delegates for patient research in the PDMP and recognizing signs of prescription drug abuse in patients who were abusing opioids. Since the protocol was implemented, some providers chose not to prescribe opioids to patients. Many providers that participated in the project stated that they did not prescribe opiates because of the frequent monitoring and the liability that is involved with safe opiate prescribing. The delegates and providers are still using the PDMP. Some of the providers are using urine drug screens more frequently since the implementation of the pain management protocol.

A key barrier was that the cost of integrating the use of the PDMP into the electronic medical records (EMR) was more than the administrators could afford in their budget. The cost of the integration of the PDMP use into the EMR that was quoted by the EMR programmers was $15,000. The licensed staff were already researching the hard copy charts every afternoon for faxed copies of lab or diagnostic imaging reports for the next day's scheduled patients, so researching the PDMP was easily incorporated into their daily research. The licensed staff expressed concern about another task with PDMP research, but when they were instructed on how to use the PDMP and after they were approved as a delegate by the North Dakota Board of

Pharmacy, they accepted the new task. The payroll cost of the licensed staff did not change as a result of the PDMP search.

Limitations

The main limitation to this project was the time frame in which it was conducted. Four months was an adequate time frame for the project, but six to eight months would have been better in that more observation could have been conducted by this student with providers' opioid prescribing practices. Another limitation was that the critical access hospital's emergency department and rural healthcare clinics were downsizing by three medical doctors, one doctor of osteopathy, and two nurse practitioners. This happened during December of 2015, so this student distributed the post-implementation surveys during November of 2015.

Another limitation was the electronic medical record upgrade in the critical access hospital's emergency department. The nurse administrator and the staff RNs were so involved with the upgrade that they were not able to give their undivided attention to the pain management protocol. Additional time was spent with the staff to provide the education and support necessary to become PDMP delegates in an effort to improve the success of the PDMP.

The integration of the protocol into the electronic medical records would have been beneficial to make the protocol more "user-friendly" and sustainable. Many of the providers would have forgotten about the protocol had it not been for the nurses researching the PDMP as delegates. The cost of integration of the protocol into the electronic medical records was an unfortunate barrier.

Recommendations for Future Research

Prescription drug abuse is a problem of a large magnitude in this country that each patient should be closely monitored for all signs of abuse and questionable drug activity. The best

centralized system for monitoring prescription drug activity in the United States is the Prescription Drug Monitoring Program (PDMP). PDMP use has already been strongly encouraged in North Dakota as well as many other states. Providers find their responsibilities easier to have delegates to conduct the online research on all patients who are prescribed opioids and other controlled substances and to recognize signs of patients who have prescription drug abuse issues, which was what this project was all about.

The area of the project with the biggest impact and potential for sustainable change in the North Dakota project involved improved PDMP utilization. Projects should be initiated within clinics and hospitals to enhance PDMP utilization rates in each state. The DEA, who executes prescriptive authority to all providers, expects all providers to research their patients in the PDMP on a regular basis. There are many electronic medical records that provide a space to document that PDMP was checked for the patient.

Implications for Practice

Dissemination of the results of this project was conducted at a local pain management center as well as at a coalition meeting for substance abuse prevention, which included providers, law enforcement, and the local school system. This student also displayed her poster describing her project at the youth network committee meeting.

This project was designed to make providers aware of the magnitude of prescription drug abuse and improve patient monitoring with a centralized electronic monitoring system. This project was not intended to substitute a provider's clinical judgment.

Future research is needed on methods to prevent prescription drug abuse. There is widespread awareness in social media and more emphasis for providers to increase patient monitoring for those who are prescribed opioids or other controlled substances. It takes all

providers to be astute with their close monitoring and communication with their patients to be aware of certain medications that have a high potential for abuse. These medications should be used as a last resort for effective therapy.

Application to DNP Roles

DNPs can be very effective leaders in initiating pain management protocols within their healthcare systems if there is not one already in place. They can advocate for close patient monitoring for prescription drug abuse problems and educate other providers to recognize signs of aberrant behavior. DNPs can also be great role models and mentors to those providers who have knowledge deficits of controlled substance prescribing, as well as those providers who have fears of legal consequences if they do prescribe controlled substances.

REFERENCES

American Pain Society & American Academy of Pain Medicine. (2012). *The clinical guidelines for the use of chronic opioid therapy in chronic non cancer pain.*

Arnold, R. M., Han, P. K., & Seltzer, D. (2006). Opioid contracts in chronic nonmalignant pain management: Objectives and uncertainties. *The American Journal of Medicine, 119(4),* 292-296. doi: 10.1016/j.amjmed.2005.09.019

Barnosky, V. (2014). Patient identification errors in computed tomography: A plan, do, study, approach to safety. *Radiologic Technology, 85(6),* 679-681.

Beauchamp, G. A., Winstanley, E. L., Ryan, S. A., & Lyons, M S. (2014). Moving beyond misuse and diversion: The urgent need to consider the role of iatrogenic addiction in the current opioid epidemic. *American Journal of Public Health, 104(11),* 2023-2029. doi: 10.2105/AJPH.2014.302147

Canales, M., Gerhard, J., & Younce, E. (2015). Lower extremity manifestations of "skin-popping" an illicit drug use technique: A report of two cases. *The Foot, 25(2),* 114-119. doi:10.1016/j.foot.2015.03.003

Carlson, R. G., Nahhas, R. W., Daniulaityte, R., Martins, S. S., Li, L., & Falck, R. (2014). Latent class analysis of non-opioid dependent illegal pharmaceutical opioid users in Ohio. *Drug and Alcohol Dependence, 134(1 January 2014),* 259-266. doi: 10.1016/j.drugalcdep.2013.10.004

Casty, F. E., Wieman, M. S., & Shusterman, N. (2013). Current topics in opioid therapy for pain management: Addressing the problem of abuse. *Clinical Drug Investigation, 33(7),* 459-468. doi: 10.1007/s40261-013-008708

Courtenay, M. & Carey, N. (2008). The impact and effectiveness of nurse-led care in the management of acute and chronic pain: a review of the literature. *Journal of Clinical Nursing, 17(15).* 2001-2013. doi: 10.1111/j.1365-2702.2008.02361.x

Crist, R. C. & Berrettini, W. H. (2014). Pharmacogenetics of *oprm1*. *Pharmacology, Biochemistry and Behavior, 123(August, 2014),* 25-33. doi:10.1016/j.pbb.2013.10.018

Daughton, C. G. & Ruhoy, I. S. (2013) Lower-dose prescribing: Minimizing "side effects" of pharmaceuticals on society and the environment. *Science of the Total Environment, 443 (15 January 2013),* 324-337. doi:10.1016/j.scitotenv.2012.10.092

Gallagher, R. M., Welz-Bosna, M., & Gammaitoni, A. (2007). Assessment of dosing frequency of sustained-release opioid preparations in patients with chronic nonmalignant pain. *Pain Medicine, 8(1),* 71-74.

Green, T., Black, R., Serrano, J., Budman, S., & Butler, S. (2011). Typologies of prescription opioid use in a large sample of adults assessed for substance abuse treatment. *PloS ONE, 6(11),* 1-10. doi:10.1371/journal.pone.0027244

Green, T. C., Mann, M. R., Bowman, S. E., Zaller, N., Soto, X., Gadea, J., Cordy, C., et al. (2012). How does use of a prescription monitoring program change medical practice? *Pain Medicine, 13(10),* 1314-1323.

Haegerich, T. M., Paulozzi, L. J., Manns, B. J., & Jones, C. M. (2014). What we know, and don't know, about the impact of state policy and systems-level interventions on prescription drug overdose. *Drug and Alcohol Dependence, 145(1 December 2014),* 34-47. doi:10.1016/j.drugalcdep.2014.10.001

Hariharan, J., Lamb, G. C., & Neuner, J. M. (2007). Long-term opioid contract use for chronic pain management in primary care practice. A five year experience. *Journal of General Internal Medicine, 22(4),* 485-490. doi:10.1007/s11606-006-0084-1

Hildebran, C., Cohen, D. J., Irvine, J. M., Foley, C., O'Kane, N., Beran, T., & Deyo, R. A. (2014). How clinicians use prescription drug monitoring programs: A qualitative inquiry. *Pain Medicine, 15(7),* 1179-1186.

Hoffman, P. K., Meier, B. P., & Council, J. R. (2002). A comparison of chronic pain between an urban and rural population. *Journal of Community Health Nursing, 19(4),* 213-224.

Inflexxion, Inc. (2008). Current opioid misuse measure (COMM).

Julien, R. M., Advokat, C. D., & Comaty, J. E. (2011). *A primer of drug action: A Comprehensive guide to the actions, uses, and side effects of psychoactive drugs.* (12th ed.). New York, NY: Worth Publishers.

Jung, J. (2010). *Alcohol, other drugs, and behavior: Psychological research perspectives.* (2nd ed.). Los Angeles: Sage.

Kronke, K., Krebs, E. E., Wu, J., Yu, Z., Chumbler, N. R., et al.. (2014). Telecare collaborative management of chronic pain in primary care: A randomized clinical trial. *Journal of the American Medical Association, 312(3),* 240-248. doi: 10.1001/jama.2014.7689

Mansouri, P., Javadpour, S., Zand, F., Ghodsbin, F., Sabetian, G., et al. (2013). Implementation of a protocol for integrated management of pain, agitation, and delirium can improve clinical outcomes in the intensive care unit: A randomized clinical trial. *Journal of Critical Care, 28(6),* 918-922. doi: 10.1016/j.jcrc.2013.06.019

Matthias, M. S., Krebs, E. E., Collins, L. A., Bergman, A. A., Coffing, J., & Bair, M. J. (2013). "I'm not abusing or anything": Patient-physician communication about opioid treatment in chronic pain. *Patient Education and Counseling, 93(2),* 197-202. doi: 10.1016/j.pec.2013.06.021.

McHugh, R. K., Nielsen, S., & Weiss, R. D. (2015). Prescription drug abuse: from epidemiology to public policy. *Journal of Substance Abuse Treatment, 48(1),* 1-7. doi: 10.1016/j.sat.2014.08.004

Miller, K., Rodger, S., Kipping, B., & Kimble, R. M. (2011). A novel technology approach to pain management in children with burns: A prospective randomized controlled trial. *Burns, 37(3),* 395-405. doi: 10.1016/j.burns.2010.12.008

National Institute on Drug Abuse. (December, 2011). Prescription drug abuse: A research update from the national institute on drug abuse. Retrieved from: http://www.drugabuse.gov/sites/default/files/prescription_1.pdf.

National Institute on Drug Abuse. (December, 2012). Prescription and over-the-counter medications. *Drug Facts.* www.drugabuse.gov.

North Dakota Board of Pharmacy. (December, 2012). Retrieved from: http://www.nodakpharmacy.com/PDMP-description.asp.

North Dakota Office of Attorney General. (07/01/2014). 2014 comprehensive status and trends report: A summary evaluation of the status of substance abuse and treatment in North Dakota, and analysis of substance abuse trends.

North Dakota PDMP Prescription Drug Monitoring Program. www.northdakota.pmpaware.net.

North Dakota State University. (2015). IRB protocol form: Exempt categories.

Pergolizzi, J., Pappagallo, M., Stauffer, J., Gharibo, C., Fortner, N., et al. (2010). The role of urine drug testing for patients on opioid therapy. *Pain Practice, 10(6),* 497-507. doi: 10.1111/j.1533-2500.2010.00375.x

Perrone, J., DeRoos, F. J., & Nelson, L. S. (2014). Prescribing practices, knowledge, and use of prescription drug monitoring programs (pdmp) by a national sample of medical toxicologists, 2012. *Journal of Medical Toxicology, 8(4),* 341-352. doi: 10.1007/s13181-012-0250-2

Phillips, J. (2013). Prescription drug abuse: problems, policies, and implications. *Nursing Outlook, 61(2),* 78-84, doi:10.1016/j.outlook.2012.06.009

Ragsdale, M. & Mueller, J. (2005). Plan, do, study, act model to improve an orientation program. *Journal of Nursing Care Quality, 20(3),* 268-272.

Smith, R. J. & Aston-Jones, G. (2014). Incentive learning for morphine-associated stimuli during protracted abstinence increases conditioned drug preference. *Neuropsychopharmacology, 39(2),* 373-379. doi: 10.1038/npp.2013.200

Stinus, L., Cador, M., & Caille, S. (2012). Repeated episodes of heroin cause enduring alterations of circadian activity in protracted abstinence. *Brain Sciences, 2(3),* 421-433. doi: 10.3390/brainsci2030421

Sullivan, L. M. (2012) *Essentials of biostatistics in public health.* (2nd ed.) Burlington, MA: Jones & Bartlett Learning.

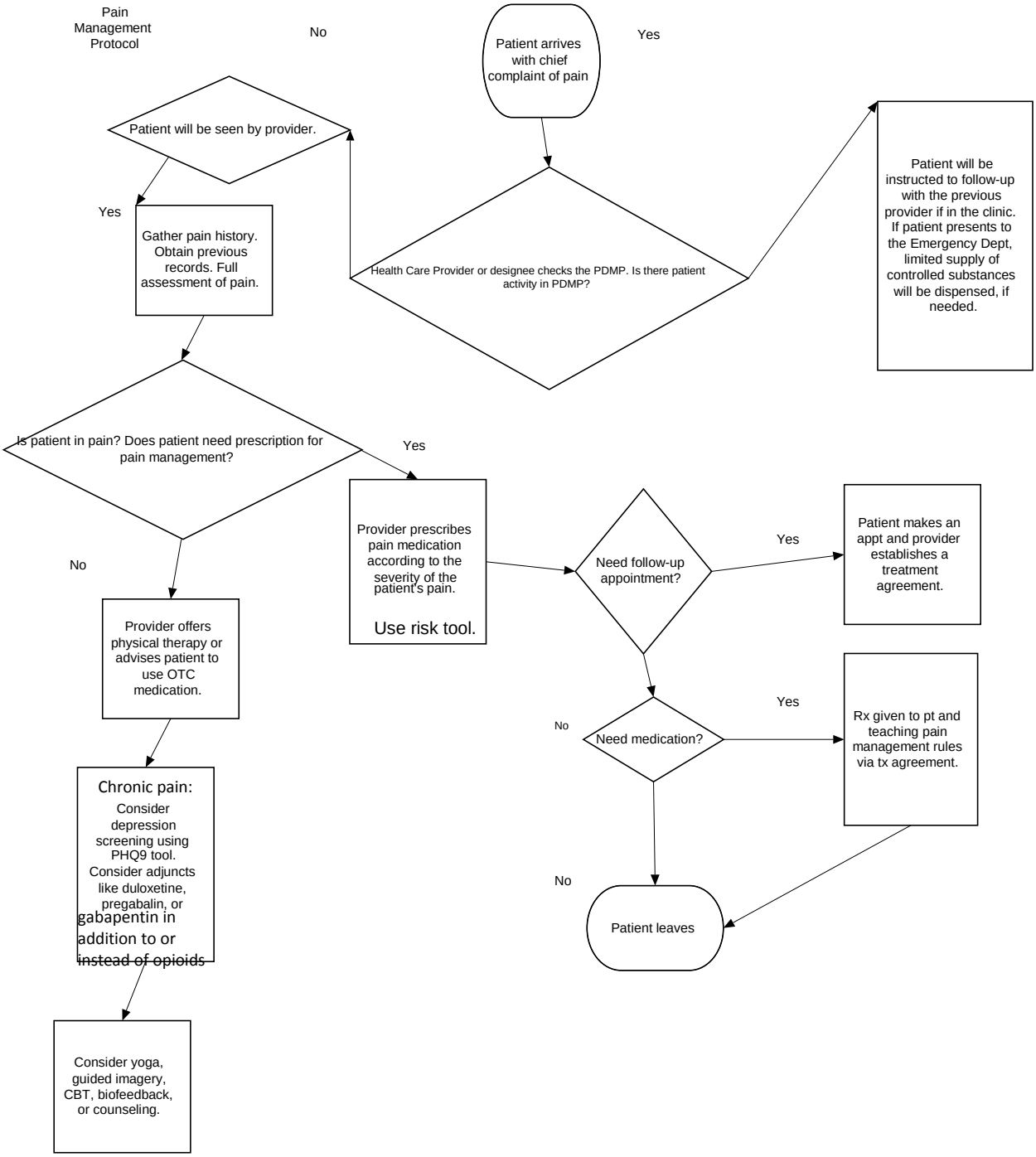
Webster, L. R. (2010). Opioid risk tool: patient form. *CARES Alliance*.

Webster, L. R. & Silva, C. M. (n.d.). Scope of pain: Safe and competent opioid prescribing education. Module 3. Boston University School of Medicine Continuing Medical Education.

Yang, H. T., Hur, G., Kwak, I., Yim, H., Cho, Y. S., et al. (2013). Improvement of burn pain management through routine pain monitoring and pain management protocol. *Burns, 39(4),* 619-624. doi: dx.doi.org/10.1016/j.burns.2012.10.025

Zaccagnini, M. E., & White, K. W. (2014). *The doctor of nursing practice essentials: A new model for advanced practice nursing.* (2nd edition). Burlington, MA: Jones & Bartlett Learning.

APPENDIX A. PAIN MANAGEMENT PROTOCOL ALGORITHM



reference: American Pain Society & American Academy of Pain Medicine. (2012).

APPENDIX B. INSTITUTIONAL REVIEW BOARD APPROVAL LETTER

NDSU NORTH DAKOTA STATE UNIVERSITY

September 21, 2015 **REVISED**

Dr. Mykell Barnacle
Nursing

Re: IRB Certification of Exempt Human Subjects Research:
Protocol #PH16025 , "Prescription Drug Abuse: Implementing an Evidence-Based Pain Management"

Co-investigator(s) and research team: Ginger Warren, Daniel Friesner, Heidi Saarinen

Certification Date: 8/27/2015 Expiration Date: 8/26/2018
Study site(s): St. Luke's Hospital, Crosby Clinic, Lignite Clinic
Sponsor: n/a

The above referenced human subjects research project has been certified as exempt (category # 2) in accordance with federal regulations (Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects). This determination is based on the original submission with updated consent (provided 8/27/2015).

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,

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: 2015.09.21 10:59:45 -05'00'

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.

APPENDIX C. PRE-IMPLEMENTATION ADMINISTRATIVE SURVEY

Please indicate level of agreement with the following statements.

1. Implementing the pain management protocol will be valuable for the daily operations of the organization.

a. Strongly disagree

b. Somewhat Disagree

c. Neither agree nor disagree

d. Agree

e. Strongly agree

If strongly disagree or somewhat disagree, why?

2. How do you anticipate the ease of implementation for the pain management protocol?

a. Very difficult

b. Difficult

c. Neutral

d. Easy

e. Very easy

If very difficult or difficult, why?

3. What do you anticipate will be the level of support from the hospital and clinic staff regarding the implementation of the pain management protocol?

a. Strongly oppose

b. Somewhat oppose

c. Neutral

d. Somewhat favor

e. Strongly favor

4. How do you anticipate the implementation of the pain management protocol will affect normal hospital and clinic daily operations?

a. Very negatively

b. Somewhat negatively

c. Neutral

d. Somewhat positively

e. Very positively

If very negatively or somewhat negatively, why?

APPENDIX D. POST-IMPLEMENTATION ADMINISTRATIVE SURVEY

1. Implementing the pain management protocol has been valuable for the daily operations of the organization.

a. Strongly disagree

b. Somewhat disagree

c. Neither agree nor disagree

d. Agree

e. Strongly agree

If strongly disagree or somewhat disagree, why?

2. How do you feel about the ease of implementing the pain management protocol?

a. Very difficult

b. Difficult

c. Neutral

d. Easy

e. Very easy

If very difficult or difficult, why?

3. What is your perception of the level of support regarding the pain management protocol implementation from the hospital and clinic staff?

a. Strongly oppose

b. Somewhat oppose

c. Neutral

d. Somewhat favor

e. Strongly favor

If strongly oppose or somewhat oppose, why?

4. How has the implementation of the pain management protocol affected normal hospital and clinic daily operations?

a. Very negatively

b. Somewhat negatively

c. Neutral

d. Somewhat positively

e. Very positively

If very negatively or negatively, why?

APPENDIX E. PRE-IMPLEMENTATION PROVIDER SURVEY

1. How would you describe your current level of knowledge regarding best practices for prescribing opiates?

a. Not at all aware

b. Slightly aware

c. Somewhat aware

d. Moderately aware

e. Extremely aware

2. Do you discuss the potential for abuse that certain medications have with the patient before you prescribe them?

a. Never

b. Rarely

c. Occasionally/Sometimes

d. Often

e. Every time

3. If you are concerned that a patient is exhibiting signs of prescription drug abuse or dependence, do you discuss your concerns with the patient?

a. Never

b. Rarely

c. Sometimes

d. Often

e. Always

4. If so, what strategies do you use to promote the health of that patient?

5. Do you currently assess risk of opioid abuse prior to prescribing chronic opioids to a patient?

a. Never

b. Rarely

c. Occasionally

d. A moderate amount

e. A great deal

If so, how?

6. What are your feelings or thoughts about the implementation of the pain management protocol?

7. What do you anticipate will be the benefits of a pain management protocol?

8. What do you anticipate will be the barriers of implementing a pain management protocol?

9. How often do you use the Prescription Drug Monitoring Program (PDMP)?

a. Never

b. Rarely

c. Sometimes

d. Often

e. Always

If not, why?

10. How often do you use a urine drug screen as part of the clinical decision-making process when prescribing controlled substances?

a. Never

b. Almost never

c. Occasionally/Sometimes

d. Almost every time

e. Every time

If not, why?

APPENDIX F. POST-IMPLEMENTATION PROVIDER SURVEY

1. How would you describe your current level of knowledge regarding best practices for prescribing opiates since the pain management protocol was implemented?

a. Not at all aware

b. Slightly aware

c. Somewhat aware

d. Moderately aware

e. Extremely aware

2. Do you discuss the potential for abuse that certain medications have with patients before you prescribe them?

a. Never

b. Rarely

c. Sometimes

d. Often

e. Always

3. If you are concerned that a patient is exhibiting signs of prescription drug abuse or dependence, do you discuss your concern with the patient?

a. Never

b. Rarely

c. Occasionally

d. A moderate amount

e. A great deal

4. If so, what strategies do you use to promote the health of that patient?

5. Do you currently assess risk of opioid abuse prior to prescribing chronic opioids to a patient?

a. Never

b. Rarely

c. Occasionally

d. A moderate amount

e. A great deal

If so, how?

6. What are your feelings or thoughts after the implementation of the pain management protocol?

7. How would you describe the ease or difficulty of the implementation of the protocol?

a. Very difficult

b. Difficult

c. Neutral

d. Easy

e. Very easy

8. How often are you using the Prescription Drug Monitoring Program (PDMP)?

a. Never

b. Almost never

c. Occasionally/Sometimes

d. Almost every time

e. Every time

If not, why?

9. How often do you use a urine drug screen as part of the clinical decision-making process when prescribing controlled substances since the pain management protocol has been implemented?

a. Never

b. Almost never

c. Occasionally/Sometimes

d. Almost every time

e. Every time

If not, why?

10. How often do you follow the protocol when you prescribe a controlled substance?

a. Never

b. Almost never

c. Occasionally/Sometimes

d. Almost every time

e. Every time

11. What are the barriers to consistent use of the protocol?

12. What are the advantages to consistent use of the protocol?

APPENDIX G. EXECUTIVE SUMMARY

Prescription drug abuse is an intentional misuse of a prescribed drug for recreational or other purposes that was not intended by the prescriber of the drug. Since 2012, fatalities from opioid overdoses have risen to approximately 17,000 per year in the United States. The clinical dissertation project was about prescription drug abuse and how to deter it by developing and implementing an evidence-based pain management protocol. This student worked at a rural health clinic and a critical access hospital's emergency department in northwestern North Dakota that did not have a standard protocol to manage acute or chronic pain. This purpose of this project was to bring about awareness on how to deter or prevent prescription drug abuse and to develop a standardized protocol within the critical access hospital's emergency department and rural health clinic in order to bring about solutions to the above problems.

Background

There were many transient oil workers and families that were patients at the rural health clinic and at the critical access hospital's emergency department in northwestern North Dakota. Many of these patients had issues with acute or chronic pain and since they were only in the area temporarily, they were receiving prescriptions from different providers in different states, thus creating a problem within the health care system. This student was advised by the administrators to refer the patients to pain management specialist in two different cities which were at least one hundred miles away. After the patients would go to the pain management specialist, they would be referred back to primary care to manage their pain. This would create more expense and inconvenience for the patient.

When this student was preparing for research, she discussed the need for a pain management protocol with each administrator and provider individually. It was unanimous that a pain management protocol was needed, so this student developed her project.

The parties involved included the North Dakota Board of Pharmacy and the administrators, providers, and nurses of the rural health clinic and critical access hospital's emergency department in northwestern North Dakota. The research process included institutional review board (IRB) approval from North Dakota State University as exempt status because humans were not directly involved in the research. After IRB approval was obtained, this student distributed pre-implementation surveys to each administrator and provider. This student provided individual instruction to each registered nurse and licensed practical nurse on what to look for during their assessment of a patient experiencing opioid withdrawal. Instructions were provided to each nurse on how to apply as a delegate on the North Dakota Prescription Drug Monitoring Program (PDMP). As a delegate, the nurses would research each patient that presented with pain symptoms, requesting controlled substance refills, or would come into the clinic or hospital for a pain management follow-up visit.

Education was given to providers about best practices regarding opioid prescribing. Providers were educated about the importance of PDMP research to know their patient's prescription drug activity before prescribing any medication to them. Providers were also educated about frequent monitoring of their patients to whom they prescribe opioids, including treatment contracts, pill counts, and urine drug screens.

The protocol was implemented for four months and did show improvement in monitoring for prescription drug abuse. After four months, a post-implementation survey was distributed to each administrator and provider.

Findings and Conclusions

The major findings are that the administrators answered in their surveys that the protocol improved the daily operations of the clinic. The providers answered in their surveys that it was helpful that the nurses were delegates in order to save the providers' time so that they could focus on the patient. Providers became more aware of the prescription drug abuse problem and were more cognizant of any of their patients' aberrant behaviors.

There were some confounding variables that affected the critical access hospital's emergency department results, however. There was a new version of the electronic medical record that was being installed and the director of nursing and the staff nurses prioritized learning the new HER rather than becoming a delegate in PDMP. Another confounding variable was that the transient population declined due to the local economy declining. Virtually all of the local oil wells closed and this student's employment contract was shortened as a result of the declining economy.

The providers did become more aware of their controlled substance prescribing practices as a result of the research. The research did improve patient safety of pain management by improving knowledge and awareness to the administrators and providers to use opioids as a last resort to treat pain and to use other modalities such as physical therapy.

The providers benefitted from the research because they were encouraged from the North Dakota Board of Pharmacy to use PDMP themselves or have a delegate. It is a new best practice for every clinic and hospital in the nation have a pain management protocol in force in order to control opioid prescribing practices and monitor patients closely for diversion.

Recommendations for Further Action

In October of 2014 the Drug Enforcement Agency (DEA) moved hydrocodone up from a Schedule III controlled substance to a Schedule II controlled substance, which limited prescribing to a quantity of a one-month supply and no refills. According to Kathy Zahn, the director of PDMP, the North Dakota Board of Pharmacy has already begun monitoring each provider's use of PDMP and if a provider is found not to be using the database, their licensing organizations will be notified for possible further disciplinary action.