

OPIOIDS: A REASON FOR CONCERN

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ABSTRACT

The opioid epidemic has drawn increasing attention as opioid prescribing rates and opioid related deaths continue to rise. Opioid prescribing by health care providers has quadrupled over the past 18 years and is directly proportionate to opioid-related overdoses. Primary care providers initiate chronic opioid pain management and frequently fail due to the multifaceted nature of chronic pain.

A rural North Dakota health care system implemented strategies to improve chronic opioid pain management. Strategies were based on the 2016 Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain. Interventions were directed at improving opioid prescribing practices for chronic non-cancer pain management of primary care providers and reducing risks of long term opioid use. Providing clinicians with education and a quick-reference sheet on current evidence-based recommendations and accepted best practices developed their knowledge to complete remaining interventions. Chart audits identified patients on chronic opioid therapy, patients with a signed pain contract, and those with daily opioid doses meeting or exceeding recommended upper daily morphine milligram equivalence. Provider notification of identified patients allowed for further recommended interventions. Chart flagging allowed providers to easily identify patients currently on a pain contract, patients eligible for a pain contract, and patients receiving the upper daily morphine milligram equivalence limits.

Evaluation was performed four months after initiation of the project. Results showed the education provided increased clinicians' knowledge and comfort in the evidence-based guidelines for managing chronic pain with opioids. Recommended monitoring strategies were improved after providers received education. Evaluation found the prescription drug monitoring program review and documentation had improved from 0 to 18. Annual urine drug screens

increased from 9 to 15. Eighty-five percent of pain contract eligible patients were enrolled in a pain contract. Evaluation of patients prescribed daily morphine milligram equivalence ≥ 50 and ≥ 90 that had appropriate recommended interventions were 57% and 50% respectively. Forty-five pain management patients were identified at the time of evaluation and flagged in the electronic health record. Overall, each intervention implemented showed improvement upon comparison of pre-implementation and post-implementation data.

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CHAPTER ONE. INTRODUCTION

Background and Significance

Multiple chronic non-cancer pain management guidelines exist for use in practice. These guidelines hold similar elements but variations of specific recommendations between guidelines cause confusion and inconsistencies in care (U.S. Department of Health and Human Services [USDHHS], 2016). The U.S. Department of Health and Human Services (2016) discussed many current guidelines and their formulation was built off evidence from studies prior to 2010. Clarity is needed between these variations of recommendations to provide clinicians with up-to-date evidence for practice. Clinicians often fail to use guidelines and practices intended to decrease misuse and abuse risks (USDHHS, 2016).

Chronic pain is a growing issue in the United States. The number of individuals affected by chronic pain are increasing each year (Hooten et al., 2013). Opioid pain medication prescribing habits of providers are directly proportionate with deaths related to prescription opioids (Centers for Disease Control and Prevention [CDC], 2014; USDHHS, 2016). In 2015, prescription opioids account for nearly half of United States opioid related deaths (USDHHS, 2016). More than 15,000 overdose deaths involving prescription opioids occurred in 2015, averaging about 46 people each day. Since 1999, prescription opioid related overdose deaths and opioid prescribing habits of providers have quadrupled (CDC, 2016).

Chronic Pain

Chronic pain can be defined multiple ways with varying durations of pain, intensity level, or activity interference (Currow, Phillips, & Clark, 2016). Chronic pain has multiple definitions throughout literature, including: pain lasting greater than three months, pain lasting greater than six months, and pain lasting longer than the normal amount of time expected for an injury

(Denenberg & Curtiss, 2016; USDHHS, 2016; Hooten et al., 2013). The Association for the Study of Pain defines pain as an emotional and unpleasant sensory experience associated with tissue damage (Rosenberg, 2013). The most prevalent definition is pain lasting longer than the expected time of healing for an injury or pain lasting greater than or equal to three months (Noble et al., 2016). Chronic pain results from underlying medical conditions, medical treatments, injury, inflammation, and unknown causes (Institute of Medicine, 2011). Many types of pain can be identified through research: nociceptive, neuropathic, psychogenic, idiopathic, inflammatory, muscle, and mechanical/compressive (Hooten et al., 2013; Rosenberg, 2013). Pinpointing pain is difficult because it is multi-faceted and ever-changing.

Chronic pain has become an increasing issue in the United States that has created a burden of opioid overuse and abuse. More than 50 million adults are affected by chronic pain each year (Hooten et al., 2013). The National Health Interview Survey provided by the CDC reported 11.2% of United States adults had experienced chronic pain daily, three months prior to taking the survey (Nahin, 2015). Opioid pain medication has been a staple in treatment for acute and chronic pain. Acute pain increases the risk of developing chronic pain (IOM, 2011). Treatment using opioids for acute pain often leads to long-term opioid use. Early exposure and higher doses of opioid use for acute pain increases the risk of long-term opioid use (Alam et al., 2012; USDHHS, 2016). Two different studies examine opioid use for acute pain leading to long-term use. The first study identified that opioid use within seven days of low-risk surgery was associated with increased likelihood of opioid use at one year with an adjusted odds ratio of 1.44. The second study found that opioid use in the first 15 days after the onset of low back pain had an increased risk of long-term opioid use with an adjusted odds ratio of 2.08 (USDHHS, 2016).

Prevalence

The prevalence of opioid prescriptions is astounding. The United States has an opioid consumption rate greater than any other nation. In 2012, 259 million opioid pain medication prescriptions were provided by health care clinicians, which is enough for every United States adult to have one bottle of opioids (CDC, 2014). From 2007 to 2012 per capita rates of opioid prescriptions increased by 7.3%. Growing popularity of prescribing opioid pain medication is seen among internal medicine, general, and family practice clinicians (Levy, Paulozzi, Mack, & Jones, 2015). Growing rates of opioid prescriptions is disproportionate to the health status of the United States population (CDC, 2014; USDHHS, 2016). According to the USDHHS (2016) “9.6-11.5 million adults, or approximately 3%-4% of the United States adult population, were prescribed long-term opioid therapy in 2005” (p. 2). A National Survey on Drug Use and Health performed by the USDHHS reported that in 2010, roughly 1 in every 20 individuals, 12 years and older, used opioids recreationally (Del Portal, Healy, Satz, & McNamara, 2016). While chronic opioid therapy possesses legitimate therapeutic uses, prescribers should consider the negative consequences that may result from chronic opioid therapy.

Negative Consequences of Opioid Prescribing

Increasing opioid prescriptions are directly proportional to abuse and overdose rates. Clinicians deem opioid abuse as a major public health issue (Del Portal, Healy, Satz, & McNamara, 2016). Opioid pain medication related deaths amounted to more than 165,000 people from 1999 to 2014 in the United States. Of these deaths, rates were highest in ages 25 to 54 years, men, non-Hispanic whites, American Indian, and Alaskan Natives as compared to non-Hispanic blacks and Hispanics (USDHHS, 2016). Prescriptions are fueling the opioid epidemic in the United States, as half of opioid related overdose deaths are a result of prescription opioids.

Over 14,000 United States deaths in 2014 were a result of prescription opioid medication (USDHHS, 2016).

Opioid use disorders are another area of concern with increasing rates of prescription opioids. In 2011, estimates of greater than 420,000 visits to the emergency room were a result of opioid pain medication misuse or abuse (USDHHS, 2013). Hahn (2011) compared non-opioid abusers to opioid abusers and found that opioid abusers have higher rates of provider and emergency room visits, hospital admissions, motor vehicle accidents, documented trauma cases, and abuse treatment. Drug abuse is the habitual or continued ingestion of addictive or illegal drugs (Martin, Zieve, & Ogilvie, 2016). Drug misuse is defined by the National Institute on Drug Abuse (2016) as “taking a medication in a manner or dose other than prescribed; taking someone else’s prescription, even if for a legitimate medical complaint such as pain; taking a medication to feel euphoria; or nonmedical use of prescription drugs” (p. 1).

Opioid use disorders are often demonstrated by the following characteristics: unsuccessful efforts to cut down, unsuccessful efforts to control use, and failure to uphold routines of life at home, work, or school (American Psychiatric Association [APA], 2013). Although opioid abuse is growing, the phenomenon should not be confused with those who have a tolerance and physical dependence to the medication. Behavior differences exist between tolerance and physical dependence. Tolerance describes reduced efficiency of medication effects, such as pain relief, after recurrent use (USDHHS, 2014). Physical dependence describes the body’s physical reliance on a medication that produces withdrawal symptoms when the medication is stopped abruptly (USDHHS, 2014). Opioid pain medication is over-prescribed for individuals with all types of pain. Over-prescribed can be defined as prescribing opioids for prolonged periods of time when not indicated, opioids being prescribed as a first-line treatment

when other non-pharmacological and non-opioid pharmacological treatments have been tried, or opioids are continually prescribed in larger doses when no therapeutic effect is achieved (USDHHS, 2016). Addiction is commonly a consequence of over-prescribing and prolonged opioid use (Wilson et. al, 2013). Evidence supports that increased opioid dosage is related to the risk of addiction and overdose associated with chronic opioid therapy (USDHHS, 2016). Further exploration into interventions reducing opioid overprescribing, opioid abuse, and overdose is needed.

Cost

Chronic pain treatment in the United States has amounted to more than half a trillion dollars every year. Pain is one main reason people seek out a primary care provider (American Academy of Pain Medicine [AAPM], 2013). Healthcare costs of opioid abusers were eight times higher than non-opioid abusers (Hahn, 2011). Further breakdown showed, on average, an individual who abuses opioids incurs increased health care costs of \$15, 884 per year. In comparison, non-abusers spend an average of \$1,830 per year (Hahn, 2011). According to Hahn (2011), “prescription costs were five times greater for abusers compared with non-abusers with a mean cost of \$2,034 vs \$386 respectively” (p. 109). An estimated \$174 billion is spent annually on pain management by society and the health care system. The estimated cost of chronic pain on lost productivity in the workforce amounts to 61.2 billion per year (Rosenberg, 2013). Improving pain management, functionality, and quality of life, while decreasing rates of opioid prescriptions, opioid misuse, and overdose would significantly affect the current cost of chronic pain management.

Impact

Chronic pain affects many aspects of life for individuals living with it including but not limited to: neurological system, emotions, behavior, ability to perform daily tasks, ability to work, social responsibilities, and quality of life (Agency Medical Directors' Group [AMGD], 2015; USDHHS, 2013; IOM, 2011). Chronic non-cancer pain has been found to be the leading cause of long-term disability. Americans affected by pain totals more than those with conditions such as diabetes, heart disease, and cancer combined (USDHHS, 2013). Increasing pressure to improve pain, management and reduce prescription opioids use occur along a continuum, making it difficult for providers to achieve balance. Patient expectations shape health care encounters. Patients seeking care expect clinicians to provide an intervention that the patient could not achieve at home, therefore, they may become dissatisfied when clinicians fail to meet those expectations. An example would be, a patient seeking care for pain and expecting to receive a prescription pain medication but instead receives a referral to physical therapy or education on at home care of pain including over the counter pain medications (Zgierska, Miller, & Rabago, 2012). Dissatisfied patients may rate the entire visit experience on whether or not they received a prescription in comparison to the overall visit experience. Due to increased focus on patient satisfaction scores providers feel pressured to achieve positive patient experiences. Quality of care and patient satisfaction target scores have become a driving force behind clinician compensation. Facilities set benchmarks on satisfaction scores and may use these scores in consideration when reviewing the provider's salary, job retention, or job promotions. Increased availability of circulating opioids, prescription opioid diversion, misuse, and related harms are direct consequences of the patient satisfaction scores driving quality of care, facility

reimbursement, and provider compensation (Zgierska, Miller, & Rabago, 2012). Chronic pain is a serious issue that needs attention and intervention (Currow et al., 2016).

Purpose

The quality improvement project provided clinicians with tools and processes using evidence-based guideline recommendations and accepted best practices offering solutions to problematic prescribing, encouraging positive change in prescribing habits, expanding provider knowledge, optimizing patient care, and improving patient safety by reducing risk of long term opioid use. The practice improvement interventions targeted primary care providers who care for chronic pain patients. Patients 18 years and older on chronic pain therapy in a rural health care setting were the population of focus. The project pushes for practice change leading to decreased circulating opioids that are being misused and contributing to the epidemic of opioid overdose (USDHHS, 2016).

Congruence of the Project to the Organization's Goals

In discussing the needs of Coal Country Community Health Clinic with Dr. Aaron Garman, medical director, opioid overprescribing, lack of confidence in opioid prescribing, and lack of education on opioid prescribing were identified as the primary needs. Working in conjunction with the organization, a plan was designed to fit best within the constraints of the project, but also providing benefit to the clinic. The overall goal of the project is to improve prescribing practices among providers in rural health settings.

Objectives

1. Provide education regarding current chronic pain management recommendations and accepted best practices from the 2016 CDC guidelines for:
 - a. Prescription Drug Monitoring Program (PDMP) use

- b. Urine drug screens (UDS)
 - c. Morphine Milligram Equivalence (MME) dosing
 - d. Pain contracts
2. Flag all patients on a pain contract within the EHR using a uniform system.
 3. Identify all patients without a pain contract who have been prescribed opioids ≥ 3 months and enroll identified patients in a pain contract over a 4-month period.
 4. Determine all patients who have been prescribed opioids ≥ 3 months and who are receiving doses that place them at increased risk (patients prescribed doses ≥ 50 MME per day and prescribed ≥ 90 MME per day). Develop strategies to reduce risk associated with upper daily limits of opioids.
 5. Develop sustainability practices to ensure compliance and continued monitoring of implemented recommendations for chronic pain management patients upon completion of project.

CHAPTER TWO. LITERATURE REVIEW AND THEORETICAL FRAMEWORK

Review of Literature

A literature review was conducted using evidence-based articles found in the following databases: EBSCOhost, PubMed, CINAHL, and Cochrane. Keywords included opioids, pain, chronic pain, pain management, contract, pain contract, prescribing, practices, prescribing practices, prescription, adherence, therapy, opioid therapy, drug, attitudes, pharmacy, risk, assessment, aberrant, behavior, primary, care, narcotics, monitoring, substance, abuse, health care, guidelines, analgesics, monitoring, diversion, and controlled substances. All searches were focused on finding articles pertaining to chronic opioid therapy for pain management. The literature review identified the CDC Guideline for Prescribing Opioids for Chronic Pain, released by the CDC in March of 2016, as the most current set of chronic pain management guideline with strong supporting evidence. The CDC guideline will be used as a footprint for this project.

Introduction

Opioid abuse and misuse continues to be a growing topic of interest. Over the past decade, the number of opioid prescriptions has increased. The strongest counterweight for opioid over-prescribing is awareness and education, and those elements are where recent efforts to curb opioid over-prescribing have been focused. Opioids are effective tools to relieve acute and chronic pain, but for clinicians, abuse and misuse of opioids creates strain on chronic pain management (USDHHS, 2016). Treating chronic pain with opioid medication poses a challenge for clinicians. Research and recent evidence provides a foundation to improve management of pain with opioids and opioid prescribing habits of clinicians through guidelines. Current guidelines focus on reducing the negative consequences of rise in opioid prescriptions while improving patient quality of life. Currently, many organizations rely on pain management

guidelines aimed at universal use for all clinicians leading to uniformed prescribing and improving quality care for all chronic pain management patients. In the early months of 2016 the CDC released a universal chronic pain management guideline based off the latest evidence (USDHHS, 2016).

Pain Management Guidelines

One suggested way to reduce overprescribing, opioid abuse, and addiction is to provide guidelines and streamline chronic non-cancer pain management (USDHHS, 2016). Clinicians have shown concern with patient misuse and addiction to opioid pain medication. Additionally, clinicians report stress related to managing chronic pain, as well as inadequate education regarding prescribing opioids (Jamison, Sheehan, Scanlan, Matthews, & Ross, 2014). Building an opioid management protocol can decrease rates of opioid prescriptions and allow for close management of those taking long-term opioid pain medication (USDHHS, 2016).

Opioid prescriptions, opioid abuse, and overdose rates continue to increase. The use of an opioid management guideline has been recommended by the American Pain Society, American Academy of Pain Medicine, Agency Medical Directors' Group, the U.S. Department of Veterans Affairs, and the CDC. Recently the USDHHS suggested using pain management guidelines as a tool for clinical decision making among health care clinicians. The overall goal for chronic pain treatment guidelines is not achieving a pain free state but aims interventions at reducing the problem of improper prescribing habits and drug abuse while improving pain management, decreasing suffering, and improving function and quality of life (AAPM, 2013; Currow et al., 2016; Denenberg & Curtiss, 2016; Rosenberg, 2013). A study done by Von Korff (2016) found that a set of guidelines in Washington state helped health care providers decrease both opioid dose amounts and excess opioid days supplied to patients.

Many different variations of opioid management guidelines exist. Evidence-based practice can be used to guide improving patient outcomes (USDHHS, 2016). One study found that when combined, referrals to specialist services, urine drug screening, pharmacy drug monitoring, treatment agreements, and patient education reduced substance misuse by 50% (Currow et al., 2016). Current research concluded with medium strength evidence that interventions such as patient assessment, risk-screening tools, controlled substance agreements, careful dose titration, opioid dose ceilings, and adherence to practice guidelines reduce the risk of inappropriate prescription drug-related behaviors (Currow et al., 2016; Denedberg & Curtiss, 2016; USDHHS, 2016). Although medium strength evidence is found throughout research, experts have taken current evidence and made strong suggestions in building new guidelines to aid in chronic pain management (Currow et al., 2016; Denedberg & Curtiss, 2016; USDHHS, 2016). Standardizing guidelines to use in practice will provide structure, improve patient care, and provide evidence-based framework across practice (AAPM, 2013). The AAPM (2013) identified the importance of patient-centered care for diagnosing and treating pain that is comprehensive, systematic, and collaborative.

Guidelines include an array of risk mitigation strategies: risk assessment instruments, opioid management plans, patient education, urine drug screening, use of prescription drug monitoring programs, pill counting, and pain management contracts. Risk mitigation is difficult to evaluate due to lack of supporting studies with sufficient evidence showing improvements in overdose, addiction, abuse, or misuse outcomes (USDHHS, 2016). One set of guidelines suggest a trial of opioid therapy prior to making a final decision to use opioids as a means of chronic pain management. The length of trial is based on clinical judgement, and enough time should be provided to make an informed decision regarding if the current prescribed opioid improves pain,

function, and quality of life (Chou et al., 2014). Current guidelines available combine multiple risk mitigation strategies.

Pain Management

The approach for pain management should be a combination of therapies to reduce pain intensity, improving functionality and quality of life (Chou et al., 2014). Safer alternatives to opioid therapy exist which can be equally effective long-term. (AMDG, 2015). Current guidelines hold similar views that begin by assessing the current individual and building a comprehensive multi-therapy management combining nonpharmacological interventions and non-opioid medication as the first line treatment (Denedberg & Curtiss, 2016; USDHHS, 2016; Hooten et al., 2013). Major goals of long-term pain management in chronic non-cancer pain is a reduction in pain level, anxiety, and adverse effects while improving functional ability, quality of life, rates of individuals returning to work, and cost-effective care (National Guideline Clearinghouse [NGC], 2013). Complete pain relief is not expected with long-term opioid therapy. Clinicians should discuss realistic expectations of benefits from therapy (USDHHS, 2016).

Non-Opioid Therapy

Chronic pain management can produce challenges in decreasing pain, improving function, and quality of life. Nonpharmacological and non-opioid pharmacologic therapies should be first line therapy for chronic pain. Non-opioid analgesics such as acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), antidepressants, and anticonvulsants have been found to be equally or more effective in treating chronic pain while inducing less risk and harm than opioids (AMDG, 2015; Denedberg & Curtiss, 2016). Initial treatment should be determined by the cause of pain (AMDG, 2015; Chou et al., 2014).

Adjunctive non-pharmacological pain interventions have not been suggested for sole use but are to be used in combination with pharmacological interventions. Nonpharmacological interventions include relaxation, guided imagery, acupuncture, massage, acupressure, aromatherapy, reflexology, yoga therapy, music therapy, use of distraction, heat and cold therapy, electrotherapy, cognitive behavioral therapy, spiritual therapy education, exercise, physical therapy, epidural injections, and steroid injections (AMDG, 2015; Denenberg & Curtiss, 2016; Gregory, 2014; USDHHS, 2016; Hooten et al., 2013; NGC, 2013; Rosenberg, 2013). Alternative treatments such as cognitive behavioral therapy have been shown to modify cognitive processes and environmental factors decreasing pain perception (USDHHS, 2016). Exercise therapy has improved pain, function, and well-being in individuals with osteoarthritis of the knees and hips, chronic low back pain, and fibromyalgia (USDHHS, 2016; Hooten et al., 2013).

Non-opioid analgesics should be used as first line treatment for chronic management (USDHHS, 2016). Non-opioid treatment options for pain include NSAIDs, acetaminophen, and cyclooxygenase 2 (COX-2) inhibitors (Chou et al, 2014; USDHHS, 2016). These medications are not advised without risk. Nonsteroidal anti-inflammatories are associated with gastritis, peptic ulcer disease, cardiovascular events, fluid retention, and can interfere with platelet aggregation. Acetaminophen is associated with hepatotoxicity (Chou et al. 2014; USDHHS, 2016).

Other non-opioid medications that providers can contemplate are tricyclic antidepressants (TCAs), serotonin-norepinephrine reuptake inhibitors (SNRIs), and anticonvulsants (gabapentin, pregabalin) for neuropathic pain, centralized pain syndromes, and fibromyalgia. Lack of long-term benefits from muscle relaxants means they should not be prescribed for more than a few

weeks (AMDG, 2015; Chou et al., 2014; Hooten et al., 2013). Guidelines agree first and second line drug management for neuropathic pain are anticonvulsants and antidepressants (USDHHS, 2016; Hooten et al., 2013).

Existing treatment guidelines hold similar beliefs in the progression of chronic pain management starting preferably with a combination of non-pharmacological and non-opioid analgesic and build up to opioids if needed (Denenberg & Curtiss, 2016; USDHHS, 2016; NGC, 2013). Once opioid therapy is initiated, risk mitigation strategies should be considered. Combining therapies that are both physical and psychological have been found to be more effective in reducing pain and improving function in comparison to single therapies (USDHHS, 2016; Lee, Crawford, & Swann, 2014).

Naloxone and methadone are not used directly for pain management, but the two medications are important in providing care to patients with high risk of opioid overdose and have an opioid addiction. Long-term opioid therapy carries concern of misuse and abuse. Incorporation of naloxone should be considered for individuals with risk factors for opioid related harms. Naloxone is an opioid antagonist that reverses the effects of opioids such as respiratory depression. The medication may be administered by family or friends to save the lives of individuals who have overdosed on opioids. For patients with physical dependence on opioids, naloxone can precipitate acute opioid withdrawal (USDHHS, 2016). Risk factors for opioid related harms include history of overdose, history of substance use disorder, higher dosages of greater than or equal to 50 MME/day, or concurrent benzodiazepine use (Currow et al., 2016; USDHHS, 2016). Concurrent with naloxone, use of mitigation strategies should be used (USDHHS, 2016). Positive outcomes by community-based prevention programs show decreased opioid overdose risk and opioid overdose deaths when prescribing naloxone in

combination with opioid therapy (Walley et al. 2013). Methadone is also recommended for when opioid therapy has failed (Manchikanti et al., 2012). Methadone should not be prescribed with chronic pain management by clinicians without proper knowledge about methadone's pharmacokinetics, unpredictable clearance, multiple drug-to-drug interactions, and additional monitoring requirements (AMDG, 2015; Chou et al., 2009). Methadone related deaths account for one-third of all opioid-related overdose deaths and is increasing (USDHHS, 2016; CDC, 2012; Ray et al., 2015).

No matter the treatment, benefits must always outweigh the risks prior to initiation and throughout therapy. Strong evidence shows more benefits and less risks are involved with nonpharmacological and non-opioid pharmacologic treatments when compared to long-term opioid therapy (USDHHS, 2016).

Opioids Therapy For Chronic Pain Management

Opioid therapy for chronic pain management remains controversial. Weak evidence supports the use of opioids for long-term therapy of chronic non-cancer pain. Poor evidence exists showing improvement of pain and function with use of opioids (USDHHS, 2016; Chou et al., 2014). Failure of opioid pain therapy to initiate early pain relief, within one month, is associated with lower success of pain relief with long-term opioid therapy (USDHHS, 2016). Opioids should be used as a last resort treatment method and should only be prescribed when other treatment modalities have failed (AAPM, 2013; AMDG, 2015; NGC, 213). The International Association for the Study of Pain identifies opioid prescriptions lasting longer than 90 days within the past 120 days constitutes chronic opioid therapy (Currow et al., 2016). Full pain relief is often difficult to achieve in individuals with chronic pain, therefore obtainable pain level goals should be discussed (USDHHS, 2016; Chou et al., 2014).

Many different opioids exist and vary in indication and strength. Treating mild to moderate pain when non-opioid treatment modalities have failed would indicate weak opioids including codeine and tramadol. Moderate to severe pain would indicate strong opioids such as hydrocodone, morphine, oxycodone, fentanyl, and hydromorphone (Gregory, 2014). Treatment regimens the patient has previously tried and the severity of their pain will help determine which opioid to prescribe.

Upon initiation of opioid therapy clinicians should start with the lowest effective short acting dose possible, and one deemed medically necessary (AMDG, 2015; USDHHS, 2016; Manchikanti et al., 2012). Long-term opioid therapy manifests tolerance and loss of effectiveness. Continued use will be dependent on factors of improved pain, physical function, quality of life, reduced adverse effects, and behaviors of misuse and abuse (AAPM, 2013; NGC, 2013). During therapy, if risks outweigh the benefits, optimization of other therapies and tapering to lower doses or discontinuing opioid therapy is appropriate (Chou et al., 2014; Denenberg & Curtiss, 2016; USDHHS, 2016). Opioid therapy for chronic pain management is absolutely contraindicated in individuals with respiratory instability, acute psychiatric instability, uncontrolled suicide risk, active or history of substance abuse, confirmed allergy to the drug, life-limiting drug interaction with another medication, or diversion (Manchikanti et al., 2012).

Prescribing opioids for acute pain can cause lasting consequences. Long-term opioid therapy often results from acute pain management with opioids (Alam et al., 2012; USDHHS, 2016). Strategies for clinicians to reduce risk of transition to long-term opioid use includes the following: prescribe the lowest dose possible, prescribe short acting narcotics whenever possible, and prescribe only the quantity needed for the expected timeframe of severe acute pain. Seven days of severe pain is rare, up to three days of opioid pain medicine will usually be sufficient to

treat severe acute pain (USDHHS, 2016). Acute pain needs to be managed appropriately to reduce risk of long-term opioid therapy.

Benefits

Opioid use for chronic pain management is a topic of interest. Evidence supporting the benefits of using long-term opioids for chronic non-cancer pain is inadequate and weak (Currow et al., 2016; Noble, 2016; AMDG, 2015). Many current guidelines acknowledge little data supporting use of opioids for long-term or more than three months (Currow et al., 2016). Although, providers should not disregard the use of opioids in treating pain. An estimated 40%-70% of patients on long-term opioid therapy for chronic pain do not achieve effective analgesia, leaving 30%-60% who do (Currow et al., 2016).

Risks

Opioid therapy for chronic pain management holds consequences. Many adverse effects are associated with opioid medications including misuse and abuse. Improper prescribing and pain management contributes to these effects. Providers should be cautious when prescribing opioids. Common side effects from opioids include: constipation, sedation, dry mouth, nausea, vomiting, respiratory depression, and dizziness. Most side effects diminish with time except respiratory depression and constipation which persist (AMDG, 2015; Chou et al., 2014; Currow et al., 2016; Denenberg & Curtiss, 2016; USDHHS, 2106). Side effects that are less common include: urinary retention, confusion, delirium, hallucinations, muscle rigidity, and hyperalgesia (AMDG, 2015; Chou et al., 2014; Currow et al., 2016; USDHHS, 2106). Gonadotrophin-releasing hormone (GnRH) suppression occurs with opioid use at the hypothalamus. GnRH suppression causes complications such as: increased bone mineral density loss, decreased muscle mass, immunologic and hormonal dysfunction, hypogonadism, amenorrhea, oligomenorrhea,

decreased sexual drive, and erectile dysfunction (AMDG, 2015; Denenberg & Curtiss, 2016; USDHHS, 2106). Side effects should be treated appropriately when opioid management benefits continue to outweigh the risks (Chou et al., 2014). At the start of long-term opioid therapy, implementation of a bowel regimen needs consideration, including: prescribing regular laxatives, medication specific for opioid induced constipation (naloxogel, methylnaltrexone, and lubiproston), stool softeners, increasing hydration, increasing fiber intake, and increasing physical activity (AMDG, 2015; USDHHS, 2016; Manchikanti et al., 2012).

Long-term opioids run the risk of tolerance, physical dependence, and withdrawal symptoms when stopped abruptly (AMDG, 2015; Chou et al., 2014; Denenberg & Curtiss, 2016). Opioid tolerance occurs at a slow rate and is used to describe the body's ability to become tolerant of certain side effects such as sedation, nausea and vomiting, euphoria, and anxiety. Tolerance to analgesic effects causes current prescribed doses to become less effective over time and can be recognized through assessment (Denenberg & Curtiss, 2016). Physical dependence is the body's ability to adapt to the opioid medication causing withdrawal symptoms when abruptly stopped, and is an expected effect of long-term opioid therapy, withdrawal symptoms occur about 12 hours after the last dose (Denenberg & Curtiss, 2016). Withdrawal symptoms are recognized as sympathetic arousal, elevated heart rate and blood pressure, pupillary dilation, goose bumps, anxiety, jittery behavior, nausea, diarrhea, runny nose, yawning, myalgia, and insomnia (Denenberg & Curtiss, 2016). Treatment for withdrawal symptoms include resuming opioids or use of an alpha-blocking agent such as clonidine. Opioid tapering will help reduce withdrawal symptoms (Denenberg & Curtiss, 2016).

Concurrent use of opioids, neuro depressants, or sedating medications increase risk of sedation, hypoventilation, falls, accidents, unintentional death and sudden death and therefore

should be limited (AMDG, 2015; Currow et al., 2016; Denenberg & Curtiss, 2016). Neuro depressants and sedating medications include: alcohol, benzodiazepines, carisoprodol, zolpidem, butalbital, gabapentin, pregabalin, hydroxyzine, and promethazine. When combining use of opioids and benzodiazepines, risk for potential fatal overdose increases by 31-61% (Dasgupta et al., 2015; Gomes et al., 2011; USDHHS, 2016; Jones & McAninch, 2015).

Risk of cardio-respiratory events increase when individuals on long-term opioid therapy have underlying sleep apnea and end-stage respiratory disease (AAPM, 2013; USDHHS, 2016). Risk of respiratory depression limits provider use of opioids in pain management (AAPM, 2013; AMDG, 2015). Risk of myocardial infarction when taking long-term opioids increases by 28% (Currow et al., 2016). Prescribing opioids to older patients doubles their risk of falls and fractures when taking greater than or equal to 50 MME daily (AMDG, 2015; Rolita, Spegman, Tang, & Cronstein, 2013). Increased risk of adverse effects increases in patients with hepatic and renal insufficiency. Impaired hepatic or renal function may result in metabolism changes causing increased half-life, amplified effects, and decreased amounts requiring respiratory depression and overdose. As individuals age, a natural decline of organ function begins, therefore, clinicians must pay special attention to individuals greater than or equal to 65 years because affects from changed metabolism occur at an increased rate (Currow et al., 2016; USDHHS, 2016).

Pregnant women using opioids are at an increased risk for birth defects, neural tube defects, congenital heart defects, gastroschisis, poor fetal growth, and neonatal opioid withdrawal syndrome occurring after birth. Opioid use during pregnancy also increases risk for preterm delivery and still births (Broussard et al. 2011; Chou et al., 2014; USDHHS, 2016; Yazdy, Mitchell, Tinker, Parker, & Werler, 2013). Opioid use during pregnancy is contraindicated.

Increased risk for opioid use disorders has been linked with mental health disorders, history of substance use disorders, and history of nonfatal overdose (USDHHS, 2016; Howe & Sullivan, 2014). Some mental health disorders such as depression increases risk of opioid related overdoses and is directly proportionate to dose (Turner & Liang, 2015). Psychological issues arise from long-term opioid use as well, depression in those not previously depressed, induced anxiety, and lower self-efficacy (Currow et al., 2016; USDHHS, 2016). Overuse and abuse of opioid therapy has become an increasing issue across the United States. Risk of misuse, psychological dependency, and overdose increases in patients on long-term opioid for chronic non-cancer pain (Currow et al., 2016).

Assessment

Assessment holds to be one key element in all clinical practice guidelines and existing research. Assessment identifies an initial pain management treatment plan based off what has or has not been tried in the past, improvement in function and pain, and drives changes in the treatment plan (Manchikanti et al., 2012). Initial assessment prior to starting any treatment should include: past medical history, extensive pain history, impact of pain, physical examination, review of previous diagnostic studies, review of previous treatments, substance use history, psychological history, psychosocial history, and comorbidities. (AAPM, 2013; AMDG, 2015; Chou et al., 2014; Denenberg & Curtiss, 2016; Hooten et al., 2013; Manchikanti et al., 2012; Rosenberg, 2013). Additional diagnostic testing may be warranted if previous tests are outdated or missing (Rosenberg, 2013).

Aside from the initial assessment, frequent reassessment aids in determining the response to pain management by assessing the functional status, pain intensity, continued analgesic effect, adverse effects, progress towards therapeutic goal achievement, quality of life, therapy

adherence, and medication misuse (AAPM, 2013; AMDG, 2015; Chou et al., 2014). Pain and functional assessment should demonstrate clinically meaningful improvement, which is defined as at least 30% improvement in pain and function compared to initial or last dosage of opioid therapy (AMDG, 2015; USDHHS, 2016). The Pain average, interference with Enjoyment of life, and interference with General activity (PEG) assessment scale is a validated tool to be used in evaluating pain and function outcomes over time (USDHHS, 2016). Decreased pain with failure to improve function does not meet the clinically meaningful improvement standard (AMDG, 2015). Long-term opioid therapy may be continued if accompanied by monitoring adherence, improved function abilities, and improved pain (Manchikanti et al., 2012). If current or increased opioid dosages fail to produce clinically meaningful improvement, opioid therapy should be tapered back or discontinued while optimizing non-opioid therapies (AMDG, 2015; Chou et al., 2014; USDHHS, 2016; Hooten et al., 2013).

Initial and continuous assessment plays a strong role in pain management. Risks and benefits should be examined with the individual prior to initiation and dose increase of pain therapy, while being revisited every three months or more as needed. Low risk individuals should be monitored every three to six months (Chou et al., 2014; USDHHS, 2016). Individuals with a history of substance use disorders, mentally demanding occupations, older adults, dysfunctional social environments, comorbid psychiatric or medical condition should be monitored more often than every three to six months. Weekly reassessment should be standard for high risk individuals (Chou et al., 2014; USDHHS, 2016). Strategies reducing risk should be incorporated into the plan of care (Chou et al., 2014; USDHHS, 2016). During reassessment pharmacy checks, urine drug screens, pill counts, and family interviews can provide useful

information on adherence (Chou et al., 2014). Assessment and monitoring require constant attention.

Assessment Tools

Multiple tools are available to measure potential and current opioid abuse risk. Experts agree that validated instruments may assist in monitoring and tracking compliance, aberrant behavior, and patient outcomes (USDHHS, 2016; Hooten et al., 2013). Among these tools that have been validated and used in existing guidelines include the Opioid Risk Tool (ORT), The Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R), and the Brief Risk Interview (BRI). Lack of sufficient evidence for all assessment tools make it difficult to decipher which one should be used (Chou et al., 2014). The ORT had a sensitivity of 75% and specificity of 86%, the SOAPP-R had a sensitivity of 25% and specificity of 73%, and the BRI had a sensitivity of 83% and specificity of 88% (Jones, Lookatch, Grant, McIntyre, & Moore, 2014; Jones & Moore, 2013). Experts recommend screening for opioid misuse and abuse even though limited evidence exists for accuracy and reliability of screening (Manchikanti et al., 2012).

Dosing Restrictions

Literature inconsistency on safe dosing of opioids makes prescribing difficult. Higher rates of opioid abuse and dependence are associated with increased doses of long-term opioid therapy in comparison to low doses (Edlund et al., 2014). One study found high opioid doses were associated with increased cases of worker's disability compensation. A decrease in the number of deaths related to opioids was found when clinicians prescribed opioid doses less than 120 MME per day (Von Koff, 2016). Throughout literature, prescribers have been cautioned against using doses greater than 90 MME to 200 MME (Currow et al., 2016). Fair evidence identifies dosing categories for opioids: low dose as 40 MME or less per day, a medium dose as

41-90 MME per day, and high doses to be somewhere greater than 91 MME per day (Manchikanti et al., 2012). Overall, overdose risk increases with higher opioid dosages (USDHHS, 2016). Increasing opioid dosages requires evidence through reassessment indicating benefits outweigh the risks of doses ≥ 50 MME/day. Clinicians should restrain from prescribing doses ≥ 90 MME/day (USDHHS, 2016). Special consideration needs to be taken when dosing opioids for opioid-naïve individuals and the elderly population (Denenberg & Curtiss, 2016).

Comparing extended-release or long-acting and immediate-release opioids has been a topic of controversy. Extended-release in comparison to immediate-release opioids are associated with increased risk of non-fatal overdose especially in the first two weeks of initial treatment (Miller et al., 2015). A study of fair-quality found initiation of extended-release or long-acting opioid therapy poses a higher overdose risk compared to initiation with immediate-release opioids (USDHHS, 2016). An evidence review also showed that extended-release and long-acting opioids were no safer or more effective than immediate-release opioids. In fact, the same study showed intermediate-release opioids posed no more threat of misuse than time-scheduled, continuous use of extended-release and long-acting opioids (USDHHS, 2016). Extended-release opioids may seem worthwhile and an easy solution for certain individuals but extended-release produced no differences in pain or function outcomes over a one-year period in comparison to immediate-release opioids (USDHHS, 2016). Initiation of opioids in chronic pain management should start with immediate-release opioids. Fair evidence supports long-acting in certain circumstances accompanied with intractable severe pain that has failed treatment with short-acting opioids (Manchikanti et al. 2012). The need for extended-release opioids include: pain that demands daily around the clock coverage, and cases where long-term immediate-release and

non-opioid treatments have failed or are not tolerated (USDHHS, 2016). Determining what works best for the patient in reducing pain and improving quality of life is important.

Tapering opioids for decreased dosages or discontinuation needs special attention as it poses risk for withdrawal symptoms and overdose (USDHHS, 2016). Tapering rates should be driven by the reason for discontinuation of the opioid, for example faster tapering would accompany psychiatric disorders, worry for overdose versus a slower tapering rate due to failure of pain relief (Chou et al., 2014). Tapering opioids should start with less than or equal to 10% of the original dose per week to a more rapid reduction of 25-30% reduction every few days. Assessing the patient's quality of life and pain status during tapering efforts should be done at each visit (AMDG, 2015; USDHHS, 2016). Titration of long-acting opioids must be done with caution reducing risk of withdrawal symptoms and overdose (Manchikanti et al., 2012).

Urine Drug Testing

Two types of drug screening tools exist that detect drugs in the system: urine and blood. The major difference is blood notifies the clinician what the patient has in his/her system and urine conveys what was in their system. It is important for clinicians to identify unique characteristic to each laboratory test. Urine drug screening is found to be more useful when monitoring long-term opioid therapy (Owen, Burton, Schade, & Passik, 2012). False readings with immunoassay urine drug testing are common and results should be evaluated with caution (Denenberg & Curtiss, 2016). If suspicious of false readings, drug-specific gas chromatography mass spectrometry may be more confirmatory.

Evidence supports urine drug screening used for risk-assessment, compliance, and to aid in reducing abuse potential (AAPM, 2013; Currow et al., 2016). When used appropriately, urine drug tests may identify that the individual does not know how to take the medication as

prescribed. Urine tests may also indicate when a patient is non-adherent to the long-term pain management plan, diversion is taking place, an unreported lost or stolen medication, and self-treatment of poorly controlled pain when screening is negative. When screening is positive for appropriate substances, adherence is noted. Urine drug screening can be found positive for other substances not prescribed displaying use of illicit or non-prescription drugs, drug abuse or addiction, aberrant behavior, and psychological issues (Chou et al., 2014; Denenberg & Curtiss, 2016; Owen et al., 2012).

Good evidence supports initiation of urine drug testing prior to initiation of long-term opioid therapy. Subsequent monitoring for adherence which is shown to decrease drug abuse and illicit drug use during chronic pain management (Manchikanti et al., 2012). Urine drug testing should be performed prior to initiation of long-term opioid therapy in every individual and at least annually thereafter (USDHHS, 2016). Urine drug screening may also be performed at any point in therapy based on provider suspicion of non-compliance, diversion, or aberrant behavior. Although research is consistent regarding using urine drug testing as a monitoring tool, inconsistencies exist as to how often subsequent screening should be performed after the initial screening. Random and unpredictable intervals of urine drug tests have an advantage over pre-scheduled screening when there are questionable aberrant behaviors. Regularly scheduled urine drug screening for low risk individuals confirms adherence. Patients anticipating a urine drug screen may change behaviors short-term to improve outcomes of screening test (Chou et al., 2014).

Pill Counts

Monitoring adherence can also be done through regular or randomized pill counts. Incorrect pill counts may reveal nonadherence, indicate financial difficulties purchasing the

medication, misunderstanding of the care plan, misuse, diversion, or taking too much due to increasing pain (Denenberg & Curtiss, 2016). Although pill counts may improve compliance rates of patient on long-term opioid therapy, there is a lack of evidence supporting pill counting in practice. Only one guideline used pill counting as a tool to monitor adherence (Chou et. al, 2014). Pill counting is an area that needs further research and discussion prior to determining its effects on adherence and practice.

Pharmacy Checks

Prescription Drug Monitoring Programs provide insight into opioid therapy compliance (AAPM, 2013). Along with urine drug testing, pharmacy checks may identify at-risk individuals for opioid misuse, overdose, and flag healthcare providers for stricter monitoring or customized interventions (Baumblatt et al., 2014). PDMP is an electronic catalog allowing clinicians access to when, where, and by whom prescriptions are dispensed for an individual (Denenberg & Curtiss, 2016).

Through PDMPs, identification of prescriptions from multiple doctors, filling of these prescriptions at multiple pharmacies, high total daily opioid dosages prescribed, or dangerous drug combinations being prescribed is possible (USDHHS, 2016). Gomez et al. (2011) found that deaths related to opioids occurred more often in individuals getting their prescriptions from multiple doctors and pharmacies. Ultimately, PDMPs aid in identifying risk factors relating to fatal overdoses (CDC, 2012). PDMPs also reduce doctor shopping, prescription drug abuse and adherence monitoring by providing evidence of noncompliance and prescription drug abuse (Manchikanti et al., 2012).

As with urine drug testing, the literature varies regarding recommended frequency of PDMP checks (Denenberg & Curtiss, 2016). The CDC guideline suggests checking PDMP prior

to initiation of chronic opioid therapy, at least every three months, but best if done at each visit (USDHHS, 2016). Chou et al. (2014) and AMDG (2015) agree that PDMP checks should increase in frequency with high-risk patients. Clinicians better understand an individual's prescription behaviors when provided PDMP information (USDHHS, 2016).

Contracts

Contract or opioid agreements are highlighted throughout literature for long-term opioid therapy for chronic pain management (Denenberg & Curtiss, 2016). Pain contracts are written agreements binding a patient to follow specific terms laid out by a provider. Effectiveness of pain agreements or contracts have not been well studied for use in chronic pain management. Pain management guidelines and clinical experts suggest incorporating pain agreements into practice as a way to set boundaries, outline expectations for providers and patients, and establish accountability (USDHHS, 2016). Inclusion data for pain agreements or contracts include: receiving opioid prescriptions from one clinician, use of a single designated pharmacy, limited refills, no refills if prescription has been lost or stolen, medication must be taken as prescribed without authorization to increase dose, patient will safeguard prescribed medication at all times without sharing it with others, individuals will adhere to random urine drug testing, use of PDMPs, pill counts, and other risk management requirements. Adherence to the contract must be followed by individuals in order to receive and continue receiving opioid therapy (Chou et al., 2014; Denenberg & Curtiss, 2016, NGC, 2013).

Opioid agreement terms should be agreed upon and signed prior to initiation of opioid therapy. At that time, clinicians should also review treatment goals, how prescription opioids are to be taken, follow-up, alternatives treatment options, adjunctive therapies, potential indicators of tapering or discontinuation, failure to progress towards goals, adverse effects, intolerable adverse

effects, or serious aberrant drug related behaviors (AMDG, 2015; Chou et al., 2014; Manchikanti et al. 2012). Prior to initiation of opioid therapy, treatment goals should be discussed. These goals should be realistic for pain and function, discussing plans for discontinuation if benefits fail to outweigh risks. (AMDG, 2015; Chou et al., 2014; USDHHS, 2016; Hooten et al., 2013). Contracts provide clear written guidelines reinforcing expectations regarding safe and appropriate use of opioids (Chou et al., 2014). According to Manchikanti et al. (2012) fair evidence supports that opioid agreements decrease overuse, misuse, abuse, and diversion. Factors strongly associated with drug abuse, misuse, or aberrant drug-related behaviors with long-term opioid therapy are personal or family history of substance use disorders (Chou et al., 2014). Prior to and intermittently throughout long-term opioid therapy, risks, realistic benefits, and patient and clinician responsibilities regarding pain management should be discussed (USDHHS, 2016). Discussing and signing an opioid contract defines patient and provider expectations.

Referrals

Chronic pain management is difficult and may require expert referrals. Clinicians may opt to seek consultation of pain medicine or other specialists depending on the provider's comfort level, the complexity of the presenting issue, and in case of high-dose opioid therapy. Consultation is often justified when current pain management is not working and all other avenues have been explored, or in other difficult situations (AAPM, 2013; AMDG, 2015; Chou et al., 2014; NGC, 2013; Manchikanti et al., 2012). Other areas needing referrals or special consultation include providing long-term opioid therapy to individuals with a history of substance use disorders or comorbid psychiatric disorders (AAPM, 2013). Involving specialists

to aid in chronic pain management when needed optimizes outcomes of chronic pain (Hooten et al., 2013).

Barriers

Barriers that pose issues with chronic pain management and use of long-term opioid therapy exist. Clinicians often lack the confidence to prescribe opioids safely or in their ability to detect opioid drug abuse (Hagemeyer, Gray, & Pack, 2013; Keller et al., 2012). Discussing the topic of abuse with patients, once detected, is difficult and adds to provider barriers of chronic pain management (USDHHS, 2016). Overall, clinicians believe that opioids can improve pain and quality of life, but concern over prescription drug abuse issues outweighs opioid use in practice (Hwang, Turner, Kruszewski, Kolodny, & Alexander, 2015). Other barriers identified in literature include scrutiny by regulatory agencies, fear of opioid toxicity, and being cheated by patients (Rosenberg, 2013). Throughout literature a general theme is reported. Clinicians feel there is a lack of uniformity and knowledge in use of guidelines and the risk mitigation tools in reducing risk of misuse (Ringwalt, Garrettson, & Alexandridis, 2014; Rosenberg, 2013; USDHHS, 2016). Clinicians find registering for access and logging into PDMP is cumbersome. The process interrupts normal work flow and increases clinical demands leading to inadequate time to discuss reasons for use of risk mitigation tools. Clinicians also cite interpreting and addressing the results of the PDMP as challenging (USDHHS, 2016; Smith et al., 2015). Variations in prescribing habits are related to a lack of pain management training, experience, and exposure to opioid related events. Repeated consultation that does not meet the patient's need and a clinician's failure to set appropriate boundaries and negotiate an alternative plan increases likelihood of inappropriate prescribing (Currow et al., 2016). Addressing clinician barriers may improve opioid prescribing and chronic pain management.

Gaps in Research

Use of opioids for long-term pain management has created great challenges. Throughout literature there is a lack of evidence regarding how effective opioids are for treating chronic non-cancer pain (Currow et al., 2016; CDC, 2016). Gaps in research fail to provide supporting evidence in use of pain management guidelines for improving pain, function, and quality of life, while decreasing abuse and overdose (AAPM, 2013). Guidelines have been more thoroughly studied in acute care settings and their effect on opioid abuse, misuse, and diversion show positive results (AAPM, 2013; USDHHS, 2016). Prescription drug monitoring programs at a state level lack assessment due to changes in prescribing habits and mortality outcomes (Haegerich, Paulozzi, Manns, & Jones, 2014). Reduction of opioid dosages raises concern that individuals may seek other forms of relief through nonprescription drugs such as heroin (Cicero, Ellis, & Surratt, 2012). Gaps in research identify areas lacking sufficient information to formulate conclusions, requiring further evaluation.

Clinicians continue to hold concern over risks of opioid dependence and misuse associated with chronic non-cancer pain management. The increasing complexity to manage multifaceted physical and psychological needs of individuals with chronic pain alone is a daunting challenge. Long-term prescribing and limitations to available treatment approaches also hinder positive outcomes of chronic pain management (Currow et al., 2016). Concerns multiply as rates of prescribed opioids continue to increase (USDHHS, 2016). As rates of prescribed opioids increase, so do rates of misuse and abuse (APA, 2013). As clinicians fight to improve pain management strategies, guidelines can provide a uniform toolkit focused on improving prescribing practices of providers leading to improved outcomes of chronic pain management, decreasing opioid misuse, and abuse.

Theoretical Framework

Theoretical framework provided guidance as a series of steps to reach a desired outcome (Melnyk & Fineout-Overholt, 2015). The Iowa Model (Appendix B) of Evidence-Based Practice provided decision making steps to guide the author through a decision-making process. The Iowa model contains seven important steps guiding implementation of evidence-based practice: identify triggers, clinical application, organizational priorities, forming a team, piloting a practice change, evaluating the pilot, evaluating practice changes, and dissemination of results. Each of the seven components of the Iowa Model were further broken down and used. Approval to use the Iowa Model was granted on December 6th, 2016 by The University of Iowa Hospitals and Clinics (Appendix A) (Titler et al., 2015). The steps of the Iowa Model and how it applied to the project are further discussed in below.

Identified Triggers

Identified triggers prompted questions about situations that potentiated change. Healthcare providers come across many barriers when managing chronic pain. One main barrier was opioid therapy used for chronic pain management and the potential for misuse, abuse, and overdose. Current opioid prescribing trends are startling. An increased awareness regarding opioid over-prescription and the unintended consequences of the high rates of opioid prescription triggered an interest in opioid therapy for chronic pain management among providers and the medical community. Today, differences between chronic pain management guidelines exist along with different recommendations on reducing over-prescribing by providers, patient misuse, abuse, overdose, and diversion. Providers lack experience, comfort, education, tools, and processes to improve prescribing habits to reduce negative behaviors associated with long-term opioid therapy.

Organizational Priorities

Looking at what an organization deemed important provided support and the means to implement the project. In March 2016, the CDC released a new set of guidelines for chronic pain management with a focus on long-term opioid therapy. The CDC issued these guidelines to aid in decreasing opioid misuse, abuse, overdose by patients and over prescribing by providers. The guidelines are a combination of strategies designed to improve prescribing habits of providers and opioid safety for patients on long-term opioid therapy. The project was implemented in rural North Dakota, at four Coal Country Community Health Center facilities. The clinic's medical director expressed concern about current opioid prescribing practices of providers at Coal Country Community Health Center along with an increased population of chronic pain patients associated with economic changes in northwestern North Dakota. Implementation of key strategies targeted helping providers improve prescribing habits and aided in decreasing destructive opioid behaviors. These strategies included maximizing PDMP use, use of urine drug screens, and calculating daily MME, and easy identification of chronic pain management patients in the electronic health record (EHR).

Team Formation

Team formation was key in successfully implementing the project. Key stakeholders included six individuals: a student seeking a doctor of nursing practice (DNP) degree, three faculty members teaching in the DNP/family nurse practitioner program, a faculty member to serve as graduate appointee, and the rural clinic medical director. Team members had an interest in the dissertation project topic, and each member played a key role. The DNP student led project development, explored ideas for practice improvement, researched up-to-date literature, collaborated with team members, implemented the project, evaluated outcomes, and

disseminated findings. Each faculty member brought something special to the table. The committee chair provided support throughout the dissertation process, provided advice to the student regarding the development, implementation, evaluation of the project and guided changes throughout the process. The remaining two School of Nursing faculty members, along with a graduate appointed faculty provided an alternative perspective to the project and made suggestions of possible ways to improve the project that had not been considered. The graduate appointed faculty held strong ties to economics and statistical analysis. The graduate appointed team member was a strong asset in data collection, organization, and presentation. The medical director, director of clinical operations, director of patient care and innovation, director of nursing, quality coordinator, and information technology personnel of the rural clinic helped facilitate the project in the clinical setting, acted as a liaison to clinic faculty members and provided access to facility resources needed throughout the project. Key team members provided feedback on corrections prior to the proposal and final defense. Collectively the team approved and supported the project development and implementation.

Research and Literature

Explored current literature and evidence-based guidelines provided a foundation for the improvement project. The section a *review of literature* provided a detailed synthesis and evaluation of current literature and evidence-based guidelines. The literature presented gaps that need further evaluation. The main gap in evidence involved application of the guidelines. There are no strong studies for the use of guidelines in improving prescribing practices, decreasing misuse, abuse, and overdose of opioid prescription drugs (AAPM, 2013). Chronic pain management guidelines lacked evidence in ambulatory care, most of the interventions within the guidelines had strong supporting evidence for improving prescribing behaviors aimed at

reducing abuse, misuse, and overdose. Therefore, the project provided clinicians with interventions aimed at improving prescribing habits in an effort to reduce risk of long term opioid use.

Piloted Practice Change

Key objectives were identified for the project focused on piloting change. These objectives provided the project a foundation and focus (Melnyk & Fineout-Overholt, 2015). The objectives led to interventions to be carried out. These objectives included:

1. Provide education regarding current chronic pain management recommendations and accepted best practices from the 2016 CDC guidelines for:
 - a. PDMP use
 - b. Urine drug screens
 - c. MME dosing
 - d. Pain contracts
2. Flag all patients on a pain contract within the EHR using a uniform system.
3. Identify all patients without a pain contract who have been prescribed opioids ≥ 3 months and enroll identified patients in a pain contract over a 4-month period.
4. Determine all patients who have been prescribed opioids ≥ 3 months and who are receiving doses that place them at increased risk (patients prescribed doses ≥ 50 MME per day and prescribed ≥ 90 MME per day). Develop strategies to reduce risk associated with upper daily limits of opioids.
5. Develop sustainability practices to ensure compliance and continued monitoring of implemented recommendations for chronic pain management patients upon completion of project.

The pilot study allowed time for identifying changes or adjustments needed to increase project success. New barriers were found as road blocks throughout the process. The pilot study allowed time for overcoming these barriers to fulfill the objectives.

Evaluated Practice Changes

Once the program had been piloted, members of the team evaluated the outcomes. The evaluation process consisted of measuring and organizing statistical data of the designated measurable outcomes. Evaluation was an important step of the process and determined the success of each intervention. Evaluation defined and identified possible areas needing change and drove project improvements that could be made. Through evaluation the project was completed and provided data for dissemination.

CHAPTER THREE. PROJECT DESCRIPTION

Project Design

Proper design is essential to project success. The CDC guideline on chronic pain management released at the beginning of 2016 was used as a blueprint for the project. The goal was to reduce over-prescribing of opioids, improve patient adherence and pain management, and reduce the risk of long term opioid use (CDC, 2016). The author met with Dr. Aaron Garman, medical director of Coal Country Community Health Center (CCCHC) and he had expressed interest in a project that brought elements of the new CDC guideline into practice. CCCHC had identified provider prescribing practices, increased opioid prescriptions, and opioid overuse in the community as a major concern that needed attention.

Objective One

Objective one consisted of providing education to providers and clinic staff regarding current chronic pain management recommendations and accepted best practices from the 2016 CDC guidelines on PDMP use, UDS use, MME dosing, and pain contracts. An education session including a presentation was set up on August 30, 2017 to provide education regarding CDC guideline elements and current recommendations. Providers, nursing staff, and certified aids were invited to the education session. The session was made mandatory for all patient-care employees by the medical director. Education specifically highlighted the importance of the prescription drug monitoring program, urine drug screening, pain contracts, upper limits of daily morphine milligram equivalence and calculation tools to improve prescribing practices, all with a focus on risk reduction strategies. Contributing to provider buy-in, the author was introduced at the education session by the medical director of Coal Country Community Health Center. The medical director discussed the projects importance and impact on the clinics. Time provided at

the end of the education session allowed providers and staff to share any feedback and further discuss chronic pain management. Most of the questions and feedback included positive thoughts and feelings about the project. The providers expressed excitement in additions to the EHR that would make pain management easier for them. A laminated copy of an algorithm based upon the CDC guideline (Appendix C) and pre-calculated MME doses for popular opioids (Appendix D) was provided to all clinicians and placed in a designated area within the clinic that provides clinicians with easy access to the references.

A post-education session questionnaire was given to all providers (Appendix E). The questionnaire focused on current understanding of information provided during the education session. Objective one also set a baseline on how providers use the current recommendations and the best practices that were reviewed during the education session, specifically observing use of the prescription drug monitoring program and urine drug screens.

Objective Two

Meeting objective two included identifying current patients with existing pain contracts within the EHR. A flag “CS Consent” standing for controlled substance consent was developed in collaboration with informational technology services (ITS). Implementation of the flagging system into the EHR was accomplished by adding “CS Consent- consent initiation date” to the face sheet under the patient alert notes section. The alert notes section is found next to the patient’s problem list, allergies, and medication list, providing simple access to important information.

Objective Three

Objective three identified all individuals who were prescribed narcotics for ≥ 3 months and determined if the identified individuals were enrolled in a pain contract. Data was pulled

with the quality management program from the EHR. Once a list of names was acquired a chart audit was performed; looking at the duration of time, ≥ 3 months, the individual has been prescribed a narcotic. Once individuals were identified, a list of patient names were provided to primary care providers and the nurse was also flagged in the EHR about pain contract eligible patients. Nursing staff and other providers were consulted prior to implementation to provide input regarding how to best integrate the process of completing patient pain contracts seamlessly into the flow of the clinic. Providers were encouraged to place eligible individuals on a pain management contract and flag the pain contract patients in the EHR.

Objective Four

The goal of objective four was to determine patients who were prescribed opioids ≥ 3 months and received doses, ≥ 50 MME and ≥ 90 MME per day, that place them at an increased risk for poor outcomes. Objective four also required development of strategies to reduce associated risks of daily opioid upper limit doses. Objective four was met by compiling a list of all current and potential pain management patients. Each patients chart was audited for MME dosing. The author built a list of patients receiving doses which increase opioid overdose risk: ≥ 50 MME dosing per day and ≥ 90 MME dosing per day. The list was provided to each primary care provider. Education on steps to take for patients exceeding ≥ 50 and ≥ 90 MME dosing per day was provided in the education session of objective one. A quick reference sheet outlining the steps to take for identified patients was provided to all clinicians (Appendix F).

Objective Five

Objective five involved development of sustainability practices to ensure compliance and continued monitoring of implemented recommendations for chronic pain management patients. The quality coordinator was designated to take responsibility to ensure providers compliance of

appropriate use of PDMP, urine drug screens, and MME dosing for chronic pain management.

The quality coordinator will work closely with the director of patient care and innovation to set forth future interventions for providers to meet recommendations. The author provided clinicians with tools needed for project sustainability including:

- education on chronic pain management recommendations and accepted best practices
- integrating a flagging system into the EHR
- use of pain contracts
- distributing laminated copies of a chronic pain management algorithm, commonly prescribed opioid medication converted into MME daily dosing ≥ 50 MME and ≥ 90 MME, and a quick reference of steps to take when patients exceed 50 MME daily and 90 MME daily

Follow-up

Project sustainability and system change can be challenging. System change and sustainability can be encouraged through provider participation and feedback on project pros and cons. Once identified by the author, suggested improvements provided project enhancement.

The author designated an individual at each clinic to be a liaison and communicate challenges and identify processes of the project that were working well and not working well. The designated staff was contacted monthly by the author to ensure open communication. Academic detailing was performed at the two-month mark. Academic detailing included the author being physically present at each facility and visiting with all staff members about the project processes, pros, cons, and possible improvements.

Project Timeline

March:

- Discuss the projected plans with the medical director of the clinic
- Determine the requirements of gaining access to the EMR and patient records
- Determine additional requirements that may be needed to fulfill project objectives

May:

- Proposal meeting

July:

- IRB application

August:

- Determine a date, time, and location of the education session
- Complete initial chart audit and data collection

November:

- Check-in with facility and determine how processes are working

January:

- Post chart review and data collection
- Data evaluation
- Write final dissertation

March

- Final dissertation defense

Resources

For this project to work, many factors came into play. The project required key stakeholders, including providers, nurses, certified aids, information technology, and

receptionists. The author maintained close contact with the medical director of the clinic, director of clinical operations, director of patient care and innovation, quality coordinator, and the director of nursing throughout the implementation and evaluation process. The author gained access to the EHR to collect data on PDMP use and documentation, urine drug screening, and MME calculation and documentation. Sustainability moving forward will rely heavily on the education provided, provider and staff willingness, if providers find interventions beneficial, minimal work flow interruptions, and the anticipated importance of the topic.

CHAPTER FOUR. EVALUATION

Evaluation Plan

Evaluation plays an important role in improving practice. Data was collected for each objective upon completion of the project. Evaluation of data provided insight into the success of the project.

Initially, four Coal Country Community Health Center clinics were supposed to be included in the project. The project was not initiated into one of the clinics due to uncontrollable circumstances relating to staffing limitations. Data regarding the non-participatory clinic was not included in the project. The remaining three clinics participated in the project and continued with implementation of objectives.

The project design and evaluation of the practice improvement project incorporated use of the Logic Model (Figure 1) (W.K. Kellogg Foundation, 2004).

Situation	<ul style="list-style-type: none"> • In 2012, 259 million opioid pain medication prescriptions were provided by health care providers. Half of the opioid related overdose deaths are a result of prescription opioids (CDC, 2014) • In March 2016, the Centers for Disease Control and Prevention (CDC) released a new Chronic Pain Management Guideline to aid in improving provider’s prescribing practices and reduce overuse and abuse of opioids (USDHHS, 2016)
Priorities	<ul style="list-style-type: none"> • Improve opioid prescribing practices of primary care providers for chronic pain management • Reduce the number of opioids prescribed for chronic pain management • Reduce the dosage of opioids prescribed for chronic pain management • Reduce misuse and overdose of opioids by patients with chronic pain secondary to improving provider prescribing habits
Inputs	<ul style="list-style-type: none"> • NDSU DNP Student & Committee • CDC Chronic Pain Guidelines • Key Stakeholders (Medical director, director of clinical operations, director of patient care and innovation, quality coordinator, and director of nursing) • Primary Care Providers • Information Technology department
Activities	<ul style="list-style-type: none"> • Provide education on current chronic pain management recommendations and accepted best practices from the 2016 CDC guideline for PDMP use, UDS, MME dosing, and Pain contracts • Flag all patients on a pain contract within the EHR using a uniform system • Identify all patients without a pain contract who have been prescribed opioids ≥ 3 months, and enroll identified patients over a 4-month period • Determine patients prescribed opioids ≥ 3 months and receiving doses placing them at an increased risk (taking ≥ 50 MME & ≥ 90 MME per day) and develop strategies to reduce risk • Develop sustainability practices to ensure compliance and continued monitoring of implemented recommendations for chronic pain management patients upon completion of the project
Outputs	<ul style="list-style-type: none"> • Post education questionnaire showing provider understanding of chronic pain management using opioids • Chart audit showing improvement in PDMP and UDS use • Chart audit showing all patients on a pain contract have been flagged within the EHR • Chart audit showing the number of patients who were placed on a pain contract after being identified as eligible • Chart audit showing the recommended steps provided during the education session were implemented for patients taking ≥ 50 MME per day and ≥ 90 MME per day
Outcomes (Short Term)	<ul style="list-style-type: none"> • Providers have tools within the EHR and strategies to help them improve chronic pain management with opioids • Providers recognize and use strategies to improve prescribing practices of opioids for chronic pain discussed in the 2016 CDC guideline
Outcomes (Long Term)	<ul style="list-style-type: none"> • Continued use of tools provided in the EHR and provided strategies to improve chronic pain management • Continued monitoring of implemented strategies for chronic pain management patients
Impact	<ul style="list-style-type: none"> • Expand provider knowledge in chronic pain management with opioids • Improve opioid prescribing practices of Primary Care Providers for chronic pain management • Improve patient safety by decreasing misuse and overdose while optimizing chronic pain management

Figure 1. Logic Model

Objective One

Evaluation of the CDC guidelines and best practices was initiated by a post-education questionnaire. Data from the post-education evaluation was collected from providers. The questionnaire evaluated the overall knowledge and understanding on chronic pain management

recommendations and accepted best practices. Additional evaluation components included tracking rates for UDS and PDMP use, which included data collection and a chart review on individuals enrolled in the opioid management program by 12 different providers.

Urine drug screen and PDMP data was more challenging to collect than originally anticipated. Data on UDS annual review was supposed to be collected through IT reports, but the current system was unable to separate out pain contract data. Therefore, 34 charts were audited looking at urine drug screens collected on all current chronic pain management patients and 11 charts were audited on urine drug screens performed on patients who were eligible and enrolled on a pain contract since initiation of the project. The second area of focus identified if providers were reviewing the PDMP at least every 3 months.

Upon development of the project, key stake holders were under the impression PDMP reports were being scanned into the patient's chart upon review. During the initial chart audit, the author discovered no PDMP reports had been scanned into the EHR. The director of patient care and innovation identified a need for simpler PDMP documentation. The key stake holders initiated an update to the EHR to place a check box reading *PDMP reviewed* that would be placed in the provider's final dictation. The implementation of the checkbox was not completed until the end of November. Data collection included the number of documented UDS and PDMP checks at the beginning and after four months of the intervention. The data will be compared to determine if UDS and PDMP use has improved.

Objective Two

Identification of all patients on a pain contract within the EHR was evaluated. The objective evaluation included developing a flagging system for the EHR such as "CS Consent" placed on the patient's face sheet. Development was done in collaboration with ITS. Tracking

the completed number of charts flagged with “CS Consent” on the face sheet concluded evaluation of objective two.

Objective Three

Evaluation of objective three was completed by determining the number of patients who were enrolled in a pain contract from those patients identified at the beginning who met chronic pain management eligibility. Individuals were identified and enrolled throughout the four-month project. At the completion of the four-month phase, data was again collected through a chart audit on all eligible individuals to determine the number of patients enrolled on a pain contract and flagged within the EHR.

Objective Four

Chart audits were performed to evaluate objective four. The chart audits identified patients taking ≥ 50 MME per day and ≥ 90 MME per day. The audit determined if recommended steps provided in the education session and on the quick reference sheet were implemented.

Objective Five

The author evaluated the completion of tools implemented for project sustainability including: education on chronic pain management recommendations and accepted best practices, integrating a flagging system into the EHR, pain contracts, and distributing laminated copies of a chronic pain management algorithm with commonly prescribed opioid medication converted into MME daily dosing meeting 50 MME and 90 MME, and a quick reference of steps to take when patients exceed 50 MME and 90 MME daily.

The author reviewed the monitoring process with the quality coordinator assigned to monitor chronic pain management recommendations. The quality coordinator will perform a

chart audit on 10 randomized charts every six months. Due to the time required to complete a chart audit along with other daily duties requiring completion by the quality coordinator, 10 biannual charts audits were recommended by the quality coordinator to be realistic goal. The data collected from the chart audit will include the following: PDMP has been checked at least every three months, urine drug screens are being checked at least annually, and MME dosing remains at or below 50 MME per day. For cases where dosing remains ≥ 50 MME and ≥ 90 MME per day, rationale clearly that dosing benefits outweigh the risks. The quality coordinator was responsible and will continue to identify that the laminated chronic pain management algorithms and common MME opioid dosing conversions are in their designated locations.

The overall goal for each objective was to improve the criteria elements in comparison to pre-project data. Therefore, the author will expect to see an increased knowledge and understanding of chronic pain management, improvement in PDMP access for providers and delegates, improved rates of UDS use, and utilization of strategies to improve chronic opioid pain management prescribing.

Protection of Human Subjects

Protecting human subjects is important for maintaining the integrity of the practice improvement project. The project poses minimal or no violation of the Health Insurance Portability and Accountability Act and patient contact was not required for completion of the project, exposing patients to minimal or no risk. Medical records were accessed using a secure login, in a private area, and patient information was only read by the author and not shared with other team members. The exempt IRB approval process best fit the project as direct contact with patients was not necessary.

Research was limited to individuals 18 years and older that were on non-cancer chronic opioid pain management. The process of data collection was obtained from the EHR on data, documents, records, and results. Information collected did not include patient identifiers such as but not limited to name, age, date of birth, and medical record numbers. Patient's risk was minimal, and the goal was to improve safe prescribing practices by providers. The goal of the project was aimed at improving prescribing practices, recognizing dangerous prescribing practices by providers, and provider recognition of patient adherence to chronic opioid pain management.

CHAPTER FIVE. RESULTS

Success of the project can be contributed to the time and effort spent on development, implementation and evaluation. The project involved building interventions, analyzing research, and evaluating results. Evaluation of the project looked at strategies aimed at improving prescribing habits of rural primary care providers managing chronic pain with opioids. Three clinics of the same organization were included in the project. Project parameters were set by the author using evidence-based research for opioid use and chronic pain management. Five pieces of data were analyzed and evaluated looking for improved practice of chronic pain management with opioids. The data collection included:

- the number of pain contract patients and how many were flagged in the EHR
- determine the number of eligible pain contract patients that were enrolled in a pain contract and flagged in the EHR
- determine the number of annual urine drug screens done before and after initiation of the project
- the number of prescription drug monitoring program reports reviewed at least every three months before and after initiation of the project
- discussing with the quality coordinator how to complete a chart audit for continued data monitoring

An initial chart review was performed on patients that IT identified as being prescribed opioids. Data was collected and placed into a flowsheet. At the completion of four months a chart review was performed on appropriate charts to determine if project parameters had improved.

Post-Education Provider Questionnaire Results

A post-education questionnaire (Appendix E) was provided to 10 clinicians who attended the education session on August 30, 2017. After the education session was completed, an open discussion was held between the providers and remaining 37 clinical staff in attendance. Nine of the 10 providers returned the questionnaire with responses. The remaining provider in attendance and the remaining two providers not in attendance did receive but did not return the questionnaire. Following are the questions and the providers' responses.

The following (Table 1) represent the questions from the post education questionnaire.

Table 1

Post Education Questionnaire

Questionnaire Responses: Themes and Associated Questions	
<p>Please answer the following questions based on the presented education Questions 1-3</p>	<ol style="list-style-type: none"> 1. Did this session meet your educational needs? 2. Did the information presented reinforce and/or improve your current skills? 3. Did the information presented provide new ideas/information you expect to use?
<p>Please rate the projected impact of this education activity on your competence, performance, and/or patient outcomes Questions 4-6</p>	<ol style="list-style-type: none"> 4. This activity increased my competence? 5. This activity will improve my performance? 6. This activity will improve my patient's outcomes?
<p>Answer the following questions regarding best practice for chronic opioid management Questions 7-14</p>	<ol style="list-style-type: none"> 7. What is your comfort level of caring for a chronic pain management patient? 8. Rate your understanding of who should be placed on a pain contract? 9. Rate your understanding on the process to follow to place a patient on a pain management contract? 10. Rate your understanding of how often the PDMP should be checked on chronic pain management patients? 11. Rate your understanding of how often UDS's should be performed on chronic pain management patients? 12. What is your understanding on how to care for patients that exceed 50 MME per day? 13. Rate your understanding on how to care for patients that exceed 90 MME per day? 14. Rate your understanding of the recommendations provided by the 2016 CDC guideline on chronic pain management?

The first three questions focused on the education presented by the author. Responses to questions one through three were based on a three-part response including no, somewhat, and yes.

The following graph (Figure 2) represents the answers to questions 1, 2, and 3.

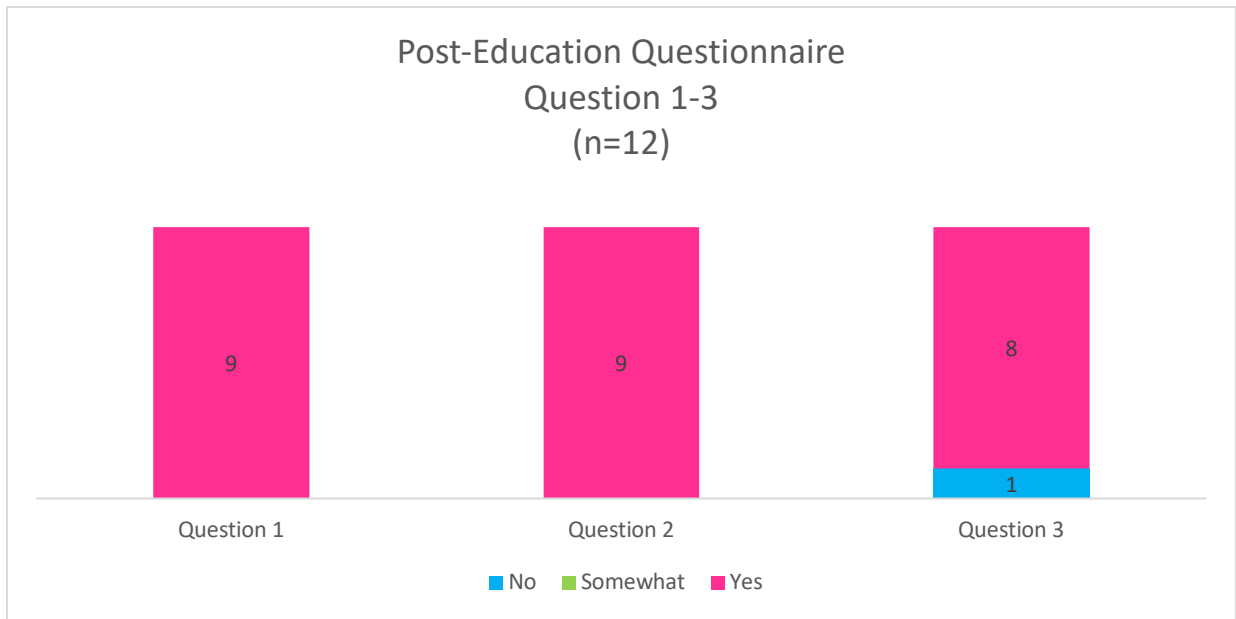


Figure 2. Questionnaire Results: Questions 1, 2, 3

Questions four through six focused on the projected impact the education had on their competence, performance, and/or patient outcomes. Responses to questions four through six were based on a three-part response including no increase, moderate increase, and great increase.

The following graph (Figure 3) represents the answers to questions 4, 5, and 6.

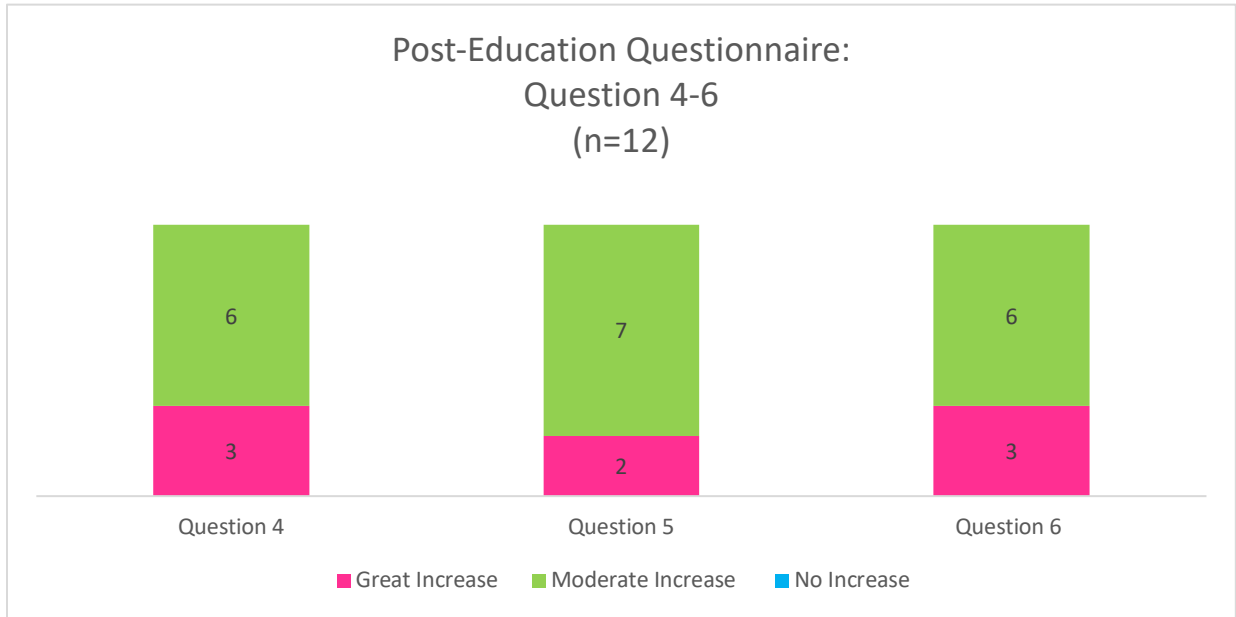


Figure 3. Questionnaire Results: Questions 4, 5, 6

Questions seven through fourteen were in regard to the best practices for chronic opioid management. Responses to questions seven through 14 were based on a five-part response including very poor, poor, acceptable, good, and very good.

The following graph (Figure 4) represents the answers to questions 7 through 14.

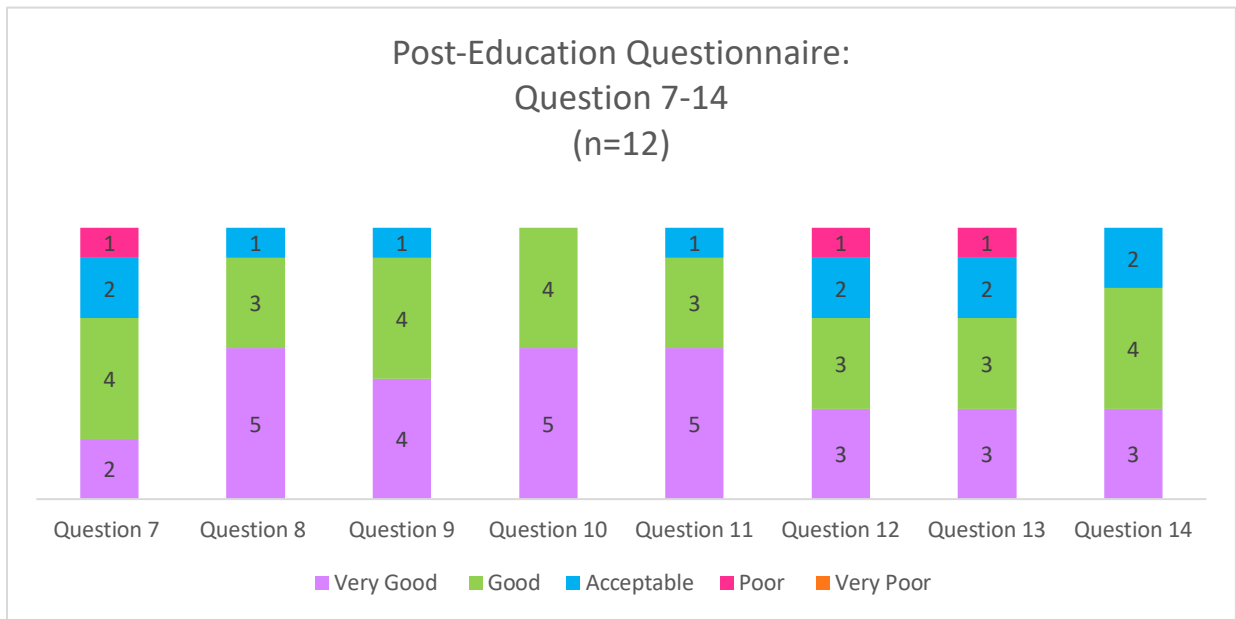


Figure 4. Questionnaire Results: Questions 7, 8, 9, 10, 11, 12, 13, 14

The final three questions on the questionnaire were open ended. One question focused on the education provided and areas of concern when treating chronic pain management.

The following graph (Table 2) represents the answers to questions 15 through 16.

Table 2

Questionnaire Results: Questions 15, 16, 17

Open Ended Questionnaire Responses		
Question 15	Question 16	Question 17
Based on the education provided, what areas of concern do you have in treating chronic pain management patients?	Based on the education provided, what issues should the system address to help you improve management of chronic pain patients?	What are the top three barriers to managing pain?
Contributing to opioid dependence	Provide an easy spot to see a patient is on a pain contract	Trouble with subjective symptoms leading to a treatment plan
Addressing high MME doses, reducing doses, and discontinuing doses with patients	Implement reminders that patients are on contracts, identify if they have been dismissed, if a UDS is due, and a program that calculates MME dosing	Troubles trusting patients
Non-compliant patients	EMR alerts for patients eligible on a pain contract	Difficult to confront patients
Lack of resources for consults, pain specialists, mental health care	Improved EMR charting	Stigma associated with pain medication use
Lack of experience	Key reminders for checking records, doses, and drug screens	Patient compliance
Effectively offer alternatives when appropriate		Psychosocial component of pain management
Time available to spend with patients		Lack of consistency across different providers
Pain is subjective		
Patients that become addicted are manipulative		

Initial Chart Review Results

The author performed an initial chart review in August 2017 prior to the education session. The initial chart review included 364 charts of patients who were being prescribed opioids. Data collection identified if the patients were prescribed opioids for ≥ 3 months and if they were on a pain contract. Forty-two patients were found to have a pain contract and 17 more

patients were identified as being eligible for a pain contract. The 42 charts reviewed of patients previously identified on a pain contract revealed zero patients had a PDMP report scanned into the EHR. The chart identified nine of the 42 patients or 21% on a pain contract had a UDS performed in the past year. Morphine milligram equivalence was evaluated for all patients on a pain contract. Seven of the 42 pain-contract patients or 16.7% were being prescribed dosages \geq 50 MME per day and nine of 42 or 21% were being prescribed dosages \geq 90 MME per day. Data analysis was also performed on patients who were eligible for pain contracts. Three of the 17 or 17.6% of patients were being prescribed \geq 50 MME per day and five of 17 or 29% were being prescribed \geq 90 MME per day.

The chart audits were completed at the Beulah CCCHC site on a provided desktop computer. The author was provided a username and password to access the EHR. The data was collected and recorded in OneDrive Business and only accessed through the clinics computer. No patient sensitive data was taken from the clinical site. Protection of data was assured throughout the project.

Final Chart Review Results

The final chart review was moved from six months to four months with approval from the project committee. This change addressed time constraints of the project due to delays in IRB approval and scheduling with the clinics to initiate the project. The final chart review was completed the first week of January 2018. The same data was reviewed and analyzed as the initial chart review.

The initial 42 patients identified on pain contracts were evaluated and three were placed on the facilities restricted list, three had their pain contract discontinued, and two were no longer

being prescribed opioids because they moved out of state. Thirty-four of the original 42 remained on a pain contract.

The following graph (Figure 5) represents the post-implementation results of the patients previously on a pain contract.

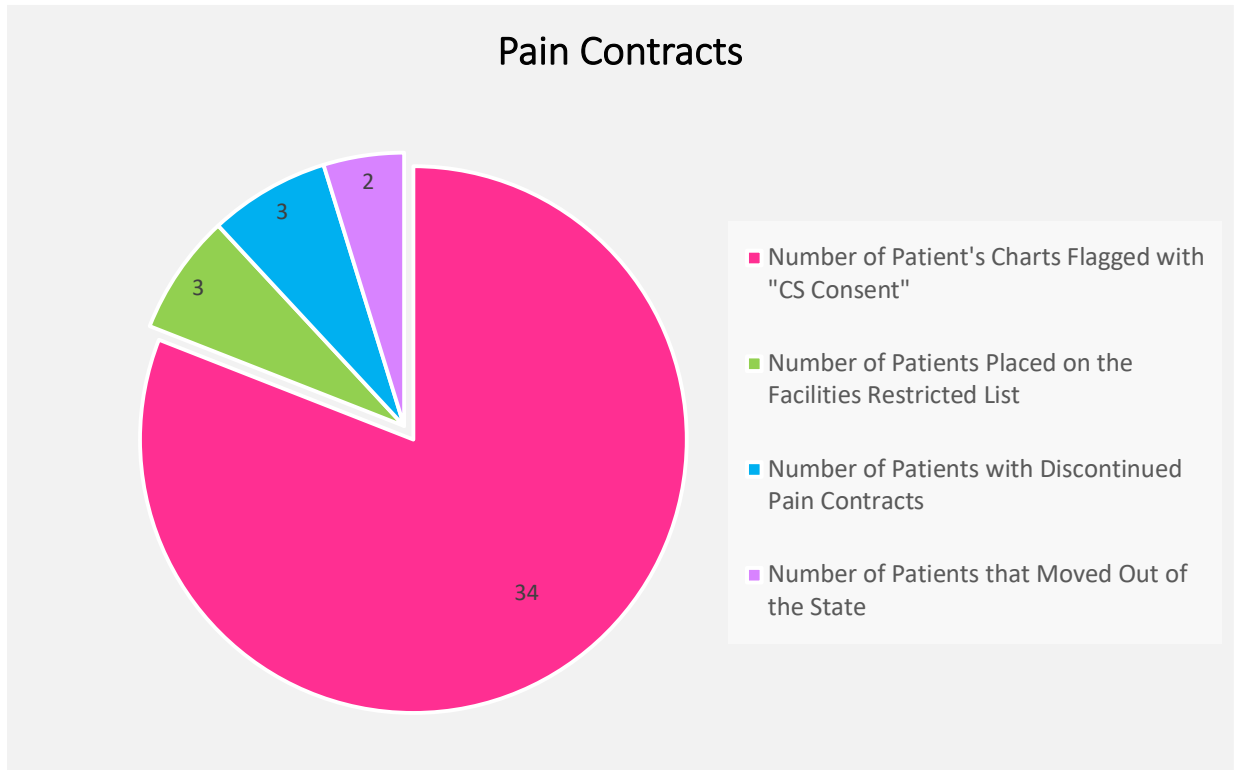


Figure 5. Post-implementation Results of Previously Identified Pain Contract Patients

The following graph (Figure 6) represents the post-implementation results of the patients meeting pain contract eligibility.

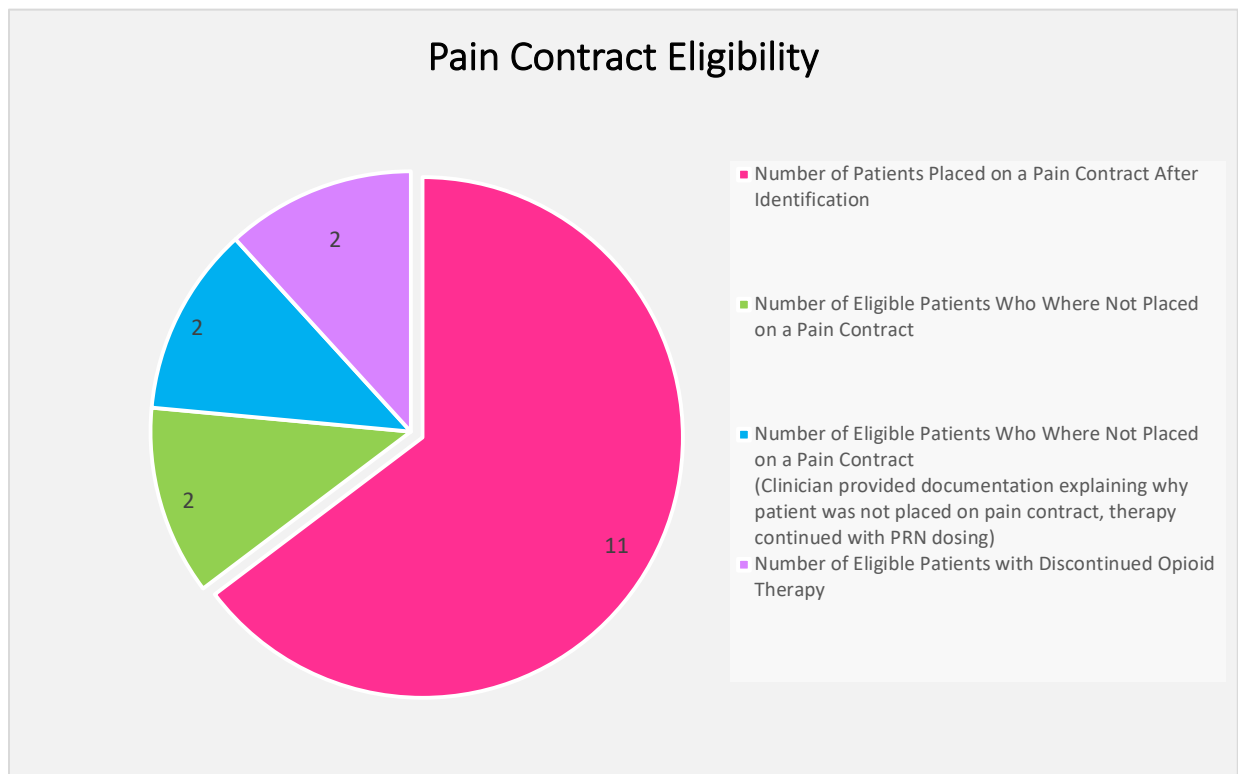


Figure 6. Post-implementation Results of Patients Meeting Pain Contract Eligibility

At the end of the project 45 patients had a pain contract, combining the 34 patients who initially were on a pain contract and the 11 eligible patients who were placed on a pain contract.

The following tables (Table 3 and 4) represent PDMP Review and UDS results.

Table 3

Pre and Post Implementation Comparison of Clinical Interventions for All Patients in a Pain Contract

Variable	Pre-Implementation	Post-Implementation	Percentage Change
	(n=42)	(n=45)	
PDMP Review	0	18	N/A
UDS	9	15	66.7%

Table 4

Pre and Post Implementation Comparison of Clinical Interventions for Patients Previously in a Pain Contract and Newly Enrolled in a Pain Contract

Variable	Previously on a Pain Contract (n=34)		Newly Placed on a Pain Contract (n=11)	
	n	Value	n	Value
PDMP Review	11	32.35%	7	63.64%
UDS	8	23.53%	7	63.64%

The following are graphs (Figure 7 and 8) represent MME daily dosing interventions.

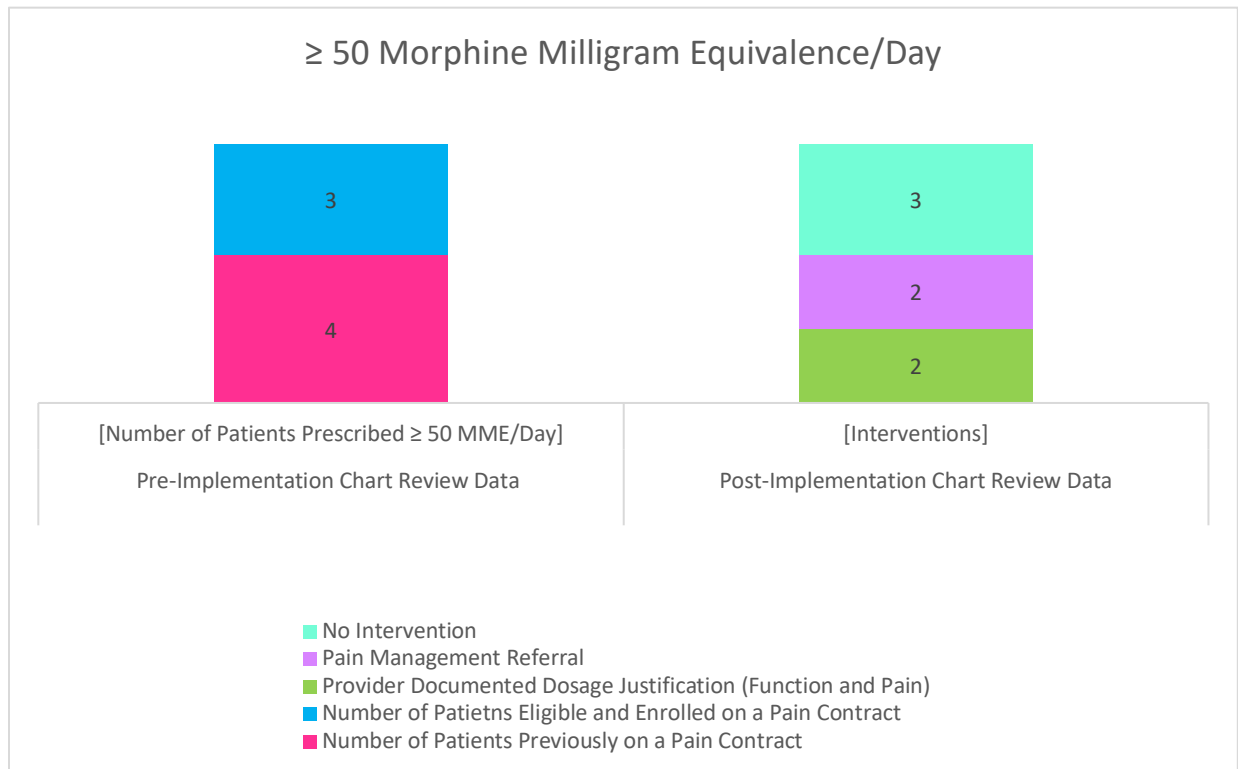


Figure 7. Pre and Post Implementation Results of Patients Prescribed ≥ 50 Morphine Milligram Equivalence per Day

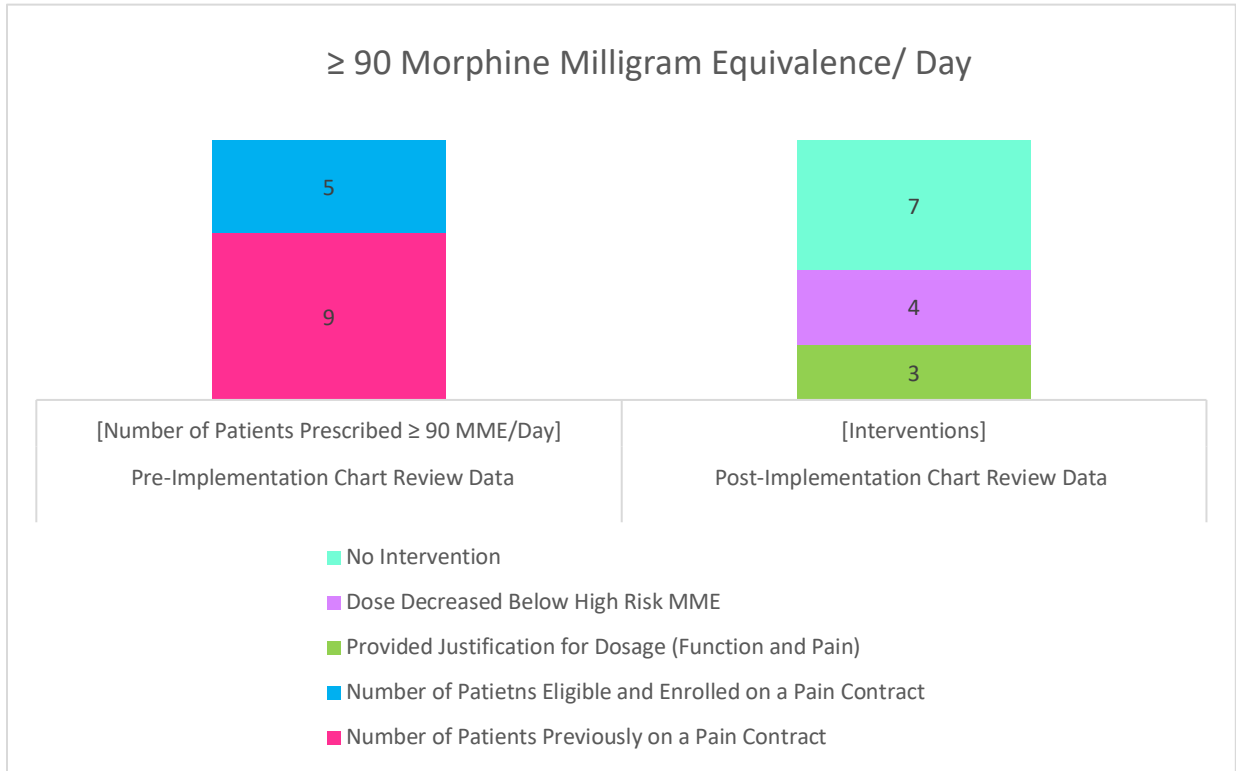


Figure 8. Pre and Post Implementation Results of Patients Prescribed ≥ 90 Morphine Milligram Equivalence per Day

CHAPTER SIX. DISCUSSION AND RECOMMENDATIONS

The practice improvement project identified the opportunity for potential improvement in both prescribing practices and chronic pain management of opioids. Findings showed providers increased their knowledge and comfort in using evidence-based practice guidelines. Based on the post-education questionnaire, providers identified lack of comfort in calculating safe MME daily doses and caring for patients with at-risk doses. Continuing education focused on MME dose calculation and patient care for high-risk doses could potentially overcome this barrier.

Discussion with individual providers revealed significant interest and need for improved opioid prescribing and monitoring strategies concerning chronic pain management patients. The chart review revealed that four of the providers followed all recommendations and accepted best practices fully. The remaining providers followed only certain elements while others did not follow any elements of the recommendations and accepted best practices. After expressing concerns about prescribing, some providers showed improved knowledge and comfort in use of guidelines but continued their current practice. Further education and intervention may help overcome this hurdle. A shift in culture at the clinic with other providers following recommendations may also lead to change in practice.

Results showed that many providers improved evidence-based monitoring strategies, which were designed to improve provider prescribing practices and reduce the risk of long term opioid use. Although improved, further intervention could build on current monitoring strategies leading to increased adherence by providers. Interventions may include further education or EHR based reminders for checking PDMPs and collecting UDSs.

Identifying patients eligible for enrollment in a pain contract was an important aspect of the project. The project identified patients eligible for a pain contract, based on a history of being

prescribed opioids ≥ 3 months. Providers demonstrated excellence in enrolling eligible patients in pain contracts. Results can be interpreted in different ways, but the results clearly show that providers understand the importance of recognizing patients using opioids long term. Results also show providers may be hesitant to acknowledge that monitoring strategies can promote positive outcomes and reduce risks associated with chronic opioid use. Further research and education could demonstrate and promote monitoring strategies among providers to improve adherence

EHR chart flagging was a need identified early in project development by the implementing facility. A universal flagging system within the EHR allowed providers to easily identify pain management patients. Providers said the flag became especially helpful when seeing another provider's patient enrolled in a pain contract.

Evaluation did not identify any facility specific trends in following guideline recommendations and accepted best practices. Individual trends and behaviors in managing patients with chronic pain were identified. The multi-site system used in the project provided a clear picture that facility trends did not disrupt the project's versatility. The project is generalizable to other clinical sites that will hold their own set of individual trends but is not limited by specific facility trends.

Overall the project showed improvement in all interventions carried out. Further interventions building on the project foundation could further improve outcomes. Allowing providers more time to carry out interventions may be a key tool in continuation of the project. Further research is needed for determining if the combined interventions produce improved patient outcomes.

Project Limitations

After initiating, implementing, and evaluating the quality improvement project, limitations were identified. Limitations are characteristics that impact the interpretation of findings (Melnyk & Fineout-Overholt, 2015). Identified limitations included UDS collection, clinic involvement, lack of provider initiative, non-distinguished pain management visits, patient limitations, shifting beliefs in pain management, and patient satisfaction scores. The limitations may have impacted the outcome of the project and need to be identified to better interpret results.

A limitation of urine drugs screens was identified. The education session discussed in great detail when pain contract patients should have a UDS collected. A chart review identified that UDS collections were falling short upon initiating pain contracts except for one provider. It was also identified that the most patients on pain contracts for greater than a year still did not receive an annual UDS after education was provided. Most providers express that they relied on the nursing staff to look up the last UDS and notify the provider of the last collection. Urine drug screen use may improve with better coordination. Strategies to improve UDS completion include: furnishing providers and nursing staff with a reference listing the steps to take when placing a patient on a pain contract; and creating a yearly deferred order within the EHR as a reminder to complete annual UDS may have improved UDS use.

In relation to clinical involvement, two of the clinics showed great interest and initiative for the project. After evaluation of the project it was evident that third clinic did not participate in any of the recommended best practices, failing to enroll eligible patients on pain contracts, and did not respond to any of the check in opportunities. Talking to one provider individually from each clinic after the education session and maintaining an open line of communication may have helped with communication at each clinic.

Lack of attendance to the education session may have contributed to the project limitations. All of the providers who were unable to make it to the education session were provided a voice over power point of the education materials and the discussion that occurred during the education session. The two providers that did not make it to the education session were given the post-education questionnaire. The questionnaires were not returned. One of the providers did not complete the questionnaire at the education session, leaving nine respondents. The author tried to keep questionnaire responses anonymous in hopes of honest feedback, therefore making it difficult to identify and discuss returning the questionnaire. Increasing the number of reminder emails to all providers may have been one way to receive the additional questionnaires.

Limitation incongruences between clinician's concern of chronic pain management with opioids and data collected through the chart audit exist. During the education session and project feedback provided during monthly check-ins and the mid-point on site follow-up providers expressed great concern about the complexity of chronic pain management with opioids as well as how opioid treatment may contribute to the opioid crisis. The concern was not reflected by the very minimal number of individuals who were discontinued on a pain contract due to noncompliance with the recommended guidelines. It is possible that the lack of follow through with guideline recommendations and accepted best practices by a few select providers may reflect that they feel the recommendations will not have an impact on such a complex issue.

Rural healthcare may be a contributing limitation. The nearest chronic pain management specialist to the practicing communities is 65 to 75 miles away. Providers may be hesitant to refer patients based on individual patient situations such as trying to accommodate transportation

or difficult work hours. Therefore, providers may continue managing chronic pain management even when they are uncomfortable.

Patients seeking chronic pain management often present with multiple complex comorbidities is a distinct limitation. Pain management and pain prescriptions may be lost within appointments discussing other co-morbid conditions. Prescription pain medication may be prescribed at appointments not designated for pain management leaving little time for providers to discuss pain management. Lack of time leads to missed opportunities to perform and complete current guideline recommendations and best practices. Although it may be in the provider's best interest to complete the recommendations and best practices, other comorbidities become a priority. Encouraging providers to make separate pain management visits may have helped this limitation.

Patients present obstacles creating project limitations. Providers may perform appropriate chronic pain management guideline recommendations and best practices, but patients fail to follow through. Patients may not follow-up as recommended or comply with provider recommendations. Due to the short project timeline, lack of follow-up may limit providers from placing eligible patients on a pain contract and performing appropriate UDS and PDMP checks. Extending the project timeline may have allowed for improved follow through regarding recommendations and best practices.

Time may present limitations for providers. Providers expressed concern at the end of the education session and in the post education questionnaire that one of the main obstacles was lack of time. Overall, providers agreed that to properly discuss pain management, visits should be about an hour long and they currently are allotted 15 minutes. Inadequate time related to short appointment times or addressing multiple problems in one visit contributes to failed chronic

opioid pain management (Krebs et al., 2014). Increasing time allotment for providers, especially at the initial visit, would have aided with the limitation of time.

Cost of urine drug screens can contribute to limitations of the project. Urine drug screens are expensive and although the clinic changed companies to try to reduce the cost, it still seems to be burdensome for patients. Depending on the patient's insurance the UDS may not be covered and the patient is required to pay out of pocket (USDHHS, 2016). Providers may hesitate to follow recommended best practices based on clinical judgement and cost of urine drug screens. Discussing the need for an annual UDS and the associated cost with patients upon initiation of the pain contract may be beneficial to practice. Urine drug screen discussions would allow patients time to ask questions and process the possible need to pay out of pocket prior to signing the contract. Removing some of the responsibility off of the provider onto the patient may help with the identified limitation.

Generational considerations may play a role in project limitations. In recent years a shift in perspective on pain management and use of opioids has changed. Pain management has changed dramatically starting in the early 1990's when pain was being undertreated. A push for improved pain management initiated adding pain as the fifth vital sign. Now overtreatment of pain is the trend especially with opioids. In 2016, the American Academy of Family Physicians recommended dropping pain as the fifth vital sign in an effort to combat the opioid crisis in the United States (American Academy of Family Physicians [AAFP], 2016; The Joint Commission, 2017). Providers who have been practicing since the early 90's may present resistance as this shift in mentality is difficult. Further and continued education may help improve the resistance to change.

Striving to improve patient satisfaction scores contributes to project limitations. An increasing emphasis has been placed on patient satisfaction scores and these scores are being linked to health care reimbursement. Pain management is one area that often falls short on patient satisfaction scores. In an attempt to improve satisfaction scores in regard to pain providers strive to satisfy patients reported pain. Although this cycle helps to improve patient satisfaction and reimbursement, it also encourages providers to prescribe opioids without limits to achieve unrealistic goals (Tompkins, Hobelmann, & Compton, 2017). The Centers for Medicare and Medicaid Services (CMS) has recently made changes to current policy by removing the pain management elements from the calculated payment based off the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) scores starting the 2018 fiscal year. Currently HCAHPS scores are used for the Hospital Value-Based Purchasing (VBP) Program, which provides incentive payments to acute-care facilities for Medicare beneficiaries provided quality care (Centers for Medicare & Medicaid Services, 2017). Change to policy regarding patient satisfaction scores and reimbursement would contribute to reducing the limitation.

Sample size presents as a project limitation. Although sample size is a limitation, the goal of the quality improvement project was not intended to generate new research. The goal of the project was to provide clinicians with evidence-based tools and strategies to improve prescribing practices and reduce risk of long term opioid therapy.

Project limitations are to be expected with the size of the project. Pain management presents a magnitude of barriers that primary care providers need to overcome. The opioid epidemic in the United States is driven by inappropriate prescribing of opioids by providers and misuse by patients. Finding a balance between managing patient's pain and prescribing opioids

appropriately is challenging. A chronic pain management guideline presents a tool to improve provider prescribing practices through evidence-based recommendations and accepted best practices to reduce misuse and abuse of opioids by patients (USDHHS, 2016). Implementing guidelines into practice comes with its own set of challenges and limitations. Throughout the project steps were taken to reduce limitations including monthly emails and a midpoint check-in. Over the four months, providers seemed to become more receptive of the project and more willing to implement the chronic pain management guidelines into their practice.

Project Site Recommendations

Strategies for project maintenance were built into the project objectives. The data analysis showed improvement in most areas of monitoring chronic pain management care. The two areas failing to show substantial improvement were providers following appropriate interventions for patients being prescribed ≥ 50 MME per day and annual urine drug screens. Recommendations for the facility include continued use of the 2016 CDC chronic pain management guideline recommendations and accepted best practices.

The author recommended that the facility implement a nurse driven protocol for new chronic pain management patients taking opioids. Nurse driven protocols have shown to help improve standardization, communication and outcomes while reducing patient harm (Committee on Professional Liability & Committee on Patient Safety and Quality Improvement, 2015). The protocol would provide strategies for the health care team to easily identify the chronic pain management population and implement guideline recommendations and best practices. This protocol would encourage nursing staff, once a pain contract was initiated, to flag “CS Consent” under patient alert notes, enter an annual health maintenance reminder, collect and order a UDS if appropriate, check the PDMP, and calculate the MME daily dosage.

Recommendations include strategies for improved collection and review of annual urine drug screens and continued evaluation of daily MME dosing. Initiating an annual health maintenance reminder for urine drug screens on all patients currently identified on a chronic pain management contract would help the provider (Alvandi, 2015). The reminder would eliminate the time it takes the provider to review charts over the last year in an attempt to figure out when a patient will need their annual UDS. Recommendations for a maintenance reminder for an annual review of the patients MME dosing would be appropriate. It may also be helpful if these two reminders could be grouped into one.

Recommendations for the facility include continued work towards implementing evidence-based strategies and recommendations set forth by the improvement project. For further growth, the author recommends that the quality coordinator works closely with the director of patient care and innovation to build on the foundation the project has made. It would be important to have analyzed data pulled biannually by the quality coordinator and the progress shared with providers. Data analysis will allow the facility to understand where adjustments need to be made and where to focus further efforts. Through this process the foundation of the project would be strengthened and built upon for continued improvement in chronic pain management.

Future Practice and Research Implications

Dissemination plays an important role in the quality improvement project. Dissemination is the process of distributing information broadly through multiple different structures (Melnyk, & Fineout-Overholt, 2015). Although the results were not complete, the project was disseminated through a poster presentation and a 5-minute presentation to attendants at the 2017 North Dakota Diabetes Summit and a poster presentation at the North Dakota Nurse Practitioner Association Pharmacology Conference in September 2017. Results of the project were

disseminated to providers and supporting staff at the participating clinics quarterly meeting in February 2018. The author will develop a three-minute thesis video that will be used to further disseminate the project. A final poster will be created and presented at the Annual Research Day at North Dakota State University at Sanford in May 2018.

Project evaluation identified areas where the interventions improved chronic pain management, areas needing further improvement, and possible additional interventions. Additional interventions would build on the foundations of the project and enhance practice beyond the scope of the project. Continued research would contribute and shape future recommendations and best practices of monitoring and managing chronic pain. Further research on the best way to monitor morphine milligram equivalence would be beneficial. Opioid related overdose deaths have been linked to MME daily dosing ≥ 50 and the risk increases at ≥ 90 MME per day. Monitoring MME daily dosages presents many barriers and unlike PDMP and UDS monitoring current guidelines fail to advise monitoring recommendations (USDHHS, 2016). One barrier identified through the provider education questionnaire was discomfort on covering topics such as decreasing or eliminating opioid dosages. Further research and education on providing counseling to patients on high risk daily dose opioids could provide a positive impact on practice. Throughout research there is a lack of evidence supporting pill counts. Further research on pill counts could determine its benefit in further monitoring chronic pain management (USDHHS, 2016). Evidence highlights the lack of support contributing to the use of opioids and achieving pain control. Research highlights the importance of offering alternative and adjunctive treatment options for chronic pain, but research is lacking on what alternative therapies would work best for specific types of pain. Improved provider knowledge and strategies on improving chronic pain management are important for the advancement of

improving practice. Formulation of new evidence helps contribute and build on provider's knowledge and practice improvement techniques.

Opioids therapy has been overused for chronic pain management and in an effort to combat the opioid crisis the CDC released a new set of chronic pain management guidelines with a focus on use of opioid therapy (Hsu, 2017). The guidelines highlight recommendations and best practices when prescribing opioids for chronic pain. Although these guidelines will help make providers more aware and understand ways to improve prescribing practices of opioids, it will not solely solve the opioid epidemic. Lawsuits against providers in regard to overprescribing of opioids is on the rise. Implementation of the quality improvement project pushes providers in the right direction by building on an evidence-based foundation that will not only help improve practice but protect providers against lawsuit. Having evidence-based interventions that target prescribing and monitoring may potentially reduce the risk of litigation for providers at the facility if safety practices were questioned (Yang, Larochelle, & Haffajee, 2017).

On October 26, 2017, President Donald Trump declared the opioid crisis in the United States a public health emergency (Johnson & Wagner, 2017). This project not only contributes to improving the opioid epidemic but also provides a foundation for further growth at the clinics where the project was implemented. The project can be adopted by primary care providers and built upon by other facilities. A push has been made by the federal government to curb the opioid epidemic. This project focuses on improved opioid prescribing practices and improved monitoring of chronic pain management patients. Although the project does not make a large impact on improving the opioid epidemic, it does contribute to the larger picture. The improvement project pushes for a movement and behavior towards improvement. Showing how

small changes can make an impact may encourage others to join the movement towards improving the opioid epidemic.

Application to Other Doctor of Nursing Practice Roles

Implementation of a quality improvement project builds and expands upon many different roles within the Doctor of Nursing Practice. During project development, scientific underpinnings played an important role as the author translates knowledge into new approaches to improve patient outcomes. Leadership played a strong role during the building, implementation, and evaluation of a quality improvement project. The author initiated and facilitated the project with a goal to promote patient safety and improve practice. Patient safety and practice improvement (developed through close collaboration with providers) further developed the leadership role. Throughout the project the author used many aspects of technology to aid the improvement of health outcomes. During the process, the author advocated for safety and improved outcomes of chronic pain management patients. DNPs are strongly recognized for their successful efforts in practicing health promotion. The efforts have not gone unnoticed as patient outcomes have improved. The project exemplifies health promotion by improving health outcomes through prescribing practices of providers and evidence-based monitoring strategies to reduce chronic opioid therapy risks. The quality improvement project not only provided growth towards practice improvement, but also augmented the author's academic and professional growth.

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APPENDIX A. PERMISSION TO USE THE IOWA MODEL

Kimberly Jordan - University of Iowa Hospitals and Clinics

December 6, 2016 at 11:06 AM

To: Kelsey.Striefel@ndsu.edu

Reply-To: Kimberly Jordan - University of Iowa Hospitals and Clinics

Permission to Use and/or Reproduce The Iowa Model (2015)

KJ

North Dakota State University

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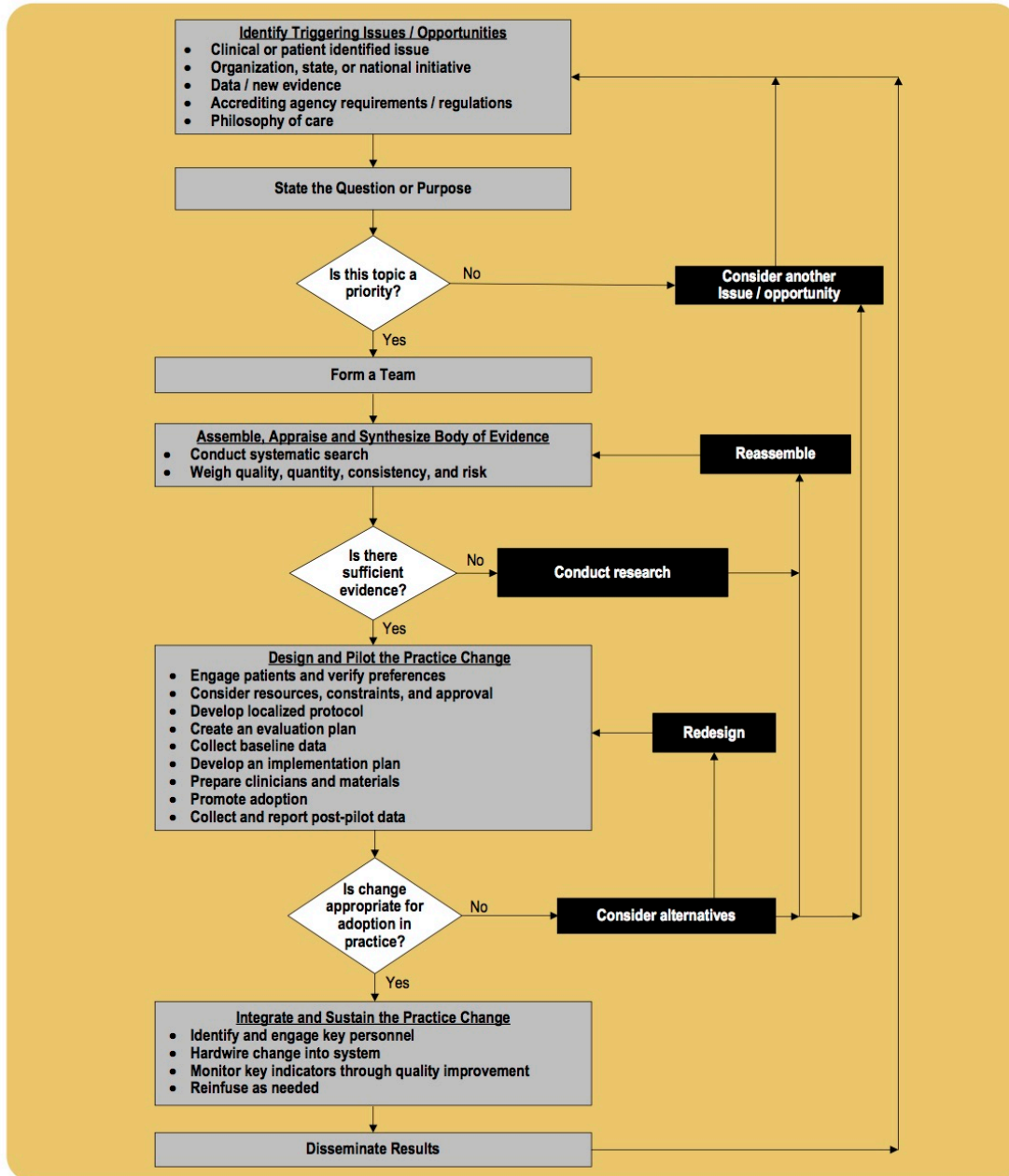
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APPENDIX B. IOWA MODEL

The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care

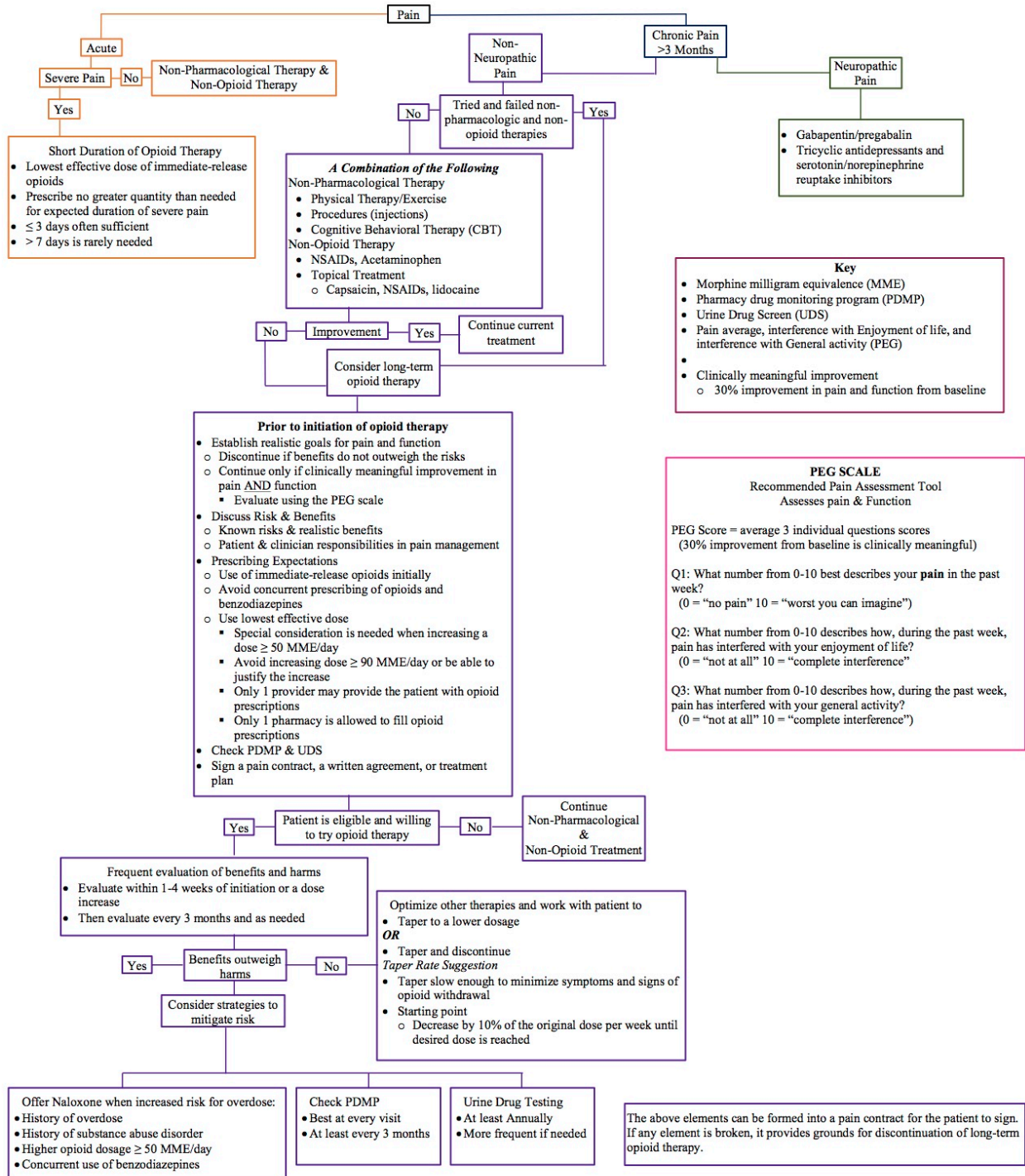


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(Titler et al., 2015)

APPENDIX C. PAIN MANAGEMENT ALOGRITHM

Pain Management Algorithm



APPENDIX D. MORPHINE MILLIGRAM EQUIVALENCE CONVERSION TABLE

<i>Morphine Milligram Equivalence Conversion</i>	
Calculating Morphine Milligram Equivalence (MME)	
<ul style="list-style-type: none"> • Calculating Total Daily Doses that would be equivalent to MME/day <ul style="list-style-type: none"> ○ (total number of desired MME/day)/(conversion factor)= Total daily dose equivalent to desired MME/day <ul style="list-style-type: none"> ▪ 50 MME / conversion factor = total daily dose equivalent to 50 MME/day ▪ 90 MME/ conversion factor = total daily dose equivalent to 90 MME/day • Example: How many mg of hydromorphone is equal to 50 MME/day <ul style="list-style-type: none"> ○ Desired MME/day ○ Conversion factor = 4 ○ 50/4=12.5 ○ 12.5 mg of hydromorphone per day =50 MME/day 	<ul style="list-style-type: none"> • Calculating MME from patient daily intake <ul style="list-style-type: none"> ○ (total number of tablets a day) x (medication dose) x (conversion factor) = Total MME/day that the patient is taking <ul style="list-style-type: none"> ▪ Example: Patient is prescribed hydrocodone/acetaminophen 5/325 mg, 1-2 tablets every 4-6 hours <ul style="list-style-type: none"> ○ Max number of tablets this patient can take a day is 2 tablets every 4 hours ○ 24/4 = patient can take medication up to 6 times a day ○ 6x2 = 12 tablets ○ Total number of tablets =12 ○ Medication dose = 5 mg of hydrocodone ○ Conversion factor = 1 ○ 12x5x1 = 60 ○ This patient is taking 60 MME / day with max dose

Commonly Prescribed Opioids				
Medication	50 MME Dose Equivalence	Estimated Number of Dosages	90 MME Dose Equivalence	Estimated Number of Dosages
Hydrocodone	50 mg of hydrocodone	10 tablets of hydrocodone/acetaminophen 5/325 mg 5 tablets of hydrocodone/acetaminophen 10/325 mg	90 mg of hydrocodone	18 tablets of hydrocodone/acetaminophen 5/325 mg 9 tablets of hydrocodone/acetaminophen 10/325 mg
Oxycodone	33 mg of oxycodone	~2 tablets of oxycodone sustained-release 15 mg ~6 tablets of oxycodone/acetaminophen 5/325 mg ~3 tablets of oxycodone/acetaminophen 10/325 mg ~6 tablets of oxycodone/ibuprofen 5/400 mg	60 mg of oxycodone	4 tablets of oxycodone sustained-release 15 mg 12 tablets of oxycodone/acetaminophen 5/325 mg 6 tablets of oxycodone/acetaminophen 10/325 mg 12 tablets of oxycodone/ibuprofen 5/400 mg
Hydromorphone	12.5 mg of hydromorphone	6 tablets of hydromorphone 2 mg 3 tablets of hydromorphone 4 mg	22 mg of hydromorphone	11 tablets of hydromorphone 2 mg 5.5 tablets of hydromorphone 4 mg
Morphine	50 mg of Morphine	~3 tablets of Morphine extended release 15mg	90 mg of morphine	6 tablets of Morphine extended release 15mg
Fentanyl Transdermal	21 mcg/hr	(1) 12mcg/hr patch < 25 mcg/hr patch	37.5 mcg/hr of Fentanyl transdermal	(1) 12mcg/hr patch + (1) 25 mcg/hr patch

(USDHHS, 2016)

APPENDIX E. POST-EDUCATION QUESTIONNAIRE

Please answer the following questions below on the presented education:

1. Did this session meet your educational needs?

No	Somewhat	Yes
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Did the information presented reinforce and/or improve your current skills?

No	Somewhat	Yes
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. Did the information presented provide new ideas/information you expect to use?

No	Somewhat	Yes
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please rate the projected impact of this education activity on your competence, performance, and/or patient outcomes:

4. This activity increased my competence

No Increase	Moderate Increase	Great Increase
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. This activity will improve my performance

No Increase	Moderate Increase	Great Increase
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. This activity will improve my patient outcomes

No Increase	Moderate Increase	Great Increase
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

* Competence is defined as giving providers new abilities/strategies/knowledge with a strategy, or what a professional would do in practice if given the opportunity.

** Performance is defined as helping physicians modify their practices.

Answer the following questions regarding best practice for chronic opioid management:

7. What is your comfort level of caring for a chronic pain management patient?

Very Poor	Poor	Acceptable	Good	Very Good
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. Rate your understanding of who should be placed on a pain contract?

Very Poor	Poor	Acceptable	Good	Very Good
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. Rate your understanding on the process to follow to place a patient on a pain management contract?

Very Poor	Poor	Acceptable	Good	Very Good
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. Rate your understanding of how often the Prescription Drug Monitoring Program (PDMP) should be checked on chronic pain management patients?

Very Poor	Poor	Acceptable	Good	Very Good
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11. Rate your understanding on how often urine drug screens should be performed on chronic pain management patients?

Very Poor	Poor	Acceptable	Good	Very Good
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12. What is your understanding on how to care for patients that exceed 50 morphine milligram equivalence (MME) per day?

Very Poor	Poor	Acceptable	Good	Very Good
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

13. Rate understanding on how to care for patients that exceed 90 morphine milligram equivalence (MME) per day?

Very Poor	Poor	Acceptable	Good	Very Good
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

14. Rate your understanding of the recommendations provided by The 2016 Center for Disease Control and Prevention (CDC) guideline on chronic pain management?

Very Poor	Poor	Acceptable	Good	Very Good
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Write a brief description to answer the following questions:

15. What changes will you incorporate into your practice as a result of the knowledge acquired during this education?
16. How do you intend to take what you learned and improve the health of your patients?
17. What are the top three barriers to managing pain?

APPENDIX F. QUICK REFERENCE SHEET

Quick Reference Sheet: Management of Patients Meeting the Upper Limit Morphine Milligram Equivalent Recommendations	
Opioids \geq 50 MME/Day	Opioids \geq 90 MME (INTERVENTIONS for 50 MME/Day PLUS)
<ol style="list-style-type: none"> 1. Reassess for evidence of benefits outweighing risks 2. Increased frequency of follow-ups <ul style="list-style-type: none"> • Every 1-4 weeks 3. Consider offering naloxone and overdose prevention education to: <ul style="list-style-type: none"> • The patient • Members of the patient’s household <ul style="list-style-type: none"> ○ Factors increasing overdose risk <ul style="list-style-type: none"> ▪ \geq50 MME/day ▪ History of overdose ▪ History of substance use disorder ▪ Concurrent benzodiazepine use • Information on naloxone prescribing: http://prescribetoprevent.org 4. Referrals to: <ul style="list-style-type: none"> • Pain specialist • Behavior health specialist 	<ol style="list-style-type: none"> 1. Avoid prescribing doses \geq 90 MME/day 2. Carefully justify and document decision to titrate dose \geq 90 MME/day <ul style="list-style-type: none"> • Discuss alternative approaches to pain management: <ul style="list-style-type: none"> ○ Consider working with patients to taper opioids to a lower dose or discontinuation while maximizing nonpharmacological and non-opioid pharmacologic treatments <ul style="list-style-type: none"> ▪ Slow taper <ul style="list-style-type: none"> ○ 10% of the original dose reduction weekly ▪ Rapid taper <ul style="list-style-type: none"> ○ 30-50% of the original dose reduction over 2-3 weeks
<p>➤ Presenting signs of an opioid use disorder clinicians should provide:</p> <ul style="list-style-type: none"> • Treatment referral <ul style="list-style-type: none"> ○ Methadone ○ Buprenorphine <ul style="list-style-type: none"> ▪ Has higher rates of preventing relapse • Behavioral therapy referral 	

APPENDIX G. IRB APPROVAL



July 5, 2017

Dr. Mykell Barnacle
Nursing

IRB Approval of Protocol #PH17254, "Opioids: A Reason for Concern"
Co-investigator(s) and research team: Kelsey Striefel

Approval period: 7/5/2017 to 7/4/2018
Continuing Review Report Due: 6/1/2018

Research site(s): NDSU Funding Agency: n/a
Review Type: Expedited category # 5, 7
IRB approval is based on the protocol submission (received 6/14/2017) with updated Additional Materials Attachment (received 7/2/2017).

Additional approval from the IRB is required:

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

Other institutional approvals:

- Research projects may be subject to further review and approval processes.

A report is required for:

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

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

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

Sincerely,

Digitally signed by Kristy Shirley
DN: cn=Kristy Shirley, o=NDSU,
ou=Institutional Review Board,
email=kristy@irb.ndsu.edu, c=US
Date: 2017.07.05 11:03:48 -0700

Kristy Shirley, CIP, Research Compliance Administrator

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

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 R2/RA university.

APPENDIX H. EXECUTIVE SUMMARY

Background and Significance

Chronic pain is a growing issue in the United States, individuals affected by chronic pain are increasing each year. More than 50 million adults are affected by chronic pain each year. Americans affected by pain totals more than those with conditions such as: diabetes, heart disease, and cancer combined. Chronic pain affects many aspects of life for individuals living with it including but not limited to: neurological system, emotions, behavior, ability to perform daily tasks, ability to work, social responsibilities, and quality of life. The United States has an opioid consumption rate greater than any other nation. In 2015, prescription opioids account for nearly half of United States. opioid related deaths. More than 15,000 overdose deaths involving prescription opioids occurred in 2015, averaging about 46 people each day. Since 1999, prescription opioid related overdose deaths and opioid prescribing habits of providers have quadrupled. In 2012, 259 million opioid pain medication prescriptions were provided by health care providers, which is enough for every United States adult to have one bottle of opioids. Opioid pain medication is over-prescribed for individuals with all types of pain. Healthcare placing more emphasis on patient satisfaction scores is driving providers to achieve patient satisfaction. Chronic pain treatment in the United States has amounted to more than half a trillion dollars every year. Healthcare costs of opioid abusers were eight times higher than non-opioid abusers. Chronic non-cancer pain has been found to be the leading cause of long-term disability. Rates of prescription opioids are concerning, and action needs to be taken.

Project Summary

The purpose of the project quality improvement project is to provide clinicians with tools and processes that will reduce problematic prescribing and subsequently reducing current and

potential misuse, abuse, and overdose. Use of evidence-based guidelines in practice offer possible solutions to problematic prescribing, change prescribing habits, improve provider knowledge, optimize care, and improve patient safety. The Population of the project will include: all patients 18 years and older on chronic opioid therapy. The setting of the project is Coal County Community Health Center which is a healthcare facility with four locations in rural North Dakota. The project started with an education session organized for all clinicians and patient care staff to provide education regarding the CDC guideline elements, current recommendations, and accepted best practices. Education highlighted the importance of using the prescription drug monitoring program (PDMP), urine drug screening (UDS), pain contracts, and calculating daily morphine milligram equivalence (MME). A laminated copy of an algorithm based upon the CDC guideline and pre-calculated MME doses for popular opioids was be provided to all clinicians. A post-education session questionnaire was given to all providers. The questionnaire focused on current understanding of information provided during the education session. Five main objects were carried out. Patients with existing pain contracts were identified and a flag reading “CS Consent” was developed in collaboration with informational technology services (ITS). The flag “CS Consent” was added onto the face sheet new patient alerts on the patients EHR. Patients prescribed opioids ≥ 3 months will be identified for pain contract eligibility. A list of identified patients will be provided to clinicians and will be flagged in the EHR as “Eligible for CS Consent.” Patients receiving opioids for ≥ 3 months and prescribed the upper limits of morphine milligram equivalence (MME), ≥ 60 and ≥ 90 MME per day, were identified through a chart audit. A list of these patients was provided to clinicians and encouraged to follow current recommended interventions for patients. At the end of the project

the quality coordinator was designated to take responsibility to ensure providers compliance with appropriate use of PDMP, UDS, and MME.

Results

Post-Education Questionnaire Results

A post-education questionnaire was provided to 10 clinicians who attended the education session on August 30, 2017. After the education session was completed, an open discussion was held between the providers and remaining 37 clinical staff in attendance. Nine of the 10 providers returned the questionnaire with responses. The remaining providers did receive but did not return the questionnaire. Following are the questions asked and the provider's responses taken from the questionnaires.

The first three questions focused on the education presented during the education session. Responses to questions one through three were based on a three-part response including no, somewhat, and yes. The first question on the questionnaire asked if the educational session met the provider's educational needs on chronic pain management. All nine providers answered yes, indicating that their educational needs on chronic pain management were met. Question two asked if the information presented reinforced and/or improved their current skills. All nine providers answered yes. The third question on the survey asked providers if the educational session provided new ideas and information that they expect to use in practice. Eight of the nine providers answered yes and one provider answered no.

Questions four through six focused on the projected impact the education had on their competence, performance, and/or patient outcomes. Responses to questions four through six were based on a three-part response including no increase, moderate increase, and great increase. Question four asked if the education session increased their competence on chronic pain

management. Three providers responded great increase and six providers responded moderate increase. The fifth question on the questionnaire asked if the education session will improve the provider's performance. Two providers responded great increase and seven providers responded moderate increase. Question six asked if the education session will improve patient outcomes. Three providers responded great increase and six responded moderate increase.

Questions seven through fourteen were in regard to the best practices for chronic opioid management. Responses to questions seven through 14 were based on a five-part response including very poor, poor, acceptable, good, and very good. Question seven asked the provider's comfort level of caring for a chronic pain management patient. Two providers responded very good, four responded good, two responded acceptable, and one responded poor. The eighth question on the questionnaire had providers rate their understanding of who should be placed on a pain contract. Five providers responded very good, three responded good, and one responded acceptable. Question nine asked providers to rate their understanding of the process to follow to place a patient on a pain management contract. Four providers responded very good, four responded good, and one responded acceptable. The tenth question on the survey had providers rate their understanding of how often the PDMP should be checked on chronic pain management patients. Five providers responded very good and four responded good. Question eleven asked providers to rate their understanding on how often urine drug screens should be performed on chronic pain management patients. Five providers responded very good, three responded good, and one responded acceptable. The twelfth and thirteenth questions on the questionnaire asked providers their understanding on how to care for patients that exceed 50 MME per day and 90 MME per day, respectively. For both questions, three providers responded very good, three responded good, two responded acceptable, and one responded poor. Question fourteen asked

providers to rate their understanding of the recommendations provided by the 2016 CDC guideline on chronic pain management. Three providers responded very good, four responded good, and two responded acceptable.

The final three questions on the questionnaire were open ended. One question focused on the education provided and areas of concern when treating chronic pain management. Providers still had concerns about:

- contributing to opioid dependence
- addressing high MME dosages with patients
- the difficulty caring for non-compliant patients
- lack of resources in the immediate area such as pain specialist and mental health care
- lack of experience caring for pain management patients
- trying to effectively offer and treat with alternative treatment options when appropriate
- referring patients back to the primary care provider
- the time it takes to care for patients with chronic pain and not having enough time to provide the care needed
- pain is subjective leaving it difficult to know when to treat and not treat
- patients misusing pain medication often become manipulative

Question sixteen providers what issues should the system address to help you improve management of chronic pain. Provider responses included:

- provide an easy spot to see the pain contract that is in place
- implement reminders that patients are on contracts
- identify on the EHR if the patient has been dismissed from their contract
- system notification of when pain contract patients are due for a UDS

- wishes the current EHR system could calculate MME
- reminders for checking records, dosages, and drug screens
- simplified pain management charting to make charting easier

Question seventeen asked what are the top three barriers to managing chronic pain.

Providers responses included:

- trouble with subjective symptoms leading to a treatment plan
- difficulty trusting patients
- difficulty confronting patients
- stigma associated with opioid use
- patient compliance
- the psychosocial component
- the lack of consistency across different providers
- lack of resources in rural health, patient expectations
- educating patients, pain is subjective
- patients lie/ manipulative patients
- patients sell and traffic their medications
- lack of pain management options
- cost of urine drug testing
- the PDMP does not include all 50 states yet
communication barriers, and pain assessment

Initial Chart Review Results

The author performed an initial chart review in August 2017 prior to the education session. The initial chart review included 364 charts of patients who were being prescribed

opioids. Data collection identified if the patients were prescribed opioids for ≥ 3 months and if they were on a pain contract. Forty-two patients were found to have a pain contract and 17 more patients were identified as being eligible for a pain contract. The 42 charts reviewed of patients previously identified on a pain contract revealed zero patients had a PDMP report scanned into the EHR. The chart identified nine of the 42 patients or 21% on a pain contract had a UDS performed in the past year. Morphine milligram equivalence was evaluated for all patients on a pain contract. Seven of the 42 pain-contract patients or 16.7% were being prescribed dosages ≥ 50 MME per day and nine of 42 or 21% were being prescribed dosages ≥ 90 MME per day. Data analysis was also performed on patients who were eligible for pain contracts. Three of the 17 or 17.6% of patients were being prescribed ≥ 50 MME per day and five of 17 or 29% were being prescribed ≥ 90 MME per day.

Final Chart Review Results

The final chart review was moved from six down to four months with approval from the project committee. This change addressed time constraints of the project due to delays in IRB approval and scheduling with the clinics to initiate the project. The final chart review was completed the first week of January 2018. The same data was reviewed and analyzed as the initial chart review.

The initial 42 patients identified on pain contracts were evaluated and three were placed on the facilities restricted list, three had their pain contract discontinued, and two were no longer being prescribed opioids because they moved out of state. Thirty-four of the original 42 remained on a pain contract. Thirty-four patient's charts were flagged with "CS consent" on the face sheet under patient alert notes. Evaluation of patients eligible for a pain contact identified two patients had documentation justifying a reason why the patients were not placed on a pain

contract. Both patients were prescribed opioids for ≥ 3 months but took one or two opioid pills per week. Opioid therapy was discontinued for two of the eligible patients.

Based on this new data, the number of eligible patients who should be placed on a pain contract decreased to 13. Eleven out of 13 or 85% of the eligible patients were placed on a pain contract. Eleven out of 11 or 100% of eligible patients placed on a pain contract had been flagged with “CS Consent and initiation date” in the EHR under patient alert notes.

At the end of the project 45 patients had a pain contract, combining the 34 patients who initially were on a pain contract and the 11 eligible patients who were placed on a pain contract. Analyzing documented PDMP use data indicated 7 of the 11 or 64% of patients that were eligible and enrolled on a pain contract had a PDMP checked within the last three months. Eleven out of 34 or 32% of patients with an existing pain contracts had PDMP review documentation. The data for urine drug screens were collected through the chart review and seven out of 11 or 64% of patients who were eligible and enrolled on a pain contract had a UDSs performed at initiation of the pain contract. Eight out of 34 or 24% of patients previously on a pain contract had a UDS performed since initiation of the project.

Evaluation of MME interventions showed a total of three patients who were eligible for a pain contract and four who were previously on a pain contract were being prescribed ≥ 50 MME per day. One out of three or 33% of eligible and enrolled patients and three out of four or 75% of patients previously on a pain contract had documented appropriate recommended interventions. Upon evaluation of patients prescribed ≥ 90 MME per day five patients eligible for a pain contract and nine patients previously on a pain contract were identified. Morphine Milligram Equivalence data analysis revealed two of the five or 40% of patients who were eligible and

enrolled in a pain contract and five out of nine or 56% of patients previously on a pain contract had appropriate interventions provided by providers.

Discussion

The practice improvement project identified opportunity: potential improvement in both prescribing practices and chronic pain management of opioids. Findings showed providers increased their knowledge and comfort in using evidence-based practice guidelines. Based on the post-education questionnaire, providers identified lack of comfort in calculating safe MME daily doses and caring for patients with at-risk doses. Continuing education focused on MME dose calculation and patient care for high risk doses could potentially overcome this barrier.

Discussion with individual providers revealed significant interest and need for improved opioid prescribing and monitoring strategies concerning chronic pain management patients. The chart review revealed that four of the providers followed all recommendations and accepted best practices fully. The remaining providers followed only certain elements while others did not follow any elements of the recommendations and accepted best practices. After expressing concerns about prescribing, some providers showed improved knowledge and comfort in use of guidelines but continued their current practice. Further education and intervention may help overcome this hurdle.

Results showed that many providers improved evidence-based monitoring strategies — strategies designed to improve provider prescribing practices and reduce the risk of long term opioid use. Although improved, further intervention could build on current monitoring strategies leading to increased adherence by providers. Interventions may include further education or EHR based reminders for checking PDMP's and collecting UDS's.

Identifying patients eligible for enrollment in a pain contract was an important aspect of the project. The project identified patients eligible for a pain contract, based on a history of being prescribed opioids ≥ 3 months. Providers demonstrated excellence in enrolling eligible patients in pain contracts. Results can be interpreted in different ways but the results clearly show that providers understand the importance of recognizing patients using opioid long term. Providers may be hesitant to acknowledge that monitoring strategies can promote positive outcomes and reduce risks associated with long term opioid use. Further research and education could demonstrate and promote monitoring strategies among providers to improve adherence

EHR chart flagging was a need identified early in project development by the implementing facility. A universal flagging system within the EHR allowed providers to easily identify pain management patients. Providers said the flag became especially helpful when seeing another provider's patient enrolled in a pain contract.

Overall the project showed improvement in all interventions carried out. Further interventions, building on the project foundation, could further improve outcomes. Allowing providers more time to carry out interventions may be a key tool in continuation of the project. Further research is needed for determining if these combined interventions produce improved patient outcomes.

Recommendations

Strategies for project maintenance was built into the project objectives. The data analysis showed improvement in most areas of monitoring chronic pain management care. The two areas failing to show substantial improvement were providers following appropriate interventions for patients being prescribed ≥ 50 MME per day and annual urine drug screens. Recommendations

for the facility include continued use of the 2016 CDC chronic pain management guideline recommendations and accepted best practices.

The author would recommend that the facility implement a nurse driven protocol for new chronic pain management patients taking opioids. Nurse driven protocols have shown to help improve standardization, communication and outcomes while reducing patient harm (Committee on Professional Liability & Committee on Patient Safety and Quality Improvement, 2015). The protocol would provide strategies for the health care team to easily identify the chronic pain management population and remember guideline recommendations and best practices. This protocol would encourage nursing staff once a pain contract was initiated to flag “CS Consent” under patient alert notes, enter an annual health maintenance reminder and collect and order a UDS if appropriate, check the PDMP, and calculating the MME daily dosage.

Recommendations include strategies for improved collection and review of annual urine drug screens and continued evaluation of daily MME dosing. Initiating an annual health maintenance reminder for urine drug screens on all patients currently identified on a chronic pain management contract would help the provider (Alvandi, 2015). The reminder would eliminate the time it takes to provider to review charts in the last year in an attempt to figure out when a patient will need their annual UDS. Recommendations for a maintenance reminder for an annual review of the patients MME dosing would be appropriate. It may also be helpful if these two reminders could be grouped into one.

Recommendations for the facility include continued work towards implementing evidence-based strategies and recommendations set forth by the improvement project. For further growth, the author recommends that the quality coordinator works closely with the director of patient care and innovation to build on the foundation the project has made. It would be

important to analyzed data pulled biannually by the quality coordinator and the progress shared with providers. Data analysis will allow the facility to understand were adjustments need to be made and where to focus further efforts. Through this process the foundation of the project would be strengthen and built upon for continued improvement in chronic pain management.