OPIOID GUIDELINE ADHERENCE FOR TRAMADOL IN THOSE WITH CHRONIC NONMALIGNANT PAIN

by

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DEDICATION

I would like to dedicate this project to my committee for all of their support, time and encouragement along the way. I could not have been here if it were not for this group of people.

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ABSTRACT

Pain is a very common problem affecting up to one-third of the entire population of the United States at any given time and for those with pain, 1 in 3 people have chronic nonmalignant pain lasting longer than 3 months (Centers for Disease Control and Prevention [CDC], 2016b). A majority of those with pain are seen in a primary care setting initially, and sometimes on an on-going basis (Gatchel, 2004; National Institute of Health [NIH], 2010). Ensuring comfort by addressing pain levels in patients is a primary, ethical nursing duty. Historically, one common modality used to treat pain is the use of opioids. However, the literature indicates that healthcare practitioners at all levels receive little education on how to manage chronic pain utilizing prescription opioids in the primary care setting. A lack of education on prescribing opioids has helped create an epidemic of dependence and overdoses on opioids. Additionally, the opioid crisis has continued despite many attempts at various levels, including executive and legislative bills, to try and stop opioid abuse and overdose. Although originally touted as a safe alternative to opioids and slightly stronger than over-the-counter analgesics, tramadol is an opioid with regulation by the Drug Enforcement Agency and Food and Drug Administration that, upon review, does not appear to be in line with the gold standards for prescribing opioids, such as the 2016 Center for Disease Control and Prevention guidelines or the 2018 Montana Utilization and Treatment Guidelines, for nonmalignant chronic pain management with opioids. The purpose of this project was to assess provider knowledge related to tramadol and providers' adherence to the present opioid guidelines when prescribing tramadol in a small, southwestern Montana community.

CHAPTER ONE—OVERVIEW

Introduction

Pain is a public health challenge affecting millions of Americans and it contributes to disability, morbidity, and mortality. Pain directly places significant demands on society's healthcare and economic resources. There is a lack of consistent and complete data on incidence, prevalence, and consequences of pain, but the goal is to support outcomes for individuals and the families of those who experience pain by adherence to guidelines (Institute of Medicine [IOM], 2011). An early definition of pain by nurse Margo McCaffery suggests that pain is "whatever the experiencing person says it is and exists whenever he says it does" (1968, p.95). The current definition of pain used by both the International Association for the Study of Pain (IASP) and the American Pain Society (APS) is "an unpleasant sensory and emotional experience associated with the actual or potential tissue damage, or described with actual or potential tissue damage, or described in terms of such damage" (McCaffery & Pasero, 1999, p.16).

Addressing patient pain can help direct the appropriate modality of treatment. A common medical management for pain, whether a short-term or long-term intervention is indicated, is the use of prescription opioids. Tramadol is an opioid that is not classified by the same Drug Enforcement Administration (DEA) scheduling that most opioids follow. With lighter restrictions on tramadol, providers can prescribe more of it and see a patient less often than with other opioids. However, tramadol is an opioid, and there are guidelines for prescribing opioids for chronic nonmalignant pain. The purpose of this project was to assess provider knowledge related to tramadol and providers' adherence to

the present opioid guidelines when prescribing tramadol in a small southwestern Montana community for chronic, nonmalignant pain. Further, strategies for addressing gaps in practice were provided in order to improve patient care and produce better future outcomes.

Background and Significance

Chronic nonmalignant pain is one of the most prevalent disorders for which patients seek primary care. Pain is reported as the number one reason adults seek medical help from primary care, generating up to 80% percent of all primary care visits (Gatchel, 2004; NIH, 2010). Henschke et al. (2015) indicate that overall prevalence rates of adults with non-cancer persistent pain are higher for women than men, as women report more severe pain and report more frequent pain than men. Depression is a risk factor for pain and a common comorbidity.

Musculoskeletal pain is most prevalent in older adults, and because pain is subjective in nature, describing the epidemiology of pain is difficult (Henschke et al., 2015). Diabetic peripheral neuropathic pain (DPN) occurs in up to 26% of the diabetic population (Rice et al., 2016). Carey and Freburger (2016) describe lower back pain (LBP) as affecting 80% of the population sometime throughout life and having a global prevalence of 9.4% (Confidence Interval [CI] 95%, 9.0% to 9.8%). Out of pocket costs for pain treatment are excessive as 59 million Americans spend an estimated total of $30.2 billion out-of-pocket dollars per year on complementary therapies for pain (Nahin et al., 2016).

In America, about 1 in 3 people suffer from pain, including acute, cancer, and persistent non-cancer pain (Doorenbos et al., 2013). Pain and depression co-occur 30% to 50% of the time in primary care patients, and some studies show bi-directional and potentially causative influences of pain and depression (Kroenke et al., 2011). Chronic pain is considered one of the most complex primary health concerns. An estimated 20% of patients presenting with a non-cancer pain-related diagnosis receive an opioid prescription (Daubresse, 2013). One factor contributing to the complexity of treatment for chronic pain is the rate of comorbid mental health issues including depression associated with chronic nonmalignant pain (Bair et al., 2009). Depression affects 5-17% of the general population; this percentage increases to 30-54% in the population of patients also diagnosed with chronic pain (Bair et al., 2003; Banks & Kern, 1996; Moitra et al., 2011).

According to Bush (2015), Drug Abuse Warning Network (DAWN) reported that over 50,000 emergency department visits annually are related to tramadol use alone. Further, these emergency visits do not include visits that relate to a combination of substances that included tramadol, and over half of these visits are related to side effects of the drug. Bush (2015) further implies that common side effects of tramadol may include headache, itching, nausea, vomiting, constipation (more common in the elderly over 75 years of age), diarrhea, heartburn, dizziness, sleepiness, nervousness, anxiety, agitation, tiredness, and stomach pain. Additional serious side effects, some of which are rare, may include addiction, abuse, and misuse, overdose and death (even at normal doses), life-threatening or fatal depressed breathing, ultra-rapid metabolism of tramadol

and other risk factors for life-threatening respiratory depression in children, neonatal opioid withdrawal syndrome, excessive sedation, serotonin syndrome, seizures associated with abuse of tramadol, suicide or attempted suicide, adrenal insufficiency, severe hypotension, gastrointestinal adverse reactions, androgen deficiency, abnormal heart rhythms, severe hypersensitivity reactions, and withdrawal.

Most of these adverse effects are included precautions with other opioids, but precautions for tramadol may exceed the precautions of some other opioids. According to NIH (2019), opioids bind to opioid receptors in the central nervous system (CNS) and are a type of alkaloid. Yaksh and Wallace (2011) define an opiate as a medication structurally similar to opium and derived from the poppy plant, while an opioid is defined as any agent regardless of structure that has the function and pharmacological effects of an opiate. Ghelardini et al. (2015) further define an opioid as including receptors (mu, kappa, and delta). Seventy-five percent of opioid receptors in the dorsal horn are located on the presynaptic neurons and 25% of opioid receptors in the dorsal horn are located on the postsynaptic neurons and any medication that activates these receptors to any degree is considered an opioid (Ghelardini et al., 2015). Because tramadol affects the mu, and to a lesser degree kappa and delta receptors in the body, it makes it an opioid by definition, but tramadol also inhibits serotonin and norepinephrine (Ultram, 2019). The inhibition of these neurotransmitters with tramadol use increases the risk of seizures and serotonin syndrome, while other opioids do not generally carry the risk of seizures and serotonin syndrome. This finding is especially important when long-term use is concurrent with benzodiazepines or antidepressants, such as selective serotonin reuptake inhibitors

(SSRIs) and norepinephrine reuptake inhibitors (SNRIs) for treating depression that commonly occurs with chronic nonmalignant pain.

Development of Guidelines

Evidence-based clinical-practice guidelines are designed to improve the quality of care and reduce practice variation by providing graded recommendations based on the best available evidence (Slade et al., 2015). There are multiple guidelines available that promote safe, effective analgesic use with opioids for chronic nonmalignant pain in adults. Most of these guidelines are consistent with the national 2016 Centers for Disease Control and Prevention (CDC) guidelines, including not having concurrent long-term use with benzodiazepines which increases the risk of overdose and death (Dowell et al., 2016).

Four major guidelines were considered in this project including: 1) the 2016 guidelines developed by the CDC, which is considered the gold standard for chronic nonmalignant pain management; 2) the 2018 Montana Utilization and Treatment Guidelines developed by the State of Montana Department of Labor and Industry employee relations division, which is specific to Montana for chronic nonmalignant pain management; 3) the 2016 Department of Veterans Affairs/Department of Defense (DoD), which is specific to veterans for chronic nonmalignant pain management; and 4) the Institute for Clinical Systems Improvement (ICSI) by Hooten et al. (2017) that is specific for use in Minnesota for chronic nonmalignant pain management, and was chosen because of its highly descriptive non-pharmacological modalities and greater detail to those prior to initiation of opioids. ICSI has been developing evidence-based clinical

practice guidelines to improve patient care since 1993. The two most pertinent guidelines and the ones guiding the project are the 2016 CDC guidelines and the 2018 Montana Utilization and Treatment Guidelines.

With respect to long-term opioid use for nonmalignant chronic pain each of these guidelines suggest that a provider should use a pain rating scale, utilize an initial five day trial, and require that patients consult with a pain specialist prior to the initiation of opioids. Furthermore, the provider should employ an opioid risk tool before initiating opioid therapy to see if opioid therapy may be contraindicated, engage in the state monitoring of prescription drug program to ensure the patient is not obtaining narcotics from other providers, and keep morphine milligram equivalent (MME) to less than 20 mg per day to lessen the chance of suicidality. Finally, a provider should: perform routine urine drug screens yearly and whenever aberrant behavior arises; obtain a provider/patient contract with informed consent; offer naloxone and instructions on how to use it; evaluate harms and benefits of ongoing opioid use on an ongoing basis at least every three months; offer tapering or stopping opioid use at every face to face meeting; and give patient education on the risks, side effects and disposal of opioids on a regular basis, at least every three months (CDC, 2016b; Montana Utilization and Treatment Guidelines, 2018).

Patients with repeated infractions of the patient-provider agreement or with known diversion can be discontinued without a taper (Hooten et al., 2017). Every patient on opioids should be offered individualized opioid tapering and additional treatment options at six-month intervals. Also noted is that long-term use of opioids is discouraged

overall by every one of the guidelines, but extreme caution should especially be used in those who are younger than 30 years of age and/or have other co-morbidities that could increase CNS depression or respiratory depression, such as current prescription with benzodiazepines (Hooten et al., 2017; CDC 2016b; Montana Utilization and Treatment Guidelines, 2018). The consistent similarities in the aforementioned guidelines will be used as a basis for the assessment tool used in the chart review for this project.

Statement of the Problem and Questions Guiding the Project

As suggested in some literature, provider training on the use of tramadol could be lacking (Doorenbos et al., 2013). Therefore, the purpose of this project was to 1) assess provider knowledge related to tramadol being an opioid and providers' adherence to the present opioid guidelines when prescribing tramadol in a small, southwestern Montana community, and 2) explore to what extent local providers are following the accepted guidelines for prescribing opioids for nonmalignant chronic pain. The guidelines regarding chronic nonmalignant pain and literature support tramadol as an opioid with regulation by the Drug Enforcement Agency and Food and Drug Administration (FDA) (2017) and that upon review does not appear to follow the gold standard recommendations provided by the 2016 CDC guidelines, or even the 2018 Montana Utilization and Treatment Guidelines, for nonmalignant chronic pain management with opioids.

Conceptual Framework

The main objective of this project was to investigate providers' adherence to the best practice guidelines to treat chronic pain specifically concerning opioids, including tramadol. The model that has been chosen to be most fitting to address this issue is Kolcaba's Comfort Model. Because the result of the problem being addressed is the patient's pain, and because healthcare providers assess patients' comfort levels in order to treat pain, this model is a logical choice. The focus of Kolcaba's Comfort Model is comfort.

The American Society for Pain Management Nursing (ASPMN) indicates that the mission of pain management for nursing is to advance optimal care for people affected by pain by promoting best practice, and this includes a nonrepresentational view of pain as a holistic experience in which physical and existential aspects coincide (ASPMN, 2016). This mission statement by ASPMN also coincides with comfort care theory by Kolcaba.

Kolcaba's Comfort Theory is a middle-range theory for health practice, education, and research and places comfort as an immediate desirable outcome of nursing care. Patients in chronic pain can benefit from assessment, measurement, and then evaluation of patient comfort or sense of relief. Advanced Practice Registered Nurses (APRNs) consider physical, psycho-spiritual, environmental, and sociocultural aspects to give holistic care using Kolcaba's Comfort Model. A simplified example is a patient who receives pain medication for chronic pain care to provide comfort relief. Other measures for treating chronic pain are non-medicinal. Kolcaba describes three forms of how comfort exists: relief, ease, and transcendence (Masters, 2012). An example of how these

three forms of comfort work together derived from Masters (2012) regarding this topic is outlined in Table 1 below:

Table 1. Kolcoba's Comfort Theory

Kolcoba's Comfort Theory			
Comfort	**Relief**	**Ease**	**Transcendence**
Physical	Pain, alteration in ability	Medication, (opioid) Massage, acupuncture, electrical stimulation, etc.	Patient belief "I am conformable and will stay that way"
Psycho-spiritual	Anxiety, stress	Therapy, Counseling	Spiritual Support from Family and Healthcare Team
Sociocultural	Family distress, Financial distress	Family Harmony	Community Assistance from others
Environmental	Cold Room, Noise	Warm room, Calmness, Peace	Reassuring Pleasant Environment for patient.

This table shows the aspect of comfort being addressed as physical, psycho-social, sociocultural, or environmental factors and the problems they need relief from such as pain, family stressors, financial burden, or the adverse presentation of the environment. It then shows a possible solution to the presented problem needing relief like supportive pain measures, counseling, family harmony, or warming up a cold room. Lastly, the positive effects of the implementation of a solution give a feeling of transcendence that the problem has been relieved.

CHAPTER TWO—REVIEW OF THE LITERATURE

Introduction

There are several concepts relevant to this study that were researched including: chronic nonmalignant pain, provider knowledge of tramadol as an opioid, provider knowledge of current guidelines for management of chronic nonmalignant pain in Montana, rural populations, education on pain management, barriers to implementing the current guidelines for chronic nonmalignant pain, and Kolcaba's Comfort Theory.

Chronic nonmalignant pain in itself is a widely researched topic and produces thousands of articles in the databases used. Narrowing the search by using the qualifier of efficacy in chronic long-term use of opioids yielded far fewer results, as this is almost non-existent. Research regarding guidelines for management of chronic nonmalignant pain resulted in many different findings. Multiple databases were searched including CINAHL, GOOGLE SCHOLAR, Cochrane, and Web of Science, and current and thorough guidelines were used for this project. Searches on tramadol reveal it is in fact an opioid by definition of mechanism of action, triggering the M1 metabolite (NIH, 2019), as well as determination by governing bodies (Dowell et al., 2016). Gong et al., (2014) define tramadol as a mixed centrally acting opioid analgesic used to relieve moderate to severe pain, which exerts its analgesic effect through at least two complementary and synergistic mechanisms: by activating the μ-opioid receptor and inhibiting the neurotransmitter reuptake. These definitive findings further strengthen the argument that tramadol should be treated equally as other opioids in the management of chronic nonmalignant pain.

Chronic Pain Management

Opioids are proven to be an excellent choice for managing moderate to severe acute pain, but for long-term management of pain, opioids do not appear to be a favored option for nonmalignant pain (DoD, 2016; Hooten et al., 2017). Noble et al. (2008) indicated the data were insufficient to answer the question of efficacy and adherence to guidelines in long-term opioid therapy, and this remains true. However, there are sufficient data to indicate that following the guidelines that are established according to Grading of Recommendations Assessment Development and Evaluation (GRADE) system outcomes are far superior (Hooten et al., 2017). Furlan et al. (2006) suggest that long-term opioid use has not been found to be more effective than no use. They also add that patients may not be willing to use multiple modalities to treat pain, although mindfulness-based strategies, physical therapy, primary care, and a variety of alternative therapies like acupuncture and tai chi have been demonstrated to be beneficial in preliminary studies (Furlan et al., 2006). There also appears to be a deficit in the patient's willingness to learn about chronic pain and pain stigma and how to change maladaptive beliefs and behaviors. As Manchikanti et al. (2012) indicate, in nonmalignant chronic pain there is limited evidence of efficacy in long-term relief from opioid therapy. This may further suggest that risks may be inherently more profound with long-term use of opioids and greater than the possible benefits until proven otherwise, especially when considering the aspect of the current crisis created by opioid misuse.

Opioid Use and Crisis

America is currently experiencing an opioid epidemic (CDC, 2017). The easy access to tramadol and misleading marketing contributed to the increase suicide overdoses experienced throughout the 2000's. Opioids invite greater risk of overdose in certain populations, including patients with substance use disorder or benzodiazepine use (CDC, 2016b). The number of people admitted with addictions to prescriptions increased more than fourfold from 2000 to 2010, and these prescription opioids are identified as being the gateway to heroin abuse (Ruben et al., 2014). With over 17,000 overdose deaths in 2011 alone, a more holistic approach to the management of chronic pain, inclusive of the patient's perspectives and desired outcomes, should be part of the treatment goal (Ruben et al., 2014). The number of adverse opioid events continues to increase, and in 2017, there were more than 70,200 drug overdose deaths in the U.S. (NIH, 2019). There was also an age-adjusted rate of 21.7 per 100,000 persons and about 43 million prescriptions nationwide for tramadol in 2017 (NIH, 2019). Among these drug overdoses, 47,600 involved opioids, and in Montana, providers wrote 61.1 opioid prescriptions for every 100 persons (NIH, 2019).

Opioid Indications

Consideration for pain relief regarding long-term opioid therapy for persistent non-cancer pain is emphasized as reduction rather than elimination, with the mean pain reduction being about 30% (DoD, 2016). Optimal success includes a balance of pain relief, limited side effects, and increased or maintained quality of life and function. Opioids should only be used after other remedies have failed using the lowest dose and

with one opioid prescriber and multiple providers involved in decision making of overall treatment (DoD, 2016).

Contraindications for long-term opioid therapy include respiratory instability, substance abuse, co-administering with other life-threatening drug-drug interactions, sleep apnea, QT prolongation, paralytic ileus, suicidal risk, complicated pain not responsive to other therapies, unwillingness to comply with the treatment plan, unwilling to change at-risk behaviors, and mental health disorders (DoD, 2016). Healthcare providers often rely on shared beliefs and personal opinions to make treatment decisions, and it is this practice of non-adherence to evidence-based guidelines that has led to the "know-do gap", that is, the gap between what is known and what is done in practice (Scott et al., 2010).

Opioids and Rise of Tramadol

Tramadol is not a new drug. Originally, tramadol was created by a German drug company that specialized in treating pain in 1962. The medication was tested for 15 years in Germany before being approved and brought to the foreign market in 1977 under the name Tramal as a weak opioid with an atypical clinical profile (Goeringer et al., 1997). Synthetic opioids were available in 1984 in the form of the combination drug hydrocodone and acetaminophen, and later in 1995, tramadol was approved by the FDA as a non-narcotic despite its clear qualification of being an opioid. With revealing studies and further literature, the stance has now changed, and the FDA identifies tramadol as an opioid partial agonist (FDA, 2017).

Under the Controlled Substance Act (CSA), effective August 18, 2014, tramadol became a Schedule IV medication at a time of growing concern related to abuse, misuse, addiction, and overdose of opioid analgesics (Harrigan, 2014). Tramadol, a synthetic opioid, was originally marketed as a non-narcotic prescription medication that was a safe alternative to opioids and was slightly stronger than over-the-counter (OTC) medications. Tramadol's mechanism of action includes serotonin and norepinephrine inhibition, which is helpful in the treatment of depression, a common co-occurring ailment of chronic pain. Tramadol is a Schedule IV medication and is sometimes overlooked as an opioid because of its mixed receptor action ((Dowell et al., 2016; DEA, 2014b). As with other opioids, emergency visits due to tramadol-related harms are rising (Substance Abuse and Mental Health Services Administration, 2015).

Pharmacodynamics/Pharmacogenetics

Opioid receptor agonists by definition are exogenous opioids, selective for either mu receptors, kappa receptors, or delta receptors, that mimic endogenous endorphins, enkephalins, or dynorphin A to produce supraspinal or spinal analgesia. Mu receptor opioid agonists include Alfentanil, Codeine, Fentanyl, Hydrocodone, Morphine, Oxycodone and tramadol among others (Janicki & Parris, 2003).

Wolters (2019) also indicates that tramadol is an opioid analgesic. The mechanism of action for tramadol is its active metabolite (M1), which binds to μ-opiate receptors in the CNS causing inhibition of ascending pain pathways, altering the perception of and response to pain. It also inhibits the reuptake of norepinephrine and

serotonin, which are neurotransmitters involved in the descending inhibitory pain pathway responsible for pain relief.

According to the DEA tramadol is an opioid (Dowell et al., 2016). The labeling for FDA approved tramadol products states that tramadol is a centrally acting opioid analgesic. The CSA defines an "opiate" as "any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability" (Harrigan, 2014). Opium, opiates, derivatives of opium and opiates, including their isomers, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, are "narcotic drugs" as defined by the CSA, (Harrigan, 2014).

Tramadol Overdose

Tramadol overdose results not only in CNS depression attributed to opioid properties, but it can also produce seizures related to non-opioid properties or serotonin and norepinephrine inhibition. Thus, a diazepam/naloxone combination is the most efficient antidote to reverse tramadol-induced CNS toxicity in rats, although not yet proven in humans (Lagard et al., 2018).

Different Schedule Conflict between Opioids

Drugs and other substances that are considered controlled substances under the CSA are divided into five schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused (Harrigan, 2014). For patients considered

at greater risk of harm, such as with a schedule II opioid, the DEA allows for three months of opioids to be given at one time, using three separate written prescriptions, whereas the schedule IV opioid tramadol can have five refills on a single prescription (Harrigan, 2014). In practice, patients on opioids are seen far less frequently than this, and often the documentation needs are not met (DEA, 2014b). While research has not yet assessed whether more frequent visits improve outcomes, opioid prescribers should be prepared to see patients frequently to ensure that treatment goals are met.

As a Schedule IV narcotic, tramadol is not regulated as highly as other opioid narcotics. When providers prescribe hydrocodone, a Schedule II opioid, they are mandated to supply only five days for initial use, and patients are required to revisit much more regularly than with tramadol. Of interest, a 50 mg dose of tramadol has the same MME as 5 mg of hydrocodone according to Centers for Medicare and Medicaid Services (CMS) (2017). This represents a gap in the management of tramadol by the guidelines and something that should be addressed for best practice and avoidance of the continuing opioid crisis.

Guideline Adherence

Consequences can be significant when clinical-practice-guidelines adherence rates are low, and non-concordance with guideline recommendations can lead to increased healthcare utilization, in addition to increased costs for the patients and payers (Chou et al., 2015). The NIH (2019) Workshop on the Role of Opioids in the Treatment of Chronic Pain identified several adverse outcomes related to chronic opioid therapy: pain treatment causing work disability, falls and fractures, motor vehicle accidents,

myocardial infarctions, sexual dysfunction, osteopenia, endocrine effects, opioid dependence/addiction, aberrant drug-related behaviors, diversion, overdose, and neonatal opioid withdrawal. There are also other more uncommon adverse outcomes related to long-term opioid therapy to be considered, such as hypogonadism and opioid induced hyperalgesia (Chu et al., 2008). Following the guidelines should help limit these types of adverse effects.

The adverse possibilities associated with tramadol's multiple mechanisms of action result in tramadol potentially being more dangerous than other opioids when comparative morphine equivalency is used, and tramadol is not completely reversed by Narcan (naloxone) alone like other opioids. Tramadol withdrawal mimics Substance Abuse and Mental Health Services Administration (SAMHSA) criteria for opioid withdrawal, but also may include seizure activity related to serotonin and norepinephrine properties (SAMHSA, 2015). Meperidine has the exact same MME as tramadol and yet it is a Schedule II opioid (CMS, 2017). Codeine has 1.5 times higher MME than tramadol but is given in much smaller, 15-60 mg, doses compared to 50-300 mg of tramadol. A 15 mg codeine dose is equivalent to 22.5 mg dose of tramadol, or otherwise slightly less than half of the typical starting dose.

Tapentadol is a new mu opioid agonist which also inhibits serotonin and norepinephrine reuptake activity, similar to tramadol, and is a Schedule II (Singh et al., 2013; CMS, 2017). Due to its dual activity it can cause seizures or serotonin syndrome, even though it only inhibits serotonin one-third as much has tramadol does, but it is more potent with respect to MME (Singh et al., 2013: CMS, 2017). A 200 mg dose of tramadol

is equivalent to a 50 mg dose of tapentadol. At those levels of tramadol, however, serotonin inhibition is 12 times the level as in tapentadol (Fuden et al., 2016).

Thiels et al. (2019) suggest that evidence-based, actionable treatments require taking a closer look at tramadol scheduling, as their study suggests a somewhat higher risk of prolonged use with tramadol alone than those receiving other common opioids. Thiels et al. (2019) also indicate that the reason the FDA continues to classify tramadol at a lower level than other opioids is because tramadol's lower affinity for the μ-opioid receptor has given it a reputation for having a more favorable side effect profile, including lower rates of constipation, respiratory depression, overdose, and addiction. However, the more research that is completed, the less favorable tramadol appears, especially considering that tramadol was originally tested and approved as a weak opioid in an intravenous form at a much lower dose than was approved in 1995 in the United States (Goeringer et al., 1997: Friderichs et al., 1978).

Barriers to Implementation of Guidelines

As provided earlier, evidence-based clinical-practice guidelines are designed to improve quality of care and reduce practice variation by providing graded recommendations based on the best available evidence (Slade et al., 2015). The literature reveals some barriers to implementing the clinical practice guidelines that can make patient/provider choices appear in opposition to the recommendation by IOM (2011). The IOM (2011) recommendation to have comprehensive and effective care with an interprofessional approach and a biopsychosocial, multifaceted team when these services are not covered, may not be met if a patient cannot afford the best choice medication.

One of the greatest barriers identified in the literature to implementing standardized guidelines is a knowledge deficit.

In the realm of prescribing providers' education, the greatest area of need now seems to be mastering basic knowledge about commonly prescribed non-opioid analgesics, adjuvant medications, and the relative potency or oral opioids (Duke et al., 2013). Despite the remarkable advances currently available, the most important component of pain management remains the knowledge, skill, and compassion of the nurse (Picot et al., 2015). One textbook that is used by a local university in the Nurse Practitioner Family Practice Program, written by Dunphy et al. (2015), indicates that tramadol is rated as non-narcotic and not an opioid. This textbook was probably written ahead of 2015 while tramadol was in the process of becoming a Schedule IV, but it is now past 2019, which is five years after the change of identifying tramadol as a Schedule IV opioid narcotic.

Doorenbos et al. (2013) state that pain management education on different pain modulators and how to appropriately treat them also remains a gap in treatment of chronic pain because providers lack formal training in general practice. To play a vital role in the management of pain, providers need to be well versed in many aspects of pain. Hooten et al. (2017) very distinctly describe many non-pharmacological modalities of treatment of pain that should be implemented prior and in addition to the use of opioids. Unfortunately, the importance of educating healthcare professionals in this realm has not been emphasized and remains inadequate (Doorenbos et al., 2013). Lippe et al. (2010) found that "in most medical school education, pain is not acknowledged as a chronic

disorder, but rather treated as a symptom" (p. 1450). Medical providers are trained in the use of a biomedical model to treat acute pain, find the cause of the symptom, and treat with medication, surgery, or other medical intervention (Lippe, 2010; IOM, 2011).

Schatman (2012) proposes that insufficient resources are allocated to the treatment of pain in the U.S., which is a contributing factor to the undertreatment of pain and reasons why pain clinic programs have drastically decreased. Concerns of healthcare providers and patients about the use of opioids, adverse effects of opioids, and risk for misuse, abuse, and increased morbidity rate create potential for undertreatment of pain (Rosenblum et al., 2008). Clinical practice is affected by insurance coverage because policies determine what therapeutic choices are affordable and available to a patient (American Academy of Pain Medicine, 2007). Kredo et al. (2016) state that clinical practice guideline implementation often requires behavior changes by healthcare professionals, patients, and other stakeholders within the healthcare system because they may need to change or discard "usual" practices considering current best evidence recommendations.

Melnyk and Fienout-Overholt (2015) identify steps for integrating evidence-based practice. These include: 1) identifying a burning question in a format to yield the best evidence; 2) searching and collecting the most relevant data; 3) critically appraising the data, implementing change, evaluating the outcomes based on the change; and 4) disseminating the outcomes. Utilizing these four steps in this project have led to the conclusion that tramadol should be included with the same precautions as other opioids in the 2016 CDC guidelines, as well as the other guidelines. Rather than having less

stringent regulations on tramadol, best practice would be to uphold tramadol to the more strict guidelines. Currently a Schedule IV narcotic, tramadol can have five refills of up to 30 MME/day, and sometimes is concurrently prescribed with benzodiazepines and serotonin inhibitors, compounding the possible negative effects of tramadol use.

Summary

The literature shows that there is limited available research on the long-term efficacy and effects of opioid use. In a Cochrane database systematic review, Noble et al. (2010) found that many patients discontinue opioid use in long-term therapy due to excessive side effects and insufficient pain relief, while quality of life and functional improvements were inconclusive. Baldini et al. (2012) further reported that opioid-related adverse effects can cause significant declines in health-related quality of life and increased health care costs.

Moreover, long-term use of opioids is discouraged due to side effects and negative or adverse actions. Guidelines of the CDC (2016b), the Montana Utilization and Treatment Guidelines (2018), the DoD (2016) guidelines, and ICSI guidelines (Hooten et al., 2017) indicate that patients should be offered to decrease or stop their use on a continuous basis after having risk/benefits discussions with their provider and/or a pain specialist. Statistical data and increased adverse effects from compound mechanisms of action combined with limitations present with insurance companies not covering certain indicated modalities asserted by the guidelines creates an even greater barrier to adherence to guidelines in rural communities. This combination of inability to pay,

unavailability, or inconvenience may increase the number of opioid prescriptions including tramadol in rural communities.

CHAPTER THREE—METHODS

The purpose of this project was to assess provider knowledge related to tramadol and providers' adherence to the present opioid guidelines when prescribing tramadol in a small, southwestern Montana community for chronic, nonmalignant pain. The Institution Review Board at Montana State University exempted the project from full review. Provider knowledge was assessed using a questionnaire assessing providers' knowledge of the opioid tramadol (Appendix A). All providers were given the opportunity to participate by being given a self-addressed stamped envelope to retain anonymity and then complete and mail back the short questionnaire developed from the literature concerning tramadol as an opioid (Appendix A).

Additionally, the information technology (IT) department at the local hospital concluded there were over 600 visits in the previous year for which patients were seen for chronic pain (M. Hickey, personal communication, May 17, 2019). Of those visits, charts were identified for 70 patients who were served at the clinics between May 2018 and May 2019, were 18 years and older, had chronic nonmalignant pain but were not on palliative care, and were prescribed tramadol. All patients had pain for an ongoing daily basis of over three months in line with the CDC (2016) definition of chronic pain. A retrospective chart review that was conducted to assess compliance and adherence to the guidelines using a tool made from the recommendations in the 2016 CDC and 2018 Montana guidelines (Appendix B).

Population and Sample

According to the United States U.S. Census Bureau (2017) one in five people live in a rural community that make up 97% of the entire land mass of the country, and having less than 2,500 people living in an area; however, "rural" continues to be defined as any population, housing, or territory outside urban areas having less than 10,000 people. Rural populations also continue to have higher percentages of elderly, poor, and lower education levels in general leading to greater disparities of uninsured people. The population of the area in this study that the local community hospital is situated in according to the U.S. Census Bureau is 9,298. Economic Research Services (ERS) (2000) states that Montana has a rural population of 50.2% compared with a national average of 31.1%, making Montana highly rural in comparison. ERS (2013) further defines this particular county in Montana as a nonmetro-urban population of 2,500 to 19,999, not adjacent to a metro area with a rural-urban continuum codes (RUCC) of seven.

The target population for this project was providers who work in a small southwestern Montana family-medicine clinic owned and operated by a local community hospital in a local rural community of Montana. There are 11 family practice providers who work at the local hospital and its owned clinics where the chart review was done.

Data Collection

In conjunction with the IT department, charts of patients receiving tramadol were identified. A data collection sheet was developed using the consistent recommendations of the two guidelines previously discussed (Appendix B). Demographics that were used in the charts for identifiers included use of tramadol for chronic nonmalignant pain,

patient age, primary service assigned by the provider to the visit using a Current Procedural Terminology code, and addressing the recommendations on the assessment tool (Appendix B). The Institution Review Board at Montana State University exempted the project from full review. Access to the charts was approved by both the chief executive officer (CEO) and human resources (HR), and electronic charts were sent via hospital encoded email from information technology (IT).

The charts cover the dates from May 1, 2018 to May 1, 2019. A total of 30 charts were reviewed by random selection to assess compliance of following the guidelines for opioids in the management of chronic nonmalignant pain. In order to maintain anonymity charts were numbered 1-30. The number 30 was chosen in order to assess an adequate number of charts and still adhere to time constraints. The same compliance tool (Appendix B) was used for every chart check.

The 11 family practice providers who work at the local hospital and its owned clinics were given a questionnaire (Appendix A). The questionnaire included a self-addressed stamped envelope that was mailed back to the student who conducted this project, and also the IRB approved consent form (Appendix C). Upon return of questionnaires in the mail, results for the questionnaire were also tallied accordingly to determine if there was a knowledge deficit, particularly in the area of understanding tramadol to be an opioid.

The literature review did not reveal a particular tool or instrumentation viable for collecting data in this particular project. Therefore, upon thorough review of the available guidelines that were used, a tool was produced by the student that had the consistent

GRADE recommendations included in all of the guidelines studied (Appendix B). There was also a tool created to assess providers' current knowledge of the status of tramadol being an opioid and questioning if tramadol should be included as other opioids in the management guidelines. (Appendix A).

Right of Human Subjects and Participants Requirement

Project approval was received from the local community hospital and exemption for full approval from the Institutional Review Board of Montana State University. The questionnaires given to providers remained anonymous by asking the providers to mail the completed questionnaires rather than return them in person, and also, they were not asked to include any personal information. The name of the facility was also left in order to avoid problems related to the results of this project. Provider participation in this project was voluntary and providers were notified that sending the questionnaire through the mail provided implied consent for results to be included in the study. The consent notification that was given with the questionnaire is included in Appendix C.

Data Analysis

When reviewing charts, the tool that was developed (Appendix B) was used to determine to what extent the guidelines for opioids were followed when prescribing tramadol. If the data could not be found after a maximum time limit of 15 minutes per question, or data were unclear in the chart review, the answer was assumed to be a no for the assessment tool (Appendix B). Data for each item on the chart review were presented as percentages.

The survey of providers who work at the local community hospital indicated their answer to the seven questions provided (Appendix A). Knowledge scores from the survey were represented using totals and percentages. The provider questionnaires were received with the answers being on a five-point Likert scale of strongly agree, agree, undecided, disagree and strongly disagree.

Using deductive analysis and Kolcaba's Comfort Theory as a base, themes were identified and interpreted through that context that can provide nursing interventions that may more appropriately meet their needs. Kolcaba's Comfort Theory offers a simple and holistic pattern for identifying needs, creating interventions to meet those needs, and evaluating the effects of those interventions. Kolcaba's Comfort Theory describes three forms of comfort as relief, ease and transcendence. This process is carried out by professional healthcare providers in a given setting addressing the patient's comfort needs and moving them toward a state of well-being. Utilizing Kolcaba's three forms of comfort, providers can relieve a patient's level of pain, this reduction helps ease their awareness and focus on said pain and thus helps produce transcendence through inspiration and ability to do more activity without the pain.

Kolcaba's (2010) comfort care theory suggests that providers can influence patient outcomes by anticipating and addressing patient comfort. When this framework is applied to the administration of opioids by following the guidelines for management of chronic nonmalignant pain using the multimodal concept described by those guidelines, the provider carries out the needs of the patient by providing consistent pain relief. This process also helps to move the patient toward a state of well-being supporting the

individual and maintains facility integrity. The use of comfort care in treating patients with chronic nonmalignant pain is an important step in alleviating their concerns about their pain that may limit activity and can help ease them through their difficult and challenging times.

CHAPTER FOUR—RESULTS

Project Purpose

The purpose of this project was to assess provider knowledge related to tramadol and providers' adherence to the present opioid guidelines when prescribing tramadol in a small, southwestern Montana community. The major clinical guidelines chosen for this project were the 2016 Center for Disease Control and Prevention guidelines, and the 2018 Montana Utilization and Treatment Guidelines, for nonmalignant chronic pain management with opioids. There were two facets of action involved in the evaluation carried out by this project. There was a chart review utilizing the consistencies in guidelines between these two main sets of guidelines, the 2016 CDC and the 2018 Montana Utilization and Treatment Guidelines, which helped to create the assessment tool produced in Appendix B. Thirty out of 70 available charts were then identified and selected randomly and evaluated using the tool.

The second action in this project was to survey existing providers at the same facility that the chart review was done to see what their perceptions of tramadol are regarding tramadol being an opioid and its possible inclusion in the aforementioned guidelines. The DNP student hypothesized that providers may not have an adequate understanding of tramadol as an opioid given its years of advertising and promotion as a safe non-narcotic from inception in the United States until 2014 when it was made a Schedule IV narcotic. It is further supposed that providers may not have been holding tramadol to the same standard as other opioids in prescribing as evidenced by non-adherence to the opioid guidelines. Because the scheduling of narcotics allows for lesser

restrictions on tramadol, providers may not feel tramadol requires as much precaution. This chapter will discuss the results of the two facets of this project.

Chart Review

Extensive chart reviews were performed on 30 of the 70 accumulated charts between May 2018 and May 2019 for patients who had received tramadol for chronic nonmalignant pain using the student assessment tool. The review included the time from which the patient had become a patient, and in some cases, constituted several years. The questions demonstrating compliance from the assessment tool can be seen with the following fractions and percentages being rounded to the nearest whole number. The percentages given are the number of charts that had a yes answer. No answers or undiscernible answers, mainly due to time constraints or inability to find, are both counted in the assessment as negative results. The findings of the assessment tool for each question and demographics were as follows:

Table 2. Assessment Tool Results

Criteria from assessment tool.	Number of charts that meet criterion (a yes answer) out of a total of 30 charts reviewed	Percentage of charts reviewed matching criteria
Has pt been seen by two providers with one being a pain specialist?	22	73%
Is there a pain contract in place?	10	33%
Is the patient seen every 3 months or less?	23	77%
Was there an initial 5-day trial?	2	7%
Are there random and yearly urine drug screens to check for compliance?	5	17%
Is the state narcotic database was accessed and documented?	4	13%
Was the patient offered to lessen or discontinue every 3 months?	11	37%

Table 2 Continued

Are there concurrent prescriptions with benzodiazepines?	14	47%
Was the patient given doses that are shown to increase suicidality (greater than 20 MME/day or 200 mg Tramadol)?	13	43%
Was there a concurrent SSRI/SNRI prescription (which is contraindicated with Tramadol)?	19	63%
Was there a pain rating scale documented on every visit?	6	20%
Was there an initial and ongoing documentation of use of an Opioid Risk Tool (ORT)?	1	3%
Was naloxone offered as evidence by being on current med list or documented?	1	3%

Of the 30 charts selected, all 11 providers, or 100%, working at this facility in family practice had ordered Tramadol at one time or another. One provider had seven different patients, or 23% of the audited chats, on tramadol throughout the year. Three providers, or 10% of providers, had only ordered tramadol only once in this chart investigation.

Table 3. Number of Patient per Provider

Provider#	Number of patients receiving Tramadol order
Provider 1.	7
Provider 2.	6
Provider 5.	3
Provider 8.	3
Provider 10.	3
Provider 6.	2
Provider 7.	2
Provider 3.	1
Provider 4.	1
Provider 9.	1
Provider 11.	1

There were 7 male and 23 female patients out of the 30 charts reviewed, or in other words 76.67% of the patients were female.

Table 4. Patient Gender

Gender	Number of patients
Male	7
Female	23

The average age of each person was 59 years old and ranged from 25 to 83 years old. The average body mass index (BMI) was overweight, or borderline obese, at 29.77 with a range from 19.19 to 53.99. It is well known that being overweight has shown in the literature to increase inflammation, which in turn can increase pain, especially in inflammatory conditions such as arthritis (Hitt et al., 2007).

Table 5. Patient Demographics

Patient	years of age	BMI	Primary Dx per EHR
1	81	19.19	Arthritis
2	62	25.83	Neck Pain
3	35	32.85	Female Annual
4	83	29.29	Osteoarthritis
5	52	21.40	Wellness
6	25	53.99	Chronic Pain
7	26	19.57	Headache
8	81	42.92	Lower Back Pain
9	69	23.29	Chronic Back Pain
10	51	26.73	Anxiety
11	72	32.11	Fibromyalgia
12	57	25.19	Psoriasis
13	57	27.17	Lumbar radiculopathy
14	63	29.42	Pain
15	58	31.28	Shoulder Pain
16	79	33.60	Preventative Visit
17	59	23.80	Screen for STD
18	45	21.47	Depression

Table 5 Continued

19	53	34.14	Nocturnal Hypoxia
20	47	26.96	ADHD
21	53	32.37	Neuropathy
22	40	25.62	Lumbar Pain
23	58	28.61	DDD
24	60	20.60	Cellulitis
25	59	33.19	Hip pain
26	69	39.16	Low Back Pain
27	79	23.30	Industrial Accident
28	49	24.79	Cervical disk radiculopathy
29	65	54.74	Positive ANA
30	70	30.42	GERD

The Electronic Health Record (EHR) was developed so that the medications given at a visit were not always assigned to their indicated use, but rather what was listed as the main initial purpose for the visit. As an example, one visit that tramadol was given for indicated in the EHR that it was given for STD (sexually transmitted disease) screening. In the chart review, the note clearly delineates that the medication was refilled for ongoing chronic pain syndrome. It can be assumed that on average, a patient was a 59-year-old female who was nearly obese and had some type of chronic pain, and more often the pain related to the musculoskeletal system, indicating that therapy of some other sort may be the most fitting for best practice and remain in line with Kolcaba's Comfort Theory.

Provider Survey Results

Table 6. Provider Survey Results

Question Stated		P 1 Response	P 2 Response	P 3 Response	P 4 Response	P 5 Response	P 6 Response	P 7 Response	P 8 Response	P 9 Response	P 10 Response	P 11 Response	% correct
1. Tramadol is an opioid.		SA	A	A	SA	U	A	SA	A	A	SA	A	91%
2. Stopping Tramadol use abruptly can cause opioid withdrawal.		SA	A	A	SA	A	A	SA	SA	A	SA	A	100%
3. Prolonged Tramadol use can result in opioid dependence.		SA	A	A	SA	A	SA	SA	SA	SA	SA	D	91%
4. Tramadol has a morphine milliequivalent (MME).		SA	A	A	SA	D	A	SA	SA	A	SA	D	82%
5. Tramadol should be treated with the same precautions as other opioids in the 2016 Centers for Disease Control and Prevention 2016 and 2018 Montana guidelines for prescribing Opioids for nonmalignant chronic pain management?		SA	A	A	SA	U	A	A	SA	A	SA	SA	91%

Table 6 Continued

6. Tramadol is NOT a safe alternative to opioid use for chronic nonmalignant pain.		A	D	U	SA	A	U	A	A	U	SA	SD	36%
7. My education included thorough instruction on chronic pain management and opioids.		SA	D	A	D	SD	D	A	SA	A	A	D	55%
	SA=Strongly Agree, A=Agree, U=Undecided, D=Disagree, SD=Strongly Disagree												

All 11of the surveys that were distributed to the providers working in the family practice clinic at the local community hospital were returned, indicating a participation rate of 100%. Ten of the 11 providers, or 91%, answered agree or strongly agree in tramadol being an opioid, leaving one undecided. Ten out of the 11 providers, or 91%, answered the survey that they agree or strongly agree that tramadol can result in opioid dependence, and one of the providers, the same one who indicated they were unsure tramadol is an opioid, stated they disagree it would cause dependence.

A majority, nine out of the eleven, or 82%, were also in agreement that there is an established MME for tramadol. Including tramadol as an opioid in the 2016 CDC and the 2018 Montana guidelines was favored by 10 out of the 11 providers, again 91%, leaving only one who had marked undecided. One of the most peculiar findings was the responses to question 6, which was about tramadol being a safe alternative to opioid use for chronic nonmalignant pain yielding every possible answer with 4 out of the 11, or 36%, choosing agree as the most common answer.

The last question on the survey asked about education concerning chronic pain management and opioids, which the literature indicates as lacking, was also answered with several different responses. These answers included four of the five-point Likert responses; all except for undecided was used throughout.

Summary

All providers in this clinic responded to a questionnaire assessing knowledge related to tramadol. The chart review indicated that the providers are holding tramadol to a higher standard than the current scheduling requirements by the CSA by adhering to

some of the indications from the 2016 CDC and 2018 Montana Utilization and Treatment Guidelines for prescribing opioids. There are also some obvious shortcomings in following guideline practice for opioids in the chart review when considering tramadol such as not offering Narcan on a regular basis or prescribing concomitantly SSRI's and benzodiazepines with tramadol on a regular basis with dosages that may increase suicidality. The survey findings were also consistent with earlier literature given showing 45% of providers disagree that they had thorough education on chronic pain management and opioids.

CHAPTER FIVE—DISCUSSION

Discussion of the Results

The purpose of this project was to assess provider knowledge related to tramadol and providers' adherence to the present opioid guidelines when prescribing tramadol in a small, southwestern Montana community. The chart review indicated that many patients were seen by a specialist on at least one occasion and some were seen on a regular basis by a specialist. This practice is consistent with desired behavior directed by the established guidelines.

About one-third of the patients were on a pain contract. This finding could indicate several possible perceptions of providers. It could mean providers did not see the need to do a pain contract every time, that they may not value a contract if it is not deemed necessary by scheduling CSA requirements, or that some did not recognize tramadol as an opioid. The pain contracts that were initiated demonstrate that some of the time there is a tendency to adhere to the pain contract component of the opioid guidelines. Hooten et al. (2017) assert that having a pain contract helps to ensure active patient involvement in treatment decisions, and without active involvement, patient treatment in chronic opioids will eventually fail.

Most patients were seen frequently and at least once every three months. There were only two patients who were initially started on a five-day trial. This is an area where the law for tramadol makes it an allowable practice, but it is not in alignment with the guidelines for opioids to give more than a five-day trial initially. Dowell et al. (2016)suggest that having only a five-day trial or fewer limits the number of surplus

opioids available and reduces the potential of opioid abuse, overdose and diversion, while it encourages frequent follow-up for pain requiring opioids and facilitates early recognition of aberrant opioid use.

Random urine drug screen monitoring was not widely practiced among these providers. It was not possible to verify if the drug database was searched unless it was charted, and there were only four instances where charting indicated that the database was accessed. There may have been some cases where it was done and not charted, butfor this project, if it isn't charted, it was not determined to be a positive result. A little over one-third of the providers charted that they were offering to reduce or stop the doseof tramadol and this finding is consistent with the use of a pain contract.

Most providers did not give a full six-month refill as current scheduling law would allow, but some charts showed evidence that, at times, patients received two-month refills over the phone when the patient had been seen within the last six months. Some patients had multiple benzodiazepine prescriptions concurrently issued along with tramadol. Almost half (47%) of the patients were on both benzodiazepines and concurrently tramadol. This practice is contraindicated by the 2016 CDC and 2018 Montana Utilization and Treatment opioid guidelines, partially due to the increased sedation achieved with both benzodiazepines and opioids alike, as well as increased dependence, overdose, and addiction. The chart reviews did not take into account concurrent prescriptions of other opioids with benzodiazepines, so it is unclear whether this finding was related to a knowledge deficit of tramadol being an opioid or some other factor. In the survey, the results showed that 91% of providers believed tramadol should

be counted as other opioids in adherence to the guidelines as 91% were also in agreement that tramadol is an opioid.

Some patients with a history of suicide attempt (10%) received doses of tramadol in excess of 20 MME/day. These patients also had up to three separate benzodiazepine medications concurrently, which increases suicide risk considerably (DoD, 2016). More than half of the patients who were taking tramadol were also on an SSRI/SNRI, and this practice puts the patient at an increased risk for serotonin syndrome (DoD, 2016). It is unclear from the survey if providers have an understanding that tramadol has a mechanism of action that contributes to serotonin syndrome since that question was not asked. Because it was beyond the scope of this project, the reason for prescribing benzodiazepines was not investigated, and this practice may have been related to psychiatric conditions that also increase suicidality. Even though it appears to be an anomaly, one patient who had a documented history of suicide attempt without evidence of referral to counseling received tramadol in excess of the recommended dose, which has been noted to cause suicidality (greater than 200mg per day) according to DoD (2016), while simultaneously having three separate benzodiazepines ordered and no opioids risk tool or offer of naloxone, and this is also quite concerning.

It was very surprising see that a pain scale was not documented or uploaded tothe EHR on a regular basis. Adding a pain scale value to a provider's note, e.g. "7 out of10," should be common practice when prescribing a medication for pain. This finding, combined with the fact that Narcan was seldom offered (3%) or on the medication list would indicate that there may not be a common belief that tramadol is an opioid. Dowel

et al. (2016) indicate that assessment of quality of life, function and pain intensity using validated tools and determining the underlying pain generators are fundamental to diagnosis and treatment of chronic pain.

Another interesting point to note for the single chart that showed evidence of the patient being offered and/or having Narcan on the medication list in the EHR as well as having an opioid risk tool of some sort, was that patient was also on concurrent opioids, which could have been the initial reason the person had the risk tool and Narcan offered originally. This finding is in alignment with the guidelines but since only 3% of the charts reviewed included documentation of Narcan could lead to question whether providers understand that Narcan has a reversal effect for the opioid mechanism of action of tramadol. This kind of dosing not only puts the patient at an increased risk for suicide, but also for possible law infractions if driving while under the influence of these drugs.

The cumulative answer to the question on the survey that inquired about tramadol being an opioid indicates that, overall at this particular facility, the providers have a good understanding that tramadol is classified as an opioid. All 11 providers indicated that they agree tramadol can cause opioid withdrawal if stopped abruptly. A confusing finding was that all of the providers answered that abruptly stopping tramadol causes opioid withdrawal, a sign that can be linked to opioid dependence, but that tramadol does not necessarily cause opioid dependence.

One provider was undecided about whether tramadol is classified as an opioid, and marked disagree to an MME for tramadol. This makes sense with respect to if a medication is not an opioid; it most likely doesn't have an MME. The majority

affirmative responses to whether tramadol should follow opioid guidelines suggests that this idea is well accepted at this facility.

Responses were highly varied about tramadol being a safe alternative to opioids (question 6). One possibility for the variance in answers could be that the question was confusing or not worded well. However, another possibility is that, because almost all providers already agreed that tramadol was an opioid, it may have been confusing to subsequently ask if tramadol is a safe alternative to an opioid.

The responses to a thorough education make sense because the providers are from various colleges and have various backgrounds, as well as different degree levels. Nearly half of the providers (5 of 11) disagreed or strongly disagreed that they had an education with thorough instruction, consistent with the findings of Duke et al. (2013). In fact, one provider who reported strongly disagree on this question is also the one provider who was undecided on tramadol being an opioid or being added to the guidelines.

From the cumulative of all the answers in the survey, the following conclusion can then be made of this small group of providers: those providers who felt they had a thorough education in the management of chronic nonmalignant pain and opioids agreed with tramadol being an opioid and in favor of its inclusion into the 2016 CDC and 2018 Montana Utilization and Treatment Guidelines for managing chronic nonmalignant pain. Therefore, the next step in this project is to meet with the CEO who granted access to the facility and charts to be done and discuss the findings. Upon further evaluation at that point, it will be decided whether or not the student will present the findings to the

providers who participated. Potentially, the project findings will be presented at one of the monthly meetings as a small luncheon.

Limitations of the Project

There are several limitations in this project. There were only 11 providers who took the survey and 30 charts that were reviewed. A larger sample of both providers and charts might result in different findings. Another limitation is that this project was conducted in a small town. Because the chart review was random and limited, it is hard to ensure that the ones chosen were a good representation of the entire population of those served.

The design of the project is also considered a weakness of the project. The survey and chart audit tool were not validated, jeopardizing the rigor of this project. Further, inadequate charting regarding narcotic database access or EHR limitations might cause skewed results. There may have been more patient education provided than what was actually documented. A retrospective review also represents a limitation because current practice could be different than past practice with new learning or change in facility policy.

Implications for Clinical Practice

Because of the high prevalence of chronic pain patients presenting in primary family practice care, implicating the use and prescribing of tramadol into the 2016 CDC and 2018 Montana Utilization and Treatment Guidelines for opioids in chronic nonmalignant pain is profound. There are several limitations found in these guidelines

that are not necessary to adhere to with tramadol's current scheduling by the DEA. By adhering to these guidelines in the use of tramadol, the workload for providers may increase. However, the flip side of this action is that patients are more safeguarded by the use of evidence-based clinical guidelines. Before including tramadol in the guidelines, it is likely that more studies of this nature or a more rigorous design would need to be conducted to see if the findings remain consistent.

The American Association of Colleges of Nursing (AACN) DNP Essentials are a guiding light for this project. According to the AACN (2006), advance practice registered nurses (APRNs)influence many patient outcomes, through the direct care of individual patients, the management of care for individuals and populations, the administration of nursing and health care organizations, and the development and implementation of health policy by enhancing advanced knowledge.

APRNs in Montana have the authority of independent practice. Further APRNs have an ethical responsibility to help foster evidenced-based practice and direct the future of care. This aspect is a fundamental basis of AACN (2006) DNP Essential II (Organizational and Systems Leadership for Quality Improvement and Systems Thinking). As an APRN, looking ahead to identify trends and changes geared toward best practices is ideal. This may include providing specific recommendations for the facility, including giving Narcan when prescribing tramadol, instituting a 5-day trial when prescribing tramadol, consider not giving benzodiazepines when prescribing tramadol, considering not giving SSRIs/SNRIs when prescribing tramadol, using opioid risk tools, and documenting pain scales when prescribing tramadol.

Like other opioids, tramadol was previously promoted as safe, while only more recently have potentially serious consequences of its use been identified. Tramadol is likely to become even more highly regulated due to its opioid profile and given risks, in addition to its inherent serotonin and norepinephrine related risks, and APRNs should anticipate this trend. From reduction in cost of care to improved patient outcomes, having nurses involved in patient care in an advanced role has shown to have a positive impact on patient care (Shneider, 2008; Wells-Federman, 2000; Wells-Federman et al., 2002). The aim of this project is consistent with AACN (2006) DNP Essentials VII (Clinical Prevention and Population Health for Improving) and VI (Interprofessional Collaboration for Improving Patient and Population Health Outcomes) in that overall health outcomes of this population could be improved by collaborating with other professionals to enhance.

As stated earlier, the focus of Kolcaba's Comfort Model is comfort. Staying in line with ASPMN's ideology that the mission of pain management for nursing is to advance optimal care for people affected by pain by promoting best practice, tramadol should be included in the 2016 CDC and 2018 Montana Utilization and Treatment Guidelines in order to best give comfort with the least risk for adverse effects.

In further following along with Kolcaba's Comfort Theory, counseling and other therapies, such as physical therapy (PT) should be an integral part of the management of those with chronic pain to address their stress, anxiety and other psychosocial aspects of life as well as implementing many other modalities, such as hot/cold compresses, soothing music, or others to make the environment as calm and soothing as possible to

help the patient achieve the physical and spiritual transcendence in addition to pain relief, especially when inflammation is the underlying culprit for the ongoing pain.

These seemingly lighter aspects of what the patient can do for themselves to help their outcome may be missed if adequate time is not spent dealing with the issues of pain, as the literature also indicates is a problem in the treatment of pain. Part of this time spent with patients should be the teaching of the above given modalities that are non-pharmacological. Nurse practitioners can play an integral role in identifying in our patients the physical, psycho-spiritual, sociocultural, and environmental factors influencing the ability to achieve transcendence in chronic pain patients as described by Kolcaba by following these supportive implementations in addition to pharmacology.

Recommendations for Future Practice

This project sought to assess providers' knowledge and adherence to the 2016 CDC and 2018 Montana Utilization and Treatment opioid Guidelines for chronic nonmalignant pain. Doing projects in this manner with larger samples of providers and charts may yield a better conclusion to providers' perceptions on a larger scale. Addressing barriers to implementation and repeating this project in other geographical areas, as discussed in this paper, may help to produce this on a wider scale. The tools used should be evaluated for reliability and validity.

Faculty at DNP, physician assistant (PA), and medical doctor (MD) schools should be knowledgeable about the problem that chronic pain presents to society, as well as the fact that the literature shows a deficit in education. Healthcare educators should continue to strive to have thorough and updated teaching on these types of subjects in the

classroom, or at least encourage students to explore it in self-study with the understanding that it is so prevalent.

Providers should seek current information regarding chronic pain management options available and current practice guidelines regarding chronic pain management. Providers need to be aware of when referrals to comprehensive pain management services are warranted and make such referrals appropriately and promptly. A further recommendation to help address the gap of inconsistent adherence to guidelines when prescribing opioids is for providers to carefully follow the guidelines for opioids when prescribing tramadol. As found in this project, many providers took some steps and almost all acknowledged tramadol as an opioid, showing an understanding that adhering to the guidelines, at least in part, is necessary for best practice and better outcomes.

The results of this project will be shared informally with the CEO of the facility where this project was conducted, and, if agreed upon, the results will be shared formally with providers and others who are engaged in the process of policy. Ideally, the facility will accept the recommendation to implement the 2016 CDC and 2018 Montana Utilization and Treatment Guidelines for the use of tramadol. Education on why tramadol should be included will be offered concurrently with the presentation of findings. This would help to ensure the best patient outcomes in lieu of current scheduling conflicts by regulating boards, and possibly help streamline the process so that all providers follow the same steps despite the level of education regarding opioids.

Conclusions

Chronic pain remains, and will continue to be, one of the most common health issues in family practice. This project uncovered inconsistencies in the application of opioid guidelines for tramadol, even though the literature indicates that tramadol is an opioid. As an opioid, tramadol should adhere to the 2016 CDC and 2018 Montana Utilization and Treatment opioid Guidelines for managing chronic nonmalignant pain. This implementation would be a step above the current scheduling by the DEA requirements, but would be the most appropriate in delivering comfort to the patient while avoiding unnecessary risks, thus decreasing expense associated with chronic pain and improving outcomes.

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APPENDICES

APPENDIX A

PROVIDER QUESTIONNAIRE

Provider Questionnaire

Please answer the following statements by circling one of the five options affiliated with each statement.

1. Tramadol is an opioid.
Strongly Agree Agree Undecided Disagree Strongly Disagree

2. Stopping Tramadol use abruptly can cause opioid withdrawal.
Strongly Agree Agree Undecided Disagree Strongly Disagree

3. Prolonged Tramadol use can result in opioid dependence.
Strongly Agree Agree Undecided Disagree Strongly Disagree

4. Tramadol has a morphine milliequivalent (MME).
Strongly Agree Agree Undecided Disagree Strongly Disagree

5. Tramadol should be treated with the same precautions as other opioids in the 2016 Centers for Disease Control and Prevention 2016 and 2018 Montana guidelines for prescribing opioids for nonmalignant chronic pain management?
Strongly Agree Agree Undecided Disagree Strongly Disagree

6. Tramadol is NOT a safe alternative to opioid use for chronic nonmalignant pain.
Strongly Agree Agree Undecided Disagree Strongly Disagree

7. My education included thorough instruction on chronic pain management and opioids.
Strongly Agree Agree Undecided Disagree Strongly Disagree

APPENDIX B

ASSESSMENT TOOL FOR COMPLIANCE

Assessment tool for chart review for guideline compliance

1. Has patient been seen by two providers with one being a pain specialist?
2. Is there a pain contract in place?
3. Is the patient seen every 3 months or less?
4. Was there an initial 5-day trial?
5. Are there random and yearly urine drug screens to check for compliance?
6. Is the state narcotic database accessed and documented?
7. Was the patient offered to lessen or discontinue opioids every 3 months?
8. Are there concurrent prescriptions with benzodiazepines?
9. Was the patient given opioid doses that are shown to increase suicidality (greater than 20 MME/day or 200 mg tramadol)?
10. Was there concurrent SSRI/SNRI prescriptions which is contraindicated with tramadol?
11. Was there a pain rating scale documented on every visit?
12. Was there an initial and ongoing documentation of use of an Opioid Risk Tool (ORT)?
13. Was naloxone offered as evidence by being on current med list or documented?

APPENDIX C

CONSENT FORM

SUBJECT CONSENT FORM

FOR

PARTICIPATION IN HUMAN RESEARCH AT

MONTANA STATE UNIVERSITY

"Opioid Guideline Adherence for tramadol in Those with Chronic Nonmalignant Pain"

You are being asked to participate in a research study regarding your perspective on tramadol as an opioid and the current best practice guidelines for opioids concerning chronic nonmalignant pain. The purpose of this project is to understand provider perceptions regarding tramadol treatment options for chronic nonmalignant pain and identify your views regarding the opioid guidelines for managing this type of pain. The following information is provided for you to decide whether you wish to participate in the current study in which there are no foreseen risks.

A short questionnaire will be provided to you along with a pre-addressed, stamped envelope. Participation is voluntary and you are free to not answer any questions you do not want to answer and/or you can stop at any time. Your name will not be associated with the research findings in any way and your identity as a participant will not be known by any identifying information. Return of the survey implies consent. There is no compensation for participation and also no known risks to you as a result of participation.

If you have questions about the research, you may contact me, Harold Horine III at (406) 490-9391 [handhboardman@gmail.com]. If you have additional questions about

the rights of human subjects you can contact the Chair of the Institutional Review Board, Mark Quinn, (406) 994-4707 [mquinn@montana.edu].