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Implementation of Evidence-Based Chronic Non-malignant Pain Management Protocol for Primary Care

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Abstract

Chronic pain is the most prevalent health condition in the United States and is the most common reason people seek healthcare (Chang, Daubresse, Kruszewski & Alexander, 2014). In 2012, health care providers wrote 259 million prescriptions for opioid pain medications despite little change in self-reported pain prevalence (Centers for Disease Control and Prevention (CDC) 2016; Chang et al., 2014). Initiatives to prevent the under treatment of pain have resulted in overreliance on opioids to treat pain. As a consequence of opioid centric prescribing, an opioid epidemic has evolved with devastating consequences such as dependence, addiction and overdose deaths related to opioid overuse (CDC, 2016). Due to increased reliance on opioids for chronic non-malignant pain management, the need for a chronic non-malignant pain protocol for a primary care clinic was identified. Baseline data gathered to determine prescribing practices of a rural primary care practice revealed a need for an evidence-based protocol to comply with State of Michigan opioid laws. The protocol included evidence-based education, protocol and electronic health record dashboard development and process evaluation. Implementation of a chronic non-malignant pain protocol resulted in a decrease in opioid-only prescribing in primary care and a 53% increase in multi-modal prescribing practices in a subsequent office visit for 141 patients over eight weeks. In addition, there was a significant increase in adherence with mandated opioid prescribing practices such as: completed urine drug screen monitoring ($p < 0.0001$), signed opioid start talking forms ($p < 0.0001$), clinician reviewed drug prescription monitoring (PDMP) ($p < 0.0001$) and chronic non-malignant pain contracts ($p <0.0001$). There was no change in the documentation of patients pain score. Implementation of an evidence-based chronic non-malignant pain management protocol that adheres to Michigan law while decreasing opioid-only prescribing results in significant quality improvement in healthcare

delivery for primary care patients.

Keywords: multi-modal prescribing, chronic pain, primary care, pain protocol, Michigan opioid law

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Chronic pain is the most prevalent health condition found among the United States (U.S.) work force and is the most costly in terms of lost production (Chen et al., 2016). The total economic burden is estimated to be $78.5 billion with over one third of this amount ($28.9 billion) relating to the increased health care and substance abuse treatment costs (Florence, Luo, Xu & Zhou, 2016). Chronic pain is defined as unpleasant sensory and emotional experience with actual or potential tissue damage or described as damage lasting beyond the normal healing period of three to six months (Owen et al., 2018). Chronic musculoskeletal pain (CMSP) is a global health care concern with most individuals presenting to primary care settings for management (Ernstzen, Louw & Hillier, 2017). Chronic musculoskeletal pain is classified as part of chronic, non-malignant pain which encompasses musculoskeletal, neuropathic and visceral pain (Ernstzen, et al., 2017). It is a complex condition that negatively impacts physical and psychosocial health, daily function, life roles, healthcare utilization and health related quality of life; therefore requiring multi-modal management (Ernstzen, et al., 2017).

Non-opioid medications such as non-steroidal anti-inflammatory drugs (NSAIDS) and acetaminophen, are first line medication treatment for patients with mild to moderate pain (Victor, Alvarez & Gould, 2009). However, opioid analgesics are among the most commonly prescribed class of analgesics for both inpatient and outpatient settings (National Center for Health Statistics, 2017). The use of opioid pain medication presents serious risks including overdose and addiction. According to the Center for Disease Control [CDC] (2016), between 1999 and 2014, more than 185,000 persons died from overdose related to opioid pain medication in the United States (National Institute of Drug Abuse, 2018), (Appendix A).

The pressure on clinicians to treat pain has led to the increase in opioid reliance for chronic pain management. Over the past several decades, the number of patients receiving opioids and the number of doses prescribed have increased dramatically. Between 8% and 45% of the population report chronic pain, with between 10% and 15% of the population presenting to their primary care provider for treatment (McQuay & Moore, 2008). Prescribing for treatment of chronic non-malignant pain with opioids changed from largely discouraged to being included in standards of care. Recommendations for treatment of chronic non-malignant pain called for the upward titration of opioid medication until the patient reported adequate pain control (Pletcher, Kertesz, Kohn & Gonzales, 2008). In response, chronic non-malignant pain was often deemed undertreated and initiatives to increase clinician identification and treatment of pain were prompted. For instance, the American Pain Society promoted "pain as the fifth vital sign", the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) created pain management standards, and the World Health Organization (WHO) pain ladder was used by providers and patients for a stepwise approach to pharmacological treatment of pain (Morone & Weiner, 2013 & Vargas-Schaffer, 2010). As a result, opioids were increasingly prescribed for first-line management of chronic pain. Between the years of 1999-2010, the quantity of prescription analgesics sold to pharmacists and hospitals and prescribed by doctors increased by 400% (CDC, 2011). Regardless of the initiatives to combat under-treatment of pain with opioids, the overreliance of opioids for chronic non-malignant pain has caused devastating consequences. In 2012, health care providers wrote 259 million prescriptions for opioid pain medications despite little change in self-reported pain prevalence (CDC, 2016; Chang et al., 2014).

A recommendation for first-line use of opioids for treatment of severe pain has been promoted by the use of the WHO pain ladder (Blondell et al., 2013). However; it should be noted

that the pain ladder was developed from expert opinion for cancer-related pain, and not built upon higher levels of evidence, such as randomized controlled trials (RCTs) (Vargas-Schaffer, 2010). A letter to the editor of the New England Journal of Medicine further promoted questioning the misconception of the safety of opioids. Porter and Jick (1980) reviewed nearly 12,000 hospitalized patients' records for evidence of opioid addiction after receipt of at least one opioid. The authors identified just four records with reasonable documentation of addiction; thus concluding that opioid addiction is rare (Porter & Jick, 1980). A limitation of the letter to the editor was that the population concerned only hospitalized patients whose treatments were overseen by medical staff, and was never intended to have any bearing on analgesic use outside short-term hospital visits.

As a consequence, efforts to decrease reliance on opioids for chronic non-malignant pain management have emerged. The CDC (2016) released guidelines providing recommendations for primary care providers prescribing opioids for chronic pain (Appendix B). Recommendations were associated with lack of evidence showing long term benefits of opioids versus non-opioids in pain management and improved daily functioning, as well as the possible harms of opioids including overdose and overuse (CDC, 2016). In addition, various policies and regulatory approaches have been initiated addressing morbidity and mortality related to prescription drug abuse and misuse. The state of Michigan enrolled House Bill No. 4408, section 7303c subsection 1 (2017) which set forth mandates for any providers prescribing opioids in attempt to combat the opioid crisis (Appendix C). Determining the adherence to evidence-based recommendations for chronic non-malignant pain and opioid laws is important in order to improve care for this population, particularly in rural primary care practices with limited resources. The clinical question addressed in the project: Does implementation of an evidence-

based chronic non-malignant pain management protocol for opioid prescribing in primary care lead to increased adherence to mandated state law opioid prescribing guidelines while also decreasing opioid-only prescribing? A chronic non-malignant pain management protocol was developed to reduce reliance on opioids for a rural Michigan primary care practice. In addition, the evidence-based chronic non-malignant pain management protocol was implemented and evaluated regarding adherence to mandated Michigan law and recommended CDC guidelines.

Assessment of the Organization

A feasibility assessment of the organization was conducted in order to be successful in implementing and sustaining the quality improvement project. The organizational assessment involved learning about the organization and discovering what is most important to the people within that organization. The practice provides primary care to families at the community level while meeting their increasing health and welfare needs. The organization's current processes and workflow were assessed and information was gathered from key stakeholders. Providers, nurses, medical assistants (MA) and clerical staff were observed using current chronic non-malignant pain management practices. The organizational assessment was guided by the Burke & Litwin Model of organizational performance and change (Burke & Litwin, 1992) (Appendix D). In addition, an analysis of the organization's strengths, weaknesses, opportunities, and threats in relation to implementation of an evidence-based chronic non-malignant pain management protocol was performed.

Organizational Assessment Framework: Burke & Litwin

The Burke & Litwin Model was used to identify and define organizational dimensions which are linked causally in order to promote and achieve change (Burke & Litwin, 1992). The Burke & Litwin model represents how variables are inter-related within an organization and

impact the internal and external environment and individual and organizational performance through a feedback loop process in a cause-and-effect relationship (Reflect & Learn, n.d.). This model involves 12 key components with transformational and transactional dynamics. The variables are illustrated in Appendix D (Burke & Litwin, 1992). The findings from the organizational assessment of the primary care practice identified the need for improved organizational and individual performance, improved systems including policy, standard work and recognized external environment factors to improve care for patients with chronic non-malignant pain.

Key Stakeholders

Influence of key stakeholders is critical to the success of a change-project (Moran et al., 2017). Key stakeholders in a rural primary care practice are those involved with or affected by the practice change. Including key stakeholders is vital while making a change within an organization in order to maintain sustainability and be successful. The key stakeholders for this project include the student's mentor, who is the physician and owner of the primary care practice, a nurse practitioner, practice manager who is also a registered nurse, three medical assistants, a radiology technician, a coder/biller, two front desk staff and patients with chronic non-malignant pain. Healthcare providers prescribe analgesics, patients receive the analgesics and the community is affected by the rapid rise of opioid abuse. The physician owner of the practice is responsible for generation of policy change. In the primary care practice, the physician and nurse practitioner performed the assessments, the registered nurse was the project champion for this project, and the medical assistants obtained the patients' vitals and assisted with process requirements and the front desk clerks scheduled the appointments.

Ethics and Protection of Human Subjects

All data for this project was collected in a de-identified codebook (Appendix E). The Doctor of Nursing Practice (DNP) student who acted as facilitator, was granted access to the EHR for the organization for the duration of the project and kept all information on the secured network provided by the organization. The reports on quality data were secured and stored in the organization's data base. An application for review and approval or exemption of this project was submitted to the University Human Research committee for Institutional Review Board (IRB). The project was determined to be non-research (Appendix F).

Current Practice

The current pain management practices of the practice were assessed. The analysis identified the extent opioids were prescribed for patients with chronic non-malignant pain as well as adherence to opioid law and CDC guidelines.

The baseline pharmacological chronic non-malignant pain management practices were assessed with a report generated from the electronic health record (EHR). Data was retrieved from the generated report on any patient currently prescribed analgesics for chronic non-malignant pain management and determined the number of patients prescribed an opioid versus non-opioid analgesic. Data was analyzed determining accurate diagnosis and pain prescribing practices. Opioid analgesics included acetaminophen/hydrocodone (Norco), oxycodone, morphine and tramadol. Non-opioid analgesics included non-steroidal anti-inflammatory drugs (NSAIDS), pregabalin, tri-cyclic antidepressants, serotonin-norepinephrine reuptake inhibitors (SNRI's) and acetaminophen. For this analysis, it was assumed that if the patient had a current prescription for the medication, they were taking the medication as prescribed.

Of the 403 patients prescribed analgesics for chronic pain management, 403 (100%) were opioid-containing analgesics (Appendix G). Prescriptions were categorized by analgesic

(Appendix H). Hydrocodone-acetaminophen was the most often prescribed opioid containing analgesic (Appendix I), followed by tramadol and oxycodone. Morphine was the least prescribed opioid containing analgesic. There was no indication in the charts that non-opioid NSAIDS such as ibuprofen or non-opioid analgesics such as acetaminophen were used.

The secured data set, excluding patient names, was analyzed by patient record number (PRN) and 10% or 40 of the 403 patients were randomly selected for manual EHR review. Manual review was required due to the limited capability of the free EHR utilized by the primary care practice to generate reports from data sets. The sample population (n=40) ranged in ages from 26 to 90 of age with a mean age of 55.3 (standard deviation [SD] 14.8) years.

A patient reported pain score is assessed by a 0-10 scale indicting severity of pain. A pain score was not recorded at the time of visit for a majority of the patients. All forty of the patients had prescriptions for analgesics. Of the patients treated for chronic non-malignant pain, 100% (n=40) were prescribed an opioid-containing analgesic.

The sample was also analyzed for usage of non-opioid medications as indicated for multi-modal approach to chronic non-malignant pain management. Results yielded that none were prescribed non-opioid NSAIDS or acetaminophen for chronic non-malignant pain. This assessment further supported the need for development of a protocol that included an algorithm for evidence-based multi-modal medication therapy as an approach to chronic non-malignant pain management.

SWOT Analysis

A SWOT analysis, as shown in (Appendix J), was performed at the primary care practice evaluating the organization's strengths, weaknesses, opportunities and threats regarding current process followed while caring for the patients with chronic non-malignant pain. Internal

strengths of an organization are attributes that give an organization a competitive edge over its competitors (Moran et al., 2017). An organization's weaknesses are internal factors that can be corrected. Opportunities are the forces in the external environment that the organization has no control over but can influence how an organization functions (Moran et al., 2017). An organization should always be invested in identifying growth opportunities. Threats are external forces that an organization has no control over and if not anticipated can influence and cause difficulty for the organization (Moran et al., 2017).

Strengths. Strengths to support practice change were identified. The clinic is a growing family practice that nurtures a consistent environment by retaining patient familiar providers and staff. The physician owner of the practice is aware and supportive of the current opioid laws driving the needed change providing a welcoming environment for practice change. In addition; the small size of the organization and management structure facilitated the opportunity for quick practice change.

Weaknesses. Weaknesses in relation to pain management practice change were identified. Since the clinic is fairly new and still developing its internal processes, Practice Fusion, a free EHR is utilized, but has limiting reporting capabilities. Patients were assigned a variety of ICD-10 diagnosis codes, none of which indicated chronic non-malignant pain. The practice also lacked a formal written chronic non-malignant pain management protocol for adherence to the recommended CDC guidelines to reduce opioid abuse. In addition, the clinic was not utilizing evidence-based recommendations for chronic non-malignant pain management. An additional concern about implementation of a chronic non-malignant pain management protocol was increased workload for front office staff. The clinic has a small number of staff and determining the responsibility for additional tasks was perceived as burdensome by front office

staff and medical assistants.

Opportunities. The location of this practice presented a potential opportunity as it is the only independent primary care clinic for several surrounding counties. There was an opportunity to develop an effective protocol for chronic non-malignant pain management and to increase adherence to state mandated guidelines resulting in decreased opioid-only prescribing. The external environment showed many incentives to implementation of guidelines for opioid therapy including the reduction of inappropriate prescribing and harmful effects such as addiction and overdose (Zgierska et al., 2018; Quanbeck et al., 2018). In addition, implementing an evidence-based chronic non-malignant pain management protocol had the potential to improve quality care.

Threats. Threats were also identified for the project. Many existing patients had transferred from other primary care practices with existing opioid prescriptions. Patients treated for chronic non-malignant pain require a complex individual assessment in a relatively limited time of an office visit. Implementing an evidence-based chronic non-malignant pain management protocol could cause a threat to the organization by increasing appointment duration and as a consequence, a loss of revenue. Threats to the practice in relation to chronic non-malignant pain management practice change include patients' preference for opioids, reimbursement tied to patient satisfaction, and potential that the staff may resist the practice change. More importantly, the practice may incur penalties for not following the mandated laws regarding opioid prescribing now in force in the state of Michigan.

Evidence-Based Initiative

In order to determine evidence-based best practices, a review of the literature was conducted. Initially, the review focused exclusively on chronic pain, but the search was narrowed to focus on literature regarding chronic non-malignant pain in primary care.

Method

The Preferred Reporting Items for Systemic Reviews and Meta-Analyses (PRISMA) guideline served as the framework for this review (Moher, Liberati, Tetzlaff, Altman, & PRISMA Group, 2009). A comprehensive electronic search was conducted in the PubMed, CINAHL and Cochrane databases and was limited to reviews in the English language during the period of 2007 to 2018. Keywords were multi-modal, combined analgesia, pain, opioid sparing, primary care, opioid consumption and pain management. Inclusion and exclusion criteria were tailored to the characteristics of the primary care practice. The focus of the literature review was to compare multi-modal analgesic therapy to monotherapy with one of the agents used in the intervention group. The questions considered in the literature review were fourfold:

- Does use of multi-modal analgesia result in improved pain management in chronic non-malignant pain than analgesic therapy with a single agent?
- Does multi-modal analgesia result in decreased opioid consumption than analgesic therapy with a single agent?
- Does the implementation of practice guidelines for opioids result in a decrease of overall opioid prescriptions?
- Does the use of a clinical tool improve provider adherence to opioid prescribing guidelines?

PRISMA Review

The search resulted in 163 CINAHL, 185 PubMed and 150 Cochrane reviews (Appendix K). After screening and in depth examination of the studies, 9 articles were included in the literature review (Appendix L).

Summary of Results

This literature review completed focused on opioid and non-opioid medications prescribed for chronic non-malignant pain in the adult population in primary care. The goal was to determine an evidence-based method to improve chronic non-malignant pain management while decreasing opioid-only prescribing and increasing adherence to state mandated guidelines.

Multi-modal analgesic results. Findings of this literature review suggested multi-modal therapy of at least two analgesics with different mechanisms of action can produce better and longer pain management without increasing adverse effects (Chaparro, Wiffen, Moore, & Gilron, 2012; Ramiro et al., 2011; Gatti et al., 2009; Romano et al., 2009). Three studies concluded that multi-modal analgesic therapy is superior to the use of a single drug therapy (Chapparo et al., 2012; Gatti et al.; 2009 & Romano et al., 2009). Two reviews found evidence supporting multi-modal analgesia over single therapy but did not make definitive conclusion (Khoromi et al., 2007; Ramiro et al., 2011). The final review concluded that opioid therapy was not found to be more beneficial or effective in increased pain control then non-opioid therapy (Kreb et al., 2018).

Chronic non-malignant pain protocol results. The review also showed that implementation of an opioid tool was effective in increasing opioid guidelines in primary care. In these studies, a clinically significant change was reported as a percentage. One study concluded that adding a dashboard in the EHR increased treatment agreement by 14%, urine drug testing (UDT) increased by 20%, a completed pain functional assessment increased by 11%, and a clinically significant decline in patients receiving opioid prescriptions by 12.5% (Anderson et al., 2015). Obtaining UDT is important in a chronic non-malignant pain management protocol because if the UDT is positive for drugs of abuse, no opioids should be prescribed. One study concluded that implementation of a risk assessment tool resulted in a 14% drop in patients receiving any opioid prescription, a 19% drop in chronic opioid patients and chronic opioid urine

drug screening increased 87% (Chen et al., 2016). The final study revealed that after implementing a opioid tool (TOPCARE), 28% more patients had guideline concordant care, a 59% increase in opioid agreement, a 17% increase in UDT and greater discontinuation of opioids with an overall 10% dose reduction or discontinuation of opioid use (Kreb et al., 2018).

Conclusion

Overreliance and prescribing of opioids for the treatment of chronic non-malignant pain is a public health issue that has led to the current opioid crisis. This review of literature revealed that multi-modal analgesia is an effective alternative approach to treating chronic non-malignant pain. Opioids will continue to play an important role in chronic pain management but can no longer be considered the primary analgesia class for chronic non-malignant pain. The findings offer evidence that changing chronic non-malignant pain management practices with multi-modal therapy and implementing opioid guidelines in primary care could impact the opioid crisis and provide safe and effective alternatives while adhering to state mandated guidelines.

Phenomenon Conceptual Model

For successful implementation and sustainability of this project, both a theoretical and an implementation model served as guide for project application. The theoretical model used to describe the phenomenon for this project was the Promoting Action on Research in Health Sciences (PARiHS) framework (Appendix M). The implementation model used for this project was Kotter's eight steps of change (Appendix N).

Theoretical Model: PARiHS

The (PARiHS) framework (Appendix M) is described by the equation where successful implementation is a product of the nature of the evidence, the context of the proposed change, and the mechanism of facilitation (Kitson, Harvey, & McCormack, 1998). The phenomenon is changing opioid prescribing practice for chronic non-malignant pain management using

evidence-based guidelines. PARiHS is a multidimensional framework that was developed to represent the complexity of implementing research-based practice to assist with successful practice change (Rycroft-Malone, 2004). The framework has been utilized by clinicians to improve the quality of care by setting clinical standards, introducing audit and quality improvements, and in changing patient services in several different health care settings (Kitson et al., 2008). Therefore, the PARiHS framework was best utilized to explore facets of change needed to facilitate opioid prescribing practices and the need for a chronic non-malignant pain management protocol in primary care.

Evidence. Kitson et al. (1998) defines evidence as the combination of research, clinical expertise and patient choice. Research ranges from low quality (anecdotal and descriptive) to high quality (systematic reviews, randomized controlled trials [RCTs]), and evidence-based guidelines). Professional consensus, or clinical experience, incorporates a spectrum of low consensus (divided expert opinion) to high consensus (consistency of view). The higher the level of research quality, the more successful the organization will likely be with a quality improvement change.

There is a significant amount of evidence supporting an evidence-based chronic non-malignant pain management protocol. Evidence clearly suggested that multi-modal medication management for chronic pain is significantly better than monotherapy (Chaparro, Wiffen, Moore, & Gilron, 2012; Ramiro et al., 2011; Gatti et al., 2009; Romano et al., 2009). The Joint Commission and the Institute for Clinical Systems Improvement recommended the combination of opioids with non-opioids in order to reduce the reliance on opioids for pain (The Joint Commission, 2012; Thorson et al., 2014). Providers were expected to include the patient in the treatment plan for managing chronic non-malignant pain. It was encouraged that providers share

the patient educational flyer that provides evidence for multi-modal analgesia when presenting patients with non-opioid alternatives to treat chronic non-malignant pain. Evidence also revealed that opioid prescribing tools in primary care including EHR dashboards, opioid treatment agreements, urine drug testing, pain and functional assessments and patient education also reduced the overreliance of opioids for chronic pain (Anderson, Zlateva, Khatri, & Ciaburri, 2018; Chen et al., 2016).

Context. The definition of context is the environment or setting where the proposed changed will occur (Kitson et al., 1998). Context can be viewed as the forces at work that give the environment its character and mood. Context includes culture, leadership, and the measurement of systems and services (Kitson et al., 1998). The leadership in the primary care practice was supportive of innovation and changes; therefore creating an environment instrumental to practice improvements. The physician owner of the practice was responsive to practice change and the employees shared the same values and vision. The culture within the practice was supportive of improvement initiatives. Staff members were encouraged to communicate openly when a problem arose and contributed at monthly staff meetings to discuss resolution. The practice change emphasized patient-centered care by encouraging the providers to partner with the patients to promote and utilize multi-modal analgesia. The providers were expected to use an evidence-based protocol utilizing both opioid and non-opioid options for chronic non-malignant pain management. The rural primary care practice had limited resources to develop the structure and processes needed to comply with mandated state guidelines, therefore the project work by the DNP student facilitated the quality improvement initiative in the practice.

Facilitation. Facilitation refers to a technique by which a person can make things easier

for others (Kitson et al., 1998). The facilitator for the project was the doctor of nursing practice (DNP) student. The staff and providers were open to education regarding the current opioid crisis and evidence-based chronic non-malignant pain management protocols. A facilitator is vital to the success or failure of the implementation of research into practice (Kitson et al., 1998). To increase facilitation, the DNP student recognized and removed barriers. Further facilitation of this DNP project required the student to display respect and flexibility to ensure the success of this practice change. The DNP student addressed concerns and suggestions for the project from all staff members throughout the entire project. The DNP student was empathetic and worked through any disruption of workflow of the change process. The DNP student presented with a unique skillset that assisted with challenges that arose with project implementation. The PARiHS framework also assisted with insight to the phenomenon and provided the facilitator with guidance to complete this quality improvement practice change.

Implementation Model: Kotter's Eight Step Change Model

Kotter's eight step change model served as the guiding framework that promoted the success of this practice change during implementation (Appendix N). After observing more than 100 companies attempt transformation, Kotter created the model (Kotter, 1996) that identified three phases, consisting of eight steps that are necessary to implement the fundamental changes needed in the practice regarding adherence to an evidence-based chronic non-malignant pain management protocol.

Creating climate for change. The first phase of Kotter's eight step process is creating a climate for change. This includes the first three steps of Kotter's eight step process: a sense of urgency, forming a powerful coalition and creating the vision for change (Kotter, 1996). To create a sense of urgency, the facilitator must inspire the clinic staff that there is an opportunity

that must be acted on immediately (Kotter International, 2017). The evidence revealed the opioid crisis and state mandated opioid prescribing guidelines had created a sense of urgency in the primary care practice. The providers and staff shared the vision that current prescribing practices for chronic non-malignant pain management needed to change. When a vision is created, staff will take personal claim to the change and adapt to the strategies necessary to achieve the vision (Kotter International, 2017).

Engaging and enabling the organization. The second phase of Kotter's eight step change model is engaging and enabling the organization. This includes the next three steps of Kotter's eight step process: communicating a vision, empowering action and engaging and enabling the organization (Kotter, 1996). The vision was unified with leadership support for the protocol change throughout the practice. Educating the staff on the opioid crisis and how their involvement in an evidence-based chronic non-malignant pain management protocol could improve the quality for the patient and community empowered action. Engagement of the staff was gained by educational sessions and by encouraging staff to share their ideas. This phase also included the creation of an evidence-based protocol and preparing the EHR for utilization. Barriers to action must be identified and removed to promote the freedom necessary to create real impact (Kotter International, 2017).

Implementing and sustaining for change. The last phase of Kotter's eight step change model is implementing and sustaining change. This includes the last two steps of Kotter's eight step process: building on change and making it stick (Kotter, 1996). Instead of assuming victory after the first signs of improvement, data was used to show that the practice changes were working therefore inspiring more people to be on board to continue the effort. The process was reinforced using evidence-based tools such as dashboards impacting practice change, decreasing

opioid-only prescribing, and increasing compliance with prescribing guidelines preventing any future penalties the state may impose for primary care. Identifying and utilizing change champions within an organization is an evidence-based strategy for increasing understanding of a practice change (Kaasalainen et al., 2015). The practice manager agreed to be the champion and needed continual mentoring by the DNP student to promote sustainability of the practice change. Partnering in the implementation effort requires building a coalition and recruiting with others (Powell et al., 2015). Finally, it is important that any new addition to staff be on board with the practice change, fostering sustainability. This was achieved by placing education about vision, opioid prescribing and a copy of the protocol in new employee folders. The practice manager mentored new staff ensuring adherence to the evidence-based practice change.

Project Plan

Purpose of Project

The purpose of the DNP project was to develop, implement and evaluate an evidence-based chronic non-malignant pain management protocol into the standard of care in a rural primary care practice. Additionally, following the protocol promoted adherence with state law as well as CDC guidelines regarding opioids. The project was developed to answer the clinical question: Does implementation of an evidence-based chronic non-malignant pain management protocol for opioid prescribing in primary care lead to increased adherence to mandated state law opioid prescribing guidelines while also decreasing opioid-only prescribing?

Objectives and Implementation Strategies

To ensure that the clinical question, purpose and objectives of this DNP project were addressed using Kotter's eight step change model as a guide for implementation. (For the project timeline, Appendix O).

1. **Created a sense of urgency**: Beginning May 2018, meetings were held with key stakeholders including the practice owner, physician and practice manager to begin the initial plans of the project.
2. **Created a coalition & created a vision**. The DNP student met with office staff in August 2018 regarding chronic non-malignant pain management protocol. The staff was supportive of the project and the practice manager agreed to champion the pilot project. The vision of addressing the opioid prescribing issues in the practice was created and supported by the staff.
3. **Communicated the vision**: The vision for the project was communicated by the physician during the November staff meeting. Education regarding an evidence-based chronic non-malignant pain management protocol for the providers and staff was provided during the week of December 1, 2018.
4. **Empowered action**: The DNP student collaborated with the physician prior to December 1, 2018 to discuss evidence for the project. The physician is the owner of the practice and the main opinion leader and provider of the clinic. Fostering this partnership encouraged colleagues to adopt an evidence-based pain management protocol into the standard of care (Powell et al., 2015).
5. **Created quick wins:** The DNP student continued to cultivate relationships with the clinic staff and requested their promotion of the project. Staff meetings were held prior to December 15, 2018 with steps needed to promote the project. Every Friday after December 15, 2018, a weekly audit including evaluation variables and feedback was provided to the staff. The feedback data was used as encouragement to staff to build on successes.

6. **Built on the change:** The project concluded after 60 days of implementation. Final report to the practice included percentage of overall adherence to the protocol and percentage change in opioid-only prescribing by March 15, 2019. Project products including the protocol were incorporated into practice processes and staff educated on maintaining change process. The worksheet remained part of the EHR after final evaluation of the protocol.
7. **Made it stick:** The DNP student mentored staff to continue dashboard and monitoring of protocol adherence to sustain the change. Additionally, educational flyers were placed in any new staff members' orientation folder to ensure new staff members had consistent orientation to the protocol. Recommendations for staff and providers to continue to monitor opioid prescribing practices were also considered.

A protocol which included an EHR worksheet, opioid guidelines and educational flyers for patients was developed. Multi-modal analgesia evidence was presented to the physician, nurse practitioner and practice manager in an informal educational session and an evidence-based worksheet was created and used with every chronic non-malignant pain management patient starting January 3, 2019 and ending March 3, 2019 (Appendix P). The evidence-based worksheet included multi-modal chronic non-malignant pain management and evidence-based guidelines and was incorporated into the EHR.

The educational flyers were created and provided to staff. The flyer included an algorithm for evidence-based chronic non-malignant pain management, tips and reminders for providers to order multiple analgesics with different mechanisms of action. Patient education flyers were created and included new state law requirements, CDC recommendations, and benefits of multi-modal therapy and risks of opioid reliance. Printed educational materials are

effective strategies to promote practice change (Farmer et al., 2008). A fifteen minute presentation regarding evidence supporting the practice change and strategies to promote the change was presented to staff. Education was provided to the RN and medical assistants on multi-modal chronic non-malignant pain management before intervention. During initial patient appointment, the physician or nurse practitioner provided the patient with the educational flyer informing the patient regarding the chronic non-malignant pain management protocol, new state law and CDC guidelines. A signed copy of the state mandated opioid start talking education form was scanned into the chart for each patient (Appendix Q).

Interventions such as feedback and educational meetings can help change professional behaviors and improve patient health outcomes (Forsetlund et al., 2009). Providing written and verbal education to patient's also assisted with acceptance and compliance to practice change. Audit and feedback was the summary of clinical performance data that allowed for monitoring, evaluation and behavior modification (Powell et al., 2015).

Implementation of best practices into standard of care is increased with the use of the EHR (O'Connor, DeCaire & Freidrich, 2005; Ozdas et al., 2006; Santolin & Boyer, 2004). The EHR is a free electronic health record called Practice Fusion, which did not have the capability of creating order sets. Order sets are designed for a specific patient population and reports can be generated from an order set. Since the EHR lacked reporting capability, worksheets were created for this specific patient population for collection of data, which required considerable facilitator time.

All analgesics for chronic non-malignant pain management prescribed in the practice between January 3, 2019 and March 3, 2019 which included two subsequent office visits that addressed pain management and percentage of adherence for each of the following variables

were measured: patients prescribed opioid only/multi-modal/non-opioid only analgesics, charting of completed UDS, PDMP, pain score, signed chronic pain management contract, and patient signed opioid education scanned into the chart (Appendix E).

Design for Evidence-based Initiative

The quality improvement project incorporated an evidence-based practice protocol regarding chronic non-malignant pain management into a rural primary care practice. The purpose of the quality improvement project was to change the delivery of healthcare through a systematic method to produce improved patient outcomes (Tasker, 2013). The project work included development, implementation and evaluation of a protocol for primary care to reduce reliance on opioids and increase adherence to mandated Michigan law and recommended CDC guidelines.

Setting and Required Resources

This DNP project took place in a rural primary care practice in West Michigan. Resources required for completion of this project included technology, people and educational materials. The EHR was the technology necessary for completion of this project. The limited reporting of a free EHR necessitated manual retrieval of pre and post- implementation data for each chronic non-malignant pain management patient for two visits within the designated time period. Human resources needed for the project included time from clinic staff (three MA's and two front office staff) and clinic leadership (physician, NP and practice manager RN). In addition, an in-kind donation of DNP student time was used to facilitate the project.

Participants

The participants for this project included providers, practice staff and data collected from de-identified patients in the practice diagnosed with chronic non-malignant pain with two office

visits between January 3, 2019 and March 3, 2019.

Data Collection and Analysis

Measuring data was essential to determine baseline practice and post-intervention change after protocol initiation. Data was collected through EHR chart review, checklists and observation. Use of multi-modal medication was determined by EHR chart review and feedback on protocol performance was provided for the staff weekly.

Adherence to the protocol was measured by percentage change pre-implementation compared to post-implementation on two subsequent patient visits between the dates of January 3, 2019 and March 3, 2019. Variables that were measured during this time frame included charting of completed UDS, PDMP, pain score, signed chronic pain management contract and patient signed opioid education (Appendix D).

Change in prescribing from opioid-only prescribing to multi-modal prescribing was also measured. The types of medications ordered per patient were evaluated from two visits between January 3, 2019 and March 3, 2019. The implementation of the protocol was reviewed for every patient prescribed an opioid for chronic non-malignant pain for two consecutive visits over the course of the pilot study to determine adherence. Chronic non-malignant pain management patients are required to have an office visit once every 30 days, therefore data was collected on two visits per chronic non-malignant pain patient. The study was limited to two visits as it is a pre-post evaluation in which baseline status was accessed, the intervention was implemented and a single follow-up measurement was collected. No more than two visits (one paired set) were included in the pilot study.

A change in prescribing practice was determined by number of change from initial visit to second visit. An increase in multi-modal analgesia in comparison to opioid-only chronic non-

malignant pain management defined that the clinicians adhered to the evidence-based medication algorithm protocol.

Overall adherence to multi-modal prescribing was evaluated as well as each variable included in the protocol was analyzed separately pre and post-implementation. Appropriate analysis including the McNemer percent version of chi-square for paired data was applied to assess change in adherence to protocol variables as well as opioid prescribing. Any percentage increase in adherence was considered successful practice change.

If adherence to the protocol was low, efforts were made to promote increased adherence during weekly feedback. Weekly audits were presented to providers including frequency and percentage of patients receiving opioid-only, multi-modal, or non-opioid therapy. Success was determined by progressively improving audits weekly. Final evaluation of the implementation of an evidence-based chronic non-malignant pain management protocol that adheres to state law and CDC guidelines occurred 60 days after the start of implementation.

Budget

The budget for this DNP project was determined (Appendix R). Most of the expenses for this project were in kind donation by the DNP student serving as the facilitator. The DNP student consulted with another primary care practice and examined how that practice developed, implemented and evaluated a protocol for chronic non-malignant pain management.

Potential cost savings of the plan to limit the primary care clinics' contribution to the opioid crisis was considered as well. With the new laws regarding opioids, primary care providers will eventually be subject to penalties for non-adherence that have yet to be determined. In Michigan, the rate of opioid-related admissions was 229.6 per 100,000 people in 2014 (Weiss et al., 2016). The population of the rural Michigan county was 63,550 in 2017

(United Census Bureau, 2017). Using these statistics, it was calculated that in 2017 there were 145 opioid- related hospital admissions for the people of the county. The average hospital length of stay when admitted for opioid-related overdose was 3.8 days while costing $29, 497 (Bachhuber, Saloner, Cunningham, & Barry, 2014). Therefore; if only one opioid-related hospital admission were prevented in the future as a result of this DNP project, nearly $30,000 in hospital costs would potentially be mitigated.

Results

Analysis. The methods to analyze the data were quantitative. The data was analyzed by viewing the data in an excel form and on graphs. When working with paired data, divergent pairs were identified and McNemars test used to determine a p value of categorical outcomes. Divergent pairs are used to identify the accumulation of differences between closely related patterns pre and post-implementation. A Kappa test was tabulated to report statistical value. Kappa serves to quantify how many patients status changed versus stayed the same from time one to time two. A Kappa of -1 means that no person had the same value at time two as they did at time one. A Kappa of 1 would mean everyone had identical scores. This study revealed a Kappa score of 0.636. Kappa is less informative than reporting percentages as it lacks content but is used in this analysis because it shows categorical change for medication prescribing practices.

The data was examined pre and post-implementation of the protocol. Pre-implementation chart review indicated that prescribing practices were opioid centric with limited multi-modal prescribing. Additionally, chart review revealed limited completion of a documented pain score, completed UDS, opioid contract, PDMP screening and patient opioid education for all chronic non-malignant pain patients. The study population (n=141) ranged in ages from 23 to 86 of age with a mean age of 52.45 (standard deviation [SD] 13.67) years.

Post-implementation revealed increased multi-modal prescribing and a decrease in opioid-only prescribing (Appendix S). Kappa value revealed that 93/141 patients changed status. Of these patients, only one patient changed from non-opioid to opioids while 75 patients (53%) changed from opioid only to either non-opioid or multi-modal management. Change of prescribing in the practice resulted in increased multi-modal prescribing (Appendix T & U). Individual medications prescribed revealed the most significant increase in prescribing with NSAIDS (26.95%) and pregabalin (29.87%) (Appendix V). Chart review revealed completed urine drug screening increased by 74.47% ($p < 0.0001$), opioid contracts increased by 85.82% ($p < .0001$), prescription drug monitoring increased by 96.45% ($p< 0.0001$) and patient opioid education for patients increased by 74.47% ($p< .0001$) (Appendix W). There continued to be a lack of documented pain score for any patient in the pilot study which resulted in insignificant results.

Limitations

Limitations to this project included that data was analyzed based on what was documented in the EHR and may not be a true reflection to patient choices of non-prescription medications. Also, the organization is a small privately own practice utilizing a free EHR with limited function, therefore requiring all data to be retrieved manually. Lack of a documented pain score limits the ability to assess reasoning for medication prescribed for chronic non-malignant pain. Lastly, during the last weeks of the project the DNP student was notified that the practice would be closing as of April 26, 2019 hindering sustainability.

Discussion

This project was initiated in a rural primary care practice with limited resources due to recent state mandates regarding opioid prescribing for chronic pain and the increase in mortality related to opioid overdose in Michigan. Evidence-based protocols for opioid prescribing can be

implemented to improve outcomes for this population. This project also aimed to improve prescribing practices with the use of multi-modal medication management protocol for chronic non-malignant pain.

During this project, process frameworks were used to organize the approach. The Burke-Litwin model was used to thoroughly analyze the needs for chronic non-malignant pain management practices at this organization. The PARiHS framework was used to understand the evidence and to develop and facilitate a practice change. A SWOT analysis was performed to determine areas in need of improvement and areas of strength at the organization. The purpose of the project was to identify the gaps in care in primary care practice to guide recommended evidence-based change and improve outcomes.

The success of the project can be contributed to the change in culture in the organization. Leadership and staff acceptance and adherence to evidence-based practice, protocol implementation and the quality improvement process was imperative, resulting in significant changes in all the measured outcomes. Results of the project successfully answer the clinical question of this project. Implementation of a chronic non-malignant pain protocol increased multi-modal prescribing resulting in decreased opioid-only prescribing. In addition, the protocol increased adherence to state of Michigan opioid laws.

Implications for Practice and Further Study in the Field

The project addresses major implications for practice. The opioid crisis is an established and growing issue. Overreliance of opioids to treat chronic non-malignant pain has led to devastating outcomes such as addiction and overdose. The majority of patients seek treatment for chronic disease in primary care. Implementation of an evidence-based chronic non-malignant pain management protocol that adheres to Michigan law and improves patient care is critical in primary care.

The project highlights the need for DNP prepared facilitators for primary care practices with limited resources to develop, implement and evaluate quality improvement. In addition, an organization's project champion is critical to the continued processes and evaluation of quality improvement projects of the clinic.

Quality improvement projects that result in policy change consistent with existing and emerging state laws regarding population health improve quality of care for the patient and community served. Implementing policies adhering to Michigan opioid laws, resulting in the improvement in health of this patient population ultimately decreases organizational contribution to the opioid crisis.

Sustainability

Even though this practice is closing, lessons learned are that chronic non-malignant pain management can be successfully impacted by implementation of an evidence-based protocol, even in a rural primary care practice with limited resources. Ongoing evaluation of opioid prescribing practice would be greatly impacted by the upgrade in technology of an EHR with report generating capabilities. It is imperative to have continued acceptance by all staff to ensure continued protocol adherence. Adherence can be achieved by weekly communication with staff regarding successful change and guidance when difficult issues arise. A project champion would continually need to mentor staff on protocol adherence and perform periodic chart review to share with staff. Lastly, it is important to consider staff in a primary care practice who would be responsible for ongoing monitoring, reporting and educational materials needed for sustainability.

Dissemination of Results

The DNP project will be presented as part of the DNP student's final defense at Grand Valley State University (GVSU) April 16, 2019. The outcomes will also be shared with the staff

at the primary care practice during a staff meeting in April 2019. Finally, the DNP student will seek out opportunities to report the outcomes to relevant professional journals and presentation to professional organizations as well as submission to ScholarWorks.

Reflection of DNP Essentials

The Essentials of Doctoral Education for Advanced Nursing Practice (AACN, 2006) were the guiding competencies the DNP prepared nurse gained by project work and immersion activities during curriculum.

Essential I: Scientific Underpinnings for Practice

AACN (2006) essential I focus is on using theory to guide practice improving delivery of healthcare for the healthy and sick, assess and implement new practices and evaluate outcomes. This project focused on evidence to determine the best care to be provided to patients with chronic non-malignant pain. Also, frameworks such as the Burke and Litwin model for change, PARiHS and Kotter's eight steps for change were utilized to identify, define and guide the practice change (Burke & Litwin, 1192; Kitson, Harvey, & McCormack, 1998; Kotter, 2017).

Essential II: Organizational and Systems Leadership

DNP essential II focuses on understanding an organizations hierarchy and how leadership within that organization collaborates to minimize disparities in healthcare and promote safety (AACN, 2006). Leadership support is monumental in order to initiate, create and maintain change. The DNP student demonstrated this essential through theory-guided organizational assessment to determine the context of the clinical problem. This information was also utilized to determine the unique needs of chronic non-malignant pain management patients in this rural primary care practice. In addition, a budget plan for the DNP project was created.

Essential III: Clinical Scholarship and Analytical Methods for Evidence-Based Practice

According to the AACN (2006), the DNP student should be prepared to translate and disseminate evidence-based research into practice. The goal was to locate relevant and applicable evidence related to the chronic non-malignant pain patient using the PRISMA method in order to provide evidence and evaluate relevant variables. The quality improvement project's goal was to improve patient care and outcomes for the population of focus. Data was collected from the EHR and manually entered into an excel sheet which was further analyzed with a statistician.

Essential IV: Information Systems Technology

The ability to understand and utilize systems technology to obtain information, analyze and display data is imperative. The DNP student needs to understand the legal, ethical and regulations that surround the using the system to evaluate outcomes for programs, provided care and systems (AACN, 2006). The student utilized the organization's EHR to gather data to formulate the dashboard for provider and staff feedback. As data was retrieved and analyzed, special consideration was taken to promote confidentiality and protect patient information. In addition, the DNP student attended a conference on the importance of systems technology as it improves the quality of healthcare delivery, increases patient safety, decreases medical errors, and strengthens the interaction between patients and healthcare providers.

Essential V: Advocacy for Health Care Policy

A DNP student needs to understand the importance of healthcare policy and application to nursing practice. This essential focuses on policy change in relation to decisions within an institute, organizational or government level (AACN, 2006). The student participated in Advocacy Day for Nurse Practitioners at the capitol to increase awareness of current policy and laws. The DNP project involved policy and practice change by implementing an evidence-based

chronic non-malignant pain protocol resulting in clinically significant results in a primary care practice.

Essential VI: Interprofessional Collaboration

This essential focuses on the collaboration between healthcare teams with the student establishing interprofessional teams (AACN, 2006). The DNP student had a leadership role collaborating with multiple interdisciplinary teams to make an impact and receive support while implementing a practice change. Collaborating with providers, medical assistants, the practice manager and front desk staff was essential for successful practice change. The DNP student also attended the interprofessional conference in September 2018 at GVSU. This conference focused on the importance of healthcare providers and professionals collaborating as a team to improve patient and population health care.

Essential VII: Clinical Prevention and Population Health

The DNP student needs to promote health and reduce risk of illness while understanding epidemiology, environmental, bio-statistical regards to a populations' health (AACN, 2006). This DNP project directly focused on chronic non-malignant pain management patients and application of an evidence-based protocol to improve outcomes. Chronic non-malignant pain is a serious public health problem in addition to opioid centric prescribing, resulting in poor outcomes and increased mortality.

Essential VIII: Advanced Nursing Practice

The DNP role is diverse and has the ability to analyze a complex system, design and implement best practice for a patient population, develop a sustainability plan, maintain professional relationships with several different specialties in order to improve outcomes of care and standardize processes of care (AACN, 2006). The DNP student's lens assisted in the

successful approach to this project work. The DNP student analyzed an organization, identified a need for practice change, performed research, developed and implemented a policy change that is sustainable. The DNP student also attended the Michigan Nursing Summit in Lansing on October 18-19. The DNP student collaborated with many other nurses and nurse practitioners and learned about mentorship for future nurses by expecting excellence instead of perfection.

Conclusion

In conclusion, the project presented a compelling case for an evidence-based chronic non-malignant pain management protocol that incorporated staff education, EHR worksheet utilization, multi-modal medication prescribing and practice guidelines. The project is a valuable contribution to the decrease of opioid prescribing by promoting an evidence-based practice regarding chronic non-malignant pain management and adherence to state mandates and CDC guidelines in a rural primary care practice with limited resources. The goal was to provide evidence-based care in order to improve outcomes and prevent morbidity and mortality for the rural primary care population. Educating staff in regard to the chronic non-malignant pain management protocol and EHR utilization can have positive outcomes not only on quality documentation and reporting, but also improved patient outcomes. The chronic non-malignant pain protocol implemented resulted in a decreased percentage of opioid-only prescribing while increasing evidence-based multi-modal prescribing practices. In addition, the protocol resulted in an increased adherence to state of Michigan opioid law. Consequently, the evidence-based chronic non-malignant pain management protocol provided quality care to all chronic non-malignant pain management patients in a rural primary care practice.

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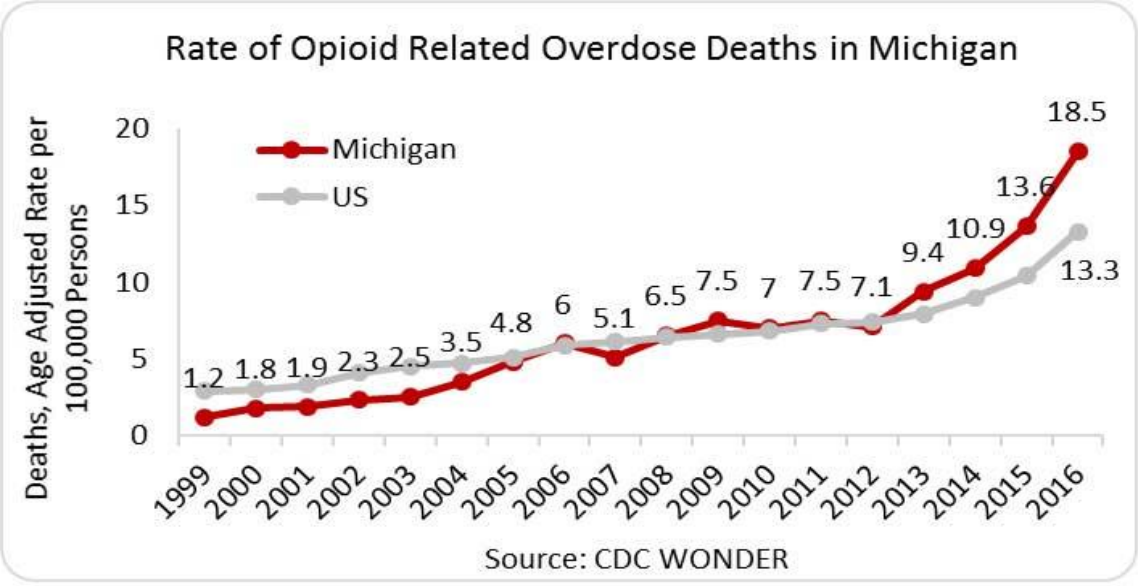
Appendix A

Rate of Opioid Related Death



Rate of Opioid related deaths in Michigan. National Institute of Drug Abuse. (2018). *Opioid-related overdose deaths*. Retrieved from https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/michigan-opioid-summary

Appendix B

CDC Guidelines for Prescribing Opioids for Chronic Pain

Determining When to Initiate or Continue Opioids for Chronic Pain **1**.Nonpharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and non-opioid pharmacologic therapy, as appropriate. **2**. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety. **3**. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy. **Opioid Selection, Dosage, Duration, Follow-up, and Discontinuation** **4**. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids. **5**. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day. **6**. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days	**7.** Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids. **Assessing Risk and Addressing Harms of Opioid Use** **8**. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present. **9**. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months. **10**. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs. **11**. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible. **12**. Clinicians should offer or arrange evidence-based treatment (usually medication assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

CDC (2016). CDC Guideline for Prescribing Opioids for Chronic Pain. Retrieved from https://www.cdc.gov/drugoverdose/prescribing/guideline.html

Appendix C

Michigan House Bill No. 4408

Act No. 246
Public Acts of 2017
Approved by the Governor
December 27, 2017
Filed with the Secretary of State December 27, 2017
EFFECTIVE DATE: December 27, 2017
STATE OF MICHIGAN
99TH LEGISLATURE
REGULAR SESSION OF 2017

Introduced by Reps. Bellino and Griffin

ENROLLED HOUSE BILL No. 4408

Sec. 7303c. (1) Except as otherwise provided in this section, beginning June 1, 2018, before a controlled substance that is an opioid is prescribed to a patient, a licensed prescriber or another health professional shall provide information on all of the following to the patient or the patient's representative:

(a) The danger of opioid addiction.

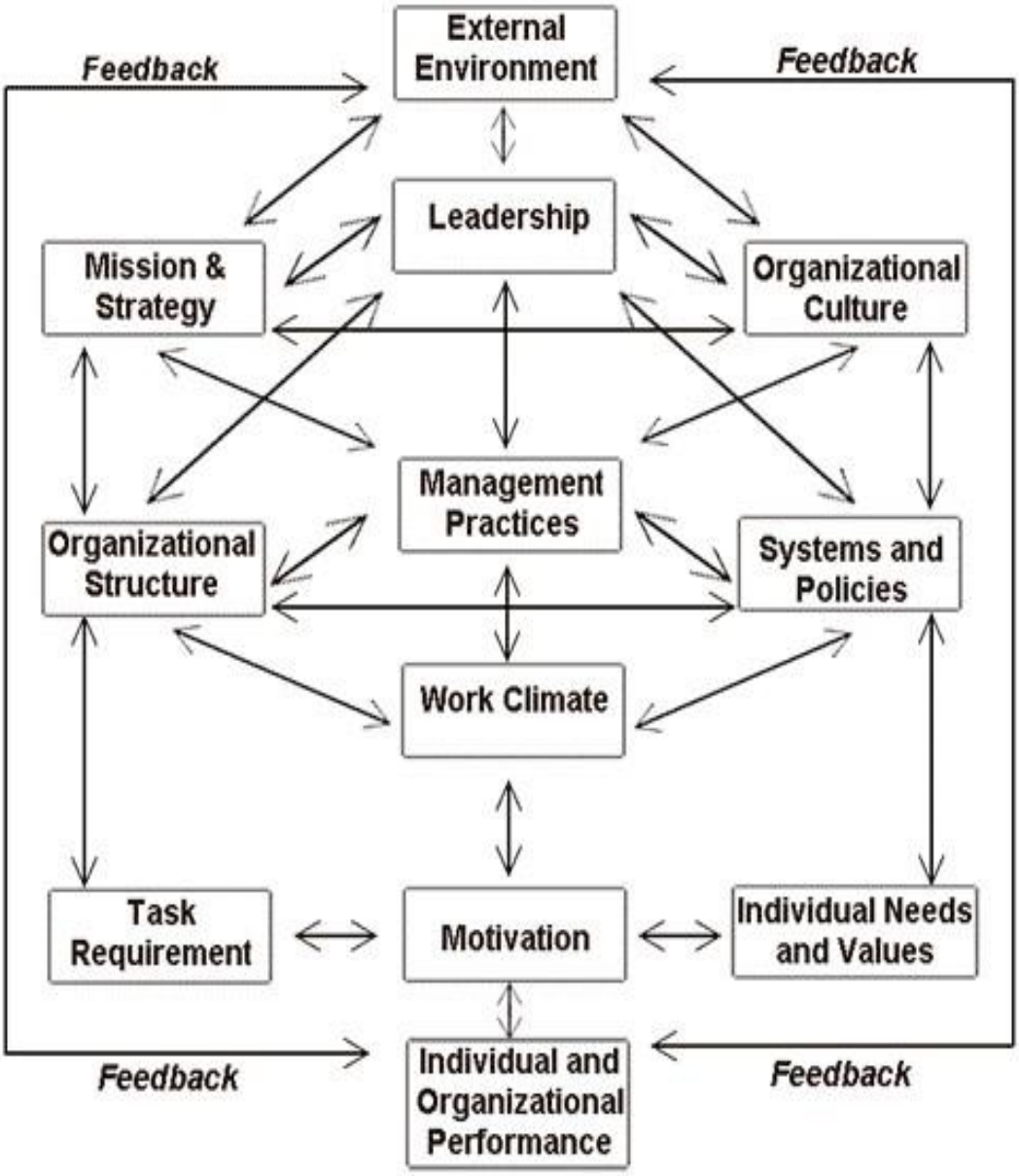
(b) How to properly dispose of an expired, unused, or unwanted controlled substance.

(c) That the delivery of a controlled substance is a felony under Michigan law.

(d) If the patient is pregnant or is a female of reproductive age, the short- and long-term effects of exposing a fetus to a controlled substance, including, but not limited to, neonatal abstinence syndrome. (2) After providing the information described in subsection (1), the licensed prescriber or other health professional shall obtain the signature of the patient or the patient's representative on a form prescribed by the department of health and human services, indicating that the patient or the patient's representative has received the information described in subsection (1). The licensed prescriber or other health professional shall include the signed form in the patient's medical or clinical record.

Appendix D

Burke-Litwin Causal Model



Adapted from "A Causal Model of Organizational Performance and Change," by W. W. Burke and G. H. Litwin, 1992, *Journal of Management, 18*, 528. Copyright 1992 by Southern Management Association.

Appendix E

Data Codebook

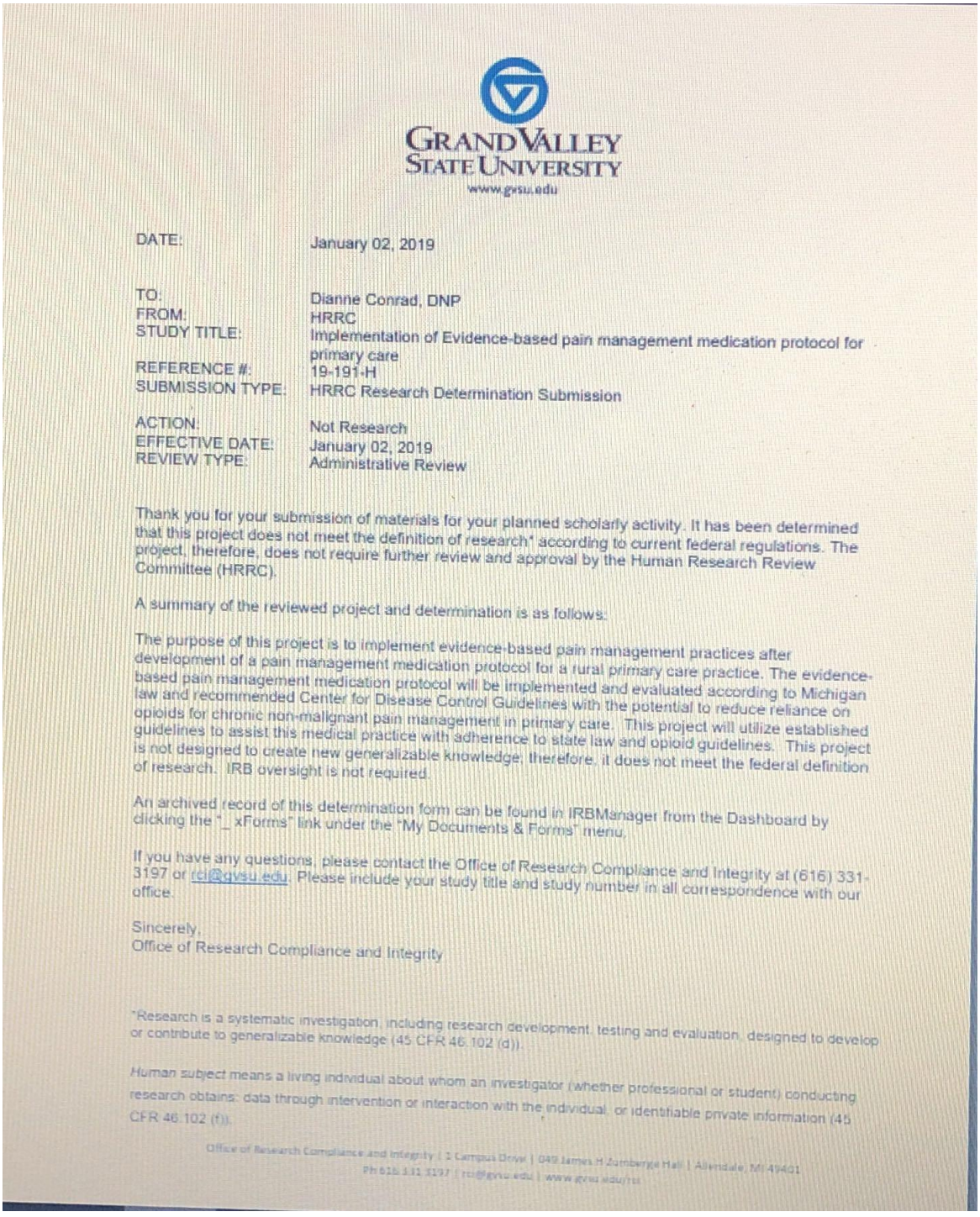
Data Set Label	Variable Label	Variable Description	Attribute Descriptor & Classification Categories	Variable Format	Measure Level
PARTICIPANT	PARTICIPANT_CODE	Participant Identification Number	0-99, 9999= Not assessed, 8888= Missing Data	Numeric	Scale
PARTICIPANT	PARTICIPANT_PCP	Primary Care Provider	0= provider 1, 1= Provider 2	Categorical	Nominal
PARTICIPANT	AGE_CLASS	Participants Age	#	Numeric	Scale
MEDICAL	DISEASE_ CHRONIC PAIN	Chronic pain	0= yes, 1= No, 9999= Not assessed, 8888= Missing Data	Categorical	Nominal
PARTICIPANT	PARTICIPANT_NEW OR EXISTING	Patient new or patient is existing	0=new, 1=existing	Categorical	Nominal
Pre Intervention is BELOW and marked T1					
PORTAL	PORT_STAT_ T1	Portal Status Pre-Intervention	0= Active, 1=Inactive	Categorical	Nominal
MEDICAL	MEDS_T1	Number of medications prescribed for pain control on file	0-99, 9999= Not assessed, 8888= Missing Data	Numeric	Scale
PORTAL	PAIN_SCORE T1	Documented pain score in patients chart	0= yes, 1= no	Categorical	Nominal
PORTAL	MAPS_T1	PDMP completed with visit and scanned into chart	0=yes, 1=no	Categorical	Nominal
PORTAL	UDS_T1	UDS up to date in chart	0= yes, 1= no	Categorical	Nominal
PORTAL	EDUCATION_ T1	Signed education form on file	0=yes, 1=no	Categorical	Nominal
PORTAL	MEDICATION_	Medication	0=opioids only,	Categorical	Nominal

	CLASS_T1	classes	1=non-opioids only, 2= multimodal		
PORTAL	MEDICATION_ PRESCRIBED_ T1	Medication prescribed for pain control management	0=oxycodone-acetaminophin, 1=oxycodone, 2=oxycontin, 3= morphine, 4 =tramadol, 5=NSAIDS, 6=acetaminophen, 7=pregabalin/ Neurontin 8=Tri-cyclic antidepressants9 =SNRI, 10=Tylenol #3	Categorical	Nominal
PORTAL	CONTRACT_ T1	Pain contract	0=yes, 1=no	Categorical	Nominal
Post Intervention is BELOW and marked T2					
PORTAL	PORT_STAT_ T2	Portal Status Post-Intervention	0= Active, 1= Inactive	Categorical	Nominal
MEDICAL	MEDS_T2	Number of medications prescribed for pain control on file	0-99, 9999= Not assessed, 8888= Missing Data	Numeric	Scale
PORTAL	PAIN_SCORE_ T2	Documented pain score in patients chart	0= yes, 1= no	Categorical	Nominal
PORTAL	MAPS_T2	PDMP completed with visit and scanned into chart	0=yes, 1=no	Categorical	Nominal
PORTAL	UDS_T2	UDS up to date in chart	0= yes, 1= no	Categorical	Nominal
PORTAL	EDUCATION_ T2	Signed education form on file	0=yes, 1=no	Categorical	Nominal
PORTAL	MEDICATION_ CLASS_T2	Medication classes	0=opioids only, 1=non-opioids only, 2=	Categorical	Nominal

			multimodal		
PORTAL	MEDICATION_PRESCRIBED_T2	Medication prescribed for pain control management	0=hydrocodone-acetaminophen, 1=oxycodone, 2=oxycontin, 3=morphine, 4 =tramadol, 5=NSAIDS, 6=acetaminophen, 7=pregabalin/ Neurontin 8=Tri-cyclic antidepressants9 =SNRI, 10=Tylenol #3	Categorical	Nominal
PORTAL	CONTRACT_T2	Pain contract	0=yes, 1=no	Categorical	Nominal

Appendix F

IRB Approval



GRAND VALLEY STATE UNIVERSITY
www.gvsu.edu

DATE: January 02, 2019

TO: Dianne Conrad, DNP
FROM: HRRC
STUDY TITLE: Implementation of Evidence-based pain management medication protocol for primary care
REFERENCE #: 19-191-H
SUBMISSION TYPE: HRRC Research Determination Submission

ACTION: Not Research
EFFECTIVE DATE: January 02, 2019
REVIEW TYPE: Administrative Review

Thank you for your submission of materials for your planned scholarly activity. It has been determined that this project does not meet the definition of research* according to current federal regulations. The project, therefore, does not require further review and approval by the Human Research Review Committee (HRRC).

A summary of the reviewed project and determination is as follows:

The purpose of this project is to implement evidence-based pain management practices after development of a pain management medication protocol for a rural primary care practice. The evidence-based pain management medication protocol will be implemented and evaluated according to Michigan law and recommended Center for Disease Control Guidelines with the potential to reduce reliance on opioids for chronic non-malignant pain management in primary care. This project will utilize established guidelines to assist this medical practice with adherence to state law and opioid guidelines. This project is not designed to create new generalizable knowledge; therefore, it does not meet the federal definition of research. IRB oversight is not required.

An archived record of this determination form can be found in IRBManager from the Dashboard by clicking the "_ xForms" link under the "My Documents & Forms" menu.

If you have any questions, please contact the Office of Research Compliance and Integrity at (616) 331-3197 or rci@gvsu.edu. Please include your study title and study number in all correspondence with our office.

Sincerely,
Office of Research Compliance and Integrity

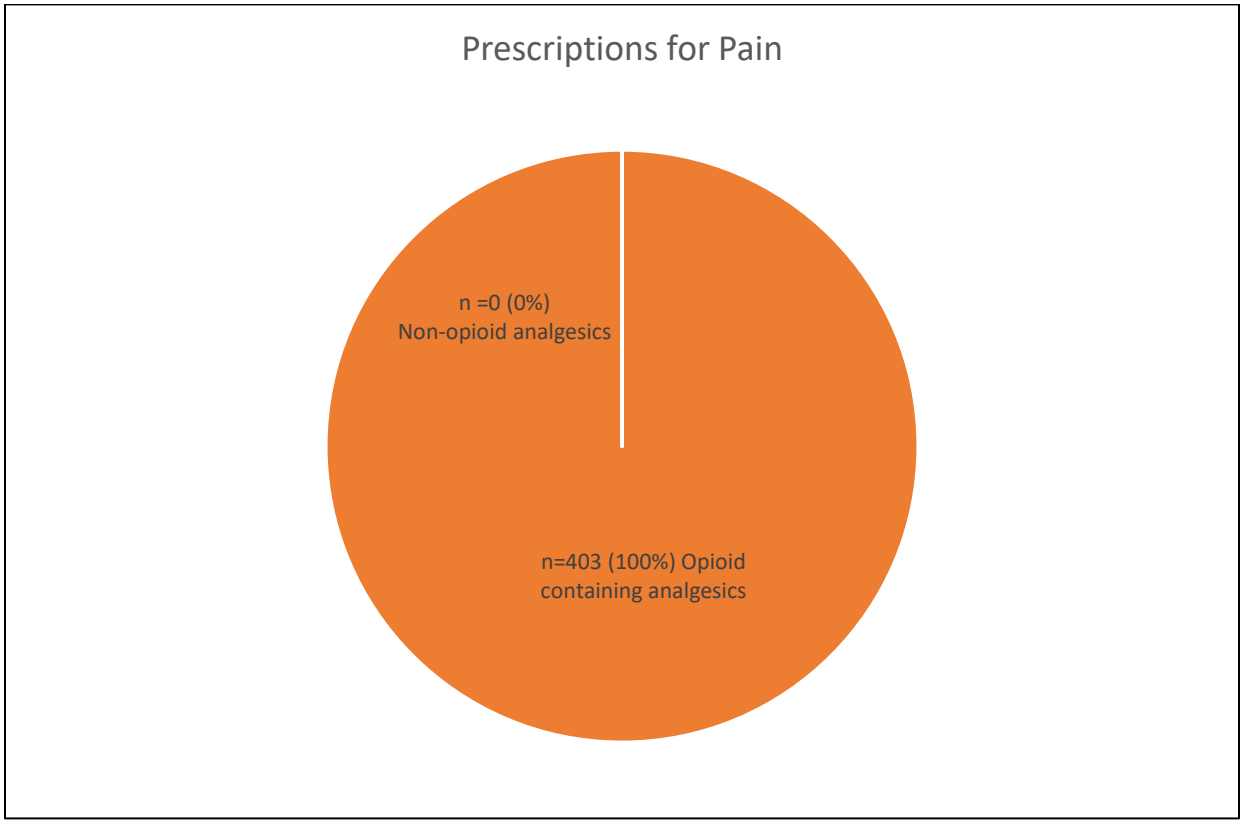
*Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102 (d)).

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains: data through intervention or interaction with the individual, or identifiable private information (45 CFR 46.102 (f)).

Office of Research Compliance and Integrity | 1 Campus Drive | 049 James H Zumberge Hall | Allendale, MI 49401
Ph 616.331.3197 | rci@gvsu.edu | www.gvsu.edu/rci

Appendix G

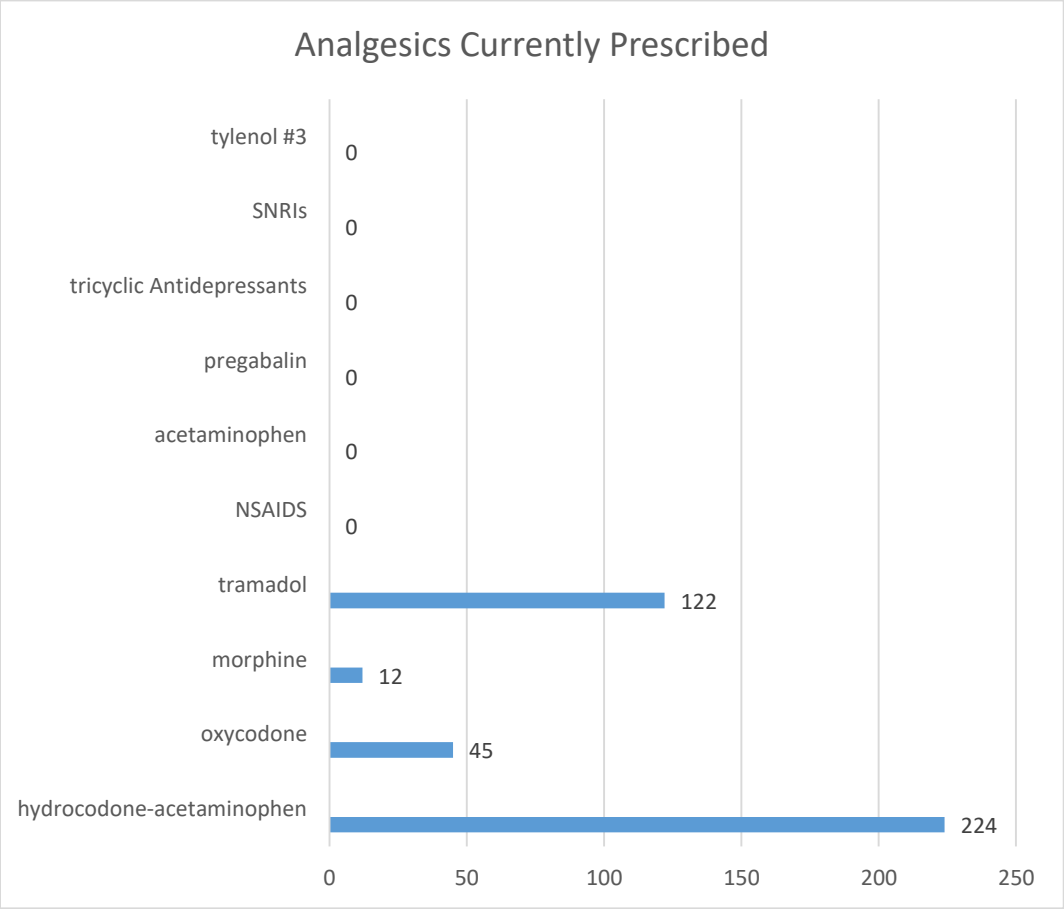
Pre-Intervention Opioid Prescribing in Clinic



Analysis of baseline opioid prescribing in primary care clinic. n = total patients in rural primary care practice from June 2016 to May 2018.

Appendix H

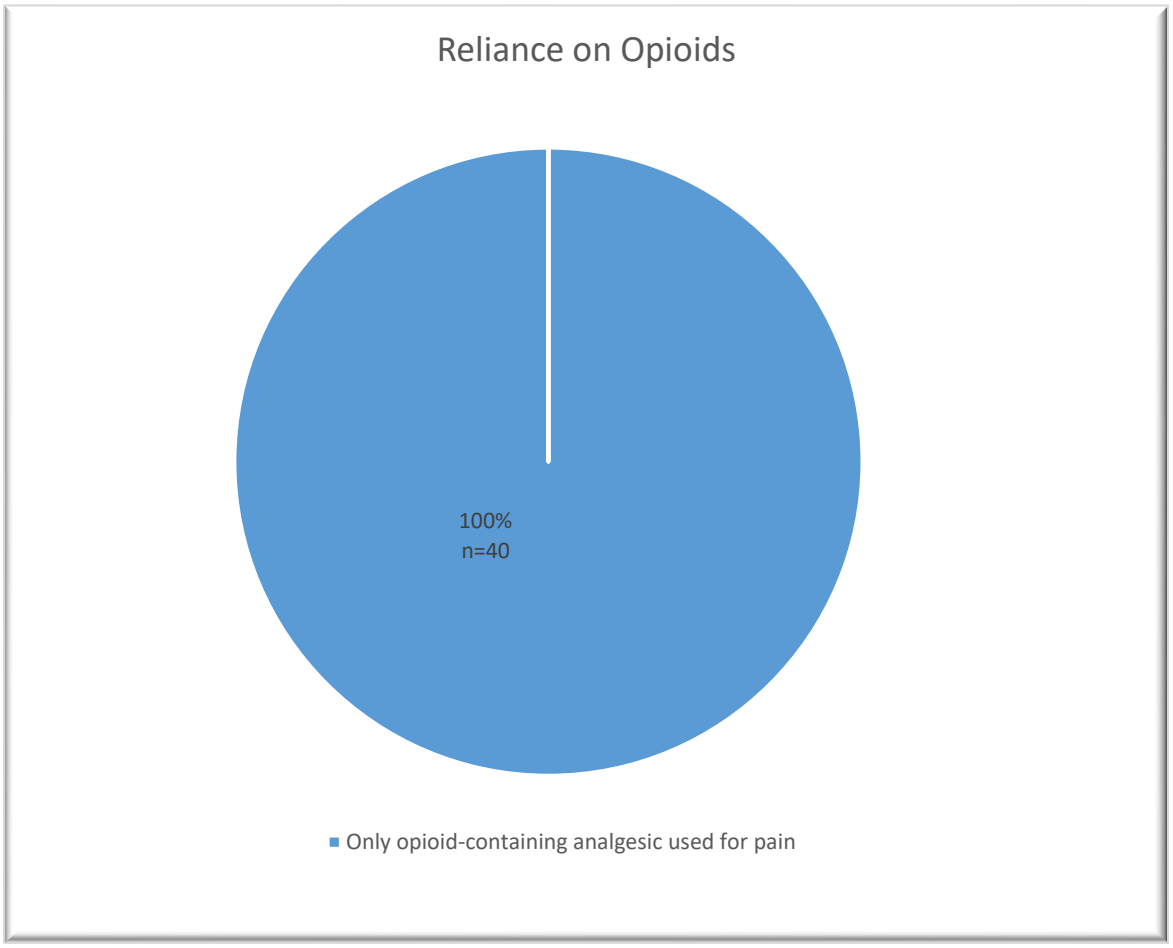
Prescription by Analgesic



Total number of prescriptions by analgesic in primary care clinic from June 2016 to May 2018.

Appendix I

Number of Sample Pre-Intervention Prescribed Opioids



Analysis of current state of opioid prescribing of sample of primary care clinic between June 2016 and May 2018.

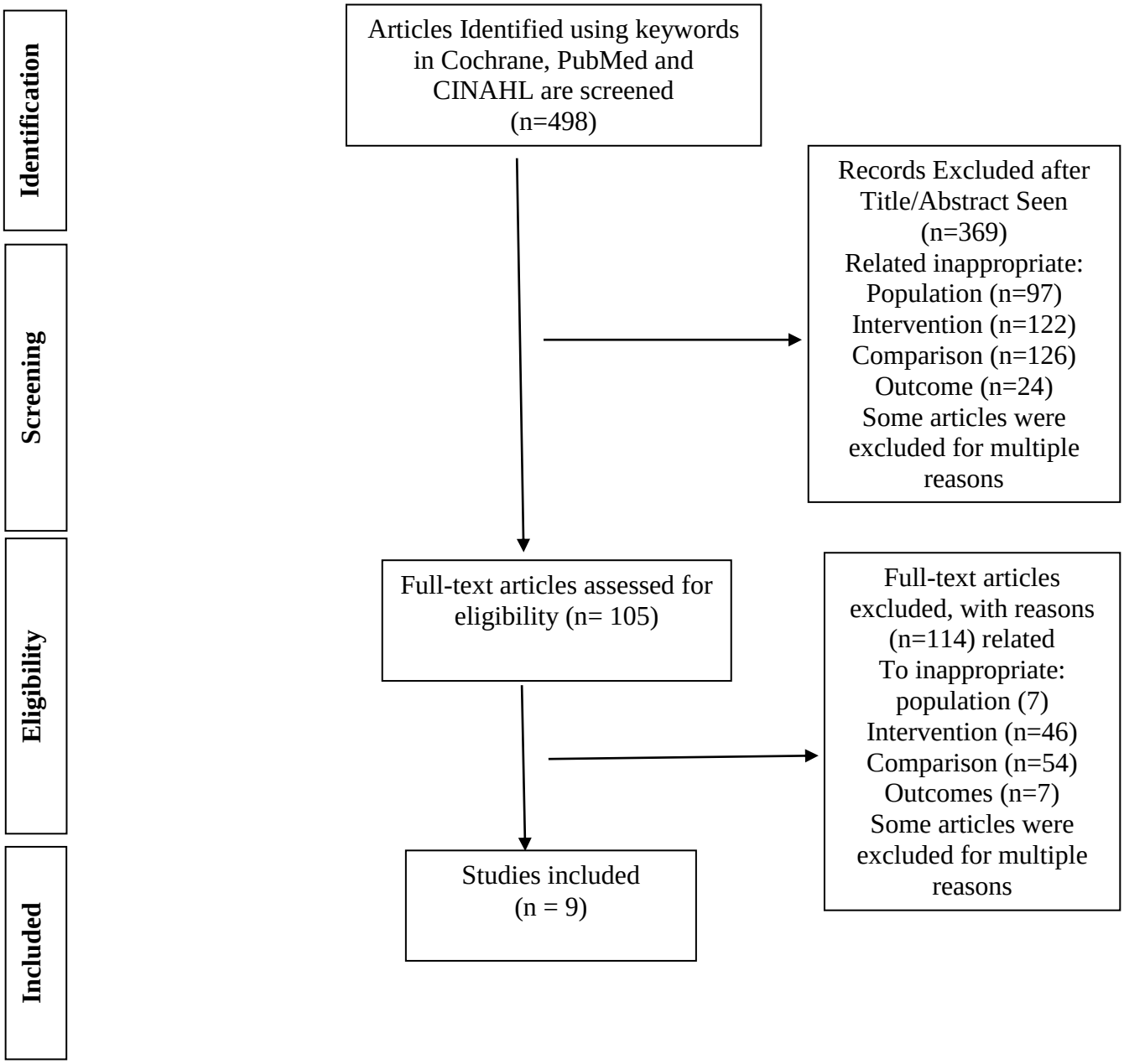
Appendix J

SWOT Analysis of the Clinic

Strengths	**Weaknesses**
Small family practice with only two providers promoting a consistent environment Private owned family practice promoting a family atmosphere Motivated leaders, management and staff that welcome process improvements	Current EHR does not have a pain management worksheet checklist and lacks reporting capabilities There is currently no pain management protocol in place Recommended evidenced-based guidelines for pain management are not being used With a small practice, consideration with additional workload will need addressed
Opportunities	**Threats**
Only independent clinic in several surrounding areas Could greatly contribute to the reduction in the opioid crisis Enhanced quality of care by implementing evidence-base pain management guidelines	Pain management related questions on patient surveys that influence reimbursement Patients disagreement with new pain management practices and decrease opioid prescriptions Potential for penalties for non-compliance with Michigan laws on opioid prescribing

Appendix K

PRISMA Flow Diagram of Systematic Search



Flow diagram of search selection process. Adapted from "Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement, "by D. Moher, A. Liberati, J. Tetzlaff, D. Altman, and PRISMA Group. Copyright 2008 by PLoS Medicine.

Appendix L

Table of Evidence

Author (Year) Purpose	Design (N)	Inclusion Criteria	Intervention vs. Comparison	Results	Conclusion
Anderson (2015) Effectiveness of an opioid dashboard in the EHR increasing adherence to practice guidelines	Pre and post implementation evaluation (N=1)	Multi-site Primary care clinics Patients ≥18 that use any individual or combination of non-liquid oral or transdermal opioid for 90 days or more	Implementation of an opioid dashboard in the EHR vs. no intervention	*Efficacy:* Post intervention 63% patients had an opioid treatment agreement increased from 49% Post intervention urine drug testing increased from 66% to 86% Patients with a completed pain functional assessment increased from 33% to 46% after 9 months of dashboard use Statistically significant decline in patients receiving opioid prescriptions decreased 12.5% (p=0.036) COT also declined from 130 (3.4%) to 1270 (3.1%) p =0.057	Implementation of an opioid dashboard in the EHR was effective in an increase in the use of opioid treatment agreements, urine drug testing, pain and functional assessments Limited studies are available and there is need for further studies

Chapparo (2012) Efficacy, tolerability, and safety of combination therapy for neuropathic pain	Double-blind RCT (N=2)	≥18 years old with neuropathic pain	Anticonvulsant + opioid compared to anticonvulsant alone	*Efficacy:* 2 studies found good/moderate pain relief for anticonvulsant + opioid (N=210) compared to anticonvulsant alone (N=213) (RR 1.30 [1.04, 1.161]; p =0.02) *Adverse Events:* 2 studies found participants dropped out due to adverse events at a higher rate with anticonvulsant + opioid (N=216) than anticonvulsant alone (N=217) (RR 2.76 [1.47, 5.21]; p=0.002)	Multimodal therapy is better for neuropathic pain than monotherapy but is associated with greater adverse events when combining opioid to anticonvulsant.
Chen (2016) Determine effectiveness of implementing opioid guidelines in primary care	A Stanford retrospective Pre and post intervention evaluation (N=1)	Primary care clinics who prescribe opioids with patients ≥18 receiving 3 or more opioid prescriptions during the evaluation period being considered chronic opioid users	Implementation of Opioid Risk Tool presented to clinic staff with a pre and post evaluation to identify changes in patient and provider behaviors vs. no tool	*Efficacy:* Post intervention found a 14% drop in patients receiving any opioid prescription (3.9% to 3.4%) p =0.02 and a 19% drop in chronic opioid patients from 2.0% to 1.6% (p=0.03) Chronic opioid urine drug screening increased 87% (9.2% to 17%) p=0.005	Dissemination of opioid guideline tools is associated with increase in urine toxicology screening and is feasible to reduce overall opioid prescription rates and increase provider compliance with opioid guidelines
Gatti (2009) Determine efficacy, adverse effects, quality of life,	open-label, prospective, multicenter comparison (N=1)	≥18 years old with moderate to severe chronic neuropathic	CR oxycodone + pregabalin compared to CR oxycodone and pregabalin alone	*Efficacy:* Study found mean reduction in pain score (score on 0-10 numerical rating scale) was significantly greater with	The combination of CR oxycodone and pregabalin was more effective in alleviating neuropathic pain,

and lowest effective dose of combination CR oxycodone and pregabalin for neuropathic pain		pain		combination therapy (80%) than with pregabalin (46%; p<0.003) or oxycodone CR monotherapy (76%; p<0.001) Study found patients receiving CR oxycodone + pregabalin were given on average 22% less CR oxycodone and 51% less pregabalin than the respective monotherapy groups The overall decrease in BPI scores at the end of treatment compared to baseline was 70.9% for CR oxycodone + pregabalin (p = 0.0009) vs. both monotherapies, 60.7% for CR oxycodone monotherapy, and 42.8% for pregabalin monotherapy *Adverse Effects:* The study of CR oxycodone + pregabalin, (45.1%) (N=10) produced less adverse events than CR oxycodone alone (N=11) (42.2%) 34.8% receiving pregabalin monotherapy reported no adverse events	improved quality of life and allowed for greater dose reduction compared to drug alone.
Khoromi (2007) Efficacy of combination therapy for	single-center four-period, crossover, randomized trial	18 years old to 65 years old in patients with chronic lumbar	morphine + nortriptyline compared to sustained-release morphine, nortriptyline and placebo alone	*Efficacy:* Study found that only the combination treatment was significantly better than placebo (p=0.04). The analysis of the	Study results suggest that opioids, tricyclic antidepressants, and combination may be ineffective in the

chronic lumbar radicular pain	(N=1)	radicular pain		first period data only for average back pain showed that treatment was significant in the overall model (p=0.005) *Adverse Event:* Study found morphine +nortriptyline produced less adverse events than morphine alone	treatment of lumbar radicular pain. These results stand in contrast to findings in painful diabetic neuropathy and post-herpetic neuralgia where TCAs and opioids have been repeatedly shown to be effective
Kreb (2018) Determine efficacy, functional response, quality of life and adverse events of opioid vs. non-opioid therapy for chronic back pain or hip/knee osteoarthritis	RCT with masked outcome assessment (N=1)	≥18 years with moderate to severe back pain or hip/knee osteoarthritic pain for 6 months or more	Opioid (morphine IR, morphine SR, transdermal fentanyl hydrocodone/acetaminophen and oxycodone) To Non-opioid (acetaminophen and NSAIDS) with adjuvant medications (nortriptyline, amitriptyline and gabapentin) or (pregabalin, duloxetine) and tramadol or topical analgesics (capsaicin, lidocaine)	*Efficacy:* Study found significant improvement in pain intensity in the non-opioid group (p=.03) (Mean BPI 3.5, SD 1.9) vs. opioid group (Mean BPI 4.0, SD 2.0) (95% CI) Study found ≥30% improvement in functional response (59% in opioid group, 60.7% in non-opioid group (95% CI, -14.4 to 11.0) p=.79 Study found that health related quality of life did not significantly differ between two groups *Adverse Events*: The study found that the opioid group had significantly more medication related adverse	Study results suggest that treatment with opioids was not superior to non-opioid treatment for moderate/severe choric back and hip/knee pain

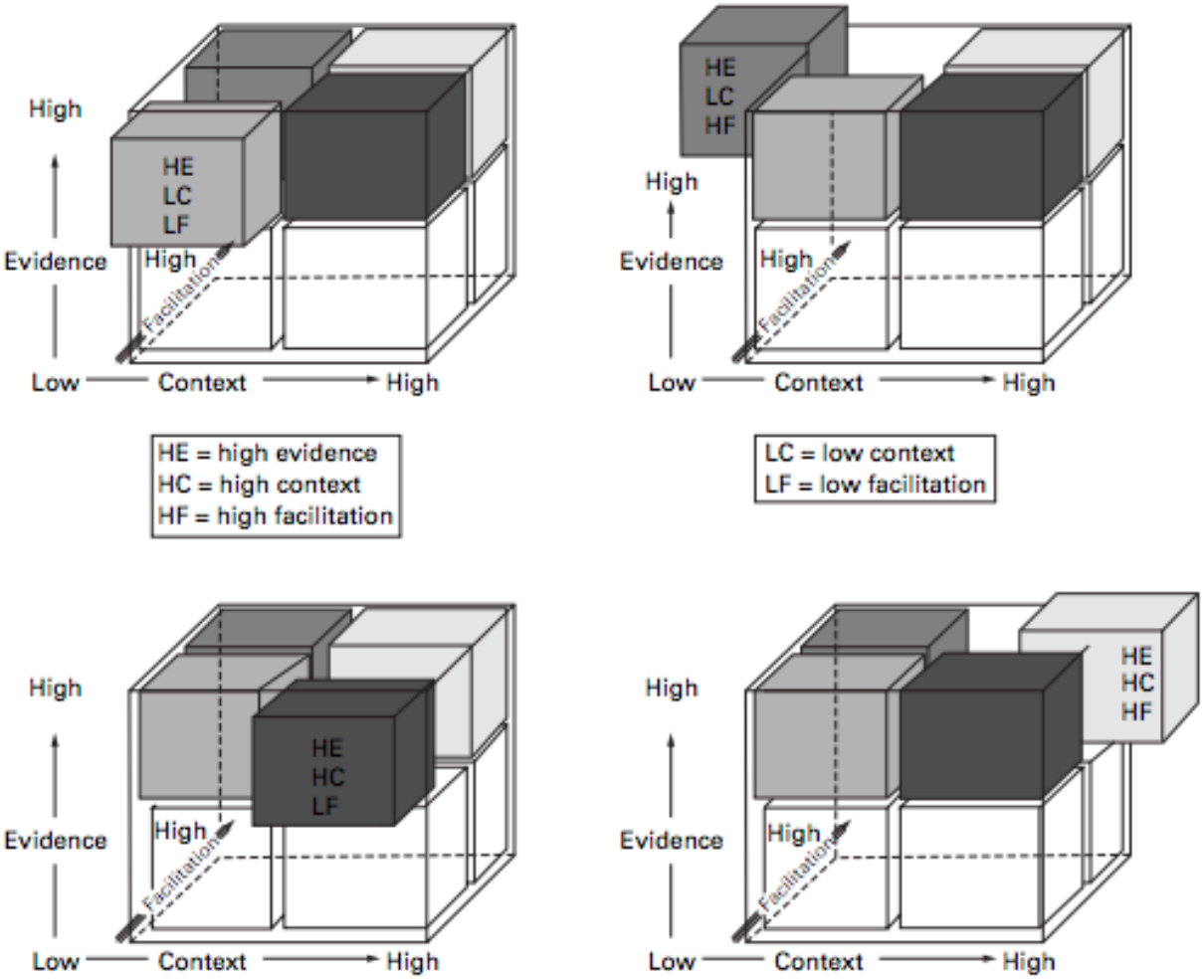
				events than non-opioid group (p=.9) (95% CI, 0.3to 1.5)	
Liebschutz (2017) Determine if an intervention TOPCARE improves guideline adherence while decreasing opioid misuse risk	Cluster RCT (N=1)	Primary care providers who had at least 4 patients ≥18 older being treated with long term opioid therapy (3 opioid prescriptions at least 21 days apart in a 6-month period	TOPCARE intervention vs. no intervention	*Efficacy:* Study found significant differences in all outcomes except early pill refills Intervention patients were more likely than control to have guideline concordant care (65.9% vs. 37.8%) p < .001, have an opioid agreement (65.9% vs. 6.0%) p<.001 and to undergo at least 1 UDT (74.6% vs. 57.9%) p<.001 Greater discontinuation of opioids in intervention vs. control (21.3% vs. 16.8%) p=.08 Intervention group was more likely than controls to have either a 10% dose reduction or opioid discontinuation (47.1% vs. 35%) p <.001	TOPCARE intervention tripled guideline concordant opioid monitoring
Romiro (2011) Determine benefits and safety of combination therapy for inflammatory	RCTs and Quasi-randomized controlled clinical trials (N=18)	≥18 years with inflammatory arthritis	At least 2 drugs: Acetaminophen, Opioids, NSAIDS, and Neuromodulators to monotherapy with one of the drugs	*Efficacy*: 2 studies found combination therapy reduces pain better compared to monotherapy; 1 study found high does NSAID was significantly better than low dose combination therapy	Evidence is limited to conclude combination therapy is better for inflammatory arthritis pain than monotherapy

arthritis				15 studies found no difference *Adverse Events*: 1 study found monotherapy had significantly more study withdrawals compared to combination therapy; 7 studies found no difference 1 study found combination therapy had more adverse events than monotherapy; 9 studies found no difference	
Romano (2009) Determine the efficacy and adverse effects of celecoxib with pregabalin for chronic low back pain	Prospective RCT (N=1)	≥18 years old with chronic low-back pain (symptoms duration: [6 months, mean: 13 ± 6 months) due to disc prolapse, lumbar spondylosis, and/or spinal stenosis;	Celecoxib + placebo to pregabalin + placebo to celecoxib + pregabalin.	*Efficacy:* Study found significant reduction in pain with patients with LANSS score <12 (N=20) with greatest pain reduction with patients with LANSS score >12 (N=16) Celecoxib + placebo (all patients, N = 36) (Mean 39.5, SD 12.2) p= 0.06 Celecoxib + placebo (LANSS <12, N = 20) (Mean 32.5, SD 15.5) p= 0.01 Celecoxib + placebo (LANSS >12, N = 16) (Mean 45.7, SD 14.3) p= 0.8 Pregabalin + placebo (N = 36) (Mean 43.1, SD. 13.5) p = 0.12 Pregabalin + placebo (LANSS<12, N = 20) (Mean 50.7, SD 13.8) p= 0.76	Combination of celecoxib and pregabalin provided better pain relief for chronic low back pain

				Pregabalin + placebo (LANSS>12, N = 16) (Mean 36.3, SD 12.7) p= 0.03 Celecoxib + pregabalin (all patients, N = 36) (Mean 28.6, SD 15.1) p= 0.0001 Celecoxib + pregabalin (LANSS <12, N = 20) (Mean 32.9, SD 13.9) p=0.009 Celecoxib + pregabalin (LANSS >12, N = 16) (Mean 23.1 SD 14.6) p=0.0001 *Adverse Events:* Study found participants dropped out due to adverse events at a higher rate with celecoxib + pregabalin (N=7) than celecoxib + placebo (N=4) and pregabalin + placebo (N=5)	

Appendix M

The PARiHS Framework



Implementation framework. Reprinted from "Enabling the implementation of evidence based practice: a conceptual framework," by A. Kitson, G. Harvey, & B. McCormack, 1998, *Quality in Health Care: QHC, 7*, p. 149-158. Copyright 1998 by Quality in Health Care.

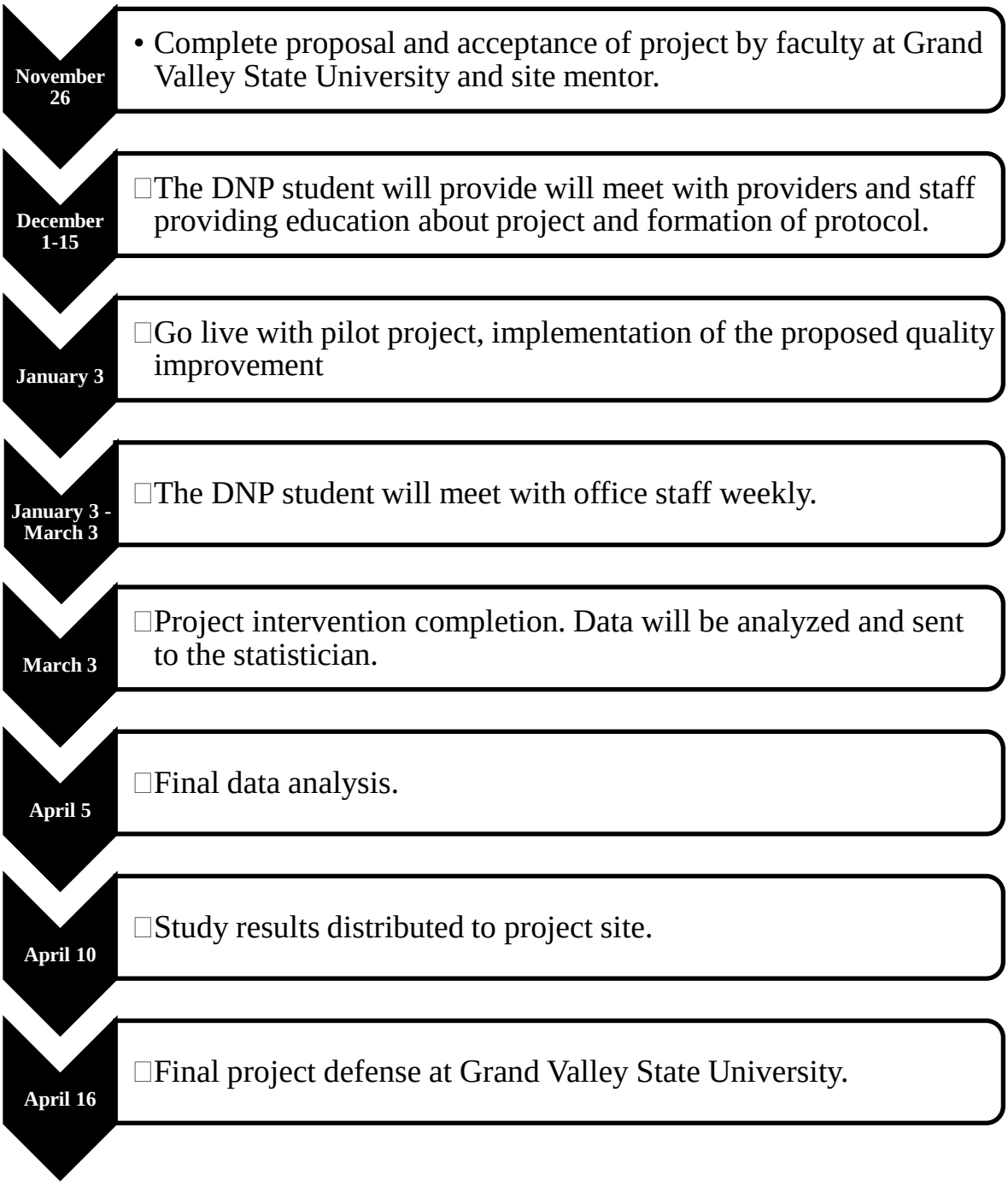
Appendix N

Kotter's Eight Step Change Model

Reprinted from Kotter, J. P. (1996). Why transformation efforts fail. *The Journal of Product Innovation Management, 2*, 170.

Appendix O

Project Timeline



Appendix P

Medication Algorithm

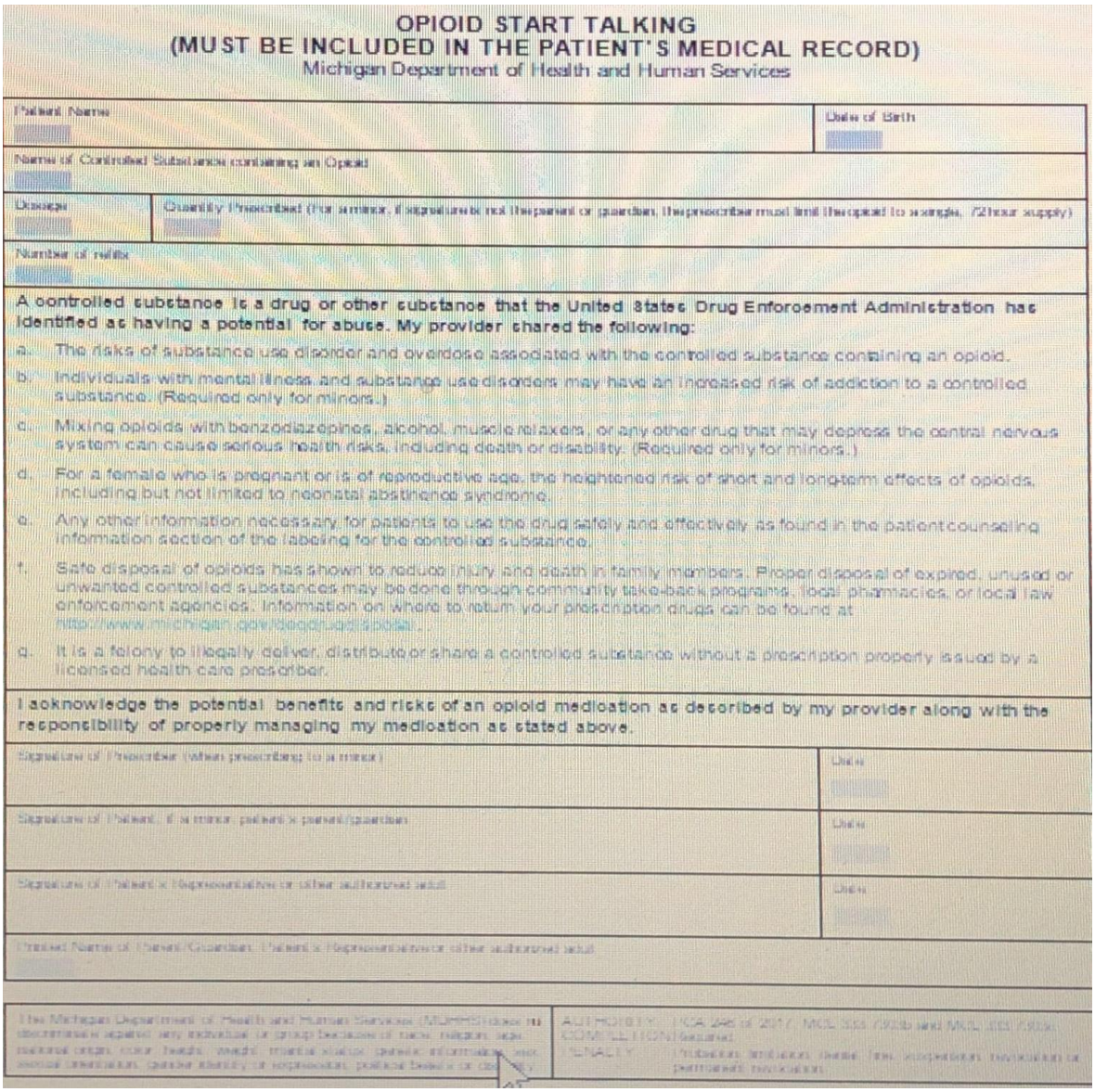
Pain Condition	First Line Pain Treatment	Later Line Pain Treatment
Osteoarthritis	NSAIDS (including Cox-2 inhibitors) Acetaminophen Hyaluronic acid Intraarticular injectable corticosteroids	Opioids (weak and strong)
Gout	Colchicine NSAIDs (including Cox-2 inhibitors) Oral corticosteroids	Adrenocorticotropic hormone
Fibromyalgia	Pregabalin and gabapentin	Opioids (weak and strong, except tramadol)
	SNRI's (all) TCAs (all)	Acetaminophen NSAIDs

Abbreviations: NSAIDS, non-steroidal anti-inflammatory drugs; SNRIs, serotonin-norepinephrine reuptake inhibitors; SSRIs, selective serotonin reuptake inhibitors; TCAs, tricyclic antidepressants

Margolis, J. M., Princic, N., Smith, D. M., Abraham, L., Cappelleri, J. C., Shah, S. N., & Park, P. W. (2017). Development of a novel algorithm to determine adherence to chronic pain treatment guidelines using administrative claims. *Journal of pain research, 10,* 327-339. doi:10.2147/JPR.S118248

Appendix Q

Opioid Start Talking Form



OPIOID START TALKING
(MUST BE INCLUDED IN THE PATIENT'S MEDICAL RECORD)
Michigan Department of Health and Human Services

Patient Name | Date of Birth

Name of Controlled Substance containing an Opioid

Dosage | Quantity Prescribed (For a minor, if signature is not the parent or guardian, the prescriber must limit the opioid to a single, 72-hour supply)

Number of refills

A controlled substance is a drug or other substance that the United States Drug Enforcement Administration has identified as having a potential for abuse. My provider shared the following:

a. The risks of substance use disorder and overdose associated with the controlled substance containing an opioid.

b. Individuals with mental illness and substance use disorders may have an increased risk of addiction to a controlled substance. (Required only for minors.)

c. Mixing opioids with benzodiazepines, alcohol, muscle relaxers, or any other drug that may depress the central nervous system can cause serious health risks, including death or disability. (Required only for minors.)

d. For a female who is pregnant or is of reproductive age, the heightened risk of short and long-term effects of opioids, including but not limited to neonatal abstinence syndrome.

e. Any other information necessary for patients to use the drug safely and effectively as found in the patient counseling information section of the labeling for the controlled substance.

f. Safe disposal of opioids has shown to reduce injury and death in family members. Proper disposal of expired, unused or unwanted controlled substances may be done through community take-back programs, local pharmacies, or local law enforcement agencies. Information on where to return your prescription drugs can be found at http://www.michigan.gov/opioid-safe-storage.

g. It is a felony to illegally deliver, distribute or share a controlled substance without a prescription properly issued by a licensed health care prescriber.

I acknowledge the potential benefits and risks of an opioid medication as described by my provider along with the responsibility of properly managing my medication as stated above.

Signature of Prescriber (when prescribing to a minor) | Date

Signature of Patient, if a minor patient's parent/guardian | Date

Signature of Patient's Representative or other authorized adult | Date

Printed Name of Parent/Guardian, Patient's Representative or other authorized adult

The Michigan Department of Health and Human Services (MDHHS) does not discriminate against any individual or group because of race, religion, age, national origin, color, height, weight, marital status, genetic information, sex, sexual orientation, gender identity or expression, political beliefs or disability.

AUTHORITY: [illegible] COMPLIANCE: [illegible] PENALTY: [illegible]

Appendix R

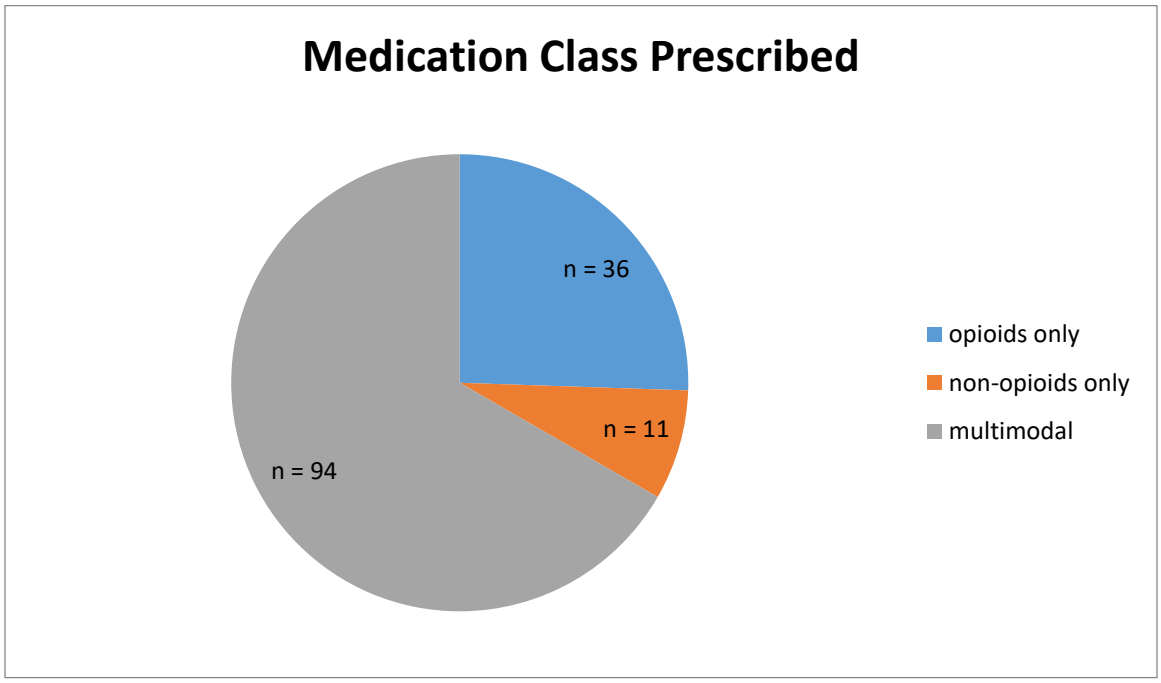
Budget for DNP Project

Initial Cost: Evidence-based Pain Management	
Transitioning focus from opioids to multimodal analgesia for pain management	
Revenue	
Project Manager Time (in-kind donation)	2,550.00
Team Member Time:	
Statistician (in-kind donation)	100.00
Potential cost mitigation 3.8-day Hospitalization (1-year period) (Prevention of 1 hospitalization and 1 ED visit related to opioid overdose per year)	29,497.00
PROJECTED TOTAL INCOME	32,147.00
Expenses	
Project Manager Time (in-kind donation)	2,550.00
Statistician (in-kind donation)	100.00
Team Member Time:	
MA's (extra time spent in staff meeting to be educated on pilot project)	6.35
Registered Nurses (extra time spent in staff meeting to be educated on pilot project)	7.50
Educate NP (time spent reading education on pilot project)	196.00
Educate Physicians (time spent reading education on pilot project)	360.00
Consultation with other primary care clinic to review practices(one-time cost occurrence)	120.00
Educational flyers, a professionally printed paper, whitepaper, and binder	100.00
TOTAL EXPENSES	3439.85

PROJECTED RETURN ON INVESTMENT	28,707.15

Appendix S

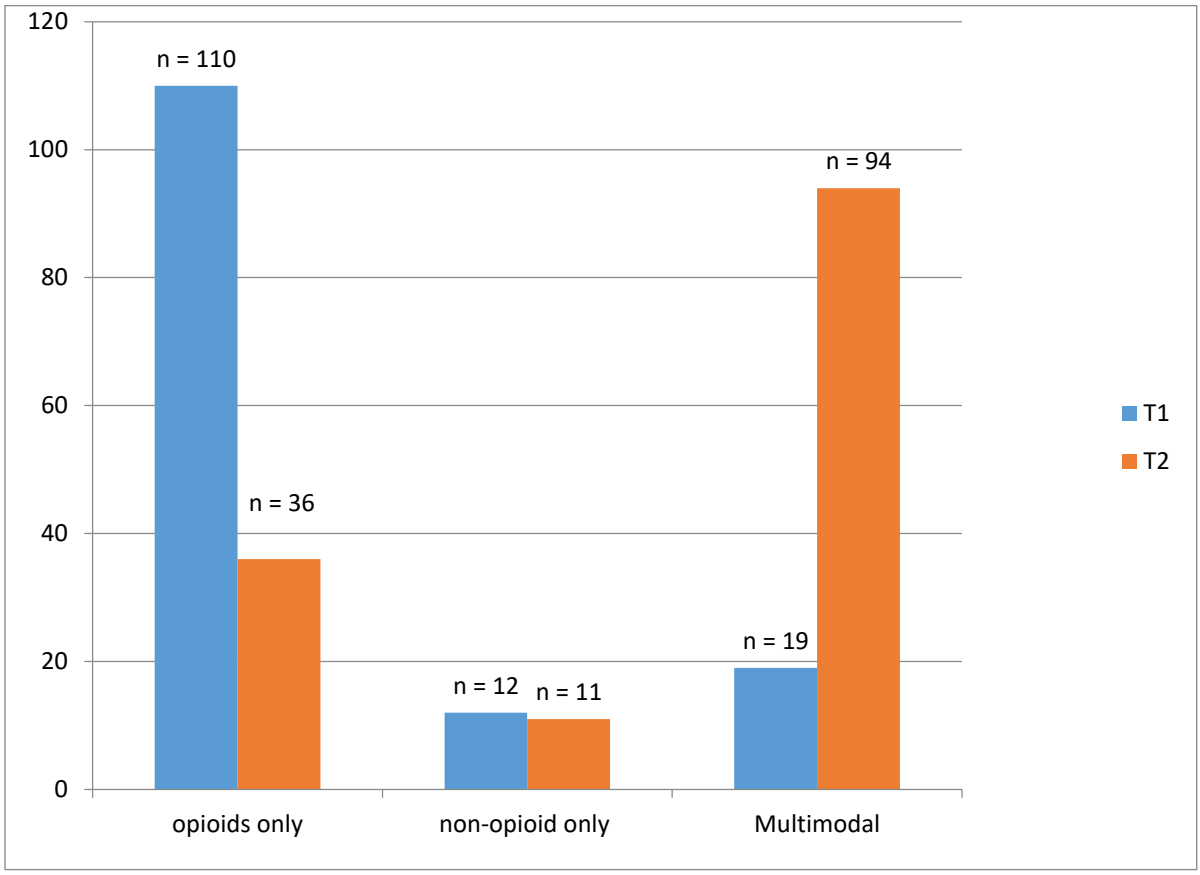
Post-Implementation Prescribing



Total post-implementation prescribing in primary care practice. (n = number of patients for each prescribing category) in pilot study from January 3, 2019 to March 3, 2019.

Appendix T

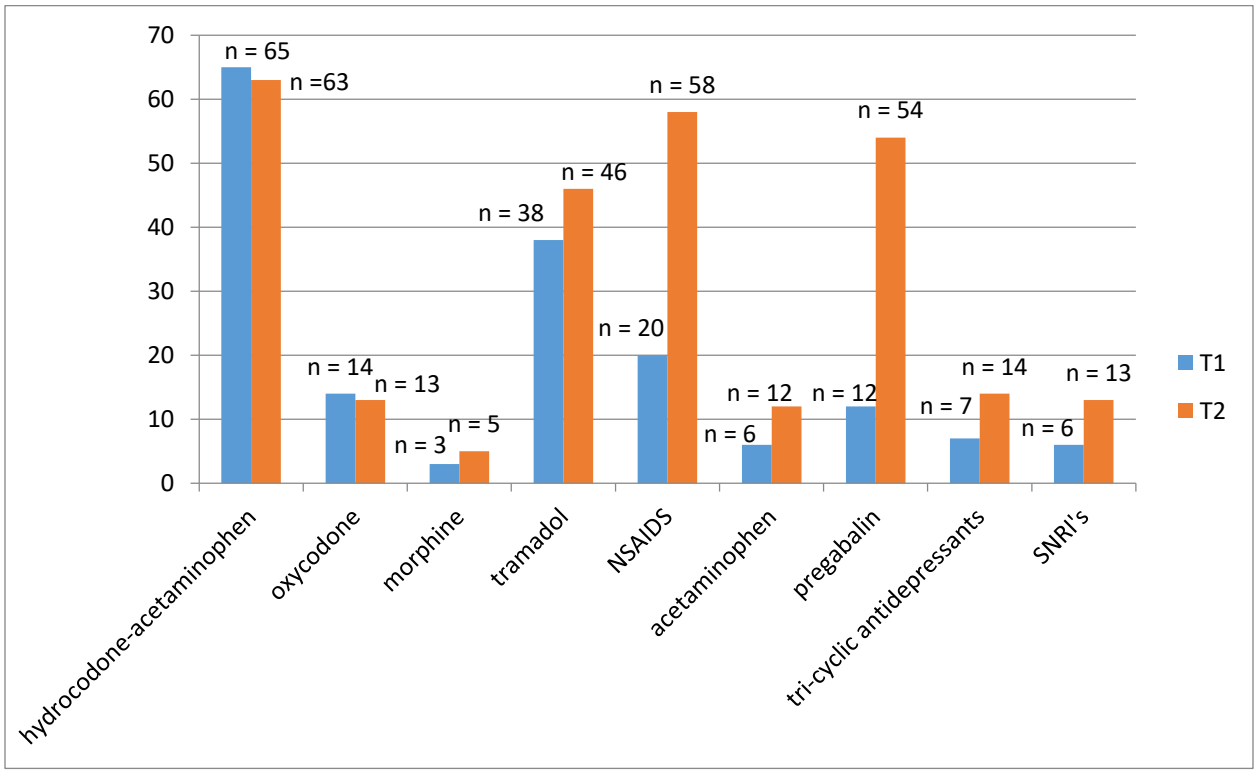
Post-Implementation Increase in Multi-modal Prescribing



Change in prescribing practice pre to post-implementation (n = number of patients for each prescribing practice).

Appendix U

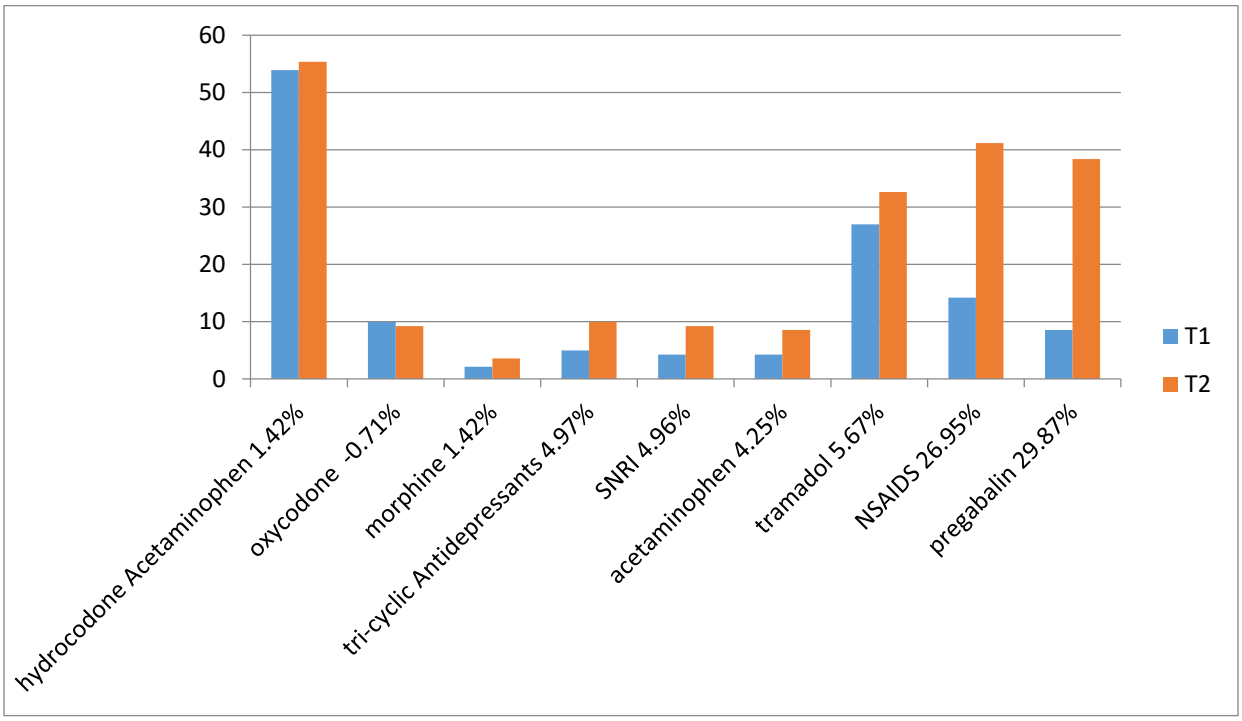
Change in Prescribing by Medication Class



Change in prescribing pre and post-implementation (n = number of patients prescribed a specific analgesic)

Appendix V

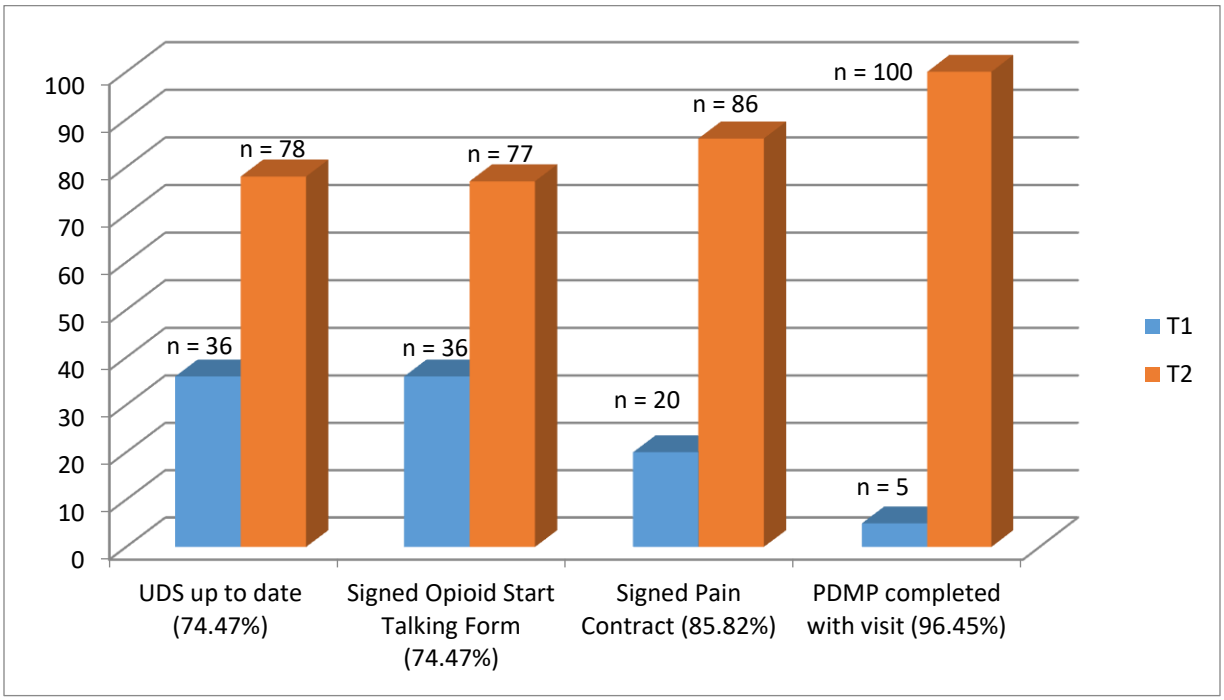
Post-Implementation Percentage Change in Prescribing by Class



Percentage change in prescribing practice by analgesic pre and post-implementation.

Appendix W

Post-Implementation Protocol Adherence



Change in protocol adherence pre and post-implementation for opioid prescribing laws

(n=number of patients adherent to protocol in T1 compared to T2)