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Implementation of an Evidenced-Based Intervention for Pain Management in Lumbar Spine Surgery

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Abstract

Introduction: Spinal surgeries are among the top procedures responsible for the highest degree of post-surgical pain. Opioids are the mainstay of current pain management practices in the post-operative period. In light of the opioid epidemic, increased opioid tolerance, and changes in legislation, there is a calling for alternative strategies in managing acute and chronic pain. The purpose of this project is to answer the following question: Does implementation of an evidence-based intervention for preoperative administration of gabapentin reduce patients' perception of pain and reduce opioid consumption in those who experience lumbar spine surgery?

Objectives: The goal of this project is to evaluate the impact of preoperative gabapentin on patient reported pain while reducing the number of opioids required post-operatively in lumbar spine surgery patients. Reduction in opioid requirements may limit side effects common to opioids including urinary retention, sedation, and nausea.

Methods: This quality improvement project was implemented with the neurosurgical team at a hospital in the Midwestern United States. Gabapentin was administered to patients who are gabapentin naïve approximately one hour prior to lumbar spine surgery. Patient reported pain, opioid use, length of stay, adverse effects, and readmissions were compared pre and post implementation to determine effectiveness of preoperative gabapentin administration.

Results: Expected results include improvement in patient perception of pain, reduction in opioid use, fewer adverse effects, shorter length of stay, and fewer readmissions for pain control.

Conclusions: Gabapentin may be effective in reducing patient perceptions of pain and opioid requirements following lumbar spine surgery. Further study with larger sample sizes are needed.

Implications: Gabapentin should continue to be administered preoperatively to patients prior to lumbar spine surgery to improve pain, reduce opioid requirements and improve post-operative adverse effects.

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Introduction

The use of opioid medications for acute and chronic pain management has grown exponentially in recent years, leading to unprecedented rates of substance abuse, overdose, and death (National Institute on Drug Abuse [NIDA], 2018). Currently this opioid epidemic results in an estimated 115 American deaths every day from opioid overdose, with prescription opioid misuse costing the United States 78.5 billion dollars each year on healthcare costs, loss of productivity, treatment for addiction, and criminal justice costs (NIDA, 2018). National attention has been brought to the opioid epidemic as medications such as hydrocodone, oxycodone, and morphine prescribed by healthcare providers for management of acute and chronic pain has led to misuse. Recent changes in legislation now limit prescribing of opioid medications in outpatient and inpatient settings. Restricting opioid prescribing will significantly impact how acute care providers manage post-operative acute pain.

Currently acute care hospitals are challenged in treating acute pain following surgical procedures for a multitude of reasons. Post-operative pain can be complicated by complex procedures, patient co-morbidities, and pre-existing opioid tolerance. Following neurological spine surgeries, it is common for patients to be discharged with a prescription for an opioid medication for acute pain (Kurd, Kreitz, Schroeder, & Vaccaro, 2017). Recent studies have

shown that 30-60% of patients continue to use opioids after the acute phase of healing following spine surgery (Deyo et al., 2018). The acute phase of healing lasts three to four months depending on evidence of bone healing on x-ray (North American Spine Society, 2018). Opioid use preoperatively is a major predictor of long-term post-operative opioid use with many patients requiring at least a 10% increase in dosage (Deyo et al., 2018). Opioid naïve patients are at substantial risk of becoming a long-term opioid user with more patients receiving long-term opioids after spine surgery than before surgery (Deyo et al., 2018). The cumulative dose of opioids prescribed in the first 30 days after surgery strongly predicts long-term post-operative opioid use (Deyo et al., 2018). Seeking alternative strategies to manage acute post-operative pain is essential.

Spine surgeries are among the top six procedures responsible for the highest degree of post-surgical pain (Bajwa & Haldar, 2015). Approximately up to 50% of patients experience inadequate pain control leading to dissatisfaction and poor mobility, while almost 25% are given excessive opioids resulting in suboptimal outcomes and adverse events (Rivkin & Rivkin, 2014). The inflammatory cascade and resulting post-operative pain begin before the patient wakes up from surgery (Rivkin & Rivkin, 2014). Therefore, strategies in managing acute post-operative pain should be implemented prior to the onset of the activation of these various pain mechanisms. Pre-emptive analgesia can be defined as administration of pain medication in the perioperative period with the purpose of providing a preventive effect against pain via inhibition of central autonomic activity (Devin & McGirt, 2015). Effective perioperative pain control is associated with improved surgical outcomes, reduced hospital length of stay, and decreased development of new chronic pain conditions (Devin & McGirt, 2015).

Opiate pain medications have been the mainstay of treatment for post-operative pain in

spinal surgery. Although effective for acute pain, opioid use has shown to prolong hospital length of stay related to side effects including respiratory depression, sedation, post-operative nausea and vomiting, urinary retention, and ileus (Tan, Law, & Gan, 2015). Adverse events related to opioid use also drives up medical costs and increases readmission rates (Tan et al., 2015). In fact, inadequate pain control is the second most common reason for 30-day readmissions following lumbar spine surgery (Kurd et al., 2017). Adequately managed pain improves functional outcomes, leads to early ambulation, early discharge, and prevents the development of chronic pain (Bajwa & Haldar, 2015). Unfortunately, treatment strategies in this patient population are complex, as many already suffer from pre-existing chronic pain with long term consumption of analgesics and opioids, altering pain perceptions in these patients (Bajwa & Haldar, 2015).

Over the past decade, multimodal approaches to post-operative pain management have been investigated. Use of opiate pain medication is effective in initially controlling acute pain, but subsequent tolerance and a reduction in pain threshold develop rapidly resulting in an opioid-induced hyperalgesia (Tan et al., 2015). This hypersensitivity to pain and tolerance to medications requires even higher doses of opiate medications, worsening the potential for adverse effects from opioid use and further increases sensitivity to pain. Enhanced Recovery After Surgery (ERAS) programs have been developed to address factors that delay post-operative recovery and prolong hospital stay, including pain management (Tan et al., 2015). Research in this area has shown that multimodal analgesia, using more than one analgesic modality, is effective in achieving pain control while limiting opioid-related side effects (Tan et al., 2015). In spine surgeries, ERAS multimodal nonopioid analgesics used in the perioperative stage include various combinations of medications including gabapentin, pregabalin,

acetaminophen, dexamethasone, ketamine, and nonsteroidal anti-inflammatory drugs (Rivkin & Rivkin, 2014). These medications, used pre-emptively, act to inhibit central autonomic hyperactivity, thus preventing pain (Ali et al., 2018). Because standard ERAS protocols for pre-emptive analgesia are multimodal, it is difficult to determine the benefits and adverse effects for each combination of medicines used (Tan et al., 2015).

Gabapentin is a second-generation anticonvulsant medication used to treat chronic neuropathic pain by binding to the α-2-δ subunit of N-type voltage-gated calcium channels to inhibit neurotransmitter release and reduce neuronal excitability while sparing normal physiologic pain transmission (Devin & McGirt, 2015). The effect of gabapentin is most pronounced after nerve or tissue injury (Devin & McGirt, 2015). Common side effects of gabapentin include dizziness, somnolence, fatigue, and ataxia (Epocrates, 2018). Contraindications include hypersensitivity to gabapentin, renal impairment, and alcohol or drug abuse (Epocrates, 2018). Drug interactions may occur with other central nervous system depressant medications resulting in an enhanced effect (Epocrates, 2018). Preoperative gabapentin has been integrated into ERAS programs as one intervention within the multimodal approach to improve pain control and limit reliance on opioid use. Pre-emptive multimodal analgesia including gabapentin has demonstrated improvement in acute post-operative pain, activity, depression and anxiety, and self-care while reducing opioid use at two weeks following surgery (Ali et al., 2018). The purpose of this quality improvement project is to implement an evidence-based intervention utilizing preoperative gabapentin that has shown to reduce opioid consumption and improve patients' perception of pain in the first 24 hours post lumbar spine surgery. Effective quality improvement is best achieved if organizational context are considered, therefore, in the next section an assessment of the organization is discussed.

Assessment of the Organization

An organizational assessment is a systematic process for evaluating the current state of an organization regarding performance, and the factors that affect that performance (Better Evaluation, 2018). The goal is to identify risks and challenges faced by the organization that impacts their future success and performance (Universalia, 2018). The purpose of this organizational assessment is to examine the current state of a West Michigan neurosurgery program. The focus of this organizational assessment is to analyze the present pain management strategies of the neurosurgery program, identify if a gap exists within the organization, present data supporting the need for evidence-based practice change, and state the clinical problem identified. Information was gathered utilizing an organizational framework and SWOT analysis tool to ensure a comprehensive assessment was completed. The Institutional and Organizational Assessment Model (IOA Model) was used to conduct the organizational assessment of the neuroscience program (see Appendix A, figure 1).

Framework for Assessment

The IOA Model analyzes organizational performance by examining the macro and micro underlying forces that drive the organization's performance including four components: external environment, motivation, and capacity (Universalia, 2018). The approach to the IOA Model further identifies factors within external environment, motivation, and capacity that impact the overall performance of the organization (Universalia, 2018). Each of these components are affected by each other, as a change in one area will impact the overall organizational performance.

External Environment. The external environment has had significant influence over the neurosurgery program at the macro-level in the past year. Like the remainder of the U.S., in the

midwestern United States, opioid overdoses increased by 70% from July 2016 through September 2017 (NIDA, 2018). In response to this epidemic, Michigan Lieutenant Governor Brian Calley signed legislation to combat opioid misuse and prevent addiction. As part of that legislation, starting July 1, 2018, Public Act 251 limits the supply of an opioid prescription that can be prescribed for acute pain to seven days (State of Michigan, 2017). Current practice at this organization is to routinely prescribe an opiate and a benzodiazepine for longer than one week at discharge from the hospital (X. XXXX, personal communication, May 25, 2018). In fact, the clinic nurses (personal communication, May 25, 2018) report requesting physician assistants to refill prescriptions for up to eight to ten weeks post lumbar fusion surgery. Some insurance companies are also limiting the prescribing of opioid medications to one week, or 60 pills/month (X. XXXX, personal communication, May 25, 2018). For example, Priority Health (2018) has a quantity limit on short acting hydromorphone of 64 mg but does not limit quantities for hydrocodone or oxycodone. Blue Cross Blue Shield of Michigan (2018) limits short acting hydrocodone, hydromorphone, oxycodone, and codeine to a five-day supply for the first prescription, then 30 days for subsequent refills. Medicare and Medicaid requirements on opioid prescribing vary depending on the provider and have similar restrictions. The State of Michigan (2017) also requires the provider to review the Michigan Automated Prescription System (MAPS) on every patient prior to prescribing opioids and at each refill, allowing a seven-day supply at a time for acute pain. Physician assistants and nurses in the outpatient neurosurgery clinic have reported increased workload, reduced efficiency, disruption in workflow, and delayed approval for prescription refills for patients (X. XXXX, personal communication, May 25, 2018). This recent change in the external environment has had direct impact on the practices in pain management from the neurosurgery program, but conversely benefits patients from the

adverse effects of opioid misuse such as somnolence, confusion, urinary retention, ileus, respiratory depression and death (Devin & McGirt, 2015). Striving for improvement of health outcomes for spinal surgery patients is the driving motivator for change.

Motivation. The motivations that drive the neurosurgery program are consistent with the core values of the whole organization. The acute care hospital is a non-profit, faith-based health care system that is a part of one of the largest multi-institutional health care delivery systems in the United States (XXXXX XXXXXX, 2018c). Core values of the organization include reverence (honoring the sacredness and dignity of each person), commitment to those who are poor (serve those who are poor, especially the most vulnerable), justice (foster relationships to promote the common good), stewardship (being accountable for the human, financial and natural resources entrusted to our care), and integrity (faithful to who we say we are) (XXXXX XXXXXX, 2018c). Guiding behaviors are reviewed at the beginning of each meeting within the entire organization to remind the participants of the culture of the organization, and the purpose of their work. The guiding behaviors include: "We support each other in serving our patients and communities; we communicate openly, honestly, respectfully, and directly; we are fully present; we are all accountable; we trust and assume goodness in intentions, we are continuous learners" (XXXXX XXXXXX, 2018c). Following these guiding behaviors is observed in this organization daily not only during department meetings, but also in collaborating with other departments, casual conversations, and while delivering patient care. As a Magnet® designated hospital, shared decision making is common practice evidenced by various nurse led committees resulting in changes utilizing evidence-based practice. An example includes initiating cryocuff use for lumbar spine surgery patients post-operatively while hospitalized and allowing patients to take the cryocuff home at discharge for continued use. Annual culture of safety scores obtained via

the Press Ganey Agency for Healthcare Research and Quality (2018) survey reveal that staff are content with their employment based on the overall culture of the organization to treat colleagues and patients respectfully, and to do good for the health of the community.

Capacity. At the micro-level, the neurosurgery program has a solid organizational structure in place. Department meetings, referred to as 'Spine Team', occur monthly and are interdisciplinary consisting of leadership, neurosurgeons, physician assistants, registered nurses, dietician, case managers, physical therapists, infection control, and pharmacists. At these meetings, collected data is presented that tracks various indicators including number of surgeries, infection rates, length of stay, readmissions, and complications. Further, the neurosurgery program is a part of the Michigan Spine Surgery Improvement Collaborative (MSSIC). MSSIC (2014) is a state-wide quality improvement collaborative of neurosurgeons and orthopedic surgeons dedicated to improving quality of care and efficiency of treatment to better patient care outcomes in spine surgery. Goals of MSSIC are to improve patient outcomes, reduce costs and episodes of care, reduce complications, and minimize the rate of repeat surgeries (MSSIC, 2014). Twenty-six Michigan hospitals are currently involved in the MSSIC project (MSSIC, 2014). MSSIC is funded by Blue Cross Blue Shield of Michigan/Blue Care Network and tracks patients who have cervical or lumbar surgeries before surgery and at 90 days, 12 months, and 24 months in a patient registry (XXXXX XXXXXX, 2018b). Quarterly state-wide meetings are held to discuss data findings and share strategies to improve outcomes across the hospitals (X. XXXX, personal communication, May 31, 2018). Data collected is vast, consisting of complications, opioid use, mobility, pre-existing conditions, etc. (X. XXXXX, personal communication, June 5, 2018). The data gathered is analyzed to see where improvements can be made to enhance patient outcomes, reduce complications and costs, and improve quality of care (XXXXX XXXXXX,

2018b).

The neurosurgery program collaborates well with other departments including anesthesia, internal medicine, and palliative care. For patients with complex pain syndromes, palliative care assists in pain medication management post-operatively. Complex pain syndromes are usually seen in patients who were taking opioid pain medications prior to surgery. Chronic neuropathic pain exacerbated by an acute surgical procedure often requires high doses of opioid medication that are challenging to wean. Uncontrolled pain has been a complication that has prolonged length of stay in the organization. Impaired mobility related to pain can lead to poor patient outcomes and increases length of stay with a potential discharge to a rehabilitation center prior to going home, causing higher healthcare costs. Longer length of stay has a negative impact on hospital reimbursement from bundle payments. The palliative care team is helpful in alleviating uncontrolled pain through daily consultation while the patient is hospitalized and provides a pain plan and prescriptions upon discharge.

In January 2018, the neurosurgery program formed a subcommittee from Spine Team to develop a neurological Enhanced Recovery after Surgery (ERAS) program. Mirrored after the successful colorectal ERAS program, the neurological ERAS subcommittee is conducting a deep dive investigation into how the neurosurgery program can continue to improve the care and outcomes for their patients. The subcommittee is looking at best evidence to optimize patient health before surgery, new strategies for intra-operative, and post-operative care. The ERAS is looking at using Lean® processes with evidence-based practice change to provide excellent care, enhance the patient experience, and improve outcomes.

Overall Performance. The neurosurgery program is a designated Spine Center of Excellence by Blue Cross Blue Shield and Priority Health that recognizes the program's

expertise and efficiency in delivering spine care (XXXXX XXXXXX, 2018d). Neurosurgical procedures help maintain the financial viability of the organization through bundle payments from insurance companies (X. XXXX, personal communication, May 31, 2018). There are also financial incentives through MSSIC via pay for performance; if the neurosurgery program shows improvement in outcome data, the hospital will be reimbursed accordingly (X. XXXX, personal communication, May 31, 2018). According to the MSSIC data registry, the organization is among the top-ranking hospitals when compared to other Michigan hospitals (X. XXXX, personal communication, May 31, 2018). Although the neurosurgery program has performed well, there are always ways to improve outcomes, and the team is continuously striving to advance care.

Ethics and Protection of Human Subjects

An application for review and approval or exemption of this project was submitted to the organization and to Grand Valley State University's Institutional Review Board (IRB). Beyond further planning, no project activities commenced until the review was completed and Board approval or exemption was granted. The purpose and scope this project are limited to evidence-based practice improvement and quality improvement. Health Insurance Portability and Accountability Act (HIPPA) privacy rules were upheld. No patient identifiable information was collected. No physical, social, psychological, legal, or economic threats to patients are associated with this project. The impact of the project posed minimal or no risk to participants. All members of the team completed human subject's protection training via the Collaborate Institute Training Initiative (CITI) and their interactions with patients were guided accordingly.

Stakeholders

Identifying key stakeholders is imperative when completing an evidence-based practice

change. A key stakeholder includes any person or persons who are critical to creating and implementing a practice change, or who will be significantly affected by the practice change (Hockenberry, Brown, & Rodgers, 2015). For assessing pain management in the neurosurgery program, key stakeholders include healthcare providers (neurosurgeons, physician assistants), registered nurses (inpatient and outpatient), pharmacists, neuroscience leadership (clinical nurse specialist, performance improvement coordinator, neuroscience program manager), and patients. The neurosurgeons must concede to the practice change and prescribe the medication, registered nurses administer the medications and document pain scores/effectiveness of medications, pharmacists assist in proper dosing and timing of medications, and the leadership team helps collect and interpret data and provides progress reports presented at monthly Spine Team meetings. Patients receive the medication for their pain and report its effectiveness. All key stakeholders are essential to success of a practice change.

Strengths Weaknesses Opportunities and Threats Analysis

Imperative to any organizational assessment is a strength, weakness, opportunity, and threat (SWOT) analysis. A SWOT analysis is another way to identify an organization's internal strengths and weaknesses, examine opportunities for growth, and determine threats from the external environment (Harrison, 2010). Figure 2 in Appendix B shows the outcomes of the SWOT analysis completed for the neurosurgery program and is explained below.

Strengths. Strengths are current factors that have generated exceptional organizational performance (Harrison, 2010). For the neurosurgery program, the structure of the program is already set up for process change, and tracking outcomes. Through Spine Team collaboration with other departments, and participating in MSSIC, the neurosurgery department demonstrates commitment to improving care of spine patients. Regarding pain management, the surgeons and

physician assistants have communicated recognition of the opioid epidemic and verbalize openness to evidence-based practice change in managing pain at department meetings. Palliative care consultation has been utilized as needed during inpatient hospitalizations.

Weaknesses. Factors that potentially increase healthcare costs and reduce quality of health care are considered weaknesses (Harrison, 2010). The neurosurgery team struggles with managing acute pain in spine surgery patients, leading to high utilization of opioid medications. Unfortunately, the palliative care team does not continue to follow patients after discharge from the hospital after prescribing them opioid medications while hospitalized. There are also many instances that patients require a longer length of stay due to uncontrolled pain, or due to poor mobility related to inadequate pain control. This, in turn, affects the financial viability of the hospital due to less income generated from bundle payments. Transfer to a rehabilitation center at discharge increases overall healthcare costs for the patient.

Opportunities. Opportunities are described as new initiatives available to the health organization such as collaborative networking and developing new healthcare programs or protocols to improve quality and efficiency (Harrison, 2010). An opportunity for the neurosurgery team is the recent development of the ERAS subcommittee. Since the colorectal ERAS has been successful, it gives the neurosurgery program guidance into developing their own program. There is opportunity within the ERAS to consider evidence-based practice change of pain management strategies. With recent changes in Michigan legislation surrounding opioid prescribing, there is opportunity to explore non-opioid interventions for pain management. Patients will benefit by improved pain control in the acute phase of recovery leading to early mobility and reduced post-operative complications related to uncontrolled pain and immobility. The patient will report a better surgical experience and hospital stay, increasing patient

satisfaction rates.

Threats. Factors that could negatively affect organizational performance are considered threats (Harrison, 2010). One major threat in acute post-operative pain management in spine surgery patients is the presence of chronic pain. Often patients are already on high doses of opioid medications prior to surgery, which makes opioid weaning difficult. In particular, neuropathic pain is common in spine surgery patients and is one of the most challenging types of pain to control. Longer length of stay due to pain management leads to lost revenue for the hospital. Threats to the neurosurgery program due to the recent legislative changes in opioid prescribing include mandatory MAPS review prior to each prescription refill, and only allowing refills for one week at a time. This is not time efficient for the physician assistants, causes delays for patients receiving refills, and also affects efficiency of clinic and surgical work flow.

Clinical Practice Question

Accordingly, an evidence-based project to answer the following clinical practice questions are proposed:

1. Does implementation of an evidence-based intervention for preoperative administration of gabapentin reduce opioid consumption among persons undergoing lumbar spine surgery for up to 24 hours post-operatively?
2. Does implementation of an evidence-based intervention for preoperative administration of gabapentin improve patient's perception of pain among persons undergoing lumbar spine surgery for up to 24 hours post-operatively?
3. Does implementation of an evidence-based intervention for preoperative administration of gabapentin reduce length of stay among persons undergoing lumbar spinal surgery?

Review of the Literature

A review of the literature was conducted to examine the current evidence to support the clinical practice questions. The formal appraisal of the literature and findings of the review are discussed.

Method

The Preferred Reporting Items for Systematic 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 CINAHL database, PubMed, and Web of Science and was limited to reviews in the English language during the period of 2013 to 2018. Keywords were gabapentin, spin*, preoperative, preventive, and pre-emptive. Similar search terms preoperative, preventive, and pre-emptive were listed by using Boolean operator OR, and the Boolean operator AND was used to narrow articles that are relevant to the review. Spin* (wild card) was used to include words such as spine and spinal.

Inclusion/Exclusion Criteria. Included were articles that featured adults age 18 or older who underwent any type of lumbar spine surgery such as laminectomy, discectomy, lumbar fusion, etc. Articles that included any other surgical procedure or trauma related spine surgery were excluded. Studies that involved preoperative administration of gabapentin as a solo intervention were included. Those that did not give gabapentin as a pre-emptive medication were excluded. Only meta-analysis and systematic reviews were included. Randomized controlled trials were excluded from this review. Articles that were chosen for this review compared preoperative gabapentin administration to placebo. One article contained a comparison of gabapentin versus pregabalin versus placebo. This article was included in this literature review to compare gabapentin to placebo and the pregabalin data was not used. Data on pregabalin is outside the scope of this review. Included were outcomes on the efficacy of gabapentin in

reducing pain scores, reducing opioid consumption, and reported adverse effects. Pain scores were measured using the visual analog scale (VAS), opioid consumption was measured in cumulative morphine equivalents consumed, and adverse effects were patient reported.

PRISMA

The search yielded a total of 145 articles. Forty-six duplicates were removed. Each review was screened using inclusion and exclusion criteria according to PRISMA criteria with a reduction of 87 articles (Moher et al., 2009) (see Appendix C, figure 3). Review of titles and abstracts resulted in removal of 8 articles that did not meet the inclusion criteria. The remaining 4 articles were included in this review (see Appendix D, table 1). Two of the studies were meta-analysis and two were systematic reviews and meta-analysis. All together these reviews represent 40 randomized control trials on preoperative gabapentin administration. All articles were obtained from peer-reviewed journals.

Summary of Results

All four studies reported a statistically significant reduction in cumulative morphine equivalents consumed. Han et al. (2017) found that reduction in cumulative morphine equivalents was statistically significant at 24 hours at all doses of gabapentin, but there was a positive correlation between dose of gabapentin and reduction of morphine. The patients who received a 1200 mg dose of gabapentin saw the greatest reduction in opioid use (Han et al., 2017).

Visual analog scores (VAS) were measured to quantify the efficacy of preoperative gabapentin in reduction of reported pain. All four studies showed statistically significant lower pain scores in patients receiving gabapentin versus placebo. Although VAS scores were measured at different time intervals following surgery, results were consistently similar in all

studies. Patient reported reduction in pain was greatest in the early hours following administration, and as time went on the difference in pain scores between the gabapentin groups and placebo lessened but were still statistically significant.

Adverse effects of preoperative gabapentin use were measured via patient self-report in three of the studies (Han et al., 2017; Liu et al., 2017; Peng et al., 2017). The most commonly reported adverse effects were nausea, vomiting, headache, dizziness, somnolence, pruritis, and urinary retention. Patients who received preoperative gabapentin reported less vomiting and pruritis in all three studies compared to those who did not receive gabapentin (Han et al., 2017; Liu et al., 2017; Peng et al., 2017). Nausea was less frequently reported in the gabapentin group in two studies (Liu et al., 2017; Peng et al., 2017). The incidence of urinary retention, dizziness, and somnolence was less in patients who received preoperative gabapentin compared to usual care (Han et al., 2017; Peng et al., 2017).

Several limitations of this literature review exist. First, the literature search yielded only four articles within the final eligibility criteria. This is likely because research in the area of gabapentin use is relatively recent (within the past 10 years), and future research is focused on a multimodal approach to ERAS protocols without measuring the effectiveness of each intervention separately. The varying doses of gabapentin presented in the review is also a limitation, as this makes it difficult to translate evidence into practice. Also, none of the articles address the concern on use of preoperative gabapentin in patients who are already taking this medication for chronic neuropathic pain, which is quite common in the spine population (Wiffen et al., 2017). Lastly, none of the articles address pain scores and opioid use for longer than 24 hours following surgery. This literature review suggests that the benefit from preoperative gabapentin administration does not extend past the second post-operative day. However, it is

common for spine surgery patients to require medication for severe pain beyond 24 hours following surgery.

Evidence to be used for Project

Findings of this literature review suggest that administration of preoperative gabapentin is beneficial in improving acute pain experienced by patients within the first 24 hours post-operatively following spine surgery. Further, preoperative gabapentin can assist in reducing the number of opioids necessary to control severe post-operative pain. Adverse effects of gabapentin use preoperatively are minimal. Overall, including gabapentin use in perioperative care of patients undergoing spine surgery is safe and effective in improving surgery outcomes.

Determining the dose of gabapentin to administer is difficult to discern from this evidence. Three of the studies compared randomized control trials that had varied doses of gabapentin ranging from 300 mg-1200 mg (Han et al., 2017; Liu et al., 2017; Yu et al., 2013). Findings suggested that higher doses of gabapentin (600 mg or higher) reflected less opioid use (Han et al., 2017; Liu et al., 2017; Yu et al., 2013). Peng and colleagues (2017) recommend the dose of gabapentin to be at least 900 mg for best outcomes. Alternatively, higher doses of gabapentin could place the patient at risk for side effects of the medication, especially if the patient is gabapentin naïve. Overall, the literature is not clear on the most efficacious dose of gabapentin as the findings were variable based on the studies. However, current evidence is strong and consistent to support administration of preoperative gabapentin to lumbar spine surgery patients.

Phenomenon Conceptual Model

The purpose of a conceptual model is to provide a framework to determine the interventions required for an evidence-based practice change (Hockenberry et al., 2015). The

conceptual model attempts to describe, explain, and/or predict a phenomenon (Hockenberry et al., 2015). The Promoting Action on Research Implementation in Health Services Framework (PARiHS) provides a conceptual map that identifies achievement of evidence-based practice change depends on the planned behavior change of individuals, teams, and organizations (Dang et al., 2015). Successful implementation is a function of three concepts: evidence, context, and facilitation (Dang et al., 2015). A visual representation of the PARiHS framework is depicted in Appendix E, figure 4. Successful implementation is based on the nature and type of evidence, the qualities of the context that the evidence is introduced, and the way the process is facilitated (Dang et al., 2015).

Evidence. Evidence is defined broadly to include knowledge from research, clinical experience, patients and caregiver's experience, and local context information (Dang et al., 2015). The conceptualization of evidence for this project is high. Research evidence via literature review indicates that preoperative gabapentin administration is beneficial for patients. Further, MSSIC supports the use of preoperative gabapentin and is already implementing preoperative gabapentin administration in other hospitals throughout Michigan. Preoperative gabapentin has been a known successful pain management strategy in other surgical procedures including orthopedics and gastroenterology.

Context. Context is defined as the environment or setting that the proposed change will be implemented (Dang et al., 2015). Contextual factors that promote successful implementation are also strong as demonstrated within the organizational assessment above. The culture of the organization is such that there is decentralized decision-making evidenced by the formation of Spine Team and ERAS. As a teaching hospital, the organization is conducive to change, and strives to continue to improve care of the neurosurgical population.

Facilitation. Facilitation is defined as the process of implementing the evidence-based change into practice (Dang et al., 2015). Facilitation depends on performance of this doctoral student the as a facilitator. Appropriate skills and knowledge to help the key stakeholders to apply evidence into practice will be critical to implementation of this project. Flexibility, patience, continuous learning and critical reflection by the facilitator are essential for success.

Project Plan

Purpose of Project and Objectives

The purpose of this DNP project is to implement an intervention of administration of preoperative gabapentin, an evidence-based pain management practice, into standard of care for lumbar spine surgeries. As part of the development of an ERAS program for all spine surgeries, administration of preoperative gabapentin is an adjunct to current pain management practices. Currently the only patients receiving gabapentin are the patients who take gabapentin as a part of their home medications. The objectives of this project are to improve patient perceptions of pain, reduce the number of opioids required in the first 24-hour post-operative period, reduce adverse effects of opioid medications, and decrease length of stay post-operatively in patients undergoing lumbar spine surgery.

Design for the Evidence-Based Initiative

This DNP project is a quality improvement project. A quality improvement project translates current evidence into practice, rather than creating new research findings. Evidence for improved outcomes with administration of preoperative gabapentin in lumbar spine surgeries is well supported in literature. This DNP project seeks to improve pain management and related outcomes utilizing best evidence-based practice strategies.

Setting

The setting for this DNP project is a 283-bed acute care hospital in West Michigan. The neurosurgery program is embedded within the larger hospital organization. The neuroscience program comprises of three neurosurgeons, three physician assistants, and four registered nurses in the outpatient clinic. Over 500 lumbar spine neurosurgeries are completed yearly (XXXXX XXXXXX, 2018a). The 34-bed inpatient unit within the acute care hospital provides care for patients post-operatively following neurosurgical procedures. The neurosurgery leadership team includes a medical director of neurosurgery held by one of the three neurosurgeons, clinical service director, neuroscience program manager, two performance improvement coordinators, clinical nurse specialist, clinical nurse leader, and managers of the outpatient clinic and inpatient nursing unit. The neurosurgery program closely collaborates with the surgical department/anesthesia, physical therapy, infection control, palliative care, nutrition, and pharmacy. Administrative approval from the organization to conduct the DNP project via the Institutional Review Board (IRB) from the organization and the university has been approved and is available upon request.

Participants

Participants in the DNP project are the neurosurgeons, neurosurgery physician assistants, registered nurses in the pre-procedural services department and inpatient unit, and patients undergoing lumbar spine surgery. The physician assistants and neurosurgeons will be the providers ordering the gabapentin, the pre-procedural registered nurses will be administering the medication, the patients will receive the medication, and the inpatient registered nurses will document patient response. Included in the project are patients age 18 and older having lumbar spine surgery who are not already taking gabapentin prior to surgery (gabapentin naïve). Patients excluded are those who are already taking gabapentin or pregabalin prior to surgery. Current

practice for these patients is to take their home dose of gabapentin or pregabalin on the day of surgery prior to hospital arrival. Also excluded are patients with chronic kidney disease stages four and five as patients with a creatinine clearance below 30 mL/min cannot safely consume more than 700 mg of gabapentin per day (Epocrates, 2018). Patients that have a clear contraindication including gabapentin allergy and pregnancy are excluded.

Model Guiding Implementation

The model used to guide implementation is the Iowa Model of Evidence-Based Practice to Promote Quality Care. The Iowa Model outlines a specific multiphase process for change with feedback loops (see Appendix F, figure 5). The Iowa Model is ideal for this DNP project as it can be easily adapted for use by multidisciplinary teams to problem-solve the steps of evidence-based practice change (Dang et al., 2015). The steps of the Iowa Model include the following: identify triggers, organizational priorities, forming a team, evidence retrieval, critique and synthesize the evidence, pilot the evidence-based practice change, and institute change in practice (Dang et al., 2015).

Identify Triggers. Triggers help identify a clinical problem by questioning current practice (Dang et al., 2015). Problem focused triggers identify an opportunity that needs improvement while knowledge focused triggers come from new research findings that lead to questions of current practice (Dang et al., 2015). Pain management in patients following lumbar spine surgery has been chronically challenging for providers. New evidence on alternatives in pain management in the literature provide evidence for an opportunity for practice change. Since research shows other organizations have had success with this intervention, this project will determine if this organization's outcomes are consistent with what is found in the literature.

Organizational Priorities. Identifying an issue that is a priority for the organization is

likely to gain support in carrying out the practice change (Dang et al., 2015). Alternatives in pain management for spine surgery is an organizational priority in light of legislative changes, and through the development of the ERAS program. This intervention also aligns with the organizational priority of decreasing hospital length of stay and improving patient experience. Acceptance for development of this DNP project is well supported by senior leadership and members of the neurosurgical team.

Forming a Team. The next step is to form a team of stakeholders to research, develop, implement, and evaluate the practice change (Dang et al., 2015). For this DNP project, the DNP student formed an advisory team with the neuroscience clinical nurse specialist at the organization and two university professors in March 2018. The DNP student is also a part of the ERAS team and Spine Team at the organization since February 2018. The ERAS team formed in January 2018 initially to explore trends in surgical site infections, then expanded to improve all areas of neurosurgical spine care. Spine Team and ERAS meet monthly. The DNP project is one important piece of the ERAS improvement work, which is a subcommittee of Spine Team.

Evidence Retrieval. A complete literature search was completed by the DNP student as outlined in this document above. This evidence retrieval was completed throughout the summer of 2018 with the formal literature review completed in August 2018.

Critique and Synthesize the Evidence. After gathering evidence from the literature, findings were critiqued to create an evidence-based practice intervention for preoperative administration of gabapentin in lumbar spine surgeries. Findings from the evidence suggest that a single dose of 600-1200 mg of gabapentin one hour prior to surgery yields best results. Since the dose was variable in the literature, an appropriate dose of gabapentin for this organization was determined. Expert opinion was sought from a neuro-palliative care physician who agreed with

the evidence found in the literature regarding proper dosing and recommended a 900 mg dose with further recommendations concerning inclusion/exclusion criteria for patients with chronic kidney disease and those who were not gabapentin naïve or prescribed pregabalin, as those variables were not found in the literature (X. XXXXXXXX, personal communication, September 4, 2018). The pharmacist in the neurosurgery department also agreed with the 900 mg dose and inclusion/exclusion criteria. This intervention is also consistent with standards used at other MSSIC hospitals in Michigan.

Pilot the Evidence-Based Practice Change. Piloting an evidence-based practice change allows for identifying potential issues in a controlled environment and allows comparison of pre- and post-pilot data to determine success and effectiveness of the intervention, providing opportunity for modification before instituting a change in practice (Dang et al., 2015). A colorectal surgeon spoke to the Spine Team regarding enhanced recovery guidelines in the colorectal department during the June 2018 Spine Team meeting, and literature findings specific to gabapentin use were presented by the DNP student at Spine Team during the July 2018 meeting. The neurosurgical physician assistants and neurosurgeons formally approved of this project at the Spine Team meeting in September 2018. The physician assistants and neurosurgeons have been educated during the Spine Team meeting in September 2018 by the DNP student on the determined dose of 900 mg gabapentin one hour prior to surgery. After obtaining approval from the organization's IRB, a 'go-live' date for the pilot was selected for December 1, 2018. The DNP student educated the registered nurses in the pre-procedural services department and in the neurosurgery clinic, so they can anticipate the order from the neurosurgeon and administer the medication appropriately. This education was disseminated from the DNP student to the clinic nurses via a Lunch and Learn in November 2018, and a

situation, background, assessment, recommendation (SBAR) communication tool explaining the intervention was given (see Appendix G). The surgery clinical nurse specialist disseminated the SBAR tool to the pre-procedural nurses and anesthesiologists in November 2018. The DNP student was present in the clinic two weeks before the 'go-live' date as surgeries are typically scheduled two weeks in advance. The DNP student was also present in the pre-procedural services department during the first week of 'go-live' to ensure the intervention is occurring.

Institute Change in Practice. Evaluation of pre- and post-pilot data determined integration of the evidence-based intervention into daily practice (Dang et al., 2015). Continued monitoring and analysis of process and outcome data with feedback will promote sustained integration of the change into practice (Dang et al., 2015). Dissemination of results of the DNP project will be reported to the university and the organization. If it is found that gabapentin is helpful in reducing pain, opioid use, and length of stay, this intervention may be expanded to use in cervical spine surgeries. Additional preoperative medications will be added in the future to develop a multimodal approach to pre-emptive pain management in patients receiving lumbar spine surgery. Administration of preoperative gabapentin prior to lumbar spine surgery is consistent with current evidence to help reduce the number of opioids consumed in the first 24 hours and improve patient perception of pain with fewer adverse effects.

Implementation Steps and Strategies

The steps for implementation of preoperative administration of gabapentin to lumbar spine surgery patients are described. Evidence-based implementation strategies guided the steps in completing this evidence-based quality improvement project.

1. Build a coalition prior to implementation on December 1, 2018 (Powell et at., 2015). Relationships with key stakeholders have been established through

participation in ERAS and Spine Team monthly meetings. Readiness for change and potential barriers and facilitators are realized and are integrated into the implementation steps.

2. Design an intervention and a process streamlined for preoperative administration of gabapentin for lumbar spine surgery patients prior to September 26, 2018. The intervention consists of administering 900 mg of gabapentin one hour prior to surgery to lumbar spine surgery patients based on best evidence from the literature. Excluding patients who are already prescribed gabapentin or pregabalin, patients with a hypersensitivity, and those with stage four and five chronic kidney disease is supported by expert opinion and gabapentin medical reference Epocrates (2018).
3. Present intervention for evidence-based quality improvement intervention at Spine Team meeting on September 26, 2018. Conduct local consensus discussion with Spine Team members including physician assistants, neurosurgeons, and pharmacist for approval of practice change (Powell et al., 2015). Spine Team approved of this intervention at the September meeting.
4. Submission of evidence-based intervention to the organization and university IRB by the DNP student prior to November 10, 2018. The organization's IRB approved this DNP project on November 13, 2018 and the university's IRB approval was obtained November 26, 2018. Approval letters from each respective IRB are available upon request.
5. Conduct education to the neurosurgery clinic and pre-procedural services department in November 2018 (Powell et al., 2015). The DNP student presented

preoperative gabapentin education to the clinic nurses via a Lunch and Learn in November 2018. The DNP student also disseminated the SBAR communication tool to the clinic nurses and the pre-procedural services department via the surgery CNS explaining the intervention in November 2018. The order for the preoperative dose of gabapentin is to be hand written on the surgical boarding slip completed by the clinic nurses and ordered by the physician starting December 1, 2018.

6. Aim for a ‘go-live’ date of December 1, 2018. Education and IRB approval were both completed in November 2018 with implementation beginning December 1, 2018.
7. The DNP student reminded clinicians of the ‘go-live’ date and intervention for the first week of implementation (Powell et al., 2015). The DNP student was present in the neurosurgery clinic for two weeks prior to the ‘go-live’ date and in the pre-procedural services department during the first week of implementation to provide clinical supervision for neurosurgery clinicians and pre-procedural registered nurses to answer questions and ensure implementation (Powell et al., 2015).
8. The DNP student gathered two months of patient data via chart review pre and post-intervention implementation. A total of two months of data was an obtainable number of subjects to allow for saturated data. Chart review began after IRB approval for pre-implementation data and corresponding to the ‘go-live’ date for post-implementation data. Data was collected until February 7, 2019.

9. The DNP student used a data expert consisting of a university statistician student to analyze and interpret data findings (Powell et al., 2015). This occurred once all the data is collected in February 2019.
10. The DNP student will disseminate findings from this evidence-based quality improvement project by March 30, 2019. The DNP student will prepare a project defense to present to the university and will relay clinical data to providers at the Spine Team meeting in April 2019 (Powell et al., 2015). It is possible that the outcomes from this DNP project be disseminated to the MSSIC organization (Powell et al., 2015).

Measures

Many measures were collected during the implementation of this evidence-based project. Protected health information was collected and stored securely. Data was collected by the DNP student via chart review from the electronic health record. Demographic measures include patient age, sex, type of surgery (laminectomy versus lumbar fusion), and history of prior lumbar spinal surgery (yes or no). Whether the patient was already taking gabapentin/pregabalin and if a preoperative dose of gabapentin was given was measured. Length of stay was measured by number of minutes the patient spent on the inpatient unit of the hospital starting at transfer from the post anesthesia recovery unit until discharge from the hospital. Discharge disposition was categorized into a home discharge, or to a rehabilitation facility regardless if considered acute or subacute.

Pain scores reported by patients were collected via the numeric rating scale. The numeric rating scale is the scale most widely used in the organization to assess pain. The numeric rating scale is proven to be reliable, valid, sensitive to change, and easy to administer for measuring

acute severe pain (Bendinger & Plunkett, 2016). The numeric rating scale defines mild pain as a score of one to three, moderate pain score four to six, and severe pain score seven to 10 (Bendinger & Plunkett, 2016). Each individual patient reported pain scores during the first 24 hours on the inpatient unit were collected. Opioid use in the first 24 hours of the post-operative period on the inpatient unit was calculated and measured in total daily morphine milligram equivalents (MME). This was calculated by the New York City Department of Health and Mental Hygiene mobile application version 2.0.2. According to the Centers for Disease Control and Prevention (CDC, 2018), calculating total daily dose of opioids identify those at higher risk of overdose. Dosages at or greater than 50 MME/day have twice the risk of overdose compared to those consuming less than 20 MME/day (CDC, 2018). Opioid tolerance has been defined in the literature as consumption of at least 60 MME for more than seven days within the prior 14 days (Young, Lund, Dasgupta, & Funk, 2018). Opioid tolerance was measured as this will likely affect the daily MME.

Potential complications from opioid and gabapentin use were assessed. Post-operative urinary retention via tracking straight catheterizations, sedation via Pasero Opioid-induced Sedation scores (POSS), and nausea via administration of antiemetics were measured during the first 24 hours on the inpatient unit. The POSS has shown adequate validity and reliability to measure level of sedation during opioid administration for pain management, is easy to use, and is already used by the organization (Nisbet & Mooney-Cotter, 2009). A POSS score of S-2 is considered acceptable, and a score of three or four unacceptable (see Figure 7).

Readmissions to the emergency department and inpatient unit within the first 30 days of discharge related to pain and sedation were also measured. There is a trend within the organizational data that patients return for pain control or complications from opioid use

including hallucinations, injury from fall, altered mental status, and constipation. This project closely monitored for changes in trends of readmissions related to opioid consumption or overuse.

Data Collection Procedures

Data collection occurred by the DNP student at the organization. Data was collected from the Cerner electronic health record. Pre-implementation data collection began once approval from the organization's IRB was obtained. The data elements that were collected during the data collection period have been described above. The sample size of each group varied according to the number of surgeries in the months of pre and post-implementation. Data was collected by the DNP student and directly documented in the Research Electronic Data Capture (REDCap) platform required from the organization. Data was then exported to statistical package for the social sciences (SPSS) software for interpretation.

Data Management

Data was carefully managed to ensure confidentiality and security. Data collected from the electronic health record was documented on a desktop computer provided by the organization in the REDCap data collection tool documenting numbers only as defined in the data collection tool dictionary. Data was also recorded on a paper copy of the data collection tool as a back-up that was kept in the CNS' locked office and will be destroyed at the completion of this project. The DNP student's computer and REDCap is password protected and is never alone in a public area. The data was analyzed with SPSS software provided by the university's graduate statistics student. The data was organized within the SPSS software at the discretion of the graduate statistics student to identify relationships among opioid use, perception of pain, and potential adverse effects. Data was not accessible to persons other than the DNP student and the graduate

statistics student but has been viewed by the members of the DNP student's advisory team.

Analysis

The analysis of the data was completed with the assistance of the graduate statistics student. Descriptive information on the patients are presented in the form of a table. Descriptive statistics include age, sex, history of prior lumbar surgery, and presence of opioid tolerance. A distribution of the variables, such as number of opioids used pre and post- implementation are shown in a box plot or histogram, at the statistician student's discretion. Length of stay, patient reported pain scores, whether gabapentin was given, whether patient was already taking gabapentin/pregabalin, discharge disposition, urinary retention, sedation, nausea, and readmissions are also presented in this manner.

Analysis of the outcome data to test for significance between pre-implementation data and post-implementation data was completed with assistance from the graduate statistics student. Significance is reported using p-values. Categorical data was analyzed using Chi square or Fisher's exact test depending on if assumptions are met. Frequency and percent were reported. Quantitative data were analyzed using independent two sample T-tests unless assumptions are not met in which case Wilcoxon rank sum test was used. For the T-test the mean and standard deviation were reported, or the median and interquartile range for the Wilcoxon rank sum test, respectively. Data is displayed in a graph, chart, or table as appropriately determined by the graduate statistics student. The data was analyzed to answer the clinical questions listed above to determine if administration of preoperative gabapentin to lumbar spine surgery patients improved pain and reduced opioid use without adverse effects.

Resources and Budget

The resources and budget required for this DNP project are minimal (see Appendix I).

The majority of the cost for this project was donated by the DNP student as the project manager. The DNP student donated time to create the implementation plan (8 hours), educate the providers at Spine Team (1 hour), educate the neurosurgery clinic staff (1 hour), be present in the neurosurgery clinic for two weeks prior to the 'go-live' date (5 hours), be present in the pre-procedural services department for the first week following the 'go-live' date (5 hours), and spent eight hours per week on chart reviews for eight weeks (64 hours). The DNP student is a registered nurse with 13 years' experience, therefore the hourly rate is calculated to be $30 per hour (Payscale, 2018b). The total donated cost for the DNP student program manager is $2,520. Since time invested by staff for education on the project occurred within the work day, there is no additional cost for education.

Other resources and cost to consider are time investment by the neuroscience clinical nurse specialist and the cost of gabapentin. The clinical nurse specialist assisted the DNP student initially with the project design, implementation, and data collection strategies. This time did not exceed three hours. The average hourly rate for a clinical nurse specialist is $40 per hour (Payscale, 2018a). The cost by the organization for one 900 mg dose of gabapentin is $0.14 (X. XXXXX, personal communication, September 13, 2018). With a sample size of 24 patients receiving the gabapentin, the total cost of gabapentin is $3.36. The university cost for the statistician is $100.

Potential cost savings for the organization is not completely known. With the implementation of preoperative gabapentin, patients may require fewer opioid medications. The organization's cost of two tablets of Norco 10/325 is $0.38 per dose, and one milligram of intravenous Dilaudid is $1.05 per dose (X. XXXXX, personal communication, September 13, 2018). If each patient requests one fewer doses of Norco, there will be a savings of $9.12 per 24

patients. For Dilaudid, the savings would be $25.20 per 24 patients. Fewer adverse effects from opioids would provide cost savings from less anti-emetic use and urinary catheterization supplies. Improved pain control may also shorten length of stay, and reduce 30-day readmissions, yielding further savings for the organization. Preventable surgical readmissions are associated with increased costs and resource utilization averaging $13,433 per readmission (Kirkner, 2017). Patients who report severe pain while in the hospital are at a higher risk of pain-related readmission or emergency room visit (Kirkner, 2017). If preoperative gabapentin can prevent one patient from returning to the hospital for pain-related symptoms, the organization could save $13,433.

Timeline

The timeline for the project was dependent on the IRB approval from the organization. The project plan was presented to Spine Team on September 26, 2018. Submission of the IRB occurred once this university approved this defense on November 10, 2018. The DNP student provided education to the clinic nurses and pre-procedural services department in November 2018. The ‘go-live’ date was selected for December 1, 2018. The project continued for two months to gather data from patient electronic health records post-implementation. Data collection was complete on February 7, 2019, with the graduate statistics student completing statistical analysis by February 15, 2019. The DNP student will present the final project defense by April 12, 2019 and will disseminate findings to the organization during the Spine Team meeting in April 2019.

Sustainability Plan

The DNP project was designed to be sustainable. A key part of the project design is stakeholder support. The neurosurgical team at the organization had already identified pain

management an integral part of the ERAS program development. The neurosurgeons and physician assistants are open to new ideas surrounding pain management strategies. Leadership in the neurosurgical department supports the work of the ERAS team. At the conclusion of this DNP project, the ERAS team plans to explore other pain management options to create their own multimodal approach to pain to improve patient outcomes.

This DNP project was implemented strategically to promote sustainability. The gabapentin order was handwritten onto the surgical boarding slip to ensure ease in compliance. Administration of gabapentin in the pre-procedural department added little workload for the providers and the registered nurses, with the potential for significant rewards.

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Appendix A

The Institutional and Organizational Assessment Model

Figure 1. A model for organizational performance and change. Reprinted from "Institutional and Organizational Performance Assessment," by Universalia, 2018, Retrieved online http://www.universalia.com/en/services/institutional-and-organizational-performance-assessment. Copyright 2018 by Universalia.

Appendix B

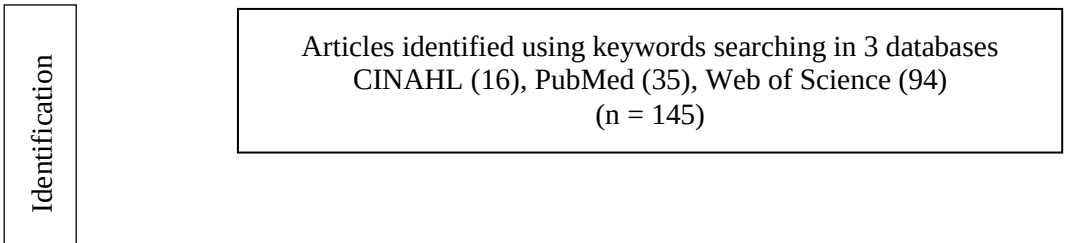
SWOT Analysis of the Neurosurgery Department

Strengths	Weaknesses
• Spine Team collaboration with other departments. • MSSIC member. • Surgeons/physician assistants recognize the opioid epidemic and are open to evidence-based practice change in pain management. • Palliative care team available for inpatient pain management.	• High utilization of opioid medications post-operatively. • Palliative care does not continue consults after discharge from the hospital. • Inadequate pain control and reduced mobility related to pain leads to longer length of stay.
Opportunities	**Threats**
• ERAS subcommittee in place. • Decrease opioid use consistent with recent Michigan legislation. • Improve patient experience scores via reduced pain. • Reduce post-operative complications and length of stay related to pain and immobility.	• Opioid use pre-operative is common. • Neuropathic pain is difficult to manage. • Lost revenue from longer length of stay for uncontrolled pain. • Less efficient due to MAPS review and frequent prescription refills (one week only).

Figure 2. SWOT analysis of the neurosurgery program

Appendix C

PRISMA Flow Diagram of Systematic Search



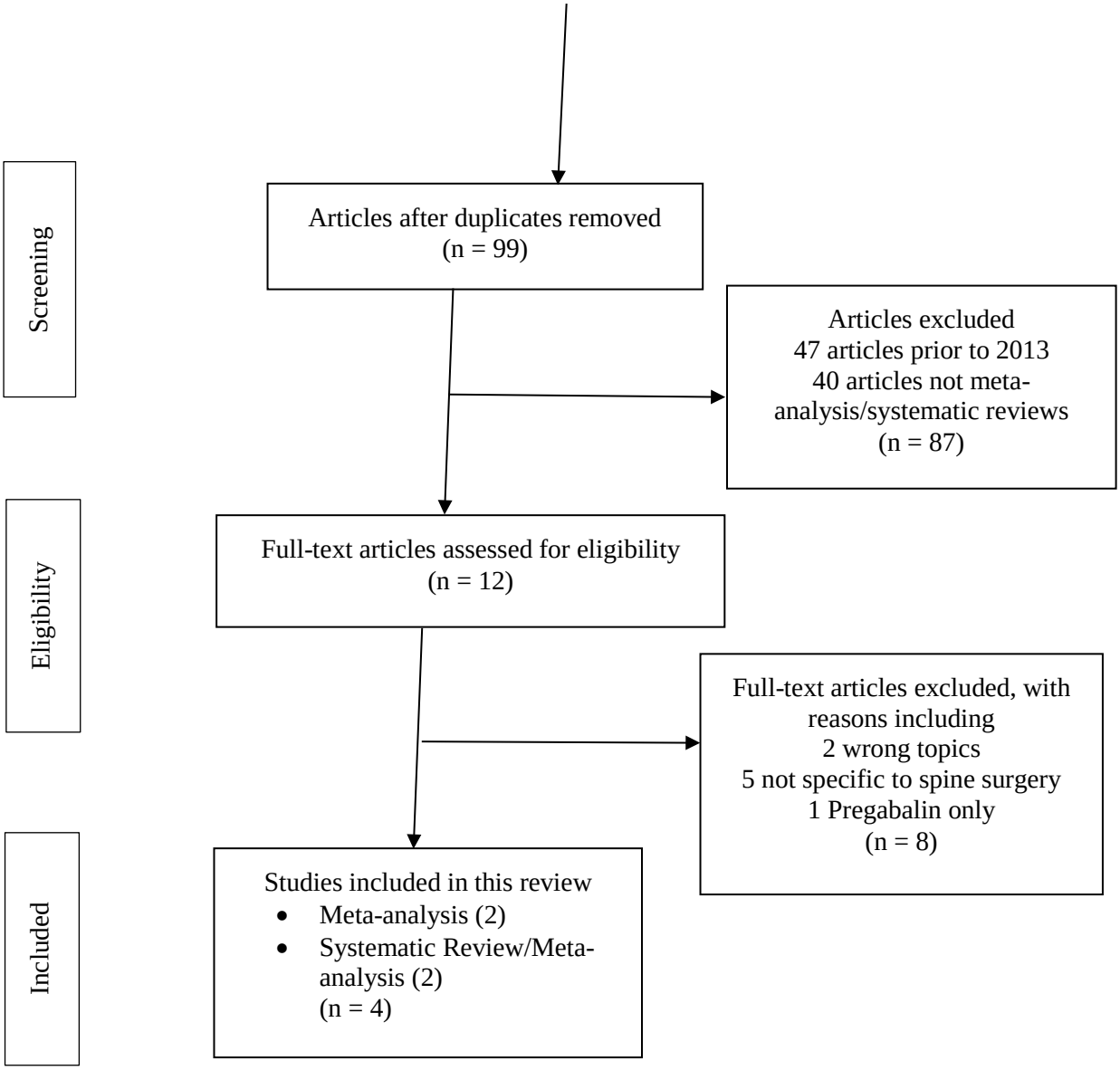


Figure 3. Flow diagram of search selection process. Adapted from "Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement," by D. Moher, A. Liberati, J. Tetzlaff, D. Altman, and PRISMA Group. Copyright 2009 by PLoS Medicine

Appendix D

Table of Evidence

Table 1. Articles included in review with author, year, purpose, design, inclusion, results, conclusions

Author (Year) Purpose	Design (N)	Inclusion Criteria	Intervention vs Comparison	Results	Conclusion
Han et al. (2017) Assess the efficacy of the pre-emptive use of gabapentin in spinal surgery	Meta-analysis of randomized control trials (N=10)	English language; gabapentin vs. placebo; reported outcomes contained either cumulative consumption of morphine equivalents at 24 hours, pain assessment score, or incidence of adverse effects	Gabapentin vs. placebo	*Efficacy:* • Cumulative consumption of morphine equivalents at 24 hours: 3 studies showed a positive effect in reduction of morphine equivalents consumed at 300 mg dose (mean difference = -1.74 [-2.55, -0.93] $p < 0.00$); 3 studies showed significant reduction of morphine equivalents consumed at 600 mg dose (mean difference = -5.36 [-6.27, -4.45] $p < 0.00$); 4 studies showed positive effect in reduction of morphine equivalents consumed at 900 mg dose (mean difference = -11.41 [-19.75, -3.08] $p < 0.00$); 4 studies showed positive effect in reduction of morphine equivalents consumed at 1,200 mg dose (mean difference = -17.84 [-28.20, -7.47] $p <0.00$) • Pain assessment score: 5 studies showed gabapentin reduced VAS scores at 2 hours compared to placebo (mean difference = -15.16 [-23.75, -6.58] $p < 0.00$); 4 studies showed gabapentin reduced VAS scores at 4 hours compared to	Compared with placebo, preoperative gabapentin could reduce cumulative morphine equivalents consumed at 24 hours post-operatively with reduced pain scores, and reduced adverse effects including vomiting, pruritis, and urinary retention. Higher doses of gabapentin resulted in less morphine equivalents consumed. There was an increase of somnolence in the gabapentin group.

				placebo (mean difference = -15.96 [-24.47, -7.44] p = 0.0002); 11 studies showed gabapentin reduced VAS scores at 6 hours compared to placebo (mean difference = -14.32 [-20.79, -7.85] p < 0.00); 6 studies showed gabapentin reduced VAS scores at 12 hours compared to placebo (mean difference = -11.64 [-15.76, -7.53] p < 0.00); 11 studies showed gabapentin reduced VAS scores at 24 hours compared to placebo (mean difference = -8.78 [-11.76, -5.80] p < 0.00) *Adverse Effects:* • Nausea: 8 studies showed no positive association between gabapentin and placebo (RR = 0.77 [0.55, 1.07] p = 0.12) • Vomiting: 12 studies showed the incidence rate was less in the gabapentin group (RR = 0.53 [0.32, 0.86] p = 0.01) • Headache: 7 studies showed no positive association between gabapentin and placebo (RR = 0.88 [0.45, 1.73] p = 0.71) • Dizziness: 7 studies showed no positive association between gabapentin and placebo (RR = 1.08 [0.68, 1.72] p = 0.75) • Somnolence: 7 studies showed a positive effect of gabapentin (RR = 2.52 [1.36, 4.67] p = 0.0003)	

				• Pruritis: 4 studies showed the incidence rate was less in the gabapentin group (RR = 0.38 [0.22, 0.66] p = 0.00) • Urinary retention: 4 studies showed the incidence rate was less in the gabapentin group (RR = 0.57 [0.34, 0.98] p = 0.04)	
Liu et al. (2017) Determine the efficacy and safety of pre-operative use of gabapentinoids (gabapentin and pregabalin) for acute postoperative pain following spine surgery	Meta-analysis of randomized controlled trials (N = 16)	Adults undergoing lumbar fusion, lumbar laminectomy, or lumbar discectomy; compared gabapentinoids vs. placebo; reported outcomes contained VAS at 6,12, and 24 hours, and complications	Gabapentinoids vs. placebo	*Efficacy:* • Cumulative consumption of morphine equivalents at 24 hours: Pooled results showed gabapentinoids reduce cumulative consumption of morphine equivalents at 24 hours (weighted mean difference = -18.55 [-23.52, -13.57] p = 0.000) • Pain assessment score: 16 studies showed VAS scores at 6 hours were reduced in the gabapentinoid group (weighted mean difference = -10.57 [-14.52, -6.63] p = 0.20); 16 studies showed VAS scores at 12 hours were reduced in the gabapentinoid group (weighted mean difference = -9.29 [-11.74, -6.85] p = 0.000); 16 studies showed VAS scores at 24 hours were reduced in the gabapentinoid group (weighted mean difference = -7.19 [-10.45, -3.93] p = 0.000) *Adverse Effects:* • Sedation: 16 studies showed no differences between groups (RR = 1.29 [0.73, 2.28] p = 0.541)	Preoperative gabapentinoids were able to reduce post-operative pain, total morphine equivalents consumed, and morphine-related complications following spine surgery. Significant decreases in risk of nausea, vomiting, and pruritis was associated with gabapentinoid use. High dose of gabapentinoids were superior to low dose in reducing acute pain and cumulative morphine equivalents consumed following spinal surgery.

				• Dizziness: 16 studies showed no differences between groups (RR = 1.44 [1.05, 1.99] p = 0.086) • Headache: 16 studies showed no differences between groups (RR = 1.10 [0.70, 1.73] p = 0.431) • Visual disturbances: 16 studies showed no differences between groups (RR =1.76 [0.76, 4.04] p = 0.142) • Somnolence: 16 studies showed no differences between groups (RR = 1.45 [0.90, 2.34] p = 0.142) • Urinary retention: 16 studies showed no differences between groups (RR = 0.61 [0.38, 0.97] p = 0.42) • Nausea: 16 studies showed reduced occurrence in the gabapentinoid groups (RR = 0.69 [0.54, 0.88] p = 0.004) • Vomiting: 16 studies showed reduced occurrence in the gabapentinoid groups (RR = 0.51 [0.34, 0.76] p = 0.004) • Pruritis: 16 studies showed reduced occurrence in the gabapentinoid groups (RR = 0.34 [0.22, 0.55] p = 0.001)	
Peng et al. (2017) Determine the efficacy and safety of gabapentin for pain	Meta-analysis of randomized controlled trials (N = 7)	Lumbar fusion, lumbar laminectomy, and lumbar discectomy surgeries; reported	Gabapentin vs. placebo	*Efficacy:* • Cumulative consumption of morphine equivalents at 24 hours: Pooled results from 6 studies showed gabapentin can reduce cumulative consumption of morphine equivalents (standard	Gabapentin was efficacious in reducing post-operative pain, total morphine equivalents consumed, and morphine-related

management following spinal surgery		outcomes contained VAS at 12 and 24 hours, total morphine equivalents consumed, and related complications		mean difference = -2.04 [-2.71, -1.37] p = 0.000) • Pain assessment score: 3 studies showed VAS scores at 12 hours were reduced in the gabapentin group (weighted mean difference = -11.18 [-13.85, -8.52] p = 0.000); 3 studies showed VAS scores at 24 hours were reduced in the gabapentin group (weighted mean difference = -9.94 [-13.99, -5.89] p = 0.000) *Adverse Effects:* • Nausea: 4 studies showed significant differences in occurrence (RR = 0.74 [0.49, 1.12] p = 0.157) • Dizziness: 3 studies showed significant differences in occurrence (RR = 1.56 [0.93, 2.61] p = 0.094) • Somnolence: No studies showed significant differences in occurrence (RR = 1.57 [0.66, 3.74] p = 0.308) • Headache: No studies showed significant differences in occurrence (RR = 0.88 [0.45, 1.73] p = 0.709) • Pruritis: 4 studies showed Gabapentin reduced occurrence (RR = 0.38 [0.22, 0.66] p = 0.001) • Urinary retention: Gabapentin showed reduced occurrence (RR = 0.57 [0.34, 0.98] p = 0.041)	complications following spine surgery. A high dose 900 mg or greater is more effective than a lower dose under 900 mg.

				• Vomiting: Gabapentin showed reduced occurrence (RR = 0.46 [0.27, 0.78] p = 0.004)	
Yu et al. (2013) Determine the efficacy of gabapentin and pregabalin in the management of post-operative pain after lumbar surgery	Systematic review and Meta-analysis of randomized control trials (N = 7)	18 years or older with elective lumbar spinal surgery; English language; reported outcomes contained postoperative consumption of morphine equivalents, pain score after surgery 0 to 6 hours, pain score after surgery 6 to 12 hours, pain score after surgery 12 to 24 hours	Gabapentin (N = 7) or pregabalin (N = 2) vs. placebo (one trial compared gabapentin, pregabalin, and placebo)	*Efficacy:* • Cumulative consumption of morphine equivalents: Gabapentin can significantly reduce post-operative opiate consumption (standard mean difference = -1.54 [-2.43, -0.64] p = 0.001); pregabalin can significantly reduce post-operative opiate consumption (standard mean difference = -1.16 [-1.71, -0.62] p = 0.0001) • Pain assessment score: 4 studies showed gabapentin can significantly reduce post-operative pain scores at 0-6 hours (standard mean difference = -1.91 [-2.62, -1.20] p = 0.0001); 4 studies showed pregabalin can significantly reduce post-operative pain scores at 0-6 hours (standard mean difference = -1.05 [-1.59, -0.51] p = 0.0001); 4 studies showed gabapentin can significantly reduce post-operative pain scores at 6-12 hours (standard mean difference = -1.30 [-2.00, -0.61] p = 0.0001); 4 studies showed pregabalin can significantly reduce post-operative pain scores at 6-12 hours (standard mean difference = -0.62 [-1.14, -0.10] p = 0.016); 4 studies showed gabapentin can significantly	Gabapentin was efficacious in the management of post-operative pain at all time points during the first day after surgery and could significantly reduce opiate consumptions. Doses of 600mg, 900mg, or 1200mg were all considered effective and safe. Pregabalin was also efficacious, but more trials are needed.

				reduce post-operative pain scores at 12-24 hours (standard mean difference = -1.05 [-1.64, -0.46] p = 0.0001); 4 studies showed pregabalin seemed to be able to reduce post-operative pain scores at 12-24 hours (standard mean difference = -0.43 [-0.95, 0.08] p = 0.097) *Adverse Effects:* • Not reported	

Appendix E

PARiHS Continua of Dimensions

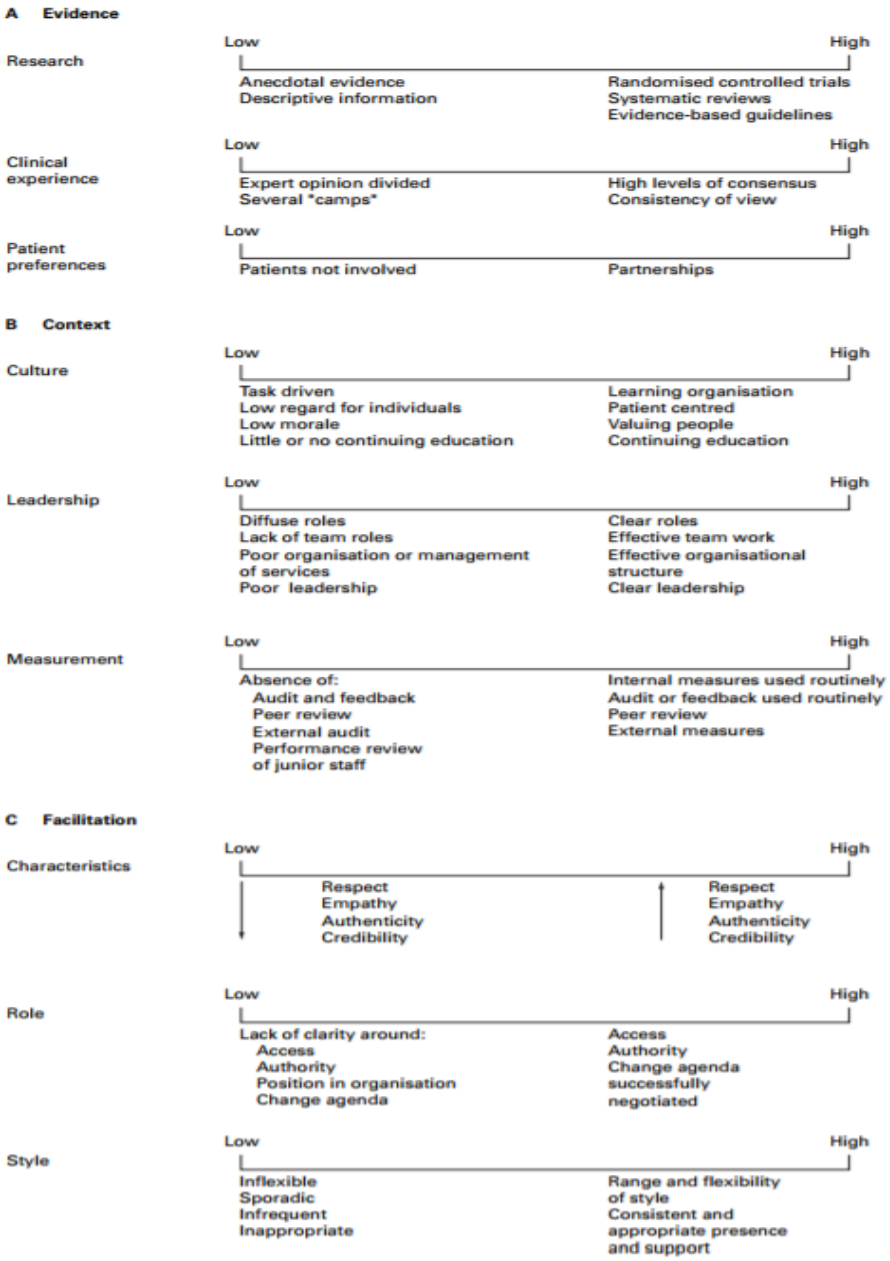


Figure 4. Adapted from "Enabling the implementation of evidence-based practice: a conceptual framework," by A. Kitson, G. Harvey, and B. McCormak. Copyright 1998 by Quality and Safety in Health Care.

Appendix F

Iowa Model of Evidence-Based Practice to Promote Quality Care

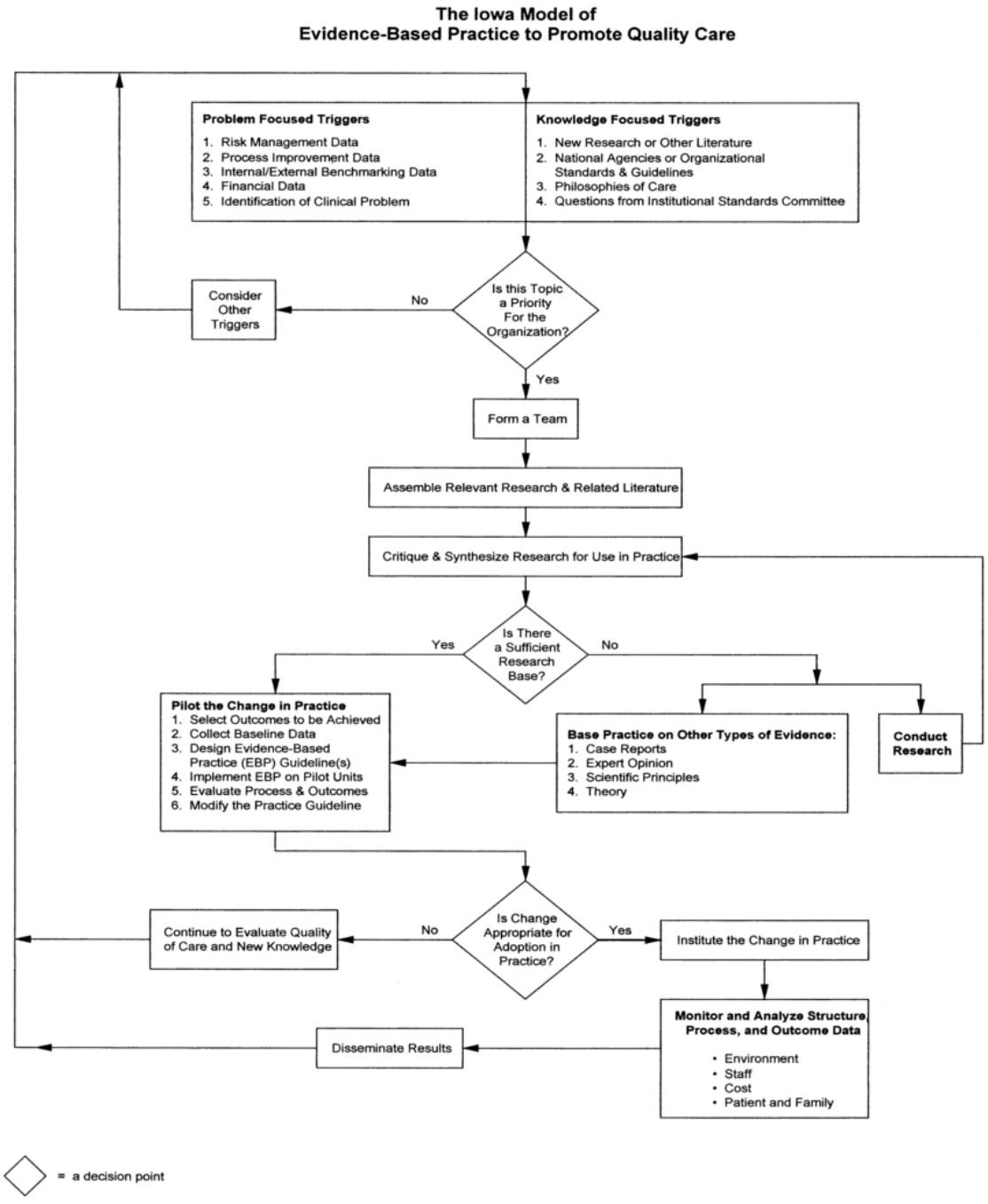


Figure 5. Adapted from "The Iowa model of evidence-based practice to promote quality care," by M. G. Titler et al. Copyright 2001 by Critical Care Nursing Clinics of North America.

Appendix G

SBAR Education for Staff

Pre-op Gabapentin for Lumbar Surgery Patients

Situation

Patients undergoing lumbar spine surgery including laminectomy with or without fusion experience significant pain in the post-operative period. Opioid medications are commonly used to help control post-operative pain, but can lead to unacceptable adverse effects including sedation, urinary retention, nausea, and constipation. Alternative strategies in managing pain in the immediate post-operative period is essential to decrease adverse effects of opioids while controlling patient reported pain.

Background

The neurosurgery department formed an Enhanced Recovery After Surgery (ERAS) team in January 2018. Patient reported pain in the post-operative period was identified by the ERAS team as an area with opportunity to improve. The aim of the ERAS team is to identify alternative strategies to manage pain that does not include high doses of opioid medications.

Assessment

Currently, opioid medications are the mainstay of treatment for patients following lumbar spine surgeries. Research of current evidence-based practices show that administering gabapentin pre-operatively may reduce pain in the first 24 hours following surgery. Evidence also shows that pre-operative gabapentin use may decrease opioid use leading to less sedation, urinary retention, nausea, and pruritis. Utilizing gabapentin in the pre-operative period is common practice to other ERAS protocols including colorectal and orthopaedic surgeries.

Recommendation

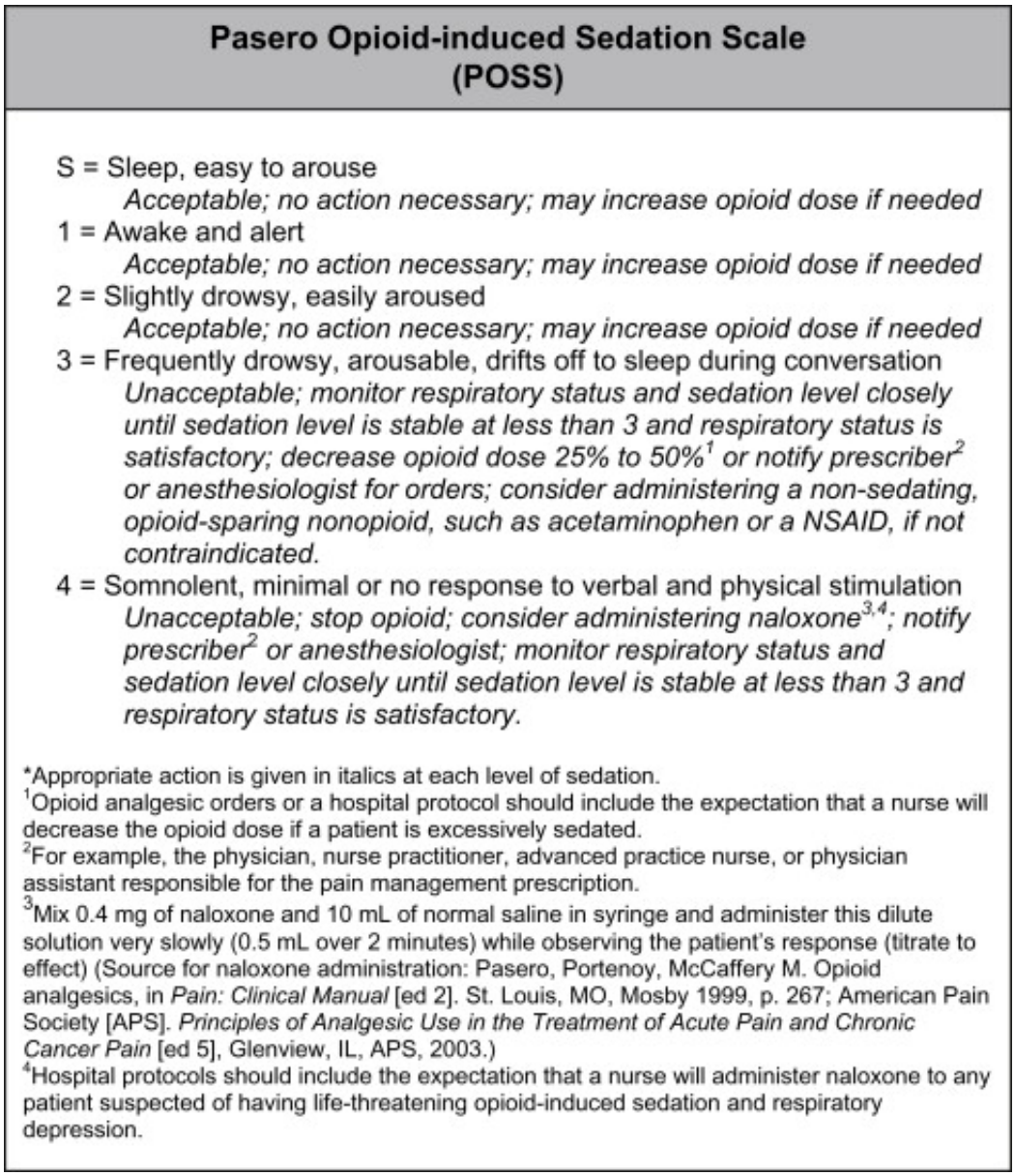
Patients undergoing lumbar spine surgery with or without fusion will receive one dose of 900 mg gabapentin one hour prior to surgery. Exclusions are as follows:

1. Patients who already take gabapentin or pregabalin are instructed to take their home dose prior to arrival to the hospital and will not receive a pre-op dose.
2. Patients with a creatinine clearance below 30 mL/min will not receive gabapentin.

The neurosurgery provider will place the order for gabapentin upon patient arrival to pre-procedural services.

Appendix H

Pasero Opioid-induced Sedation Scale



Pasero Opioid-induced Sedation Scale (POSS)

S = Sleep, easy to arouse
Acceptable; no action necessary; may increase opioid dose if needed

1 = Awake and alert
Acceptable; no action necessary; may increase opioid dose if needed

2 = Slightly drowsy, easily aroused
Acceptable; no action necessary; may increase opioid dose if needed

3 = Frequently drowsy, arousable, drifts off to sleep during conversation
Unacceptable; monitor respiratory status and sedation level closely until sedation level is stable at less than 3 and respiratory status is satisfactory; decrease opioid dose 25% to 50%[1] or notify prescriber[2] or anesthesiologist for orders; consider administering a non-sedating, opioid-sparing nonopioid, such as acetaminophen or a NSAID, if not contraindicated.

4 = Somnolent, minimal or no response to verbal and physical stimulation
Unacceptable; stop opioid; consider administering naloxone[3,4]; notify prescriber[2] or anesthesiologist; monitor respiratory status and sedation level closely until sedation level is stable at less than 3 and respiratory status is satisfactory.

*Appropriate action is given in italics at each level of sedation.
[1]Opioid analgesic orders or a hospital protocol should include the expectation that a nurse will decrease the opioid dose if a patient is excessively sedated.
[2]For example, the physician, nurse practitioner, advanced practice nurse, or physician assistant responsible for the pain management prescription.
[3]Mix 0.4 mg of naloxone and 10 mL of normal saline in syringe and administer this dilute solution very slowly (0.5 mL over 2 minutes) while observing the patient's response (titrate to effect) (Source for naloxone administration: Pasero, Portenoy, McCaffery M. Opioid analgesics, in *Pain: Clinical Manual* [ed 2]. St. Louis, MO, Mosby 1999, p. 267; American Pain Society [APS]. *Principles of Analgesic Use in the Treatment of Acute Pain and Chronic Cancer Pain* [ed 5], Glenview, IL, APS, 2003.)
[4]Hospital protocols should include the expectation that a nurse will administer naloxone to any patient suspected of having life-threatening opioid-induced sedation and respiratory depression.

Figure 6. Adapted from "Comparison of selected sedation scales for reporting opioid-induced sedation assessment," by A. T. Nisbet & F. Mooney-Cotter. Copyright 2009 by Pain Management Nursing.

Appendix I

Budget for DNP Project

Doctor of Nursing Practice Project Financial Operating Plan

Effectiveness of Perioperative Gabapentin for Pain Management in Lumbar Spinal Surgery

Revenue	
Project Manager Time (in-kind donation)	2,520.00
Consultations	
Statistician (in-kind donation)	100.00
Revenue Source	
One less dose of Dilaudid given per patient	25.20
One less dose of Norco given per patient	9.12
One less readmission for pain control	13,433.00
TOTAL INCOME	16,087.32
Expenses	
Project Manager Time (in-kind donation)	2,520.00
Team Member Time:	
Clinical Nurse Specialist	120.00
Consultations	
Statistician (in-kind donation)	100.00
Cost of Gabapentin	3.36
TOTAL EXPENSES	2,743.36
Net Operating Plan	13,343.96

DNP Project Results

Structured Abstract

Background: Spinal surgeries are among the top procedures responsible for the highest degree of post-surgical pain. The opioid epidemic and health care legislation necessitate alternative strategies in managing pain. The purpose of this quality improvement project was to determine if preoperative gabapentin improves pain and reduces opioid use after lumbar spine surgery.

Objectives: To evaluate the effectiveness of a single 900 mg dose of gabapentin to impact post-operative opiate use, patient perception of pain, and length of stay in lumbar spine surgery patients.

Methods: Quality improvement evidence-based project at a hospital in the Midwestern United States. Gabapentin was administered to patients who are gabapentin naïve one hour prior to lumbar spine surgery. Opioid use, patient reported pain, length of stay, adverse effects, and readmissions were compared to determine effectiveness.

Results: Three groups were compared: received gabapentin; qualified, but did not receive; did not qualify. No differences between groups were found in all outcome measures. No adverse effects of gabapentin were noted.

Conclusions: Preoperative gabapentin use as a solo intervention did not impact patient reported pain, opioid use, or length of stay.

Implications: A larger sample will assist in usefulness of gabapentin as a solo intervention for pain. Further study is needed for the role of gabapentin in a multimodal pain regimen.

Keywords: Lumbar Spine Surgery, Pain Management, Gabapentin, Preoperative

Introduction

Use of opioid medications for pain management has grown exponentially in recent years, leading to unprecedented rates of substance abuse, overdose, and death (National Institute on Drug Abuse [NIDA], 2018). This opioid epidemic results in an estimated 115 American deaths daily from opioid overdose, with prescription opioid misuse costing the United States 78.5 billion dollars yearly on healthcare costs, loss of productivity, treatment for addiction, and criminal justice costs (NIDA, 2018). Changes in legislation limits prescribing opioid medications in outpatient and inpatient settings. Restricting opioid prescribing impacts acute care providers in managing post-operative acute pain.

Acute care hospitals are challenged in treating acute pain following surgical procedures for a multitude of reasons. Post-operative pain can be complicated by complex procedures, patient co-morbidities, and pre-existing opioid tolerance. Recent studies have shown that 30-60% of patients continue to use opioids after the acute phase of healing following spine surgery (Deyo et al., 2018). Opioid naïve patients are at substantial risk of becoming a long-term opioid user with more patients receiving long-term opioids after spine surgery than before surgery (Deyo et al., 2018). The cumulative dose of opioids prescribed in the first 30 days after surgery strongly predicts long-term post-operative opioid use (Deyo et al., 2018). Seeking alternative strategies to manage acute post-operative pain is essential.

Spine surgeries are among the top six procedures responsible for the highest degree of

post-surgical pain (Bajwa & Haldar, 2015). Up to 50% of patients experience inadequate pain control leading to dissatisfaction and poor mobility, while almost 25% are given excessive opioids resulting in suboptimal outcomes and adverse events (Rivkin & Rivkin, 2014). The inflammatory cascade and resulting post-operative pain begin before the patient wakes up from surgery (Rivkin & Rivkin, 2014). Strategies in managing acute post-operative pain should be implemented prior to the onset of the activation of these various pain mechanisms. Pre-emptive analgesia is administration of pain medication in the perioperative period with the purpose of providing a preventive effect against pain (Devin & McGirt, 2015). Effective perioperative pain control is associated with improved surgical outcomes, reduced hospital length of stay, and decreased development of new chronic pain conditions (Devin & McGirt, 2015).

Opiate pain medications have been the mainstay of treatment for post-operative pain in spinal surgery. Although effective for acute pain, opioid use has shown to prolong hospital length of stay related to side effects including respiratory depression, sedation, post-operative nausea and vomiting, urinary retention, and ileus (Tan, Law, & Gan, 2015). Adverse events related to opioid use also drives up medical costs and increases readmission rates (Tan et al., 2015). Inadequate pain control is the second most common reason for 30-day readmissions following lumbar spine surgery (Kurd, Kreitz, Schroeder, & Vaccaro, 2017). Adequately managed pain improves functional outcomes, leads to early ambulation, early discharge, and prevents the development of chronic pain (Bajwa & Haldar, 2015). Treatment strategies in this patient population are complex, as many already suffer from pre-existing chronic pain with long term consumption of analgesics and opioids, altering pain perceptions in these patients (Bajwa & Haldar, 2015).

Multimodal approaches to post-operative pain management have been investigated. Use

of opiate pain medication is effective in initially controlling acute pain, but subsequent tolerance and a reduction in pain threshold develop rapidly resulting in an opioid-induced hyperalgesia requiring higher doses of opiate medications, worsening the potential for adverse effects from opioid use and further increases sensitivity to pain (Tan et al., 2015). Enhanced Recovery After Surgery (ERAS) programs have been developed to address factors that delay post-operative recovery and prolong hospital stay, including pain management (Tan et al., 2015). Research has shown that multimodal analgesia, using more than one analgesic modality, is effective in achieving pain control while limiting opioid-related side effects (Tan et al., 2015). In spine surgeries, ERAS multimodal nonopioid analgesics used in the perioperative stage include various combinations of medications including gabapentin, pregabalin, acetaminophen, dexamethasone, ketamine, and nonsteroidal anti-inflammatory drugs (Rivkin & Rivkin, 2014). Used pre-emptively, these medications act to inhibit central autonomic hyperactivity, thus preventing pain (Ali et al., 2018). Because standard ERAS protocols for pre-emptive analgesia are multimodal, it is difficult to determine the benefits and adverse effects for each combination of medicines used (Tan et al., 2015).

Gabapentin is a second-generation anticonvulsant medication used to treat chronic neuropathic pain by reducing neuronal excitability while sparing normal physiologic pain transmission (Devin & McGirt, 2015). The effect of gabapentin is most pronounced after nerve or tissue injury (Devin & McGirt, 2015). Side effects of gabapentin include dizziness, somnolence, fatigue, and ataxia (Epocrates, 2018). Contraindications include hypersensitivity to gabapentin, renal impairment, and alcohol or drug abuse (Epocrates, 2018). Preoperative gabapentin has been integrated into ERAS programs in a multimodal approach to improve pain control and limit opioid use. Pre-emptive multimodal analgesia including gabapentin has

demonstrated improvement in acute post-operative pain, activity, depression and anxiety, and self-care while reducing opioid use at two weeks following surgery (Ali et al., 2018). The purpose of this quality improvement project is to implement an evidence-based intervention utilizing preoperative gabapentin to reduce opioid consumption and improve patient perception of pain in the first 24 hours post lumbar spine surgery.

Methods

A review of the literature was conducted to examine current evidence using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline (Moher, Liberati, Tetzlaff, Altman, & PRISMA Group, 2009). A comprehensive electronic search conducted in CINAHL, PubMed, and Web of Science was limited to reviews in the English language from 2013 to 2018. Keywords included gabapentin, spin*, preoperative, preventive, and pre-emptive. Similar search terms preoperative, preventive, and pre-emptive were listed by using Boolean operator OR, and the Boolean operator AND was used to narrow articles that are relevant to the review. Spin* (wild card) was used to include words such as spine and spinal. Four articles including two meta-analysis and two systematic reviews and meta-analysis representing 40 randomized control trials on preoperative gabapentin administration from peer-reviewed journals were found (see Figure 1). Findings suggest that administration of preoperative gabapentin is beneficial in improving acute pain experienced by patients within the first 24 hours post-operatively following spine surgery and reduce opioid use for severe post-operative pain (Han et al., 2017; Liu et al., 2017; Peng et al., 2017; Yu et al., 2013). Adverse effects are minimal. Including gabapentin in perioperative care of patients undergoing lumbar spine surgery is strongly supported in the literature to be safe and effective for improving surgery outcomes.

The dose of gabapentin to administer was difficult to discern from this evidence. Higher doses of gabapentin (600 mg or higher) reflected less opioid use (Han et al., 2017; Liu et al., 2017; Yu et al., 2013). Peng and colleagues (2017) recommend the dose of gabapentin to be at least 900 mg for best outcomes. Findings from the literature review were utilized in the design of the project intervention.

Intervention

An evidence-based practice intervention was created for preoperative administration of gabapentin in lumbar spine surgeries. Evidence suggests that a single dose of 600-1200 mg of gabapentin one hour prior to surgery yielded best results. Expert opinion from a neuro-palliative care physician and pharmacist in the neurosurgery department agreed with the evidence and recommended a 900 mg dose with inclusion/exclusion criteria for patients with chronic kidney disease and who were not gabapentin/pregabalin naïve, as those variables were not found in the literature (X. XXXXXXXX, personal communication, September 4, 2018). The intervention consists of administering 900 mg of gabapentin one hour prior to surgery to lumbar spine surgery patients, excluding patients who are already prescribed gabapentin or pregabalin, patients with a hypersensitivity, and those with a creatinine clearance below 30 mL/min (Epocrates, 2018). The gabapentin was ordered with the preoperative medications by the neurosurgery clinic during the preoperative visit, and administered by the registered nurses in pre-procedural services.

Approach

The design of this project was a pre- and post-implementation comparison. Approval of the project was obtained from Spine Team; an interdisciplinary team consisting of neuroscience leadership, neurosurgeons, physician assistants, registered nurses, dietician, case managers, physical therapists, infection control, and pharmacists. Registered nurses in the pre-procedural

services department and in the neurosurgery clinic received education prior to implementation. Education was disseminated to the clinic nurses via a Lunch and Learn, and a situation, background, assessment, recommendation (SBAR) communication tool explaining the intervention (see Figure 2). The pre-procedural services nurses were educated by their clinical nurse specialist and given the SBAR communication tool.

Data was collected for two months pre- and post-implementation. Data collection began after approval from the organization's Institutional Review Board (IRB). The sample size was reliant on the number of surgeries scheduled during data collection. Data was directly documented in the Research Electronic Data Capture (REDCap) platform required from the organization. Data was then exported to statistical package for the social sciences (SPSS) software for interpretation by a university graduate statistics student.

Measures

Data was collected via chart review from the Cerner electronic health record. Demographic measures include patient age, sex, type of surgery (laminectomy versus lumbar fusion), opioid tolerance, and history of prior lumbar spine surgery. Whether the patient was already taking gabapentin/pregabalin and if a preoperative dose of gabapentin was given were measured for compliance. Length of stay was measured by number of minutes the patient spent on the inpatient unit of the hospital starting at transfer from the post anesthesia recovery unit until discharge from the hospital. Discharge disposition was categorized into a home discharge or to a rehabilitation facility.

Pain scores were collected via the numeric rating scale. The numeric rating scale is widely used in the organization and is proven to be reliable, valid, sensitive to change, and easy to administer for measuring acute severe pain (Bendinger & Plunkett, 2016). The numeric rating

scale defines mild pain as a score of one to three, moderate pain score four to six, and severe pain score seven to 10 (Bendinger & Plunkett, 2016). Each patient reported pain score during the first 24 hours on in the inpatient unit was collected. Opioid use in the first 24 hours of the post-operative period on the inpatient unit was calculated and measured in total daily morphine milligram equivalents (MME). This was calculated by the New York City Department of Health and Mental Hygiene mobile application version 2.0.2. Opioid tolerance is defined as consumption of at least 60 MME for more than seven days within the prior 14 days (Young, Lund, Dasgupta, & Funk, 2018). Opioid tolerance was measured as this will likely affect the daily MME.

Potential complications from opioid and gabapentin use were collected. Post-operative measures include urinary retention via number of straight catheterizations, sedation via Pasero Opioid-induced Sedation Scale scores (POSS), and nausea via antiemetic administration collected during the first 24 hours on the inpatient unit. The POSS has shown adequate validity and reliability to measure level of sedation during opioid administration for pain management and is easy to use (Nisbet & Mooney-Cotter, 2009). A POSS score of S-2 is acceptable, and a score of three or four unacceptable. Readmissions to the emergency department and inpatient unit within the first 30 days of discharge related to pain and sedation were measured to monitor for changes in trends of readmissions related to opioid consumption or overuse.

Analysis

The data analysis was completed with the assistance of a graduate statistics student. A total of 140 charts were reviewed (77 pre-implementation, 63 post-implementation). In the post-implementation group, 34 patients qualified for the intervention with 24 patients receiving the intervention (70.6% compliance). Differences across all qualitative data points between pre- and

post-intervention groups were not found to be statistically significant due to the small number of patients who received the intervention in the post-implementation group (see Table 1). Therefore, three groups were compared for analysis: patients who received preoperative gabapentin; patients who qualified for gabapentin but did not receive; and those who did not qualify. Numerical outcome measures were analyzed via ANOVA comparison between the three groups. Categorical data utilized Chi Square statistical analysis to compare binary outcomes.

Ethical Considerations

An application for review and approval of this project was submitted to the organization and to the university's IRB. The purpose and scope of this project are limited to evidence-based practice improvement and quality improvement. Health Insurance Portability and Accountability Act (HIPPA) privacy rules were upheld. Protected health information was collected and stored securely. No patient identifiable information was collected. No physical, social, psychological, legal, or economic threats to patients are associated with this project. It was anticipated that the impact of the project will pose minimal or no risk to participants. All members of the team have completed human subject's protection training via the Collaborate Institute Training Initiative (CITI).

Data collection occurred at the organization to ensure confidentiality and security. Data was collected from the Cerner electronic health record from a computer provided by the organization. Data was directly documented in the REDCap platform required from the organization documenting numbers only. The computer and REDCap program are password protected. Data was exported to SPSS software for interpretation at the discretion of the graduate statistics student to identify relationships among opioid use, perception of pain, length of stay, and potential adverse effects.

Results

This project was implemented over a period of four months with 140 surgeries analyzed. Pre-intervention data revealed 41 males and 36 females with post-intervention data reporting 32 males and 31 females. Ten males and 14 females received the intervention, 33 males and 25 females qualified, but did not receive, and 30 males and 28 females did not qualify. The distribution of age between groups did not significantly differ (see Figure 3). For those who received the intervention, 14 were laminectomy surgeries and 10 were fusions. The qualified but did not receive group consisted of 30 laminectomies and 28 fusions, and the did not qualify group represented 26 laminectomies and 32 fusions. No statistically significant differences in type of surgery was found between the three groups (Chi Square $p = 0.5075$). Opioid tolerance was minimal in all groups with $p = 0.2991$, and history of prior lumbar surgery was not statistically significant between groups with $p = 0.9286$. Demographic data for each treatment group is presented in Table 2. No significant differences in age, gender, type of surgery, opioid tolerance, or history of prior surgery between the three groups were found.

Opioid consumption in the first 24 hours after surgery was not significantly different pre- and post-implementation (see Table 1). The variation in MME between the three treatment groups are presented in Figure 4. Comparing MME between the three treatment groups yielded statistical significance (see Table 3). Post hoc analysis indicated the significant difference was found between those who did not qualify, and those who qualified but did not receive the intervention (see Table 4). Those who did not qualify used an average of 80.98 MME (standard deviation [SD] = 60.92) compared to 56.27 MME (SD = 46.15) consumed by those who qualified but did not receive the intervention (see Table 3). The difference between the mean MME consumed is 24.71 mg of morphine.

Patient perception of pain was not significantly affected by the intervention. Comparison of pre- and post- intervention data in Table 1 reveals insignificant mean pain scores ($p = 0.4309$). The between groups comparison in pain scores confirm no significant differences are found (see Table 3).

Hospital length of stay was not improved with this project. Length of stay was not statistically different between pre- and post-intervention data (see Table 1). Between groups, the shortest length of stay was found in the qualified, but did not receive group followed by the received intervention group (see Table 3). However, length of stay in between group comparisons were not statistically different (see Table 3).

Categorical outcomes contained adverse effects including presence of acute renal failure, urinary retention requiring a straight catheterization, antiemetic use, sedation, discharge disposition, and readmission related to pain or sedation. Chi Square analysis found no significant differences between the three groups for urinary retention, antiemetic use, discharge disposition, and readmission related to pain (see Table 5). Although not statistically significant, there were fewer readmissions related to pain in the received intervention group compared to the qualified but did not receive group (4% versus 8.6%). Sedation, acute renal failure, and readmission for sedation were found infrequently in all groups (see Table 5). The zero counts made approximating with Chi Square distribution unreliable.

Discussion

Compliance for those who qualified to receive gabapentin was 70.6%. There were 34 patients who qualified for preoperative gabapentin during the two months of post-intervention with 24 patients receiving the medication and 10 patients who did not. Of the 10 patients who should have received gabapentin, four patients did not have the medication ordered, five patients

had it ordered correctly, but was not transcribed into the medication administration record by pharmacy, and one patient received an under-dose of 300 mg due to transcription error. During implementation one clinic nurse was on medical leave and did not attend the Lunch and Learn education session which may have impacted compliance. Pharmacy errors were reported to their department. Education to the pharmacy department was a missed opportunity. Providing the SBAR education to the pharmacy department may have reduced the number of medication errors. In the pre-procedural services department, many disciplines are initiating various ERAS protocols that are not consistent causing confusion for the staff. Pre-procedural services will be provided a single page tool with all the components of the lumbar spine ERAS protocol.

Results indicate no statistically significant associations between the three groups in all outcome measures. Preoperative gabapentin did not show to significantly alleviate patient reported pain or reduce opioid use and length of stay, which were the intended outcomes of this intervention. There were missed opportunities to determine effectiveness of the intervention with over 40% of patients qualifying, but not receiving the medication. Gabapentin did not cause harm nor improve adverse effects related to opioid use. This data contradicts what is found in current research literature. Reasons for these differences are unknown. The significant difference in opioid use between the did not qualify and qualified but did not receive groups cannot be explained by the intervention. The outlier seen in the did not qualify group may have caused the statistically significant finding when compared to the qualified but did not receive group (see Figure 4). In all groups, there was large variability in MME use perhaps contributing to insignificant findings.

The difference in number of readmissions for pain between the received intervention and the qualified but did not receive groups is clinically significant. Although not statistically

significant, each patient that does not have to return for pain symptoms is meaningful for improving patient outcomes, patient satisfaction, and financial viability for the organization. Preventable surgical readmissions are associated with increased costs and resource utilization averaging $13,433 per readmission (Kirkner, 2017). During the four months of data collection, the organization potentially spent $13,433 on readmissions for pain from the received intervention group, and $67,165 on the qualified but did not receive group. The projected annual cost for readmission for pain is estimated at $40,299 for the received intervention group and $201,495 for the qualified but did not receive group (see Table 6). There is a potential for an estimated annual savings of $161,196 if those who qualified actually received the intervention. The cost by the organization for one 900 mg dose of gabapentin is $0.14 (X. XXXXX, personal communication, September 13, 2018). Eighty-two patients qualified for gabapentin during the four months of data collection costing $11.48 if all patients had received the intervention. A projected annual cost of gabapentin is $34.44. The overall savings for the organization is approximated at $161,161.56 annually. The financial benefits of preoperative gabapentin for the organization are substantial.

Literature findings suggest using gabapentin as part of a multimodal pain regimen for lumbar spine surgery patients. Perhaps the synergistic effect between gabapentin and other medications such as acetaminophen, NSAIDs, and others provide a greater impact on patient reported pain and opioid use than gabapentin alone. The 900 mg dose used in this project was cultivated from findings from the literature and expert opinion, but variances in appropriate dosing used in other studies may have impacted the results of this project. Since the cost burden of gabapentin is minimal with few adverse effects, it is reasonable to consider continuation of preoperative gabapentin to collect a larger sample size for group comparisons.

Limitations

Limitations for this project relate to sample size and compliance. The sample sizes in the data analysis are small with only 24 out of the 140 charts reviewed receiving the intervention. Gathering data over a longer time period will increase the sample sizes and provide more robust data to generate reliable conclusions on the impact of preoperative gabapentin on pain control and opioid use. It is difficult to generalize the data findings from this project without collecting a larger sample.

Compliance with a change in practice takes time. Unexpected barriers such as medical leave and pharmacy transcription of written orders were unforeseen during project implementation. With continued data collection, there will likely be an increase in compliance as the intervention becomes standard practice.

Conclusion

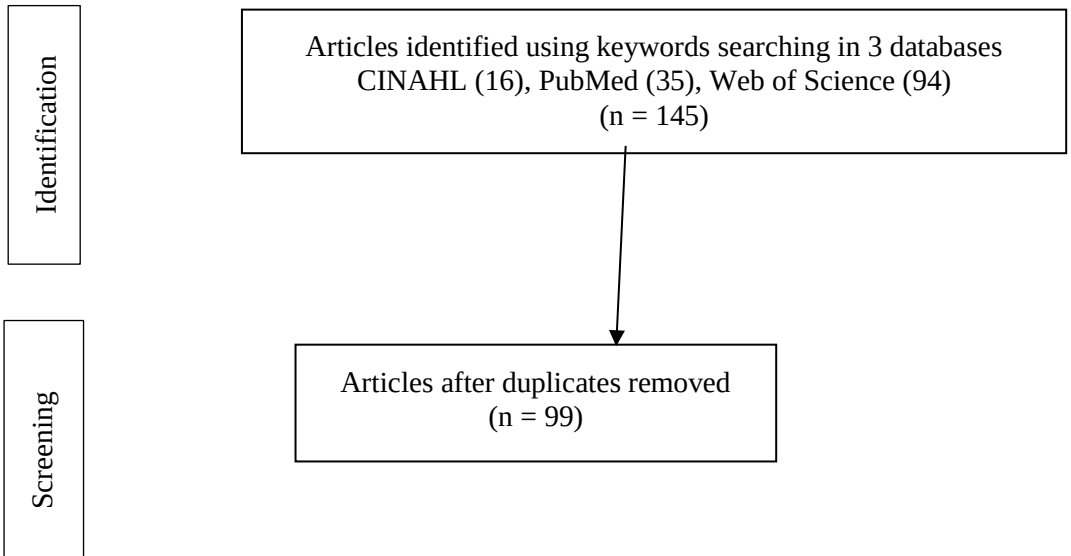
Seeking alternative therapies for pain management is important as the healthcare system struggles with opioid use. Administration of preoperative gabapentin to lumbar spine surgery patients is a useful project, but further study is needed to discern proper dose and usefulness as a multimodal analgesic regimen. Neuropathic post-surgical pain is challenging to treat requiring the synergistic effect of multiple interventions. This project is sustainable as the process change of preoperative gabapentin use becomes standard practice in the neurosurgery and pharmacy departments.

Implications for Practice and Further Study in the Field

Further work is needed to understand why preoperative gabapentin use for lumbar spine surgery patients was not effective. This organization will continue to collect patient data to obtain a larger sample size for comparison of groups to determine if gabapentin does make a

significant difference on pain symptoms. Gabapentin has not shown to have any adverse effects reported, and does not carry a financial burden in cost or workload for the neurosurgery clinic, pharmacy, or pre-procedural services. Continuation of the project for further study is reasonable. Dissemination of findings from this project to the organization and others is also reasonable. The organization will need to discern if they wish to continue gabapentin use based on the data from larger sample sizes. Creating a multimodal analgesic regimen that includes preoperative gabapentin is logical based on the evidence in the literature. Additional projects in the future include usefulness of acetaminophen, NSAIDs, intraoperative interventions, and other pain modalities to improve patient outcomes.

Figures



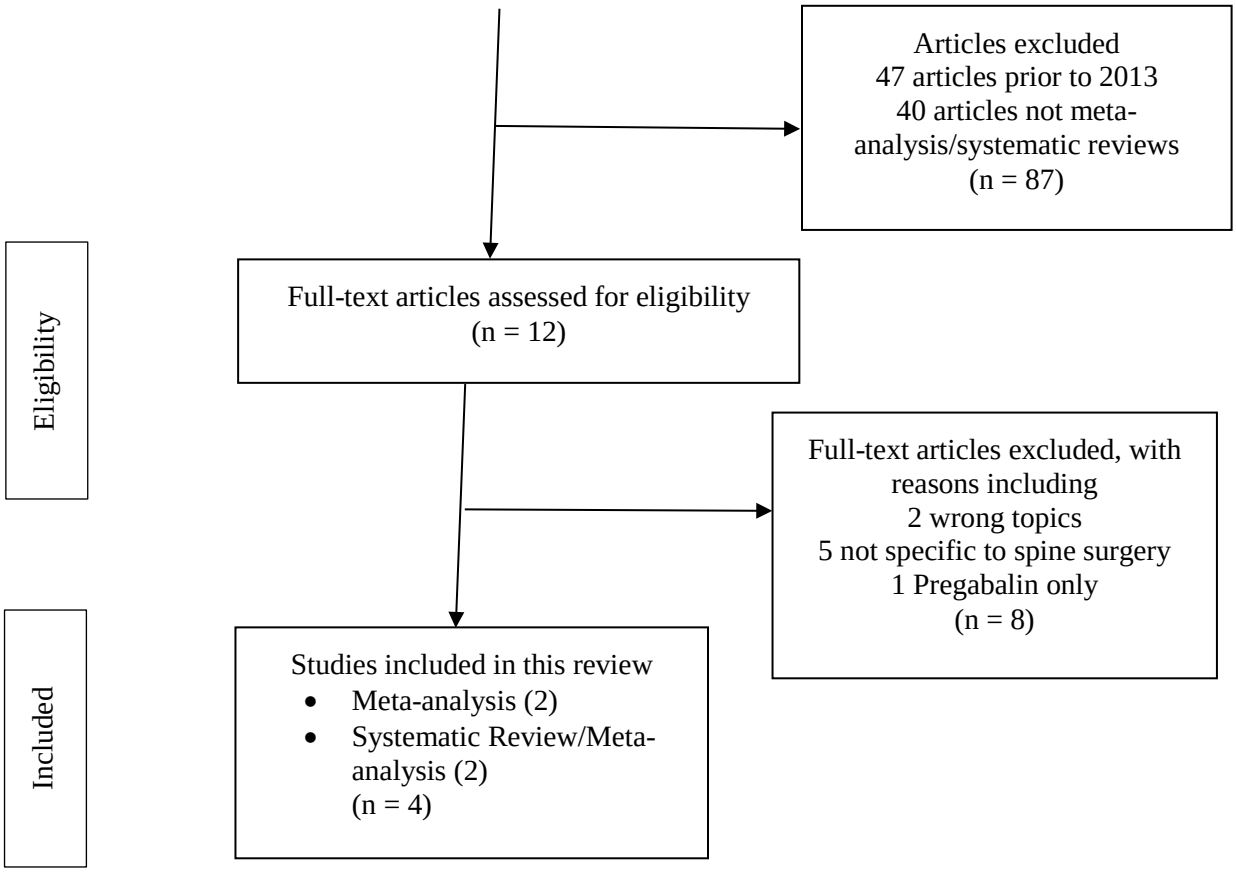


Figure 1. Flow diagram of systematic search selection process. Adapted from "Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement," by D. Moher, A. Liberati, J. Tetzlaff, D. Altman, and PRISMA Group. Copyright 2009 by PLoS Medicine

Pre-op Gabapentin for Lumbar Surgery Patients

Situation

Patients undergoing lumbar spine surgery including laminectomy with or without fusion experience significant pain in the post-operative period. Opioid medications are commonly used to help control

post-operative pain, but can lead to unacceptable adverse effects including sedation, urinary retention, nausea, and constipation. Alternative strategies in managing pain in the immediate post-operative period is essential to decrease adverse effects of opioids while controlling patient reported pain.

Background

The neurosurgery department formed an Enhanced Recovery After Surgery (ERAS) team in January 2018. Patient reported pain in the post-operative period was identified by the ERAS team as an area with opportunity to improve. The aim of the ERAS team is to identify alternative strategies to manage pain that does not include high doses of opioid medications.

Assessment

Currently, opioid medications are the mainstay of treatment for patients following lumbar spine surgeries. Research of current evidence-based practices show that administering gabapentin pre-operatively may reduce pain in the first 24 hours following surgery. Evidence also shows that pre-operative gabapentin use may decrease opioid use leading to less sedation, urinary retention, nausea, and pruritis. Utilizing gabapentin in the pre-operative period is common practice to other ERAS protocols including colorectal and orthopaedic surgeries.

Recommendation

Patients undergoing lumbar spine surgery with or without fusion will receive one dose of 900 mg gabapentin one hour prior to surgery. Exclusions are as follows:

1. Patients who already take gabapentin or pregabalin are instructed to take their home dose prior to arrival to the hospital and will not receive a pre-op dose.
2. Patients with a creatinine clearance below 30 mL/min will not receive gabapentin.

The neurosurgery provider will place the order for gabapentin upon patient arrival to pre-procedural services.

Figure 2. SBAR education for staff.

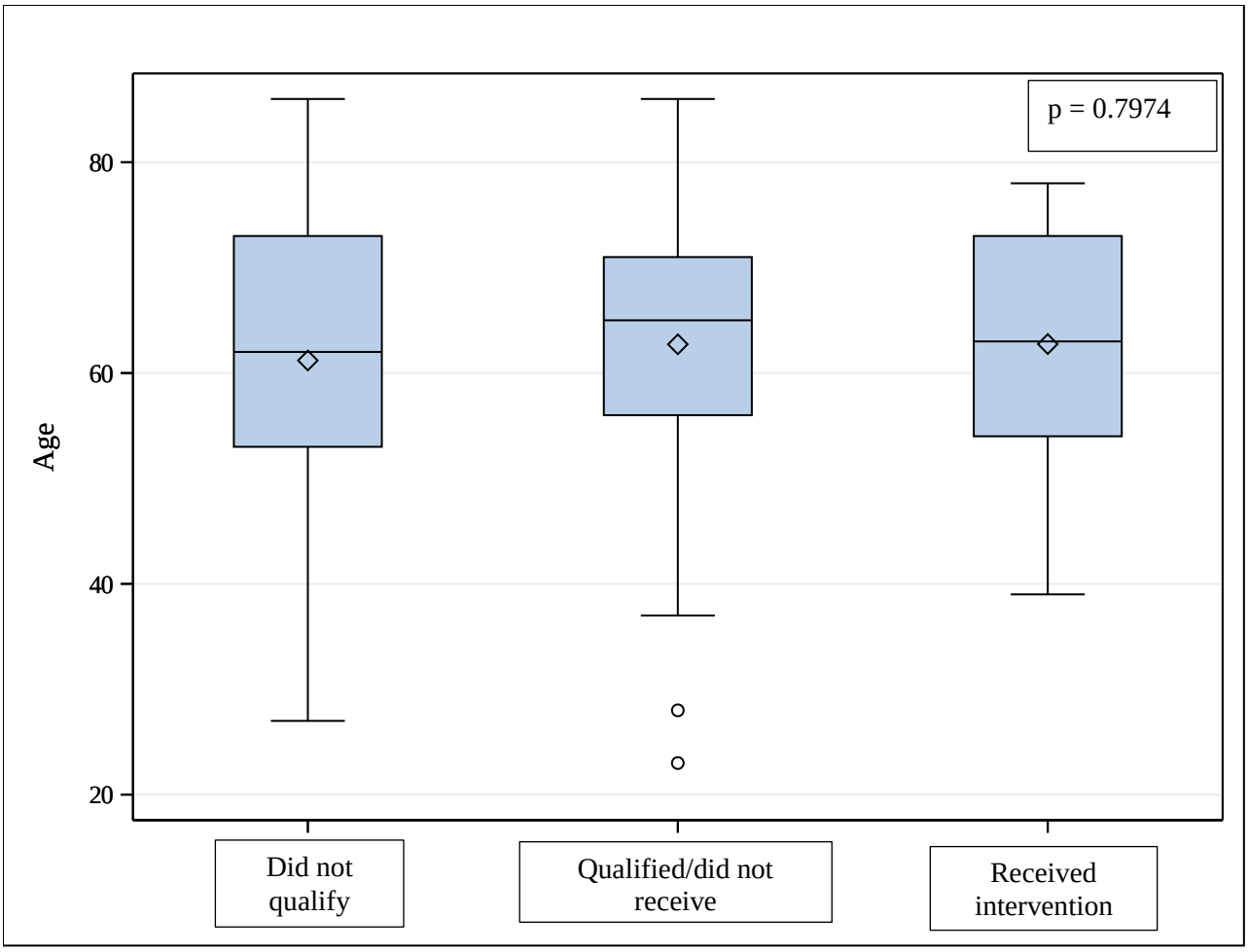


Figure 3. Distribution of age between groups.

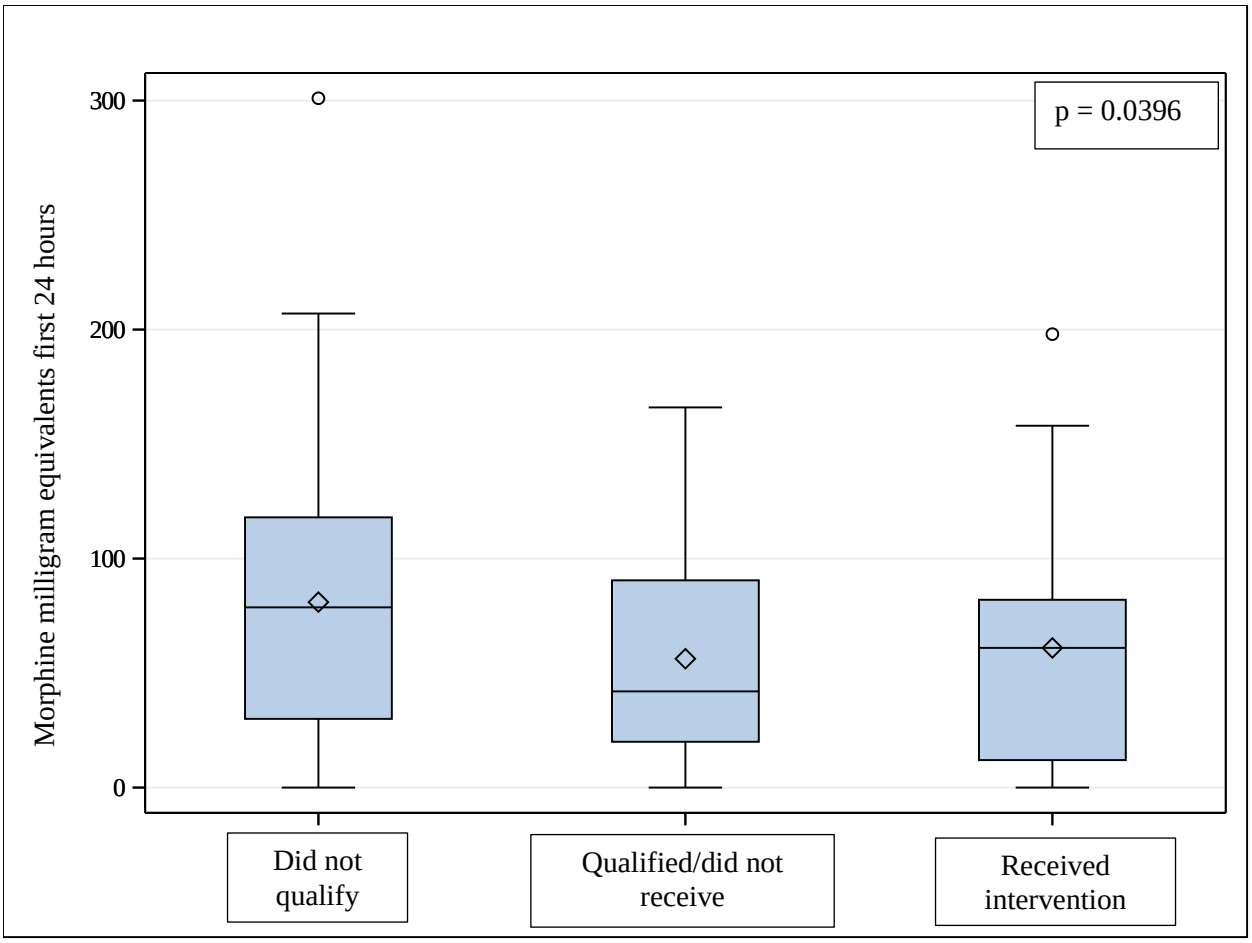


Figure 4. Distribution of morphine milligram equivalents between groups.

Tables

Table 1.

Comparison of qualitative data pre/post-intervention

Group	N	Variable	Mean	Standard deviation	Wilcoxon two-sample test p-value
Pre-intervention	77	Age	62.84	12.68	0.6085
		Length of stay in days	2.48	1.47	0.6928
		MME	63.23	51.07	0.4309
		Average pain score	4.82	1.67	0.6107
Post-intervention	63	Age	61.17	14.00	
		Length of stay in days	2.41	1.50	
		MME	72.30	58.04	
		Average pain score	4.98	2.10	

Note. MME = Morphine milligram equivalents. P-value < 0.05 determines significance between groups.

Table 2.

Demographics for groups compared in project analysis

Group	N	%	Mean	SD	p-value group comparisons
Received Intervention	24				
Age (years)			62.75	11.02	0.7974
Gender					0.4527
Male	10	41.67			
Female	14	58.33			
Type of surgery					0.5075
Laminectomy	14	58.33			
Fusion	10	41.67			
History of prior surgery					0.9286
No	15	62.50			
Yes	9	37.50			
Opioid tolerant					0.2991
No	22	91.67			
Yes	2	8.33			
Qualified/Did Not Receive	58				
Age (years)			62.72	13.33	
Gender					
Male	33	56.90			
Female	25	43.10			
Type of surgery					
Laminectomy	30	51.72			
Fusion	28	48.28			
History of prior surgery					
No	35	60.34			
Yes	23	39.66			
Opioid tolerant					
No	53	91.38			
Yes	5	8.62			
Did Not Qualify	58				
Age (years)			61.19	14.19	
Gender					
Male	30	51.72			
Female	28	48.28			
Type of surgery					
Laminectomy	26	44.83			
Fusion	32	55.17			
History of prior surgery					
No	37	63.79			
Yes	21	36.21			

Opioid tolerant		
No	48	82.76
Yes	10	17.24

Note. SD = Standard deviation. P-value < 0.05 determines significance between groups.

Table 3.

Outcomes data for group comparison

Group	**N**	**Mean**	**Standard deviation**	**F value group comparison**	**p-value group comparison**
Received intervention	24				
MME		60.98	50.30	3.31	0.0396
Pain scores		4.72	2.01	2.09	0.1274
LOS		2.51	1.72	0.76	0.4700
Qualified/did not receive	58				
MME		56.27	46.15		
Pain scores		4.58	1.72		
LOS		2.28	1.48		
Did not qualify	58				
MME		80.98	60.92		
Pain scores		5.27	1.91		
LOS		2.61	1.39		

Note. MME = Morphine milliequivalents; LOS = Length of stay in days. P-value < 0.05 determines significance between groups.

Table 4.

Post hoc comparison of morphine milligram equivalents (MME)

Comparison of MME between groups with Tukey adjusted p-values			
	Did not qualify	**Qualified/did not receive**	**Received intervention**
Did not qualify		0.0369	0.2745
Qualified/did not receive			0.9299
Received intervention			

Note. P-value < 0.05 determines significance between groups.

Table 5.

Adverse effects outcomes data between groups

	No	**Yes**	**Home**	**Rehab**	**POSS S**	**POSS 1**	**POSS 2**	**Chi square p-value**
Urinary retention								0.1882
Received intervention	21	3						
Qualified/did not receive	55	3						
Did not qualify	49	9						
Antiemetic use								0.8097
Received intervention	17	7						
Qualified/did not receive	44	14						
Did not qualify	45	13						
Discharge disposition								0.2739
Received intervention			22	2				
Qualified/did not receive			55	3				
Did not qualify			50	8				
Readmission related to pain								0.5193
Received intervention	23	1						
Qualified/did not receive	53	5						
Did not qualify	51	7						
Sedation								
Received intervention					0	23	0	
Qualified/did not receive					1	55	1	
Did not qualify					2	54	0	
Acute renal failure								
Received intervention	24	0						
Qualified/did not receive	58	0						
Did not qualify	56	2						
Readmission for sedation								
Received intervention	24	0						

Qualified/did not receive	57	1
Did not qualify	56	2

Note. POSS = Pasero Opioid-induced Sedation Scale; S = Sleep, easy to arouse, 1 = Awake and alert, 2 = Slightly drowsy, easily aroused. P-value < 0.05 determines significance between groups.

Table 6.

Estimated annual cost savings for the organization

Group	Number of patients readmitted for pain in 4 months	Cost per admission (x $13,433)	Projected total annual cost for readmission for pain
Received intervention	1	$13,433	$40,299
Qualified, did not receive	5	$67,165	$201,495
			Savings $161,196
			Cost of gabapentin $34.44
			Total annual savings $161,161.56

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DNP Project Oral Defense Presentation

Implementation of an Evidenced-Based Intervention for Pain Management in Lumbar Spine Surgery

Mary R. Draper

DNP Project Final Defense

April 12, 2019

Grand Valley State University
Kirkhof College of Nursing

Acknowledgements

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Objectives for Presentation

1. Review the clinical problem.
2. Assess the organization.
3. Review the evidence.
4. Present the project plan.
5. Review the results.
6. Discuss next steps.

Introduction

- Spine surgeries: top six procedures responsible for the highest degree of post-surgical pain. (Bajwa & Haldar, 2015)
- Post-operative pain complicated by complex procedures, patient co-morbidities, and pre-existing opioid tolerance.
- Opioid epidemic: 115 American deaths every day costing the United States 78.5 billion dollars each year. (National Institute on Drug Abuse, 2018)
- Opioid naïve patients: substantial risk of becoming a long-term opioid user, more patients receiving long-term opioids after spine surgery than before surgery. (Deyo et al., 2018)
- 30-60% of patients continue to use opioids after the acute phase of healing following spine surgery. (Deyo et al., 2018)

Introduction

- Up to 50% of patients experience inadequate pain control
  - Leads to dissatisfaction and poor mobility
  - Almost 25% are given excessive opioids resulting in suboptimal outcomes and adverse events. (Rivkin & Rivkin, 2014)

- Opioid use prolongs hospital length of stay related to side effects
  - Respiratory depression, sedation, nausea, vomiting, urinary retention, and ileus.
  - Drives up medical costs and increases readmission rates. (Tan, Law, & Gan, 2015)

- Inadequate pain control is the second most common reason for 30-day readmissions following lumbar spine surgery. (Kurd, Kreitz, Schroeder, & Vaccaro, 2017)

Assessment of Organization

- West Michigan neurosurgery program
  - Two neurosurgeons, three physician assistants, and three registered nurses in the outpatient clinic
  - Over 500 lumbar spinal neurosurgeries are completed yearly. (XXX, 2018a)
- 283-bed acute care hospital
  - 34 bed inpatient unit
- Designated Spine Center of Excellence by Blue Cross Blue Shield and Priority Health (XXX, 2018b)
- Michigan Spine Surgery Improvement Collaborative (MSSIC)
- Spine Team
- Enhanced Recovery after Surgery (ERAS) program January 2018

Framework: Institutional and Organizational Assessment Model

Universalia. (2018). Institutional and organizational performance assessment. Retrieved from http://www.universalia.com/en/services/institutional-and-organizational-performance-assessment

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SWOT

Strengths	Weaknesses
Spine Team collaboration with other departments. MSSIC member. Surgeons/physician assistants recognize the opioid epidemic and are open to evidence-based practice change in pain management.	High utilization of opioid medications post-operatively. Palliative care does not continue consults after discharge from the hospital.
Opportunities	**Threats**
ERAS subcommittee in place. Decrease opioid use consistent with recent Michigan legislation. Improve patient experience scores via reduced pain. Reduce post-operative complications and length of stay related to pain and immobility.	Opioid use preoperative is common. Neuropathic pain is difficult to manage. Lost revenue from longer length of stay for uncontrolled pain.

Harrison, J. P. (2010). Strategic planning and SWOT analysis. *Essentials of strategic planning in healthcare* (pp. 91-97). Chicago: Health Administration Press.

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Clinical Practice Question

Does implementation of an evidence-based intervention for preoperative administration of gabapentin:

1. Reduce opioid consumption among persons undergoing lumbar spine surgery for up to 24 hours post-operatively?
2. Improve patient's perception of pain among persons undergoing lumbar spine surgery for up to 24 hours post-operatively?
3. Reduce length of stay among persons undergoing lumbar spinal surgery?

Literature Review

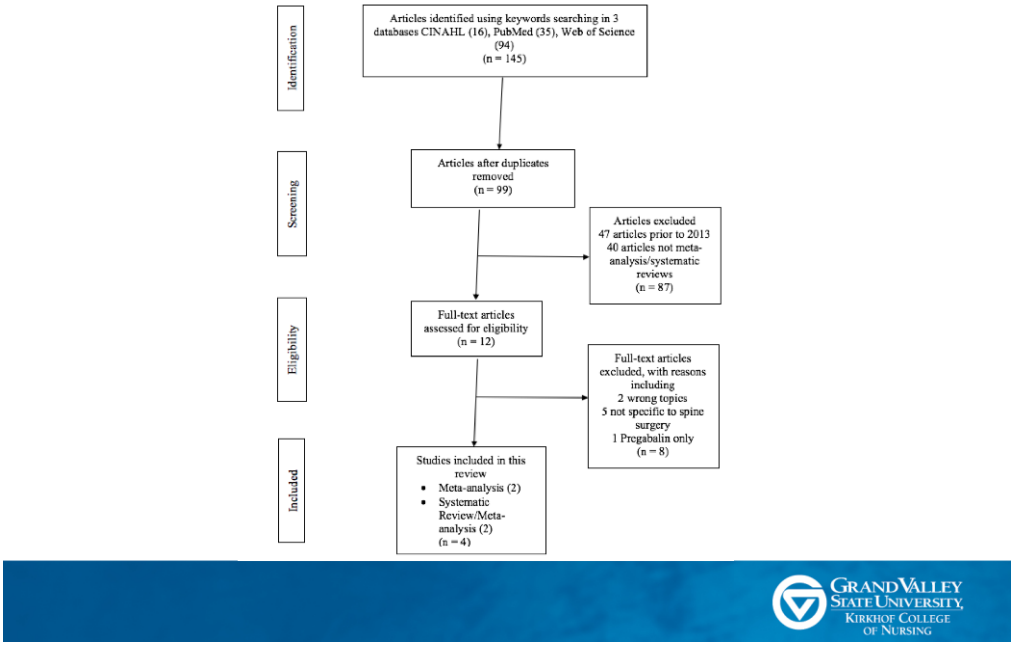
- Purpose: Evaluate the effectiveness of perioperative gabapentin in lumbar spinal surgery

- Aims:
  1. Determine effectiveness in providing acute post-operative pain control as a solo intervention (not multimodal)
  2. Determine effectiveness at reducing opioid use among persons undergoing lumbar spinal surgery
  3. Determine improvement in patient's perception of pain among persons undergoing lumbar spine surgery for up to 24 hours post-operatively

Review Method

- Framework: Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher, Liberati, Tetzlaff, Altman, & The PRISMA group, 2009)
- CINAHL, PubMed, Web of Science 2013-2018
- Meta-analysis and systematic reviews were included

PRISMA Figure



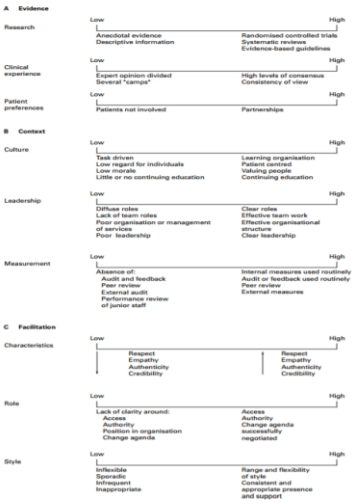
Summary of Literature Review

- Han et al. (2017) 300 mg - 1,200 mg
  - Reduce cumulative morphine equivalents consumed at 24 hours post-op with reduced pain scores, reduced adverse effects including vomiting, pruritis, and urinary retention. Higher doses of gabapentin resulted in less morphine equivalents consumed. There was an increase of somnolence in the gabapentin group.
- Liu et al. (2017) 300 mg – 1,200 mg
  - Preoperative gabapentinoids were able to reduce post-operative pain, total morphine equivalents consumed, and morphine-related complications following spine surgery. Significant decreases in risk of nausea, vomiting, and pruritis was associated with gabapentinoid use. High dose of gabapentinoids were superior to low dose in reducing acute pain and cumulative morphine equivalents consumed following spinal surgery.
- Peng et al. (2017) 300 mg – 1,200 mg
  - Gabapentin was efficacious in reducing post-operative pain, total morphine equivalents consumed, and morphine-related complications following spine surgery. A high dose 900 mg or greater is more effective than a lower dose under 900 mg.
- Yu et al. (2013) 300 mg – 1,200 mg
  - Gabapentin was efficacious in the management of post-operative pain at all time points during the first day after surgery and could significantly reduce opiate consumptions. Doses of 600mg, 900mg, or 1200mg were all considered effective and safe.

Evidence for Project

- Gabapentin shown to reduce cumulative morphine equivalents consumed for the first 24 hours post-operatively.
- Gabapentin shown to improve patient perception of pain for the first 24 hours post-operatively.
- Reports of less nausea, vomiting, urinary retention, dizziness, somnolence, and pruritis.
- Higher doses more efficacious.

Model to Examine Phenomenon



Promoting Action on Research Implementation in Health Services Framework (PARiHS)

Successful implementation is a function of three concepts: evidence, context, and facilitation.

Dang, D., Melnyk, B. M., Fineout-Overholt, E., Ciliska, D., DiCenso, A., Cullen, L., . . . Stevens, K. R. (2015). Models to guide implementation and sustainability of evidence-based practice. In B. M. Melnyk & E. Fineout-Overholt (Eds.), *Evidence-based practice in nursing & healthcare* (3rd ed., pp. 274-315). Philadelphia: Wolters Kluwer Health.

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Project Plan

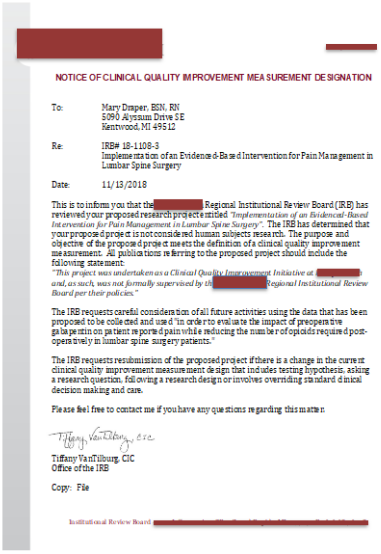
- Purpose: Implement the intervention of administration of preoperative gabapentin into standard of care for lumbar spine surgeries

- Objectives:
  1. Reduce the number of opioids required in the first 24-hour post-operative period
  2. Improve patient perceptions of pain
  3. Decrease length of stay
  4. Reduce adverse effects of opioid medications

Design

- Quality Improvement Project
- Translation of Evidence into Practice
- Evaluation of Effectiveness of Intervention at the Organization

IRB Approval



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NOTICE OF CLINICAL QUALITY IMPROVEMENT MEASUREMENT DESIGNATION

To: Mary Draper, BSN, RN
5090 Alyssum Drive SE
Kentwood, MI 49512

Re: IRB# 18-1108-3
Implementation of an Evidenced-Based Intervention for Pain Management in Lumbar Spine Surgery

Date: 11/13/2018

This is to inform you that the [redacted] Regional Institutional Review Board (IRB) has reviewed your proposed research project entitled *"Implementation of an Evidenced-Based Intervention for Pain Management in Lumbar Spine Surgery"*. The IRB has determined that your proposed project is not considered human subjects research. The purpose and objective of the proposed project meets the definition of a clinical quality improvement measurement. All publications referring to the proposed project should include the following statement:
"This project was undertaken as a Clinical Quality Improvement Initiative at [redacted], and, as such, was not formally supervised by the [redacted] Regional Institutional Review Board per their policies."

The IRB requests careful consideration of all future activities using the data that has been proposed to be collected and used "in order to evaluate the impact of preoperative gabapentin on patient reported pain while reducing the number of opioids required post-operatively in lumbar spine surgery patients."

The IRB requests resubmission of the proposed project if there is a change in the current clinical quality improvement measurement design that includes testing hypothesis, asking a research question, following a research design or involves overriding standard clinical decision making and care.

Please feel free to contact me if you have any questions regarding this matter.

Tiffany VanTilburg, CIC

Tiffany VanTilburg, CIC
Office of the IRB

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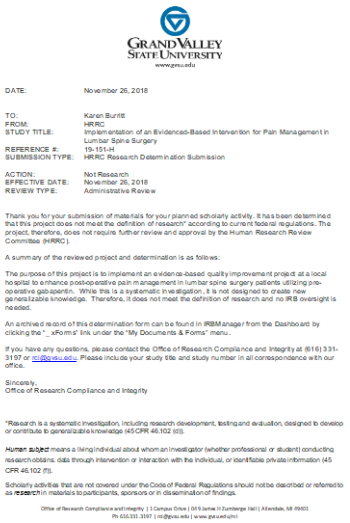
Institutional Review Board [redacted]



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www.gvsu.edu

DATE: November 26, 2018

TO: Karen Burritt
FROM: HRRC
STUDY TITLE: Implementation of an Evidenced-Based Intervention for Pain Management in Lumbar Spine Surgery
REFERENCE #: 19-151-H
SUBMISSION TYPE: HRRC Research Determination Submission

ACTION: Not Research
EFFECTIVE DATE: November 26, 2018
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 an evidence-based quality improvement project at a local hospital to enhance postoperative pain management in lumbar spine surgery patients utilizing pre-operative gabapentin. While this is a systematic investigation, it is not designed to create new generalizable knowledge. Therefore, it does not meet the definition of research and no IRB oversight is needed.

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 [redacted]. 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)).

Scholarly activities that are not covered under the Code of Federal Regulations should not be described or referred to as research in materials to participants, sponsors or in dissemination of findings.

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

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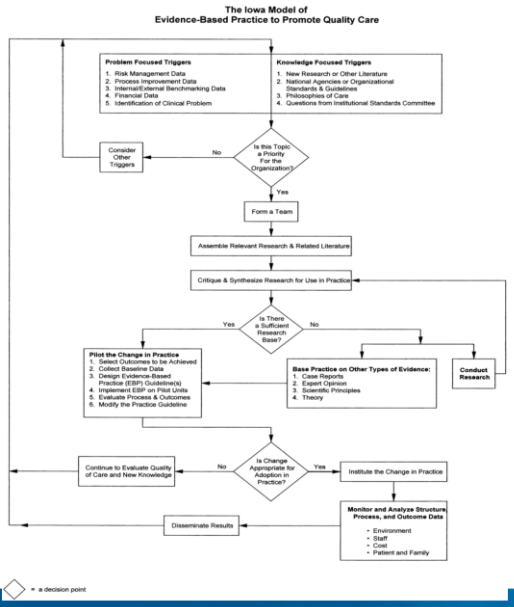
Setting & Participants

- 283-bed acute care hospital in West Michigan
- Participants/Stakeholders:
  - Neurosurgeons
  - Neurosurgery physician assistants
  - Registered nurses in the clinic, pre-procedural services department, inpatient unit
  - Pharmacy
  - Spine Team/ERAS committee
  - Patients undergoing lumbar spine surgery

Implementation Model



Iowa Model of Evidence-Based Practice to Promote Quality Care

Titler, M. G., Kleiber, C., Steelman, V. J., Rakel, B. A., Budreau, G., Everett, L. Q., . . . Goode, C. J. (2001). The Iowa model of evidence-based practice to promote quality care. *Critical Care Nursing Clinics of North America, 13,* 497-509. doi: 10.1016/S0899-5885(18)30017-0

Implementation Strategy & Element

Expert Recommendations for Implementing Change (ERIC) (Powell et al., 2015).

1. Build a coalition

2. Design an intervention and streamlined process
   - 900 mg of gabapentin one hour prior to surgery
   - Exclusions: patients who are already prescribed gabapentin or pregabalin, hypersensitivity, creatinine clearance below 30 mL/min

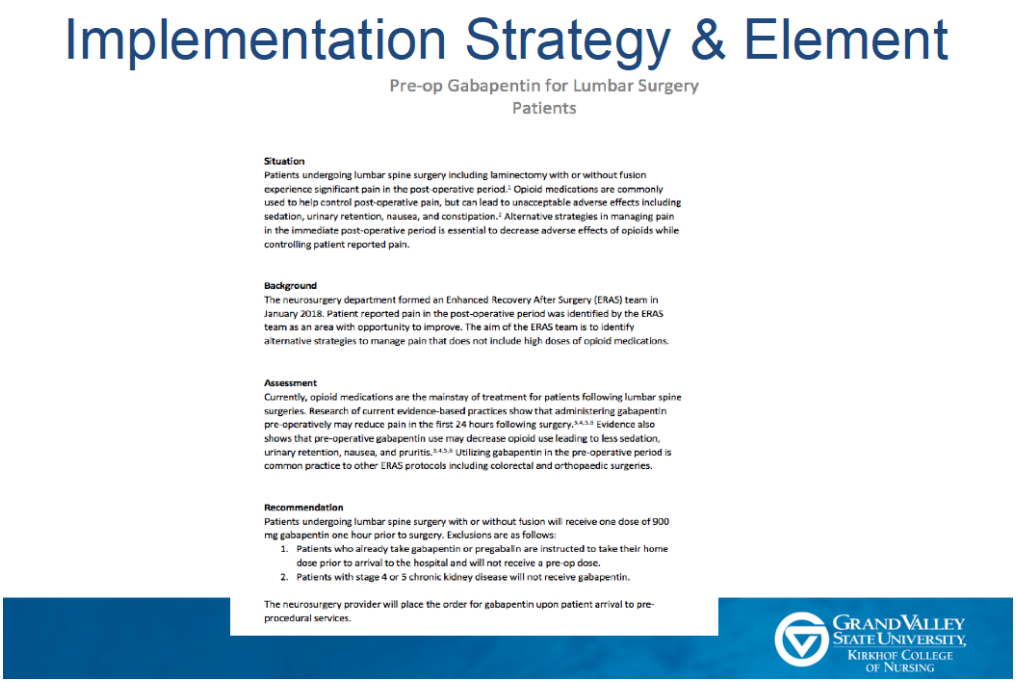
Implementation Strategy & Element

3. Present intervention for approval at Spine Team

4. Submission for IRB

5. Education for neurosurgery clinic and pre-procedural services department

6. 'Go-live' date. Presence in the clinic and pre-procedural services for two weeks.


Implementation Strategy & Element
Pre-op Gabapentin for Lumbar Surgery Patients
Situation
Patients undergoing lumbar spine surgery including laminectomy with or without fusion experience significant pain in the post-operative period.[2] Opioid medications are commonly used to help control post-operative pain, but can lead to unacceptable adverse effects including sedation, urinary retention, nausea, and constipation.[2] Alternative strategies in managing pain in the immediate post-operative period is essential to decrease adverse effects of opioids while controlling patient reported pain.
Background
The neurosurgery department formed an Enhanced Recovery After Surgery (ERAS) team in January 2018. Patient reported pain in the post-operative period was identified by the ERAS team as an area with opportunity to improve. The aim of the ERAS team is to identify alternative strategies to manage pain that does not include high doses of opioid medications.
Assessment
Currently, opioid medications are the mainstay of treatment for patients following lumbar spine surgeries. Research of current evidence-based practices show that administering gabapentin pre-operatively may reduce pain in the first 24 hours following surgery.[3,4,5,6] Evidence also shows that pre-operative gabapentin use may decrease opioid use leading to less sedation, urinary retention, nausea, and pruritis.[3,4,5,6] Utilizing gabapentin in the pre-operative period is common practice to other ERAS protocols including colorectal and orthopaedic surgeries.
Recommendation
Patients undergoing lumbar spine surgery with or without fusion will receive one dose of 900 mg gabapentin one hour prior to surgery. Exclusions are as follows:
1. Patients who already take gabapentin or pregabalin are instructed to take their home dose prior to arrival to the hospital and will not receive a pre-op dose.
2. Patients with stage 4 or 5 chronic kidney disease will not receive gabapentin.
The neurosurgery provider will place the order for gabapentin upon patient arrival to pre-procedural services.
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Implementation Strategy & Element

7. Two months of data collection via chart review pre- and post-intervention implementation

8. Data analysis/interpretation with graduate statistician student

9. Disseminate findings
   - Project Defense April 12, 2019
   - Spine Team meeting April 24, 2019

Evaluation & Measures

- Chart review
  - Research Electronic Data Capture (REDCap)
  - Statistical Package for the Social Sciences (SPSS)
- Demographic data
- Morphine milligram equivalents
- Numeric rating scale
- Length of stay in days
- Adverse effects

Analysis Plan

- Compare pre- post- intervention data
  - Categorical data: Chi square to compare binary outcomes
  - Quantitative data: Wilcoxon two sample T-test, ANOVA between groups comparison, Tukey adjusted p-value

Resources & Cost

Based on 50 patients post-intervention

Doctor of Nursing Practice Project Financial Operating Plan	
Effectiveness of Perioperative Gabapentin for Pain Management in Lumbar Spinal Surgery	
Revenue	
Project Manager Time (in-kind donation)	2,520.00
Consultations	
Statistician (in-kind donation)	100.00
Revenue Source	
One less dose of Dilaudid given per patient ($1.05/dose)	52.50
One less dose of Norco given per patient ($0.38/dose)	19.00
One less readmission for pain control	13,433.00
TOTAL INCOME	16,124.50
Expenses	
Project Manager Time (in-kind donation)	2,520.00
Team Member Time:	
Clinical Nurse Specialist	120.00
Consultations	
Statistician (in-kind donation)	100.00
Cost of Gabapentin ($0.14/dose)	7.00
TOTAL EXPENSES	2,747.00
Net Operating Plan	**13,377.50**

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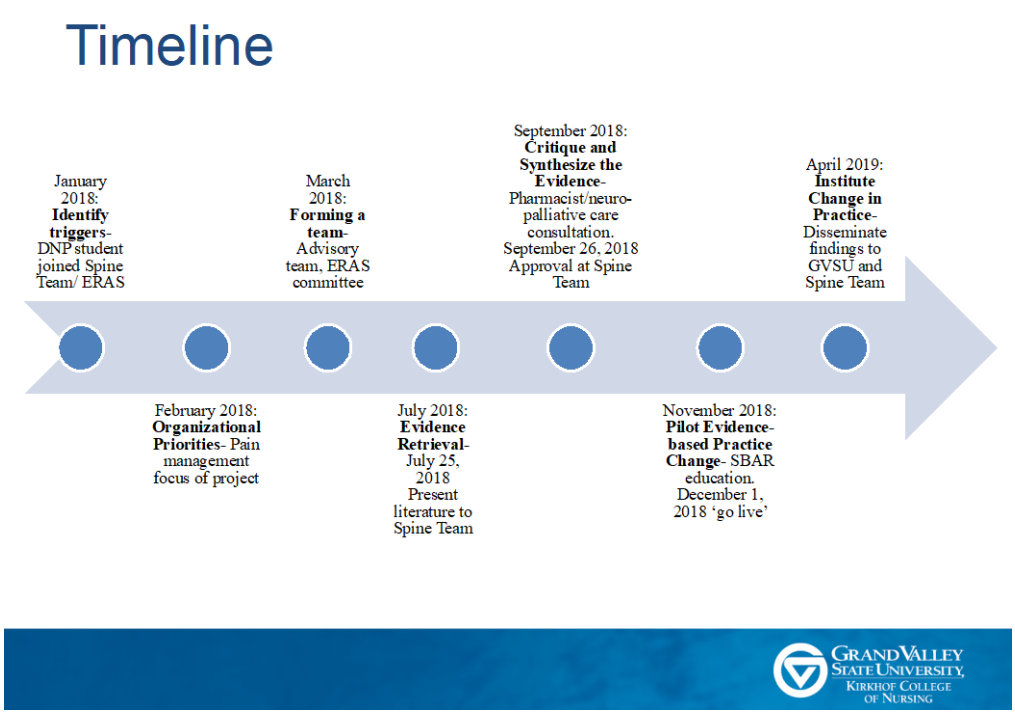
Timeline
January 2018: **Identify triggers**- DNP student joined Spine Team/ ERAS
February 2018: **Organizational Priorities**- Pain management focus of project
March 2018: **Forming a team**- Advisory team, ERAS committee
July 2018: **Evidence Retrieval**- July 25, 2018 Present literature to Spine Team
September 2018: **Critique and Synthesize the Evidence**- Pharmacist/neuro-palliative care consultation. September 26, 2018 Approval at Spine Team
November 2018: **Pilot Evidence-based Practice Change**- SBAR education. December 1, 2018 'go live'
April 2019: **Institute Change in Practice**- Disseminate findings to GVSU and Spine Team
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Results

140 charts reviewed

- 77 pre-implementation
- 63 post-implementation
  - 24 of the 34 patients in the post implementation group who qualified received gabapentin (70.6% compliance)

Results Pre/Post Data

Group	N	Variable	Mean	Standard deviation	Wilcoxon two-sample test p-value
Pre-intervention	77	Age	62.84	12.68	0.6085
		Length of stay in days	2.48	1.47	0.6928
		MME	63.23	51.07	0.4309
		Average pain score	4.82	1.67	0.6107
Post-intervention	63	Age	61.17	14.00	
		Length of stay in days	2.41	1.50	
		MME	72.30	58.04	
		Average pain score	4.98	2.10	

Results: Demographics

Group	N	%	Mean	SD	p-value group comparisons
Received Intervention	24				
Age (years)			62.75	11.02	0.7974
Gender					0.4527
Male	10	41.67			
Female	14	58.33			
Type of surgery					0.5075
Laminectomy	14	58.33			
Fusion	10	41.67			
History of prior surgery					0.9286
No	15	62.50			
Yes	9	37.50			
Opioid tolerant					0.2991
No	22	91.67			
Yes	2	8.33			
Qualified/Did Not Receive	58				
Age (years)			62.72	13.33	
Gender					
Male	33	56.90			
Female	25	43.10			
Type of surgery					
Laminectomy	30	51.72			
Fusion	28	48.28			
History of prior surgery					
No	35	60.34			
Yes	23	39.66			
Opioid tolerant					
No	53	91.38			
Yes	5	8.62			
Did Not Qualify	58				
Age (years)			61.19	14.19	
Gender					
Male	30	51.72			
Female	28	48.28			
Type of surgery					
Laminectomy	26	44.83			
Fusion	32	55.17			
History of prior surgery					
No	37	63.79			
Yes	21	36.21			
Opioid tolerant					
No	48	82.76			
Yes	10	17.24			

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Results: Outcomes Data

Group	N	Mean	Standard deviation	F value group comparison	p-value group comparison
Received intervention	24				
MME		60.98	50.30	3.31	0.0396
Pain scores		4.72	2.01	2.09	0.1274
LOS		2.51	1.72	0.76	0.4700
Qualified/did not receive	58				
MME		56.27	46.15		
Pain scores		4.58	1.72		
LOS		2.28	1.48		
Did not qualify	58				
MME		80.98	60.92		
Pain scores		5.27	1.91		
LOS		2.61	1.39		

Comparison of MME between groups with Tukey adjusted p-values			
	Did not qualify	**Qualified/did not receive**	**Received intervention**
Did not qualify		0.0369	0.2745
Qualified/did not receive			0.9299
Received intervention			

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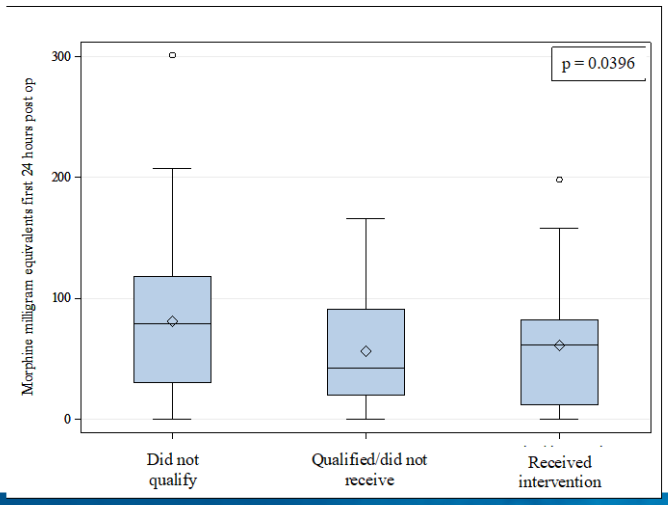
Results: Morphine Milligram Equivalents Between Groups



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Results: Adverse Effects

	No	Yes	Home	Rehab	POSS S	POSS 1	POSS 2	Chi square p-value
Urinary retention								
Received intervention	21	3						0.1882
Qualified/did not receive	55	3						
Did not qualify	49	9						
Antiemetic use								
Received intervention	17	7						0.8097
Qualified/did not receive	44	14						
Did not qualify	45	13						
Discharge disposition								
Received intervention			22	2				0.2739
Qualified/did not receive			55	3				
Did not qualify			50	8				
Readmission related to pain								
Received intervention	23	1						0.5193
Qualified/did not receive	53	5						
Did not qualify	51	7						
Sedation								
Received intervention					0	23	0	
Qualified/did not receive					1	55	1	
Did not qualify					2	54	0	
Acute renal failure								
Received intervention	24	0						
Qualified/did not receive	58	0						
Did not qualify	56	2						
Readmission for sedation								
Received intervention	24	0						
Qualified/did not receive	57	1						
Did not qualify	56	2						

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Results: Budget/Cost Savings

Group	Number of patients readmitted for pain in 4 months	Cost per admission (x $13,433)	Projected total annual cost for readmission for pain
Received intervention	1	$13,433	$40,299
Qualified, did not receive	5	$67,165	$201,495
			Savings $161,196 Cost of gabapentin $34.44 Total annual savings $161,161.56

Discussion

- No statistically significant differences between groups
  - Large variability in MME use
  - No increased harm
- Clinical significance in reduction in readmission for pain
- Missed opportunities: pharmacy transcription errors, compliance of clinic staff

Limitations

- Gabapentin dose variance in the literature
  - Gabapentin naïve only
  - Multimodal interventions
- Small sample size
- Compliance in clinic/pharmacy

Implications for Practice

- Synergistic effect in multimodal pain regimen
- Low cost, Cost savings in less readmissions
- Reasonable to continue data collection to gather larger sample size

Sustainability Plan

- Further education to pre-procedural services/pharmacy
  - Many ERAS protocols in development
- Accountability at Spine Team
  - Stakeholder support
  - Future development of ERAS program

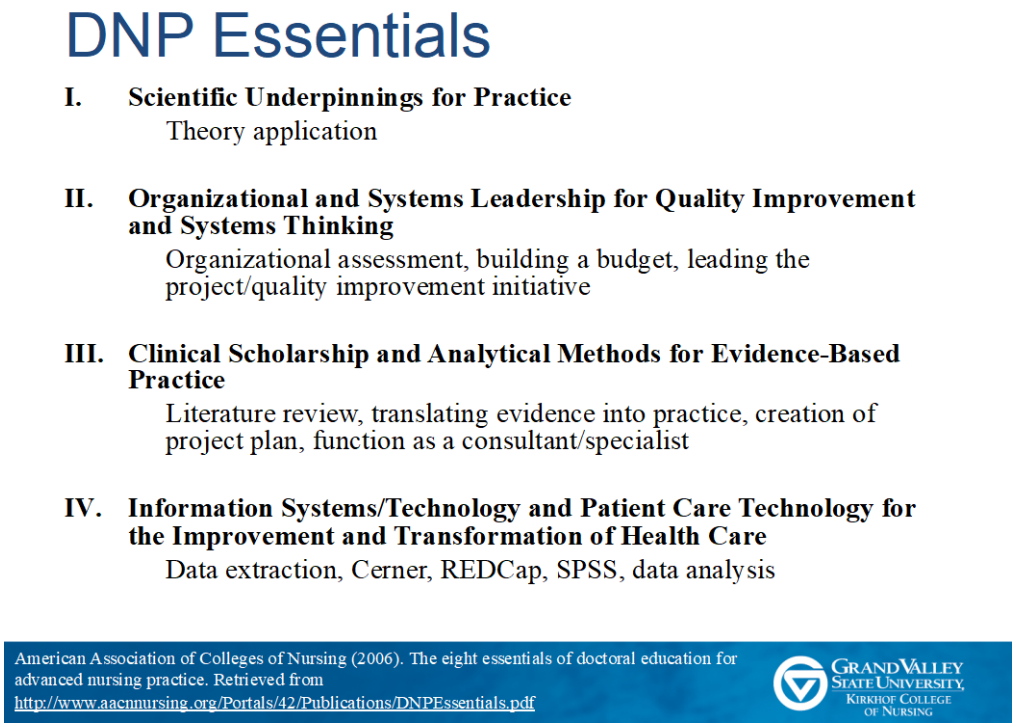
Conclusions

- Preoperative gabapentin was not effective as a solo intervention in reducing opiate use, patient reported pain, or length of stay.

- Further work is needed to determine effective dose and usefulness in multimodal pain management.

Dissemination

- Grand Valley State University Doctoral Project Defense
- Spine Team April 24th 2019
- Submission to ScholarWorks


DNP Essentials
I. Scientific Underpinnings for Practice
Theory application
II. Organizational and Systems Leadership for Quality Improvement and Systems Thinking
Organizational assessment, building a budget, leading the project/quality improvement initiative
III. Clinical Scholarship and Analytical Methods for Evidence-Based Practice
Literature review, translating evidence into practice, creation of project plan, function as a consultant/specialist
IV. Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care
Data extraction, Cerner, REDCap, SPSS, data analysis
American Association of Colleges of Nursing (2006). The eight essentials of doctoral education for advanced nursing practice. Retrieved from http://www.aacnnursing.org/Portals/42/Publications/DNPEssentials.pdf
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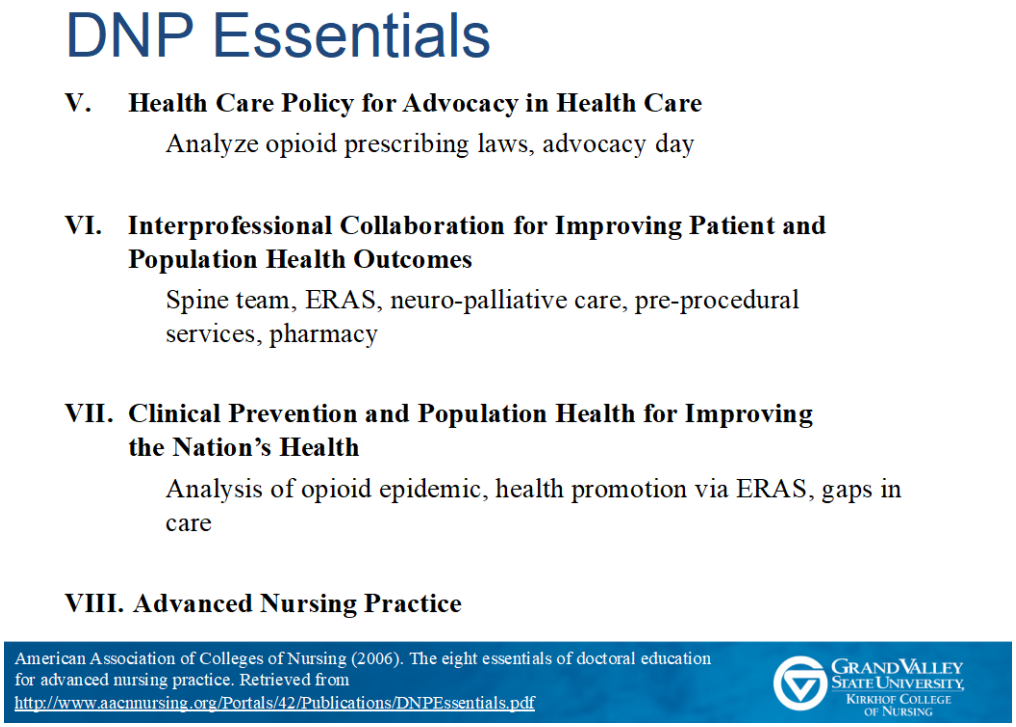
DNP Essentials
V. Health Care Policy for Advocacy in Health Care
Analyze opioid prescribing laws, advocacy day
VI. Interprofessional Collaboration for Improving Patient and Population Health Outcomes
Spine team, ERAS, neuro-palliative care, pre-procedural services, pharmacy
VII. Clinical Prevention and Population Health for Improving the Nation's Health
Analysis of opioid epidemic, health promotion via ERAS, gaps in care
VIII. Advanced Nursing Practice
American Association of Colleges of Nursing (2006). The eight essentials of doctoral education for advanced nursing practice. Retrieved from http://www.aacnnursing.org/Portals/42/Publications/DNPEssentials.pdf
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