REDUCING POSTOPERATIVE NARCOTIC USE IN OPIOID NAÏVE PATIENTS UTILIZING A STANDARDIZED OPIOID TITRATION PROTOCOL

A Doctor of Nursing Practice Project Report

by

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MSN, Texas A&M University – Corpus Christi, 2016

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This Doctor of Nursing Practice Project Report meets the standards for scope and quality of Texas A&M University-Corpus Christi College of Nursing and Health Sciences and is hereby approved.

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August 2021

DEDICATION

I would like to dedicate this work to my beloved grandmother and my wonderful husband. My grandmother believed in me, even when I didn't believe in myself. She is not in the present, but I know she is looking down from above and smiling. The love and support of my husband has kept me going every step of the way. It is through both their love and support, and the strength of the Almighty which has given me the ability to achieve my goal.

ACKNOWLEDGEMENTS

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ABSTRACT

Background: Due to the current opioid crisis, physicians and policymakers are increasingly focusing on ways to decrease opioid overuse and misuse in the United States. Surgeons are noted to be some of the highest prescribers of opioids. When prescriptions are issued for acute postoperative pain management to opioid naive patients, the risk for acute opioid use progressing to chronic use can become problematic. **Objective:** To implement an evidence-based standardized opioid titration protocol postoperatively to improve clinical practice and reduce long-term postoperative opioid exposure in the orthopedic clinic. **Method:** To improve quality of care, we developed and implemented a standardized opioid titration protocol and applied it to 25 postoperative patients over a six-week period. The protocol consisted of a four-step process, which allowed opioid narcotics to be systematically weaned down consistently over a six-week process. We evaluated patient pain levels and prescription refills biweekly to determine efficacy. **Results:** 98% (n=24) of patients experienced satisfactory pain relief by week 6, 71% (n=17) of patients stopped opioid use by week 2, and 100% (n=25) of patients did not require further refills after 4 weeks. When compared to prior prescribing practices, overall refill rates were found to be significantly decreased by 10% (p= 0.025). **Implications:** Implementation of a standardized opioid titration protocol was associated with fewer opioid pills being prescribed, fewer requests for opioid prescription and fewer refills, in addition to lower pain scores.

Keywords: opioid prescription, acute pain, tapering protocol, postoperative pain, surgery

Reducing Postoperative Narcotic Use in Opioid Naïve Patients Utilizing a Standardized Opioid Titration Protocol

INTRODUCTION

Background and Significance

Patient deaths in the United States (US) arising from prescription opioid use were four times higher in 2018 when compared to opioid related deaths in 1999 (CDC, 2020) resulting in great cost to human life as well as economic cost. Greater than $78 billion have been spent annually in the United States (US) on opioid-related abuse and overdose since 2018 (CDC Centers for Disease Control and Prevention [CDC], 2020). Americans consume over 99% of the global hydrocodone supply and up to 80% of the worldwide supply of opiates. Opioid-related mortality due to drug overdose has increased in recent years, with over 700,000 people succumbing to opioid overdose from 1999 to 2018 (CDC Centers for Disease Control and Prevention [CDC], 2020). The Centers for Disease Control (2018) has issued guidelines for prescribing opioids in the primary care setting; however, the guidelines pertain to the management of chronic pain and offer little guidance for the management of acute pain or postoperative surgical pain. Further studies have shown surgeons are the highest prescribers of opioid pain medication postoperatively and are contributing to the prescription drug opioid epidemic by their practices (Hill et al., 2017). Excessive postoperative prescribing of opioid pain medication has shown to increases the potential for patient abuse and increased medical costs (Starks et al., 2017). Significant variation in opioid prescribing practices among surgeons cannot be explained solely by patient factors (Thiels, et al., 2017). According to Gaddis et al. (2019) the use of opioid medication for management of acute conditions is directly linked to a 13% increase in the use of chronic pain medication, suggesting a distinct problem with opioid prescribing

practices for management of acute conditions. The Carter Whitehouse brought to light the problem of abuse and misuse of opioids and the Trump Administration dedicated the presidency to eliminating and fighting against the opioid epidemic (Dasgupta et al., 2018).

According to the National Institute on Drug Abuse (2020), healthcare providers in Texas wrote approximately 47.2 opioid prescriptions for every 100 persons in 2018, the lowest rate in the state since 2006; however, the rate of synthetic opioid deaths remained steady. In comparison, the average rate for opioid prescriptions in the US was 51.4 for every 100 persons. In addition, Texas currently has the highest healthcare costs related to opioid use and abuse, totaling over $1.9 billion annually. Healthcare costs in the U.S. totaled over $635 billion dollars annually (National Institute on Drug Abuse [NIH], 2020). Moreover, further studies indicate that large opioid prescriptions utilized for acute postoperative pain management can increase overall opioid consumption when compared to smaller initial prescriptions provided, specifically when dealing with opioid naive patients (Gaddis, et al., 2019).

Leroux et al. (2019) identified opioid naive patients as those who had not been taking daily opioid medication prior to surgical intervention. According to Tamboli et al., (2019), chronic opioid use postoperatively has been defined as continued opioid usage beyond the 90-day time frame with opioid naive patients at risk of becoming a chronic user at a rate of 7%. Little information exists regarding how best to develop or implement standardized opioid titration protocols for acute postoperative pain; however, several studies suggest a titration protocol should be utilized (Feinburg et al., 2018). In addition, varying prescribing practices by surgeons without the standardized opioid titration protocols may increase the risk of opioid abuse or misuse for opioid naive patients. Surgeons require specific guidelines and education in assisting with acute postoperative pain management. Implementing a standardized opioid

titration protocol (SOTP) postoperatively would help prevent excessive prescribing practices and chronic opioid use, thus decrease postoperative opioid use in general. There is increasing evidence that reducing the amount of opioid exposure postoperatively can enhance the postoperative recovery period (Frankel, et al., 2020).

Review of the Literature

A review of the literature indicated there was a gap in practice regarding proper titration of opioids for acute postoperative pain management, largely due to varying prescribing practices among surgeons (Thiels, et al., 2017). Studies conducted by Thiels et al. (2017) and Gaddis et al. (2019), further supported a need for evidence-based standardized opioid prescription guidelines for acute postoperative pain management to reduce opioid misuse and/or abuse. Both studies found most patients undergoing surgical interventions were opioid naive and were overprescribed opiates postoperatively (Thiels, et al., 2017 and Gaddis, et al., 209). Opioid naïve patients were described as those patients who had not received opioids 90-days prior to recommended surgical intervention. Significant variations in prescribing practices were also noted, with large amounts of opioids being prescribed for the management of acute pain and not completely consumed by the patient on further evaluation of opioid intake. According to Gaddis et al. (2019) identifying opioid prescribing practices after elective surgery and developing specific prescribing practice subsets for the most common surgical procedures would help eliminate over-prescribing of narcotic medications.

Additional studies further support the need for interventions of developing a protocol and implementing a protocol to decrease over-prescribing of opioids. A cohort study by Leroux et al. (2019) indicated opioid naive patients were at increased risk for opioid abuse and found 1 in 7 patients continued utilizing opioids 180 days post-surgery. Prescribing fewer opioids was

associated with an increased reduction in unused opioids and did not increase pain scores or affect patient reported outcomes (Leroux, et al., 2019). A systematic review conducted by Feinberg et al. (2018) indicated closer review and analysis of the relationships between prescription opioids given for acute pain management and those actually consumed by the patient postoperatively found the unused portion of opioids could be as great as 50%. Feinberg et al. (2018) further revealed proper education is required for providers with regard to establishing guidelines and prescribing practices for acute postoperative pain management. A quality appraisal performed by Hah et al. (2017) suggested a standardized plan for tapering opioids should be instituted and discontinued the use by six (6) weeks in accordance with the Agency for Medical Directors' Group Interagency guidelines (Washington State Agency Medical Directors' Group [AMDG], 2020). A quantitative study performed by Hill et al. (2017) found only 28% of pills prescribed for acute post-surgical pain were consumed by the patient. Telephone surveys conducted post hospital discharge determined that patients utilized over-the-counter medications to manage their pain and less than 2% of the patients studied required refills from their initial postoperative prescription. The authors claimed that adequate pain control should be considered when implementing an opioid titration protocol for effectiveness of the protocol.

Description of the Problem

Currently, prior to this project, each surgeon in the facility utilized their own postoperative pain management regimen. No noted standardization in their postoperative prescribing practices among the group collectively was noted in their postoperative prescribing practices. Senior surgeons on-call for the group, had reported an increase in the volume of calls received from patients, with numerous requests for pain medication, especially over the weekend call schedule. To provide more background information, a 3-month retrospective chart review of

surgical patients in the past 3 months revealed some patients continued to receive pain medications for several months postoperatively due to chronic pain complaints, without any noted complications of their surgeries or other abnormalities noted on diagnostics. Furthermore, the nursing staff expressed their frustration with patients who became upset and at times irate, and in certain situations even verbally hostile, when requests for further narcotics were denied past the postoperative period. The nursing staff further stated there were no detailed discussions held with the patient with regard to the length of time medications would be prescribed postoperatively, or for that matter when prescriptions would be discontinued. The nursing staff felt this should be discussed with the patient during their preoperative visit, so all parties would be aware of their responsibilities, responsibilities of the clinic, and plan of care. The nursing staff further suggested if a plan of care for medication management were discussed with the patient preoperatively, this may help alleviate patient's anxiety regarding pain management postoperatively.

The clinic expressed a desire to move forward with implementing a standardized opioid titration protocol (SOTP), as data showed a protocol could help eliminate excessive prescribing practices, eliminate wasteful visits for continued chronic drug therapy, help facilitate patient education and expectations postoperatively, thereby establishing a firm plan of care. In addition, the SOTP could help reduce the possible incidence of hostile situations being created by those patients who were demanding opioid prescriptions, thereby improving patient safety and morale. The clinic's mission has always been to provide orthopedic excellence and priority care to improve patient outcomes and provide the best, safest, possible treatment for all patients.

Project Purpose and Project Aims

The purpose of the QI project was to develop an evidenced-based standardized opioid titration protocol (SOTP) to determine if it improved management of postoperative pain management in opioid naive patients, thus reducing total opioid consumption and decreasing refill of opioid prescriptions postoperatively. The clinical practice question which guided the QI project was: In opioid naive patients of this orthopedic clinic, does development and implementation of a SOTP improve management of postoperative pain and decrease narcotic refills over six (6) weeks postoperative period?

Aim #1: To develop and implement evidence-based SOTP based on a review of the literature, current clinical practice guidelines established by the Washington State Medical Directors' Group (AMDG, 2020), and expert opinion from the providers in the clinic as evidenced by a standardized protocol approved by the provider who agreed to trial the protocol in the clinic by January 1, 2021. The rationale for implementing this protocol was supported by Thiels et al. (2017) findings, who identifying a wide variation of and over prescription of opioids leading to overuse, a randomized controlled trial by Gaddis et al. (2019) who evaluated the findings of large initial prescription sizes and its rebound effect of opioid overuse.

Aim #2: To decrease the number of patients experiencing pain levels >3 postoperatively by 50% and decrease the number of opioid prescription refills ordered or filled by six (6) weeks postoperatively by 40% by the end of the project period (six (6) weeks). The rational for choosing to decrease pain levels in 50% of patients was supported by evidence from Reagan et al. (2017) who reported a similar finding. The rationale for choosing to decrease opioid prescription refills by 40% was supported by evidence from randomized control trial by Reagan et al. (2017) who reported similar findings.

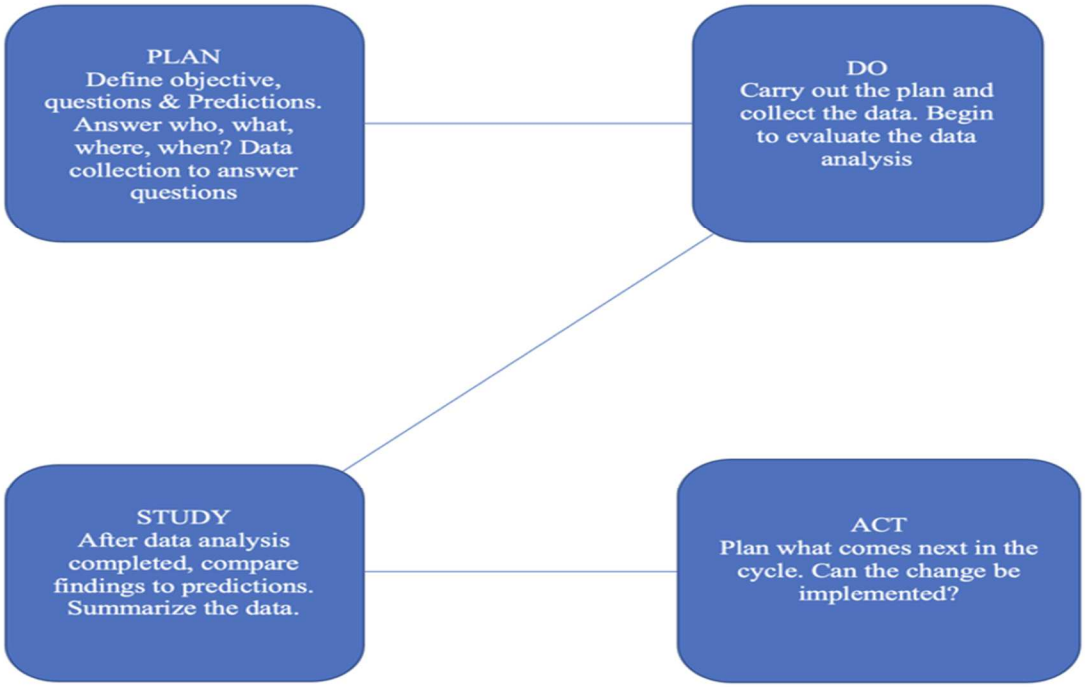
Aim #3: To increase the percentage of patients who were managed by using the SOTP to 100%. The rationale for choosing a goal of 100% of patients receiving the protocol was to make the protocol a standardized procedure in the orthopedic clinic in line with recommendations from current research evidence and clinical practice guidelines.

The DNP Essentials exemplified by this project were DNP Essential III – Clinical Scholarship and Analytical Methods for Evidenced-Based Practice and allows the scholar to apply knowledge learned to a solve a problem by way of scholarship application. The integration of knowledge from multiple sources and integrating this knowledge into practice and assist in solving clinical practice problems. DNP Essential V – Health Care Policy for Advocacy in Health Care allows the DNP scholar to design and implement quality improvement changes and evaluate outcomes, allowing the DNP graduate to be potent influencers in policy changes. Finally, DNP Essential VII – Clinical Prevention and Population Health for Improving the Nation's Health (Johnson & E., 2019) guides the DNP scholar in improving health status by improving clinical education, focus on health promotion and implement protocols based on evidence-based practice.

Guiding Frameworks

The Plan-Do-Study-Act (PDSA) framework initially began as the Plan-Do-Check-Act cycle and was first established by Walter Shewart in the 1920s (see Figure 1). The cycle was based on Dr. W.E. Demings approach to organizational development and leadership, which then developed into the PDSA cycle we know today (ACT Academy, n.d.). This framework served

Figure 1: PDSA Framework

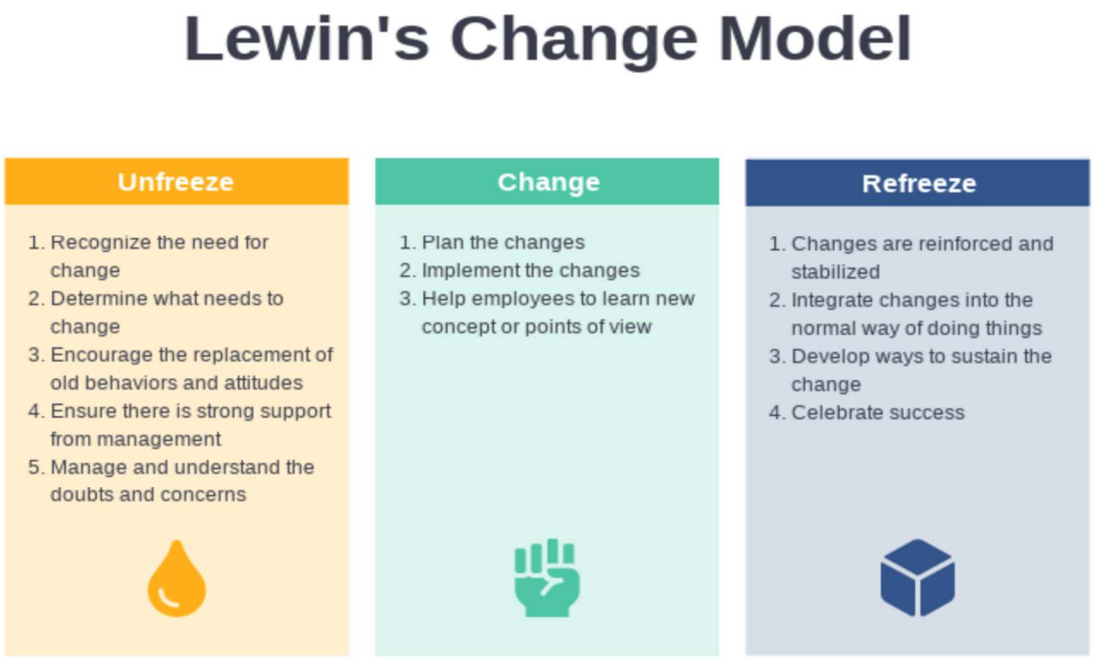


as an overarching guide for this project. The PDSA is a cyclical model and allowed small changes to be accomplished using a four-step process thus safer for the patient, thereby, causing less disruption to the QI project. In addition, the PDSA cycle allowed questions to be answered prior to making changes to the protocol and allowed development of the project further and evaluation of data, leading to improved practice.

To implement planned change to the orthopedic practice the project was specifically guided by the Lippitt, Watson, and Westley Planned Change Model (Wagner, 2018). The Planned Change Model expanded on Kurt Lewin's original Change Theory, implementing seven (7) planned steps of changing practice to include 1) diagnosing the problem; 2) assessing motivation and capacity for change in the system; 3) assessing resources and motivation for change; 4) establish change objectives and strategies; 5) determining the role of the change

agent; 6) gradually terminating the of helping relationship as change becomes part of the organizational culture (see Figure 2). The Planned Change Model assisted in guiding the QI project systematically and allowed recognition and the capacity for change within the organization, placing an emphasis on those affected by the change and problem-solving strategies.

Figure 2: Conceptual Framework



METHODS

Ethical Considerations

This project plan was reviewed by the Texas A&M University – Corpus Christi Research Compliance Office and received a determination of "Not Human Subjects Research" and permission to proceed as a Quality Improvement project (see Appendix A). Participants were assigned an alphanumeric code and all patients were labeled by alphanumeric code in numerical

order as patients were recruited. The key codes with participants information and name were kept via the Athena Database under password-protected file held only by the Project Director (PD); however, the surgeon and head medical assistant were allowed access to files if updates were required when the PD had to be out of the office. The administrator for the orthopedic clinic and collaborative physician gave full support for the QI project (see Appendix B).

Project Design

This quality improvement (QI) project used a before and after design with a retrospective chart review and interviews with other providers in the clinic to develop and implement the developed SOTP.

Participants and Recruitment

The SOTP was implemented for patients undergoing soft tissue spinal procedures performed by the collaborating physician, beginning January 2021. As the PD, I recruited participants obtained from a convenience sample of patients seen for preoperative visits for spinal surgical intervention, specifically laminectomy, discectomy and/or other spinal soft tissue procedure. Patients were actively recruited from January 1, 2021, through April 5, 2021. The inclusion criteria for participants in this project included: (1) Post-operative patients aged 19-85 years indicated for laminectomy, discectomy, and/or soft tissue spinal procedures, (2) Post-operative patients interested in participating in the QI project, and (3) being Opioid Naïve (non-daily opioid use 90-days prior to procedure).

Settings

The orthopedic clinic, located in the South Texas area, was a very busy orthopedic practice with a diverse population (45% Caucasian, 45% Hispanic, 8% African American; 2% other). The group employed nine (9) physicians, three (3) nurse practitioners and three (3)

physicians assistants. The fear of Covid-19 among the patients appeared to decrease the number of patients being seen in the office. The fear of contracting the Covid-19 virus also affected those who wished to undergo surgery during the period of January 1, 2021, through March 31, 2021, and patients wished to delay surgical intervention until later in the year. As PD, in February of 2021, I held a discussion with the collaborating physician requesting to include more spinal surgical procedures in the QI Project. Originally, the project included only patients undergoing soft tissue procedures such as laminectomies and discectomies. Due to fewer scheduled surgeries at this time, additional patients undergoing procedures such as foraminotomies and paralateral discectomies, were added to increase the number of patient participation in the QI project.

Intervention

Risks identified for the QI project included lack of patient participation, fear of inadequate pain management by the patient, continued complaints of pain six (6) weeks post-surgery despite successful surgical outcome, and lack of physician buy-in to utilize the SOTP by the other surgeons in the group. Safeguards included preoperative counseling with the patient prior to surgery and informing patients of the SOTP and the expectation that pain medications would be titrated and weaned by six (6) weeks postoperatively, for their safety and best outcomes. Patients were also informed consideration for continued opioid use for those patients requiring physical therapy/aquatic therapy could be justifiable due to possible increase in pain. For those medical partners resistant to change to a new protocol, the SOTP, the gap in practice from the literature was presented to them with an emphasis on trialing this new protocol to observe the effects on the practice and the outcomes of the patients.

The research team consisted of myself as the Project Director (PD), collaborative physician, surgical coordinator, and two medical assistants in this QI project. As the Project

Director (PD), I was in charge of developing an evidence-based standardized opioid titration protocol (SOTP) based on literature review, clinical practice guidelines, and on expert opinion from the providers in the clinic (see Table 1). I performed A 3-month retrospective chart review on surgeries performed by collaborative physician, who agreed to serve as a pilot trial (Phase I). The assistance of the surgical coordinator was incorporated to ensure accurate record of surgeries. The 3-month retrospective chart review was conducted for the period of January 1, 2020, to March 31, 2020. I also interviewed other physicians in the clinic to examine their existing inconsistent prescribing practices. The purpose of the 3-month retrospective chart was to review and identify varied prescribing practices, initial prescriptions given postoperatively and to assess the total amount of opioid pills prescribed to patients who underwent laminectomy and/or other related soft tissue lumbar surgeries. Information gathered was void of specific patient identifiers and personal information thus avoiding HIPAA violation. The 3-month retrospective chart review was compared and contrasted against other opioid protocols obtained from the other providers in the group. The data I obtained of the varied prescribing practices served to aid in the development of a single standardized opioid titration protocol with the assistance of the collaborative physician. The specific aim was to implement a standardized opioid titration protocol for the most common spinal surgical procedures and determine if the protocol could reduce the amount of opioid intake while still managing the patient's pain effectively. A meeting was held with the administrator and the collaborative physician with data obtained from the 3-month chart review, the literature review and record of prescribing practices from the other physicians in the practice. After lengthy discussion with the collaborative physician, a single protocol was developed. After careful review of the protocol, approval was received from the administrator and collaborative physician to proceed with implementing the protocol.

Table 1: Standardized Opioid Titration Protocol (SOTP)

Post-OpWeek	Opioid Instruction	Length of Rx
1	Hydrocodone 10/325 1 tablet PO q4h PRN for pain #42	7- 14 days
2	Hydrocodone 5/325 1 tablet PO q6-8h PRN for pain #30	7-14 days
3	Tylenol/Codeine #3 1 tablet PO BID PRN for pain #20	10 days
4	Tramadol 50mg 1 tablet PO BID PRN for pain #20	10 days

Note: Based on clinical practice guidelines set forth by the Washington State Agency Medical Directors' Group. (2020).

As the PD, I held a separate meeting in December of 2020 with the medical team notifying them of the protocol, with copies provided to all. Questions and concerns regarding the protocol were addressed to staff satisfaction. Positive feedback was received from the staff about the protocol and its titration protocol and were excited about implementation January 1, 2021.

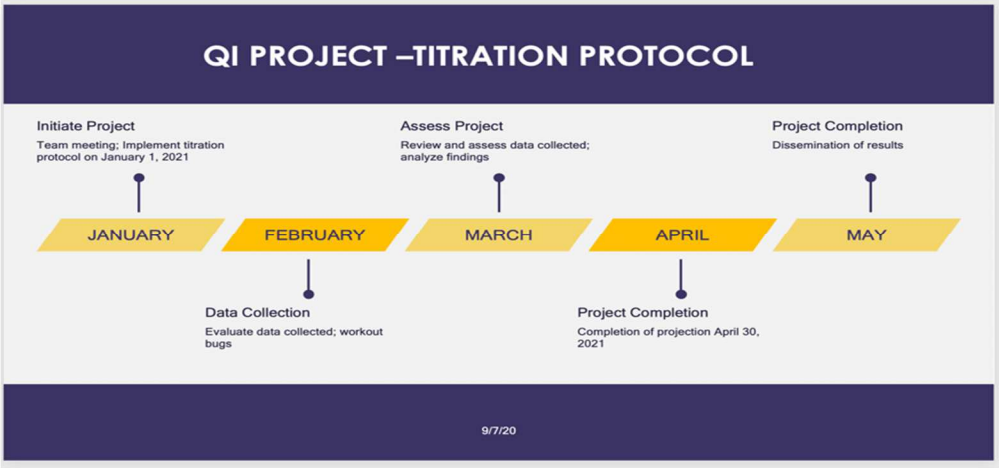
The SOTP was initiated on January 1, 2021. All qualified candidates were informed of the SOTP during their preoperative visits and verbal consent was obtained to apply the SOTP during their postoperative discharge. As the PD, a preoperative visit was scheduled with the patient to review preoperative and postoperative instructions. The SOTP was presented to them during the preoperative visit and patients were informed of the titration protocol. Patients were notified titration of opioid medication would begin two weeks after surgery was performed.

Patients were also instructed over-the-counter Tylenol Extra Strength could be supplemented with their, or instead of, opioid medication if they so desired. All questions and concerns were answered to patient's satisfaction and verbal consent obtained.

Following surgical intervention, I conducted a post-intervention chart review to determine the number of opioid pills given on initial prescription, pain level via Visual Analog Scale (VAS) of 0-10, the total number of opioid pills taken, the total number of opioid pills remaining, and the number of opioid prescription refills given during the 6-week postoperative period. I collected the data every two weeks and data collection was documented at intervals of two weeks, four weeks and six weeks.

Completion of the project was initially projected for April of 2021; however, due to the limited number of cases being scheduled (affected by the Covid-19 pandemic) and after discussion with the project team, project completion was extended until May 5, 2021. No special training was required for project team members, as part of their job description included assessing pain level at follow-up visits prior to implementation of the SOTP; this practice was continued during the QI project and confirmed by the PD during follow-up. Due to the extended completion date for the project, dissemination of findings was disclosed to the administrator in June of 2021 (see Figure 3).

Figure 3: QI Project - Timeline



Data Collection

The SOTP was initiated on January 1, 2021. All qualified candidates were informed of the SOTP during their preoperative visits and verbal consent was obtained to apply the SOTP during their postoperative discharge. As PD, I tracked postoperative prescription refill rates via the Athena Electronic Medical Record (EMR) and the Texas Prescription Monitoring Program (PMP) database weekly. In addition, with the help of the Medical Assistant (MA), at follow-up visit bi-weekly pain levels were collected based on the VAS pain scale. Candidates rated their pain from 0-10, with zero being no pain and 10 being the worst pain (see Appendix C). In addition, the number of opioid tablets taken attempted to be recorded, however, some patients were found to leave their pill bottles at home and could not always give an accurate count of pills taken or number of pills remaining. Concerns over the accuracy of self-report data regarding the number of opioid pills taken and number of opioid pills remaining loomed. Patients were found to inadvertently forget to bring their prescription bottles to the office, even after reminders from staff. Due to the inability to obtain true and reliable data concerning the accuracy of the opioid pill count, this data was removed from the QI project. I reviewed the Texas PMP Database at the

time of follow-up to assess opioid prescription refill status via Athena EMR, as mandated by the State of Texas. The State of Texas mandates prior to any refill of opioid prescription, and to ensure no other opioid prescriptions were being provided to the patient, the database must be reviewed.

Measurement Tools

Assessment of the number of opioid refill prescriptions given and the initial number of opioid pills given postoperatively among those patients who underwent laminectomy, discectomy and/or related soft tissue procedures were tracked via Microsoft Excel spreadsheet via Athena EMR and Texas PMP Database (Texas Prescription Drug Monitoring Program [TX PMP], 2020). The Athena EMR is a cloud based program which was developed for any sized practice and offers a wide array of services. The system allows for a patient portal system, in addition for reminders to be given to the patients via email or text message. The system allows for maximum clinical productivity and allows clinicians to benefit from access to a clinical network (AthenaHealth EHR, 2021).

The Texas PMP Database is a drug prescription monitoring program set up by the State of Texas and is mandatory for all prescribers to review prior to initiating narcotic prescription. The program collects and monitors all patient prescription data to include Schedule II, III, IV and V controlled substances dispensed by pharmacies. The Texas PMP Database is managed by the State Board of Pharmacy and gives real-time outpatient prescription data (*Texas Pmp Awarxe*, 2020).

The Visual Analog Scale (VAS) pain scale (0-10) was utilized to assess pain levels (self-reported) over a 6-week period following surgery (see Appendix C). The pain measures from score of zero (0) to 10 with zero (0) indicating no pain and 10 being the worst pain (Delgado et

al., 2018). The use of VAS scale requires little training to administer and score, and has been found to be acceptable to patients from children to older adult population. The VAS pain scale has been validated as a reliable subjective measure for self-reported acute and chronic pain for those in aged more than 18 years old (Begium & Hossain, 2019).

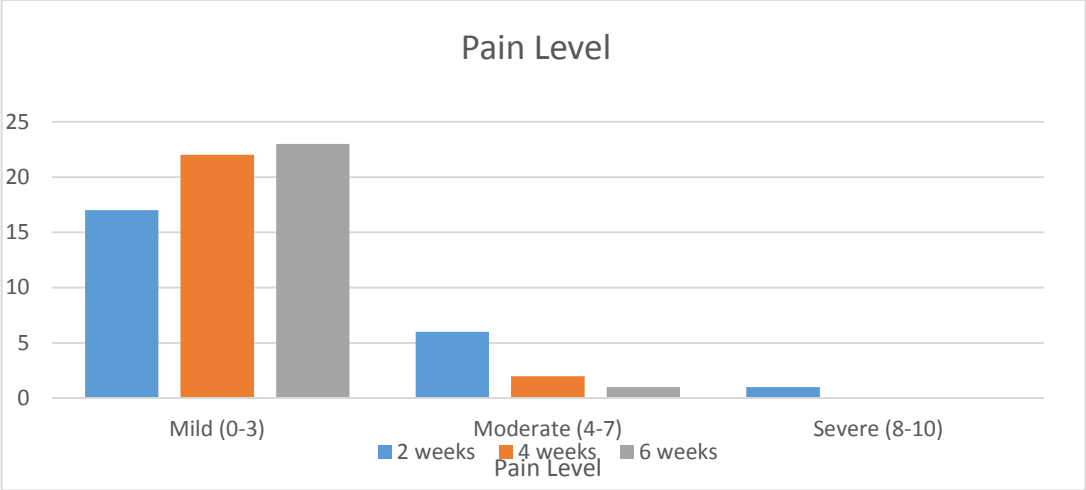
Data Analysis

The Microsoft Excel program was utilized to analyze data. All participant demographic data, collected data, and data analysis results for this QI project were securely stored in a password protected computer that could be accessed only by the PD, senior surgeon, and head medical assistant. Data analysis of demographic data will be based on sex, age, ethnicity, and insurance.

To determine if Aim 1 was met, following an extensive review of the literature, study of current clinical practice guidelines, a retrospective chart review of the collaborating physician's charts to determine current practice, and conversations with clinic surgeons to determine their practice and protocols they followed individually; a brief opioid titration protocol was developed citing the evidence supporting each step. Further approval of this protocol was received from the collaborating physician to trial it on his patients for project purposes.

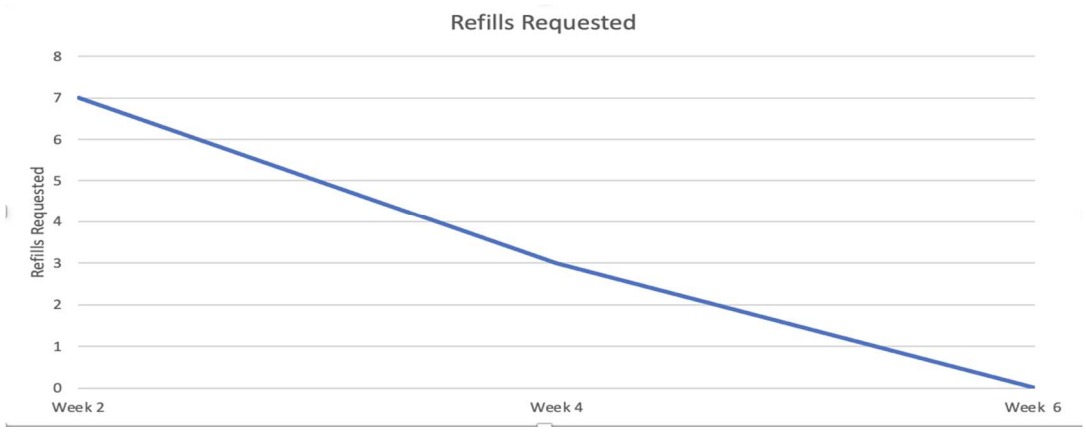
To determine if Aim 2 was met, pain level data analysis was displayed in table format with x-axis displaying number of patients and y-axis displaying pain levels of mild (0-3), moderate (4-7), and severe (8-10). The columns were color-coded for easy identification to consist of the following: navy indicating pain level at two (2) weeks, orange indicating pain level at four (4) weeks, and gray indicating pain levels at six (6) weeks (see Figure 4). Prescription

Figure 4: Pain Level – Post Intervention Group



refill rates over the 6-week period were displayed in a run chart (see Figure 5). Fisher's Exact testing was used to assess if there was statistically significant improvement post-intervention between prescription refill rates for the intervention group (patients participating in the project) versus the control group (patients whose charts were reviewed prior to the project).

Figure 5: Refills Over 6 Weeks – Post Intervention Group



Demographics for the comparison group and the intervention group, including sex, age, ethnicity and insurance payor were essentially similar across the groups.

To determine if Aim 3 was met, the number of eligible patients were managed by the protocol was divided by the number of patients who could be managed by the protocol to determine the percentage of eligible patients who were managed using the SOTP. A bar chart was used to show the monthly increase in percentage of eligible patients managed with the SOTP.

RESULTS

Outcomes

Overall, we screened 39 patients, 21 females and 18 males. We enrolled 25 patients in the Quality Improvement (QI) project, fifteen females (60%) and 10 males (40%). The mean age of participants was 63 (SD 16.7). There were 16 Caucasians (65%) and nine (35%) Hispanics who participated. Of those who participated 12 were covered by Medicare (49%) and 13 (51%) covered by private insurance. The comparison group (retrospective chart review group) included 28 participants, nine females (35%) and 19 males (65%). The mean age was 68 (SD 13.5). There were 17 Caucasians, nine Hispanics and two African Americans in this group. For the comparison group 17 (68%) were covered by Medicare, nine (33%) by private insurance and two (2%) were self-pay (see Table 2).

Table 2: Demographics Table

	Pre-Intervention Group N=28	Post Intervention Group N=25
Sex:		
Female	9 (35%)	15 (60%)
Male	19 (65%)	10 (40%)
Age (Mean):	68 (*SD* 13.5)	63 (*SD* 16.7)
Ethnicity:		
Caucasian	17 (68%)	16 (65%)
Hispanic	9 (30%)	9 (35%)
African American	2 (2%)	0
Other	0	0
Insurance:		
Medicare	17 (68%)	12 (49%)
Private Insurance	9 (33%)	13 (51%)
Self Pay	2 (2%)	0

Aim #1: To develop an evidence-based standardized opioid titration protocol (SOTP) based on a review of the literature, clinical practice guidelines and on expert opinion from the providers in the clinic and implement by 1/1/21. This goal was met. An evidence-based SOTP was developed and applied to patients undergoing soft tissue spinal procedures effective January 1, 2021 (see Table 1).

Aim #2: To decrease the number of patients experiencing pain levels >3 postoperatively by 50% and decrease the number of opioid prescription refills ordered or filled by six (6) weeks postoperatively by 40%. This goal was met. Findings showed 98% (n=24) of patients experienced satisfactory pain relief of <3 on the VAS Pain Scale by six (6) weeks (see Appendix C). Approximately 73% (n=18) of patients were found to stop using opioid pain medication by

week two (2). In addition, 100% (n=25) of patients did not require further opioid prescription refills after four (4) weeks postoperatively (see Figure 6). When compared to prior prescribing practices, refills were found to be decreased by 10% (p=0.025) and was found to be statistically significant.

Aim #3: To increase the percentage of patients who were managed by using the SOTP to 100% by 7/1/2021. This goal was met. Dissemination of findings are currently being evaluated by administration. A temporary target date of August 2021 is currently being discussed to allow for additional tailored subsets to be developed for those procedures which may require significant hardware such as lumbar and cervical fusions, hip, knee and ankle replacements.

After completion of the QI project all findings were presented to the administrator and the collaborative physician involved in Phase I on June 3, 2021. A chart review to assess how many physicians in the PD's clinic replated their pain prescription practice with the SOTP is pending, as full dissemination of findings to all physicians is projected for August of 2021 at the next business meeting. Provider buy-in by all physicians in the clinic continues to be a factor, as most physicians have their own protocol and do not wish to stray from their current practices. Further education to physicians regarding clinical practice guidelines and prescribing guidelines will be warranted to provide further guidance on prescribing acute postoperative opioids.

DISCUSSION

The purpose of this QI project was to develop a standardized opioid titration protocol (SOTP) and examine its effective management of postoperative pain in opioid naive patients at the orthopedic clinic.

The first specific aim of this QI project was to develop and implement a standardized opioid titration protocol. This aim was achieved, and we were able to develop an evidence-based

protocol and implement it in one physician's patients over a six week period. The second specific aim was to decrease the number of patients experience pain levels >3 being managed on the protocol postoperatively and decrease the number of opioid prescription refills ordered or refilled by six (6) weeks postoperatively. This aim was achieved with 98% (n=24) of patients experiencing satisfactory pain relief of <3 by six (6) weeks. Seventy-three percent (n=18) of patients were found to discontinue opioid use by week two (2) postoperatively. One hundred percent (n=25) of patients did not require further refills after four (4) weeks postoperatively. When compared to prior prescribing practices, refills decreased by 10% (p=0.025) and was found to be statistically significant.

This project was conducted in a busy orthopedic practice in South Texas. The development of the SOTP reduced the total amount of opioids prescribed compared to prior inconsistent prescribing practices demonstrated from data collected during the 3-month retrospective chart review. Postoperative pain levels were maintained to less than three (3) in 24 out of 25 patients, which was considered mild pain on the VAS pain scale over a 6-week period following surgical intervention (see Figure 4). Results indicated no opioid refills were ordered or prescribed following the 6-week period (see Figure 5). After completion of the QI project all findings were presented to the administrator and the collaborative physician involved in Phase I on July 1, 2021.

The results of this single-center QI project showed development and implementation of a standardized opioid titration protocol (SOTP) demonstrated a decrease in the total number of opioids prescribed and the number of refills requested over a six (6) week period. A decrease in opioid refills and pain levels persisted through six-weeks post discharge. Utilizing the SOTP decreased the number of opioid tablets prescribed well below levels initially thought required.

Decreasing the use of opioids in general and specifically targeting overprescribing are both state and national public health priorities. Further education to healthcare professionals regarding evidence-based practice, clinical practice guidelines and prescribing guidelines will further provide guidance on managing acute postoperative pain for those most common surgical interventions in opioid naïve patients. The protocol was found to be extremely efficacious, with only 1 out of 25 patients found not to have satisfactory (<3) pain relief and requiring further refills. One patient sustained a reinjury one week following surgery, hence the continuation of opioid medication and continued pain. Preoperative education regarding the SOTP with the patients prior to surgical intervention, along with clinic expectations were found to allay the patient's fear regarding pain management.

The ultimate goal of the QI project was to bring about a positive change in practice in this busy orthopedic surgery clinic. Following dissemination of findings by the PD to the administrator, a temporary target date of August 2021 is currently being discussed to allow for additional tailored subsets to be developed for those surgeons who are performing other orthopedic procedures (i.e. hip replacement, knee replacement, and ankle replacement) which may require significant hardware such as multilevel lumbar and cervical fusions, hip, knee and ankle replacements. The collaborative physician has agreed to the SOTP being applied to one-level cervical and lumbar fusions and has allowed replacement of his current postoperative prescription practices for these procedures. This has indicated a successful change in his practice and better patient outcome.

Additional studies were found to support the establishment of an evidence-based opioid titration protocol in the clinic setting to reduce postoperative opioid use. A quality improvement project implemented an enhanced recovery after surgery (ERAS) protocol for patients

undergoing 1-2 level lumbar fusion (Smith et al., 2019). A pre-ERAS phase (n=123) and a post-ERAS phase (n=96) with comparable demographics and comorbidities were shown to have minimal effect in decreasing length of hospital stay. However, the data indicated a significant decrease in postoperative opioid use and decrease in rescue antiemetic use in their study of 230 patients from October 2013 to May 2017 (Smith et al., 2019). The study also implemented a post-surgical protocol and found it resulted in decreased postoperative use, which agrees with our findings.

A retrospective cohort study was conducted by Tamboli et al., (2019) applying a multidisciplinary, patient specific, opioid discharge protocol for patients undergoing total hip arthroplasty (THA). Tamboli et al., (2019) believed this would thereby decrease the amount of morphine milliequivalent (MME) dose prescribed postoperatively. Data including preoperative surgical home database and prescription data were collected three months pre and post surgically. The total opioid dosage in MME prescribed and opioid refills for up to six weeks post surgically was evaluated. Secondary outcomes included total number of tablets prescribed at discharge (including MME), in-hospital consumption of opioids, postoperative complications, and length of stay. It was determined overall refill rates did not differ; however, implementation of a patient-specific opioid tapering protocol did decrease dosage of opioids prescribed by 63% following THA without increasing refill rate, which agrees with our findings (Tamboli et al., 2019).

A systematic review was conducted by Bossenbroek Fedoriw et al., (2020), from chart audits utilizing electronic health record data from 2015 to 2018. The University of North Carolina Family Medicine Center had developed and implemented an opioid prescribing protocol which was initiated practice-wide. The policy created a controlled medication advisory

board (CMAB), trained selected providers in the management of opioid use disorder, and provided regular feedback to clinicians on opioid prescribing practices. Over the course of 4 years, between 2014 and 2018, opioid prescribing rates decreased by 31% per every 100 patient visits, with the use of benzodiazepines and opioids concomitant use decreasing by 56%. It was further revealed an evidence-based standardized protocol, in addition to support from providers and patients, can help improve prescribing practices and improve patient safety and outcomes; thereby increasing quality of patient care. This study supports the need for an evidence-based standardized protocol which aligns with our QI project and has proven to decrease opioid usage. Several studies support the development and application of evidence-based opioid protocols resulting in noted decrease in opioid usage postoperatively. Physicians and policymakers continue to seek ways to decrease the current opioid crisis and evidence-based protocols can help by decreasing opioid prescriptions and opioid intake while managing pain effectively.

Limitations

Compliance with the SOTP was mixed among the providers, as each provider preferred to utilize his or her own protocol. Although success of this first PDSA cycle was achieved, only one physician participated. Buy-in among the other providers will continue to be addressed to facilitate clinic-wide adoption. Physician education regarding clinical practice guidelines and prescribing guidelines as well as research evidence will continue to be presented to gain buy-in on using a standardized opioid titration protocol.

Additional limitations included patient fear of the Covid-19 pandemic, which limited the number of surgical patients seen in the practice due to restrictions set forth by the CDC. Many patients voiced concerns over possible contraction of the virus from other patients or while being hospitalized, which further decreased the number of surgical procedures being performed and

caused the surgery schedule to be sporadic. The study was conducted in a busy orthopedic practice with over 300 patients seen per day. Our findings may differ with those clinics with lower volume. We believe the study sample accurately represented the population and the results to be clinically and statistically significant.

Interpretation

The PDSA framework was used as an overarching guide for this project. It allowed for questions to be answered prior to making changes to the protocol and aided in the success of the QI project. The PDSA cycle allowed for processing and development of an evidence-based protocol by planning, assessing, initiating and implementing the protocol in a stepwise approach. During the planning stage, objective questions and concerns were evaluated and re-evaluated by the project team with predictions made about possible outcomes. The Planned Changed Model assisted in guiding the QI project in a time-wise fashion and allowed the project team to recognize the capacity for change within the clinic in the planning phase for providers, nursing staff and patients. In keeping with the Planned Changed Model, unfreezing allowed for recognizing and diagnosing there was a problem in the practice with various prescribing practices and allowed for evidence-based data to be presented. The clinic recognized a need for change and motivated the facility to implement change. The moving phase allowed for a step-wise approach to evaluating the protocol, assessing patient's response during the initial implementation of the protocol, and allowed for changes to be made to the protocol after evaluating raw data and following team discussion.

As the Covid-19 pandemic case numbers decline and more of the population is vaccinated, it is the hope of the clinic more patients will proceed with surgery and will increase the application of the SOTP. This QI project described a relatively simple intervention and

designed a way to provide a tapered use of opioid medication relatively safely and based on evidence. The protocol revealed patient cooperation and overall effective pain management post-operatively. Implementation of preoperative education with the patient and explanation of clinic expectations regarding postoperative treatment, led to decreased opioid use and discontinuation of use far earlier than the six-week projected timeframe. Moving forward, implementing gabapentin and acetaminophen into the SOTP may be considered as part of the standard opioid titration protocol (Chang et al., 2016).

In addition, projected costs to the facility with implementation of the SOTP were minimal. Athena EHR was already in place and projected costs analyzed to include cost projection for MA time and PD time. Other practices could adopt the same protocol with minimal expense to their clinic. The SOTP served to decrease follow-up visits for chronic drug therapy (ICD10-Z79.899) and increase revenue. This allowed more patient slots for new patient evaluation to become available ($650) and limited needless follow-up visits ($150) for chronic drug therapy which was recognized by the administrator. The SOTP served to facilitate patient education and expectations with regards to narcotic use postoperatively. Discussion regarding the SOTP held with patients during preoperative visits allowed them to participate in their healing process and be aware of prescribing practices, establishing a firm plan of care.

Challenges exist to improve opioid prescribing practices at this orthopedic clinic, as lack of physician buy-in from the other providers may hinder further phases being implemented. However, the collaborating physician and administrator were in favor of with keeping the protocol in place for the soft tissue spinal procedures. Further assessment, via chart review and follow-up, revealed patients undergoing one-level cervical and lumbar fusions discontinued opioid medication 2-3 weeks postoperatively. The collaborative physician has allowed the SOTP

to be implemented for one level cervical and spinal fusions from this point forward, as the protocol provides a four-step weaning process.

Implications

Communication was improved between the preoperative team and the patient with detailed instruction provided on the SOTP, which improved preoperative education and patient expectations. As a result, 98% (n=24) of patients who utilized the SOTP were found to require the initial prescription and nothing further. Stakeholder knowledge of facility use of an evidence-based SOTP could have a positive effect on the community. Referral sources to the facility would have the peace-of-mind knowing their patients would be at low risk for excessive opioid use and efforts were being made to decrease their chances of opioid abuse.

Going forward, recommendation for a separate protocol for those surgeons performing joint replacement surgeries, with tailored protocols for specific procedures can be developed to continue aiding in combating the current opioid epidemic and assist with provider buy-in. Finally, the evidence-based SOTP has shown effective pain management and tapering protocol after discharge, with little added expense to the clinic. A similar protocol could easily be implemented in other clinics managing acute pain.

Conclusion

Overall, implementation of the standardized opioid titration protocol (SOTP) was associated with fewer opioid pills being prescribed, fewer opioid prescription refills and requests, and lower pain scores. The findings support the need for a universal protocol. As knowledge of a facility based SOTP is being utilized and becomes more widely known in the community, healthcare providers and insurance carriers will be opened to referring patients to the orthopedic clinic, knowing a plan is in place to decrease chronic opioid drug use and increase patient safety.

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LIST OF APPENDICES

APPENDIX PAGE

APPENDIX A: IRB Designation Letter

From: irb@tamucc.edu <donotreply@redcap.tamucc.edu>
Sent: Wednesday, February 24, 2021 4:41 PM
To: Lee, Kyoung <Kyoung.Lee@tamucc.edu>
Cc: IRB <irb@tamucc.edu>
Subject: NHS Determination: IRB Required

Dear Kyoung Lee,
Activities meeting the DHHS definition of research or the FDA definition of clinical investigation and involves human subjects are subject to IRB review and approval.
On 12-21-2020, the Office of Research Compliance reviewed the project below and determined that the proposed activity IRB Review is required:

Type of Review:	Not Human Subjects Determination
IRB ID:	TAMU-CC-IRB-2020-12-120
Project Lead:	Kyoung Lee
Title:	Reducing Postoperative Opioid Use in Opioid Naive Patients

The IRB determined that the proposed activity is research involving human subjects as defined by regulations.
Rationale: Withdrawing this submission as it is covered under TAMU-CC-IRB-2020-12-133
IRB review and approval are required prior to starting this project.
Action required: Click here to access the IRB submission form to submit for IRB review.
Please do not hesitate to contact me with any questions at irb@tamucc.edu.
Respectfully,
Germaine Hughes-Waters
Office of Research Compliance

APPENDIX B: Facility Letter of Support

601 TEXAN TRAIL, SUITE 300, CORPUS CHRISTI, TEXAS 78411
TELEPHONE: (361)854-0811 FAX: (361)806-5040
www.SouthTexasBoneandJoint.com

August 9, 2020

Dr. Sara Baldwin
Associate Dean for Academic Programs
College of Nursing and Health Sciences
Texas A&M University – Corpus Christi
6300 Ocean Drive
Corpus Christi, TX 78412

Dear Dr. Baldwin,

The purpose of this letter is to provide Mary K. Schoolcraft, a Doctor of Nursing Practice student at Texas A&M University College of Nursing and Health Sciences, support in conducting a quality improvement project at South Texas Bone & Joint. The project, Decreasing Opioid Use Post Surgery, entails titration of opioid use following the most common spinal surgical procedures.

The purpose of this project is to decrease chronic opioid use. South Texas Bone & Joint was selected for this project because Mary Schoolcraft is employed at this institution and has an interest in improving patient care for our facility.

I, Reginald Jackson, Administrator of South Texas Bone & Joint, do hereby fully support Mary Schoolcraft in conducting this quality improvement project, Decreasing Opioid Use Post Surgery at South Texas Bone & Joint.

I also approve Mary Schoolcraft accessing protected health information (PHI) for purposes of conducting this quality improvement project. She has signed appropriate HIPAA release forms.

Sincerely,

Reginald Jackson
Administrator

RJ/kf
Cc: File

APPENDIX C: VAS Pain Scale

Numeric rating scales (NRS)