Preemptive Multimodal Analgesia for Knee and Hip Arthroplasty: A Clinical Practice Guideline

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DNP Scholarly Project

Total joint arthroplasty is a surgical procedure of removal and replacement of arthritic or damaged joints such as knees and hips. It is mainly performed to enhance quality of life by alleviating pain and improving mobility (Lowis, Gunta, Mitchell & Bobay, 2012). A National Hospital Discharge Survey showed that 332,000 hips and 719,000 knee replacements were performed in 2010 in the United States (Center for Disease Cot=ntrol and Prevention, 2010). According to Barratta, Schwenk, & Viscusi (2014), 80% of surgical patients experience acute pain and 50% end up with chronic pain despite the use of postsurgical pain medications. Pain is greatly subjective and highly individualized. The International Association for the Study of Pain (IASP, 2012) defines it as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage… (p.1). "

Postsurgical pain is a result of tissue damage, irritation of nerves and release of neurotransmitters. Its severity depends on patients' tolerance level and expectation, the extent and location of the surgery, and pain management method implemented by the provider (Vivian, Abrishami, Peng, Wong & Chung, 2009). Some of the physiological and psychological consequences of pain are impaired pulmonary function, high blood pressure, immobilization, thromboembolism, impaired immune function, increased cardiac demands, anxiety, depression, and stress induced inflammatory cascades release (American Society of Anesthesiologists, 2012: Barratta et al., 2014). Therefore, pain management is a critical aspect of managing the post-operative patient. Opioids such as fentanyl or morphine intravenous patient controlled analgesic (PCA) have been used mostly for patients who underwent joint arthroplasty (McKenzie, Goyal & Hozack, 2013). Pain, drowsiness and nausea/vomiting are respectively the three most common reasons for delayed discharge after surgery (Valdivelu, Mitra & Narayan, 2010). Unfortunately,

drowsiness, hyperalgia, nausea, vomiting, headache, and constipation are the most common side effects of opioids (Lee, Chung & Choi, 2015).

Pain management is a critical aspect in the management of postsurgical pain. Traditionally, opioid such as fentanyl or morphine is provided using an intravenous patient controlled analgesic (PCA) device in patients undergoing joint arthroplasty. However, this method of analgesia is fraught with some unacceptable side effects. Foremost among these side effects are somnolence, drowsiness, hyperalgesia, nausea, vomiting, headache and constipation. In addition, opioids can lead to respiratory depression, which may require critical care interventions such as mechanical ventilation and hemodynamic support.

However, there is an alternative to traditional opioid therapy. This method called multimodal pain management incorporates "… a multidisciplinary approach to analgesia that targets both peripheral and central nerve transduction and various biochemical pathways, enzymes, and receptors that signal painful stimuli and inflammation" (McKenzie, 2013, p. 87). According to Post et al. (2010), the use of a multimodal approach to pain management by giving a combination of Tylenol, Lyrical and Celebrex preoperatively and postoperatively decreases the need for opioids and their side effects often seen after TKA.

At a community hospital located in suburban Baltimore, Maryland, over 600 hip and knee arthroplasties were performed in 2014. However, there is no clinical practice guideline available to address preemptive multimodal pain management at this particular hospital. Researchers have shown that the use of multimodal therapy preemptively decreased the occurrence of postsurgical pain, reduces opioid consumption and prevents their side effects (Lee et al., 2015). The Tylenol, Lyrica, and Celebrex (TLC) protocol is a practice guideline that includes giving Tylenol, Lyrica, and Celebrex preemptively for patients undergoing total hip and

knee arthroplasty (McKenzie, 2013). The use of Lyrica, preemptively, decreases the incidence of opioid-induced hyperalgia and sensitization centrally (Lee et al.)

The propose of this DNP scholarly project was to develop a clinical practice guideline for preemptive multimodal analgesia for knee and hip arthroplastypies at a community hospital in suburban Baltimore, Maryland. It is anticipated that this clinical practice guideline will be a valuable tool for the effective management of postsurgical pain and increase overall patient satisfaction rate. Furthermore, it is anticipated that patients will receive fewer narcotics while experiencing decreased postoperative pain.

Theoretical Framework

The Diffusion of Innovations Theory (DIT), developed by Everett Rogers in 1962 provides a theoretical framework for this scholarly project. It was used to develop and evaluate a clinical guideline for knee and hip arthroplasty pain management. The DIT's innovation process communication channels are knowledge, persuasion, decision, implementation, and confirmation. During the first three stages, knowledge, persuasion and decision stages, it became obvious that this particular institution does not have clinical guidelines to address the use of multimodal therapy. Therefore, based on the clinical issue identified, extensive literature review was done. In the next step, the decision stage, the literatures were synthesized and decision was made to frame the clinical guideline based on the results. During the next step, the implementation stage, the final guideline was presented to the institution and recommendation was given to implement it. Finally, during the confirmation stages, the guideline was evaluated by surveying the end users.

Literature Review

In order to formulate an evidence-based practice guideline for preemptive multimodal analgesia, a thorough literature review was done. Four clinical trials were presented starting from

the highest to the lowest level evidence examining the effects of multimodal therapy on pain levels, total requirement of opioids, length of stay, and side effects, the review presented multimodal therapy effects such as pain level, opioid requirement, side effects, and length of stay. A detailed evaluation of the evidence can be found in the evidence table in appendix A.

Lee, Chung, and Choi (2015) randomized 41 patients aged 55 to 80 who were scheduled for elective knee arthrolpasty in a prospective, double blind study to evaluate postoperative pain levels and opioid consumption. Patients randomized to the controlled group (n-=20) received 400mg of celecoxib and those in the study group (n=21) receive 400mg of celecoxib and 150mg of pregabalin one hour before surgery. During the first 48 hours, the amount of fentanyl consumed in average was lower in the study group ($p<0.05$). Patients in the study group experienced less pain during the first 12 hours at rest ($p<0.01$) but pain level after 12 hours was not different significantly as compared to the control group. With activity, pain scores were lower in the study group that the control group during the first 48 hours (P.0.01). The researches excluded patients with renal, liver, and ischemic heart diseases as well as American Society of Anesthesiologist (ASA) physical status (number and extent of coexisting diseases) grade four from this study. Based on the result of power analysis done to determine the number of the subjects needed for the study, 41 was deemed sufficient to asses pain score and opioid consumption but insufficient to assess the occurrence of side effects. Even though studying side effects was not the purpose of the study, it could be seen as a weakness of the study.

Post et al (2010) set out to evaluate pain level, opioid consumption, and related side effects when using patient controlled analgesia (PCA) in comparison to TLC therapy. The authors enrolled 50 patients aged 43 to 79 in the PCA group and 50 patients aged 32 to 82 I the TLC group. Using power analysis, it was deemed that the number of subjects was sufficient to

evaluate the proposed outcomes. Patients with a history of liver, kidney, inflammatory bowel disease as well as chronic opioid use and sulfa allergy were excluded from this study. The TLC group was given 975mg acetaminophen, 400 mg celecoxib, and 75 mg pregablin by mouth (PO) an hour before surgery. These medications were continued postoperatively. In the PCA group, the patient controlled analgesia was discontinued on day one surgery and the participants were started on oral medication. The PCA group consumed high amounts of opioids (P=0.001) and exhibited a higher incidence of side effects such as nausea) P=0.005), itching (P=0.005) as well as well as experienced higher pain levels (P=0.001) in the first 24 hours as compared to the TLC group. The PCA group has also exhibited more incidences of dizziness (P=0.003) and constipation (P=0.001) during the first 48 hours. One limitation of this study was the fact that patients were assigned to each group based on their surgeons instead of randomization, which threats internal validity. Also the patients in the PCA group did not receive any medication preoperatively but were given fentanyl using PCA pump postoperatively.

Similarly, Michelson, Addante, and Charlson (2013) enrolled a total of 220 patients who underwent foot and ankle surgeries in a university hospital in a retrospective trial. The purpose of the study was to evaluate the effect of multimodal therapy on length of stay (LOS). In the study group, 175 patients received 10 mg oxycodone, 200 mg celecoxib, 75 mg pregablin, 1000 mg acetaminophen, and 40 mg prednisone based on a multimodal pain protocol used for other types of surgeries in the same institution. The control group comprised of 45 patients, were started on PCA after surgery then switched to oral medications as soon as possible. Then both groups were kept on routine pain medications such as oxycodone, celecoxib, and acetaminophen postoperatively. The researchers reported a decreased LOS in the study group, two and half days as compared to the controlled group, over four days. One of the limitations of the study was the

fact that it was a nonrandomized retrospective experiment. Another limitation was that the exclusion criteria of this trial were not mentioned.

Trabulsi, Patel, Leonard and Lallas (2010) evaluated the effects of preemptive multimodal therapy on total opioid requirement. Patient in the study group (n=3-) received 150mg pregablin, 400 mg celecoxib, and 975 mg acetaminophen two hours prior to incision. The average amount of opioids consumed by the study group patients were then compared retrospectively with 30 patients' (control group) charts who received 15 – 30 mg ketorolac interveniously, five to 10mg oxycodone, and 325 – 650 mg acetaminophen every four hours. The opioids administered were converted to morphine equivalent dose to make cumulative calculation and comparisons possible. The authors reported that the patients in the study group has less opioid requirement in terms of morphine (75.3 mg) as compared to the control group (49.1 mg). The authors also reported that the study group did not experience pregablin related side effects such as dizziness and somnolence. Assessment of opioid side effects such as nausea and vomiting were not looked at in this study, which could be considered as limitation. Instead, the authors looked at antiemetic medications consumption to determine the occurrence of nausea and vomiting.

The difference in demographics between the two groups was reported to be insignificant. The limitation of the study is the fact that the researchers did not include patients' pain scores using a standardized tool; instead, they evaluated only the amount of opioids consumed by patients. Also the inclusion and exclusion criteria for this study were not disclosed. However, it was mentioned that the dose of ketorolac, 15 – 30 mg was given based on the patient's age and renal function. Another limitation noted was that the power analysis was not done to determine the number of subjects needed for the study. In addition, two patients were excluded from each

group due to refusal and chronic opioid use. The researches completed this study on patients undergoing prostatectomy. However, the findings still apply for any surgical patients since the mechanism of actions are similar.

In this paragraph, the overall synthesis of the four clinical trials will be presented. Post et al (2010) used 75 mg pregablin with 400 mg celecoxib and added 975 mg acetaminophen as opposed to another study done by Lee et al (2015) where they used 150 mg pregabalin and 400 mg celecoxib. They both reported that the study groups consumed less opioids as compared to the control groups. Similarly, Trabulsi et al (2010) used 150 mg pregabalin, 400 mg celecoxib, and 975 mg acetaminophen. They also reported that the study group required less opioids than the control group without experiencing side effects from pregabalin. On the other hand, Michelson et al (2013), used 200 mg celecoxib, 75 mg pregabalin, 1000 mg acetaminophen, 10 mg oxycodone, and 40 mg prednisone. The researches of this study reported that the patients' LOS was shorter than the control group sine their postsurgical pain was appropriately controlled. Even though, the type and doses of these preemptive multimodal analgesics differ slightly among all the studies, the results revealed that the use of preemptive multimodal analgesia is effective and help to lowed side effects by decreasing the amount of opioid consumptions.

Methods

Design, Setting and Sample

The design of this scholarly project was a quality improvement that includes the development and evaluation of a Clinical Practice Guideline (CPG) for preemptive multimodal analgesia for knee and hip arthroplasties. The setting was an anesthesia department at a community hospital in suburban Baltimore, Maryland. There were two phases to this scholarly project with two sets of samples that will be discussed further in the procedure section.

Procedure

Phase I.

During phase one of the CPG development, the initial step was recruiting members of the expert panel. The sample size for the expert panel was two, the chief orthopedic surgeon and a Registered Nurse Anesthetist (CRNA). Once the expert panel was formed, the expert panel members were contacted to set up the first meeting. Hard copies of the CPG proposal (see Appendix D) and the AGREE II Tool (see Appendix E) were handed to the expert panel. During the meeting, the overall plan and the AGREE II tool were discussed in detail. Also their role, which is evaluating and grading the CPG, was discussed. During the second meeting, the initial CPG was presented to the expert panel and they were asked to rate it using AGREE II tool. The CPG was presented again during the third meeting after revising it based on the feedback given after the presentation. Also, the CPG was presented to the chief anesthesiologist and verbal approval of the CPG was granted. The idea of developing a CPG and what medication would be involved in the plan has been presented to the director of pharmacy at this phase. The overall response of the director of the pharmacist was positive and encouraging.

Phase II.

During this phase, a presentation session was scheduled during the anesthesia department monthly meeting to discuss the CPG. At the beginning of the presentation, hard copies of the PFQ (see Appendix E) and CPG were given to all the participants. The end-users surveyed the CPG using a modified Practitioner Feedback Survey at the end of the presentation. The data collected from the expert panel using the AGREE II Tool and the end-users using the PFQ will be analyzed and synthesized using descriptive statistics. See appendix B for scholarly project timeline.

Data Collection, Analysis and Evaluation

The AGREE II Tool consists of 23 items organized in to six domains and was developed to

evaluate the quality of guidelines by assessing the methods used to develop it. A 7-point scale (1-strongly disagree to 7-strongly agree) is used to rate all the items. Summing up all the items under each domain separately and scaling the percentage of the maximum possible score for that domain will give a quality score for that domain. The validity of the AGREE II Tool was established by study that participated a convenience sample of 30 guideline developers, researchers and clinicians. The investigators were able to establish the validity of the tool and reported that the majority of the content designed to be of high quality ($P<0.05$) (Brouwers et al, 2010). The inter-rater reliability of the AGREE II Tool has been established as well by analyzing the internal consistency; Chronbach alpha scores were reported to range from 0.64 to 0.89 for the six domains (Broumers et al, 2010).

The modified Practitioner Feedback Survey contains 23 items and was developed to measure guidelines of oncologists' assessments in oncology (Brouwers, Graham, Hanna, Cameron and Browman, 2004). The instrument has been proven to be reliable with alpha coefficient of 0.75 to 0.85 (Brouwers, 2004). The first item in the survey is a general question to evaluate the applicability of it to the participant. Item two to 23 are rated on three scales: strongly are, neither agree or disagree and strongly disagree. As part of the modification, two questions have been added in order to collect non-identifier demographic data. The demographic data added were whether the provider is a CRNA or an anesthesiologist and years of experience (see appendix C). Finally, all the data were analyze and evaluated using descriptive statistics.

Human Rights Protection

This is considered a quality improvement project for the purpose of a specific organization and is intended neither for generalizable knowledge nor to be applied to another setting. This project was submitted to the University of Maryland Baltimore Institutional Review Board (IRB) for determination of a non-human subject research. It has also been submitted to the IRB of the host facility and has been

approved by both. Participation was voluntary during both the development and evaluating process of the CPG. Any demographic data collected as part of the PFQ were non-identifier. Only the two DNP students have access to all the data collected using the AGREE II Tool and PFQ.

Results and Discussion

When grading the AGREE II Tool, the maximum possible score is seven and the minimum score is one. See Table 1 for domain one results presented as a sample and Table 2 for the overall results of all the domains. In order to calculate the quality scores for each domain individually, the following formula was used:

Maximum possible score = 7 (strongly agree) x 3 (items) x 2 (appraisers) = 42

Minimum possible score = 1 (strongly disagree) x 3 (items) x 2 (appraisers) = 6

$$\frac{\text{Obtained Score} - \text{Minimum possible Score}}{\text{Maximum Possible Score - Minimum possible score}}$$

$$\frac{36 - 6}{42 - 6} \times 100 = \frac{30}{36} \times 100 = 83.3\ \%$$

Table 1.
AGREE II Tool sample: Domain 1 quality score

	Appraiser 1	Appraiser 2	Total
Domain 1. Scope And Purpose			
1. The overall objective(s) of the guideline is (are) specifically described.	6	6	12
2. The health question(s) covered by the guideline is (are) specifically described.	6	6	12
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	6	6	12
Total	18	18	36
Domain Score	83.3%		

Table 2.
AGREE II Tool domains quality scores

Domains	Appraiser 1	Appraiser 2	Total obtained score	%
1. Scope and Purpose	6	6	12	83.3
2. Stakeholder involvement	6	6	12	83.3

3. Rigour of development	6	6	12	83.3
4. Clarity and presentation	6	6	12	83.3
5. Applicability	6	6	12	83.3
6. Editorial independence	6	6	12	83.3
Overall assessment	6	6	12	83.3

Domain one contains three questions and it deals with the potential health impact of the CPG on the target patient population. It also evaluates the presence of the overall objectives for the guideline. Domain two includes three questions as well and it deals with involving stakeholders at the earlier stage of the development phase, which helps in getting the facility's buy-in. It specifically asks if relevant professionals have been included during the development stage of the guideline and if the intended target users have been specified. Domain three addresses rigour of the CPG development and has seven questions. This domain evaluates if strengths and limitations of the evidence as well as the method used have been described clearly. It also asks if the risk, benefits and side effects have been taken into consideration for the development of the CPG. Domain four contains three questions and deals with the clarity of the CPG. It evaluates the specificity and clarity of the key recommendations. Domain five consists of four questions evaluating the applicability of the CPG. It evaluates if facilitators and barriers for implementation have been mentioned. It also asks if there is clear guidance on how the recommendation can be applied into practice. Domain six consists of two questions evaluating editorial independence. This domain evaluates if there are any conflicts of interest. All of the domains have been given a score of 83.3% individually, which correlates with the CPG having a high quality. The overall score for the quality of the CPG was 86% and both of the appraisers have recommended the guideline to be implemented with minor modification. See appendices C and D for further information.

Table 3.
Demographic Data of the PFQ participants (N=20)

Demographic Variables	n	%
Type of Provider		
CRNA	16	80

MDA	4	20
Years of Experience		
0-5 years	8	40
6-10 years	4	20
> 10 years	8	40

A total of 20 anesthesia providers had completed the PFQ voluntarily after the CPG was presented at their monthly meeting. Eighty percent of the participants were CRNAs and 20% were MDAs. The majority of the participants had either less than 6 years (40%) or greater than 10 years (40%) of experience as anesthesia provider. Twenty percent of the participants had 6 to 10 years of experience as anesthesia providers. See Table 3 for complete list of the demographics.

The PFQ was used to collect survey data from the end users, CRNAs and MDAs regarding the quality of the CPG and the likelihood of implementing it. The majority of the participants (90%) have agreed that the DNP students have written the CPG recommendations and the rationale for developing it clearly. Of the 20 participants, 85% of them agreed that the CPG would result in higher benefits. If the CPG is implemented at their facility, they will be comfortable with their patients receiving the analgesics. Eighty percent of the participants agreed that there was a need for a CPG for the intended patients group and this CPG will help to use resources more effectively. About 70% of the participants believed that majority of their colleges will support the CPG recommendations and the patient outcomes will be obvious if it is followed. Only 20% of the participants said that the CPG recommendations were too rigid and 15% said that it would be too expensive or technically challenging to apply. See Table 4for a sample of the PFQ and appendix E for the PFQ complete results.

Table 4.
The CPG Quality Rating Result Sample from the Practitioners Feedback Questioners (N=20)

	Agree %	Neither %	Disagree %
1. The rationale for developing a guideline is clear	90	10	0

2. There is a need for a guideline on this topic	80	15	5
3. The literature search is relevant and complete	75	25	0
4. I agree with the methodology used to summarize the evidence included in this draft guideline	80	20	0
5. The results of the evidence described in this draft guideline are interpreted according to my understanding of the evidence	90	10	0

Barriers and Facilitators

Barriers

Currently, all aspects of care/treatment are not based on evidence of best practice at this particular organization. Based on the evaluation assessment, this particular organizational management has high regards for staff autonomy, which could be a barrier for implementation of a guideline. Some practitioners may be unaware of the latest evidence based practice and other practitioners might be unsure of how to integrate new ways to provide high quality patient care. However, there might also be some practitioners who would feel that guidelines take away their autonomy (National Institute for Health and Clinical Excellence, [NICE] 2007). At times, some anesthesia providers resist changing the way they practice. Another barrier could be the fact that structured education programs are unavailable at this facility to all providers.

To overcome these barriers, having educational meetings such as workshops, lectures and conferences, in addition to educational material such as booklets and online tools will be helpful to inform the end-users of the current evidence based practice (NICE, 2007). Currently, the providers have meetings every first Friday of the month; therefore, adding education sessions and workshops to their meetings will be easily achieved.

Facilitators

Cultural assessment of the organization was done and it has revealed that the anesthesia providers receive feedback about their practice and outcomes based on results of clinical audits.

"Audits can be a positive way of generating changes… and feedback is particularly effective when combined with educational materials and meetings" (NICE, 2007). Thus performing audits and providing feedback to the providers once the guideline is implemented will help to increase the compliance rate.

This particular organization seemed to hierarchical, which could be considered as an enabler. Leaders are respected and looked up to as role models by other employees; therefore, using their influence is one of the effective ways to disseminate information (NICE, 2007). Having the key stakeholders buy-in earlier in the process may garner support in order to implement the guideline successfully. The chief anesthesiologist and the chief orthopedic surgeon are in support of the CPG. "Assessing barriers to and facilitators of the use of knowledge is closely linked to the adaptation and uptake of the evidence" (Harrison, Legare, Graham and Fervers, 2009). Understanding the barriers will allow pinpointing the action that is needed to implement change successfully (Chaplin, 2008).

Implications

Economical and Operational Feasibility

Implementing this CPG will be feasible economically. The costs of all medications included in the CPG have been examined. 1000mg PO acetaminophen costs about $ 0.03, 150mg PO pregabalin costs $6.70, and 400mg PO celecoxib costs $2.33. If a patient receives these three drugs as recommended in the CPG, the total cost would be around $9.06. At this particular facility, every qualified patient who undergoes knee or hip arthroplasty receives 1000mg IV acetaminophen currently, which costs about $39. Therefore, the saving from a single patient will be $29.94 when the CPG becomes implemented. In addition, by decreasing hospital length of stay related to effective postoperative pain management, the hospital would decrease total cost of

patient care. Implementing the CPG will not be complicated or technically challenging; therefore, it will be feasible operationally as well.

Recommendation

In conclusion, adding acetaminophen, pregabalin and celecoxib to the current regimen for knee and hip arthroplasty patients was recommended. These multimodal analgesics should be given preemptively, an hour before incision time. Also replacing gabapentin for pregabalin was given to the hospital as an option considering the price differences. The decision was made by the hospital's Enhanced Recovery After Surgery (ERAS) guidelines committee leader to exclude pregabalin from the CPG. Currently, this CPG is in the final stage of being implemented as their orthopedic ERAS protocol order-set. Incorporating this CPG will result in better postsurgical pain management, minimize the risk of opioid related side effects, decrease length of hospital stay and increase patient satisfaction rate. As a result, the hospital could decrease cost of patient care.

Future recommendation

As mention before, decision was made by the facility to exclude pregabalin at this time. Recommendation has been given to the facility by the two DNP students to incorporate pregabalin to the order-set in the near future after performing their own research on the effectiveness of it when combined with acetaminophen and celecoxab. This DNP project focused mainly on preoperative phase; therefore, recommendation has been given to the facility to develop a guideline addressing postoperative period as well. Postoperative period is as equally important as preoperative period to achieve effective postsurgical pain management.

In addition, the importance of postoperative patient visit has been emphasized in order to follow up on the outcome of the CPG. Finally, recommendation has been given to educate the anesthesia staff and preoperative nurses frequently to increase compliance to the guideline.

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Appendix A

Johns Hopkins Evidence-Based Practice Individual Evidence Summary

Study #	Author and Date	Evidence Type	Sample and Sample Size	Result / Recommendations	Limitations	Strength/ Quality
1	Lee, Chung, & Choi, 2015	Prospective, randomized, controlled, double-blind study	55-80 years old patients of American Society of Anesthesiology (ASA) physical status grade I-III undergoing Total Knee Arthroplasty (TKA). The study group, Group L (n=21), received 400 mg celecoxib plus 150 mg pregabalin orally 1 hour pre-operatively. The control group, Group C (n=20), received 400 mg celecoxib orally1hour pre-operatively. There were no statistically significant differences between the two groups' demographic data.	The total consumption of fentanyl in average was lower in the study group as compared to the control group during the first 48 hours. The study group experienced less pain during the first 12 hours at rest as compared to the controlled group. But their pain level did not differ after 12 hours at rest. With activity, pain scores were lower in the study group than the control group during the first 48 hours.	The authors have mentioned that the number of subjects (n=41) used was deemed sufficient to assess pain score and opioid consumption based on the result of power analysis. However, it was insufficient to assess the occurrence of side effects.	I / A
2	Michelson, Addante, & Charlson, 2013	Retrospective comparative study	Study group (multimodal therapy, n=175) versus control group (PCA, n=45)	Decreased LOS in the study	Nonrandomized retrospective study	II/B

3	Post, (2010)	Prospective study	The study group (TLC, n=50) versus control group, PCA, n=50)	The study group experienced lower pain scores Decreased opioid requirement Fewer side effects of opioids.	Patients were assigned to each group based on their surgeons instead of randomization. The PCA group did not receive any preoperative medication preoperatively like the TLC group	II/A
4	Trabulsi, Patel, Viscual, Gomella, & Lallas, 2010	Present retrospective study	Study group (using updated guideline, n=30) versus controlled group (prior to the guideline being updated (n=30)	Decreased total opioids consumption by the study group No side effect from pregabalin	Pain scores were not evaluated using standardized tool Power analysis was not done Internal validity threat - two patients were excluded from each group due to refusal and chronic opioid use.	II/B

Appendix B

Scholarly Project Timeline

- Submitted initial CPG to committee members by April 2016
- Presented CPG proposal to committee members for approval by May 2016
- Submitted CPG proposal at UMB and host facility IRBs for approval by May 2016
- Implemented the project from September 2o16 to December 2016
    - Submitted the CPG proposal and the AGREE II Tool to the expert panel members by October 2016
    - Revised CPG based on the expert panel members' feedback by November 2016
    - Presented CPG and Practitioner Feedback Questionnaire to the end-users by December 2016
- Analyzed, synthesized and evaluated collected data by January to February 2017
- Submit final scholarly project to committee members for review and approval by February 2017
- Present the final scholarly project to committee members and public by March 2017

Appendix C

Guideline Title: Preemptive Multimodal Analgesia for Knee and Hip Arthroplasty: A Clinical Practice Guideline

I. Scope and Practice

a. Guideline Objective

To improve postoperative pain in patients undergoing knee and hip arthroplasties at GBMC by utilizing pre-emptive multimodal analgesia.

b. Health Question Covered by the Guideline

Effectiveness of pre-emptive multimodal analgesia in improving postoperative pain in patients undergoing knee and hip arthroplasties.

c. Target Population

Adult patients (age 18 and over), undergoing knee or hip arthroplasty.

d. Clinical Specialty

Anesthesia

II. Stakeholder Involvement

a. Individuals/ Professionals Included in the Guideline Development

The Chief of Orthopedic Surgery, a Certified Registered Nurse Anesthetist (CRNA) reviewed the clinical practice guideline using the AGREE II tool. The Chief of Anesthesia and the Director of Pharmacy was also consulted during the entire process. Then, the clinical practice guideline was modified and presented to the anesthesia providers.

b. Target Users

The target users are the anesthesiologists, CRNAs, and orthopedic surgeons at GBMC.

III. Methodology

a. Methods

Extensive literature review was performed using several electronic databases such as Cumulative Index to Nursing and Allied Health Literature, Medline, Nursing Academic Edition, Cochrane, and PubMed using the inclusion and exclusion criteria. The keywords entered included preemptive analgesia, and postoperative pain. Then literatures, which fulfilled the inclusion and exclusion criteria were analyzed and served as a basis for the clinical practice guideline.

b. Inclusion and Exclusion Criteria

Inclusion criteria included full-text articles, written in English, and published from 2006 to 2016. Literatures focusing on pediatrics were excluded.

c. Strengths and Limitations

i. Methods Used to Assess the Quality and Strength of Evidence

Johns Hopkins Nursing Evidence-Based Practice

ii. Rating Scheme for the Strength of Evidence

A total of four studies were identified to be pertinent to the topic, the effectiveness of preemptive multimodal analgesia in improving postoperative pain in patients undergoing knee and hip arthroplasties. One Level 2 randomized controlled trial, and four Level 3 cohort studies were included. The Level 2 studies had high quality of evidence and all of the Level 3 studies had good evidence. The studies had enough sample size, consistent data collection process, and inter-rater reliability. Based on the level of evidence, Level 3 and above are considered high quality findings.

d. Methods Used to Formulate the Recommendations

Two Doctoral of Nursing Practice student registered nurse anesthetists developed the guideline. The formulation of recommendations was based on extensive literature review and assessment of the strength of evidence using the Johns Hopkins Evidence-Based Practice Evaluation Tool and suggestions by the stakeholders and target users.

e. Link Between the Recommendations and Supporting Evidence

(See Recommendation Section, IV)

f. Guideline Development

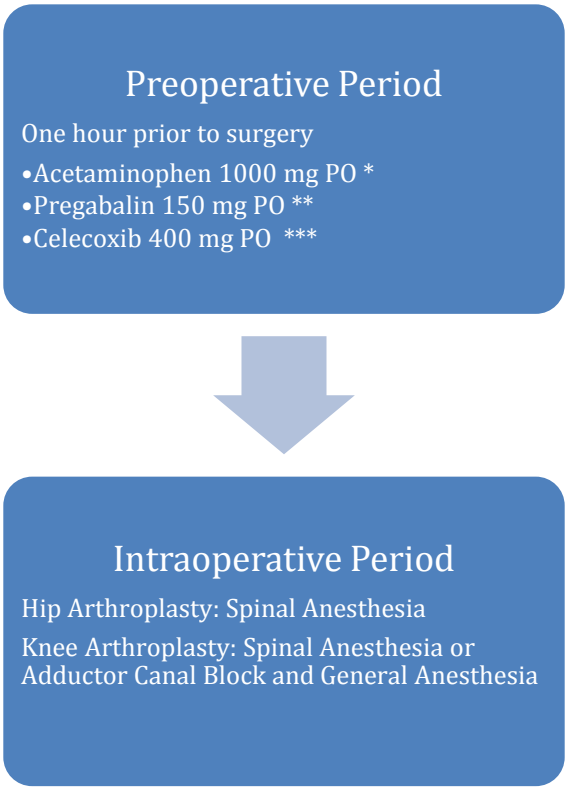
The need for this guideline was identified after a thorough assessment of the facility. Then, a systematic review of literature on preemptive multimodal analgesia was done. During the guideline development, collaboration was done with the Chief of Anesthesia and Director of Pharmacy. The initial clinical practice guideline was evaluated by the Chief of Orthopedic Surgery and a CRNA using the Appraisal of Guidelines for Research and Evaluation (AGREE) II Tool. The AGREE II Tool is an instrument that involves methodological strategies that can be utilized in the guideline development to minimize variability in quality. The tool provided an opportunity to address improvements and recommendations needed for the guidelines.

After the guideline was revised based on the AGREE II Tool, a one-hour long presentation about the guideline was given to the anesthesia department. The attendees were requested to fill up the PFQ. The PFQ is a tool that practicing clinicians can use to assess a drafted guideline. It is composed of 23 items that reflects scientific quality, methodological rigor, and applicability, and acceptability of the guideline. All items are scored on a five point scale- strongly agree, agree, neither agree or disagree, disagree and strongly disagree. After the CPG, a copy of the presentation was e-mailed to the entire anesthesia department.

The CPG was revised based on the feedback provided by anesthesia staff. Then, the finalized CPG was presented to the Chief of Anesthesia and Chief of Orthopedic Surgery.

IV. Recommendation

a. Pre-operative Period



*Do **NOT** give Acetaminophen to patients with active liver disease or increased liver enzymes.

Do **NOT give Pregabalin to patients on hemodialysis and age 80 or older. Decrease dose for patients with reduced renal functioning and BMI of <25 kg/m2.

***Do **NOT** give Celecoxib to patients with allergic-type reactions to sulfonamides.

Based on the review of the research studies, one major component noted was the utilization of preemptive analgesia. The multimodal pain analgesics included in each study was administered in the preoperative phase. Preemptive administration of analgesics plays a role in postoperative pain (Lee et al., 2015; Michelson et al., 2013; Trabulsi et al., 2010).

Among the different multimodal pain management reviewed, celecoxib, acetaminophen, and pregabalin are the frequently utilized medications to facilitate preemptive analgesia. These three medications are indicated to be effective in treating post-operative pain because of their opioid sparing effect (Michelson et al., 2013; Post et al., 2010).

V. Health Benefits, Side Effects, and Risks

a. Potential Benefits

Benefits include effective management of postoperative pain (Lee et al., 2015; Michelson et al., 2013; Trabulsi et al., 2010), lower pain scores (Lee et al., 2015; Lewis et al., 2012; Post et al., 2010), decreased intraoperative and

postoperative narcotic consumption (Lee et al., 2015; Post et al., 2010; Trabulsi et al, 2010), and lower incidence of adverse effects associated with high dose narcotics such as pruritus and nausea (Lewis et al., 2012; Post et al., 2010) Lee et al., 2015; Michelson et al., 2013; Trabulsi et al., 2010. Furthermore, it will shorten patient's hospital stay (Lewis et al., 2012; Michelson et al., 2013) and improve patient's ability to participate in physical therapy (Post et al., 2010).

b. Side effects:

Medication	Mechanism of actions (MOA)	Side effects and contraindications
Acetaminophen	The exact MOA is still unclear but it is believed to work on the central nervous system by blocking pain receptors in the brain (Gandhi & Viscusi, 2009).	Contraindicated with elevated liver enzymes, active liver disease, and hypersensitivity to acetaminophen (Gandhi & Viscusi, 2009).
Pregabalin	Binds to presynaptic voltage-gated channels α2δ-1 subunit in the CNS. Inhibits excitatory neurotransmitters and Ca2+ influx in the spinal and supraspinal pathways (Gandhi & Viscusi, 2009).	Contraindicated in patients aged 80 or older. Decrease the dose by have for patients with BMI below 25.0 kg/m2. Adverse reactions: double or blurred vision, asthenia, dizziness, or disorientation. Caution should be taken in patient with decreased renal function since is eliminated via the kidneys unchanged (about 90%) (Gandhi & Viscusi, 2009).
Celecoxib	It inhibits the conversion of arachidonic acid to prostaglandins. Do not affect platelet functions as other NSAIDs (Gandhi & Viscusi, 2009).	Contraindicated in patients with hypersensitivity to sulfonamides, active gastrointestinal ulcer, asthma, elevated blood urea nitrogen (BUN) or creatinine levels (Gandhi & Viscusi, 2009).

VI. Applicability

a. Facilitators and Barriers to Application

The facilitators identified in the implementation of the clinical practice guideline include collaborative relationship between healthcare providers and patients; presence of transformational leaders; patient centered practice; and support for evidence based practice. The chief of anesthesia, the chief orthopedic surgeon, a CRNA, the entire anesthesia providers, and the director of pharmacy had an active role in the process of the guideline development. Having the key stakeholders buy-in earlier in the process may garner support in order to implement the guideline successfully.

One of the possible barriers could be the possibility of delay in administering the medications. In order to overcome this barrier, patients should be educated about the importance of arriving at the preoperative area on time; and educating pre operative nurses about the importance of giving the medications as early as possible. Furthermore, some practitioners may be unaware of the latest evidence based practice and other providers could resist changing the way they practice. To overcome these, having educational meetings such as workshops, lectures and conferences; educational material such as booklet and online tool will be helpful to inform the end-users of the current evidence based practice (National Institute for Health and Clinical Excellence, 2007).

b. How the Recommendations Can Be Implemented

Successful implementation will require proper information dissemination and education. Buy-in from the anesthesia and orthopedic surgeons is essential. Pre-operative nurses will be educated about the guideline. This can be done through in-service education and poster presentation to the anesthesia department, orthopedic surgeons, and preoperative nurses during grand rounds.

Continuous protocol evaluation and modification should be done every two years based on new evidence-based practice. Flyers containing the summarized guideline recommendations will be distributed to the anesthesia providers, orthopedic surgeons, and nurses.

c. Potential Resource Implications of Applying the Recommendations

The prices for each medication are Acetaminophen 1000 mg PO- $0.03; Pregabalin 150 mg PO- $6.70; and Celebrex 400 mg PO- $2.33. If these three medications will be administered, the total cost will be $9.06. The total cost of utilizing the medications mentioned in the CPG would be roughly $5,600 in one year, which can result to a 78% savings when compared to their current practice.

d. Monitoring and/or Auditing Criteria

Pain level using the visual analog scale should be assessed between emergence and postoperative day one.

VII. Identifying Information and Availability

a. Funding Body/ Competing Interests

The development of this guideline was developed without external funding. Everyone who is involved in the development of this guideline confirmed that they have no competing interests.

b. Principal Authors

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Jocelyn M. Datud, SRNA, BSN, CCRN

c. Key Contributors

Joseph Pellegrini, PhD, CRNA
Fran Valle, DNP, CRNP, WCC
Doug Kircher, MSN CRNA

d. Date Released

Projected to be April 2017

VII. References

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Appendix D

Agree II Tool: Appraisal of Guidelines for Research & Evaluation II

DOMAIN 1. SCOPE AND PURPOSE

1. The overall objective(s) of the guideline is (are) specifically described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

2. The health question(s) covered by the guideline is (are) specifically described

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 2. STAKEHOLDER INVOLVEMENT

4. The guideline development group includes individuals from all relevant professional groups

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

5. The views and preferences of the target population (patient, public, etc.) have been sought.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

6. The target users of the guideline are clearly identified.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 3. RIGOUR OF DEVELOPMENT

7. Systematic methods were used to search for evidence.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

8. The criteria for selecting the evidence are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

9. The strengths and limitations of the body of evidence are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

10. The methods for formulating the recommendations are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

11. The health benefits, side effects, and risk have been considered in formulating the recommendations.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

12. There is an explicit link between the recommendations and the supporting evidence.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

13. The guideline has been externally reviewed by experts prior to its publication.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

14. A procedure for updating the guideline is provided.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 4. CLARITY OF PRESENTATION

15. The recommendations are specific and unambiguous.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

16. The different options for management of the condition or health issue are clearly presented.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

17. Key recommendations are easily identifiable.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 5. APPLICABILITY

18. The guideline describes facilitators and barriers to application.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

19. The guideline provides advice and/or tools on how the recommendation can be put into practice.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

20. The potential resource implications of applying the recommendations have been considered.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

21. The guideline presents monitoring and/or auditing criteria.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 6. EDITORIAL INDEPENDENCE

22. The views of the funding body have not influenced the content of the guideline.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

23. Competing interests of guideline development group members have been recorded and addressed.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

OVERALL GUIDELINE ASSESSMENT

1. Rate the overall quality of this guideline.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

2. I would recommend this guideline for use.

Appendix E
Practitioner Feedback Questionnaire

Title: ☐ Anesthesiologist ☐ CRNA ☐ Others: Please Specify_____
Years of Experience: ☐ 0-5 years ☐ 6-10 years ☐ >10 years

For each item, please check off the box that most adequately reflects your opinion.

1. Are you responsible for the care of patients for whom this draft guideline report is relevant? This may include the referral, diagnosis, treatment, or follow-up of patients.	Yes ☐		No ☐	Unsure ☐	
	Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
2. The rationale for developing a guideline is clear.	☐	☐	☐	☐	☐
3. There is a need for a guideline on this topic.	☐	☐	☐	☐	☐
4. The literature search is relevant and complete (e.g., no key evidence was missed nor any included that should not have been) in this draft guideline.	☐	☐	☐	☐	☐
5. I agree with the methodology used to summarize the evidence included in this draft guideline.	☐	☐	☐	☐	☐
6. The results of the evidence described in this draft guideline are interpreted according to my understanding of the evidence.	☐	☐	☐	☐	☐
7. The draft recommendations in this report are clear.	☐	☐	☐	☐	☐
8. I agree with the draft recommendations as stated.	☐	☐	☐	☐	☐
9. The draft recommendations are suitable for the patients for whom they are intended.	☐	☐	☐	☐	☐
10. The draft recommendations are too rigid to apply to individual patients.	☐	☐	☐	☐	☐
11. When applied, the draft recommendations will produce more benefits for patients than harms.	☐	☐	☐	☐	☐
12. The draft guideline presents options that will be acceptable to patients.	☐	☐	☐	☐	☐
13. To apply the draft recommendations will require reorganization of services/care in my practice setting.	☐	☐	☐	☐	☐
14. To apply the draft guideline recommendations will be technically challenging.	☐	☐	☐	☐	☐
15. The draft guideline recommendations are too expensive to apply.	☐	☐	☐	☐	☐
16. The draft guideline recommendations are likely to be supported by a majority of my colleagues.	☐	☐	☐	☐	☐
17. If I follow the draft guideline recommendations, the expected effects on patient outcomes will be obvious.	☐	☐	☐	☐	☐
18. The draft guideline recommendations reflect a more effective approach for improving patient outcomes than is	☐	☐	☐	☐	☐

current usual practice. (If they are the same as current practice, please tick NA). *NA* ☐					
19. When applied, the draft guideline recommendations will result in better use of resources than current usual practice. (If they are the same as current practice, please tick NA). *NA* ☐	☐	☐	☐	☐	☐
20. I would feel comfortable if my patients received the care recommended in the draft guideline.	☐	☐	☐	☐	☐
21. This draft guideline should be approved as a practice guideline.	☐	☐	☐	☐	☐
22. If this draft guideline were to be approved as a practice guideline, I would use it in my own practice.	☐	☐	☐	☐	☐
23. If this draft guideline were to be approved as a practice guideline, I would apply the recommendations to my patients.	☐	☐	☐	☐	☐

Suggestions:_____

_____

_____

_____

Adapted from: Brouwers, M.C., Graham, I.D., Hanna, S.E., Cameron, D.A., & Browman, G.P. (2004). Clinicians' assessments of practice guidelines in oncology: The CAPGO survey**.** *International Journal of Technology Assessment in Health Care*, *20*(4), 421-6.

Appendix F

	Appraiser 1	Appraiser 2	Total
Domain I. Scope And Purpose			
1. The overall objective(s) of the guideline is (are) specifically described.	6	6	12
2. The health question(s) covered by the guideline is (are) specifically described.	6	6	12
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	6	6	12
Total	18	18	36
Domain Score	85.7		

Domain 2. Stakeholder Involvement	Appraiser 1	Appraiser 2	Total
4. The guideline development group includes individuals from all relevant professional groups.	6	6	12
5. The views and preferences of the target population (patients, public, etc.) have been sought.	6	6	12
6. The target users of the guideline are clearly defined.	6	6	12
Total	18	18	36
Domain Score	85.7		

Domain 3. Rigour Of Development	Appraiser 1	Appraiser 2	Total
7. Systematic methods were used to search for evidence.	6	6	12
8. The criteria for selecting the evidence are clearly described.	6	6	12
9. The strengths and limitations of the body of evidence are clearly described.	6	6	12
10. The methods for formulating the recommendations are clearly described.	6	6	12
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	6	6	12
12. There is an explicit link between the recommendations and the supporting evidence.	6	6	12
13. The guideline has been externally reviewed by experts prior to its publication.	6	6	12
14. A procedure for updating the guideline is provided.	6	6	12
Total	48	48	96

Domain Score	85.7		

Domain 4. Clarity Of Presentation	Appraiser 1	Appraiser 2	Total
15. The recommendations are specific and unambiguous.	6	6	12
16. The different options for management of the condition or health issue are clearly presented.	6	6	12
17. Key recommendations are easily identifiable.	6	6	12
Total	18	18	36
Domain Score	85.7		

Domain 5. Applicability	Appraiser 1	Appraiser 2	Total
18. The guideline describes facilitators and barriers to its application.	6	6	12
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.	6	6	12
20. The potential resource implications of applying the recommendations have been considered.	6	6	12
21. The guideline presents monitoring and/or auditing criteria.	6	6	12
Total	24	24	48
Domain Score	85.7		

Domain 6. Editorial Independence			
22. The views of the funding body have not influenced the content of the guideline.	6	6	12
23. Competing interests of guideline development group members have been recorded and addressed.	6	6	12
Total	12	12	24
Domain Score	85.7		

Rate the overall quality of this guideline	6	6	
I would recommend this guideline for use			
Yes			
Yes with modifications	X	X	
No			

Appendix G

The CPG Quality Rating Result from the Practitioners Feedback Questioners

	Agree	Neither	Disagree
	%	%	%
1. The rationale for developing a guideline is clear	90	10	0
2. There is a need for a guideline on this topic	80	15	5
3. The literature search is relevant and complete	75	25	0
4. I agree with the methodology used to summarize the evidence included in this draft guideline	80	20	0
5. The results of the evidence described in this draft guideline are interpreted according to my understanding of the evidence	90	10	0
6. The draft recommendations in this report are clear	90	10	0
7. I agree with the draft recommendations as stated	80	20	0
8. The draft recommendations are suitable for the patients for whom they are intended	90	10	0
9. The draft recommendations are too rigid to apply to individual patients	20	25	55
10. When applied, the draft recommendations will produce more benefits for patients than harms	85	10	5
11. The draft guideline presents options that will be acceptable to patients	90	10	0
12. To apply the draft recommendations will require reorganization of services/care in my practice setting	65	20	15
13. To apply the draft guideline recommendations will be technically challenging	15	25	60
14. The draft guideline recommendations are too expensive to apply	15	25	60
15. The draft guideline recommendations are likely to be supported by a majority of my colleagues	70	30	0
16. If I follow the draft guideline recommendations, the expected effects on patient outcomes will be obvious	70	20	10
17. The draft guideline recommendations reflect a more effective approach for improving patient outcomes than is current usual practice	70	25	5
18. When applied, the draft guideline recommendations will result in better use of resources than current usual practice.	80	15	5
19. I would feel comfortable if my patients received the care recommended in the draft guideline	85	10	5
20. This draft guideline should be approved as a practice guideline	75	20	5
21. If this draft guideline were to be approved as a practice guideline, I would use it in my own practice	85	10	5