TITLE: Determining the effect of an "alternate management protocol" versus current standard of care after cesarean section

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OBJECTIVES AND SPECIFIC AIMS:
This randomized controlled trial will compare two different approaches to patient recovery after cesarean section: the current standard of care versus an alternate management protocol. The goal of this study is to investigate whether an "alternate management" protocol after cesarean sections will yield the same results as alternate management in other surgical fields, including decreased narcotic consumption and quicker return of bowel function, without compromising patient morbidity or satisfaction.

We will assess postoperative narcotic consumption as the primary outcome. Secondary outcomes will be return of bowel function, length of hospital stay, pain control, patient satisfaction, post-operative complications, and overall morbidity and mortality.

Hypothesis: Initiating the alternate management protocol for cesarean sections will decrease narcotic consumption and hasten return of bowel function, without compromising patient satisfaction, level of pain control, or post-operative morbidity.

Background:

"Enhanced recovery" is a multi-modal, evidence based approach to peri-operative care, with the goal of accelerating recovery and return to normal activity after surgery (1). Initially introduced in colorectal surgery, some of the key changes in management include: preoperative patient education, reduction in preoperative fasting, peri-operative euvolemia, early removal of urinary catheters, multimodal and standing analgesia, early postoperative mobilization, and earlier return to a regular diet. Results have shown stable pain control with a decrease in narcotic consumption, a quicker return of bowel function, and decreased length of hospital stay and cost with no change in level of patient satisfaction, morbidity, or readmission rate. The thought is that these interventions speed recuperation by attenuating the stress response associated with surgery, subsequently decreasing time spent in the hospital and improving quality of life (1,2).

The largest retrospective cohort study demonstrating the successful implementation of the "enhanced recovery" protocol in gynecology was conducted at the Mayo Clinic, published in 2013 (1). This protocol was created by general gynecologists, gynecology oncologists, urogynecologists, anesthesiologists, pharmacists, and nursing, and was initiated as a quality improvement project. This "enhanced recovery" protocol was used as the template for our alternate management order set. The results showed an 80% reduction in opioid consumption,

stable pain scores and patient satisfaction, a 1 day earlier return of bowel function, and 4 day reduction in hospital stay with subsequent significant cost savings (1). An obstetric alternate management protocol was created at Lankenau, trying to incorporate the most current recommendations in "enhanced recovery" while accounting for issues unique to obstetric patients. This protocol is currently being used by certain obstetricians. Please see appendix 1 and 2 for protocol details.

The only literature published on "enhanced recovery" being implemented in the field of obstetrics was an observational study conducted with 708 C-sections at the Jessop Wing Obstetric Unit, in Sheffield, England, published in 2015. See below for the protocol used (3).

Table 1 Different aspects of perioperative care for the enhanced recovery protocol

Aspect of perioperative pathway	Management for enhanced recovery
Patient selection	All patients presenting for elective CS
Patient information	New preoperative patient information document produced
Preoperative fluids	Clear fluids up to 2 h before surgery
Carbohydrate drink	Non-fizzy sports drink up to 2 h before surgery
Intraoperative fluid balance	At discretion of perioperative team
Surgical technique	At discretion of surgeon
Patient warming	Active under-patient warming
Postoperative mobilisation and removal of urinary catheter	The morning after surgery
Perioperative analgesia	Spinal diamorphine, regular paracetamol, NSAIDS with oral morphine for breakthrough pain
Prevention of postoperative nausea and vomiting	At discretion of perioperative team
Postoperative clear fluids	Within 30 min of the end of surgery
Postoperative food	One hour after surgery
Neonate	Delayed cord clamping and skin-to-skin contact in theatre encouraged

Figure 1, Reference 3

The development of an obstetric "enhanced recovery" plan resulted from a desire for earlier discharge following cesarean section, due to pressure on national health service budgets to cut costs. There was an increase in day 1 discharges following uncomplicated cesarean sections from 1.6% to 25 % with the above mentioned protocol, and a stable 30 day readmission rate. Their conclusion was that "an enhanced recovery program was successfully implemented... Many of the interventions were straighforward and could be adopted easily elsewhere." (3)

A somewhat controversial element of the "enhanced recovery" protocol is the use of gabapentin in pregnancy. Gabapentin is a Category C drug, meaning that risk cannot be ruled out in pregnancy and that the drug should be given if potential benefits outweight potential risks (4). Our alternate management order set includes giving 1 dose of 600mg of pre-operative gabapentin. There have been many papers documenting its safety when given as a single dose pre-operatively. A randomized controlled trial published in 2011 in the Society of Obstetric Anesthesia and Perinatology, evaluated the peri-operative use of gabapentin for cesarean sections. Neonatal outcomes were evaluated for the gabapentin group, involving 600mg pre-operatively, as well as the placebo group. See figure 2 for results; there was no significant difference in neonatal outcomes (5). A second study published in 2015 in the American Society of Anesthesiologists also showed no difference in neonatal outcomes with a single pre-operative dose of 600mg gabapentin (6). See figure 3 for results. Lactmed, a database that lists drugs and dietary supplements that may affect breastfeeding, endorsed by the American Academy of Pediatrics, states that "maternal doses of gabapentin up to 2.1 grams daily produce relatively low levels in infant serum," and that " a single PO dose of 600 mg prior to cesarean section appeared to have no effect on breastfeeding initiation." (15)

Figure 2, Reference 8

Table 4. Neonatal Outcomes

	Gabapentin group (n = 21)	Placebo group (n = 23)	P value
Weight (g)[a]	3520 (407)	3341 (431)	0.16
1-minute Apgar[b]	9 (8–9)	9 (8–9)	0.94
5-minute Apgar[b]	9 (9–9)	9 (9–9)	na
Umbilical artery pH[a]	7.26 (0.04)	7.29 (0.06)	0.14
NICU admission[c]	1 (5%)	0	0.48

Figure 3: Reference 9

	Gabapentin Group (n = 100)	Placebo Group (n = 97)	P Value
Birth weight (g)*	3,408 (450)	3,347 (506)	0.37
Apgar score (1 min)†	9 (9, 9)	9 (9, 9)	0.23
Apgar score (5 min)†	9 (9, 9)	9 (9, 9)	0.46
Umbilical arterial blood pH‡	7.3 (0.07)	7.3 (0.10)	0.77
Positive pressure ventilation§	3 (3.0)	3 (3.1)	>0.99
NICU admission§	1 (1.0)	4 (4.1)	0.21
Breast-feeding difficulties§	16 (17.6)	17 (19.3)	0.76

Given that the national cesarean section rate in the United States is 32.2%, implementing an "enhanced recovery" protocol in obstetrics could have a huge impact in how we care for women in the post-partum period (8). The widespread adoption of "enhanced recovery" stems from evidence showing reduced narcotic consumption, earlier return to normal activities, and even reduced morbidity in some studies (2). From a post-partum standpoint, given the increased risk of DVT until 6 weeks post-partum, and the additional increased risk after cesarean section, encouraging ambulation and return to normal activity seems beneficial (9). Also, the potential to decrease narcotic use has great implications in both the post- partum and post- operative period. The CDC has recently published guidelines on prescribing opioids, given that opioid abuse is a growing epidemic in this country (10,11). The American Congress of Obstetricians and Gynecologist had responded saying that we would try to combat the use of prescription opioids across the country and that we should be using current best prescribing practices and all possible options for multimodal pain relief (12,13). Additionally, the American Academy of Pediatrics published an update to their Transfer of Drugs and Therapeutics in Human Breast Milk Series in 2013 (14). The AAP states that acetaminophen and ibuprofen should be used as first line therapy for post-partum pain management, and discourages the use of codeine, hydrocodone, and oxycodone when breast feeding. One study found that as high as 20% of infants exposed to oxycodone through breast milk had central

nervous system depression (14). Also, the state of Pennsylvania has started a breast feeding quality improvement project, called the Keystone 10 Initiative, developed by the department of health (15). The goal is to promote and support breastfeeding to "improve the health of mothers and babies," through changes such as more skin to skin contact and less time infants spend in the nursery (15). Given that the most common side effect of narcotic use is somnolence, seen up to 42% of the time, this may interfere with the mother's ability to care for her newborn. (16). Therefore, it is clear that an "enhanced recovery" protocol after cesarean sections has potential to improve care post-operatively and post-partum on multiple levels.

Study Design: Randomized controlled trial

Methods:

A randomized control pilot study will be performed with the primary outcome of narcotic utilization in the post-operative period. After IRB approval, patients will be recruited for the study in the outpatient setting or upon their arrival to the labor and delivery floor, for their scheduled cesarean section. They will be consented by the principal investigator, or his designee. Consent for the study will include a series of questions related to the exclusion criteria listed below in addition to the risks and benefits of the study. The patient will be randomized to either the alternate management group, or the standard cesarean section group, via computer randomization.

The regular Lankenau cesarean section order set includes routine vital signs, labs, IV fluids, and fetal heart monitoring. Post standard cesarean section orders include IV fluids running at 125 cc/ hour, along with routine post-partum care. In terms of pain control, most patients receive 9 doses of 30mg of IV ketorolac every 6 hours, along with hydromorphone, oxycodone/acetaminophen, or a hydromorphone PCA, per patient or attending request.

With the alternate management protocol, the pre-operative order set is the same, with the addition of a single preoperative dose of acetaminophen 1 g IV x1, gabapentin 600 mg PO x1, and ondansetron 8 mg IV x1. Post-operatively, patients receive the same ketorolac 30mg x 9 doses every 6 hours, as well as acetaminophen 975 mg every 6 hours, both given standing. These two are timed so the patient is receiving one of the two medications every 3 hours during their inpatient stay. After 9 doses of ketorolac, the patient receives 600mg of ibuprofen PO, also given standing, instead of the ketorolac. If the patient requires narcotics, they may receive them on an as needed basis. IV fluids are running at 80 cc/ hour. Patients are encouraged to ambulate, including the evening of the surgery, have their foley catheter removed 12 hours post-operatively, and can have a regular diet immediately.

The morphine equivalent score will be used to calculate total narcotic use while the patient remains as an inpatient (18). See appendix 5. Secondary outcomes will include presence of flatus, assessed at 8 hour intervals, and pain via the visual analogue scale. Patient satisfaction will be assessed using the validated survey used in the Mayo Clinic Trial, to be filled out prior to discharge (1). See appendix 7. Post-operative complications and readmissions will be noted during the inpatient stay. Information regarding patient satisfaction, pain score, and presence of flatus will be gathered by nursing, and will be self-reported by the patient. Total narcotic use will be calculated. The results will be analyzed according to the description below.

Please see attached appendices for further detail.

Sample Size: 65 standard recovery patients, 65 alternate management patients

Using the Vanderbilt power calculator, and an alpha value of 0.5, and a beta of 20%, to achieve a 50% reduction in narcotic use, approximately 65 patients will be required in each group. We will perform an interim analysis on our data, after 65 subjects have been recruited, both for efficacy and assessment of any adverse outcomes. This will help us determine if we need fewer or more patients in order to achieve a statistically significant difference in narcotic consumption.

Inclusion Criteria:

- Women ages 18-45 y/o
- Scheduled to undergo a cesarean section

Exclusion Criteria:

- Existing diagnosis of chronic pain
- Need to undergo a vertical skin incision
- AST > 50, ALT > 70
- Platelets below 80,000 on admission
- Need to undergo general anesthesia
- Tubal ligation at time of Cesarean section
- Prior or known allergy to any of the medications being utilized in this study

Statistical Analysis: Data gathered from this study will be analyzed using statistical software. The primary outcome is the number of morphine-equivalents of opioid pain medication used by the subjects after Cesarean section in the standard of care group versus the alternate management group. These results will be analyzed using either a student's t-test or a Mann-Whitney test, depending on the underlying distribution.

Outcomes

- 1) Primary outcome
  - Narcotic utilization measured with Morphine Equivalent Score (see appendix 5)
- 2) Secondary outcomes
  - Flatus (assessed at 8 hour intervals)
  - Pain via Visual Analog Scale (assessed at 8 hour intervals) (see appendix 6)
  - Patient satisfaction (see appendix 7)
  - Postoperative complications during the inpatient stay
  - Length of stay

Study Duration:

- From time of consent until hospital discharge.

Additional Registration:

This trial will be registered with clinicaltrials.gov

Risks and Benefits

Risks:

The alternate management order set calls for 1 dose of 600mg pre-operative gabapentin. Gabapentin is technically a category C drug in pregnancy, meaning that risk in pregnancy cannot be ruled out. The literature shows no adverse neonatal outcomes with 1 single pre-operative dose of 600mg of PO Gabapentin, prior to cesarean delivery (8,9). There has been no issue with initiation of breastfeeding with a single pre-operative dose of 600mg according to Lactmed, a database endorsed directly by the American Academy of Pediatrics (14). Additionally, registries evaluating maternal gabapentin use throughout pregnancy do not seem to show an additional risk of pregnancy or neonatal complications, or an increased risk of congenital malformations (17).

There is always a risk of loss of confidentiality.

Benefits:

The goal of "alternate management" after surgery is to accelerate recovery and return to normal activity after surgery. Results have been promising in the fields of colorectal surgery, gynecology, urology, orthopedics, and bariatric surgery. One of the consistent results seen has been a decrease in narcotic consumption (2). The benefit of decreasing narcotic use with breastfeeding mothers includes minimizing the narcotic exposure to the infant, and the potential of infant CNS depression. (14). Additionally, the most common adverse effects with post-operative opioid analgesia for the patient include somnolence, gastrointestinal effects, pruritus, and urinary retention (16). Avoiding unnecessary narcotic use benefits both the patient as well as her infant.

Confidentiality:

There is always a slight risk of loss of confidentiality. Every effort will be made to ensure that subjects' records are kept confidential. After signing consent, subjects will be assigned a coded ID. All forms will be kept in a locked cabinet in the principal investigator's office and any files that link the subject identification to the coded ID will be stored on a password-protected computer. The linking file will be destroyed at the end of the study.

Any publications that result from this study will not identify individual subjects.

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Appendix 1. Labor and Delivery Admission: Cesarean Section Pre-op Orders (CPOE)

Medications

☐ Bicitra 30 mL PO 15 minutes before transport to the OR

Appendix 2. Labor and Delivery Admission: Cesarean Section Post-op Orders (CPOE)

Admission Info

☐Transfer to: Post Partum Unit

☐Code Status

☐Working Diagnosis: Post Partum State

Vital Signs

☐Vital Signs every 1/2 hour x 2; every 1 hour x 2; every 4 hours x 24; then every 8 hour shift with Maternal Obstetric

Assessment

☐If BP systolic >160 or diastolic > 100, repeat in 15 minutes. If either value remains out of parameters on repeat, notify physician/resident/NP

Allergies

☐Enter Allergies

Activity

☐May Shower as tolerated

Nursing (Patient Care) Orders

☐Administer the Edinburgh Postpartum Depression Tool on the first Postpartum Day

☐Administer Rhogam if indicated (if lab calls about Type and Screen results)

☐Apply Ice to: Incision x 24 hours

☐Remove Dressing 24 hours after delivery

☐Complete Tdap assessment and screening to determine if patient meets eligibility criteria for Tdap vaccine

☐Compression Device Intermittent continue use of Intermittent Compression Device until patient is ambulating. Once ambulating, then discontinue

☐K-Pad for muscle discomfort , PRN

☐Notify: Physician/Midwife for diastolic pressure over 105 mm/Hg or systolic pressure less than 81 mm/Hg

☐Notify: Physician/Midwife for Heart Rate greater than 100 beats per minute

☐Notify: Physician/Midwife for heavy vaginal bleeding

☐Notify: Physician/Midwife for Urine output less than 30ml/hour

☐Record Intake and Output until IV and Foley discontinued unless otherwise indicated

☐Discontinue On-Q when Medication Ball is empty or upon patient request

☐Post Partum Voiding Management -----open for details

☐If patient is unable to void 6 hours after delivery or catheter removal, perform a bladder scan and follow the Post

Partum Voiding Management Algorithm.

☐At any time, if patient feels the urge to void, but is unable to, perform a bladder scan and follow the Post Partum

Voiding Management algorithm

Diet/Nutrition

☐Nursing: Advance Diet to Regular Diet as Tolerated

IV Fluids

☐Sodium Chloride 0.9% IV 1000 mL bag at 125 mL/hour

☐Oxytocin 20 Unit in 1000 mL Lactated Ringers; 125 mL/hr x1 liter

---OR---

☐Convert to Med Lock when tolerating PO Fluids and vaginal bleeding WNL

Medications

☐Ketorolac (Toradol) 30 mg IV x1; loading dose give in OR/PACU

☐Ketorolac (Toradol) for Cesarean Post Partum (CPOE)

Ketorolac (Toradol) Choose One:

☐Ketorolac (Toradol) 30 mg IV Q6H for 9 doses

☐PCA hydromorphone (Dilaudid) - GYN Post-op

Opiate Status:

☐Opiate Status

IV PCA Orders: (Note: Usual doses are for opiate-naïve adults)

Drug: Hydromorphone (Dilaudid)

Standard Concentration: 1mg/ml

☐Hydromorphone 50 mg/50 mL PCA SYRINGE IV infusion

Bolus 0.2mg Basal 0 mg PCA Dose 0.2 mg PCA Delay Interval (Lockout) 10 min 1 hour Limit (excluding initial bolus):

1.2 mg

☐Hydromorphone PCA Standard 0.2 mg Bolus (usual 0.2 - 0.5 mg)

☐Hydromorphone PCA Basal 0 mg/hr Dose 0.2 mg Q10min Max 1.2mg

For coverage of over sedation/opiate toxicity:

☐Naloxone 0.04mg/ml (1ml of dilution) IV slow push every 2min PRN

PRN Pain Medications

Mild Pain (MLHS Pain Scale 1-4)

☐Ibuprofen (Motrin) for Cesarean Post Partum (CPOE)

Ibuprofen (Motrin) Choose One:

☐☐Ibuprofen (Motrin) 600 mg PO Q6H PRN mild pain; after ketorolac

☐Acetaminophen (Tylenol) 650 mg PO Q4H PRN Mild Pain

Guideline: Only one NSAID should be given at any one time; Acetaminophen may be given at the same time as a NSAID.

☐Oxycodone/Acet (Percocet) 5/325 mg 1 TAB PO Q4H PRN Moderate Pain

☐Oxycodone/Acet (Percocet) 5/325 mg 2 TAB PO Q4H PRN Severe Pain

☐Hydromorphone (Dilaudid) 2 to 4 mg PO Q4H for moderate to severe pain

Laboratory Tests

☐CBC (Complete Blood Count) Post-partum Day #1 In AM

☐Notify: Physician/Midwife for hemoglobin less than 8 grams

Appendix 3. Labor and Delivery Admission: Cesarean Section Pre-op – Enhanced Recovery Orders

Medications

☐ Bicitra 30 mL PO 15 minutes before transport to the OR

☐ Acetaminophen (Tylenol) 1 g IV on call prior to OR

☐ Gabapentin 600 mg PO on call prior to OR

☐ Ondansetron (Zophran) 8 mg IV on call prior to OR

Appendix 4. Post –Op Cesarean Section – Enhanced Recovery Orders

Admission Info

☐Transfer to: Post Partum Unit

☐Code Status

☐Working Diagnosis: Post Partum State

Vital Signs

☐Vital Signs every 1/2 hour x 2; every 1 hour x 2; every 4 hours x 24; then every 8 hour shift with Maternal Obstetric

Assessment

☐If BP systolic >160 or diastolic > 100, repeat in 15 minutes. If either value remains out of parameters on repeat, notify physician/resident/NP

Allergies

☐Enter Allergies

Activity

☐May Shower as tolerated

☐Out of Bed with assistance for at least 2 hours evening of surgery

☐Encourage early ambulation

☐All meals in chair

Nursing (Patient Care) Orders

☐Administer the Edinburgh Postpartum Depression Tool on the first Postpartum Day

☐Administer Rhogam if indicated (if lab calls about Type and Screen results)

☐Apply Ice to: Incision x 24 hours

☐Remove Dressing 24 hours after delivery

☐Complete Tdap assessment and screening to determine if patient meets eligibility criteria for Tdap vaccine

☐Compression Device Intermittent continue use of Intermittent Compression Device until patient is ambulating. Once ambulating, then discontinue

☐K-Pad for muscle discomfort , PRN

☐Encourage patient to chew sugar-free gum

☐Notify: Physician/Midwife for diastolic pressure over 105 mm/Hg or systolic pressure less than 81 mm/Hg

☐Notify: Physician/Midwife for Heart Rate greater than 100 beats per minute

☐Notify: Physician/Midwife for heavy vaginal bleeding

☐Notify: Physician/Midwife for Urine output less than 80 ml/ 4 hours

☐Record Intake and Output until IV and Foley discontinued unless otherwise indicated

☐Discontinue On-Q when Medication Ball is empty or upon patient request

☐Post Partum Voiding Management -----open for details

☐If patient is unable to void 6 hours after delivery or catheter removal, perform a bladder scan and follow the Post

Partum Voiding Management Algorithm.

☐At any time, if patient feels the urge to void, but is unable to, perform a bladder scan and follow the Post Partum

Voiding Management algorithm

Diet/Nutrition

☐Regular Diet

IV Fluids

☐Sodium Chloride 0.9% IV 1000 mL bag at 80 mL/hr

☐Oxytocin 20 Unit in 1000 mL Lactated Ringers; at 80mL/hr x 1 liter

☐Convert to Med Lock when PO fluid intake is greater than 600 ml

☐Discontinue Med Lock when all IV medications have been completed, patient is tolerating PO Fluids, and vaginal bleeding is WNL

Medications

Standing Pain Meds, not PRN

☐Ketorolac 30 mg IV Q6H x 9 doses; start 3 hours after preop dose of IV acetaminophen 1 g

☐Acetaminophen (Tylenol) 975 mg PO Q6H; start 3 hours after 1st dose of IV ketorolac

☐Ibuprofen (Motrin) 600 mg PO Q6H; start 6 hours after last dose of IV ketorolac

FOR Patients Unable to Take NSAIDS

☐Tramadol 100 mg PO Q6H; start 3 hours after first dose of IV acetaminophen

PRN Pain Medications

For Breakthrough Pain Only

Moderate to Severe Pain (MLHS Pain Scale 5-10)

☐ Oxycodone 5 mg PO Q4H PRN Moderate Pain breakthrough pain

☐ Oxycodone 10 mg PO Q4H PRN Severe Pain breakthrough pain

—OR—

☐Hydromorphone (Dilaudid) 2 mg PO Q4H PRN Moderate Pain breakthrough pain

☐Hydromorphone (Dilaudid) 4 mg PO Q4H PRN Severe Pain breakthrough pain

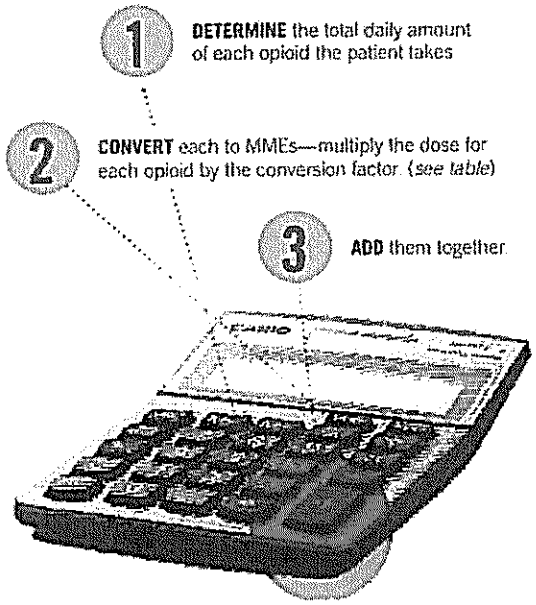
Laboratory Tests

☐CBC (Complete Blood Count) Post-partum Day #1 In AM

☐Notify: Physician/Midwife for hemoglobin less than 8 grams

Appendix 5. Center for Disease Control and Prevention Morphine Equivalent Score

HOW SHOULD THE TOTAL DAILY DOSE OF OPIOIDS BE CALCULATED?



Calculating morphine milligram equivalents (MME)

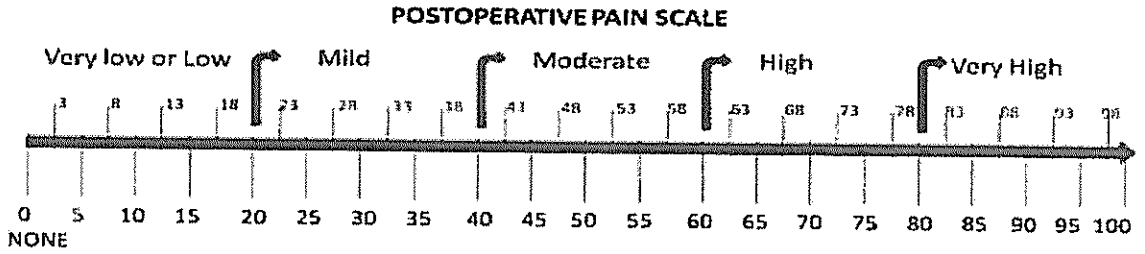
OPIOID (doses in mg/day except where noted)	CONVERSION FACTOR
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1-20 mg/day	4
21-40 mg/day	8
41-60 mg/day	10
≥ 61-80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3

These dose conversions are estimated and cannot account for all individual differences in genetics and pharmacokinetics.

Tramadol: 0.1 conversion factor

Toradol: 0 conversion factor

Appendix 6. Visual Analog Scale



Please, select a point on the scale indicating the level of pain you are feeling or felt in the indicated period. The number 0 indicates no pain and 100 the worst pain possible and felt in the period.

Appendix 7. Patient Satisfaction Survey

1. How would you rate the nursing care and service you received?

   Excellent Very Good Good Fair Poor

2. How did the Nursing care meet your expectations?

   Excellent Very Good Good Fair Poor

3. How would you rate the overall discharge process?

   Excellent Very Good Good Fair Poor

4. In regard to any education you were given prior to your surgery, how prepared do you feel you were?

   Excellent Very Good Good Fair Poor

5. Please rate your pain control during your hospital stay.

   Excellent Very Good Good Fair Poor

6. Please rate your nausea management during your hospital stay.

   Excellent Very Good Good Fair Poor

Appendix 8: Gabapentin: Drug Information (19)

>10%:

Central nervous system: Dizziness (IR: 17% to 28%; children 3%; Gralise: 11%), drowsiness (IR: 19% to 21%; children 8%; Gralise: 5%), ataxia (1% to 13%), fatigue (11%; children 3%)

Infection: Viral infection (children 11%)

1% to 10%:

Cardiovascular: Peripheral edema (IR: 2% to 8%; Gralise: 4%), vasodilatation (1%)

Central nervous system: Hostility (children 5% to 8%), tremor (7%), emotional lability (children 4% to 6%), hyperkinesia (children 3% to 5%), headache (children and adolescents 3%), abnormality in thinking (2% to 3%; children 2%), abnormal gait (2%), amnesia (2%), depression (2%), nervousness (2%), pain (Gralise: 1% to 2%), hyperesthesia (1%), lethargy (Gralise: 1%), twitching (1%), vertigo (Gralise: 1%)

Dermatologic: Pruritus (1%), skin rash (1%)

Endocrine & metabolic: Weight gain (IR: Adults and children 2% to 3%; Gralise: 2%), hyperglycemia (1%)

Gastrointestinal: Diarrhea (IR: 6%), nausea and vomiting (3% to 4%; children 8%), xerostomia (IR: 2% to 5%; Gralise: 3%), constipation (IR: 1% to 4%; Gralise: 1%), abdominal pain (3%), dyspepsia (IR: 2%; Gralise: 1%), dry throat (2%), dental disease (2%), flatulence (2%), increased appetite (1%)

Genitourinary: Impotence (2%), urinary tract infection (Gralise: 2%)

Hematologic & oncologic: Decreased white blood cell count (1%), leukopenia (1%)

Infection: Infection (5%)

Neuromuscular & skeletal: Weakness (6%), back pain (IR: 2%; Gralise: 2%), dysarthria (2%), limb pain (Gralise: 2%), myalgia (2%), bone fracture (1%)

Ophthalmic: Nystagmus (8%), diplopia (1% to 6%), amblyopia (4%), blurred vision (3% to 4%), conjunctivitis (1%)

Otic: Otitis media (1%)

Respiratory: Rhinitis (4%), bronchitis (children 3%), nasopharyngitis (Gralise: 3%), respiratory tract infection (children 3%), pharyngitis (1% to 3%), cough (2%)

Miscellaneous: Fever (children 10%)