

Enhanced Recovery After Surgery for Cesarean Delivery
Clinical Practice Guideline: Postoperative Interventions

by

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Abstract

Problem & Purpose: In the United States, the cesarean delivery rate is approximately 32% of all births, with well over a million performed each year. Compared to women who performs spontaneous vaginal births, cesarean deliveries are associated with a prolonged length of stay. These women are usually young and healthy, possess the ability to achieve a rapid recovery, and have a unique incentive to return to their baseline functional capacity in order to care for their newborn. Enhanced Recovery After Surgery (ERAS) is a standardized set of perioperative interventions implemented to improve surgical outcomes, optimize patient care, and reduce hospital costs. Even though there is an enormous amount of evidence to support the improvements ERAS has made for perioperative care pathways among many surgical specialties, obstetrical surgery lacks established protocols based on such principles. The purpose of implementing the ERAS clinical practice guideline (CPG) is to standardize care throughout the perioperative period and optimize recovery for parturients undergoing elective cesarean deliveries.

Methods: The CPG was created using high quality evidence and subsequently evaluated by elected stakeholders using the Appraisal of Guidelines for Research and Evaluation (AGREE) II tool. Dissemination took place following the incorporation of stakeholder recommendations and feedback. A Practitioner Feedback Questionnaire (PFQ) survey following the formal presentation of the CPG during grand rounds was given to anesthesia staff to assess acceptability and usability of the CPG.

Results: Feedback received from the AGREE II Tool and PFQ show satisfactory results on the quality, usability, applicability, and acceptance of the CPG.

Conclusion: The favorable AGREE II Tool assessment results, widespread acceptance of the interventions among staff as evidenced by the PFQ results, as well as the strength of evidenced utilized to create the recommendations included in the CPG, will facilitate the quality and safety of recovery for elective cesarean deliveries at the institution of interest.

Introduction

Enhanced recovery after surgery (ERAS) is a model of patient care that was developed in the late 1990's by a group of general surgeons in Northern Europe (Melnyk, Casey, Black & Koupparis, 2011). The group created a multimodal perioperative care pathway that was designed to achieve early recovery for patients undergoing major surgery (Melnyk et al., 2011). This concept of enhanced recovery was developed to challenge traditional perioperative care practices and replace them with evidence-based approaches to optimize and accelerate postoperative recovery (Melnyk et al., 2011). The statistical evidence generated following ERAS protocol implementation revealed a significant reduction in length of hospital stay, readmissions, and postoperative complications, in addition to increased patient satisfaction scores and decreased hospital costs (Ljungqvist, 2014). Since this revolutionary evidence surfaced, there has been widespread adoption of ERAS guidelines among many surgical specialties that have reported very similar improvements in patient outcomes and the quality of care delivered (Ljungqvist, 2014). Even though there is an enormous amount of evidence to support the effectiveness of ERAS regarding perioperative care pathways among various surgical specialties, obstetrical surgery lacks established protocols based on ERAS principles (Huang, Cao, Nelson & Wilson, 2018). Furthermore, obstetrical procedure rooms are often secluded from the general operating rooms, which unfortunately, can slow the introduction and acceptance of newly developed evidence-based practice initiatives (Corso et al., 2017).

The surgical procedure most performed in modern healthcare is the cesarean delivery (Caughey et al., 2018). In the United States the cesarean delivery rate is approximately 32% of all births, with well over a million performed each year (Caughey et al., 2018). At the tertiary medical center of interest, cesarean deliveries accounted for 29.9% of births in 2016 and 31.2% of births in 2017. Compared to women who give birth vaginally, cesarean deliveries are associated with a prolonged length of stay, averaging about two days following the procedure, maternal dissatisfaction,

postoperative complications, and delayed functional and physiological recovery. The patient population of interest is comprised of women who are young, healthy, possess the ability to achieve a rapid recovery, and have a unique, overarching incentive to quickly return to their baseline functional capacity, in order to provide exceptional care for their newborn (Corso, et al., 2017). The ever-increasing prevalence of cesarean delivery procedures, the effectiveness of ERAS initiatives across the board, matched with the advantageous characteristics of the patient population involved, create the perfect window of opportunity for drastic improvements in perioperative care pathways to take effect.

The purpose of this scholarly project was to create and evaluate a CPG derived from the core elements of ERAS for those undergoing elective cesarean deliveries. The evidence-based recommendations within the CPG focused solely on the postoperative period for the peripartum population at a large community hospital in eastern Maryland. The necessity of the protocol was emphasized by stakeholders, who noted a lack of standardization among the postoperative care practices as well as maternal dissatisfaction following analysis of the Press-Ganey scores over a two-year period. The practice changes endorsed for the postoperative period will not only increase maternal comfort during the postsurgical period, but also improve outcomes and facilitate optimal return of physiological function. The postoperative interventions emphasized early foley catheter removal to improve maternal comfort and facilitate earlier mobilization, hasten optimal return of bowel function and reduce occurrences of ileus with the establishment of gum chewing intervals, and lastly, challenge the traditional fasting guidelines to promote faster return of gastrointestinal functional and physiological recovery with the early initiation of a solid diet in the postsurgical period.

Literature Review

A literature search was executed to gather relevant evidence and current, best practices for postoperative optimization among parturients undergoing elective cesarean deliveries. Refer to Appendix A for further review of the evidence grading criteria utilized. Please refer to the table labeled *Hierarchy and Quality of Evidence Table* located in Appendix A at the end of this report for a detailed account of each article.

Three articles met the predetermined criteria which included consistent results with an adequate sample size, adequate control, produced definitive conclusions, as well as evaluated outcomes for the postoperative intervention to initiate early removal of the indwelling urinary catheter. Basbug, Yuksel, and Ellibes conducted a prospective randomized control trial to compare postoperative Foley catheter removal 2 versus 12 hours after elective cesarean section (2018). The results showed a significant reduction of urinary frequency ($p=0.04$) and incidence of microscopic hematuria ($p=0.04$), in the early Foley catheter removal group (Basbug et al., 2018). Additionally, the onset time of postoperative mobilization was earlier ($p=0.01$) and the length of hospital stay was reduced ($p=0.0009$). No adverse events or negative outcomes were noted among the study participants. El-Mazny, El-Sharkawy, and Hassan conducted a prospective randomized control trial to compare immediate and 12-hour postoperative removal of the urinary catheter after elective cesarean section (2014). The incidence of postoperative significant bacteriuria ($p=0.020$), dysuria ($p=0.030$), burning on micturition ($p=0.016$), urinary frequency ($p=0.031$), and urgency ($p=0.011$) were significantly lower in those who received immediate catheter removal compared to the delayed catheter removal group (El-Mazny et al., 2014). The mean postoperative ambulation time ($p<0.001$), time until the first void ($p<0.001$), and length of hospital stay ($p<0.001$) were significantly shorter in the early catheter removal group as well (El-Mazny et al., 2014). Menshawy et al., conducted a systematic review and meta-analysis of 3 randomized controlled trials to evaluate the evidence about the outcomes of early versus delayed catheter removal of indwelling urinary catheters after elective

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cesarean delivery (2018). The statistical analyses demonstrated early Foley catheter removal significantly reduced dysuria (RR = 0.60, 95% CI [0.38, 0.95], $p=0.03$), urinary frequency (RR = 0.32, 95% CI [0.16, 0.66], $p=0.002$) and significant bacteriuria (RR = 0.49, 95% CI [0.30, 0.83], $p=0.007$) than delayed removal (Menshaw et al., 2018).

Two articles met the predetermined criteria which included consistent results with an adequate sample size, adequate control, produced definitive conclusions, as well as provide strong evidence for **outcomes related to postoperative intervention to initiate gum chewing following** elective cesarean sections. Gum chewing is intended to hasten gastrointestinal return of function as well as decrease the occurrence of abdominal distention, vomiting, and ileus postoperatively. Altraigey et al., conducted a randomized control trial to evaluate the impact of chewing gum on gastrointestinal complications, hospital stay, and return of function following elective cesarean delivery (2018). The results of this study revealed chewing gum improves gastrointestinal recovery with faster return of bowel movements, intestinal sounds, passing of flatus, and passing of feces ($p=0.0001$) (Altraigey, 2018). The results of this study also showed gum chewing shortened the duration of hospital stay as well as the duration of parenteral intravenous fluid requirements ($p=0.0001$) (Altraigey, 2018). Morais et al., conducted a systematic review and meta-analysis to evaluate the effects of gum chewing on postoperative recovery and duration of postoperative ileus following cesarean delivery (2016). Time to passage of first flatus was 7 hours shorter among those who were assigned to the gum chewing group (Morias et al., 2016). The rate of ileus on average was over 60% lower in the gum chewing groups compared to the control groups across all studies (Morias et al., 2016).

Three articles met the predetermined criteria which included consistent results with an adequate sample size, adequate control, produced definitive conclusions, as well as provide strong supportive evidence for the postoperative intervention to initiate early oral intake following elective

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cesarean delivery. Hsu et al., conducted a systematic review and meta-analysis to evaluate whether early oral intake after cesarean delivery influences gastrointestinal outcomes during postpartum recovery (2013). Return of gastrointestinal function was reduced in the early oral intake group with bowel sounds returning 9.2 hours earlier (Hsu et al., 2013). Additionally, time to passing flatus occurred 10 hours earlier and bowel evacuation occurred 14.6 hours sooner (Hsu et al., 2013). Masood et al., conducted a randomized control trial to compare the effects of early (2 hours post-delivery) versus delayed (18-hours post-delivery) oral intake after cesarean delivery (2014). Upon conclusion of the study, it was found that lower intensities of thirst and hunger and a higher rate of maternal satisfaction were prominent in the early oral feeding group ($p < 0.05$) (Masood et al., 2014). Additionally, 53.8% of women who received food 2 hours after delivery were able to ambulate within 15 hours after surgery compared to 27.9% in the conventional feeding group (Masood et al., 2014). Nantasupha, Ruengkachorn, and Ruangvutitert conducted a randomized control trial to compare time to regular diet tolerance among conventional scheduled feeding, early oral feeding, and early oral feeding in addition to domperidone in women following cesarean delivery (2016). There were no differences between the two early feeding groups, suggesting that domperidone does not enhance postoperative gastrointestinal function (Nantasupha, 2016). The majority of the women in the early oral feeding group achieved regular diet tolerance within 24 hours, while the women with the conventional diet schedule achieved regular diet tolerance 48 hours after delivery (Nantasupha, 2016).

The literature review revealed compelling evidence to support the inclusion of the postoperative recommendations included in the CPG. The implementation strategies regarding each intervention varied among studies but produced reliable and uniform results, significantly improved patient outcomes, and increased maternal satisfaction scores. The strength and consistency of the

evidence permit the inclusion of the postoperative interventions in the CPG for elective cesarean deliveries.

Theoretical Framework

Kurt Lewin, also known as the father of social psychology, theorized a well-known model of the change process in human systems (Kritsonis, 2019). Lewin theorized a three-stage Model of Change known as the *Unfreezing-Change-Refreeze* Model, that requires the rejection and replacement of previously learned information (Kritsonis, 2019). Lewin's change theory has been operated successfully to improve care processes and ultimately improve patient outcomes (Wiseman & Kaprielian, 2005). Application of the *Unfreezing-Change-Refreeze* Model was appropriately utilized to guide the actions and decision-making processes to create and evaluate an evidence-based CPG using core elements of the ERAS pathway.

The first essential step in Lewin's Model is *Unfreezing* (Kritsonis, 2019). This vital stage involves finding a method of making it possible for people to let go of a previous way of doing things in order to overcome resistance (Kritsonis, 2019). *Unfreezing* began by identifying the problem of high concern which is the lack of postoperative optimization for women undergoing elective cesarean sections. Analysis of the data began by first extrapolating statistical information derived from relevant literature to be used as a driving force to signify the need for change. Development of a strategy was initiated to create an effective and easily reproducible CPG to guide the perioperative period in a standardized manner and increase buy-in from stakeholders.

Change is the next essential step in Lewin's model (Kritsonis, 2019). This step involves altering thoughts, feelings, or behavior, ultimately increasing productivity (Kritsonis, 2019). Biweekly meetings were held with stakeholders from multiple disciplines involved in the perioperative care pathway in order to introduce the institutional need for a CPG, communicate the goals of establishing the CPG, and illustrate how the CPG will positively impact this patient

population. Stakeholder buy-in was crucial to create and preserve the driving force for change (Kritsonis, 2019). Execution of the CPG occurred in the form of a formal PowerPoint presentation to all anesthesia providers. Educating staff on the benefits of ERAS and its impact was an additional driving force for the desired change processes to occur (Kritsonis, 2019).

Refreezing, the last step in Lewin's model, involves establishing change as a new habit, thus preventing relapse (Kritsonis, 2019). The initial draft of the CPG was presented to stakeholders for evaluation and feedback. Modifications to the CPG were made following stakeholder evaluation to improve the quality and usability of the CPG, thus improving the rate of departmental adherence to the recommendations prior to its implementation.

Methods

The key elements within the CPG included postoperative recommendations for the peripartum population undergoing elective cesarean sections at a tertiary medical center in Maryland. Women undergoing urgent, emergent, and/or complicated cesarean deliveries were excluded from this project.

Changes that were established and executed included the thorough evidence review, CPG evaluation, and subsequent feedback from stakeholders. Additional changes included effective staff education in the form of a formal presentation during grand rounds and subsequent evaluation to determine usability and widespread acceptance.

The Appraisal of Guidelines for Research and Evaluation (AGREE) II tool was a process measure that was completed by the appointed clinical experts as well as the Doctor of Nursing Practice (DNP) students assigned to the Quality Improvement (QI) team to assess the quality, variability, rigor, and transparency of the initial draft of the CPG. This structured methodology enables the critical team members to make necessary adjustments to the guideline, measure progress, and ensure its usefulness, quality, and reliability prior to its utilization in clinical practice. The

guideline in its entirety is located in Appendix C. The Practitioner Feedback Questionnaire (PFQ) was another process measure that was distributed to the anesthesia department staff immediately following the formal presentation. Analysis of the PFQ scores provided essential feedback to gauge usability and staff acceptance of the CPG recommendations.

Data collection included the results from the AGREE II tool and the PFQ surveys, located in Appendix D and E, respectively. The AGREE II tool, completed by stakeholders and the DNP students included in the implementation team, was comprised of 23 items divided into 6 domains which were independently scored using a Likert scale ranging from 1 (Strongly Agree) to 7 (Strongly Disagree). Domain scores were calculated by adding up the scores of items in each domain and dividing that number by the maximum possible score for that specific domain. The AGREE II tool has been proven to be valid and reliable for guideline development.

The PFQ was distributed to departmental staff and returned upon completion of the formal PowerPoint presentation during grand rounds. The PFQ has been proven to be a valid and reliable tool used to measure quality, usability, gauge staff acceptance and obtain necessary feedback.

The number of practitioners completing the AGREE II tool was measured as a percentage (response rate). This was calculated as the number of completed AGREE II tools divided by the total number of distributed AGREE II tools multiplied by 100. Additionally, the scores of each domain on the AGREE II tool were evaluated. There were 23 items to be graded on a Likert scale from 1 (lowest) to 7 (highest). Each item was classified as one of the six domains: scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence. A composite score for each domain was determined based on the instructions outlined in the tool.

The number of practitioners completing the PFQ questionnaire were measured as a percentage (response rate). This was calculated by the number of completed PFQs divided by the total number of

distributed PFQs, multiplied by 100. The PFQ included questions that evaluated the utility, usability, and strength of the ERAS CPG utilizing a three-point Likert scale (1 assigned to the lowest score and 3 assigned to the highest score). Each question on the PFQ received a mean score. Providers were also encouraged to write comments and give specific feedback, which failed to yield responses.

In order to protect human rights, the proposal was submitted to UMSON Institutional Review Board (IRB) for a Non-Human Subjects Research (NHSR) determination. Identifying information was not collected or exploited during any phase of the QI project. All submitted paper documents were secured in a file cabinet located in a locked office. Electronic data used for the purpose of the CPG was stored on a password protected computer. The CPG was not intended for utilization at any other institution or facility.

Results

The AGREE II Tool was completed by the DNP students as well as the appointed stakeholders with favorable results for each of the six domains. The response rate was 100% (N=5). The final score for each domain was greater than 80%. The scope and purpose domain received 91.7%. Stakeholder involvement received 94.4%, Rigor of development 86.4%, Clarity of presentation 91.7%, Applicability 83.3%, and Editorial independence 100%. The overall guideline assessment score was a 91.7%. Furthermore, the stakeholders strongly recommended utilizing the CPG in clinical practice. Results from the AGREE II Tool are summarized in Appendix F.

The PFQ results were completed by anesthesia providers who attended grand rounds. A total of 39 providers were in attendance, and 17 PFQs were completed (43.6% response rate). Thirty-five percent of the respondents were anesthesiologists, 26% were Certified Registered Nurse Anesthetists, and 17% were Student Registered Nurse Anesthetists. A large majority of the respondents had 0-3 years of anesthesia experience (64.7%), followed by ≥ 10 years of experience (23.5%), and lastly, 4-6 years of experience (11.8%). Demographic data of PFQ respondents are summarized in Appendix G.

Percentage agreement of the PFQ included five subscales of interest. The quality subcategory received a strongly agree rating among 97.6% of respondents, acceptance received a strongly agree rating among 87.5%, applicability received a strongly agree rating among 39%, comparative value received a strongly agree rating of 75%, and outcome variable received a strongly agree rating of 78.1%. Overall, the PFR results were highly favorable and widely accepted among anesthesia staff as evidenced by 87.46% agreement, with a standard deviation of 6.6 and a 95% confidence rating. Demographic data is summarized in Appendix G. The results of the PFQ are displayed in Appendix H.

Facilitators of the CPG creation and evaluation process included the evidence search and stakeholder involvement. The selected articles followed an extensive, exhaustive literature review. The articles chosen were of high quality and included strong supportive data, thus permitting the inclusion of each intervention in the CPG. Stakeholder involvement, feedback, and their participation regarding the CPG analysis and assessment process, strengthened the quality and rigor of the CPG. Additionally, stakeholder engagement facilitated the allotment of ample time to present the CPG during grand rounds and educate staff about each of the recommendations included. Furthermore, departmental leadership was highly committed to implementing change; this led to increased acceptance and awareness of the CPG among anesthesia staff.

Barriers that had to be strategically overcome during the scholarly project included possible feelings of resistance among staff towards CPG implementation due to an interruption in workflow. To overcome the identified barrier, the presentation included an emphasis on the ease of applicability for each intervention. During the presentation it was also stressed that the translation of the recommendations into practice will not involve additional training or interrupt current workflow, which was positively received as evidenced by the PFQ results pertaining to the acceptance and quality subcategories.

Discussion

Results of the AGREE II Tool and PFQ survey were very consistent among all respondents, regardless of their specified role in anesthesia, or years of experience. The strength and reliability of the evidence-based recommendations, education regarding ERAS and its evidence-driven benefit, in addition to stakeholder involvement, assessment, and feedback, were three major strengths that lead to a high-quality CPG with widespread favorability among staff. This was demonstrated by the overall guideline assessment score pertaining to the AGREE II Tool, as well as the staff acceptance scores pertaining to the PFQ. The anticipated and subsequent outcomes of the scholarly project were achieved with desirable results.

An unforeseen limitation was the poor response rate among the PFQs. There was a 43.6% response rate following the formal presentation, which may not accurately reflect the opinions of the entire anesthesia department. Efforts made to increase attendance during grand rounds included email reminders with detailed instructions regarding the completion of the PFQ surveys. Printed copies of the PowerPoint presentation and CPG, as well as additional PFQ surveys, were also strategically placed in the anesthesia break room to increase data generation and educate those who failed to attend grand rounds.

Another undesired limitation was that the lowest AGREE II domain score and PFQ subcategory score reflected applicability. After reviewing verbal feedback received during the grand rounds presentation, the researchers noted an unforeseen challenge regarding the implementation of the gum chewing intervention. Additional costs associated with providing the gum for each patient were a potential barrier, as the hospital does not currently distribute gum to the peripartum patients who undergo cesarean deliveries. Applying for grant funding for the gum chewing intervention could help alleviate the cost burden associated with the distribution of sugar free gum.

Lack of feedback generated from ancillary specialties, including the obstetrical team and labor and delivery nursing staff, introduced bias to the acceptability of the CPG, represented by the PFQ scores. Efforts made to minimize this limitation included the involvement of the Director of Maternal and Fetal Medicine, obstetrical surgical resident, and Labor and Delivery Unit Nurse Leader during the creation and evaluation process of the CPG. Generalizability of the CPG as well as the results generated via the process measures, is limited due to the institution-specific nature of this project.

Conclusion

The CPG was successfully drafted in collaboration with key stakeholders at the institution of interest and evaluated with highly favorable results, thus achieving the overarching goal and purpose of this scholarly project. The highly graded literature and strength of the associated evidence permits the relevancy and utilization of the specific recommendations included in the guideline. Furthermore, the widespread acceptance of the interventions among staff, as well as the overall CPG assessment score and its endorsement from each of the stakeholders involved, permits the application and usability of the CPG in clinical practice.

Plans for sustainability of this quality initiative include continued stakeholder support and engagement, ongoing staff education, tracking adherence via auditing, data collection and feedback, as well as appointing change champions to facilitate long-term compliance. Review of emerging data should continue periodically; if mounting evidence of high-quality supports modifications of the current CPG recommendations, revisions should then be drafted, evaluated, and approved by the appropriate stakeholders.

Future extension of this quality improvement project would include evaluating the desired effectiveness of the CPG in improving maternal satisfaction scores, reducing postoperative complications, and reducing the overall length of stay for the population of interest.

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Appendix A

Table A1. *Hierarchy & Quality of Evidence*

Author, Year	Study Objective	Study Design	Sample	Outcomes Studied (How Measured)	Results	Evidence Level	Rating Quality
Altraigey, A., Ellaithy, M., Atia, H., Abdelrehim, W., Abbas, A. M., & Asiri, M. (2018).	To evaluate the impact of chewing gum on gastrointestinal complications, hospital stay, and return of function following cesarean delivery.	Randomized Controlled Trial	A total of 372 women were eligible to participate in the study. (N=372) Group 1 (Gum Chewing): (n=124) Group 2 (Oral Fluids): (n=124) Group 3 (Control Group): (n=124)	The primary outcome measure was the time from the end of the procedure to first passage of stool; defined as the time in hours from the end of surgical procedure until the first passage of stool. The secondary outcomes included the time of the first passage of flatus, the first hearing of normal intestinal sounds, the duration of hospital stay, the duration of parenteral therapy by intravenous fluids, the time of initiating breastfeeding, and the cost of hospital stay. Statistical analysis was performed using SPSS version 21.0. Group 1 chewed sugar free gum 2 hours after delivery for 0.5 hours at minimum, and at 2-hour intervals during the daytime. Group 2 received oral fluids 6 hours after delivery. Group 3 received intravenous fluids for 24 hours until return of intestinal function. Each group had intestinal sounds assessed every 6-8 hours.	Chewing gum improves gastrointestinal recovery with faster return of bowel movements, intestinal sounds, passing of flatus, and passing of feces. ($p = 0.0001$) Gum chewing shortened the duration of hospital stay as well as the duration of parenteral intravenous fluids. ($p = 0.0001$) Non-gum chewing study participants (Group 2 and 3), had significantly higher occurrences of abdominal distention, vomiting, and ileus postoperatively. Gum chewing participants had no occurrence of paralytic ileus or adverse events.	II	A
Basbug, A., Yuksel, A., & Ellibeş Kaya, A. (2018).	To compare early versus delayed Foley catheter removal on postoperative recovery for women receiving elective cesarean sections.	Prospective Randomized Controlled Trial	A total of 134 women were included in the study. (N=134) Group A (Early Catheter Removal Participants): (n=62) Group B (Delayed Catheter Removal)	The primary outcomes studied included irritative urinary symptoms (recatheterization, dysuria, urgency, and frequency), bacteriuria, hematuria, length of hospital stay, and mobilization time. The term dysuria was used to describe painful urination, abnormally frequent urination (once every hour) was termed as urinary frequency and an abrupt, strong, often overwhelming need to urinate is termed as urinary urgency, which often signify an infection of the lower urinary tract. The definition of urinary retention was, lack of spontaneous micturition 6 hours after the removal of catheter or bladder volume exceeding 200mL measured by transabdominal ultrasound. Significant microscopic bacteriuria was defined as greater than or equal to 100,000-bacteria per mL urine in a midstream sample, and microscopic hematuria was defined as three or more red blood cells per high-	Urinary frequency ($p = 0.04$), microscopic hematuria incidence ($p = 0.04$), postoperative mobilization time ($p = 0.01$), and length of hospital stay ($p = 0.009$) were significantly lower in Group A, the early catheter removal group than in the delayed group, Group B.	II	A

El-Mazny, A., El-Sharkawy, M., & Hassan, A. (2014).	To compare outcomes related to immediate and delayed postoperative removal of urinary catheter after elective cesarean section.	Prospective Randomized Controlled Trial	Participants): (n=74)	<p>power field. Urine samples were obtained by clean-catch midstream void procedure, 6h after the catheter withdrawal. The analysis of numerical data was done using IBM SPSS Statistics for Windows, version 22.</p> <p>Group A participants had their Foley catheter removed 2 hours following delivery.</p> <p>Group B study participants had their Foley catheter removed 12 hours following their surgical procedure.</p> <p>The main outcome measures were significant bacteriuria (100,000 bacteria per ml urine in a midstream sample collected 24 hours postoperatively) and urinary symptoms (urinary retention necessitating re-catheterization, dysuria, burning on micturition, urinary frequency, and urgency). Other outcome measures were the time till start of oral rehydration and return of intestinal sounds after the operation, the time of first voiding, postoperative ambulation time, and the length of hospital stay. Data analysis was performed using the Statistical Package for the Social Sciences program, version 16.0.</p> <p>Group A participants had their Foley catheter removed immediately following delivery.</p> <p>Group B study participants had their Foley catheter removed 12 hours following their surgical procedure.</p>	<p>The incidence of postoperative significant bacteriuria ($p = 0.020$), dysuria ($p = 0.030$), burning on micturition ($p = 0.016$), urinary frequency ($p = 0.031$), and urgency ($p = 0.011$) were significantly lower in group A compared with group B.</p> <p>The mean postoperative first ambulation time ($p < 0.001$), time until the first void ($p < 0.001$), and length of hospital stay ($p < 0.001$) were significantly shorter in group A.</p>	II	A
Hsu, Y.-Y., Hung, H.-Y., Chang, S.-C., & Chang, Y.-J. (2013).	To evaluate whether early oral intake after cesarean delivery influences gastrointestinal function following cesarean delivery.	Systematic Review and Meta-analysis of Randomized Controlled Trials	17 studies included 2,966 women with the sample size for each study ranging from 100-221. (N=2,966)	<p>The outcomes studied included return of gastrointestinal function measured by the hours between delivery and the return of bowel sounds, passing flatus, and bowel evacuation. Gastrointestinal complications were also measured and included the recording of ileus, nausea, vomiting, abdominal distention, and diarrhea.</p> <p>All the early intake interventions took place within 8 hours after cesarean delivery. 4 studies initiated oral intake 2 hours after delivery. Most of the studies provided early oral intake between 6 and 8 hours post operatively. The early intake consisted of water or a liquid diet. A solid diet was implemented in 4 studies. A semi-liquid diet was introduced in 2 studies. The control group initiated their oral intake between 8-48 hours after delivery, or until bowel sounds were present.</p>	<p>Early oral intake significantly improved gastrointestinal function compared with delayed oral intake. Return of gastrointestinal function was reduced in the early oral intake group with bowel sounds returning 9.2 hours earlier, time to passing flatus occurred 10 hours earlier, and bowel evacuation occurred 14.6 hours sooner. Early oral intake did not have a significant effect on the occurrence of gastrointestinal complications. ($p = <0.001$)</p>	I	A

Masood, S. N., Masood, Y., Naim, U., & Masood, M. F. (2014).	To compare the effects of early versus delayed oral intake after cesarean delivery.	Randomized Control Trial	1,174 women with an uncomplicated cesarean delivery under spinal anesthesia. (N=1,174) Early Feeding Group consisted of 587 women. (n=587) Conventional Feeding Group consisted of 587 women. (n=587)	Primary outcome measures included the time to ambulation from delivery and the level of maternal satisfaction. Secondary outcomes were gastrointestinal complications and the duration of hospital stay. Intensities of thirst and hunger as well as maternal satisfaction were measured on a visual analog scale (VAS). Numerical data was analyzed with SPSS version 15.0 computer software. Subjects either received early oral feeding (2 hours post-delivery) or conventional initiation of feeding (18 hours post-delivery).	Lower intensities of thirst and hunger and a higher rate of maternal satisfaction were identified in the early oral feeding group. ($p < 0.05$) 53.8% of women who received feeding 2 hours after delivery were able to ambulate within 15 hours after surgery compared with the conventional feeding group (27.9%).	II	A
Menshaw, A., Ghanem, E., Menshaw, E., Taher Masoud, A., El-Sharkawy, M., Taher, A., ... Abbas, A. M. (2018).	To evaluate the evidence from published randomized clinical trials about the outcomes of early versus delayed removal of indwelling urinary catheter after elective cesarean delivery.	Systematic Review and Meta-analysis of Randomized Controlled Trials	Three randomized controlled trials with a total of 609 study participants. (N=609) Group A (Early Removal): (n=298) Group B (Delayed Removal): (n=311)	The main outcome measures were significant bacteriuria, urinary symptoms (urinary retention necessitating re-catheterization, dysuria, urinary frequency, and urgency), postoperative oral rehydration and length of hospital stay. The definition of urinary retention was lack of spontaneous micturition 6 hours after removal of urinary catheter. Dysuria means painful urination, while urinary frequency means abnormally frequent urination (once every hour). Urgency is an abrupt, strong need to urinate. Significant bacteriuria was defined as 100,000-bacteria per mL urine in a midstream sample. Data were pooled as mean difference in a fixed effect meta-analysis model using the inverse variance method of review Manager software for windows, version 5.3. Group A study participants had their Foley catheter removed immediately following cesarean delivery. Group B study participants had their Foley catheter removed between 12- and 24-hours following delivery.	The statistical analyses demonstrated that early Foley catheter removal significantly reduced dysuria (RR = 0.60, 95% CI [0.38, 0.95], $p = 0.03$), urinary frequency (RR = 0.32, 95% CI [0.16, 0.66], $p = 0.002$) and significant bacteriuria (RR = 0.49, 95% CI [0.30, 0.83], $p = 0.007$) than delayed removal.	I	A

<p>Nantasupha, C., Ruengkhaichorn, I., & Ruangvutilert, P. (2016).</p>	<p>To compare time to regular diet tolerance among conventional scheduled feeding, early oral feeding, and early oral feeding in addition to domperidone in women following cesarean delivery.</p>	<p>Randomized Control Trial</p>	<p>A total of 120 women were eligible to participate in the study. (N=120) Group A (Conventional Schedule): (n=40) Group B (Early Oral Feeding): (n=40) Group C (Early Oral Feeding plus Domperidone): (n=40)</p>	<p>The primary outcome studied was the time between end of surgical procedure and regular diet tolerance. Secondary outcomes included time to first flatus, time to ambulation, length of hospitalization, postoperative pain scores, patient satisfaction scores, and rate of postoperative complications. Visual analog scales, blind assessors (healthcare practitioners) and specially designed forms to be recorded by study participants were utilized to obtain data. Statistical analysis was performed using SPSS version 21.0. Group A, conventional schedule: women fasted for 18–24 hours postoperatively, then sipped water, had a liquid diet, soft diet, and regular diet, consecutively. Group B, early oral feeding: women started sipping water at 3–8 hours postoperatively, followed by a soft and then a regular diet. Group C had the same feeding regimen as group B, in addition to domperidone.</p>	<p>Median time to regular diet tolerance, in hours, were 52.3 (50.8–54.7), 28.5 (24.8–31.4), and 29.6 (26.5–44.8) in groups A, B and C, respectively. ($p < 0.001$) The two early feeding groups had significantly earlier ambulation and shorter hospitalization compared with the control. There were no differences between the two early feeding groups proving that domperidone does not enhance postoperative gastrointestinal function. The rate of postoperative gastrointestinal symptoms, pain scores and patients' satisfaction scores were similar among the three groups.</p>	<p>II</p>	<p>A</p>
<p>Pereira Gomes, E., Morais, E., Riera, R., Porfirio, G. J., Macedo, C. R., Sarmiento Vasconcelos, V., de Souza Pedrosa, A., & Torloni, M. R. (2016).</p>	<p>To evaluate the effects of gum chewing on postoperative recovery and duration of postoperative ileus following cesarean delivery.</p>	<p>Systematic Review and Meta-analysis of Randomized Controlled Trials</p>	<p>A total of 17 randomized trials with a total of 3,149 participants. (N=3,149)</p>	<p>Primary outcomes of the review included: 1. The time between delivery to passage of first flatus in hours. 2. The proportion of women with ileus as defined by the study authors or signs and symptoms of gastrointestinal disturbances such as nausea, vomiting, abdominal cramping, or abdominal distention within the first 72 hours after delivery. 3. Tolerance to gum and adverse effects of gum chewing (such as jaw discomfort), within the first 72 hours following cesarean delivery. Two review authors independently extracted data, resolved discrepancies, and entered the data into Review Manager (RevMan) to check accuracy. Intervention groups were assigned to a variation of gum chewing regimens among the selected studies. Gum chewing was initiated immediately after delivery up to 12 hours postoperatively. The duration of each session varied from 15 minutes to 60 minutes. The number of gum chewing sessions per day were between 3 and 6.</p>	<p>Time to passage of first flatus was 7 hours shorter in the gum chewing groups. The rate of ileus on average was over 60% lower in the gum chewing group compared to the control group. Tolerance to gum chewing was high. Only one study had a complaint. None of the studies included reported adverse effects of gum chewing postoperatively.</p>	<p>I</p>	<p>A</p>

(Melnik & Fineout-Overholt, 2014; Newhouse, 2006).

Appendix B

Table B1. *Rating System for Hierarchy of Evidence*

Level of Evidence	Type of Evidence
I	Evidence from systematic review, meta-analysis of randomized controlled trials (RCTs), or practice-guidelines based on systematic review of RCTs.
II	Evidence obtained from well-designed RCT
III	Evidence obtained from well-designed controlled trials without randomization
IV	Evidence from well-designed case-control and cohort studies
V	Evidence from systematic reviews of descriptive and qualitative studies
VI	Evidence from a single descriptive or qualitative study
VII	Evidence from the opinion of authorities and/or reports of expert committees

(Melnyk & Fineout-Overholt, 2014).

Table B2. *Rating Scale for Quality of Evidence*

Quality Rating	Rating Description
A	High – consistent results with adequate sample size, adequate control, and definitive conclusions; consistent recommendations based on extensive literature review that includes thoughtful reference to scientific literature.
B	Good – reasonably consistent results; adequate sample size, some control, with fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence.
C	Low/major flaw – Little evidence with inconsistent results; insufficient sample size; conclusions cannot be drawn

(Newhouse, 2006).

Appendix C

**CLINICAL PRACTICE GUIDELINE:
ENHANCED RECOVERY AFTER CESAREAN DELIVERY****1. Background and Significance**

Enhanced recovery after surgery (ERAS) is a model of patient care that was developed in the late 1990's by a group of general surgeons in Northern Europe (Melnyk, Casey, Black & Koupparis, 2011). They created a multimodal perioperative care pathway that was designed to achieve early recovery for patients undergoing major surgery (Melnyk et al., 2011). This concept of enhanced recovery was developed to challenge traditional perioperative care practices and replace them with evidence-based approaches to optimize and accelerate patient recovery (Melnyk et al., 2011). ERAS standardizes the perioperative pathway and succeeds in enhancing the management of patients and improving the quality of care (Melnyk et al., 2011). ERAS protocols were first executed in patients undergoing colorectal surgery (Ljungqvist, 2014). The statistical evidence generated following the first ERAS protocol implementation revealed a significant reduction in length of hospital stay, readmissions, and postoperative complications, in addition to increased patient satisfaction (Ljungqvist, 2014). Since this game-changing evidence surfaced, there has been widespread adoption of ERAS guidelines in many other surgical specialties that have reported very similar improvements in patient outcomes (Ljungqvist, 2014).

The surgical procedure most performed in modern healthcare is the cesarean delivery (Caughey et al., 2018). In the United States the cesarean delivery rate is approximately 32% of all births, with well over a million performed each year (Caughey et al., 2018). Even though there is an enormous amount of evidence to support the improvement in perioperative pathways for many surgical specialties with ERAS, obstetrical surgery lacks established protocols based on ERAS principles (Huang, Cao, Nelson & Wilson, 2018). Furthermore, obstetrical surgical units are often secluded from the general operating rooms, which unfortunately can slow the introduction and acceptance of newly developed evidence-based practice protocols (Corso et al., 2017). The need for ERAS evidence-based recommendations to be applied and implemented for such a large surgical patient population is clearly warranted.

2. Scope and Purpose

The purpose of this scholarly project is to create and implement a clinical practice guideline (CPG) by January 2020 that has been derived from the core elements of the Enhanced Recovery After Surgery (ERAS) pathway, to provide best practice, evidenced-based, recommendations for perioperative care among those receiving elective cesarean sections. The key elements within the guideline will include postoperative recommendations for the peripartum population at a large community hospital in eastern Maryland. The CPG will facilitate the quality and safety of cesarean deliveries for improved maternal perioperative outcomes, enhanced physiological and functional recovery, decreased hospital length of stay, as well as increased maternal satisfaction. The guideline will be created based on a departmental need identified and disclosed by stakeholders within the organization, for the development of a standardized perioperative care pathway to facilitate both clinical benefits, including reductions in length of stay and postoperative complications, as well as health system benefits, including reduction in departmental costs.

3. Methods

A literature search was executed to find relevant evidence on postoperative optimization for elective cesarean sections. The specific postoperative interventions researched to enhance maternal recovery include early Foley catheter removal, early oral intake, and gum chewing. Following the completion of the evidence search, 8 studies were included.

The Melnyk & Fineout-Overholt criteria were utilized to critically appraise current literature and rate the level of evidence for each study included in the review that support the postoperative interventions incorporated into the CPG (2014). Newhouse's Quality Rating Scheme was used to rate the quality of evidence pertaining to each study (2006). Refer to Appendix B, Table 1 and 2, for further review of the rating criteria. The evidence retrieved was made up of meta-analyses, clinical practice guidelines, and systematic reviews of randomized controlled trials, all which received a level A or B evidence grade. Please refer to the table labeled *Hierarchy and Quality of Evidence Table* located in Appendix A, for a detailed account of each article.

4. Postoperative Practice Recommendations

The following practice recommendations are generated based on current research. Guideline updates, revisions, and enhancements will be put in place as new evidence-based improvements in perioperative care surface.

4.1 Foley Catheter Removal

Three articles met the predetermined criteria which support the postoperative intervention to initiate early removal of the indwelling urinary catheter. Basbug, Yuksel, and Ellibes conducted a prospective randomized control trial to compare postoperative Foley catheter removal 2 versus 12 hours after elective cesarean section (2018). The results showed a significant reduction of urinary frequency ($p=0.04$) and incidence of microscopic hematuria ($p=0.04$), in the early Foley catheter removal group (Basbug et al., 2018). Additionally, the onset time of postoperative mobilization was earlier ($p=0.01$) and the length of hospital stay was reduced ($p=0.0009$).

El-Mazny, El-Sharkawy, and Hassan conducted a prospective randomized control trial to compare immediate and 12-hour postoperative removal of the urinary catheter after elective cesarean section (2014). The incidence of postoperative significant bacteriuria ($p=0.020$), dysuria ($p=0.030$), burning on micturition ($p=0.016$), urinary frequency ($p=0.031$), and urgency ($p=0.011$) were significantly lower in those who received immediate catheter removal compared to the delayed catheter removal group (El-Mazny et al., 2014). The mean postoperative ambulation time ($p<0.001$), time until the first void ($p<0.001$), and length of hospital stay ($p<0.001$) were significantly shorter in the early catheter removal group as well (El-Mazny et al., 2014).

Menshawy et al., conducted a systematic review and meta-analysis of 3 randomized controlled trials to evaluate the evidence about the outcomes of early versus delayed catheter removal of indwelling urinary catheters after elective cesarean delivery (2018). The statistical analyses demonstrated that early Foley catheter removal significantly reduced dysuria (RR = 0.60, 95% CI [0.38, 0.95], $p=0.03$), urinary frequency (RR = 0.32, 95% CI [0.16, 0.66], $p=0.002$) and significant bacteriuria (RR = 0.49, 95% CI [0.30, 0.83], $p=0.007$) than delayed removal (Menshawy et al., 2018).

The study results are conclusive in demonstrating early catheter removal times are superior to the traditional guidelines. The strength of the evidence and significant benefits revealed warrant the inclusion of the practice recommendation stated below.

Practice Recommendation: It is recommended to remove the urinary catheter within 2 hours following cesarean delivery.

4.2 Gum Chewing

Two articles met the predetermined criteria which support postoperative gum chewing following elective cesarean sections. Altraigey et al., conducted a randomized control trial to evaluate the impact of chewing gum on return of gastrointestinal function following elective cesarean delivery (2018). The intervention group chewed sugar-free gum 2 hours after delivery for 0.5 hours at minimum, and at 2-hour intervals during the daytime. The results of this study revealed chewing gum improves gastrointestinal recovery with faster return of bowel movements, intestinal sounds, passing of flatus, and passing of feces ($p=0.0001$) (Altraigey, 2018). The results of this study also showed gum chewing shortened the duration of hospital stay as well as the duration of parenteral intravenous fluid requirements ($p=0.0001$) (Altraigey, 2018).

Morais et al., conducted a systematic review and meta-analysis of 17 randomized controlled trials with a total of 3,149 participants to evaluate the effects of gum chewing on postoperative recovery and duration of postoperative ileus following cesarean delivery (2016). Time to passage of first flatus was 7 hours shorter among those who were assigned to the gum chewing group (Morias et al., 2016). The rate of ileus on average was over 60% lower in the gum chewing groups compared to the control groups across all studies (Morias et al., 2016).

Evidence proves chewing gum postoperatively improves gastrointestinal recovery. The strength of the evidence and significant benefits warrant the inclusion of the practice recommendation stated below.

Practice Recommendation: It is recommended to initiate sugar-free gum chewing 2 hours after delivery as tolerated by the parturient. Additional recommendations include the initiation of at least 3 gum chewing sessions, beginning the day after surgery. Each session should last 15-30 minutes.

5.3 Early Oral Intake

Three articles met the predetermined criteria upon the conclusion of the evidence search, which support the intervention of early oral intake after cesarean delivery. Hsu et al., conducted a systematic review and meta-analysis of 17 published to evaluate whether early oral intake after cesarean delivery influences gastrointestinal outcomes during postpartum recovery (2013). All the early intake interventions took place between 2 and 8 hours after cesarean delivery. The results showed that early oral intake significantly improved gastrointestinal function compared with delayed oral intake ($p < 0.001$) (Hsu et al., 2013). Return of gastrointestinal function was reduced in the early oral intake group with bowel sounds returning 9.2 hours earlier, time to passing flatus occurred 10 hours earlier, and bowel evacuation occurred 14.6 hours sooner (Hsu et al., 2013).

Masood et al., conducted a randomized control trial to compare the effects of early (2 hours post-delivery) versus delayed (18-hours post-delivery) oral intake after cesarean delivery

(2014). Upon the conclusion of the study, it was found that lower intensities of thirst and hunger and a higher rate of maternal satisfaction were prominent in the early oral feeding group ($p < 0.05$) (Masood et al., 2014). Additionally, 53.8% of women who received food 2 hours after delivery were able to ambulate within 15 hours after surgery compared to the conventional feeding group (27.9%) (Masood et al., 2014).

Nantasupha, Ruengkachorn, and Ruangvutilert, conducted a randomized control trial to compare time to regular diet tolerance among conventional scheduled feeding, early oral feeding, and early oral feeding in addition to domperidone in women following cesarean delivery (2016). The two early oral feeding groups had significantly earlier ambulation and shorter hospitalization compared with the control (Nantasupha, 2016). There were no differences between the two early feeding groups, proving that domperidone does not enhance postoperative gastrointestinal function (Nantasupha, 2016). Most of the women in the early oral feeding group achieved regular diet tolerance within 24 hours, while the women with the conventional diet schedule achieved regular diet tolerance at 48 hours after delivery (Nantasupha, 2016).

Early oral intake significantly improves gastrointestinal return of function. The strength of the evidence and significant benefits warrant the inclusion of the practice recommendation stated below.

Practice Recommendation: It is recommended to initiate a solid diet 2 hours after cesarean delivery, as tolerated by the parturient.

5. Applicability

Facilitators to assist the CPG execution phase have been identified and include departmental education, stakeholder involvement, and ongoing assessment of adherence in order to make revisions during implementation. Barriers have been identified and include the lack of pilot testing prior to widespread implementation. Overcoming this specific barrier is possible with adequate education to all perioperative labor and delivery staff prior to the execution phase. Resource implications for the application on the CPG recommendations have been considered. Stakeholders have allocated adequate funding in the form of a grant which has been issued by Sinai Hospital of Baltimore.

6. Monitoring/Auditing

Measuring compliance has been proven to be a necessary standard for ERAS guideline success, adherence, and sustainability. A development is presently underway whereby the postoperative Cesarean delivery guidelines are being translated into a feasible audit system in order to ensure compliance, improve patient outcomes, as well as enhance the delivery of peripartum care.

7. Editorial Independence

This statement is a declaration stating there was no acceptance of funds from any source to subsidize or compensate the students or stakeholders involved in the planning, development, or creation of the clinical practice guideline. Additionally, there was no financial body influencing the creation or content delivery within this clinical practice guideline.

This is an explicit declaration that I, Alexandra Wali, do not have any competing interests that would influence the guideline process or development of recommendation.

Appendix D

AGREE II Tool

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA
DOMAIN 1: SCOPE AND PURPOSE	
<p>1. OBJECTIVES <i>Report the overall objective(s) of the guideline. The expected health benefits from the guideline are to be specific to the clinical problem or health topic.</i></p>	<p>Health intent(s) (i.e., prevention, screening, diagnosis, treatment, etc.) Expected benefit(s) or outcome(s) Target(s) (e.g., patient population, society)</p>
<p>2. QUESTIONS <i>Report the health question(s) covered by the guideline, particularly for the key recommendations.</i></p>	<p>Target population Intervention(s) or exposure(s) Comparisons (if appropriate) Outcome(s) Health care setting or context</p>
<p>3. POPULATION <i>Describe the population (i.e., patients, public, etc.) to whom the guideline is meant to apply.</i></p>	<p>Target population, sex and age Clinical condition (if relevant) Severity/stage of disease (if relevant) Comorbidities (if relevant) Excluded populations (if relevant)</p>
DOMAIN 2: STAKEHOLDER INVOLVEMENT	
<p>4. GROUP MEMBERSHIP <i>Report all individuals who were involved in the development process. This may include members of the steering group, the research team involved in selecting and reviewing/rating the evidence and individuals involved in formulating the final recommendations.</i></p>	<p>Name of participant Discipline/content expertise (e.g., neurosurgeon, methodologist) Institution (e.g., St. Peter’s hospital) Geographical location (e.g., Seattle, WA) A description of the member’s role in the guideline development group</p>
<p>5. TARGET POPULATION PREFERENCES AND VIEWS <i>Report how the views and preferences of the target population were sought/considered and what the resulting outcomes were.</i></p>	<p>Statement of type of strategy used to capture patients’/publics’ views and preferences (e.g., participation in the guideline development group, literature review of values and preferences) Methods by which preferences and views were sought (e.g., evidence from literature, surveys, focus groups) Outcomes/information gathered on patient/public information How the information gathered was used to inform the guideline development process and/or formation of the recommendations</p>

<p>6. TARGET USERS <i>Report the target (or intended) users of the guideline.</i></p>	<p>The intended guideline audience (e.g. specialists, family physicians, patients, clinical or institutional leaders/administrators) How the guideline may be used by its target audience (e.g., to inform clinical decisions, to inform policy, to inform standards of care)</p>
<p>DOMAIN 3: RIGOUR OF DEVELOPMENT</p>	
<p>7. SEARCH METHODS <i>Report details of the strategy used to search for evidence.</i></p>	<p>Named electronic database(s) or evidence source(s) where the search was performed (e.g., MEDLINE, EMBASE, PsychINFO, CINAHL) Time periods searched (e.g., January 1, 2004 to March 31, 2008) Search terms used (e.g., text words, indexing terms, subheadings) Full search strategy included (e.g., possibly located in appendix)</p>
<p>8. EVIDENCE SELECTION CRITERIA <i>Report the criteria used to select (i.e., include and exclude) the evidence. Provide rationale, where appropriate.</i></p>	<p>Target population (patient, public, etc.) characteristics Study design Comparisons (if relevant) Outcomes Language (if relevant) Context (if relevant)</p>
<p>9. STRENGTHS & LIMITATIONS OF THE EVIDENCE <i>Describe the strengths and limitations of the evidence. Consider from the perspective of the individual studies and the body of evidence aggregated across all the studies. Tools exist that can facilitate the reporting of this concept.</i></p>	<p>Study design(s) included in body of evidence Study methodology limitations (sampling, blinding, allocation concealment, analytical methods) Appropriateness/relevance of primary and secondary outcomes considered Consistency of results across studies Direction of results across studies Magnitude of benefit versus magnitude of harm Applicability to practice context</p>
<p>10. FORMULATION OF RECOMMENDATIONS <i>Describe the methods used to formulate the recommendations and how final decisions were reached. Specify any areas of disagreement and the methods used to resolve them.</i></p>	<p>Recommendation development process (e.g., steps used in modified Delphi technique, voting procedures that were considered) Outcomes of the recommendation development process (e.g., extent to which consensus was reached using modified Delphi technique, outcome of voting procedures) How the process influenced the recommendations (e.g., results of Delphi technique influence final recommendation, alignment with recommendations and the final vote)</p>

11. CONSIDERATION OF BENEFITS AND HARMS	Supporting data and report of benefits Supporting data and report of harms/side effects/risks Reporting of the balance/trade-off between benefits and harms/side effects/risks Recommendations reflect considerations of both benefits and harms/side effects/risks
<i>Report the health benefits, side effects, and risks that were considered when formulating the recommendations.</i>	
12. LINK BETWEEN RECOMMENDATIONS AND EVIDENCE	How the guideline development group linked and used the evidence to inform recommendations Link between each recommendation and key evidence (text description and/or reference list) Link between recommendations and evidence summaries and/or evidence tables in the results section of the guideline
<i>Describe the explicit link between the recommendations and the evidence on which they are based.</i>	
13. EXTERNAL REVIEW	Purpose and intent of the external review (e.g., to improve quality, gather feedback on draft recommendations, assess applicability and feasibility, disseminate evidence) Methods taken to undertake the external review (e.g., rating scale, open-ended questions) Description of the external reviewers (e.g., number, type of reviewers, affiliations) Outcomes/information gathered from the external review (e.g., summary of key findings) How the information gathered was used to inform the guideline development process and/or formation of the recommendations (e.g., guideline panel considered results of review in forming final recommendations)
<i>Report the methodology used to conduct the external review.</i>	
14. UPDATING PROCEDURE	A statement that the guideline will be updated Explicit time interval or explicit criteria to guide decisions about when an update will occur Methodology for the updating procedure
<i>Describe the procedure for updating the guideline.</i>	
DOMAIN 4: CLARITY OF PRESENTATION	
15. SPECIFIC AND UNAMBIGUOUS RECOMMENDATIONS	A statement of the recommended action Intent or purpose of the recommended action (e.g., to improve quality of life, to decrease side effects) Relevant population (e.g., patients, public) Caveats or qualifying statements, if relevant (e.g., patients or conditions for whom the recommendations would not apply) If there is uncertainty about the best care option(s), the uncertainty should be stated in the guideline
<i>Describe which options are appropriate in which situations and in which population groups, as informed by the body of evidence.</i>	
16. MANAGEMENT OPTIONS	Description of management options Population or clinical situation most appropriate to each option
<i>Describe the different options for managing the condition or health issue.</i>	

<p>17. IDENTIFIABLE KEY RECOMMENDATIONS <i>Present the key recommendations so that they are easy to identify.</i></p>	<p>Recommendations in a summarized box, typed in bold, underlined, or presented as flow charts or algorithms Specific recommendations grouped together in one section</p>
<p>DOMAIN 5: APPLICABILITY</p>	
<p>18. FACILITATORS AND BARRIERS TO APPLICATION <i>Describe the facilitators and barriers to the guideline's application.</i></p>	<p>Types of facilitators and barriers that were considered Methods by which information regarding the facilitators and barriers to implementing recommendations were sought (e.g., feedback from key stakeholders, pilot testing of guidelines before widespread implementation) Information/description of the types of facilitators and barriers that emerged from the inquiry (e.g., practitioners have the skills to deliver the recommended care, sufficient equipment is not available to ensure all eligible members of the population receive mammography) How the information influenced the guideline development process and/or formation of the recommendations</p>
<p>19. IMPLEMENTATION ADVICE/TOOLS <i>Provide advice and/or tools on how the recommendations can be applied in practice.</i></p>	<p>Additional materials to support the implementation of the guideline in practice. For example: Guideline summary documents Links to check lists, algorithms Links to how-to manuals Solutions linked to barrier analysis (see Item 18) Tools to capitalize on guideline facilitators (see Item 18)</p>
<p>20. RESOURCE IMPLICATIONS <i>Describe any potential resource implications of applying the recommendations.</i></p>	<p>Outcome of pilot test and lessons learned Types of cost information that were considered (e.g., economic evaluations, drug acquisition costs) Methods by which the cost information was sought (e.g., a health economist was part of the guideline development panel, use of health technology assessments for specific drugs, etc.) Information/description of the cost information that emerged from the inquiry (e.g., specific drug acquisition costs per treatment course) How the information gathered was used to inform the guideline development process and/or formation of the recommendations</p>

21. MONITORING/ AUDITING CRITERIA <i>Provide monitoring and/or auditing criteria to measure the application of guideline recommendations.</i>	Criteria to assess guideline implementation or adherence to recommendations Criteria for assessing impact of implementing the recommendations Advice on the frequency and interval of measurement Operational definitions of how the criteria should be measured
<hr/> DOMAIN 6: EDITORIAL INDEPENDENCE <hr/>	
22. FUNDING BODY <i>Report the funding body's influence on the content of the guideline.</i>	The name of the funding body or source of funding (or explicit statement of no funding) A statement that the funding body did not influence the content of the guideline
23. COMPETING INTERESTS <i>Provide an explicit statement that all group members have declared whether they have any competing interests.</i>	Types of competing interests considered Methods by which potential competing interests were sought A description of the competing interests How the competing interests influenced the guideline process and development of recommendations

AGREE Next Steps Consortium (2009). The AGREE II Instrument [Electronic version]. Retrieved from http://www.agreetrust.org/wp-content/uploads/2013/10/AGREE-II-users-manual-and-23-item-instrument_2009_UPDATE_2013.pdf.

Appendix E

Practitioner Feedback Questionnaire

Please select the appropriate demographic category that most accurately describes you.

Type of anesthesia provider:			Years practiced in current role:					
CRNA	Anesthesiologist	SRNA	<5	5-10	10-15	15-20	20-25	>25
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

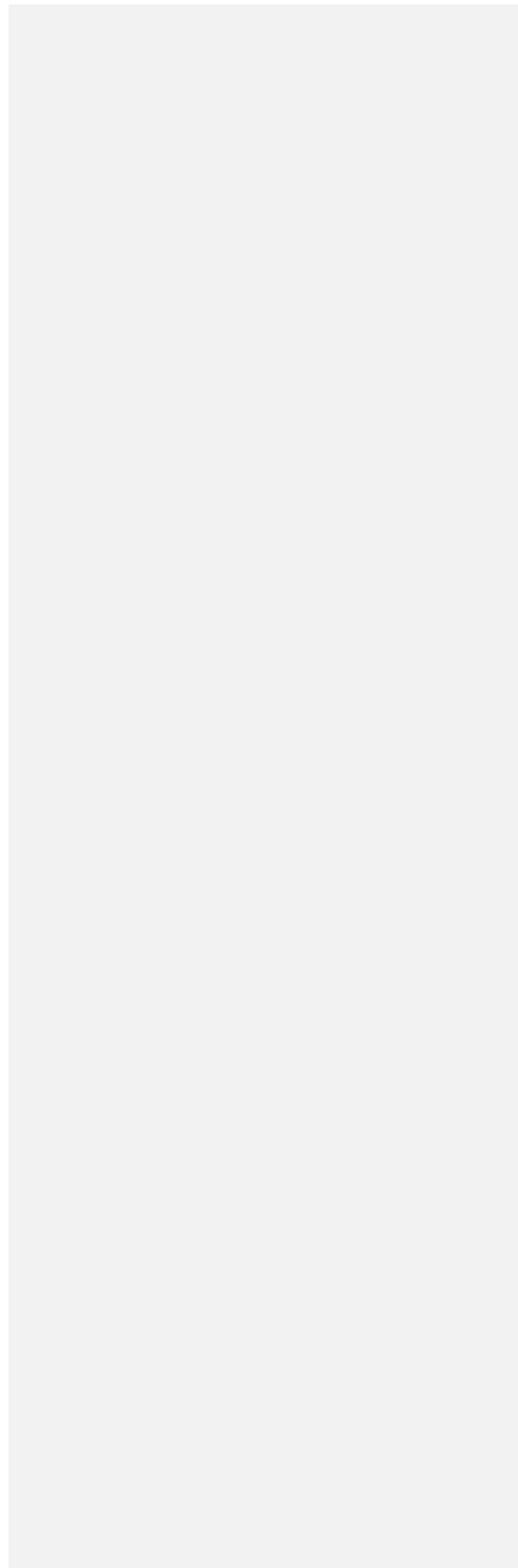
For each item, please check off the box that most adequately reflects your opinion.

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 <input type="checkbox"/>	No <input type="checkbox"/>	Unsure <input type="checkbox"/>
If you answered "No" or "Unsure", there is no need to answer or return this questionnaire. If you answered "Yes", please answer the questions below and return to [enter expected destination of surveys] .			
	Strongly agree	Neither agree or disagree	Strongly disagree
2. The rationale for developing a guideline is clear.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. There is a need for a guideline on this topic.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I agree with the methodology used to summarize the evidence included in this draft guideline.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. The results of the evidence described in this draft guideline are interpreted according to my understanding of the evidence.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. The draft recommendations in this report are clear.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I agree with the draft recommendations as stated.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. The draft recommendations are suitable for the patients for whom they are intended.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. The draft recommendations are too rigid to apply to individual patients.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. When applied, the draft recommendations will produce more benefits for patients than harms.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. The draft guideline presents options that will be acceptable to patients.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. To apply the draft recommendations will require reorganization of services/care in my practice setting.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. To apply the draft guideline recommendations will be technically challenging.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. The draft guideline recommendations are too expensive to apply.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. The draft guideline recommendations are likely to be supported by a majority of my colleagues.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. If I follow the draft guideline recommendations, the expected effects on patient outcomes will be obvious.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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 <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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 <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

20. I would feel comfortable if my patients received the care recommended in the draft guideline.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. This draft guideline should be approved as a practice guideline.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. If this draft guideline were to be approved as a practice guideline, I would use it in my own practice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. If this draft guideline were to be approved as a practice guideline, I would apply the recommendations to my patients.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:

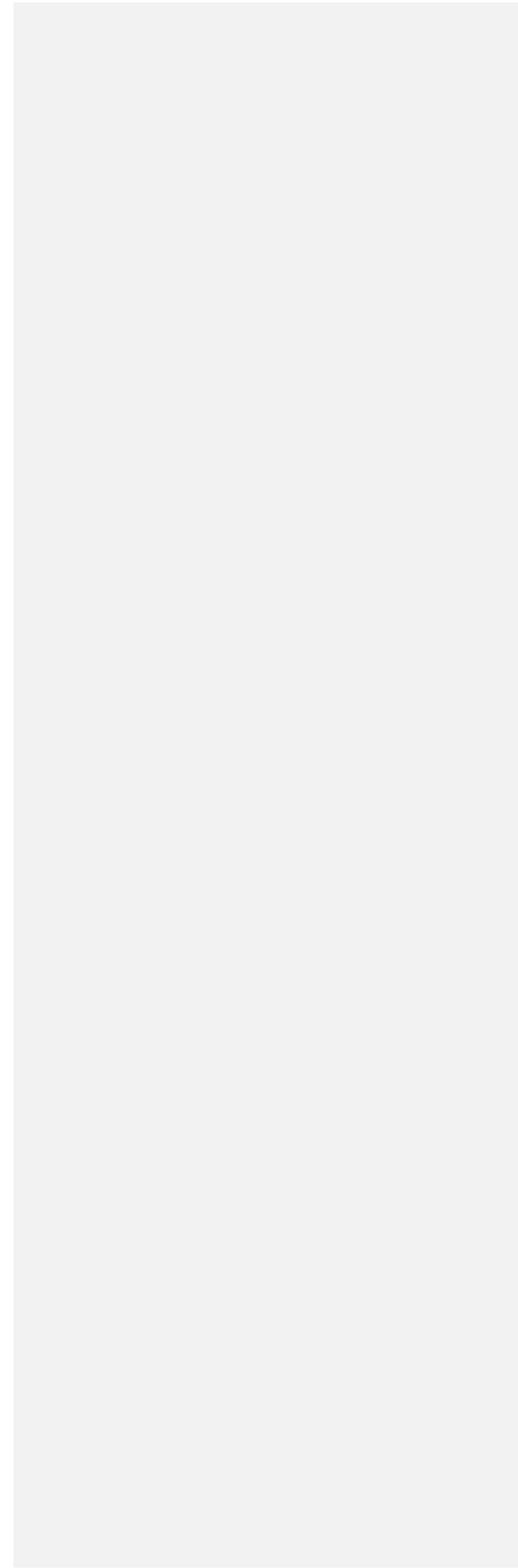
Adapted from: Brouwers, M.C., Graham, I.D., Hanna, S.E., Cameron, D.A., & Browman, G.P. (2004). Clinicians' assessments of practice guidelines in oncology: The CAPGO survey. *International Journal of Technology Assessment in Health Care*, 20(4), 421-6.



Appendix F

Table F1. AGREE II Tool Results

Domain	Percentage Score
Scope and Purpose	91.7%
Stakeholder Involvement	94.4%
Rigor of Development	86.4%
Clarity of Presentation	91.7%
Applicability	83.3%
Editorial Independence	100%
Overall Guideline Assessment	91.7%

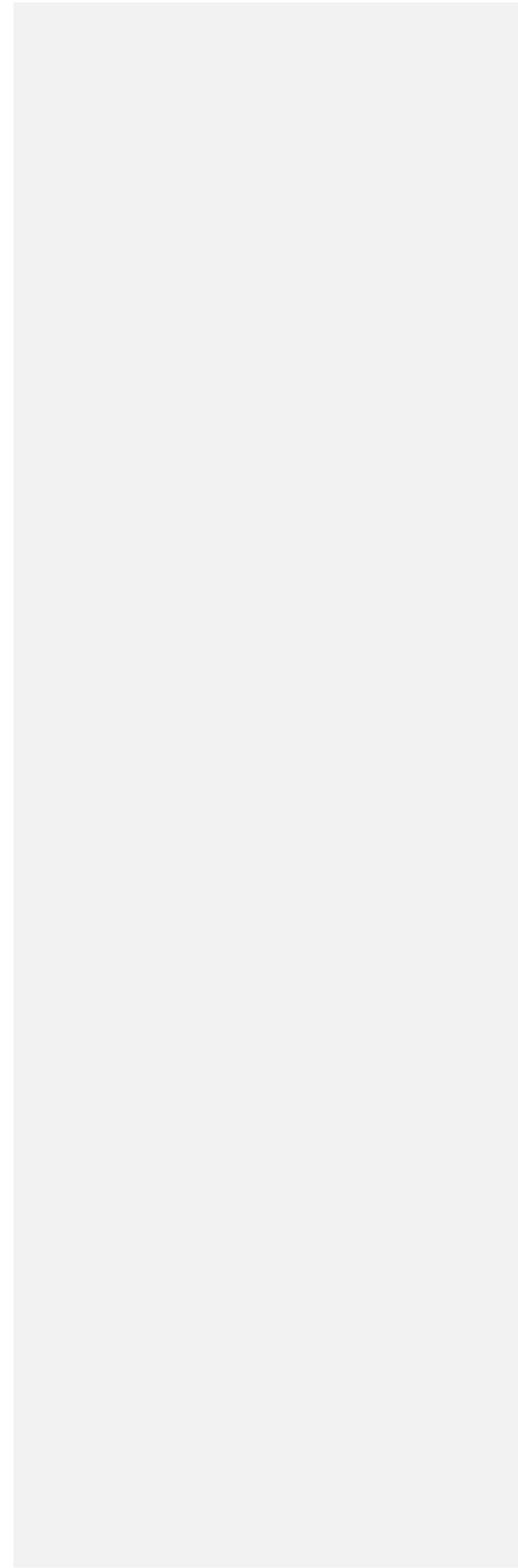


Appendix G

Table G1. Demographic Data of PFQ Respondents

Title	n	Percentage Responded
Anesthesiologist	6	35.3%
CRNA	4	23.5%
SRNA	7	41.2%
Total Providers	17	

Years of Experience	n	Percentage Responded
0-3 years	11	64.7%
4-6 years	2	11.8%
7-9 years	0	0%
≥ 10 years	4	23.5%



Appendix H

Figure 1. PFQ Results

