Clinical Practice Guideline for Planned Cesarean Section: Intraoperative Interventions

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Abstract

Problem & Purpose: Thirty percent of all births in the United States are performed by cesarean delivery (CD) making it the most common surgical procedure performed. Common complications include Spinal Induced Hypotension (SIH) and Post Spinal Shivering (PSS), which can have a detrimental impact on the mother and the fetus. Another factor that contributes to infant morbidity and mortality is not practicing delayed cord clamping (DCC). Lack of guidelines to manage intraoperative complications and DCC results in a variation in practice among anesthesia providers, leading to an increase in maternal and fetal morbidity and mortality. The purpose of this quality improvement project was to develop a clinical practice guideline (CPG) incorporating evidence based best practice interventions to standardize and optimize care of women undergoing planned CD to reduce the incidence of SIH and PSS. It also included the standardization of delayed cord clamping (DCC) times to decrease morbidity and mortality among healthy infants.

Methods: An extensive literature review focused on management of SIH, PSS and DCC was conducted. A CPG was drafted and presented to a team consisting of Director of Obstetrics Anesthesia and Director of Fetal and Maternal medicine who analyzed the CPG utilizing the Appraisal of Guidelines for Research and Evaluation II (AGREE II) tool. Modifications were made based on results and the CPG was presented to the anesthesia providers within organization who evaluated the usability of the CPG utilizing the Peer Feedback Questionnaire (PFQ).

Results: Two AGREE II tools were distributed and completed representing a 100% response rate. Each of the domains on AGREE II tool received a score greater than 70% indicating good quality. The overall guideline assessment score was 91.7%. A total of 39 PFQs were distributed to anesthesia providers, 17 were completed representing a 43% response rate. Analysis of the

PFQ revealed a total percentage of agreement of 87.4% with a standard deviation of 6.6. The percentage of agreement was also calculated for the five subscales. Quality and acceptance of CPG received the highest scores of 97.9% and 87.5% respectfully while the lowest score of 39% was obtained in applicability.

Conclusion: Favorable results on AGREE II tool and PFQ demonstrated the CPG was of good quality and well accepted by anesthesia providers. Implementation of the CPG has the potential to improve the standardization and optimization of women undergoing planned CD as well as standardizing DCC times to improve infant morbidity and mortality.

Introduction

According to the 2018 National Vital Statistics report over 3 million births occurred in the U.S. Of those births, 31.9% were performed by cesarean delivery (CD), making it the most common surgical procedure in the U.S. (Martin, 2018). In Maryland 33.9% of all births were performed by cesarean section (CDC, 2017). In line with the national average, the target institution had 1,967 births in 2017, with 614 (31%) performed by cesarean section.

Women delivering by CD are at increased risk for developing complications compared to women having vaginal deliveries. The primary anesthetic for women undergoing planned CD is neuraxial anesthesia with hyperbaric bupivacaine (0.75%) that results in a decrease in systemic vascular tone that can result in hypotension (Choudhary & Bajaj, 2018; Neves, 2010). Spinal induced hypotension (SIH) occurs in 60-80% of healthy parturient, and is potentially detrimental to mother and fetus (Choudhary& Bajaj, 2018; Mahboob et al., 2018; Neves et al., 2010). Post spinal shivering (PSS) occurs in 40-60% of patients receiving neuraxial anesthesia. Shivering is not a benign process and can result in a significant increase in oxygen consumption, cardiac output and arterial hypoxia (Tie et al., 2014).

In addition, delayed cord clamping (DCC), has demonstrated a positive effect on infant brain maturation (Mercer et al., 2014), increased neonatal hematocrit levels resulting in less anemia (Chen, et al., 2018; Fogarty et al., 2018; Macdonald et al., 2014,) and decreased hospital mortality rates (Rabe et al., 2012). Despite guidelines recommended by The American Congress of Obstetricians and Gynecologists (ACOG) to wait 30-60 seconds, cord clamping generally occurs within the first 15-20 seconds of life.

Purpose Statement and Goals

The purpose of this DNP project was to implement a clinical practice guideline (CPG) for the perioperative management of women undergoing planned CD in a community hospital in Central Maryland. The short-term goal of this project was the acceptance of the CPG as evidenced by positive feedback on the Appraisal of Guidelines for Research and Evaluation II (Agree II) Tool and the Practitioner Feedback Questionnaire (PFQ). Additional goals included 100% compliance from anesthesia providers subsequently resulting in a significant decrease in the incidence of SIH and PSS, and an increase in DCC times.

Literature Synthesis

An extensive literature review was conducted to identified and evaluate recommendations for the management of maternal SIH, PSS and identify optimal times for neonatal DCC (Table 1).

Spinal Induced Hypotension

The primary anesthetic for women undergoing planned cesarean delivery is subarachnoid injection of hyperbaric Bupivacaine (0.75%). This results in a decrease in systemic vascular resistance, venous return and cardiac output (Choudhary & Bajaj 2018; Neves 2010). Because uterine blood flow is not auto regulated and solely dependent upon mean arterial pressures, maternal hypotension can lead to fetal hypotension, bradycardia and acidosis. Secondary effects of maternal hypotension include nausea and vomiting, which is hypothesized to be a result of brain stem ischemia due to decreased cardiac output (Habib, 2012; Siddik-Sayyid et. al. (2014). There have been a number of interventions studied in an effort to counteract the detrimental effects of spinal anesthesia. The administration of boluses phenylephrine, an alpha-adrenergic agent, after hypotension has occurred was the current practice. Studies have been performed to

optimize and standardize the appropriate regimen of phenylephrine to prevent SIH thus improving hemodynamic stability. Siddik-Sayyid et al. (2014) and Mahboob and Burki (2018) looked at two randomized groups. One group received boluses of phenylephrine when the blood pressure decreased 20% of baseline and the second group was started on a phenylephrine infusion prophylactically. Neves et al. (2010) investigated three groups: one group was started on a phenylephrine infusion, one group received one bolus dose of 50 ug of phenylephrine prophylactically and one group received rescue boluses of phenylephrine only if they became hypotensive.

Mahboob and Burki (2018) found that the group receiving the phenylephrine infusion had less hypotension (p <0.001) and less fluid requirements intraoperatively (p = 0.039). On average the group receiving the phenylephrine infusion did receive more phenylephrine than the bolus group (p <0.001) which had been previously reported in various studies. However, no adverse effects to the higher dosages were reported. There was no significance between the two groups in terms of provider interventions (p= 0.06).

Similarly, Siddik-Sayyid et al. (2014) conducted a randomized double-blind control study to explore the effects of phenylephrine infusion vs. bolus on physician interventions, hypotension and nausea and/or vomiting. One major difference between the two studies is that Siddik-Sayyid used a weight-based dose of phenylephrine titrated to blood pressure while Mahboob and Burki (2018) utilized a set dose of 0.75 ug/kg/min. Siddik-Sayyid et al., (2014) not only concluded there was a significant decrease in hypotension and nausea/vomiting (p<0.001) in the phenylephrine infusion group, but by titrating infusions to blood pressures, they had better control in terms of patients becoming hypertensive which is associated with reflex bradycardia and a decrease in cardiac output as well.

Neves's (2010) primary outcomes included hypotension, nausea/vomiting and Apgar scores. They randomized participants into three groups: group 1 received a continuous infusion of phenylephrine at 0.15 ug/kg/min, group 2 a single dose of 50 ug of phenylephrine after the spinal, and group 3 received a bolus of phenylephrine if their blood pressure dropped to less than 20% of baseline. Neve's results were very similar to the previously mentioned studies. There was a significant decrease ($p<0.001$) in hypotension in groups one and two which received some form of phenylephrine prophylactically. Nausea and vomiting was greatest in group three, which only received a rescue dose of phenylephrine if they became hypotensive ($p = 0.02$).

All studies concluded that a phenylephrine infusion was superior to bolus doses in decreasing incidences of SIH. The starting dose needs more exploration, however titrating phenylephrine infusion based on maternal blood pressures appeared to provide more hemodynamic stability as demonstrated by the study performed by Siddik-Sayyid (2014). The strengths of the three studies was they were all randomized and obtained similar results. Weaknesses include relatively small sample sizes, as well as the fact that none of the interventions completely abolished SIH.

Post Spinal Shivering (PSS)

Shivering is a common unpleasant experience associated with spinal anesthesia with a reported incidence ranging from 30-60% and is unrelated to axillary temperature (Nallam et al., 2017; Sharma et al., 2018; Tie et al., 2014). The mechanism of PSS as it relates to neuraxial anesthesia is related to numerous factors which include vasodilation caused by local anesthetics (Tie et al., 2014) changes in distribution of body heat and a reduction in body core temperature. (Badawy & Mokhtar, 2017 & Sharma et al., 2018). Shivering is not only uncomfortable, physiologic consequences include an increase in oxygen consumption, increased $C0_2$ levels and

lactic acidosis (Badawy & Mokhtar, 2017). There are a variety of drug modalities that are effective in decreasing PSS, however, for women undergoing cesarean delivery, finding a drug with a low side effect profile is paramount. Several studies indicated ondansetron, a 5HT3 antagonist, as a viable option. Ondansetron is primarily used to treat nausea and vomiting but has shown potential in the ability decrease shivering as well preventing SIH.

Although Marashi et al, (2014) had a primary focus on the use of ondansetron's effect on blood pressures after spinal anesthesia, reduction in shivering was a secondary outcome. The results of the study indicated a statistically significant decrease in nausea and vomiting in the groups that received ondansetron (p=.02). However, the difference in shivering between the two groups receiving ondansetron was not significant, perhaps the lower dose may be adequate.

Tie et al., (2014) performed a meta-analysis of six studies, to examine the effects of ondansetron on PSS. Unlike Marashi et al., (2014) who focused solely on women receiving spinal anesthesia for CD, Tie's et al., (2014) study encompassed spinal anesthesia in a variety of surgical settings including orthopedics cardiac, gynecological, as well as CD. The overall conclusion was that ondansetron could reduce incidences of PSS. The weaknesses noted included a relatively small sample sizes, different definitions and grading scales for shivering, and the doses of ondansetron were not standardized (Tie et al., 2014).

Badawy and Mokhtar (2017) also examined the effects of ondansetron in the prevention of PSS. They performed a double-blinded, prospective, randomized, trial that included 80 parturients. The control group received normal saline and the experimental group received 8 mg of Ondansetron IV. Shivering was assessed using a validated scale and incidences of PSS were treated with meperidine. Results indicated there was a higher incidence of shivering in the

control group (p=0.007) which also correlated with a higher use of Meperidine in the control group (p =0.01), and shivering scores were also higher in the control group (p=0.005).

In conclusion the results of all three studies concluded that the administration of ondansetron can reduce incidences of PSS.

Delayed Cord Clamping (DCC)

Delayed cord clamping after the delivery of an infant allows for blood to continue to flow from the placental to the infant via the umbilical cord. In a term infant, DCC can result in a transfusion of 24-32 ml/kg of blood from the mother to the baby in the first two minutes of life (McAdams, 2015). It was hypothesized that this techniques had a variety of positive outcomes that included; reduced infant mortality, decreased need for blood transfusions, and decreased incidences of intraventricular hemorrhage in the preterm infant (Fogarty et al., 2018). In a systematic review and meta-analysis which examined the effects of early versus delayed cord clamping on preterm infant's morbidity and mortality there was a significant decrease in hospital mortality (p=0.05), (Fogarty et al., 2018).

Chen et al. (2016) acknowledged that DCC was beneficial, however his study analyzed different time intervals for DCC and focused on full term infants. Outcomes measured included hematocrit, jaundice, admission to neonatal department and the amount of postpartum blood loss. The study concluded that DCC of 60 seconds was the most beneficial time in increasing hematocrit levels, without adverse effects to mother or infant (Chen et al., 2016).

McDonald et al., (2014) completed a Cochrane review to examine the effects of cord clamping timing. Their review concluded that delayed cord clamping was associated with increased birthweight, hematocrit and iron stores.

The three studies all demonstrated the benefits to DCC. Though each study looked at slightly different outcomes, there were no harmful effects associated with DCC. As Mercer et al., (2018) concludes, "it is a no-cost approach" with an associated decrease in infant morbidity.

Theoretical Framework: Lewin's Change Theory

Theoretical frameworks are utilized to aid in the conceptualization of how and why change happens. Theory is instrumental in facilitating change and sustaining long-term success. Evaluation of a theory is necessary to determine if it is useful or modifiable to fit the evidence-based practice change (Chinn and Kramer, 2015). The Kurt Lewin's Theory of Planned Change has shown to be influential in the deployment and sustainment of organizational change (Burnes & Cooke, 2013). Lewin's (1997) theory speculates that change is affected by two forces; driving and opposing. Driving forces encourage change and opposing forces are the barriers that prevent change from occurring. Sustainability comes by finding a balance between the two forces. Lewin (1951) also theorized change happens in three phases; unfreezing, movement and refreezing.

This framework was utilized to support the implementation of the intraoperative measures of the CPG for CD. In Phase one, unfreezing occurred identifying the necessary practice change (Shirey, 2013). Analysis of procedures for planned cesarean deliveries was performed and it was noted that care provided was not standardized and varied from provider to provider. External review of the literature was completed to identify the common adverse events that may occur during CD and to identify evidence-based interventions as a solution.

Stakeholders and potential barriers to change was identified. By educating providers on current evidence and allowing them to provide feedback via Practitioner Feedback Questionnaire (PFQ), providers were encouraged to recognize the need for change. The movement phase was the actual implementation of the new protocol. During this phase the anesthesia and labor and

delivery (L&D) staff were educated on the new guidelines and its implementation. The final phase was the refreezing stage which represents sustainability. Sustainability will be achieved by garnering leadership support, addressing the barriers to change, audits and constantly evaluating guidelines to ensure they continue to be based on best practice.

Methods

The purpose of this quality improvement project was to develop, evaluate and implement a clinical practice guideline (CPG) following Enhanced Recovery after Surgery (ERAS) principles, thereby standardizing and optimizing the intraoperative management of women undergoing planned CD. In addition, the CPG included a recommendation to standardize DCC times for the healthy infants to decrease infant morbidity and mortality. An extensive literature review focused on management of SIH, PSS and timing of cord clamping was conducted. A CPG was written and presented to a team consisting of the Director of Obstetrics Anesthesia and the Director of Fetal and Maternal medicine who analyzed the CPG utilizing the Appraisal of Guidelines for Research and Evaluation II (AGREE II) tool. Modifications were made based on results and the CPG was presented to the anesthesia providers within the organization who evaluated the quality, acceptability and applicability of the CPG utilizing the Peer Feedback Questionnaire (PFQ).

The CPG was implemented in a large community hospital in Central Maryland which performed over 1900 births in 2017, 30% were performed by CD. This rate was comparable to national rates. The CPG was applicable to all women undergoing planned CD. It excluded women undergoing urgent or emergent CDs, or women with a complicated obstetric history. Delayed cord clamping was limited to infants not requiring resuscitation at birth as determined by Neonatal Resuscitation Protocols (NRP). An Institutional Review Board (IRB) as well as

University of Maryland (UMB) IRB approval was obtained prior to initiating the quality improvement project. No identifying data or specimens on human subjects were collected for this project. All participation in completion of the AGREE II and PFQ tools was voluntary. Permission was obtained from the facility prior to presenting or publishing results of this quality improvement project.

Implementation Strategies

In order to facilitate change and improve sustainability, changes to organizational structure were made. The lack of a policy governing the intraoperative management of women undergoing planned CD, recommended cord clamping times and a need for staff education were identified. Implementing a CPG inaugurates the framework for clinical decisions based on best practices and the implementation strategy consisted of three phases (Appendix A).

During phase one, the findings of the literature review, suggested interventions and potential benefits were presented to the Director of Obstetrics Anesthesia. An interdisciplinary team of clinical experts included the Director of Anesthesia, Director of Maternal Fetal Medicine, a Surgical Resident, and the Labor and Delivery Nurse Leader was assembled. A CPG was drafted, the team was consulted, and modifications were made to the CPG to meet the needs of the organization. Once a consensus was reached on the components of the CPG, it was revised and the team was tasked with evaluating the CPG's quality and suitability utilizing the Appraisal of Guidelines for Research & Evaluation (AGREE) II Tool, (Appendix B). Modifications were made to the CPG based on AGREE II tool analysis and clinical expertise.

Once the CPG was approved by stakeholders, it was presented to the staff via a PowerPoint presentation which introduced the current evidence-based recommendations. Staff were given the opportunity to analyze the CPG utilizing the Practitioner Feedback Questionnaire

(PFQ) (Appendix C). Once analysis and feedback was received, final revisions to the CPG was completed and distributed (Appendix D).

Process measures are the evidence-based best practices that represent the efforts taken to systematize improvement efforts and reduce variation in care delivery. They are utilized to evaluate the effectiveness of the clinical practice change recommendations. The process measures that were implemented included the initiation of a phenylephrine infusion and administration of Zofran prior to the administration of a SAB. Additionally, DCC would occur for a minimum of 30-60 seconds in infants not requiring resuscitation immediately after birth.

Data Collection

Data collections included results from the AGREE II tool in addition to PFQ surveys. Each stakeholder independently evaluated the CPG utilizing the AGREE II tool. The Appraisal of Guidelines for Research & Evaluation (AGREE) II Tool was developed in 2003 by AGREE Enterprise. It provided methodical approach to the development of a CPG and allowed for the quantitative evaluation of a CPG. Inter-rater reliability and validity of the tool was measured with an alpha coefficient range of 0.64 to 0.89 and face, construct, and criterion-related validities were established (Brouwers et al., 2010a; Brouwers et al., 2010b). It was comprised of 23 items categorized in six domains as well as assigning an overall assessment score. Scoring was based on a 7-point scale with 1 strongly disagree and 7 strongly agree.

The PFQ, developed in 2004, aided in predicting the practitioners' intentions to incorporate the recommendations in the guideline into practice (Brouwers, Graham, Hanna, Cameron, & Browman, 2004). It allowed practitioners to provide feedback in regard to their assessment of the quality, acceptability, applicability and of a CPG. The PFQ is composed of twenty-three core items that uses a three-point scale with answers ranging from "strongly agree,"

"neither agree nor disagree," or "strongly disagree." Questions 10,13,14,15 were negatively worded and required reverse scoring. Inter-rater reliability was deemed not relevant and the alpha coefficient ranged from 0.75 to 0.85 (Brouwers, Graham, Hanna, Cameron, & Browman, 2004). For the purpose of this project the PFQ was modified to include specific provider roles and years of experience. The PFQ was distributed to the anesthesia providers who attended the educational session during Grand Rounds and time was allotted at the end of the presentation to allow providers to complete the PFQ. To ensure anonymity, providers were instructed to place completed PFQs in a box prior to exiting the meeting room. Additional PFQs were left in the anesthesia breakroom to give providers extra time to complete them.

Data Analysis

Analysis focused on the results obtained from the results of the AGREE II tool and PFQ. The AGREE II tool was analyzed using individual domain percentage scores, overall domain score and percent compliance. Domain percentage scores were calculated by utilizing the instructions provided in the tool and the overall domain score was an average of the individual domain scores. Percent compliance was analyzed by taking the total number of AGREE II tools distributed divided by the total number completed. Since the AGREE II Enterprise has not established a minimum score to delineate between strong and weak guidelines, stakeholders used their own judgment in determining whether they would recommend the guideline, recommend it with modifications or not recommend.

Likewise, the PFQ was also analyzed for response rate by taking the number of PFQs completed divided by the total number of PFQs distributed. Percent of agreement for each questionnaire was calculated by taking the total number of "strongly agree" and dividing it by the total number of items. The total percent of agreement was calculated by averaging the

individual percentages of agreement. Percent of agreement was also calculated for each PFQ subscales which included Quality, Acceptance of Recommendations, Applicability of Recommendations (reverse scored), Comparative Value and Outcome Variables.

Results

Two AGREE II tools were distributed and completed representing a 100% response rate. Domain scores of the AGREE II Tool were utilized to identify the strengths and limitation of the CPG. Domain scores greater than 70% indicate high quality (Brouwers et al., 2010). Each domain was rated above 70% and the overall guideline assessment score was 91.7% (See Table 2).

A total of 39 PFQs were distributed to anesthesia providers that included Anesthesiologists, Certified Registered Nurse Anesthetists (CRNA) and Student Registered Nurse Anesthetists (SRNA) and 17 were completed representing a 43% response rate. Analysis of the PFQ revealed a total percentage of agreement of 87.4% with a standard deviation of 6.6. The percentage of agreement was also calculated for the five subscales. Quality and acceptance of CPG received the highest scores of 97.9% and 87.5% respectfully while the lowest score of 39% was obtained in applicability (See Figure 1).

Discussion

The primary goal of this QI project was to develop, evaluate and implement a CPG to optimized the intraoperative management of women undergoing planned CD as well as standardize DCC for healthy infants. Overall the CPG received favorable scores on both the AGREE II tool and the PFQ. A major strength of the study included the endorsement of key stakeholders. Their expertise, as well as recent guidelines published by the Enhanced Recovery after Surgery Society for Cesarean Delivery (Caughy, 2018) was utilized in the selection and

prioritization of the recommendations and was further validated with high quality evidence. Favorable PFQ results indicated the staff accepted the recommendations outlined in the CPG as well.

There were limitations that required attention. In regards to the PFQ there was a small sample size of anesthesia providers, (N=39) which can jeopardize the validity of the results. There was also a limited response rate (35%) which may not reflect an accurate viewpoint of the entire anesthesia department. In an effort to ensure maximum participation, the CPG was presented during grand rounds, which is mandatory time allotted for staff education. Also, staff were given additional opportunities to review the PowerPoint presentation and CPG which were placed in the staff lounge, however, the response rate remained unchanged.

Low Applicability scores indicated providers perceived potential barriers in the ease of incorporating the recommendations into their current practice. Some staff expressed concerns the recommendations altered their normal work flow and would be time consuming. Through discussion, concerns were alleviated as staff agreed the medications and interventions did not changed, the guidelines were essentially recommending them to be proactive instead of reactive. It was also noted that DCC was geared more towards the delivery team and had no impact on anesthesia times. Appointment of change champions to aid in the transition and continued collaboration/education with end-users will be paramount. Continuous auditing of the electronic health record (EHR) will aid in tracking staff compliance. Feedback of audit results is vital and will aid in the identification and management of additional barriers. The next steps for this project will include data collection and analysis of the process measures to evaluate the effectiveness of the CPG

Conclusion

Obstetrics surgery is unique in the aspect that complications like SIH and PSS that occur during surgery can have a detrimental impact on the mother, as well as the fetus. DCC is a factor that has demonstrated positive outcomes for healthy infants at no extra cost. Synergistically, variations in practice correlates to poor patient outcomes, decrease in patient satisfaction, as well as an increase in medical cost (Cook et al., 2018). A systematic review has demonstrated that there are current evidence-based treatment modalities that can decrease the incidence and severity of SIH and PSS. Research also indicates that delayed cord clamping is a safe an effective practice that decreases infant morbidity and mortality. Future data analysis of these outcome measures will be required to track the success of the CPG. Continued stakeholder support in addition to auditing and feedback are the pillars of sustainability. Change champions are also fundamental in facilitating and sustaining change. Additionally, continuing education should be provided to ensure new staff is educated on practice guidelines. Literature reviews and guideline modifications will need to be completed on an annual basis to ensure guidelines are in line with current evidence-based research.

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Table 1

Evidence Review

Author, year	Study objective/intervention or exposures compared	Design	Sample (N)	Outcomes studied (how measured)	Results	Level and Quality Rating
(Fogarty et al., 2018)	Delayed vs early umbilical cord clamping for preterm infants	Systematic Review and Meta-analysis	Eighteen randomized controlled trials compared delayed vs early clamping in 2834 infants.	Delayed cord clamping (>30 seconds) vs early cord clamping (<30 seconds) clamping in infants born <37 weeks' gestation	Delayed clamping reduced hospital mortality (risk ratio, 0.68; 95% confidence interval, 0.52e0.90; risk difference, e0.03; 95% confidence interval, e0.05 to e0.01; p<.005; Delayed clamping increased peak hematocrit by 2.73 percentage points (95% confidence interval, 1.94e3.52; p < .00001) and reduced the proportion of infants having blood transfusion by 10% (95% confidence interval, 6e13%; p < .00001).	1A
Mcdonald Middleton, Dowswell, & Morris, 2014)	To determine the effects of early cord clamping compared with late cord clamping after birth on maternal and neonatal outcomes	Cochrane review of Randomized Control Trials	15 trials involving a total of 3911 women and infant pairs.	Maternal outcomes: postpartum hemorrhage, use of uterotonic drugs, mean blood loss. Neonatal outcomes: mortality, Apgar, birthweight, hemoglobin concentrations	There were significantly lower infant hemoglobin concentrations at birth for babies in the in the early clamping group compared with those in the late clamping group (MD -2.17 g/ dL 95% CI -4.06 to -0.28; random-effects model). e early cord clamping groups showed significantly lower infant hemoglobin concentrations 24 hours after birth than the late clamping groups (MD -1.49 g/dL 95% CI -1.78 to -1.21; 884 infants) decreased birthweight in babies in the early cord clamping arm with a mean difference in	1A

					birthweight of -101.18 g (95% CI -157.59 to -44.76, 3139 infants).	
(Chen, Li, Chang, Li, & Cui, 2018)	To evaluate the effect and safety of different umbilical cord clamping (UCC) timing.	Randomized Trial	720 term mothers/infants	Randomized to immediate cord clamping (ICC) within 15 s, delayed cord clamping (DCC) by 30, 60, 90, 120, 150, or 180 s, or when the umbilical cord pulsation ceased.	24 h after delivery, the mean infant hematocrit levels were 56.5, 57.3, 58.8, 59.7, 59.5, 59.7, 60.3, and 61.0% in the ICC, 30, 60, 90, 120, 150, and 180-second DCC, and no pulsation groups, respectively (*p*= 0.021, 0.001, 0.003, 0.001, <0.001, and <0.001, respectively; standard deviations ranging 5.4–8.7%)	2A
(Badawy & Mokhtar, 2017)	The role of ondansetron in prevention of post-spinal shivering (PSS) in obstetric patients:	Double-blind, placebo-controlled, Randomized study.	Two equal groups of 40 (ASA) physical status I or II full term parturients. Group O [Ondansetron]: received 8 mg/4 ml ondansetron, Group S [Saline] received 4 ml normal saline as placebo.	Shivering was graded by a blinded observer during the intraoperative and postoperative period on a validated scale: 0-4. Grades 3, and 4 shivering for at least 3 min were considered positive, and maximum shivering was considered if generalized shivering interfering with ECG monitoring or ability of the mother to hold the baby.	Statistically significant higher incidence of shivering in group (S), [19/37 (51%)] compared to group (O), [10/38 (26%)], (*p* value = 0.007) and the statistically significant higher incidence of maximum shivering scoring in group (S) compared to group (O), being [8/37 (22%) and 3/38 (7.8%)], respectively, (*p* value = 0.004). The median range of shivering score in group (S) was [2 (1–4)] which was statistically significant higher than group (O) [1 (0–4)], (*p* value = 0.005)	2A

(Marashi, Soltani-Omid, Soltani Mohammadi, Aghajani, & Movafegh, 2014)	Comparing Two Different Doses of Intravenous Ondansetron With Placebo on Attenuation of Spinal-induced Hypotension and Shivering	Randomized double blinded clinical trial	210 American Society of Anesthesiologists (ASA) physical status, I or II divided into 3 equal groups: control group received normal saline and intervention groups received 6 mg or 12 mg of intravenous ondansetron 5 minutes before spinal anesthesia	Mean arterial pressure (MAP), heart rate (HR), and shivering were recorded before and after spinal anesthesia every 5 minutes during first 20 minutes of surgery	Incidences of shivering were 4% (3.70) in 6 mg and 2% (2.70) in 12 mg ondansetron induced groups respectively (*p = .07*). Incidence of shivering was 45% (32.70) in the control group that was statistically more than ondansetron groups *(p = .02).*	2A
Tie et al., 2014)	Efficacy and safety of ondansetron in preventing post anesthesia shivering:	Meta-Analysis of Randomized Control Trials	Six trials including 533 subjects	Post anesthesia shivering and bradycardia	Ondansetron was associated with a significant reduction of PSS (RR 0.43, 95% CI, 0.27-0.70), without an increased risk of bradycardia (RR 0.37, 95% CI, 0.12-1.15)	1A
Mahboob, S., & Burki, A. M. (2018)	Compare the effect of prophylactic phenylephrine infusion on the fluid management and physician intervention as compared with rescue boluses of phenylephrine alone.	Randomized Control Trial	70 patients divided into 2 groups: e. Group A given prophylactic phenylephrine infusion at the rate of 0.75ug/kg/minute for 5 minutes after initiation of spinal anesthesia. Group B was given 50ug rescue bolus of phenylephrine when hypotension occurred	Maternal hypotension and number of physician interventions, meaning number of phenylephrine boluses and total amount of fluid administered	The total fluid administered in group A was lower than group B, 1634.2ml (±232.5) versus 1777.1 ml (±328.1); *p-value 0.039*. The group A received a much higher dose of phenylephrine, mean dose 287.2ug ± 48.8 versus 64.2ug ± 64.8; *p value<0.001*. An average of 0.23 (±0.49) number of physician interventions were done in hypotensive patients in group A versus 1.26 (±1.29 in group B; p-value 0.06. mean rescue phenylephrine bolus dose in group A was 15.7ug (±31.5) in group A versus 64.2 ± 64.8ug, p-value<0.001;	2 A

Siddik-Sayyid, Taha, Kanazi, & Aouad, 2014)	A combination of crystalloid solution co-load with a variable rate phenylephrine infusion and phenylephrine rescue boluses may be associated with fewer physician interventions needed to maintain maternal systolic blood pressure within 20% of baseline and greater hemodynamic stability than crystalloid solution coload with phenylephrine rescue boluses alone.	Prospective Double-Blind Study	80 Patients were randomized to receive a prophylactic variable rate phenylephrine infusion starting at 0.75 μg/kg/min (group P) or infusion of normal saline (group S). Maternal	Number of physician interventions (primary outcome), hemodynamic performance, nausea/vomiting and umbilical cord blood gas values were compared between the groups. Maternal blood pressures maintained within 20% of baseline.	Incidence of hypotension (8/40 [20%] vs 35/39 [90%]) were lower in group P compared with group S ($p < 0.001$). Group P, 4/40 (10%) patients had nausea/vomiting compared with 17/39 (44%) in group S ($p = 0.001$).	2A
das Neves et al., 2010)	Compare the efficacy of the administration of therapeutic or prophylactic doses of phenylephrine to maintain blood pressure in patients undergoing spinal block for planned cesarean section.	Prospective, Randomized, Double Blind Study.	120 Gravidas randomly divided in three equal groups. Group 1, continuous infusion of phenylephrine, at 0.15 μg/kg/min-1 was administered after the spinal block. In Group 2, a single dose of prophylactic phenylephrine 50 μg was administered after the spinal block, and Group 3 received a single dose of phenylephrine 50 μg in case of hypotension	Drop in SBP and/or DBP of up to 20% of baseline levels. Incidences of nausea and vomiting were recorded as well	The incidence of hypotension was significantly greater in Group 3, affecting 85% of the gravidas. In Groups 1 and 2 hypotension was seen in 17.5% and 32.5% of the cases respectively ($p < 0.001$). The incidence of nausea was much higher in Group 3 affecting 40% of the patients while in Groups 1 and 2 it was 10% and 15% respectively which was statistically significant.	2 A

Rating System for Hierarchy of Evidence

Level of the Evidence	Type of the Evidence
I (1).	Evidence from systematic review, meta-analysis of randomized controlled trails (RCTs), or practice-guidelines based on systematic review of RCTs.
II (2)	Evidence obtained from well-designed RCT
III (3)	Evidence obtained from well-designed controlled trials without randomization
IV (4)	Evidence from well-designed case-control and cohort studies
V (5)	Evidence from systematic reviews of descriptive and qualitative studies
VI (6)	Evidence from a single descriptive or qualitative study
VII (7)	Evidence from the opinion of authorities and/or reports of expert committees

Melnyk, B.M. & Fineout-Overholt, E. (2014). *Evidence-based practice in nursing & healthcare: A guide to best practice* (3rd ed.). New York: Lippincott, Williams & Wilkins.

Rating Scale for Quality of Evidence

A: High – consistent results with sufficient sample, adequate control, and definitive conclusions; consistent recommendations based on extensive literature review that includes thoughtful reference to scientific literature

B: Good – reasonably consistent results; sufficient sample, 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, R.P. (2006). Examining the support for evidence-based nursing practice. *Journal of Nursing Administration, 36*(7-8), 337-40.

Table 2

AGREE II Tool Results by Domain

Domain	Percentage
Scope & 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%

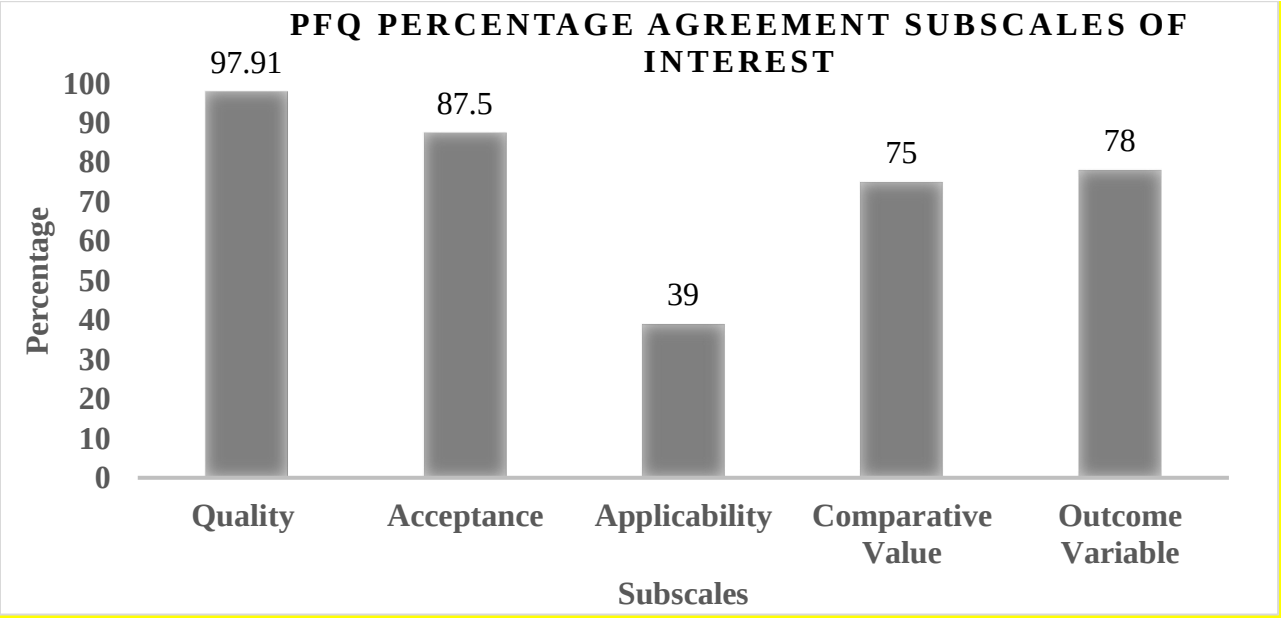

Figure 1. Scores obtained from the evaluation of PFQ Subscales of interest.

Appendix A.

Timeline

1. Timeline of DNP Quality Improvement Project

a. January 2019: Meeting with Stakeholders

b. April 2019: Initial draft of CPG completed

c. June 2019: Submit Proposal to UMB's and the medical center's IRBs
d. June 2019: CPG submitted to stakeholders for analysis utilizing AGREE II Tool

d. June 2019: Revisions made to CPG based upon AGREE II Tool results

e. July 2019: Formal CPG Presentation to Clinical Site Representative

f. July 2019: Formal presentation to Anesthesia Providers and Labor & Delivery staff during Grand round on Thursdays, distribute PFQs

f. July 2019: Revise CPG based upon PFQ results

g. August 2019: Completed CPG posted on bulletin boards and distributed via email.

h. September 2019- January 2020: Project Implementation Period:

i. February 2020: Analyze data

j. April 2020: Data reports and dissemination

Appendix B

AGREE II Score Sheet

Domain	Item	AGREE II Rating						
		1 *Strongly Disagree*	**2**	**3**	**4**	**5**	**6**	**7** *Strongly Agree*
Scope and purpose	1. The overall objective(s) of the guideline is (are) specifically described.							
	2. The health question(s) covered by the guideline is (are) specifically described.							
	3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.							
Stakeholder involvement	4. The guideline development group includes individuals from all the relevant professional groups.							
	5. The views and preferences of the target population (patients, public, etc.) have been sought.							
	6. The target users of the guideline are clearly defined.							
Rigor of development	7. Systematic methods were used to search for evidence.							
	8. The criteria for selecting the evidence are clearly described.							
	9. The strengths and limitations of the body of evidence are clearly described.							
	10. The methods for formulating the recommendations are clearly described.							
	11. The health benefits, side effects and risks have been considered in formulating the recommendations.							
	12. There is an explicit link between the recommendations and the supporting evidence.							
	13. The guideline has been externally reviewed by experts prior to its publication.							
	14. A procedure for updating the guideline is provided.							
Clarity of presentation	15. The recommendations are specific and unambiguous.							
	16. The different options for management of the condition or health issue are clearly presented.							
	17. Key recommendations are easily identifiable.							
Applicability	18. The guideline describes facilitators and barriers to its application.							
	19. The guideline provides advice and/or tools on how the recommendations can be put into practice.							
	20. The potential resource implications of applying the recommendations have been considered.							
	21. The guideline presents monitoring and/ or auditing criteria.							
Editorial independence	22. The views of the funding body have not influenced the content of the guideline.							
	23. Competing interests of guideline development group members have been recorded and addressed.							
Overall Guideline Assessment	1. Rate the overall quality of this guideline.	**1** *Lowest possible quality*	**2**	**3**	**4**	**5**	**6**	**7** *Highest possible quality*
Overall Guideline Assessment	2. I would recommend this guideline for use.	*Yes*	*Yes, with modifications*					*No*

Appendix C

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 ☐ ☐ ☐ ☐ ☐ ☐ ☐

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

1. Are you responsible for the care of patients for whom this draft guideline report is relevant? This may include the referral, diagnosis, treatment, or follow-up of patients.	Yes ☐	No ☐	Unsure ☐
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.	☐	☐	☐
3. There is a need for a guideline on this topic.	☐	☐	☐
4. The literature search is relevant and complete (e.g., no key evidence was missed nor any included that should not have been) in this draft guideline.	☐	☐	☐
5. I agree with the methodology used to summarize the evidence included in this draft guideline.	☐	☐	☐
6. The results of the evidence described in this draft guideline are interpreted according to my understanding of the evidence.	☐	☐	☐
7. The draft recommendations in this report are clear.	☐	☐	☐
8. I agree with the draft recommendations as stated.	☐	☐	☐
9. The draft recommendations are suitable for the patients for whom they are intended.	☐	☐	☐
10. The draft recommendations are too rigid to apply to individual patients.	☐	☐	☐
11. When applied, the draft recommendations will produce more benefits for patients than harms.	☐	☐	☐
12. The draft guideline presents options that will be acceptable to patients.	☐	☐	☐
13. To apply the draft recommendations will require reorganization of services/care in my practice setting.	☐	☐	☐
14. To apply the draft guideline recommendations will be technically challenging.	☐	☐	☐
15. The draft guideline recommendations are too expensive to apply.	☐	☐	☐
16. The draft guideline recommendations are likely to be supported by a majority of my colleagues.	☐	☐	☐
17. If I follow the draft guideline recommendations, the expected effects on patient outcomes will be obvious.	☐	☐	☐
18. The draft guideline recommendations reflect a more effective approach for improving patient outcomes than is current usual practice. (If they are the same as current practice, please tick NA). *NA* ☐	☐	☐	☐
19. When applied, the draft guideline recommendations will result in better use of resources than current usual practice. (If they are the same as current practice, please tick NA). *NA* ☐	☐	☐	☐
20. I would feel comfortable if my patients received the care recommended in the draft guideline.	☐	☐	☐
21. This draft guideline should be approved as a practice guideline.	☐	☐	☐
22. If this draft guideline were to be approved as a practice guideline, I would use it in my own practice.	☐	☐	☐
23. If this draft guideline were to be approved as a practice guideline, I would apply the recommendations to my patients.	☐	☐	☐

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 D
Clinical Practice Guideline

Scope/Purpose

The purpose of this clinical practice guideline (CPG) is to provide a guideline to standardize the perioperative management for women undergoing elective cesarean delivery (CD) at a large community hospital in Central Maryland. The clinical benefits will be to decrease rates of Spinal Induced Hypotension (SIH), Post Spinal Shivering (PSS) and institute Delayed Cord Clamping (DCC). This will facilitate the recovery, thereby decreasing length of stay (LOS), and healthcare costs while increasing maternal satisfaction.

BACKGROUND

Extensive research has shown the Enhanced Recovery After Surgery (ERAS) pathways to be successful in enhancing surgical care, resulting in decreased morbidity, faster recovery and shorter length of stay (Gustafsson et al., 2013). Cesarean delivery is one of the most common surgical procedures in the United States. Though women undergoing planned cesarean deliveries are healthy and 25.7% of cesarean deliveries are considered low risk, complications that include spinal induced hypotension (SIH) and post spinal shivering (PSS) arise during the intraoperative phase, leading to increased morbidity and mortality rates as well as decreased patient satisfaction. Delayed cord clamping (DCC) is another factor that significantly decreases morbidity in neonates.

Method

A literature review was performed to find best evidence-based interventions to manage SIH, PSS and to support DCC. The search was conducted utilizing University of Maryland Health Science and Human Service Library (HSHL) One Search which includes databases and PubMed, CINAHL, EBSCO, and Scopus. Google Scholar and Cochrane Library were utilized as well. Key search terms included, “enhanced recovery”, “cesarean section”, “spinal induced hypotension”, “shivering”, post spinal shivering, delayed cord clamping and “nausea and vomiting”. Titles and abstracts were screened for relevancy. Evidence consisted of meta-analysis, systematic reviews and randomized control trials (RCTs). Inclusion criteria include peer reviewed, full text articles in English published within the past eight years. The level of evidence was rated using the Melnyk & Fineout-Overholt criteria. Quality of evidence was determined by the Newhouse’s Quality Rating Scheme (2006). Refer to Appendix A for explicit details of evidenced retrieved.

The CPG was drafted with input from a panel of experts that included the Director of OB Anesthesia, Director of Fetal Medicine, a registered nurse from Labor and Delivery, an obstetrics resident as well as the hospital statistician.

TARGET USERS

The CPG is intended for use by Anesthesiologists, Certified Nurse Anesthetists (CRNAs) MDs, registered nurses, nurse practitioners

Intraoperative Recommendations:

Spinal Induced Hypotension

Initiate a phenylephrine infusion at 0.75 mcg/kg/min IV within five minutes of the administration of spinal anesthesia. Refer to Table 1 for titration recommendations.

Mahboob and Burki, (2018), Siddik-Sayyid et al., (2014), and Neves et al. (2010) performed RCTs looking at the effects of continuous prophylactic phenylephrine infusion versus phenylephrine boluses in response to hypotension, fluid administration and the number of provider interventions. Siddik-Sayyid et al., (2014) and

Mahboob & Burki (2018) included two randomized groups; one group received boluses of phenylephrine when the blood pressure decreased 20% of baseline and the second group was started on a phenylephrine infusion prophylactically. Mahboob and Burki (2018) found that the group receiving the phenylephrine infusion had less hypotension (p <0.001) and less fluid requirements intraoperatively (p = 0.039). Siddik-Sayyid et al., (2014) not only concluded there was a significant decrease in hypotension and nausea/vomiting (p<0.001) in the phenylephrine infusion group, but by titrating infusions to blood pressures, they had better control in terms of patients becoming hypertensive which is associated with reflex bradycardia and a decrease in cardiac output as well.

Neves et al. (2010) Randomized participants into three groups: group 1 received a continuous infusion of phenylephrine at 0.15 ug/kg/min, group 2 a single dose of 50 ug of phenylephrine after the spinal and group 3 received a bolus of phenylephrine if their blood pressure dropped to less than 20% of baseline. The results are very similar to the previously mentioned studies; there was a significant decrease (p<0.001) in hypotension in group one and two which received some form of phenylephrine prophylactically.

The strengths of the three studies include the fact that they were all randomized and obtained similar results. Weaknesses include relatively small sample sizes as well as the fact that none of the interventions completely abolished incidences of SIH.

Table 1.
Intraoperative Management of Maternal Blood Pressures

Systolic Blood Pressures	**Intervention Recommendations**
SBP < 120 % of baseline	Continue infusion
Hypotensive: SBP <80% and/or less than 100 mmHg	Give phenylephrine bolus 100 ug IV increase infusion by 0.25 mcg/kg/min
Hypertensive: SBP>120% of baseline	Stop infusion, once SBP<120% of baseline restart infusion reduced by 0.25 mcg/kg/min
Bradycardia: HR less than 50 bpm and hypotensive	Give atropine 0.4 mg IV after 1 min if still hypotensive give phenylephrine 100 ug IV and increase infusion by 0.25 ug/kg/min
Bradycardia: HR less than 50 and not hypotensive	Stop infusion, restart when no longer bradycardic, reduce dose by 0.25 ug/kg/min

Post Spinal Shivering

Administer Ondansetron 4 mg IV within five minutes of spinal anesthesia and document shivering scores. Refer to Table 2.

Marashi et al, (2014) study's primary focus was the use of ondansetron to study its effect on blood pressures after spinal anesthesia, and a reduction in shivering was a secondary outcome. They conducted a randomized trial in which the control group received normal saline, one group received 6 mg of ondansetron intravenously (IV) and the other group received ondansetron 12 mg IV The results indicated a statistically significant decrease in nausea and vomiting in the groups that received ondansetron (p=.02). However, the difference in shivering between the two ondansetron groups was not significant, potentially indicating the lower dose may be adequate.

Tie et al., (2014) performed a meta-analysis which included six studies, to examine the effects of ondansetron on PSS. Unlike Marashi et al., (2014) who focused solely on women receiving spinal anesthesia for CS, Tie et al., (2041) encompassed spinal anesthesia in a variety of surgical settings that include orthopedics, cardiac, gynecological as well as CS. The overall conclusion was that ondansetron could reduce incidences of PAS.

Badawy and Mokhtar (2017) also examined the effects of ondansetron in the prevention of PSS. They performed a double-blinded, prospective, randomized, trial that included 80 parturients. The control group

received normal saline and the experimental group received Ondansetron 8 mg IV. Shivering was assessed using a validated scale and incidences of PSS were treated with meperidine. Results indicated there was a higher incidence of shivering in the control group (p=0.007) which also correlated with a higher use of Meperidine in the control group (p =0.01), and shivering scores were also higher in the control group (p=0.005). In conclusion the results of all three studies concluded that the administration of ondansetron can reduce incidences of PAS.

Table 2.
Shivering Grading Scale

Shivering Activity	**Score:**
No shivering	0
Piloerection or peripheral vasoconstriction but no visible shivering	1
Muscular activity in one muscle group	2
Muscular activity in more than one muscle group but not generalized shivering	3
Shivering involving the whole body	4
Note. Tool developed and validated by Crossley AWA, Mahajan RP. The intensity of postoperative shivering is unrelated to axillary temperature. Anesthesia 1994; 49: 205-7.	

Delayed Cord Clamping (DCC)
Delay umbilical cord clamping for 60 seconds after delivery. Proceed only if infant is stable (See Table 3.)

In a systematic review and meta-analysis to examine the effects of early versus delayed cord clamping on preterm infant morbidity and mortality there was a significant decrease in hospital mortality (p=0.05), but no difference in other associated neonatal mortalities (Fogarty et al., 2018)

Chen et al., (2016) acknowledged that DCC was beneficial, however his study analyzed different time intervals for DCC and focused on full term infants. Outcomes measured included hematocrit, jaundice, admission to Neonatal Intensive Care Unit (NICU) and amount of postpartum blood loss. The conclusion of the study indicated that DCC of at least 60 seconds was the most beneficial in increasing hematocrit levels, without adverse effects to mother or infant.

McDonald et al., (2014) completed a Cochrane review to examine the effects of cord clamping timing. Their review concluded that delayed cord clamping was associated with increased birthweight, hematocrit and iron stores.

The strengths of the three studies is the demonstrated benefits to DCC. Though each study looked at slightly different outcomes, there were no harmful effects associated with DCC. As Mercer et al., (2018) concludes, “it is a no-cost approach” with an associated decrease in infant morbidity.

Table 3.

Delayed Umbilical Cord Clamping (DCC) Protocol

1.	Prior to delivery, establish a consensus that cord clamping will be delayed for at least 60 seconds
2.	Prepare two warm sterile towels for transfer of the infant from the obstetrician to the neonatologist.
3.	An assigned timekeeper starts a timer as soon as the infant is delivered from the womb, and thereafter announces the time in 15-second intervals.
4.	DCC: Upon delivery, the infant is held in the warm towel by the obstetrician with the cord attached.
5.	When the delay interval of 60 seconds has been reached, the obstetric provider clamps the umbilical cord in standard fashion and announce “Cord clamped!”
6.	The infant is transferred to the neonatologist’s warm towel and routine newborn resuscitation is performed per current Neonatal Resuscitation Program (NRP guidelines).
7.	The duration of DCC is recorded in the electronic medical record.

Monitoring

Audits will be performed on a semiannual basis. Guidelines will be reviewed and adjusted as needed to ensure guidelines are based on the most current research.

Editorial Independence

There is no financial support and sponsorship and no conflicts of interest have been identified. This project is done for quality improvement.