Protocol Title:	Family-Centered Cesarean: A Randomized Controlled Trial
Protocol Version:	11
Protocol Date:	3/15/2019
Locations:	Aurora Sinai Medical Center, Milwaukee, Wisconsin Aurora BayCare Medical Center, Green Bay, Wisconsin

I. BACKGROUND AND SIGNIFICANCE

Cesarean sections are one of the most common surgical procedures performed world-wide. They are performed for both maternal and neonatal indications. Today, cesarean sections account for 20% of all births globally.[1] From 1996-2009, the rates of cesarean sections in the United States rose approximately 60%; these rates have remained unchanged since 2010. The national rate of cesarean deliveries in 2012 was 32.8%.[2]

As the number of cesarean sections increase and vaginal deliveries decrease, women report that they are less satisfied with their overall child birthing experience.[1, 3-6] Mother and partner experiences differ between cesarean and vaginal delivery; the biggest difference is that, during vaginal delivery, the newborn is more often directly given to mom immediately after birth, which initiates early mother-newborn interactions through skin-to-skin contact and breastfeeding. Additionally, a mother and her support people are able to see their child enter the world without a barrier between them. Cesarean sections create a delay in the mother-newborn interaction, as the newborn is routinely separated from the mother. Such separation leads to later skin-to-skin contact and makes it harder for mothers to initiate breastfeeding.[1, 4] This separation also leads to greater dissatisfaction with the birthing process and a mother is more likely to feel she was unable to participate in the birth of her child.[3]

To improve the overall child birthing experience, the family-centered/gentle cesarean delivery method mimics a vaginal birthing experience. Similar to a vaginal delivery, a mother can watch the birth, and the newborn is immediately placed on the mother's chest following cesarean delivery. Studies have shown that immediate mother-newborn interactions and skin-to-skin contact is advantageous in promoting the bond between mother and newborn, breastfeeding, and overall patient satisfaction with the birthing process.[1, 5] The family-centered/gentle cesarean method is relatively new. Limited information is available in regards to differences in maternal and neonatal outcomes when comparing traditional cesarean methods to that of the family-centered/gentle cesarean. Additionally, available information often refers to this methodology as either family-centered cesarean or gentle cesarean; we will refer to this method as the family-centered cesarean from here on out.

One European study conducted in Germany compared family-centered and traditional cesarean delivery methods, and determined that no additional complications arose for mother or newborn when using the family-centered cesarean method.[6] Although the Memorial Hospital of Rhode Island has implemented the family-centered cesarean method as the standard of care during cesarean delivery, to our knowledge, no studies have been conducted in the United States that compare the family-centered cesarean method to traditional methods of cesarean delivery.[4] Magee et al. further supports that the techniques used in their hospital have not been evaluated and that the hospital's approach to family-centered cesarean deliveries should be further examined as it relates to maternal and neonatal outcomes, as well as overall patient satisfaction.[4]

The purpose of this study is to determine if patient birthing experiences differ between the family-centered and traditional cesarean methods. We hypothesize that the family-centered cesarean method will lead to more unique and personalized cesarean birthing experiences without increasing the risks of adverse neonatal and maternal outcomes from those documented

with the traditional cesarean.

II. SPECIFIC AIMS

Primary Objective

The primary objective of this study is to compare patient satisfaction of the family-centered cesarean birthing experience with that of the traditional cesarean experience.

Secondary Objective

The secondary objective of this study is to determine if skin-to-skin contact (i.e., family bond initiation) occurs earlier and in-hospital breastfeeding initiation is more likely with the family-centered cesarean delivery method than traditional cesarean delivery method.

Tertiary Objective

The tertiary objective of this study is to determine if differences in maternal and neonatal outcomes exist between cesarean delivery methods (family-centered versus traditional cesarean).

III. STUDY DESIGN

Subject Enrollment

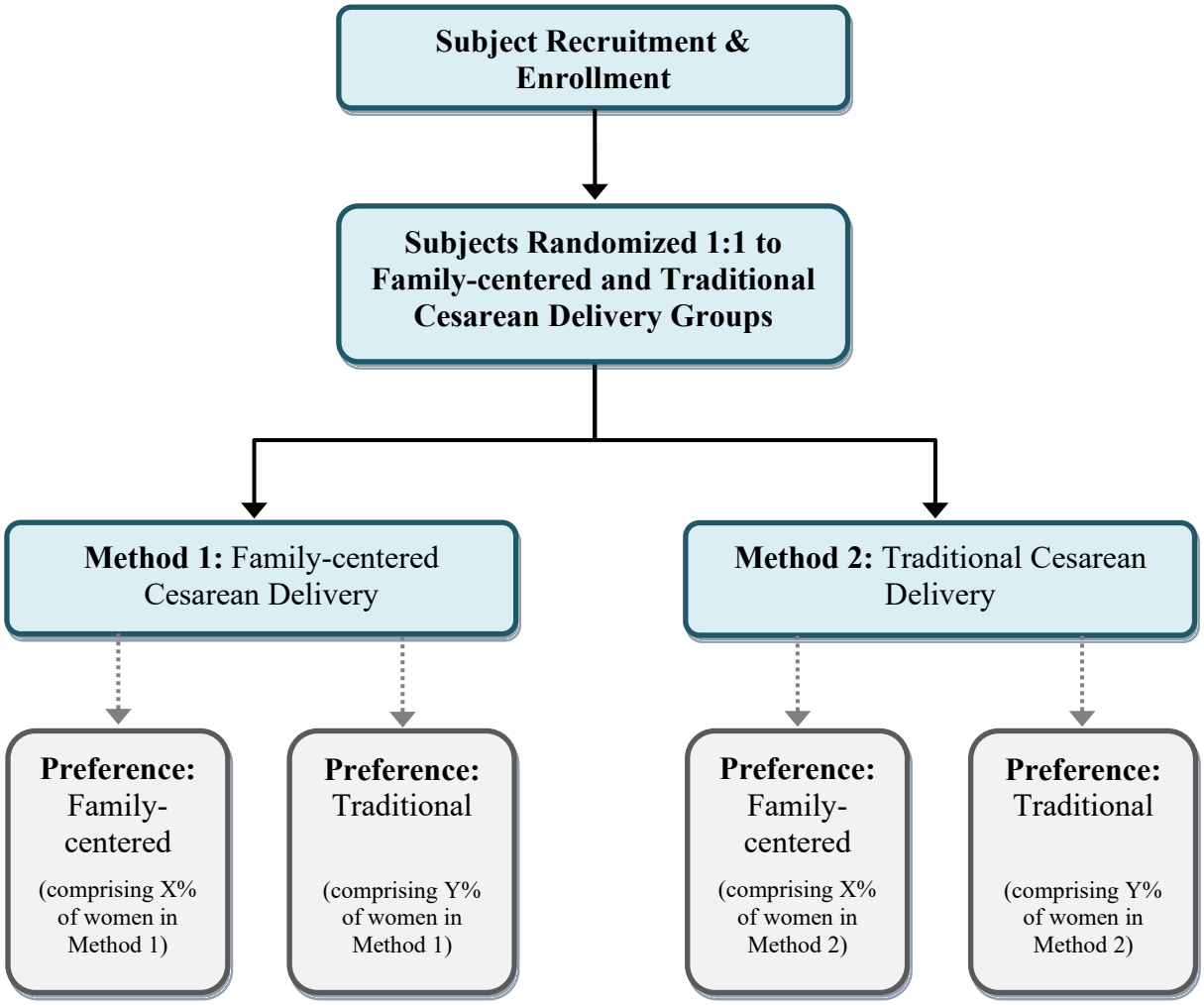
Women undergoing a scheduled cesarean delivery at ≥38 weeks of gestation who present at Aurora Sinai Medical Center and Aurora BayCare Medical Center and have their babies delivered by obstetrics and gynecology physicians during June 1, 2016 through May 31, 2019 will be enrolled in this study. Patients who meet the study criteria will be recruited via obstetrics and gynecology physicians on the day of their scheduled cesarean section. Patients who agree to participate in this study will be formally consented. The study will be described to the patient using the following script, containing objective language so as to minimize bias or influence when the patient is later asked to identify her preference of the 2 cesarean delivery methods. Note that Method 1 below describes the family-centered delivery method, while Method 2 describes the traditional delivery method.

> "We are conducting a patient satisfaction study on two methods of cesarean section. Both of these methods are used throughout the United States, and neither has been proven to be better than the other. Method 1 involves lowering part of the surgical drape exposing a transparent window through which you can watch the birth of your baby; the baby will be placed on your chest immediately after the delivery. Cleaning and evaluation of your baby will be done by a nurse who is standing next to you at the head of the bed. Method 2 involves keeping the surgical drape up throughout the entire surgery so that the birthing process will not be visible, and your baby will be taken to the warmer to be evaluated and cleaned after birth but is available to be laid on your chest at any point upon request."

Randomization to Method

Eligible patients will be formally consented on the day of their scheduled cesarean sections by the research coordinator, resident physician(s), charge nurse or nurse. Following enrollment, each patient will be asked to state which method of cesarean delivery she would prefer, if given the option to choose. Preference represents a potential factor influencing patient satisfaction that will be later incorporated into the statistical analysis, based on a 2 x 2 factorial (Method x Preference) design. Documentation of preference at this time (versus following random assignment to cesarean delivery method) is important for minimizing the bias or influence of the random assignment upon the patient's declared preference.

The patient will be randomized to 1 of the 2 delivery methods by the research coordinator, resident physician(s), charge nurse or nurse, who will present the patient with a sealed envelope. The envelope will contain a slip of paper identifying the patient's random assignment to either the family-centered cesarean delivery method (Method 1) or the traditional delivery method (Method 2). Fifty percent of all envelopes preassembled for patients will contain paper slips stating "Family-centered", while the remaining 50% will contain slips stating "Traditional," allowing for a 1:1 allocation of delivery methods.



Assessment of patient satisfaction following delivery
The primary objective of this study is to compare levels of patient satisfaction with the birthing experience between the two cesarean delivery methods. To assess patient satisfaction, each patient will be verbally surveyed by the study coordinator using an 11-item questionnaire. Similar to the questionnaire used by Armbrust and his colleagues[6], items on our questionnaire will relate specifically to the mother's birthing experience and answers available per item will be in the form of a modified Likert scale, ranging from 1, the lowest level of agreement or degree of satisfaction, to 5, the highest level of agreement or degree of satisfaction. The survey questions will be asked before discharge (approximately within 48 hours after the delivery), to allow sufficient opportunity for the mother and newborn to bond before discharge.

IV. STUDY POPULATION

Pregnant patients who plan to deliver at Aurora Sinai Medical Center (ASMC) and Aurora BayCare Medical Center (ABMC) will be enrolled in this study. ASMC is a 177-bed, urban community-based hospital located in Milwaukee, Wisconsin. In 2014, 2,479 deliveries were performed at this facility with 26.4% of births delivered via cesarean sections. ABMC is a 167-bed, urban community-based hospital, located in Green Bay, Wisconsin. In 2014, 1,623 deliveries were performed at this facility with 26.4% of births delivered via cesarean section. These numbers reflect all cesarean deliveries, but do not necessarily reflect deliveries that are planned, which may total less than ½ of all cesarean deliveries.

Inclusion

- Women ≥18 years of age
- Women with planned cesarean section
- ≥38 weeks of gestation
- Singleton fetus
- Reassuring fetal status (status of scheduled, green and some yellow)

Exclusion

- Women with an urgent or emergency clinical situation in which the medical staff caring for the patient determines that obtaining consent would interfere with the patient's clinical care
- Patients that decline to consent to participate (an opt out log including the consenters initials, time of day, and reason is kept)
- Patients with anticipated heavy intraoperative bleeding (bleeding disorders, placenta previa, suspected placenta abruption, etc.)
- Known maternal co-morbidities that could impact neonatal well-being (e.g., uncontrolled diabetes, etc.)
- Chorioamnionitis or prolonged rupture of membranes (≥18 hours in duration)
- Known fetal anomalies
- BMI ≥45 kg/m^2
- Estimated fetal weight <2000 grams

V. SAMPLE SIZE

No randomized controlled trials have focused on outcomes associated with the family-centered

cesarean method in the United States. Furthermore, the only randomized controlled trial published in the obstetrics literature was a study conducted in Berlin, Germany by Armbrust and his colleagues, who assessed the eligibility of 250 women with indication for planned cesarean section. From this initial population, 205 total women were randomized to the study groups of Charité (family-centered) cesarean delivery and traditional cesarean delivery.[6]

In our study, a factorial design with 2 design variables (Cesarean Delivery Method [Gentle, Traditional] and Preference of Method [Gentle, Traditional]) will be used. A sample size of 508 total patients (127 patients in each of the 4 Method x Preference combinations) has been determined necessary to detect a 0.5-point difference in mean satisfaction scores (on a 5-point scale) and a 15-minute difference in time-to-initiation of family bond between the 2 groups of each design variable, given 2-factor generalized linear modeling with normally-distributed (or log-transformed) responses, standard deviation of 2 points (for satisfaction score) and 1-hour (for family bond initiation), alpha of 0.05, and power of 0.80. Moreover, to detect a 15% difference in probability of breastfeeding prior to discharge between the 2 groups of each design variable using logistic regression, a sample size of 432 total patients (108 patients in each of the 4 Method x Preference combinations) would be necessary. To detect clinically-relevant differences for all outcomes (responses) of interest in the Primary and Secondary Objectives, we will target 508 total patients.

VI. DESCRIPTION OF DELIVERY METHODS

Method 1: Family-centered cesarean
Standard preoperative preparation will be performed in the patient's room, including surgical site hair clipping, chlorhexidine wash (at ASMC only), IV placement, completion of pre-procedure operating room checklist, and administration of prophylactic antibiotics, antiemetics (at ASMC only), and fluids. The patient will then be taken to the operating room. The pulse oximeter will be placed on the mother, and the electrocardiogram leads will be placed away from anterior chest wall or via an EKG back-patch to allow space for newborn and mom skin contact. Regional spinal anesthesia will be administered in normal fashion. The mother will lie down on the bed and, once sufficient anesthesia block is obtained, her gown will be removed and a blanket will be provided for her to cover her chest, allowing for easier skin-to-skin contact after delivery. Prior to the lowering of the drape, the mother's head will be elevated. Fetal heart tracing will be monitored until adequate block is obtained to confirm fetal well-being.

Preoperative preparation will continue with abdomen preparation. We will then wait 3 minutes from wash to dry before placing the blue drape on the mother's abdomen and attaching it to the IV poles, thereby screening the mother from the first part of the surgery. After the fetal head enters the uterine incision, the opaque layer of the drape will be lowered, exposing a transparent drape layer that will enable the mother and her support person to watch the birth. The drape will only be lowered and the rest of the family-centered technique carried out if no complications occur during the operation. In the event of unexpected complications, such as heavy bleeding or problems with delivery of the newborn's head, the surgical drape will not be lowered. Provided that the technique is continued, the newborn's head, followed by the rest of the body, will be delivered by the surgeon in full view of the mother. The umbilical cord will be clamped and cut by the surgeon, and the newborn will then be handed off to the nurse waiting by the mother's

head. The nurse will be holding a sterile drape to receive the newborn and prevent contamination of the surgeon's hands. The nurse will then immediately place the newborn on the mother's bare chest skin, or be given to the mother's support person, where the newborn will be dried and warmed with fresh towels. The opaque layer the drape will then be raised back up, screening the mother from the remaining surgery.

While on the mother's chest, the newborn's well-being will be initially evaluated by the nurse and respiratory therapist per hospital cesarean section protocol. APGAR scores will be obtained, and the pulse oximeter will be applied to the newborn's right hand. Suctioning needed at that time will be performed using a bulb or mechanical suction. The nurse will remain near the patient's head, as long as needed to ensure maternal and neonatal well-being. Should the mother develop complications that prevent her from being able to comfortably hold the newborn, such as nausea/vomiting, fatigue, or drowsiness from medications, the nurse will be available to help with the newborn. As long as the patient remains stable, the newborn will be laid on mother's chest in a way that allows suckling. The newborn vitamin K administration and erythromycin ointment can be applied per hospital protocol, either while she is holding the newborn or after she is in recovery. The newborn will be weighed following surgery, while the mother is transferred to her bed, unless she requests it be done earlier.

Method 2: Traditional cesarean
Standard preoperative preparation will be performed in the patient's room, including surgical site hair clipping, chlorhexidine wash (at ASMC only), IV placement, completion of pre-procedure operating room checklist, and administration of prophylactic antibiotics, antiemetics (at ASMC only), and fluids. The patient will then be taken to the operating room. The pulse oximeter will be placed on the mother's finger, and electrocardiogram leads will be placed in the usual fashion on the chest. Regional spinal anesthesia will be administered in normal fashion. The mother will lie down on the bed, and fetal heart tracing will be monitored until adequate block is obtained to confirm fetal well-being.

Preoperative preparation will continue with abdomen preparation. We will then wait 3 minutes from wash to dry before placing the blue drape on the mother's abdomen and attaching it to the IV poles, thereby screening the mother from the entire surgery. After delivery, the newborn will be handed off to a nurse waiting at the side of the mother who will take the newborn to the warmer on the opposite side of the operating room. The newborn will be dried and warmed with fresh towels on the warmer, while being evaluated by the nurse and respiratory therapist per hospital cesarean section protocol. The nurse will then proceed with newborn measurements, weight, bath, and administration of vitamin K and erythromycin ointment. The newborn will be swaddled and kept in the warmer until the mom requests that the newborn be brought to her or until the surgery has been completed and the mom is ready to be transferred to the recovery room.

VII. DATA COLLECTION

Patients will be followed throughout their hospital stay. The following variables of interest will be retrospectively collected from EPIC or recorded during the surgery on the OR Worksheet (* - Note, the OR Worksheet was updated on 2/16/2018.):

Maternal Variables of Interest

- Medical record number
- Date of birth
- Delivery Hospital (0=ASMC; 1=ABMC)
- Date of consent for scheduled cesarean section
- Date of procedure
- Calculated maternal age
- Race
- Ethnicity
- Gravidity (Gx)
- Parity (Pxxxx)
- Gestational Age (XwXd)
- Height (inches)
- Weight (lbs)
- Calculated BMI (kg/m^2)
- History of previous vaginal delivery (0=No; 1=Yes)
- History of previous cesarean delivery (0=No; 1=Yes)
- Reason for previous cesarean delivery
- History of previous abdominal/pelvic surgery (0=No; 1=Yes)
- Reason for planned cesarean delivery
- Type of cesarean delivery technique (0=Family-centered; 1=Traditional)
- Identified mother preference (0=Family-centered; 1=Traditional)
- Type of cesarean delivery (0=NA; 1=Classical; 2=Low Transverse)
- Type of skin incision (0=NA; 1=Pfannenstiel; 2=vertical)
- Operative start time (00:00:00)
- Operative stop time (00:00:00)
- Duration of operation (minutes)
- Estimated blood loss (mL)
- Hemorrhage EBL >1000mL (0=No; 1=Yes)
- Complications occurred (0=No; 1=Yes)
- Type(s) of complication(s) that occurred
- If the mother's delivery technique was family-centered, was she switched to a traditional cesarean? (0=No; 1=Yes)*
- Was mom offered to view the birth of her baby? (0=No; 1=Yes)*
- If offered to view the birth of her baby, was the drape dropped? (0=No; 1=Yes)*
- Was mom/other support person offered baby right away? (0=No; 1=Yes)*
- Physician Name
- Did family bond occur in the OR? (0=No; 1=Yes)*
- Time from birth to initiation of family bond (minutes)*
- Person who initiated family bond (0=Mother; 1=Father; 2=Other Support Person)*
- Family bond interrupted in the OR (0=No; 1=Yes)*
- Reason family bond interrupted in the OR*
- If the family bond DID NOT occur, why not?*

- Surgical site infection associated with this surgery (0=No; 1=Yes)
- Time to skin-to-skin contact & all other related skin-to-skin variables identified
- Breastfeeding status flowsheet data (3=Unknown; 2=No; 1=Yes)

Neonatal Variables of Interest

- Birth weight
- 1-min APGAR
- 5-min APGAR
- Documented neonatal infection (0=No, 1=Yes)
- Newborn heart rate at 10 minutes*
- Newborn respiratory rate at 10 minutes*
- Newborn temperature at 10 minutes*
- Time taken for newborn to reach oxygen saturation >90%*

Assessment of patient satisfaction will be conducted following delivery. Questions from an 11-item questionnaire will be asked of the patient by the study coordinator, Jessica Kram, or one of the resident physicians or the nurses/charge nurses at ASMC and study coordinator, Taylor Romdenne, or one of the nurses or charge nurses at ABMC. Please see the questionnaire displayed in a separate document.

Please note, that while we aim to obtain the OR worksheet and patient satisfaction survey from all patients enrolled in the study, there may be circumstances in which one or the other were not completed. If a patient has either the OR worksheet or the patient satisfaction survey completed, we will not exclude them from the study/analyses, but it will be adjusted for.

We will perform interim analyses throughout the study. In order to identify those individuals who may not have been asked to participate within our study or who did not participate within our study (we will not know specifically who declined or who was not asked to participate), we are requesting data from our Quality Teams, within our labor and delivery units, and Research Analytics. Individuals who were classified as scheduled or planned non-emergent (green or yellow) cesarean deliveries will be identified, as planned emergent (those deemed red) cesarean deliveries are not eligible for the study. Additionally, all variables of interest identified above may be requested in addition to variables of interest that would allow us to further determine whether a patient was ever eligible for the study (see study inclusion and exclusion criteria).

Please note, the OR Worksheet and patient satisfaction surveys were updated on 2/16/2018. Based on our interium analyses, we have decided to change the OR worksheet and patient satisfaction surveys to further clarify how we want data to be collected/recorded. Our biostatistician carefully reviewed the changes to make sure that we are acquiring the same information, but in a clearer manner (i.e., there is less room for interpretation). Furthermore, changes on the translated patient satisfaction survey were reviewed by a certified Aurora Translator, who verified that the document was clear/the changes made are appropriate.

VIII. STATISTICAL PLAN

To describe our study population and assess equivalency in characteristics among patients in the 4 Method x Preference combinations, we will compute frequencies, means with 95% confidence intervals, and medians with interquartile ranges, as appropriate per variable type. Differences among the groups will be tested using the Pearson chi-squared test of independence, Student's t-test, or Wilcoxon's rank sum test, respectively. To generally describe the outcomes (responses) corresponding to each of our 3 study objectives, both within and across the 4 Method x Preference combinations, we will again compute frequencies, means with 95% confidence intervals, and medians with interquartile ranges, as appropriate per variable type.

For each outcome of interest, we will also develop a mixed regression model to examine the fixed main and interaction effects of Method and Preference. All models will be structured with appropriate response distributions, likely including the lognormal (normal distribution with natural log-transformed response) for continuous responses (e.g., time, weight, vitals), multinomial for survey questions of satisfaction, and binomial for 2-category outcomes (e.g., breastfeeding). Following back-transformation or exponentiation of parameter estimates, model results will be interpreted, respectively, as the percentage difference between groups, ratio of odds of a lower value, and ratio of odds of an outcome occurring. Unobserved outcome heterogeneity will be captured by the delivering physician nested within hospital, each combination of which will define a separate random variable and model intercept.

IX. POTENTIAL RISKS AND BENEFITS

Risks associated with Method 1 (family-centered cesarean delivery) include unforeseen patient and/or family discomfort with viewing the surgical field. Patients will be made aware of the potential risk of such discomfort prior to consenting to participating in the study. Notably, risks of this nature are a normal component of any cesarean delivery. Therefore, we will discuss the risk of viewing discomfort with all patients regardless of study participation. An additional risk associated with participating in either method could be loss of confidentiality due to obtaining limited protected health information. However, to minimize risk, all data will be stored on a password protected computer.

A potential benefit of our study is that we may be able gather level-1 evidence to support local, regional, and possibly broader use of a novel method of cesarean delivery, currently being explored nationally and internationally. We hypothesize that there will be improved maternal satisfaction using the family-centered method. We also hypothesize that neonatal morbidity will not be increased and benefits may include earlier skin-skin contact and greater likelihood of breastfeeding.

X. REFERENCES

1. Alba-Romero C, Camaño-Gutiérrz I, López-Hernández P, et al. Postcesarean Section Skin-to-Skin Contact of Mother and Child. Journal of Human Lactation. 2014; 30(3): 283-286.
2. Martin JA, Hamilton BE, Osterman MJK, et al. National Vital Statistics Report - Births: Final Data for 2012. Centers for Disease Control and Prevention. 2013; 62(9).
3. Smith J, Platt F, Fisk NM. The natural cesarean: a woman-centred technique. BJOG. 2008; 115:1037-1042.

4. Magee SR, Battle C, Morton J, Nothnagle M. Promotion of Family-Centered Birth with Gentle Cesarean Delivery. Journal of American Board of Family Medicine. 2014; 27(5): 690-693.
5. Moran-Peters JA, Zauderer CR, Goldman S, et al. A Quality Improvement Project Focused on Women's Perceptions of Skin-to-Skin Contact After Cesarean Birth. Nursing for Women's Health. 2014; 18(4): 296-303.
6. Armbrust R, Hinkson L, Von Weizsäcker K, Henrich W. The Charité cesarean birth: a family orientated approach of cesarean section. The Journal of Maternal-Fetal & Neonatal Medicine. 2015; 1-6.