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Every Drop Counts: Quantifying Blood Loss Can Lead to Early Detection and Intervention for Postpartum Hemorrhage

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Every Drop Counts: Quantifying Blood Loss Can Lead to Early Detection and Intervention for Postpartum Hemorrhage

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Dedication

To my husband Agapios, children Paul, Anastasia, and Demitri: Your unwavering love, support, and patience with me during my education and this process… I am forever grateful. To my mom Olga: Thank you. Words cannot express the gratitude I have for you. I would not be who I am today without you. And to my stepdad George, my silent cheerleader: I would not be where I am today without you.
I love you.

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Abstract

A visual estimation has been the standard measurement for blood loss post vaginal or cesarean section delivery. Research has shown that visual estimation also known as estimated blood loss has led to an underestimation of total blood loss volume. This results in over 100,000 women per year in the United States that experience an adverse effect due to delayed recognition and treatment for postpartum hemorrhage. By quantifying blood loss, the volume is measured by a one to one ratio; one-gram weight is equal to one-milliliter blood volume. To promote the evidence-based practice of quantifying blood loss, a quality improvement project was designed and implemented in a labor and delivery department of a suburban, community-based hospital on the city limits of Philadelphia, Pennsylvania. Data were collected via a retrospective record review before and following the implementation of quantifying blood loss measurement during the recovery period of all deliveries. Results: Clinical significance was noted utilizing quantified blood loss during the recovery period following vaginal and cesarean section deliveries. The rate of postpartum hemorrhage did decrease from 7.6% pre-intervention to 5.6% post-intervention, although this result was not statistically significant.

Keywords: Postpartum hemorrhage, postpartum blood loss, maternal mortality, maternal morbidity, estimated blood loss, quantified blood loss

Table of Contents

List of Tables

List of Figures

Every Drop Counts: Quantifying Blood Loss Can Lead to Early Detection and Intervention for Postpartum Hemorrhage

Chapter 1

Introduction and Background

Postpartum Hemorrhage

According to the Association of Women's Health, Obstetric, and Neonatal Nurses (AWHONN) (2019), postpartum hemorrhage is the leading cause of maternal mortality in the United States. Fifty-three to 94% of deaths from postpartum hemorrhage have been identified as preventable. Every year, 125,000 women in the United States will experience a postpartum hemorrhage resulting from a failure to treat excessive blood loss (Association of Women's Health, Obstetric, and Neonatal Nursing [AWHONN], 2014). In an article by Brown (2017), the author states the American College of Obstetricians and Gynecologists (ACOG) defines postpartum hemorrhage as a cumulative blood loss of 1000 milliliters or more regardless of delivery route and may be accompanied by signs and symptoms of hypovolemia within 24 hours after delivery. The American College of Obstetricians and Gynecologists also notes that a blood loss greater than 500 milliliters in a vaginal delivery should be considered abnormal and serve as an indication for further investigation of increased blood deficit (Brown, 2017).

Traditionally, obstetric providers estimate the amount of blood loss after every delivery, whether vaginal or cesarean section. Providers estimate the amount of blood on the pads and active bleeding a mother experiences postpartum. AWHONN and the American College of Obstetricians and Gynecologists (ACOG) have determined the most accurate way to measure blood loss is to quantify the amount of blood. By using calibrated containers and weighing all bloodied pads, providers can get a cumulative amount of blood loss (ACOG, 2019). To decrease

the occurrence of obstetric hemorrhage, quantified blood loss (QBL) needs to be implemented into practice by providers and nursing staff. With education and training, this practice change can be easily added to postpartum care.

According to AWHONN (2019), Georgia, New Jersey, and Washington, DC., are states with the highest occurrence of postpartum hemorrhage and therefore the first to implement QBL into their practice (AWHONN, 2014). Currently, this author's facility does not have this assessment as part of their practice.

In an article by Girault, Deneux-Tharaux, Sentilhes, Maillard, & Goffinet (2018), women with untreated postpartum hemorrhage may experience heart palpitations, breathlessness, fatigue, infections, and/or death. They are also at risk for maternal stress, anxiety, emotional instability, and postpartum depression. These signs and symptoms can affect maternal- newborn bonding and can also be associated with developmental delays in the infant (Girault et al., 2018, p. 2). Using QBL to measure blood loss can aid in interventions for both mother and infant if increased blood loss after delivery is identified.

Costs

Postpartum hemorrhage can affect costs due to an extended length of stay, staffing to care for the patient, resources such as medications, equipment, and blood products and can go into the tens of thousands or more. In an article by Marshall et al., (2017), the authors state the financial impact on the length of stay has not been thoroughly examined but, data from the length of stay for inpatient daily obstetric charges was extrapolated for their study and showed that the increased cost was approximately $106.7 million annually due to a result of postpartum hemorrhage. The authors also mentioned that postpartum hemorrhage negatively affected other

aspects of the patients' and family's lives such as the legal costs and payments incurred due to poor patient outcomes (p. 344.e4).

Recent research

The World Health Organization (WHO) recommends visual estimation of blood loss as the standard for blood loss measurement, but there has been evidence to show there is underestimation which potentially leads to delayed recognition and interventions for the treatment of postpartum hemorrhage. Visual estimation compared to spectrophotometry, a light-absorbing measurement has shown a 30-50% discrepancy in the amount of estimated blood loss (Ambardekar, Shochet, Bracken, Coyaji, & Winikoff, 2014; Borovac-Pinheiro et al., 2018; Gabrielloni, Armellini, Barbieri, & Schirmer, 2014; Lilley et al., 2015). Accurate measurement of blood loss post-delivery assists in the management of postpartum patients and allows for the readiness of the healthcare team for resuscitative measures. According to the Association of Women's Health, Obstetric, and Neonatal Nursing (AWHONN) (2015), research studies cited from Brant, 1967; Pritchard, 1965; Al Kadri, Al Anazi, & Tamim, 2011; Jones, 2015 discuss that quantitative measurement of blood loss is an accurate method and should be used in place of visual estimation. Doing so will allow the health care team to recognize and treat postpartum hemorrhage earlier during the recovery period ("AWHONN," 2015).

Outcomes and Limitations

There were two desired outcomes of this project. One outcome was to implement QBL to decrease the incidence of complications associated with postpartum hemorrhage. Early recognition and initiation of intervention(s) are key components to decreasing postpartum hemorrhage. By implementing QBL in place of estimated blood loss (EBL), physicians and staff can diagnose and treat this potential complication of childbirth promptly. The other desired

outcome after implementation was to have a QBL flowsheet row or another designated area of documentation built into the electronic health record (EHR) to differentiate the amount that was quantified versus estimated.

Limitations to implementing quantified blood loss would be due to inadequate education and training of new staff to the policies and procedures for postpartum hemorrhage. Staff resistance to change may also be a possible limitation. Currently, the staff does not weigh any bloodied pads or other items such as gowns or sheets. With this implementation, staff will be weighing all bloodied pads and items for two hours beginning from the start of the recovery period.

PICOT Statement

In postpartum patients, is quantifying blood loss compared with estimating blood loss more accurate in diagnosing postpartum hemorrhage?

Methodology

The study was a retrospective record review of data collected and analyzed over six weeks, pre-and post-implementation of the practice change of quantified blood loss (QBL). Until a designated area for QBL is implemented into the EHR, the nursing staff was educated and trained on quantifying blood loss and entering the value and comment to state QBL value into the EBL row of the Intake and Output flowsheet. Through a retrospective record review, the project coordinator evaluated whether QBL measurements are a more accurate measure of blood loss during the two-hour recovery period after delivery compared to estimated blood loss (EBL). The retrospective data was extracted and collected from the electronic health record available from the health system, and then an analysis of pre-and-post-implementation of the practice change of quantified blood loss measurement was performed.

Through reviewing the literature, it has shown that visual estimation is not as reliable as was once believed in measuring blood loss after vaginal or cesarean section delivery. Therefore, I am going to educate and implement quantified blood loss measuring to the nursing staff and then conduct a retrospective record review to compare estimated blood loss (EBL) versus quantified blood loss (QBL) to determine if QBL is more accurate in diagnosing postpartum hemorrhage.

Chapter 2

Literature Review

Overview

The literature review contains the definitions and descriptions of the variables and concepts involved in this quality improvement project of how quantifying blood loss compared to estimated blood loss can lead to early detection and intervention for postpartum hemorrhage. Also included in the description of the theoretical framework used and how it applies to this project, a review of the current literature on estimated and quantified blood loss measurements and gaps in the literature.

Definitions of variables and concepts

For this quality improvement project, postpartum hemorrhage (PPH), also known as obstetric hemorrhage is defined as a blood loss of greater than 500 ml for a vaginal delivery and greater than 1000 ml for cesarean delivery (California Maternal Quality Care Collaborative, 2015; Sentilhes et al., 2016, p. 14). According to the Mayo Clinic (2020), Cesarean delivery is a surgical procedure used to deliver a baby through incisions in the abdomen and uterus (Mayo Clinic, 2020). Cesarean section and Cesarean delivery are used interchangeably. Estimated blood loss (EBL) and visual estimation of blood loss are also used interchangeably. Quantified blood loss (QBL) and quantitative blood loss are interchangeable. The patients referenced in this project and review of the literature are also referred to as maternal and/or mother.

Theoretical framework

The theoretical framework for this quality improvement project is Neuman's System Model of nursing. According to Aylward (2005), Betty Neuman first developed the Neuman's Systems Model in 1970 for student learning. Today the model is widely used as a nursing

conceptual model (Aylward, 2005, p. 281). Nursing, the fourth concept in Neuman's model, focuses on maintaining a stable client system. To maintain a stable client system, the nurse must assess the effects and potential risks to the client and assist with adjustments to the environment to obtain or maintain optimal wellness. Neuman labeled these actions as preventions, primary prevention, secondary prevention, and tertiary prevention. Each of these preventions leads to the same end goal of obtaining and maintaining optimal wellness (Aylward, 2005, p. 288).

Fawcett (2017), describes primary prevention in Neuman's Systems Model as retaining wellness by increasing the strength in the line of defense to decrease stress and risk factors. An example of primary prevention related to this quality improvement project is to measure the patient's post-delivery bleeding by quantifying blood loss and monitoring vital signs for any changes outside of their normal threshold. By promoting a stable and healing environment for the postpartum patient, they can bond with their infant and the mother's life is not in danger (Fawcett, 2017, p. 164).

Secondary prevention in Neuman's Systems Model is described as increasing the strength of resistance by symptom management and treatment. Should the patient experience increased vaginal bleeding and a change in vital signs related to blood loss, the postpartum hemorrhage protocol is to be initiated to avoid further changes in the patient's status. Interventions such as medications, intravenous fluid therapy, or resuscitation, would be instituted. Continuous quantification of blood loss is necessary to obtain an accurate measure of the amount of blood loss. The patient would remain on close observation within the labor suite on continuous monitoring (Fawcett, 2017, p. 164).

Tertiary prevention is the maintenance of wellness by supporting the patient's strengths and reserves. The patient in this prevention has had a severe postpartum hemorrhage, has been

given the appropriate therapies and treatments to stabilize their bleeding and has been transferred to the intensive care unit for further observation (Fawcett, 2017, p. 164). (Figure 1)

Review of the literature

A thorough review of the literature was conducted using electronic databases PubMed, CINAHL Google Scholar, and Ovid. The search terms and keywords used included *blood loss, estimated blood loss (EBL), quantified blood loss (QBL), hemorrhage, postpartum hemorrhage (PPH), vaginal delivery, cesarean delivery, cesarean section, OB emergencies, obstetric hemorrhage, visual estimation, maternal death, maternal morbidity, maternal mortality.* The inclusion criteria included English language, peer-reviewed, human subject, and published between 2010 and 2019. Exclusion criteria were bleeding disorders, clotting disorders, hemophilia, termination of pregnancy, non-obstetric patients. The search resulted in 50 current sources, of which 15 were selected based on the significance of the focus of this literature review. The two main focal areas are quantitative and estimated blood loss. The articles included prospective observational studies, simulations, case reviews, clinical opinion, cross-sectional study, practice briefs, quality improvement initiative, randomized trials, systematic reviews, and evidence-based quality improvement projects.

Postpartum hemorrhage

According to the literature, postpartum hemorrhage is the leading cause of maternal morbidity and mortality worldwide. In 2015, more than 80,000 maternal deaths occurred secondary to postpartum hemorrhage. Blood loss amounts after a vaginal delivery versus a cesarean section vary greatly with a difference of a few hundred milliliters. In the literature, volumes range from less than 500ml to 1000ml respectively by visual estimation and most women tolerate postpartum blood loss well apart from preexisting comorbidities. Risk factors

for postpartum hemorrhage include but are not limited to placental implantation issues, multiple gestation, anemia, and advanced maternal age (Bamberg et al., 2016; Borovac-Pinheiro et al., 2018; Briley et al., 2014; Pacagnella et al., 2013; "AWHONN," 2015; Lilley et al., 2015).

Estimated blood loss

The World Health Organization (WHO) recommends visual estimation of blood loss as the standard for blood loss measurement, but there has been evidence to show there is underestimation which potentially leads to delayed recognition and interventions for treatment. Visual estimation compared to spectrophotometry has shown a 30-50% discrepancy in the amount of blood loss estimated (Ambardekar, Shochet, Bracken, Coyaji, & Winikoff, 2014; Borovac-Pinheiro et al., 2018; Gabrielloni, Armellini, Barbieri, & Schirmer, 2014; Lilley et al., 2015). Studies conducted using high fidelity simulation for visual estimation of blood loss for physicians and midwives also found visual underestimation by 40-49% (Hancock, Weeks, & Lavender, 2015). Simulations conducted in the operative areas also show that blood loss measurement by visual estimation is an inaccurate and unreliable method for measuring regardless of provider specialty or level of expertise (Rothermel & Lipman, 2016).

Quantitative blood loss

Accurate measurement of blood loss post-delivery assists in the management of postpartum patients and allows for the readiness of the healthcare team for resuscitative measures. According to the Association of Women's Health, Obstetric, and Neonatal Nursing (AWHONN) (2015), research has shown that quantitative measurement of blood loss is an accurate method and should be used in place of visual estimation. Doing so will allow the health care team to recognize and treat postpartum hemorrhage earlier during the recovery period ("AWHONN," 2015). Almost twice as many patients have been diagnosed with postpartum

hemorrhage when blood loss is quantified (Borovac-Pinheiro et al., 2018). Vaginal delivery simulation studies using an under-bottom drape and sponges have shown that quantified measured blood loss was found to be more accurate compared to visual estimation especially as blood loss volume increases (Lertbunnaphong, Lapthanapat, Leetheeragul, Hakularb, & Ownon, 2016; Lilley et al., 2015).

The California Maternal Quality Care Collaborative (California Maternal Quality Care Collaborative, 2015) (CMQCC) developed a toolkit for healthcare providers to utilize in the early recognition and treatment of postpartum hemorrhage. The act of quantification measurement is simple, but the staff needs to determine how to best incorporate this practice into their workflow. Weighing blood-soaked materials on a designated scale and documenting their values in their documentation records supports this ongoing initiative. Participants of the Collaborative have also reported that using quantitative blood loss helps to improve interprofessional communication and situational awareness during emergent events such as maternal hemorrhage ("AWHONN," 2015; Bingham, Lyndon, Lagrew, & Main, 2011; Kerr et al., 2016) (Figure 2).

Research gaps

In reviewing the literature, this author has recognized that the length of time for quantification has not been fully explored. For this project, the amount of time for quantifying blood loss is two hours from when the recovery period begins. Only one study was discovered to mention the healthcare team quantified blood loss for two hours post-delivery (Bamberg et al., 2016). No other studies were found to mention that certain time frame or a longer period of measurement. Many of the studies supporting the quantification of blood loss occurred in other countries with more recent research in the United States as evidenced by the

California Maternal Quality Care Collaborative (California Maternal Quality Care Collaborative, 2015). It has been suggested by the CMQCC that sole quantification of blood loss is not possible and that a cumulative blood loss, estimated and quantified, is needed due to the mixing of other body fluids at delivery. Further studies need to be done to identify the correct time frame of monitoring, two hours versus a longer period, and how to best measure blood loss with a minimal margin of error.

Summary

As the literature has shown, postpartum hemorrhage is a leading cause of maternal morbidity and mortality. Early recognition and intervention are paramount to the prevention of poor patient outcomes. By quantifying blood loss after vaginal or cesarean deliveries, the healthcare team can better determine maternal status and management of her postpartum bleeding in a more safe, timely, efficient, effective, equitable, and patient-centered manner (Pavord & Maybury, 2015). The purpose of this quality improvement project using postpartum patients is to determine if quantifying blood loss compared with estimating blood loss is more accurate in diagnosing postpartum hemorrhage.

Chapter 3

Methods

Methodology

This study is a retrospective record review of data that was analyzed over a six- week consecutive period, pre-and post-implementation of the practice change of quantified blood loss (QBL). A retrospective record review is a process aimed at obtaining and analyzing recorded data to determine the appropriateness of a diagnosis, problem identification, treatments and care planning, and the adherence to benchmarks and standards (Sarkar & Seshadri, 2014, p. JG01). The project coordinator evaluated whether QBL measurement is a more accurate measure of blood loss over two hours during recovery after delivery compared to estimated blood loss (EBL). The hypothesis this quality improvement focuses on is QBL and this measure leads to early recognition and intervention of postpartum hemorrhage compared to EBL.

The data was collected and extracted retrospectively from the electronic health record available from the health system using the inclusion and exclusion criteria within the set date ranges for pre- and post-intervention implementation. Retrospective data analysis was performed of pre-and-post- implementation of the practice change of quantified blood loss measurement. The electronic health record, EPIC (Epic, 2017), has already been in place at the facility for two years. Reports built previously within the system can be edited or built to meet the needs of the requestor and the system. The reports built in the system for data extraction and collection were made with parameters requested by the requestor. Reports were edited by changing the inclusion parameters such as age, dates, or other patient information.

To best assist the nursing staff with quantifying blood loss, pictures of dry weight items were taken to show them in their unbloodied state. Nursing staff can use this dry weight

reference sheet as a guide to subtract the difference between the items and obtain an accurate amount of blood loss (Figure 3). Scales have been purchased by the facility and calibrated by biomedical staff. The scales have been placed in the labor rooms only and on the postpartum units. The cesarean section deliveries will recover in the labor room once the subjects enter the recovery phase of care.

Setting

The change in the practice of quantifying blood loss during recovery took place in the setting of a suburban, community-based hospital on the city limits of Philadelphia, Pennsylvania. The hospital is part of a multi-facility, nonprofit healthcare organization. The unit is a labor and delivery suite that includes 10 labor rooms and three operating rooms. The average number of deliveries per year is 3,000 deliveries and all subjects were from the same facility. Data was collected for six weeks of pre-intervention implementation for vaginal and cesarean section deliveries during the period of September 2, 2019, to October 14, 2019. Post-intervention implementation data was collected for three months during the period of January 13, 2020, to February 19, 2020. The inclusion criteria are females of child-bearing age, 18 to 50 years old, singleton pregnancy, low risk, vaginal or cesarean delivery; primary or repeat, total blood loss of 1000 milliliters, or more. Exclusion criteria are multiple gestation, history of bleeding or clotting disorders, termination of pregnancy, or non- pregnant subjects (Table 1).

Stakeholders for project

Key stakeholders include the hospital and nursing administration who approved and supporting this project at the specified site. Once the project is complete, their support will also be paramount in making this practice change system-wide. The obstetricians, nursing staff, pharmacy, residents, obstetrical technicians, anesthesia, and all other ancillary bedside staff are

important for the care of the patients and the continuation of quantifying the blood loss post-delivery. The clinical informatics department for electronic health record maintenance and reporting of data, and the biomedical staff for calibration and preservation of scales for quantifying blood loss. Other stakeholders include but are not limited to: the patients and their families; the medical records department and IT for the electronic health record (EHR); ancillary departments such as the lab and blood bank; other hospital units such as the ICU; finance; legal; community members; and the insurers. All stakeholders involved in direct patient care require education and hands-on practice with return demonstration of quantifying blood loss and following the postpartum hemorrhage protocol.

Sample

As stated in the inclusion criteria, the subjects were females of child-bearing age, 18 to 50 years old, with low risk, singleton pregnancies, that have delivered either by vaginal or cesarean section with a total blood loss of 1000 milliliters or more. There are typically seven scheduled events daily in labor and delivery, either three to four scheduled induction of labor or three to four scheduled cesarean sections. This number does not include patients that arrive due to spontaneous events such as labor or rupture of membranes. On average, there are 240 deliveries per month at this facility. To allow for inclusion and exclusion criteria to be met for the six weeks pre- and post-implementation, data will be collected on a minimum of 148 subjects pre- and post-intervention, respectively.

Ethical Considerations

For human subject protection and Institutional Review Board (IRB) approval, a proposal and application were submitted to the IRB and research committee of this project coordinator's university. Once the university IRB approval was obtained, this project coordinator also

obtained IRB approval from the healthcare facility (Appendix A and B). No direct contact was made with any subject(s), nor was any identifying subject information used. This project was a retrospective record review of de-identified information, which resulted in minimal to no risk to human subjects. Any data collected was in electronic form, with no hard copies maintained. The electronic data was housed on a computer within the locked labor unit which required badge access. The computer required a user assigned log-on and password issued by second-level security through the health system. All information used for this project will be destroyed after three years in a confidential manner.

Budget

The budget for implementation of this project has a few expenses but does not require any outside financial support. The costs for the tabletop scales used to quantify blood loss are estimated to be $172.00 per scale (WW Grainger Inc., 2019) and the labor unit will need a total of 10 scales for the labor rooms and postpartum will need two for their units. This totals $2.064.00 for the countertop infant size scales. The funding for the infant scales is provided by the facility. As this author has been working through the process of this project, the obstetrics department has begun discussing incorporating QBL into practice and with that the purchase of scales. The cost of education materials for staff such as references for dry weights and the hemorrhage protocol will be covered by the department education cost center. The estimated costs for laminated reference sheets are $25.00 for both the labor and delivery rooms and postpartum units (Table 2).

Staff received an education during their working hours through lunch and learns and in-services conducted on the unit by the primary investigator. The staff that was identified as super-users, required manager approval for extra time worked to assist in facilitating education

and demonstrations. Every labor room has a tabletop scale calibrated by biomedical staff. If a scale should not measure accurately, biomedical staff would be notified, and a replacement would be available.

Support and Timeframe

There is extensive support for this QBL project from various sources mentioned in the review of literature as well as older sources from around the world. The education for the change in the practice of estimated blood loss (EBL) to quantified blood loss (QBL) during recovery took place over two weeks. Based on the postpartum hemorrhage initiatives from AWHONN (2015) and the California Maternal Quality Care Collaborative (2015), this healthcare facility's obstetrics clinical environment workgroup began discussions on how best practices are needed for mothers and their families. This project coordinator collaborated with the clinical environment workgroup and subgroup for postpartum hemorrhage to identify key stakeholders, equipment, education, and a timeline to implement the practice change. A ticket has been submitted to clinical informatics to build a flowsheet row within the Blood Loss group in the electronic health record. This will allow the correct documentation of QBL. To date, the only available option is the EBL flowsheet row in Epic. A potential barrier to this documentation was if the QBL flowsheet row is or cannot be built promptly. The staff will have to document within the EBL flowsheet row and flag the entry with a QBL notation. To date, this barrier has been solved. The analysts in the informatics department have built options for QBL documentation. Staff will decide which workflow best works for them and the documentation change will be implemented on April 18, 2020.

The health system administrators are also involved in the obstetric clinical environment workgroup. The nurse managers of the labor and delivery and postpartum units and campus

nurse executive of the campus were approached to discuss the implementation and practice change plan. The project coordinator next met with the assistant nurse managers of the respective units as well as the nursing staff, nurse practitioners, residents, obstetricians, and discussed the plan for practice change. This project coordinator met with the staff and administrators during staff meetings, huddles, and system committee meetings to discuss planning, education, and identifying staff was willing to assist as unit champions. The unit champions received the same education and hands-on practice with the scales that the other staff received as well as extra copies of the dry weights reference sheets to show the staff. Once the staff was educated, the dry weight reference sheets were laminated and available in every labor room.

On the date of the practice change launch, this project coordinator was on-site, along with the unit champions to offer support for QBL and documentation. All reference sheets and calibrated scales were available in each labor room for staff use. Post-launch, in the following one to two weeks, this project coordinator rounded to follow up with staff to review and troubleshoot any issues with measuring via QBL and documentation.

Data Collection

Data collection was from de-identified subjects that met the inclusion criteria. Using the electronic health record, the staff documents in the designated flowsheet for two hours post-delivery and inputs the total QBL amount into the output section. A report built by a reporting analyst from the informatics department pooled the data six weeks before implementation and then the same report was used to pool data for six weeks post-implementation of the practice change. This project coordinator, with the assistance of a statistician, input the data into a program called Stata/MP 15.1 (StataCorp, 2017) program for data analysis.

To provide feedback to the stakeholders, this project coordinator provided dissemination of findings in a written report and present at the obstetrics clinical environment workgroup. A presentation provided the findings to the committee and if adopted, may become a systemwide practice change for all obstetric subjects.

Data Analysis

An independent sample T-test and analysis were performed for the EBL (pre-) and the QBL (post-) groups in the study to determine if the QBL group shows early recognition of untreated postpartum hemorrhage such as a blood loss of 1000 milliliters or more, heart palpitations, breathlessness, fatigue, infections, and/or death and interventions such as blood transfusion for the postpartum subjects.

Rigor

Using the Intake and Output flowsheet in the electronic health record and reports from the Epic system (Epic, 2017), data entered was gathered consistently and run monthly as set forth by the reporting parameters. The method for subject selection for the retrospective record review, as per the inclusion criteria, were selected based on pre-determined criteria to avoid potential bias. The flowsheet used for data entry was tested and calibrated to calculate total output through the Epic corporation (Epic, 2017). Any subjects that did not meet criteria or data entry that is not complete were not included in the record review or monthly reports as it would show data to be inconclusive.

Chapter 4

Results

Data and Analysis

The study was a retrospective record review and data analysis to determine if quantifying blood loss in place of estimated blood loss leads to early detection and intervention of postpartum hemorrhage. This project coordinator consulted with an independent statistician who is not associated with the project but affiliated with the health care facility in which the project was conducted. Data examined included females of child-bearing age, that delivered a full-term singleton pregnancy, either by vaginal delivery or cesarean section, and did not have any blood clotting or pre-existing conditions that would contribute to bleeding.

Pre-intervention data were collected between September 2, 2019, to October 14, 2019. There were originally 330 records in the pre-intervention cohort. Thirty were excluded due to gestational age less than 37 weeks, seven were excluded due to a history of a blood clotting disorder or having a pre-existing condition that could cause bleeding, and 18 were excluded due to missing EBL. This resulted in a final cohort of 275 records for the pre-intervention group. Post-intervention data were collected between January 13, 2020, to February 19, 2020. There were originally 255 records in the post-intervention cohort. Twenty-six were excluded due to a gestational age of less than 37 weeks, 6 were excluded due to a history of a blood clotting disorder, or had a pre-existing condition that could cause bleeding, and ten were excluded due to missing EBL. This resulted in a final cohort of 213 records for the post-intervention group.

The ages of the participants ranged from 16 to 44 (Mean = 31.6, SD = 5.1) and the gestational age ranged from 37 to 41 weeks (Mean = 39.0, SD = 1.0). Delivery methods cesarean section (Mean = 146, SD = 29.9), vaginal delivery (Mean = 340, SD = 69.7), unknown denotes delivery

method not noted in record (Mean = 2, SD = 0.4). Table 3 shows the distribution of participants according to the records reviewed. For this project, a p-value of < 0.05 is considered statistically significant (Table 3).

Table three seeks to determine if the mother's age, gestational age, and delivery method were similar between the two periods. If they are not similar, these factors could potentially affect outcomes instead of just the intervention. A two-sample t-test was used to compare the average mother's age at delivery and average gestational age between the pre- and post-intervention groups. Chi-square tests of independence were used to compare categorical distributions between the two periods. There were no significant differences in age between the two groups, as the average age was 31 in both periods (p=0.743). The average gestational age was about 39 in both groups as well, and this was not significantly significant between the two periods (p=0.163). About 30% of both periods had a cesarean section and 69% of the pre-intervention group and 70% of the post-intervention group had vaginal deliveries. The distribution of the delivery method was not significantly different between the two periods (p=0.451) (Table 4).

The Chi-square test of independence was again used to compare categorical distributions between the two groups (i.e. medication administered for blood loss, transfusion of any blood product, transferred to the Intensive Care Unit (ICU), Postpartum Hemorrhage (PPH)). The Wilcoxon-Rank Sum test was used to compare the distributions for the variables summarized using medians (EBL/QBL). No p-value was computed for the "time to" variables or the amount transfused, as our sample size was insufficient. In the pre-intervention period, the median EBL was 470 (interquartile range: 300-734), and post-intervention, the median QBL was 425 (interquartile range: 300-700). There were no significant differences in the distribution of EBL/QBL between the two time periods (p=0.546). Pre-intervention, 7% (n=18 patients)

received medication for blood loss compared to 3% (n=7 patients) post-intervention. The rate of blood-loss medication administration was not significantly different between the two periods (p=0.105). Pre-intervention, the rate of transfusion (all blood products) was 1.8% (n=5) and post-intervention this rate was 1.4% (n=3 patients). There were no significant differences in the rate of transfusion between the two periods (p=0.724). The median (interquartile range) amount transfused (all blood products) in the pre- and post-intervention periods was 853 milliliters (ml) (355-975 ml) and 650 (325-650 ml), respectively. These two amounts were not statistically compared, and there were only five patients pre-intervention and three patients post-intervention.

The median amount of Red Blood Cell (RBC) transfused was the same in both groups at 650 ml. The median (interquartile range) amount of time (in hours) from delivery to RBC transfusion was 2.7 hours (0.9-17.9 hours) in the pre-intervention group and 65.1 hours (2.2-103.1 hours) in the post-intervention group. While they appear different, there were only 3 RBC transfusions post-intervention, and they occurred 2.2 hours, 65.1 hours, and 103.1 hours post-delivery, thus making the median time 65 hours. Only one patient was transferred to the ICU, and this was a post-intervention patient. It took this patient 2.2 hours from delivery to be transferred to the ICU. The rate of PPH was 7.6% (n=21 patients) in the pre-intervention group and 5.2% (n=11 patients) in the post-intervention group. This was not statistically different between the two time periods (p=0.274).

The next table reviews the same outcomes as the above table, except just for patients who experienced a postpartum hemorrhage (Table 5). The same tests were used in Table 4. There were 21 PPH patients pre-intervention and 11 PPH patients post-intervention. The pre-intervention PPH patients had a median (interquartile range) EBL of 1400 ml (1021-1600 ml) and the post-intervention PPH patients had a median of 1262 ml (1105-1700 ml). There were

no significant differences in the EBL/QBL for PPH patients between the two time periods (p=0.921). The data collected and analyzed shows that the number of PPH patients that received medication for blood loss pre-intervention is 14.3%, (n=3 patients) compared to 9.1% (n=1 patient) of PPH patients' post-intervention. There was no significant difference in the rate of medication administered for PPH patients between the two time periods (p=0.673). 19.1% (n=4 patients) of the PPH patients received a transfusion of any blood product pre-intervention compared to 9.1% (n=1 patient) post-intervention (no significant difference; p=0.461).

The median (interquartile range) total transfused for PPH patients was 914 ml (589-1518 ml) in the pre-intervention period and the one PPH patient who received a transfusion post-intervention received 650 ml (all RBC). The median (interquartile range) of RBC transfused for PPH patients was 813 ml (488-1138 ml) pre-intervention and the one PPH patient who received a transfusion post-intervention received 650 ml. This patient received it 2.2 hours post-delivery, and the median time to RBC transfusion was 1.8 hours (0.7-11.7 hours) in the pre-intervention group. None of the PPH patients pre- or post-intervention were transferred to the ICU.

The results of using QBL instead of EBL for early detection and intervention for postpartum hemorrhage were compared pre- and post-intervention. Of the records reviewed during the six-weeks pre- and post-intervention, no major differences in outcomes were identified. The rate of PPH did decrease from 7.6% pre-intervention to 5.6% post-intervention, although this result was not statistically significant.

Chapter 5

Discussion

Review of the Problem

Regardless of the mode of delivery, whether via vaginal or cesarean section, every woman experiences some blood loss. During pregnancy, the woman's blood volume will increase to accommodate the extra work her body exerts to grow and deliver her baby. Women are usually able to show minimal effects of this blood loss as their bodies compensate for this change in volume. There are, however, over 100,000 women per year in the United States that experience a postpartum hemorrhage. This blood loss volume is 1000ml or more regardless of the delivery method. Until recently, blood loss was measured by visual estimation by the delivery provider. Research has shown that blood loss measurement by visual estimation has led to underestimating the total loss and an increase in the incidence of postpartum hemorrhage. Quantified blood loss measurement has shown that blood loss measurement is more accurate and allows the healthcare team to identify and implement interventions for postpartum hemorrhage before the woman experiences adverse effects.

This project was a retrospective record review of postpartum patients, to compare quantifying blood loss (QBL) with estimating blood loss (EBL) and determine if it was more accurate in diagnosing postpartum hemorrhage.

The theoretical framework used for this project was Neuman's Systems Model, Fawcett (2017), using Primary, Secondary, and Tertiary prevention. Primary prevention for this quality improvement project was measuring the patient's post-delivery bleeding by quantifying blood loss and monitoring vital signs for any changes outside of their normal threshold. Secondary prevention was if the patient experienced increased bleeding and a change in vital signs related

to blood loss, the postpartum hemorrhage protocol was initiated to avoid further changes in the patient's status. Tertiary prevention was the patient had a severe postpartum hemorrhage, was administered appropriate therapies and treatments to stabilize their bleeding and transferred to the intensive care unit for further observation (Fawcett, 2017, p. 164).

Key Findings

Retrospective record review of six weeks pre-intervention (EBL measurement) and six weeks post-intervention (QBL measurement) were reviewed. The results of data collected and analyzed display women of childbearing age, with a low-risk, singleton, term pregnancy, and no pre-existing bleeding disorders were included in the sample. Pre-term gestation, high-risk deliveries, and pre-existing bleeding disorders were excluded. The average age was 31 years old in both periods and the results showed there were no significant differences in age between the two groups (pre- and post-intervention),. The average gestational age was 39 weeks in both groups and was found to be not statistically significant between the two periods. The distribution of the delivery method was also not significantly different between the two evaluation timeframes.

Medications administered for blood loss, transfusion of any blood products, transferred to the Intensive Care Unit (ICU), Postpartum Hemorrhage (PPH) were found to have no significant differences in the distribution of EBL/QBL between the two time periods. Of the total number of PPH, there were 21 PPH patients pre-intervention and 11 PPH patients post-intervention. There were no significant differences in the EBL/QBL for PPH patients between the two time periods. The results of using QBL instead of EBL for early detection and intervention for postpartum hemorrhage were compared pre- and post-intervention. Of the records reviewed during the six-weeks pre- and post-intervention, no major differences in outcomes were identified. The rate of

PPH decreased from 7.6% pre-intervention to 5.6% post-intervention, and although this result was not statistically significant, it was clinically significant. A larger sample size, such as three months pre- and post-intervention would be needed to show statistical significance.

Implications for Practice, Education, and Policy

This study showed quantifying blood loss for two hours post-delivery allowed the healthcare team to identify and begin treatment of postpartum hemorrhage before the patients began to experience adverse events. The nursing staff continues to quantify blood loss for two hours after every delivery in the Labor and Delivery room. If the patient experiences a postpartum hemorrhage on the postpartum unit, the nursing staff also quantify the blood loss and report the volume to the healthcare provider and follow the PPH protocol instituted by the healthcare facility.

Currently the nursing staff document the volume of the QBL and EBL in the Blood flowsheet within the EHR. This project coordinator discussed with the Chair of Obstetrics the importance of needing a designated space for QBL documentation for accurate data entry and collection for any future reports or studies done for QBL and postpartum hemorrhage. This project coordinator also discussed that with the current data entry, if the staff does not differentiate between EBL and QBL documentation with the current workflow there can be incorrect and/ or skewed data in the reports. With the support of the Chair of Obstetrics and the OB Clinical Work Environment workgroup, this project coordinator requested a QBL flowsheet row for documentation to be built into the current EHR.

The Clinical Informatics team demonstrated a QBL calculator and flowsheet row for data entry in the EHR that has been built and tested implementation of the documentation addition will be added to the EHR on April 18, 2020, per the Clinical Informatics Team. Once the

documentation addition is completed, the staff will be educated on the location and the use of the QBL calculator for accurate data entry. Reports run quarterly show completed documentation compliance. This project further enhanced the body of knowledge on quantified blood loss by showing that even with a small sample size of six weeks pre- and post-intervention, there was clinical significance noted. The decrease in the rate of postpartum hemorrhage secondary to QBL measurement shows that weighing the bloodied pads during recovery aids in early recognition and intervention for these postpartum patients and can intercept potential adverse events.

Future Research

This project was expanded to the other acute care sites within the health system as a systemwide practice change for all obstetric patients. The next steps for further research would be to conduct a study to ascertain if there is an increase in the incidence of postpartum hemorrhage in patients with QBL measured greater than two hours post-delivery. Specifically looking at a four and/or six-hour time frame postpartum. There are instances when the patient has had a blood loss that is within the normal range during their recovery but experiences a hemorrhage once they arrive in the postpartum unit. This further research will show if QBL needs to be continued for an extended time outside of the two-hour window. Also, further research can be conducted to determine if there are any differences in other areas such as race, high-risk status, and various diagnoses for example, and their effects on QBL and the rate of postpartum hemorrhage.

Limitations and Bias

This study had a couple of limitations and there was no bias since this was a retrospective record review of patient data. There were no patient identifiers used, only the inclusion and exclusion criteria for all patients that delivered during the six-week pre- and post-intervention timeframe. Of note, there were no design limitations to the study. The most significant limitation was the lack of adequate documentation for QBL. Until the proper flowsheet row and QBL calculator are added to the EHR, the nursing staff must enter the amount of QBL to the EBL flowsheet row and add a comment noting that the value is for QBL. If the notation is not made, the value entered could inadvertently be mistaken for an EBL entry. Also, there were a few instances where the staff entered the QBL value in the Peripad flowsheet row which did not calculate a total output value. The Peripad row is solely used for a singular pad count value. Records with this incorrect data entry had to be excluded from the sample of records reviewed.

Another limitation of this study was if the patient experienced an extended repair post-delivery. The staff was instructed to begin weighing the bloodied pads once the patient enters the recovery period which includes the conclusion of the repair. If the patient has an extended repair, whether vaginal or cesarean, the time to begin QBL measurement can be delayed. The providers still use EBL for their portion of the delivery until the patient enters recovery. Staff questioned if the blood lost during this extended repair time falls into the EBL or QBL value.

Conclusion

The outcome of this study supports and reinforces the use of QBL measurement for postpartum blood loss. Every woman experiences blood loss after delivery and improving patient outcomes is the responsibility of the entire healthcare team. Using a standardized method of measurement to communicate effectively helps to identify hemorrhage early and initiate the

appropriate interventions to deliver safe, timely, effective, efficient, equitable, and patient-centered care that can and does lead to positive patient outcomes.

In this study, the practice change occurred in a suburban hospital that is located on the borderline of the city and the suburbs. There is a vast variety of patients with differing attitudes towards health and wellness. While every patient and delivery are different, the healthcare team needs to take a standardized approach to how blood loss is measured. The difference may not be noticed in an uncomplicated, healthy patient, but every drop can make all the difference to someone else.

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Table 1

Inclusion and Exclusion Criteria

Inclusion criteria
• Female • Age 18 to 50 • Singleton pregnancy • Low-risk pregnancy • Delivery method: vaginal or cesarean section • Cesarean section: primary or repeat • Total of 1000 milliliters blood loss or more
Exclusion criteria
• Multiple gestation • History of bleeding disorders • History of clotting disorders • Termination of pregnancy • Non-pregnant subjects

Table 2

Costs of Equipment and Educational Resources

WW Grainger Inc. (2019). Tabletop Scales Cost -- $172.00/scale
Number of Labor and Delivery Rooms (10) / Postpartum units (2) –12 scales needed
Cost of Education materials (laminated reference sheets) $25.00 total
Total Cost of Equipment and Resources -- $ 2089.00

Table 3. Patient, Pregnancy, and Delivery Characteristics by Intervention Period (n=488)

	Pre-Intervention (n = 275)	Post-Intervention (n = 213)	p-value	All Patients (n = 488)
Mother's Age at Delivery (Mean, SD)	31.5 (5.4)	31.7 (4.7)	0.743	31.6 (5.1)
Gestational Age (Mean, SD)	39.0 (1.0)	38.9 (1.0)	0.163	39.0 (1.0)
Gestational Age, n(%)			0.347	
37	23 (8.4)	23 (10.8)		46 (9.4)
38	40 (14.6)	43 (20.2)		83 (17.0)
39	135 (49.1)	90 (42.3)		225 (46.1)
40	57 (20.7)	44 (20.7)		101 (20.7)
41	20 (7.3)	13 (6.1)		33 (6.8)
Delivery Method			0.451	
C-Section	83 (30.2)	63 (29.6)		146 (29.9)
Vaginal	190 (69.1)	150 (70.4)		340 (69.7)
Unknown	2 (0.7)	0 (0.0)		2 (0.4)

SD = Standard Deviation

Table 4. Patient Outcomes by Intervention Period, All Patients (n=488)

	Pre-Intervention (n = 275)	Post-Intervention (n = 213)	p-value	All Patients (n = 488)
EBL/QBL, Median (IQR)	470 (300-734)	425 (300-700)	0.546	440 (300-712)
Medication Administered for Blood Loss, n(%)	18 (6.6)	7 (3.3)	0.105	25 (5.1)
Transfusion of Any Blood Product, n(%)	5 (1.8)	3 (1.4)	0.724	8 (1.6)
Total Transfused, Median (IQR)	853 (355-975)	650 (325-650)	NA	650 (340-914)
Total RBC Transfusion, Median (IQR)	650 (355-975)	650 (325-650)	NA	650 (340-813)
Time from Delivery to RBC Transfusion (Hours), Median (IQR)	2.7 (0.9-17.9)	65.1 (2.2-103.1)	NA	10.3 (1.5-42.9)
Transferred to ICU, n(%)	0 (0.0)	1 (0.5)	0.255	1 (0.2)
Time from Delivery to ICU Transfer (Hours)	NA	2.2 (NA)	NA	NA
Postpartum Hemorrhage, n(%)	21 (7.6)	11 (5.2)	0.274	32 (6.6)

IQR = Interquartile Range (25th percentile-75th percentile), RBC = Red Blood Cells

NA = Not Applicable, Sample Size Inadequate

Table 5. Outcomes for Postpartum Hemorrhage Patients by Intervention Period (n=32 total)

	PPH Patients Only			
	Pre-Intervention (n = 21)	**Post-Intervention** (n = 11)	p-value	**All PPH Patients** (n = 32)
EBL/QBL, Median (IQR)	1400 (1021-1600)	1262 (1105-1700)	0.921	1323 (1044-1650)
Medication Administered for Blood Loss, n(%)	3 (14.3)	1 (9.1)	0.673	4 (12.5)
Transfusion of Any Blood Product, n(%)	4 (19.1)	1 (9.1)	0.461	5 (15.6)
Total Transfused, Median (IQR)	914 (589-1518)	650 (NA)	NA	853 (650-975)
Total RBC Transfusion, Median (IQR)	813 (488-1138)	650 (NA)	NA	650 (650-975)
Time from Delivery to RBC Transfusion (Hours), Median (IQR)	1.8 (0.7-11.7)	2.2 (NA)	NA	2.2 (0.9-2.7)
Transferred to ICU, n(%)	0 (100.0)	0 (100.0)	NA	0 (100.0)

IQR = Interquartile Range (25th percentile-75th percentile), RBC = Red Blood Cells

NA = Not Applicable, Sample Size Inadequate

Figure 1

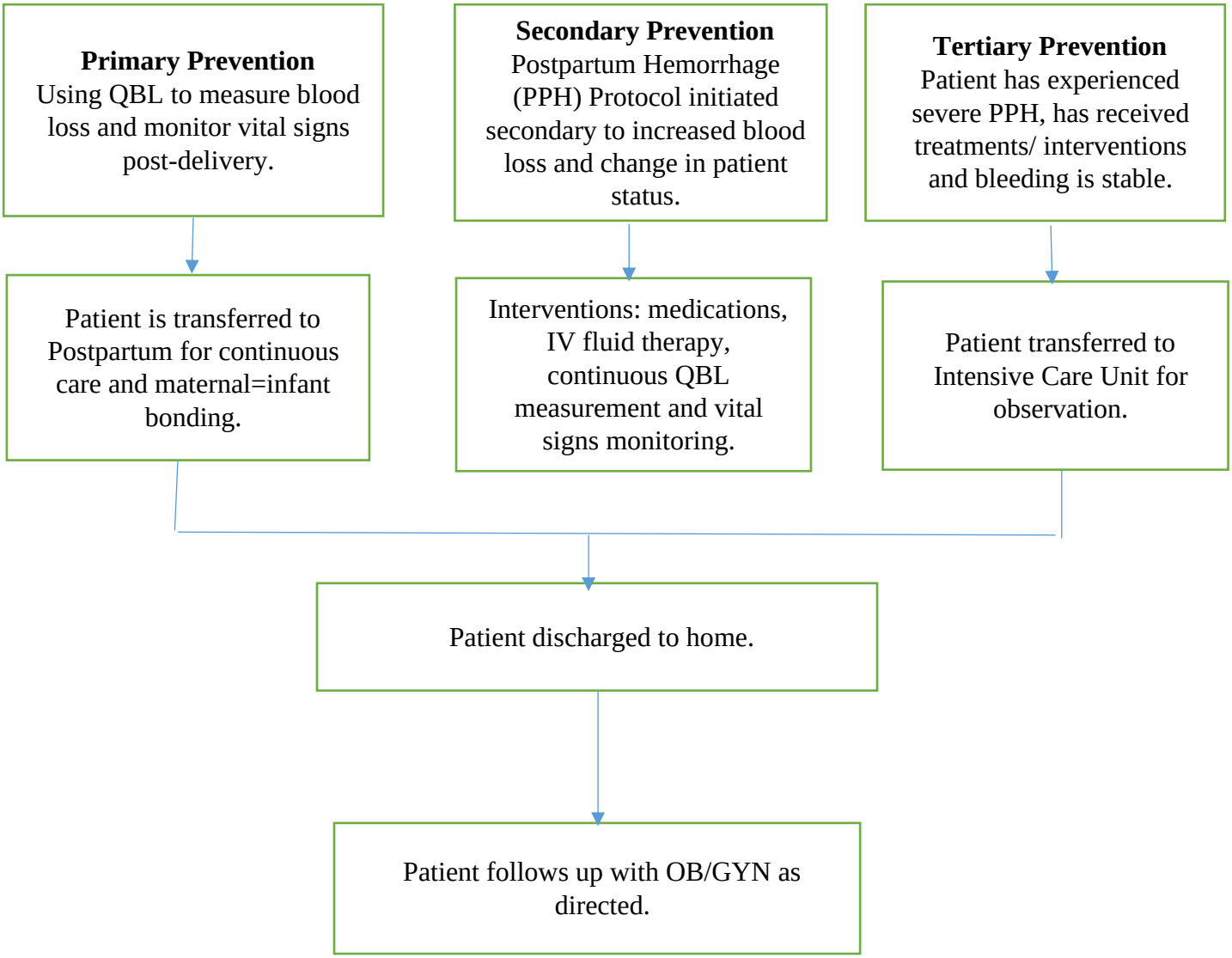


Figure 1. Quantified Blood Loss (QBL) using Neuman's System Model. Adapted from Neuman's System Model (Fawcett, 2017).

Figure 2

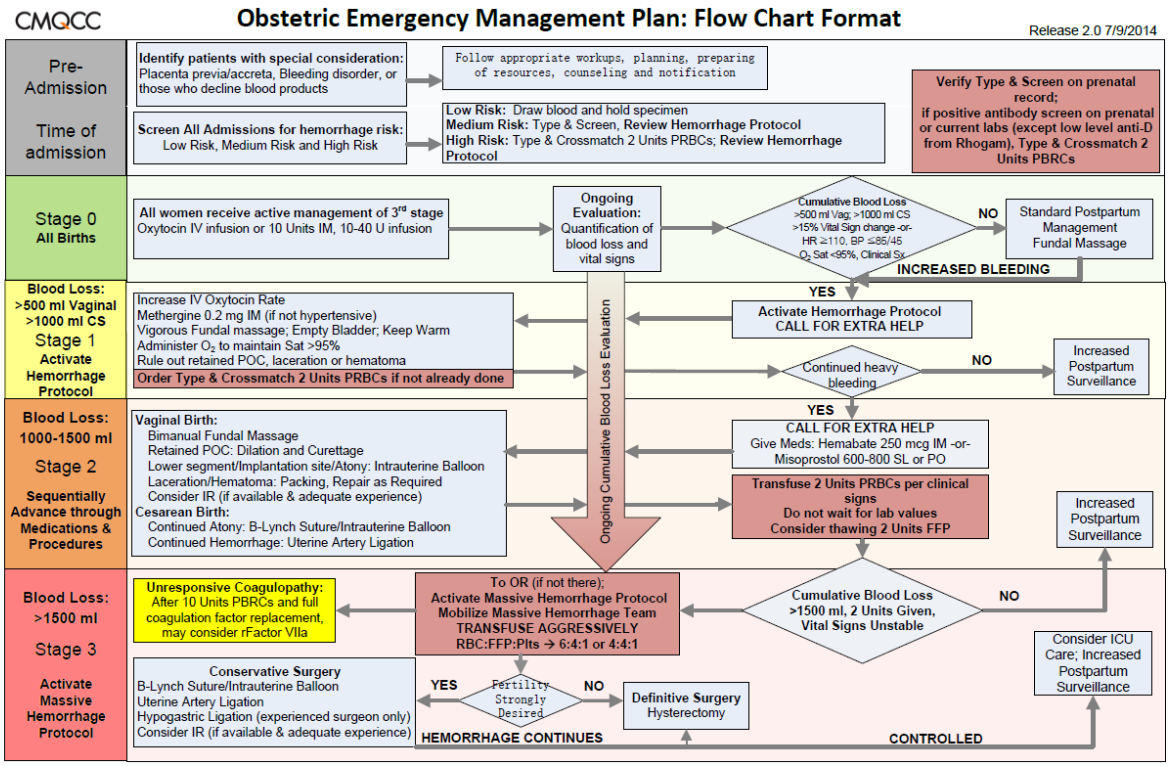


Figure 2. Obstetric Emergency Management Plan: Flow Chart (California Maternal Quality Care Collaborative, 2014). Stanford grants a personal, non-exclusive, non-transferable license to access and use the Sites. Users may download material from the Sites only for User's own organizational, internal use (August 12, 2019). Retrieved from: Terms of Use: https://www.cmqcc.org/terms-of-use

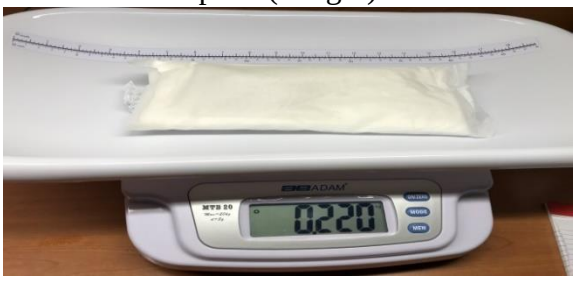
Figure 3

Small Chux (20gm)

Peripads 25gm (1 pad = 12.5gm)

Large chux (60gm)

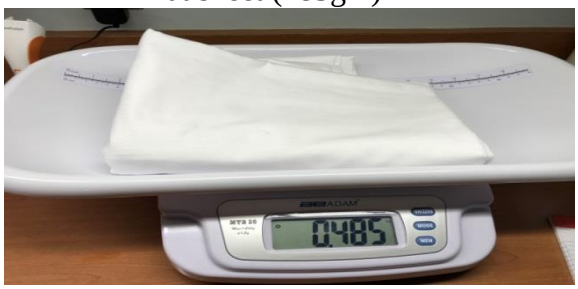
Ice pack (220gm)



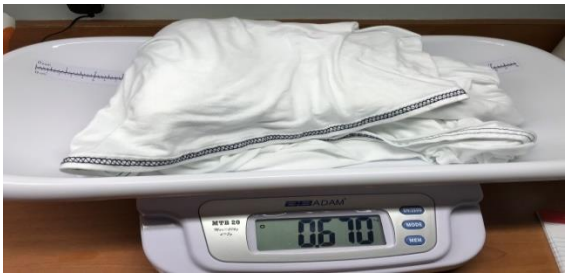
Mesh underwear (25gm)

Patient gown (380gm)

Flat sheet (485gm)



Fitted sheet (670gm)



Cloth bed pad (520gm)

Personal photos of dry weights of items for QBL reference

Appendix A

WCU
WEST CHESTER
UNIVERSITY

Office of Research and Sponsored Programs | West Chester University | Ehinger Annex
West Chester, PA 19383 | 610-436-3557 | www.wcupa.edu

Protocol ID # 20191203C
This Protocol ID number must be used in all communications about this project with the IRB.

TO: Christina Bouikidis

FROM: Nicole M. Cattano, Ph.D.
Co-Chair, WCU Institutional Review Board (IRB)

DATE: 11/26/2019

Project Title: Every Drop Counts: Quantifying Blood Loss Can Lead to Early Detection and Intervention for Postpartum Hemorrhage

Notification of Initial Study Exemption Determination

☒**Exempt From Further Review**

This Initial Study submission meets the criteria for exemption per the regulations found at 45 CFR 46.104 (4). As such, additional IRB review is not required.

The determination that your research is exempt does not expire, therefore, annual review is not required and no expiration date will be listed on your approval letter. If changes to the research are proposed that would alter the IRB's original exemption determination, they should be submitted to the WCU IRB for approval, using the IRB application form (check off I.G. Revision).

Your research study will be archived 3 years after initial determination. If your Exempt study is archived, you can continue conducting research activities as the IRB has made the determination that your project met one of required exempt categories. The only caveat is that no changes can be made to the application. If a change is needed, you will need to submit a NEW Exempt application. Please see www.wcupa.edu/research/irb.aspx for more information.

However, it is very important that you *close-out your project when completed or if you leave the university*. Faculty mentors are responsible for oversight of student projects and should ensure exempt studies are completed and closed-out before the student leaves the university.

The Principal Investigator and/or faculty mentor is responsible for ensuring compliance with any applicable local government or institutional laws, legislation, regulations, and/or policies, whether conducting research internationally or nationally. Please contact the WCU Office of Sponsored Research and Programs at irb@wcupa.edu with any questions.

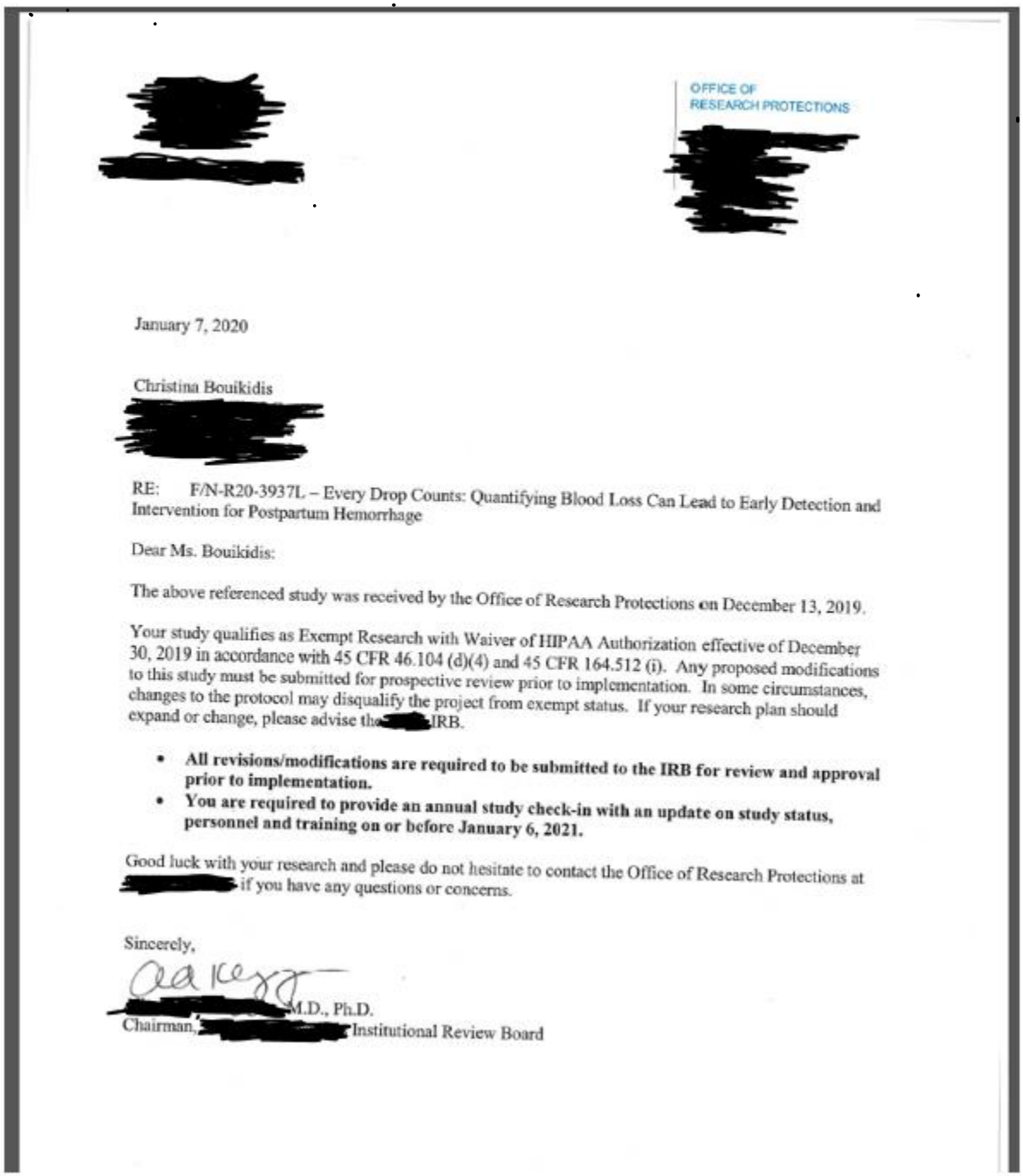
Sincerely,

Co-Chair of WCU IRB

WCU Institutional Review Board (IRB)
IORG#: IORG0004242
IRB#: IRB00005030
FWA#: FWA00014155

West Chester University is a member of the State System of Higher Education

Appendix B



[redacted]

OFFICE OF
RESEARCH PROTECTIONS

[redacted]

January 7, 2020

Christina Bouikidis
[redacted]

RE: F/N-R20-3937L – Every Drop Counts: Quantifying Blood Loss Can Lead to Early Detection and Intervention for Postpartum Hemorrhage

Dear Ms. Bouikidis:

The above referenced study was received by the Office of Research Protections on December 13, 2019.

Your study qualifies as Exempt Research with Waiver of HIPAA Authorization effective of December 30, 2019 in accordance with 45 CFR 46.104 (d)(4) and 45 CFR 164.512 (i). Any proposed modifications to this study must be submitted for prospective review prior to implementation. In some circumstances, changes to the protocol may disqualify the project from exempt status. If your research plan should expand or change, please advise the [redacted] IRB.

- **All revisions/modifications are required to be submitted to the IRB for review and approval prior to implementation.**
- **You are required to provide an annual study check-in with an update on study status, personnel and training on or before January 6, 2021.**

Good luck with your research and please do not hesitate to contact the Office of Research Protections at [redacted] if you have any questions or concerns.

Sincerely,

[redacted] M.D., Ph.D.
Chairman, [redacted] Institutional Review Board