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Abstract

Objective: To determine whether postpartum hemorrhage (PPH) protocols lead to decreases in maternal morbidity and mortality.

Design: Systemic literature review.

Methods: The clinical question investigated is whether the implementation of PPH protocols has measurable impact on maternal morbidity and mortality. Searches were done through PubMed using the keywords: "maternal hemorrhage postpartum protocol." Studies were eliminated if they were more than 10 years old, conducted outside the United States, published in a non-English language, used other animal subjects besides humans, used non-female subjects, if they did not answer the clinical question, or were review articles. Eventually, three cohort studies were included for analysis.

Results: Cohort studies by Shields *et al.* and Skupski *et al.* were chosen for analysis as they met the inclusion/exclusion criteria for the proposed clinical question.

Conclusions: All of the studies clearly demonstrate an improvement across a variety of measures of maternal morbidity.

Introduction

Obstetric hemorrhage (OH) is one of the leading causes of maternal mortality with a 27% prevalence worldwide. [1] OH is defined as excessive bleeding antepartum, intrapartum or postpartum. While developing countries carry the highest percentage of births affected by hemorrhage, developed countries are still affected with 16% of overall maternal deaths due to obstetric hemorrhage.[1] Ironically, obstetric hemorrhage is considered to be one of the most preventable causes of maternal deaths[2]. For example, California and North Carolina found 70-93% of maternal deaths due to obstetric hemorrhage were preventable.[3,4]

Postpartum hemorrhage (PPH), a subset of obstetric hemorrhage, is responsible for significant maternal morbidity and mortality in the United States. PPH is defined as "excessive bleeding, ≥1,000mL, within the first 24 hours after birth, [and] up to 12 weeks postpartum,"[5]. It is relatively common for patients to receive a late diagnosis of PPH; this is due to both the difficulties of accurately estimating blood loss as well as the ability of healthy patients to remain asymptomatic until a significant volume of blood has been

lost.[6] These difficulties in diagnosis help explain why protocol-driven care has been associated with improved outcomes in maternal mortality.

In 2010, the Joint Commission on the Accreditation of Healthcare Organizations recommended that protocols regarding PPH should be implemented. In 2013, the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal Fetal Medicine (MFM) along with several other groups formed The National Partnership for Maternal Safety (NPMS) which also recommended the adoption of postpartum hemorrhage protocols.[6] Currently, hospital protocols for intervention in PPH range from using pharmacologic therapies to massive transfusions and invasive procedures. However, within these therapies, there is still disagreement on who qualifies to receive each treatment as well as timing parameters and quantity of ordered treatments.[2] One of the top priorities of NPMS is the implementation of a unit-standard obstetric hemorrhage protocol. In 2014, four years after the Joint Commission's recommendations, a survey found only 67% of academic obstetric anesthesia units had a PPH protocol.[6] *Kacmar et al.* suspected the overall percentage of obstetric units nationwide with implemented PPH protocol was lower than 67% due to responder bias and the exclusion of community hospitals from the survey.[6] The effort begun by NPMS was intensified in 2015 through a partnership of 26 organizations to implement The Alliance for Innovation on Maternal Health (AIM).[7] This is a "national data-driven maternal safety and quality improvement initiative" that incorporates approaches that have improved maternal safety in the United States, including the implementation of standardized procedures and protocols.[7] As of September 2017, there were 13 states and 3 health networks that were active in this program, which represented approximately 1.5 million births.[5,7]

PPH is a preventable condition that causes significant adverse outcomes potentially leading to death. Recent studies have suggested that the implementation of PPH protocols lead to decreased maternal mortality. The purpose of this review is to determine the impact of PPH protocols in hospitals on maternal hemorrhage and patient safety.

PICO:

Population: Women giving birth in hospital setting
Intervention: Implementation of hospital hemorrhage protocols
Comparison: No implementation of hospital hemorrhage protocols
Outcome: Decreased maternal mortality

<u>Clinical Question:</u>

Do female deliveries occurring in hospitals with protocols for maternal hemorrhage experience fewer maternal deaths in hospital deliveries than those occurring in hospitals without such protocols?

<u>Methods</u>

An initial search of PubMed was performed in September 2018 using the search terms "maternal hemorrhage postpartum protocol." One hundred ten articles were identified and no duplicates were found. They were then screened for eligibility. Exclusion criteria included articles published before 2008, non-English language, animal subjects other than humans, non-female subjects, and articles with only abstracts. This yielded 70 articles. The remaining 70 articles were screened and articles were excluded if they did not answer the clinical question, were review articles or were research performed outside of the United States (Figure 1). Three cohort analyses qualified for this research.
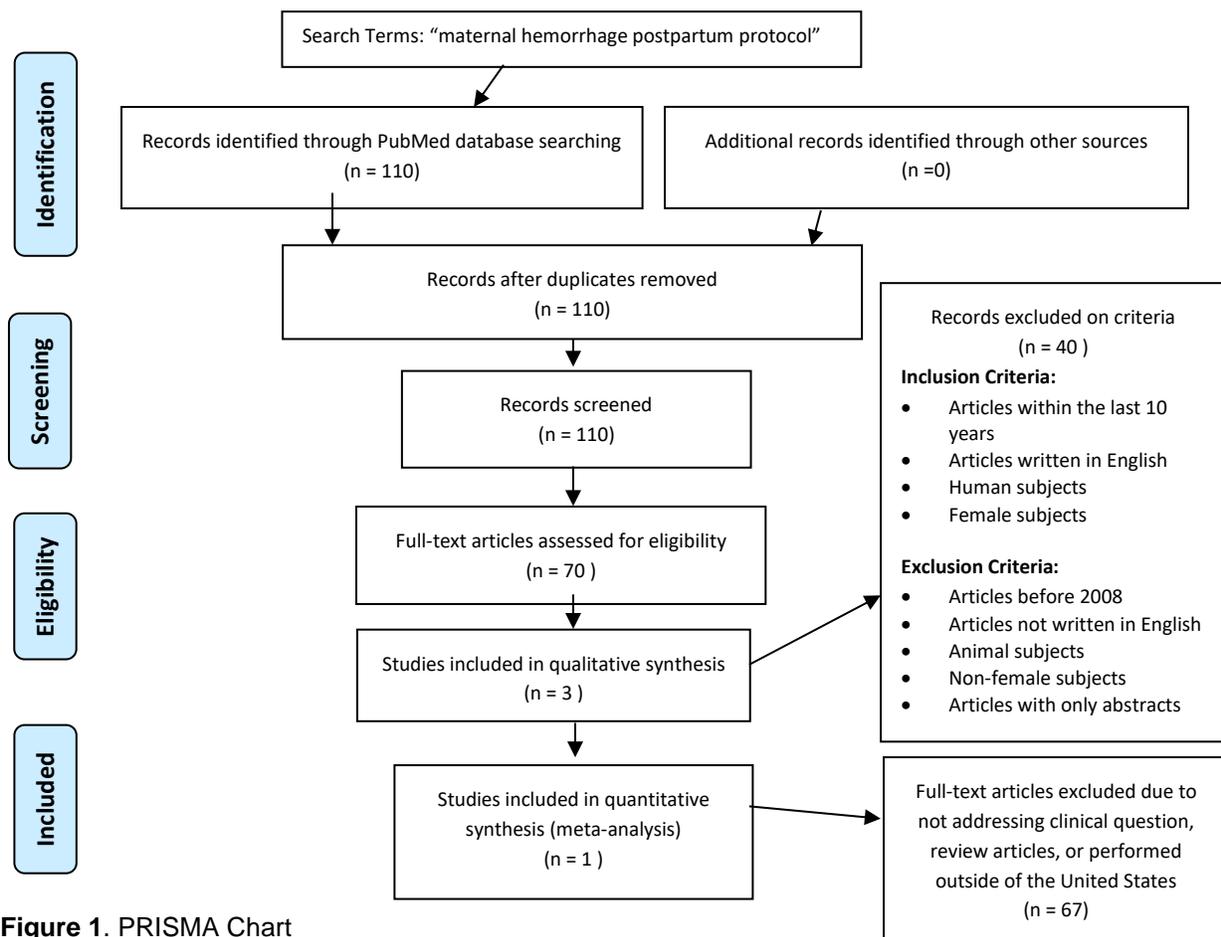

Figure 1. PRISMA Chart

<u>Results</u>

Study #1

Comprehensive maternal hemorrhage protocols improve patient safety and reduce utilization of blood products. Shields et al. (2011)

<u>Study Objective:</u> To assess the effectiveness of instituting a comprehensive protocol for the treatment of maternal hemorrhage.

<u>Study Design:</u>

This was a retrospective and prospective cohort study performed at a medium-sized rural hospital in California with less than 3,000 deliveries per year. Before the protocol was initiated, there were three main phases of preparation: development, education, and team training. Development took place in November 2008 through January 2009, and included communication and actions needed between health care providers and clinical services and defining each hemorrhage stage. Stage 0 was a normal intrapartum and postpartum course. Stage 1 was bleeding greater than normal vaginal delivery (500mL) or cesarean section (1000mL). Stage 2 was bleeding that did not respond to conservative measures used in stage 1. Stage 3 was continued bleeding >1500mL. Education took place February 2009 through April 2009, and included feedback and suggestions that were implemented by protocol groups. Team training then consisted of nursing staff participating in a blood loss skills training, and labor and delivery simulations were performed. This was done so each member of the protocol team could practice and learn about their role and the role of others. The protocol was then implemented in May 2009.

The patient's status and the interventions were grouped into 4 categories (stages 0-3). The protocol started when the patient was admitted to the labor and delivery floor. Each patient was evaluated on their risk for obstetric hemorrhage. They were put into a low risk, medium risk, or high risk category. Their risk category determined their level of "status alert" given to the blood bank; clot-tube requested, type and screen performed, and cross-matched blood initiated, respectively. Blood loss was measured by collection systems, weighing lap sponges and bed-ware. The nonblood fluids in the collection systems were subtracted. During the protocol, symptoms or abnormalities of vital signs escalated patients to stage

2 or stage 3. These symptoms and abnormalities included: maternal heart rate >100bpm, blood pressure <85/45mmHg, shortness of breath, confusion, or agitation. [8]

Those in stage 1 after delivery were assessed by nursing staff and if needed, given a single dose of an uterotonic agent after consulting with the physician. In stage 2, more healthcare personnel were recruited which included the obstetrician and on-call anesthesiologist and an obstetrical hemorrhage cart was brought to the patient's room. In stage 3, additional nursing staff and physicians (including surgeons and interventional radiology) were utilized. Additionally, fixed blood products in an obstetrical hemorrhage pack were prepared for release. This pack included units of fresh frozen plasma, packed red blood cells, platelets and cryoprecipitate. The goal was to maintain the patient's labs as followed: HCT >24%, INR <1.4, platelets >50,000/uL, fibrinogen >100,000mg/dL, pH >7.2, base excess >-5, temperature >95°F, and a normal ionized calcium. [8]

Stage 2 patients were monitored in labor and delivery for 24 hours postpartum and laboratory studies were taken at hour 1 and 4. Vital signs were taken more frequently during the first 6 hours after bleeding normalized. Stage 3 patients were monitored in the ICU with critical care, anesthesia, and obstetrics.

A survey was sent out to treating physicians and nursing staff 1 year after initiation of the protocol. The responses were evaluated using a 5-point system. The perceptions of physicians and staff were analyzed by paired t-test. The question on whether the protocol reduced the severity of hemorrhage was answered by comparing patients advancing to each stage before and after the protocol was initiated. The control period was 4 months in duration (985 deliveries), and interventional time was 12 months divided into 3 different 4-month blocks (2874 deliveries). [8] This data was analyzed by analysis of variance for changes in the number of patients treated at each stage[8]. Additionally, information on the patients who received blood products and units transfused were collected from the blood bank. The data for this was used comparing a 12-month period before the protocol (2939 deliveries) and a 12-month period after the protocol (2874 deliveries). This information was analyzed by t-test.

Study Results:

Amongst the 5813 deliveries during the study, the overall maternal hemorrhage rate was 3.6%. Combining only stage 2 and stage 3, the hemorrhage rate was 1.5%. The total number of patients in

stage 1 or stage 3, before and after the protocol was initiated, did not change. However, after the protocol was initiated, there was more successfully treated patients in stage 1 and a decrease of patients entering stage 2, both having a P=0.02 and R^2=0.95 (table 1). These findings are consistent with the goal of implementing education and training to allow better intervention and successful treatment of the patients.

Table 1. Changes in stage of hemorrhage before and after protocol initiation[8]

Stage	Preprotocol	Post-period 1	Post-period 4	Post-period 3
1[a]	35% (22)[b]	51% (25)	69% (27)	82% (49)
2[a]	53% (33)	45% (22)	18% (7)	8% (5)
3	11% (7)	4% (2)	13% (5)	10% (6)

[a] P _ .02; [b] Numbers in parenthesis are total patients at that stage in that time period.
Shields. Maternal hemorrhage protocol. Am J Obstet Gynecol 2011.

The percentage of patients that had a greater blood loss than expected, stage 3, did not change during the study. However, before and after protocol, there was a reduction of total number of blood products transfused and average blood products used per month; 16.7 units/month pre-protocol and 6.3 units/month post-protocol, P<0.01). The rate of disseminated intravascular coagulation (DIC) was reduced by 64%.

The study found less blood products were used even when readily available as patients experienced less overall blood loss demonstrated by the decrease in advancement of stages during the protocol. Additionally, with earlier intervention, fewer patients resulted in DIC. After one year of implementation, the survey results revealed increasing provider and staff comfort in hemorrhage situation as well as team communication during the situations, P<0.01.

Study Critiques:

This study had a relatively small number of deliveries compared to other hospitals in their system with over 3000 deliveries/year. However, those hospitals already have a protocol in place. Even though the study tried to calculate the pure blood products lost, there were most likely some over estimates due to these extra substances being weighed; extra fluids, membranes, bedding, and supplies. For the survey, it was only returned by 61% of physicians and 32% of nursing staff. So the results from these healthcare personnel may not represent the entire population involved in the protocol.

The study explained the stages very well and each patient was assessed based on the criteria of each stage. Additionally, the results used a stricter p-value of 0.01 and rejected the null of the survey and study. Since the null was rejected, there was a difference pre and post-protocol hemorrhage outcomes and healthcare personnel confidence of involvement. The results of this study are consistent with the Joint Commission recommendation to establish a PPH protocol to reduce maternal hemorrhage rates and improve maternal safety.

Study #2

Comprehensive maternal hemorrhage protocols reduce the use of blood products and improve patient safety. Shields et al. (2015)

Study Objective: To evaluate the effectiveness of a comprehensive maternal hemorrhage protocol in reducing the use of perinatal blood products and unplanned hysterectomies during childbirth.

Study Design:

This was a prospective cohort study of 32,059 deliveries by patients who were admitted for labor and delivery in a large health system. [9]

During a series of three 2-month time periods spread out over a year, data was collected from a clinical patient safety monitoring program for Dignity Health System. This health system involved 29 hospitals with a total number of about 60,000 births per year; individual maternity units ranged in size from a rural unit with <200 deliveries per year to much larger urban units with over 6000 deliveries per year. A hemorrhage protocol with standardized interventions per patient risk level was given to all 29 hospitals in 2010, and compliance with this protocol began to be assessed monthly in November 2011 by perinatal safety nurses and collected data was audited by perinatal nurse specialists. To qualify as "compliant," all of the components from Table 2 had to be met.

Table 2. Checklist for protocol compliance and data collection[9]

□ Admission hemorrhage risk assessment completed
□ Correct blood bank request requested, based on risk
□ Blood and blood clots weighed per protocol
□ Correct laboratory results obtained for stage 2 and 3 hemorrhage
□ Were >2 uterotonics given without the medical doctor present
□ Blood products administered according to protocol

Quantity blood products are administered and which ones[a]
Number of peripartum hysterectomies[a]

These items were used to assess compliance with the protocol. If any item was not checked, the care was deemed noncompliant.

[a]Additional data that were collected but not used to assess compliance with the protocol.

The protocol was initiated when the patient was admitted to labor and delivery, and interventions were mostly targeted towards postpartum hemorrhage. The first part of the protocol involved the use of graded assessments of patient acuity. Stage 0 and 1 were defined as "normal intrapartum and postpartum course" and "bleeding greater than expected", respectively, where bleeding greater than expected was considered more than 500 mL for vaginal delivery or 1000 mL for cesarean section. These stages were distinguished from the higher acuity Stages 2 and 3 primarily by vital signs: a heart rate >110 bpm, blood pressure ≤85/45 or >15% drop from baseline, or oxygen saturation ≤94% qualified patients for Stage 2 or 3. Additionally, clinical symptoms such as shortness of breath, confusion or agitation also prompted the clinician to categorize the patient in a higher stage. Bleeding that did not respond to conservative treatment was designated as Stage 2 while Stage 3 was defined as continued bleeding to exceed 1500 mL. [9]

Standardized interventions were based on the stage the patient was in. For example, key parts of the Stage 1 hemorrhage interventions included a conference with the physician and a single dose of a supplemental uterotonic if uterine atony was suspected, while key components of Stage 2 interventions included the addition of more clinical staff to the patient's care as well as the obstetrics hemorrhage cart (either at the bedside or in the operating room). In general, the system-wide protocols included the use of quantitative estimates of blood loss, continual assessment of patient bleeding status, fixed ratios of transfused blood products and the development of a designated obstetrics hemorrhage cart. Additionally,

as patient acuity increased, defined target values were set for hematocrit, INR, platelet count, fibrinogen level, pH, temperature and serum calcium because these factors all influence coagulation.

Three time periods were compared for data analysis with the first being a 2-month long baseline period in November-December 2011 before the protocol was implemented. This was followed by additional 2-month periods; one in April-June 2012, 5 months post-implementation, and one in September-October 2012 at 10 months post-implementation. Initial data interpretation involved comparison of the peripartum hysterectomy rate between 2011 and 2012; data was analyzed by t-test. The use of blood products was similarly compared across time points.

Study Results:

Throughout the study, the health system showed improved compliance in its implementation of the maternal hemorrhage protocol. At the start, the compliance rate was 54%; this increased to 80% by period 2. As the protocol compliance increased, more patients were correctly recognized as being in higher risk categories and higher stages of active hemorrhage. For example, the number of patients who were placed into "stage 3" hemorrhage increased by 60% from the baseline time point to the last measurement. At the same time that overall protocol compliance increased (54% at baseline to 80% at the end of the study), the overall use of blood products was significantly reduced, by 25.9% per 1000 births (P <0.01). This correlated with a 14.8% reduction in the number of patients who had both obstetric hemorrhage and peripartum hysterectomy, although this decrease was not found to be statistically significant (P = 0.2).[9]

Study Critique

Strengths included the large number of research subjects. Using over 32,000 births in this study provided a robust data set.

Limitations of this study are that even after more than a year spent on implementing the maternal hemorrhage protocol, up to 20% of births in this hospital systems were not in compliance with the protocol. This affects the result validity. Additionally, the authors note that there were difficulties with accurately estimating maternal blood loss, so much so that specific skills workshops were added to the implementation period. Inter- and intra-observer variability likely caused some patients to be mis-categorized within the protocol, which again would affect the validity of the study's results.

Study #3

Improvement in Outcomes of Major Obstetric Hemorrhage Through Systematic Change. Skupski et al. (2017)

Study Objective: To investigate the effect of a multiyear systematic institutional effort to improve the care of women with obstetric hemorrhage of >1500 mL.

Study Design:

This was a retrospective cohort study of 57,694 births at a tertiary care facility that included a level IIIB neonatal intensive care unit, level III maternity care and level I trauma.[10] From 2000 to 2014, baseline conditions, morbidity and mortality were compared across three time periods for women who had documented major obstetric hemorrhage (estimated peripartum blood loss of >1500 mL). The data that was collected about patient baseline condition included age, multiparity, prior cesarean delivery, and morbidly adherent placenta. Measures of morbidity included the presence of: hypothermia, defined as less than 38°C; acidemia, defined as maternal arterial pH less than 7.32; coagulopathy; pulmonary embolus; pneumonia; organ damage; and the transfusion of 4 or more units of packed red blood cells. The time periods compared included January 2000 to December 2001 (period 1), January 2002 to August 2005 (period 2), and September 2005 to December 2014 (period 3).[10] There were 5,811 births in period 1; 12,912 births in period 2; and 38,971 births in period 3. Hemorrhage cases were collected to be entered into the research database by the authors and validation of data was performed by a senior author.

The management protocol contained a variety of interventions including the development of an obstetric rapid response team and a massive transfusion protocol; standard evaluation and treatment of postpartum bleeding to include collection of frequent vital signs, application of uterine massage, and common use of arterial blood gas measurement; frequent trainings and emergency drills; and the development of clinical pathways regarding the diagnosis of placenta previa and accreta. Screening for placenta previa took place in the second trimester and all patients with positive findings on ultrasound received a second scan at 30-32 weeks of gestation. Maternal-fetal medicine was consulted if patients

had continued placenta previa or suspected placenta accreta at their second scan, with the goal of a scheduled early delivery between 35 and 36 weeks for placenta accreta without bleeding and 38 weeks for placenta previa without bleeding. The presence of bleeding in conjunction with abnormal placenta led to earlier delivery. Additionally, they recommended a planned cesarean hysterectomy for patients with a diagnosis of placenta increta or percreta.

Data from the different time periods were analyzed by Fisher exact test, Wilcoxon rank-sum test and unpaired t-test.

Study Results

While the rate of obstetric hemorrhage increased over the course of the study from 2.1 cases/1000 births in period 1 to 5.3 cases/1000 births in period 3, a decrease in measures of morbidity was found over the same time span. Improvements included a decrease in cases of maternal hypothermia, acidemia and coagulopathy between period 3 vs. period 1 (P = <0.001 for all). There was also an improvement in mortality in period 3 compared to period 1 (P = 0.001).[10]

Study Critique

Strengths of this study included the long time period that was investigated. Data showed trends over the span of 14 years, enough time to show evidence of how changes in practice were affecting outcome.

Limitations included the fact that the study took place at a single hospital. Also, some planned components of their protocol to improve obstetric hemorrhage outcomes were not yet in place during the time they reported, including the implementation of quantitative blood loss techniques.

Discussion

Maternal hemorrhage is a serious condition with significant impact on morbidity and mortality during labor and in the postpartum period. After reviewing all three articles, the results showed that PPH protocols reduced the maternal hemorrhage rates along with increasing the overall safety of the patient.

Some strength and weakness in our research included sample size, variety of protocols used, estimated blood loss, and different facilities in which the studies took place. Study 1 had a smaller sample size compared to the other two studies reviewed. However, this study was chosen to compare and

contrast a protocol once it was implemented in a single hospital. There were different protocols compared within our articles, so drawing conclusions from one protocol versus another protocol made it harder to extrapolate PPH protocols as a whole. However, despite the variability in the protocols used within these three articles, all three studies revealed an improved outcome in maternal health after PPH protocols were implemented. Additionally, each study had to determine the amount of blood loss for each patient. Study 3 measured blood loss by qualitative means whereas the other two studies measured blood loss quantitatively. Patients were from different areas within the United States but all found an improvement with PPH protocols which helped eliminate geographic area as a confounding variable.

Shields et al (2011) found that after the implementation of a PPH protocol, there was a reduction in the total number of blood products transfused (P<0.01). They also were able to successfully keep more patients in a lower acuity stage, finding a decrease of patients entering stage 2 (P=0.02), as well as a decreased rate of DIC. Shields et al (2015) also found that as overall protocol compliance increased within a health care system, the use of blood products was reduced by 25.9% (P <0.01). There was also a reduction in the number of patients with concomitant obstetric hemorrhage and peripartum hysterectomy, but this decrease was not found to be statistically significant (P = 0.2). Skupski et al (2017) reported that despite an increase in rates of obstetric hemorrhage over a period of 14 years, a decrease in measures of morbidity and mortality was found over this same time span as a PPH protocol was implemented in a large tertiary care center. Mortality decreased (P=0.001) along with cases of maternal hypothermia, acidemia and coagulopathy (P = <0.001). Overall, each study showed statistically significant improvements in a wide range of maternal peripartum health markers.

It has been shown that so-called "near miss" events (blood loss of ≥ 1500 mL) occur in about 15% of patients with postpartum hemorrhage. Studies have also shown that many of the negative outcomes of maternal hemorrhage are preventable, and several recent efforts have been made to quantify the effect that protocol-driven care has on episodes of hemorrhage in the peripartum period.

Conclusion

PPH protocols are effective and efficient interventions with proven safety benefits and low risk of complications. This sort of stepped-care plan has the potential to improve quality of care in a wide variety

of hospital settings, including both low-volume rural hospitals and large tertiary care centers in urban areas. A negative effect of implementing such protocol may be the time it takes to organize it and train/educate healthcare professionals in their role during the protocol. Additionally, there may be some concern on overuse of transfusions.

There are currently a variety of different postpartum hemorrhage protocols between facilities. From our research, we know that PPH protocols are beneficial in maternal health, but we did not investigate protocol specifics. A recommendation for future research would be looking into specific protocols to determine if one is superior to another. In the future, if one protocol is superior to others, we believe this would be the most beneficial with implementation of a protocol. It seems reasonable to assume that PPH protocols are a low-cost intervention as they utilize resources already in place, just in a more organized manner. However, our research did not incorporate data on the cost of implementing a PPH protocol in either a single institution or across a large health system. This would also be a reasonable area for future research.

References

1. Say L, Chou D, Gemmill A, et al. Global causes of maternal death: a WHO systemic analysis. *The Lancet Global Health*. 2014;2(6):e323-333. doi:10.1016/ S2214-109X(14)70227-X.
2. Obrien KL, Shainker SA, Lockhart EL. Transfusion Management of Obstetric Hemorrhage. *Transfusion Medicine Reviews*. May 2018. doi:10.1016/j.tmrv.2018.05.003.
3. Berg CJ, Harper MA, Atkinson SM, et al. Preventability of pregnancy-related deaths: results of a state-wide review. *Obstetrics & Gynecology*. 2005;106 (6):1228–1234. doi:10.1097/01.AOG.0000187894.71913.e8.
4. Main EK, Mccain CL, Morton CH, Holtby S, Lawton ES. Pregnancy-Related Mortality in California. *Obstetrics & Gynecology*. 2015;125(4):938-947. doi:10.1097/aog.0000000000000746.
5. The American College of Obstetricians and Gynecologists. ACOG Expands Recommendations to Treat Postpartum Hemorrhage. https://www.acog.org/About-ACOG/News-Room/News-Releases/2017/ACOG-Expands-Recommendations-to-Treat-Postpartum-Hemorrhage. Published September 21, 2017
6. Kacmar RM, Mhyre JM, Scavone BM, Fuller AJ, Toledo P. The Use of Postpartum Hemorrhage Protocols in United States Academic Obstetric Anesthesia Units. *Anesthesia & Analgesia*. 2014;119(4):906-910. doi:10.1097/01.aoa.0000469465.38369.e9
7. AIM. Alliance for Innovation on Maternal Health Program. https://safehealthcareforeverywoman.org/aim-program/. Published 2018
8. Shields L, Smalarz K, Reffigee L, Mugg S, Burdumy T, Propst M. Comprehensive maternal hemorrhage protocols improve patient safety and reduce utilization of blood products. *American Journal of Obstetrics and Gynecology*. 11AD;205(4):368.e1-368.e8. doi:10.1016/j.ajog.2011.06.084.
9. Shields L, Wiesner S, Fulton J, Pelletreau B. Comprehensive maternal hemorrhage protocols reduce the use of blood products and improve patient safety. *American Journal of Obstetrics and Gynecology*. 2015;212(3):272-280. doi:10.1016/j.ajog.2014.07.012.
10. Skupski DW, Brady D, Lowenwirt IP, et al. Improvement in Outcomes of Major Obstetric Hemorrhage Through Systematic Change. *Obstetrics & Gynecology*. 2017;130(4):770-777. doi:10.1097/aog.0000000000002207.