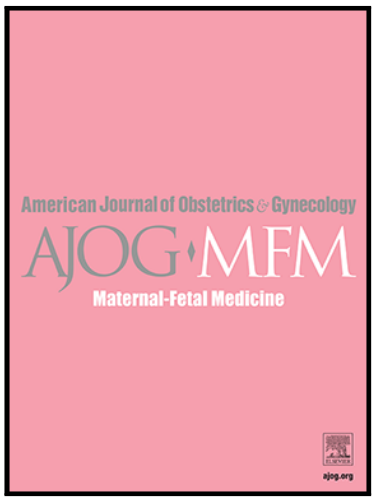

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Expert Reviews | Expert Review

Postpartum hemorrhage protocols and benchmarks: Improving care through standardization

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Declaration of Competing Interest

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ABSTRACT

Postpartum hemorrhage (PPH) remains a leading cause of maternal morbidity and mortality in the United States. Several State maternal morbidity and mortality committees have reviewed areas of opportunity in regard to PPH management and found common patterns include delays in recognition and response to hemorrhage.[1, 2] Hospital systems and State perinatal quality collaboratives (PQCs) have found that comprehensive, interdisciplinary response to PPH care improves patient outcomes and in some instances, has reduced racial disparities.[3] A key component of this focus involves implementation of stage-based hemorrhage protocols for PPH management. Stage-based hemorrhage protocols are designed to reduce delays in diagnosis and management and avoid the pitfalls of cognitive biases. These protocols are complex, and their effectiveness is tied to the quality of their implementation. Systematic benchmarking and development of quality metrics for adherence to PPH bundles would be expected to improve

clinical outcomes, but evidence regarding the effectiveness of this practice in the literature is sparse. In this review, we outline key features of stage-based interventions, and evidence regarding use of quality metrics for PPH protocol adherence.

Keywords: Postpartum Hemorrhage, Quality Improvement, Maternal Death, Pregnancy, Obstetric Labor Complications

Condensation

Adequately implemented stage-based protocols may reduce PPH morbidity if they lead to timely recognition and directed response to hemorrhage.

AJOG: MFM at a Glance:

A. Postpartum hemorrhage is a common cause of maternal morbidity and mortality.

B. Key aspects of postpartum hemorrhage protocols that lead to improvements in outcomes include timely use of uterotonics and early intrauterine balloon usage, and a focus on implementation including team training via simulation and auditing for compliance.

EVIDENCE FOR PPH MANAGEMENT PROTCOLS AS SYSTEMS ISSUES

Management of postpartum hemorrhage (PPH) involves a team of clinicians working in a coordinated fashion to obtain hemostasis and to manage the effects of acute blood loss. Thus, when opportunities in outcomes after PPH are found, they are often related to systems-level factors.[1,2] A PPH event, for example, might raise any of the following potential quality issues:

1. *Access*: Has the patient had the opportunity to seek timely prenatal care to have risk factors optimized (example: identification and treatment of peripartum anemia)? Did they deliver in a non-hospital setting (e.g., home) due to lack of access to hospital care, resulting in delayed management?

2. *Structure*: Does the hospital have equipment in place to address hemorrhage, such as provision of standardized hemorrhage carts and ready access to uterotonics? Are hospital teams prepared to respond to PPH via participation in team trainings and simulations for PPH management? Does the hospital have a standardized stage-based management protocol that teams have been trained to follow?
3. *Process:* How is blood loss measured and communicated to team members during acute hemorrhage?

Several State maternal morbidity and mortality committees have reviewed areas of opportunity in regard to PPH management and found common patterns include delays in recognition and response to hemorrhage.[1, 2] These findings are consistent with previous work demonstrating that preventable maternal mortality is often a function of delays in seeking care, arriving at a health facility, and provision of adequate care.[4]

Delays in PPH Recognition and PPH Response

Providers find it difficult to precisely estimate blood loss. Obstetric literature indicates certain patterns exist, including over-estimation in low volume blood loss events, and under-estimation in higher blood loss deliveries (*i.e.*, providers estimates are biased toward the median blood loss). Underestimation of blood loss during PPH can result in delays in diagnosis and management, which have been associated with maternal mortalities.[1]Quantitative blood loss (QBL) has been proposed as an alternative approach intended to reduce these cognitive biases. QBL can be performed using traditional gravimetric and volumetric techniques such as graduated under buttock drapes, and weighing of laparotomy pads and irrigation canisters; it can also be performed using newer techniques adding real-time imaging of laparotomy pads and irrigation canisters.[5] These techniques have been shown to be more accurate than EBL when compared to

"gold standard methodologies" such as hemoglobin change, but disappointingly have not yet been shown to alter clinical outcomes.[6] There are several potential pitfalls for QBL in practice which may limit its effectiveness. Practitioners can focus on the attainment of an "accurate" QBL value at the expense of a timely QBL value, resulting in time delays in recognition of hemorrhage. QBL which does not facilitate early recognition of the onset or severity of hemorrhage is not useful. Providers may resist activation of PPH protocols until the blood loss threshold is "proven" by QBL, and the effort to measure and maintain QBL may distract attention from other aspects of acute PPH management; QBL could thus paradoxically if not well implemented delay rather than accelerate PPH response. Patients may have very different responses to a given level of QBL, based on their baseline hemoglobin, height, and medical comorbidities. Finally, QBL is a diagnostic intervention, and diagnostic interventions can only improve clinical outcomes when paired with effective therapeutics.[7]

Data demonstrates an association between timely treatment of recognized PPH and outcomes. In a large Canadian cohort of vaginal deliveries, each 5 minute additional delay in administration in a second uterotonic (after Pitocin) from recognition of PPH was associated with 31% higher odds of hypotension and 34% higher odds of transfusion. Similar associations were found in a French cohort between delay in oxytocin administration and manual uterine cavity examination and rates of severe PPH,[8] and in a joint Beninese and Malian cohort between oxytocin administration times and severe PPH rates. Among second-line interventions, early use of an intrauterine tamponade balloon appears to reduce the risk of needing subsequent procedures.[9] With respect to adjunctive interventions, the landmark WOMAN trial for PPH treatment demonstrated that TXA given early in the course of PPH was more effective in reducing the risk of PPH-related maternal morbidity or mortality.[10] Therefore, further evaluation of blood loss recognition strategies that

specifically lead to earlier management of hemorrhage are important. This may include creating validated quality measures that focus on the connection between recognition and response to hemorrhage, and not just the process of blood loss estimation.

Cognitive Biases

Several forms of cognitive bias have been described in the literature.[11] In the management of PPH, many of these can adversely impact patient care and result in deviations from optimal medical and team-based management. Anchoring bias can result in providers becoming committed to one etiology for PPH (*e.g.*, atony) which can delay a search for other potential etiologies (*e.g.*, laceration or retained products of conception). Normalcy bias leads people to disbelieve or minimize threat warnings and therefore fail to recognize signs of danger as being abnormal (such as bleeding volume is "normal" or tachycardia is related to "anxiety"). Availability bias reflects the human tendency to over-weight recent experiences when evaluating a new situation (*e.g.*, a recent case of amniotic fluid embolism may cause a provider to suspect amniotic fluid embolism in subsequent patients more commonly, even when other explanations for hemorrhage may be more likely). Implicit biases occur when attitudes and stereotypes affect our understanding, actions, and decisions in an unconscious manner (unconscious discrimination). Implicit bias is a well-recognized cause of healthcare inequities leading to racial and ethnic disparities in health outcomes, and is suspected that this bias may contribute to differences in response to postpartum hemorrhage resulting in the known disparity in SMM rates related to PPH.[12] Many organizations, researchers and advocacy groups have published about the effects of implicit bias and recommended strategies such implicit biases trainings, development of respectful care models and including people with lived experiences in quality improvement teams. However, there is less evidence-based literature about other cognitive

biases, including strategies to help healthcare teams identify during the case review process when biases result in patient adverse outcomes, and how to develop corrective action strategies to reduce them.

PPH PROTOCOLS IMPROVE SYSTEMS OF CARE, BUT ARE DEPENDENT ON IMPLEMENTATION

Postpartum hemorrhage protocols are intended to standardize the recognition and management of PPH (both for obtaining hemostasis and for resuscitating the patient), reduce cognitive biases by standardizing response and help teams have a common understanding of the pathway to stop hemorrhage. We note that PPH protocols are only one component of larger PPH bundles. By "hemorrhage protocols", we refer to the stage-based process by which PPH risk is assessed and appropriate peripartum anticipatory and prophylactic actions taken, and then guides management for patients who do experience a PPH. Using structured blood loss measurement techniques and objective vital signs threshold to define PPH and stage its severity is designed to reduce delays in diagnosis, while recommendations to implement interventions at different thresholds of blood loss (such as additional uterotonics) are intended to reduce delays in management. Additionally, PPH protocols provide structured guidance on considering a wide differential for PPH, which is designed to reduce the risk of providers developing anchoring bias and similar cognitive biases. Because PPH protocols emphasize the importance of objective measures of blood loss and vital signs in identifying and staging PPH and prescribe a recommended response at each stage of hemorrhage, application of PPH protocols may minimize implicit biases.

However, evidence indicates that the mere presence of a stage-based protocol may not reduce the PPH rate or rate of SMM related to PPH.[13] Proponents of PPH bundles argue that this is related to the lack of protocol implementation, also known as the "implementation gap," in other

conditions.[14, 15] Hospital systems and state perinatal quality collaboratives that have focused on implementation have showed reduction in morbidity in patients experiencing PPH. Investigators in California compared the rates of severe hemorrhage-related morbidity among deliveries in hospitals preceding and following implementation of a state perinatal quality collaborative focused on PPH, and found that participation in the collaborative was associated with a 20.8% reduction in hemorrhage-related morbidity.[16] While the California Maternal Quality Care Collaborative provides extensive guidance on PPH management, local leaders customized their protocols to reflect facility-specific needs and opportunities. [16, 17] As an example, a large health system (Dignity Health, a California-based not-for-profit public-benefit corporation that operates hospitals and ancillary care facilities in three States – California, Arizona, and Nevada) developed a hemorrhage bundle which included specific auditing for compliance, including PPH risk assessment, blood product crossmatch according to PPH risk, quantitative (not qualitative) blood loss assessment, laboratory results obtained in stages 2 and 3 hemorrhages, permission to give more than two uterotonics without a physician present when necessary, and blood product administration per protocol. When compliance was less than expected, safety nurses visited the hospitals to provide staff education and simulation. The bundle compliance increased from 54% to 80% over this period, during which recognition and correct designation of the stages of hemorrhage also improved and the overall use of blood products decreased (25.9% reduction per 1,000 births in blood product use at 10 months post-implementation). These successful PPH bundles and stage-based protocols highlights the importance of implementation and verification of practice change.

GUIDANCE ON BENCHMARKS FOR PPH MANAGEMENT

Current PPH quality improvement initiatives incorporate assessment of care delivery into their efforts. Current experienced organizations in bundle implementation, including The Alliance for Innovation on Maternal Health (AIM) and CMQCC divide metrics into several categories: process, structure and outcome measures.[21, 22] Process measures include components of early recognition including assessment of hemorrhage risk assessment and quantitative assessment of blood loss. They also include process for fostering a culture of safety and improvement via systems-based learning, including case reviews for all hemorrhage cases that have complications (such as transfusion of > 4 units packed red cells or ICU admissions) and event debriefs for cases of hemorrhage above a specific threshold.

The World Health Organization emphasizes the importance of administration of a prophylactic uterotonic as an important process metric, but also recognizes that locally-agreed, more specific indicators may be employed as well. Importantly, none of this guidance addresses directly how to measure the quality of the efforts to obtain hemostasis during PPH – either the interventions performed or the timing in which they are performed.

There is some evidence to suggest that focused attention to the interventions and timing of procedures performed for PPH management may improve outcomes. French investigators from two facilities participating in a cluster-randomized trial of a PPH bundle continued ongoing reviews of PPH hemorrhage cases.[18] During that time, cases of PPH were audited to ensure provision of "optimal care", which included: 1. examination of the uterine cavity and/or manual removal of the placenta within 15 min of the PPH diagnosis, 2. call for additional staff, 3. instrumental examination of the vagina and cervix, 4. intravenous administration of oxytocin, and 5. if PPH persisted and due to atony, IV administration of sulprostone (prostaglandin E2 agonist; second-line agent) within 30 min of initial diagnosis. The findings of the audit were

presented during quarterly multidisciplinary meetings in which the treating providers and audit team had the opportunity to discuss both the audit results and other lessons from each PPH. The investigators found that over the four years the auditing process, there was a statistically significant improvement in the rate of severe PPH (bleeding requiring blood transfusion, surgical intervention, or resulting in a hemoglobin decline of ≥4 g/dL or maternal death) at both facilities (1.52% to 0.96% at one facility, and 2.08% to 0.57% at the other), while rates of adherence to their guidelines improved over the study period. While they did not assess clinical outcomes, investigators in Malawi and Ethiopia also demonstrated that criteria-based clinical audits could improve adherence to PPH process metrics.[19, 20]

Finally, outcome measures that have been used for PPH include severe maternal morbidity (SMM) in hemorrhage cases, transfusions > 4 units, and hemorrhage rates. Each of these strategies has limitations. SMM in hemorrhage cases is a measure reported using delivery diagnosis related group (DRG) codes in association with many ICD-10 codes validated as being associated with morbidity. Limitations include that coding data does not reliably distinguish between 1 versus 100 units of blood, and these codes are not risk stratified. As an example, a hospital that is a referral center for placenta accreta spectrum may have higher rates of transfusion than a level one facility that transfers all patients with a high risk of hemorrhage to another center. Hemorrhage rates are also fraught with potential error, as quantitative blood loss often leads to higher numeric volumes of blood loss being reported simply related to more accurate assessments.

PROPOSED BENCHMARKS AND FURTHER DIRECTIONS

We would suggest consideration of a few specific management strategies in stage-based hemorrhage protocols, based on existing literature (Table). We selected these as benchmarks

based on the evidence reviewed above - that timely use of uterotonics, TXA, and procedural placement reduces the risk of severe hemorrhage sequela and need for additional procedures. Hospital systems and PQCs that include auditing in their implementation strategies reported improvements in PPH outcomes, while hospitals that merely have a protocol without measuring compliance do have not had similar improvements noted.

We recognize that the benefits of timely PPH management raises the question of whether specific PPH treatment time standards should be recommended. Clearly, timeliness for PPH response matters greatly. However, the authors believe that implementation of PPH care benchmarks involving specific time standards should include an evaluation of their effectiveness prior to broad implementation. Despite good intentions, quality metrics in medicine, particularly in obstetrics, remain challenging to define and implement.[21] There is precedent in the medical literature regarding unintended adverse consequences of mandating process metrics based on time. Based on observational data that provision of antibiotics within 4 hours of hospitalization for patients with community acquired pneumonia was associated with improved outcomes, [22] the Infectious Disease Society of American included this benchmark as a practice guideline, and it was tied to quality reporting and reimbursement.[23] This benchmark created a strong incentive to prescribe antibiotics in any patient potentially at risk for community acquired pneumonia, which is often difficult to diagnose. Consequently, there was a significant increase in antibiotic prescriptions for hospitalized inpatients, an increased rate of incorrect diagnosis of community acquired pneumonia, and no improvement in outcomes for patients in which the CAP diagnosis was confirmed.[24] Based on this evidence, this benchmark was removed from guidelines.

One could imagine that a similarly plausible phenomenon might be possible for PPH benchmarks – that a benchmark might prompt reflexive delivery of these services, even in

patients in which it is unlikely to benefit, to ensure the provider gets "credit" for the intervention. Considering the example of uterotonics, for example, all available agents have potential adverse effects (*e.g.*, hypertension for methylergonovine, bronchospasm for carboprost, fever for misoprostol). The need to precisely document times of hemorrhage recognition and management steps, and the PPH etiology (since most of these guidelines are primarily pertinent to PPH due to uterine atony) would also significantly increase data collection burden for participating sites. For this reason, we would advocate for a prospective observational study, ideally with a difference-in-difference design, but if not possible via a pre-/post- design, to evaluate whether routine measurement and reporting of time-based PPH management benchmarks improves adherence, and whether it improves PPH outcomes, considering outcomes such as transfusion of 4 units or more of blood products, need for additional procedure, and ICU admission.

CONCLUSION

Postpartum hemorrhage remains a significant etiology of maternal morbidity and mortality world-wide. Recognition that a hemorrhage is occurring is essential to lead to management via Stage-based protocols. We recommend these protocols include a focus on early uterotonic use, TXA and intrauterine balloon tamponade. Finally, a focus on implementation using team training, simulation and auditing for compliance are essential features to ensure protocols lead to a reduction in hemorrhage management.

Table 1: Suggested benchmarks for PPH protocol implementation

For hemorrhage involving uterine atony, administration of a second uterotonic (after Pitocin) without delay once PPH is recognized, typically either methylergometrine or carboprost unless contraindicated.
For patients with PPH, administration of TXA as rapidly as feasible after diagnosis.

For patients whose PPH due to atony and is refractory to a second uterotonic, early placement of an intrauterine tamponade balloon (e.g., Bakri balloon) or intrauterine vacuum device (e.g., Jada device) before blood loss exceeds 1.5 L.
Auditing of PPH cases to ensure teams are following PPH bundles and stage-based protocols, with corrective action plans to include re-education and simulation when compliance is suboptimal; with escalation to processes such as peer review reserved for cases in which specific providers do not alter practice patterns despite re-education.

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