

# National Partnership for Maternal Safety

## Consensus Bundle on Obstetric Hemorrhage

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Hemorrhage is the most frequent cause of severe maternal morbidity and preventable maternal mortality and therefore is an ideal topic for the initial national maternity patient safety bundle. These safety bundles outline critical clinical practices that should be implemented in every maternity unit. They are developed by multidisciplinary work groups of the National Partnership for Maternal Safety under the guidance of the Council on Patient Safety in Women's Health Care. The safety bundle is organized into four domains: Readiness, Recognition and Prevention, Response, and Reporting and System Learning. Although the bundle components may be adapted to meet the resources available in individual facilities, standardization within an institution is strongly encouraged. References

contain sample resources and "Potential Best Practices" to assist with implementation.

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Obstetric hemorrhage is the most common serious complication of childbirth and is the most preventable cause of maternal mortality.<sup>1,2</sup> Furthermore, recent data suggest that rates of obstetric hemorrhage are increasing in developed countries, including the United States,<sup>3</sup> and that rates of hemorrhage-associated severe maternal morbidity exceed the morbidities associated with other obstetric and medical conditions.<sup>4,5</sup>

Standardized, comprehensive, multidisciplinary programs have demonstrated significant reductions in morbidity.<sup>6,7</sup> Therefore, a workgroup of the Partnership for Maternal Safety, within the Council on Patient Safety in Women's Health Care and representing all major women's health care professional organizations, has developed an obstetric hemorrhage safety bundle.<sup>8</sup> The goal of the partnership is the adoption of the safety bundle by every birthing facility in the United States. A patient safety bundle is a set of straightforward, evidence-based recommendations for practice and care processes known to improve outcomes.<sup>9</sup> Such a bundle is not a new guideline, but rather represents a selection of existing guidelines and recommendations in a form that aids implementation and consistency of practice. The consensus bundle on obstetric hemorrhage is organized into four action domains: Readiness, Recognition and Prevention, Response, and Reporting and Systems Learning. There are 13 key elements within these four action domains (Box 1). It is anticipated that few, if any, hospitals will have 100% of these elements in place at the start of this quality improvement process, and this document should serve as a checklist from which to work. Low-resource hospitals should be able to accomplish most of these recommendations, but, if some are

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not achievable (eg, sufficient blood bank inventory), consideration should be given to directing higher-risk patients to another facility. Furthermore, given the wide diversity of birthing facilities, we are not recommending a single national protocol, but we are asking that every facility address each domain and use our examples to assist them in their journey to improved maternal safety. This document was developed by official representatives from the American Association of Blood Banks, the American Academy of Family Physicians, the American College of Nurse-Midwives, the American College of Obstetricians and Gynecologists (the College), the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN), the Society for Maternal-Fetal Medicine, and the Society for Obstetric Anesthesia and Perinatology.

Historically, estimated blood loss more than 500 mL after vaginal birth and more than 1,000 mL after cesarean birth were widely used to define postpartum hemorrhage, but these estimates are hindered by the near-universal tendency to underestimate blood loss at birth.<sup>10,11</sup> These volumes are actually close to the average blood loss for vaginal and cesarean births. The College's nomenclature consensus conference (reVITALize) recently revised the definition of early postpartum hemorrhage as "cumulative blood loss of  $\geq 1,000$  mL OR blood loss accompanied by signs and symptoms of hypovolemia within 24 hours following the birth process," with a note that "cumulative blood loss of 500–999 mL alone should trigger increased supervision and potential interventions as clinically indicated."<sup>12</sup> Therefore, careful and cumulative assessment of blood loss is a crucial component of this safety bundle. The twin themes of "denial and delay" are a recurrent finding in case reviews of severe hemorrhage events and represent important quality improvement opportunities addressed throughout the bundle.<sup>2</sup>

## READINESS (EVERY FACILITY)

The Readiness domain includes five areas of focus to be addressed by every facility to prevent delays and prepare for the optimal management of obstetric hemorrhage cases. Delays in diagnosis or treatment of hemorrhage account for most adverse outcomes and present an opportunity for significant improvement.<sup>2,13</sup>

### 1. Hemorrhage Cart

A cart containing the necessary supplies should be immediately available on the birthing unit, with similar materials available on antepartum and postpartum floors. Cart contents should be determined with input from obstetric, anesthesiology, nursing, midwifery, and

## Box 1. Obstetric Hemorrhage Safety Bundle From the National Partnership for Maternal Safety, Council on Patient Safety in Women's Health Care

### Readiness (Every Unit)

1. Hemorrhage cart with supplies, checklist, and instruction cards for intrauterine balloons and compression stitches
2. Immediate access to hemorrhage medications (kit or equivalent)
3. Establish a response team—who to call when help is needed (blood bank, advanced gynecologic surgery, other support and tertiary services)
4. Establish massive and emergency-release transfusion protocols (type-O negative or uncrossmatched)
5. Unit education on protocols, unit-based drills (with postdrill debriefs)

### Recognition and Prevention (Every Patient)

6. Assessment of hemorrhage risk (prenatal, on admission, and at other appropriate times)
7. Measurement of cumulative blood loss (formal, as quantitative as possible)
8. Active management of the 3rd stage of labor (department-wide protocol)

### Response (Every Hemorrhage)

9. Unit-standard, stage-based obstetric hemorrhage emergency management plan with checklists
10. Support program for patients, families, and staff for all significant hemorrhages

### Reporting and Systems Learning (Every Unit)

11. Establish a culture of huddles for high-risk patients and postevent debriefs to identify successes and opportunities
12. Multidisciplinary review of serious hemorrhages for systems issues
13. Monitor outcomes and process metrics in perinatal quality improvement committee

Modified from: <http://www.safehealthcareforeverywoman.org/>

pharmacy providers. It is also valuable for the cart to contain cognitive aids for infrequently performed technical procedures, such as placement of uterine tamponade balloons and uterine compression sutures. Unit leadership must determine a system to ensure consistent cart stocking and maintenance. Examples of cart contents have been published.<sup>14,15</sup>

### 2. Immediate Access to Hemorrhage Medications (Kit or Equivalent)

The need for immediate medication availability must be balanced with security and safety. Storing

medications in the hemorrhage cart will necessitate locking the cart and providing limited access. Some uterotonic medications require refrigeration, making emergency-cart storage impractical. Consideration should be given to having several standard uterotonic drugs together in a hemorrhage kit. Many automated medication-dispensing machines allow for multiple medications to be released at once or as a kit, providing faster access. Units should work with the pharmacy department to determine medication storage and immediate access policies. Monitoring the time interval from the request for uterotonic medication to administration should be a part of routine hemorrhage drills.

### 3. Establish a Response Team

It is critical that all institutions determine who will be part of the core response team for obstetric hemorrhage and the method for immediate communication. The composition of the response team will depend on facility resources and the severity and clinical context of each hemorrhage. In addition to the primary maternity care provider and nurse, the team will likely engage clinicians from anesthesiology, transfusion service (blood bank), pharmacy, advanced gynecologic surgery, critical care medicine, the main operating room, interventional radiology, and additional nursing resources.<sup>16</sup> Support programs and personnel such as social service or chaplains should be available as needed. All of these departments should be part of the hemorrhage response planning team. A critical part of the plan will be determining a simple and reliable way to notify required team members using readily available phone or pager numbers or a “rapid response” or “code” system.

### 4. Protocols for Emergency Release of Blood Products and for Massive Transfusion

Transfusion protocols for obstetric hemorrhage addressing emergency release of blood products and massive transfusion should be implemented.<sup>17,18</sup> Emergency release is typically used for an actively bleeding woman with unstable vital signs despite fluid boluses. Emergency-release products can be universally compatible (ie, group O, Rh (D)-negative red blood cells [RBCs] or AB plasma) or type-specific (A to a group A patient) if the patient’s blood type is on record and sufficient quantities of that type are available in the blood bank. Facilities with limited blood supply should develop plans with local and state emergency services for immediate blood shipment. Higher-risk patients

with potential need for multiple units of blood products should be triaged to facilities with larger transfusion services.

A massive transfusion protocol facilitates rapid dispensing of RBCs, plasma, and platelets in a pre-defined ratio intended to preclude development of a dilutional coagulopathy that can result if a significant percentage of the patient’s blood volume is replaced with large quantities of crystalloid, colloid, or RBCs. These blood products are often dispensed in combination packs, addressing the important logistic challenge of providing large volumes of blood components in a short time. In the setting of continued active hemorrhage, and after the first several units, there is retrospective and some prospective evidence supporting an RBC-to-plasma ratio between 1:1 and 2:1 for the total transfused units.<sup>17–19</sup> The administration of a dose of apheresis platelets for approximately every 6–8 units of RBCs is commonly accepted.<sup>18</sup> Unit protocols should include guidance about early coagulation testing and serial laboratory monitoring and, in some instances, point-of-care technologies to assess the maternal coagulation profile and guide ongoing correction.<sup>19</sup> Fibrinogen is consumed rapidly during obstetric hemorrhage, so it is important to monitor fibrinogen levels and replace with cryoprecipitate as needed (some centers have added cryoprecipitate to their obstetric massive transfusion protocols).<sup>20</sup>

### 5. Unit Education on Protocols: Regular Unit-Based Drills With Debriefs

Once an obstetric hemorrhage management plan has been developed at an institution, education about the protocol is a critical next step.<sup>7</sup> Unit-based drills are an effective way to familiarize every team member with the entire safety bundle and the new management plan. Drills serve multiple purposes, including review and imprinting of the protocol, identification of correctable systems issues, and practice of important team-related skills; in addition, drills have been shown to improve outcomes.<sup>21</sup> Post-drill debriefings provide an invaluable opportunity to learn from the experience, specifically to reinforce areas of the drill that went well, discuss areas in need of improvement, share lessons learned, and highlight systems issues to allow for concrete planning for potential solutions.<sup>22–24</sup> Debriefs after drills model the process for debriefs that should occur after actual hemorrhages. Drills may be combined with practicing infrequently used hemorrhage technical skills (placing a tamponade balloon or a compression suture) using simple aids.

## RECOGNITION AND PREVENTION (EVERY PATIENT)

The Recognition and Prevention domain addresses three areas that should be incorporated into the care of every patient.

### 6. Assessment of Hemorrhage Risk

Identification of risk factors for postpartum hemorrhage can help to improve readiness, allow increased surveillance and early recognition, increase the use of preventive measures, and prepare the team to initiate an early, aggressive response to bleeding.<sup>10</sup> Risk assessment should be considered at multiple time points during patient care, including antepartum, on admission to labor and delivery, later in labor (as new risks such as chorioamnionitis or prolonged labor evolve), and on transfer to postpartum care. Examples of such anticipatory planning include ensuring the availability of an adequate supply of blood products, developing a specific patient-care plan, and identifying the availability of support personnel. Antepartum risk assessment and anticipatory planning should include consideration of transfer of care for women with the highest risk of hemorrhage (such as placenta accreta or prior cesarean deliveries with placenta previa) to a tertiary center with an experienced team and robust blood bank resources.<sup>25</sup> Women who refuse blood products, including those who self-identify as Jehovah's Witnesses, present a significant opportunity for antenatal planning and should have a multidisciplinary plan.<sup>14,23</sup>

Multiple risk-assessment tools are available and are useful in planning, but it should be understood that they are imperfect.<sup>10,13-15</sup> Typically these tools identify 25% of women to be at higher risk who will then develop 60% of the severe hemorrhages (requiring transfusion).<sup>26,27</sup> Therefore, because approximately 40% of postpartum hemorrhages occur in low-risk women, every birth has to be considered to have risk, reinforcing the need for universal vigilance.

### 7. Measurement of Cumulative Blood Loss

Imprecise provider estimation of actual blood loss during birth and the postpartum period is a leading driver of delayed response that can result in preventable morbidity or worse.<sup>28</sup> Appropriate management plans commonly rely on assessment of the amount of blood lost; therefore, careful assessment of blood loss is a critical step and involves two concepts: 1) using careful, direct, and accurate measurement of blood lost (ie, quantitative blood loss) and 2) keeping a cumulative record of blood loss for all women throughout the birthing process.

Visual estimation of blood loss, sometimes called "a glance and a guess," is common practice in maternity care, but the inaccuracy of this practice was well-established in the 1960s.<sup>11</sup> Visual estimation can result in underestimation of blood loss by 33–50%, particularly when large volumes are lost.<sup>11,29</sup> Clinicians can significantly improve their estimation skills after training with visual aids but will experience skill decay within 9 months, necessitating frequent retraining to maintain competence.<sup>10</sup> Therefore, techniques for direct measurement of blood loss are under investigation.

Direct measurement of blood loss can be accomplished by two complementary approaches. The easiest to initiate is to collect blood in calibrated, under-buttocks drapes for vaginal birth or in calibrated canisters for cesarean birth. Institutions have avoided the problem of measuring nonblood fluids by starting measurement after the birth of the neonate. The second approach is to weigh blood-soaked items and clots. These items can be collected in a single bag and weighed using a gravimetric method. By using this method, the weight of dry pads is subtracted from the total weight to obtain an estimate of blood loss. Calculation aids built into electronic health records can simplify the process. Practical details for successful implementation of quantitative blood loss have been described, and future investigation should clarify which approaches are the most precise and the most practical.<sup>24,30</sup>

Each maternity unit should strive for the most accurate blood-loss assessment for every mother. In addition, measurement of cumulative blood loss (analogous to measurement of urinary output) is important for escalating the hemorrhage management plan and should be considered at set points during the birthing process and more frequently if bleeding is brisk. This is particularly important for communicating blood loss in the recovery period, when the maternity care provider is no longer in direct attendance.

### 8. Active Management of Third Stage of Labor

Active management of the third stage of labor has been demonstrated to be the single most important approach to preventing postpartum hemorrhage.<sup>31</sup> Of the three classic components—oxytocin, uterine massage, and cord traction—recent studies have indicated that oxytocin is the key component.<sup>32,33</sup> A 2013 Cochrane systematic review found that prophylactic usage of oxytocin, 10 units by intravenous infusion (not intravenous bolus) or intramuscular injection, remains the most effective medication with the fewest

side effects compared with ergot alkaloids (nausea and vomiting) and misoprostol (hyperpyrexia).<sup>34</sup> Postponing oxytocin after delayed cord clamping does not increase the risk of hemorrhage. Earlier studies found no consistent difference between oxytocin administered with delivery of the anterior shoulder or with delivery of the placenta.<sup>35</sup> Every facility should have a departmental protocol for oxytocin use in the immediate postpartum period.<sup>36</sup> The World Health Organization, the College, the American Academy of Family Physicians, and AWHONN recommend oxytocin administration after all births.<sup>37-40</sup> Policies should include informing women about the use of active management of the third stage labor with oxytocin to reduce risks of postpartum hemorrhage. Women without risk factors having a physiologic birth (spontaneous onset of labor, without epidural analgesia or other medications) who make an informed choice to forgo prophylactic oxytocin can be supported in their decision.<sup>41</sup>

## RESPONSE (EVERY HEMORRHAGE)

The Response domain describes two key interventions that should be utilized in every hemorrhage.

### 9. Obstetric Hemorrhage Emergency Management Plan

Each delivery area should have a detailed management plan for response to obstetric hemorrhage emergencies similar to Code Blue for cardiopulmonary arrest.<sup>16</sup> Because obstetric hemorrhage represents a diverse group of diagnoses, a critical initial step is to determine the etiology. Without an accurate diagnosis, providers can be led down the wrong pathway, with potentially serious consequences.<sup>42</sup> Uterine atony accounts for more than 70% of cases, but a careful examination (with good lighting and exposure) is important for identifying vaginal or cervical lacerations or a retained placenta. Evaluation strategies are covered in more detail in the sample protocols and should include the potential for concealed or intra-abdominal hemorrhage.

Stage-based management plans have been found to facilitate an organized, stepwise response to blood loss and maternal warning signs. They ensure that resources are not wasted while each patient receives optimal therapy.<sup>7,9,14</sup> The emergency management plan should provide direction for the following: 1) determining the actual diagnosis, 2) triggering vital signs and blood loss for each stage, 3) defining the response team members and their roles for each stage, 4) creating a communication plan for activating response, and 5) identifying the medications,

equipment, and other tools needed by personnel at each stage.

Standardization of obstetric hemorrhage emergency response facilitates staff training, drills, and understanding and promotes team-building.<sup>43</sup> As institutions gain experience with electronic medical records, clinical algorithms such as a standardized hemorrhage emergency plan can be embedded in order sets, documentation tools, decision rules, and alerts to aid clinicians.

No single plan is appropriate for every facility. Several examples (all quite similar) have been field tested in California,<sup>14</sup> New York,<sup>22</sup> and Florida<sup>44</sup> and by AWHONN.<sup>24</sup> Shields et al<sup>7</sup> adapted and implemented the California plan and documented impressive improvements in hemorrhage care within a 37-hospital health system. Each institution needs to adjust the plan to meet its individual capabilities. The management plan often involves new institutional policies and procedures for many of the topics discussed earlier. Once defined and implemented, the plan can be used to guide formal drills and should be refined by debriefs and in-depth reviews after actual events.

### 10. Support Program for Patients, Families, and Staff

Severe maternal hemorrhage is a highly traumatic event for every individual involved, including the mother, family, and clinicians. Obstetric hemorrhage can occur rapidly, and the excitement and joy of childbirth shifts abruptly when the maternity team is required to focus on management of the bleeding, which may include procedures that are uncomfortable or painful. Family members are often moved from the bedside while the woman experiences invasive measures that cannot be fully explained by the clinician because of time constraints. Such actions, although undertaken with the intent of addressing a clinical emergency, can leave all involved (including the clinicians) shaken and in need of support.<sup>45,46</sup>

Women and their families need timely information, reassurance, opportunities to discuss the incident with the maternity care provider, and referrals to support resources. Furthermore, women and their families who experience severe hemorrhage benefit from caring, supportive words and actions by clinicians who recognize the potential for posttraumatic stress disorder, which can occur even with satisfactory clinical resolution of the hemorrhage.<sup>47</sup>

The maternity team needs to debrief after the incident and have access to informal or formal counseling through their facilities.<sup>47</sup> Resources are available.<sup>9,14,44,48</sup>

## REPORTING AND SYSTEMS LEARNING (EVERY UNIT)

The Reporting and Systems Learning domain includes a focus on systems improvements that should be implemented by every unit providing maternity care.

### 11. Establish a Culture of Huddles and Debriefs

Although a discussion of team training is beyond the scope of this article, there are some key features of every team-training program that will help establish a culture of safety and ensure successful implementation of safety bundles such as this one. Briefs, huddles, and debriefs need to be routine. Briefs are planning meetings that are used to form the team, designate roles and responsibilities, establish climate and goals, and engage the team in short-term and long-term planning. Huddles are brief ad hoc team meetings designed to regain situational awareness, discuss critical issues and emerging events, anticipate outcomes and contingencies, assign resources, and express concerns.<sup>49</sup> Debriefs are short, informal feedback sessions that occur after events and are designed to identify opportunities to improve teamwork, skills, and outcomes.<sup>50</sup>

These concepts are built into the hemorrhage bundle to remind members to communicate with the entire team. As briefings and huddles become more routine, members of response teams will have more awareness of their roles and they will be better able to use available resources. Teams will learn from each event, identify and correct systems issues, and continue to grow and improve. Furthermore, it is important for birthing facilities to support a culture in which all multidisciplinary team members are able to communicate their concerns and questions regarding care of obstetric emergencies.<sup>51</sup> Resources are available to help facilitate and guide institutions and teams as they begin to incorporate these important concepts into daily practice.<sup>22,49,50</sup>

### 12. Multidisciplinary Review of Serious Hemorrhages

Multidisciplinary reviews are different from debriefs; they are formal meetings including staff involved in the incident, unit and facility leadership, and risk-management personnel.<sup>52</sup> The purpose of these reviews is to identify systems issues or breakdowns that influenced the outcome of the event. These reviews should be accomplished as soon as possible after a severe event. A multidisciplinary Perinatal Quality Committee is an ideal body to review cases and track process and outcome measures. As emphasized in the recent College and Society for Maternal-Fetal Medicine

consensus statement on levels of maternal care, assisting small hospitals with quality reviews and improvement is an important role for regional centers.<sup>25</sup>

Reviews should be sanctioned by the facility, protected from discovery in legal proceedings, and include a thorough record review, event timeline, and focused root-cause analysis. As of January 2015, The Joint Commission recommends multidisciplinary, systems-focused reviews for all severe obstetric hemorrhages (four or more units of RBCs or intensive care unit admissions).<sup>53,54</sup> Suggested forms for accomplishing reviews can be found at [www.safehealthcareforeverywoman.org](http://www.safehealthcareforeverywoman.org).

### 13. Monitor Outcomes and Process Metrics

Monitoring process and outcome measures is important for the successful introduction of quality-improvement projects. Process measures typically document how often a new approach (eg, risk screening, huddles, quantitative blood loss, debriefs) is actually used and can be predictive of an institution's readiness to respond to a hemorrhage event. Process measures reinforce the change process and provide forward momentum. Quick wins are important for staff morale and project success. Tracking adherence with key elements of the hemorrhage management plan is useful and may be facilitated with a short debrief tool used immediately after an event.<sup>22,50</sup>

Project success is generally measured by improved outcomes. The overall goal is to reduce the number of obstetric hemorrhages that escalate into major blood loss resulting in severe maternal morbidity or mortality. We recommend that facilities track the number of women who receive four or more units of RBCs or require care in the intensive care unit.<sup>55</sup> These occurrences are relatively uncommon (2–4/1,000 births). Although not appropriate for interhospital comparison, these measures do allow tracking progress over time. The Joint Commission's recommendation of these case-review indicators creates an incentive for hospital quality departments to identify and track these cases.<sup>53,54</sup> Care should be taken not to discourage the appropriate administration of blood when needed. We would welcome the development of additional low-burden process measures to promote implementation, such as monthly debriefs after a significant hemorrhage (defined locally based on frequency of hemorrhages).

## CONCLUSION

The goal of this safety bundle is to reduce the frequency of severe hemorrhages and improve maternal outcomes. The bundle is inherently multidisciplinary and

is designed to assist in establishing a culture of safety. Although we recognize the need to individualize the specific details of these protocols to fit available resources, every unit should strive to implement all 13 elements of the bundle. We present a series of comprehensive resources to support implementation of the safety bundle and direct providers to a growing number of state and national quality collaboratives that stand ready to assist.

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