Comprehensive maternal hemorrhage protocols reduce the use of blood products and improve patient safety

Laurence E. Shields, MD; Suzanne Wiesner, RN; Janet Fulton, RN, PhD; Barbara Pelletreau, RN

The purpose of this study was to assess the effectiveness of instituting a comprehensive protocol for the treatment of maternal hemorrhage within a large health care system. A comprehensive maternal hemorrhage protocol was initiated within a health care system with 29 different delivery units and with >60,000 annual births. Compliance with key elements of the protocol was assessed monthly by a dedicated perinatal safety nurse at each site and validated during site visits by system perinatal nurse specialist. Outcome variables were the total number of units of blood transfused and the number of puerperal hysterectomies. Three time points were assessed: (1) 2 months before implementation of the protocol, (2) a 2-month period that was measured at 5 months after implementation of the protocol, and (3) a 2-month period at 10 months after implementation. There were 32,059 deliveries during the 3 study periods. Relative to baseline, there was a significant reduction in blood product use per 1000 births (−25.9%; P < .01) and a nonsignificant reduction (−14.8%; P = .2) in the number of patients who required puerperal hysterectomy. Within a large health care system, the application of a standardized method to address maternal hemorrhage significantly reduced maternal morbidity, based on the need for maternal transfusion and peripartum hysterectomy. These data support implementation of standardized methods for postpartum care and treatment of maternal hemorrhage and support that this approach will reduce maternal morbidity.

Key words: maternal hemorrhage, patient safety, transfusion

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Received April 21, 2014; revised June 17, 2014; accepted July 3, 2014.

The authors report no conflict of interest.


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http://dx.doi.org/10.1016/j.ajog.2014.07.012

MONTH 2014 American Journal of Obstetrics & Gynecology 1
Materials and methods

The data that were collected for this report were from an approved ongoing clinical patient safety monitoring program and as part the hospital system’s continuous quality improvement programs.

Data were collected from 29 Dignity Health System hospitals with maternity units. The hospitals vary in size from a small rural center with <200 deliveries per year to large urban hospitals with >6000 births annually. There are approximately 60,000 births annually within the hospital system. In 2010, the hemorrhage protocol was distributed to all hospitals within the system with the recommendation that each facility have an onsite dedicated hemorrhage cart. Compliance with the protocol was not assessed until November 2011. In November 2011, all hospitals were required to have a dedicated perinatal safety nurse and prospectively to collect data that were related to any obstetric hemorrhage and that met the criteria outlined in the protocol (Table 1). Records and processes were audited to assess compliance with hemorrhage protocol recommendations. To be considered compliant, all components that are outlined in Table 1 had to be met. If a single element was not met, the case was considered noncompliant. Compliance with the protocol was assessed monthly; each center’s results were distributed to all sites through monthly perinatal safety conference calls, and the results were posted to an internal website. Physician leaders at each facility were encouraged to participate in the monthly conference calls. To encourage compliance and administrative support, senior administrative leaders were required to present their data at corporate leadership meetings. In addition, 2 perinatal safety nurses made scheduled site visits to audit the accuracy of the data that were submitted. When compliance was less than expected at any facility, the perinatal safety nurse was encouraged to address any specific concerns with the physician staff. If issues or concerns were still present, the lead author made site visits to obstetrics department meetings to review the protocol, rationalization for implementation, and data that supported its use. Hospital administration also attended these meeting. Compliance after site visits uniformly improved. At each site, staff education of all key elements and low fidelity drills were encouraged.

The protocol was designed to provide graded assessments of patient acuity with standardized interventions based on the acuity status of the patient. It is important to point out that this was not designed or implemented as a stand-alone transfusion policy. Based on our previous experience, it was assumed that early standardized intervention and aggressive early transfusion with component blood therapy would decrease the severity of hemorrhage and use of blood products. The protocol that was used was similar to our previous report with minor modifications (Figures 1-4).

The protocol was initiated at the time of admission to labor and delivery. At that time, an initial risk assessment was completed that was related to the patient’s potential risk for obstetric hemorrhage (Table 2). Patients were then categorized as low, medium, or high risk; based on this admission risk assessment, different levels of “status alerts” were given to the blood bank. The validity of this risk assessment approach has been validated recently by others. This process was done primarily to streamline the initial rapid access to blood products when needed. In the event that there was no immediately available cross matched blood when patients reached stage 3, uncrossed type O-negative or type-specific blood was released for use.

Although each patient’s status was assessed in both the intrapartum and postpartum time periods, protocol interventions were designed primarily to address postpartum hemorrhage. Skills training that was related to recognition of blood loss was used to improve accuracy. Because of recognized inaccuracies in blood loss estimates, even after training, we recommended that a quantitative estimate blood loss be used. This was accomplished by weighing all lap-sponges, bed linens if needed, and fluid in collection systems. Non-blood fluid in delivery collection systems, particularly before delivery of the placenta, was subtracted from the estimated blood loss. Although there is some risk that amniotic fluid is included in the blood loss estimate, this method of assessment has been shown to improve the accuracy of blood loss estimates.

The patient’s bleeding status was assessed continuously and assigned a clinical “hemorrhage stage,” which were grouped into 4 categories (stages 0-3). Stage 0 was designated as a normal intrapartum and postpartum course. Stage 1 was defined as bleeding greater than expected for normal vaginal delivery (500 mL) or cesarean delivery.

<p>| TABLE 1 |</p>
<table>
<thead>
<tr>
<th>Checklist for protocol compliance and data collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Admission hemorrhage risk assessment completed</td>
</tr>
<tr>
<td>☐ Correct blood bank request requested, based on risk</td>
</tr>
<tr>
<td>☐ Blood and blood clots weighed per protocol</td>
</tr>
<tr>
<td>☐ Correct laboratory results obtained for stage 2 and 3 hemorrhage</td>
</tr>
<tr>
<td>☐ Were &gt;2 uterotonics given without the medical doctor present</td>
</tr>
<tr>
<td>☐ Blood products administered according to protocol</td>
</tr>
<tr>
<td>Quantity blood products are administered and which ones**</td>
</tr>
<tr>
<td>Number of peripartum hysterectomies*</td>
</tr>
</tbody>
</table>

* Additional data that were collected but not used to assess compliance with the protocol.

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

Stage 2 was defined as bleeding that did not respond to conservative treatment, as outlined in Stage 1. Stage 3 was defined as continued bleeding, with actual or expected blood loss to exceed 1500 mL. There were minor changes to the originally published protocol based on facility feedback and recommendations from physicians and nursing staff within the Dignity Health System. Details of each stage are outlined below and in Figures 1–4.

Patients whose condition was activated to stage 1 after vaginal delivery were treated primarily by nursing staff. This stage was designed to encourage prompt assessment and treatment of uterine atony. If uterine atony was suspected, a single dose of an uterotonic, in addition to oxytocin used for the third stage of labor, could be given after discussion with the physician. If there were a need for a second dose of a supplemental uterotonic agent, the patient’s status was upgraded to stage 2. The details of stage 2 are outlined in Figure 3, A (vaginal delivery) and B (cesarean delivery). The most significant components of stage 2 was the commitment of additional personnel to assist with patient care; both the patient’s obstetrician and anesthesiologist were required to report to the patient’s bedside. This requirement was believed to be critical and was designed to prevent continued use of therapies that may be either ineffective or would limit timely physician evaluation and treatment. In addition, most interventions that were included in stage 2 require physician assessment. Based on previous experience, aggressive intervention at this stage should limit the number of patients that would progress to “near miss” or life-threatening hemorrhage and/or disseminated intravascular coagulation.11,14,18,27 To facilitate treatment, an "obstetrics hemorrhage cart" was developed, and it was recommended that there be 1 cart assigned to both labor and delivery and any of the operating room areas where obstetrics patients may be treated. The hemorrhage cart was designed and organized to contain all of the routine and unique supplies necessary for patient treatment. The recommended contents of the cart have been previously described.18,28 At stage 2, the hemorrhage cart was brought to the patient’s room.

The patient’s status was elevated to stage 3 if the estimated blood loss exceeded or was expected to exceed 1500 mL (Figure 4). The primary goals of stage 3 were to mobilize all necessary resources towards reducing further blood loss and to reduce the risk of the development of disseminated intravascular coagulation. Additional nursing staff were assigned, and considerations for additional physician support (obstetrics, anesthesia, general, or urologic surgeons and interventional radiology personnel) were also suggested, as deemed necessary. At this point, fixed ratios of blood products in a designated "obstetrics hemorrhage pack" were prepared for immediate release from the blood bank. Details of the “obstetrics hemorrhage pack” are outlined in Table 2. In the event that either a severe placental abruption or an amniotic fluid embolism was suspected, preparation of 10 units of cryoprecipitate was also recommended. Blood (packed red blood cells [pRBCs]) and fresh frozen plasma (FFP) were given in fixed ratios of 3:2.18,29,30 This ratio was increased to 1:1 after the transfusion of the first 6 units of pRBCs and 4 units of FFP. The use of high ratios of plasma to red blood cells has been shown to improve survival in trauma-related hemorrhage31-33 and to improve outcomes in obstetrics patients whose condition required transfusion.18,34 Treatment was directed towards the goal of maintaining the hematocrit level at >24%, international normalized ratio at <1.5, platelet count at >50,000/μL, and fibrinogen level at >100,000 mg/dL. Additional treatment goals were suggested that included maintaining the patient's pH at >7.2, base excess at <-5, temperature at >95°F (35°C), and a normal ionized
calcium level, because all of these factors are known to influence coagulation.

Postpartum care was also modified for those patients whose condition was activated to stage 2 or stage 3; stage 3 patients were assigned to labor and delivery or transferred to the intensive care unit, depending on their acuity. The decision for intensive care unit admission primarily was based on concerns related to the presence of pulmonary and/or renal compromise. The minimal frequency and duration of vital signs and laboratory assessments were also outlined by the protocol.

For data analysis, the 3 time periods were compared. Time point 1 was a 2-month baseline collection period (November and December 2011). Then, 2 additional postimplementation time periods (April-June 2012 and September-October 2012) were assessed. Compliance with the protocol was assessed monthly based on the 5 components that are given in Table 1. Comparison of peripartum hysterectomy rates were done with the use of 2011 rates relative to 2012 rates when the hysterectomy was associated with coding that was consistent with hemorrhage or transfusion codes (ie, 666.x, 285.1, 99.04-99.07) (Table 1). Data were analyzed by t test and by comparison of the differences between independent proportions with the use of the online statistical program, Vassar Stats (www.vassarstats.net).

**Results**

During the 3 time periods that were evaluated, there were a total of 32,059 deliveries or approximately 10,000-11,000 deliveries per 2-month assessment (Table 3). As expected during the course of monitoring, compliance of all 5 monitored parameters increased from

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**FIGURE 2**

Protocol algorithm for stage 1 hemorrhage

- **Vaginal Delivery**
  - EBL >500 mL
  - Call for help
  - Weigh Blood Loss
  - Increase IV rate
  - Increase oxytocin rate
  - VS Q 5 minutes
- **C-Section**
  - EBL >1000 mL
  - Presumed Uterine Atony
    - Methergine 0.2 mg IM
    - Hemabate 250 mcg IM
    - Cytotec 800-1000 mcg Rectal
  - O₂ via mask
  - Pulse Oximeter
  - Uterine Massage
  - Empty Bladder
  - Notify MD/SBAR
  - If Atony Suspected Uterotonic per Physician Request
  - Bleeding Controlled
  - Routine Postpartum Care
  - Continued Bleeding Move to Stage 2

In the event of bleeding after stage 0 care, additional support was given to the patient; after a conference with the physician, a single dose of a supplemental uterotonic was given if atony was suspected.

C, cesarean; EBL, estimated blood loss; IM, intramuscularly; IV, intravenously; MD, medical doctor; O₂, oxygen; Q, every; SBAR, situation background assessment recommendation; VS, vital signs.

54% at baseline to 80% at time of assessment point 2. The primary reasons for lack of protocol compliance were physicians being reluctant to follow the protocol or to initiate stage 2 and 3 guidelines. As expected, with increased protocol compliance and correct designation of hemorrhage stage, the number of patients correctly elevated to stage 2 increased by 37% (7.01/1000 deliveries at baseline compared with 9.58/1000 deliveries at assessment time point 2), and the number of patients categorized as stage 3 increased by 60% (2.68/1000 deliveries at baseline compared with 4.29/1000 deliveries at assessment time point 2). Although the number of patients who were escalated to stage 3 care increased by 60%, where the protocol dictated early transfusion, the use of blood products was reduced. At the second time point, the use of pRBCs was reduced by 15%, platelets by 60%, and cryoprecipitate by 58%. As expected, by the requirement for concurrent use of FFP as part of transfusion regimen, there was a 60% increase in the use of FFP. Overall, there was a 23.9% reduction per 1000 births in the use of blood products (pRBC, platelets, FFP, and cryoprecipitate) 10-months post-implementation monitoring period ($P < .01$; Table 3). Improved use of blood products was also related to overall protocol compliance because protocol compliance increased from 54% at baseline to 80% at assessment time point 2.

As part of the protocol, alternative methods of treatment of uterine atony (such uterine artery embolization, use of the Bakri balloon, or uterine compression suture) were encouraged as alternatives to hysterectomy. The specific number of cases in which a Bakri balloon was used or the number of patients who underwent uterine artery embolization was not collected as part of this project. Consistent with the reduction in blood use, there was a 14.8% reduction in the number of patients who had obstetrical hemorrhage and underwent a peripartum hysterectomy in the year before the protocol initiation relative to after (1.22 vs 1.04 per 1000 births), this change was not significant, ($P = .2$; Table 3).

**Comment**

The primary goal of this report was to assess the feasibility and effect of the initiation of a comprehensive protocol for the treatment of maternal hemorrhage within a large health care system. Based on results from a single institution, we expected that adoption of the
standardized approach would result in improved use of blood resources and patient outcomes. As noted earlier, this goal was met with 30-60% reductions in the use of blood products (pRBC, platelets, and cryoprecipitate) and the reduction in the need and/or use of peripartum hysterectomy.

The results of this study are consistent with the goals from recent recommendations from the Joint Commission that recommended the adoption of protocols to address maternal death and morbidity that are associated with hemorrhage and more recently with the goals of the Safe Healthcare for Every Woman (safehealthcareforeverywoman.org) collaboration. Individual states (New York and Illinois) have mandated training that is directed towards treatment for maternal hemorrhage. California, through the California Maternal Quality Care Collaborative, developed a comprehensive protocol that addresses maternal hemorrhage.28 Web-based resources are available from both the New York (http://www.health.state.ny.us/professionals/protocols_and_guidelines/maternal_hemorrhage/) and the California programs (http://www.cmqcc.org/ob_hemorrhage) and are expected soon from the safehealthcareforeverywoman.org project. The protocol presented here and from California Maternal Quality Care Collaborative were both designed to produce early intervention, the on-site presence of physician personnel, and the prevention of repeated use of unsuccessful interventions. It is important to note that the protocol outlined in this report was not designed to be an obstetrics transfusion policy but rather was designed to mandate specific interventions at specific levels of patient acuity. There are relatively few published data regarding the impact of these interventional programs. A group from Ireland reported the impact of the institution of hemorrhage policy that included staff education and many

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**FIGURE 3**

Protocol algorithms for stage 2 vaginal delivery and stage 2 cesarean delivery (continued)

A, Key components of stage 2 were the addition of a number of additional support personnel and the presence of the obstetrician and anesthesiologist to the patient’s bedside. The obstetrics hemorrhage cart was also brought to the patient’s bedside. Patients who reached this level of care also had modified postpartum care. B, Key components of stage 2 were the addition of a number of additional support personnel. The obstetrics hemorrhage cart was also brought into the operating room to facilitate other potential interventions. Patients reaching this level of care also had modified postpartum care.

C, cesarean; D&C, dilation; EBL, estimated blood loss; IV, intravenously; L&D, labor and delivery; Lab, laboratory; O2, oxygen; OB, obstetrics; OR, operating room; POC, products of conception; PP, postpartum; Q, every; VS, vital signs.

of the elements that are included as part of our stage 1 response. Similar to our results, they noted a reduction in the rate of transfusion for uterine atony, the need for transfusion, peripartum hysterectomy, and a significant reduction in the severe hemorrhage. Similar to the recommendations here, Sheikh et al noted that stricter adherence to formulated protocols and guidelines was going to be essential for improvement in the outcomes in patients with massive postpartum hemorrhage.

The hemorrhage protocol described here was first reported from a medium-sized rural facility with slightly fewer than 3000 deliveries per year. Those recommendations for care were then rolled-out throughout a large hospital system. Obstetrical volumes from 29 hospitals range from <200 to >6000 deliveries per year. Individual hospitals made minor modifications that allowed smaller facilities to cross-train staff from other areas or rapid response teams to meet local staffing needs. Our results suggest that that use of the algorithms presented here, or similar approaches presented by others, should be transferable to any size hospital and should produce meaningful improvement in outcomes of women who experience obstetrical hemorrhage. It is important to note that we did not simply introduce a massive transfusion protocol. The algorithms presented here were designed as a comprehensive approach to maternity care. It important to note that the obstetrics safety nurse not only collected data related to protocol compliance, but also directed nursing and physician education that was related to protocol, nursing estimated blood loss skills training, and other areas that were believed to be deficient. Further, senior leadership both locally at each hospital and within the hospital system were engaged and accountable for their
hospital’s results. The authors believe that all of these factors likely played an important role in the success of this safety initiative.

We hope that other institutions will take the data presented here, along with the resources that are readily available from other online sources and produce hemorrhage response systems that will be tailored to their facility. Based on the success of the protocol presented here and reported elsewhere, the primary goals of those endeavors should include (1) enhanced communication with all members of the hospital who may be part of the treatment team, (2) on-going staff education regarding key elements of the protocol, (3) blood loss assessment training, (4) standardized treatment that changes as the acuity of the patient changes and prevents repeated use of ineffective intervention, (5) early requirement for physician (obstetric and anesthesia) bedside assessment, and (6) early intervention with fixed ratios of blood products. These recommendations should facilitate staff and physician

### TABLE 3

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>Assessment 1</th>
<th>Assessment 2</th>
<th>Change from baseline to assessment 2, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deliveries, n</td>
<td>10,433</td>
<td>10,457</td>
<td>11,169</td>
<td>+7</td>
</tr>
<tr>
<td>Stage 2, n</td>
<td>73</td>
<td>99</td>
<td>107</td>
<td></td>
</tr>
<tr>
<td>Stage 2 per 1000 deliveries, %</td>
<td>7.01</td>
<td>9.47</td>
<td>9.58</td>
<td>+37</td>
</tr>
<tr>
<td>Stage 3, n</td>
<td>28</td>
<td>32</td>
<td>48</td>
<td></td>
</tr>
<tr>
<td>Stage 3 per 1000 deliveries, %</td>
<td>2.68</td>
<td>3.06</td>
<td>4.29</td>
<td>+60</td>
</tr>
<tr>
<td>Packed red blood cells, n</td>
<td>232</td>
<td>180</td>
<td>197</td>
<td>−15 (P = .02)</td>
</tr>
<tr>
<td>Platelets, n</td>
<td>65</td>
<td>37</td>
<td>26</td>
<td>−60 (P &lt; .01)</td>
</tr>
<tr>
<td>Cryoprecipitate, n</td>
<td>43</td>
<td>18</td>
<td>18</td>
<td>−58 (P &lt; .01)</td>
</tr>
<tr>
<td>Fresh frozen plasma, n</td>
<td>35</td>
<td>24</td>
<td>56</td>
<td>+60 (P &lt; .01)</td>
</tr>
<tr>
<td>Total blood products, n</td>
<td>375</td>
<td>354</td>
<td>297</td>
<td></td>
</tr>
<tr>
<td>Blood products per 1000 deliveries, %</td>
<td>35.9</td>
<td>33.9</td>
<td>26.6</td>
<td>−25.9 (P &lt; .01)</td>
</tr>
<tr>
<td>Year</td>
<td>2011</td>
<td>2012</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemorrhage with peripartum hysterectomy, n</td>
<td>82</td>
<td>67</td>
<td></td>
<td></td>
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<tr>
<td>Hysterectomy per 1000 births</td>
<td>1.22</td>
<td>1.04</td>
<td>−14.8 (P = .2)</td>
<td></td>
</tr>
</tbody>
</table>

Baseline and assessments 1 and 2 were 2 months in duration.

* Data are for entire calendar year.

REFERENCES


acceptance and have been proved to be essential elements of the results presented here.