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

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OBJECTIVE: The purpose of this study was to assess the effectiveness of instituting a comprehensive protocol for the treatment of maternal hemorrhage.

STUDY DESIGN: The protocol was separated into 4 stages, designated 0-3, based on the degree of blood loss and the patient response to interventions. Key components included admission risk assessment, measurement of blood loss, early but limited use of uterotonic agents, early presence of obstetrical and anesthesia staff, and transfusion with fixed ratios of blood products. Data were collected retrospectively and prospectively relative to the start of the protocol.

RESULTS: We noted a significant shift toward resolution of maternal bleeding at an earlier stage (P < .01), use of fewer blood products (P < .01), and a 64% reduction in the rate of disseminated intravascular coagulation. In addition, there were significant improvements in staff and physician perceptions of patient safety (P < .01).

CONCLUSION: Comprehensive maternal hemorrhage treatment protocols improve patient safety and reduce utilization of blood products.

Key words: comprehensive, maternal hemorrhage, patient safety, protocol


Material and Methods

Collection of data for this study was approved as part of an ongoing clinical patient safety monitoring program and as
part of an approved hospital continuous quality improvement program.

There were 3 main phases of preparation prior to protocol initiation: development, education, and team training/simulation. Protocol development, November 2008 through January 2009, was designed to optimize prompt action from health care providers and clinical services, as well as a system that facilitated communication between health care providers and ancillary services (diagnostic laboratories and blood bank).9,10,12,14,15 After development and designation of the hemorrhage stages, an educational phase was carried out from February 2009 through April 2009. At this time, adjustments and modifications were suggested and adopted by the different groups that were going to participate in the protocol. Nursing personnel also had blood loss skills training.16-18 Finally, labor and delivery simulations were carried out. These were designed to enable each member of the team to practice their role and to determine how the different aspects of the protocol are integrated.19 After this was accomplished, the protocol was officially launched in May 2009.

The overall goal of the protocol was to facilitate early intervention, early treatment with blood products, and reduce the incidence of disseminated intravascular coagulation (DIC). Key elements of the protocol were graded assessments of patient acuity and standardization of interventions. The patient’s status and the interventions were grouped into 4 categories (stages 0-3). The protocol was initiated at the time of admission to labor and delivery. At that time, an initial risk assessment was made related to patient’s potential risk for obstetrical hemorrhage (Table 1).2,20,21 Patients were then categorized as low, medium, or high risk. Based on the admission risk assessment, different levels of “status alerts” were given to the blood bank. Patients initially assessed as low risk had a request for a clot-tube to be held in blood bank. Medium-risk patients had a “type and screen” carried out, and those patients who were deemed high risk had cross-matched blood prepared. The patient’s risk status could change during the course of her labor and delivery. This process was done primarily to streamline rapid access to blood products when needed.

Although patient status was assessed in both the intrapartum and postpartum time periods, protocol interventions were primarily designed to address postpartum hemorrhage interventions. The bleeding status of each patient was continuously assessed and assigned a clinical hemorrhage stage. 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 section (1000 mL).22 Stage 2 was defined as bleeding not responding to conservative treatment outlined in stage 1, and stage 3 was defined as continued bleeding with actual or expected blood loss >1500 mL. Additional details of each stage are outlined in Figures 1-4.

Due to recognized inaccuracies in blood loss estimates even after training,16 measurement of blood loss was assessed by weighing all lap sponges, bedware if needed, and fluid in collection systems.23 Nonblood fluid in delivery collection systems, particularly prior to delivery of the placenta, was subtracted from the estimated blood loss. Although there is some risk that there will be amniotic fluid included in the blood loss estimate, this method has been shown to improve the accuracy of blood loss.18,24 After delivery, bedding was changed to eliminate the risk of amniotic fluid contamination from that point forward. Aberrations of maternal vital signs (sustained heart rate >100 bpm, blood pressure <85/45 mmHg, or patient symptoms [shortness of breath, confusion, or agitation]) were deemed significant enough to warrant a higher-level care.13 At any time during the course of care, symptoms or aberrations of vital signs caused patient care status to be elevated to either stage 2 or stage 3.

### Table 1

**Admission risk assessment**

<table>
<thead>
<tr>
<th>Low risk (clot-to-hold)</th>
<th>Medium risk (type and screen)</th>
<th>High risk (cross-matched and blood bank alert)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unscarred uterus</td>
<td>Prior uterine surgery</td>
<td>Previa/accreta</td>
</tr>
<tr>
<td>No Hx of postpartum hemorrhage</td>
<td>Hx of postpartum hemorrhage</td>
<td>Hematocrit &lt;30% with other risk factor</td>
</tr>
<tr>
<td>≤4 previous vaginal deliveries</td>
<td>≥4 previous vaginal deliveries</td>
<td>Bleeding on admission</td>
</tr>
<tr>
<td>Singleton pregnancy</td>
<td>Multiple gestation</td>
<td>Coagulation defect</td>
</tr>
<tr>
<td></td>
<td>Large uterine fibroids</td>
<td>Platelets &lt;100,000</td>
</tr>
<tr>
<td></td>
<td>Chorioamnionitis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Magnesium sulfate use</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Positive antibodies on</td>
<td></td>
</tr>
<tr>
<td></td>
<td>antepartum screen</td>
<td></td>
</tr>
</tbody>
</table>

*Hx, history.

* Depending on factors involved, larger numbers of blood products may be prepared.

Patients activated to stage 1 after vaginal delivery were primarily treated by nursing personnel. Uterine atony remains the most common cause of postpartum hemorrhage, and this stage was designed primarily for prompt assessment and treatment of uterine atony. If uterine atony was suspected, a single dose of an uterotonic could be given after discussion with the physician. Additional aspects of stage 1 care are noted in Figure 2. If there was a need for a second dose of an uterotonic agent, the patient’s status was upgraded to stage 2. A similar approach to the treatment of uterine atony at cesarean section was used, and patients not responding to oxytocin infusion and an uterotonic were elevated to stage 2. The details of stage 2 are outlined in Figure 3 (vaginal delivery and cesarean section).

The most significant component of stage 2 was a commitment of additional personnel assigned to the patient’s care. This included the addition of a second nurse and notification of the on-call nursing supervisor to facilitate assignment of additional nursing and operating room support as needed. The second major component of stage 2 for vaginal deliveries was that both the patient’s obstetrician and the on-call anesthesiologist were required to report to the patient’s bedside, or the operating room if the treating nurse believed that the patient would be better served in that location. This requirement was believed to be critical and designed to prevent continued use of therapies that were either ineffective or would limit timely physician evaluation and treatment. It was hoped that aggressive intervention at this stage would limit the number of patients who went on to experience life-threatening hemorrhage and/or DIC.

To facilitate treatment, an “obstetrical hemorrhage cart” was created and assigned to both labor and delivery and the main operating room. The hemorrhage cart was designed and organized to have all of the routine and unique supplies that would be necessary for patient management. At stage 2, the hemorrhage cart was brought to the patient’s room. The specific items of the hemorrhage cart are outlined in Table 2.

If the estimated blood loss was at or expected to be >1500 mL, the patient’s status was elevated to stage 3 (Figure 4). The primary goal of stage 3 was to mobilize and orchestrate all available resources toward reducing further blood loss or development of DIC. Additional nursing support was assigned, and considerations for additional physician support (obstetrical, anesthesia, general or urologic surgeons, and interventional radiology) were also suggested. At this point, fixed ratios of blood products in a designated “obstetrical hemorrhage pack” were prepared for immediate release from the blood bank. The maternal hemorrhage pack included 3 U of packed red blood cells, 2 U of fresh frozen plasma, 1 pheresis U of platelets, and 10 U of cryoprecipitate. Blood (packed red blood cells) and fresh frozen plasma were given in fixed ratios of 3:2. This ratio was increased to 1:1 after the transfusion of the first 6 U of packed red blood cells and 4 U of fresh frozen plasma, as this combination has been shown to improve survival in trauma-related hemorrhage. Treatment was directed toward the goal of maintaining the hematocrit >24%, international normalized ratio <1.4, platelet count >50,000/μL, and fibrinogen >100,000 mg/dL. Additional goals included maintaining the patient’s pH >7.2, base excess >−5, temperature >95°F (35°C), and a normal ionized calcium as all of these factors are known to influence coagulation.

Because patients activated to either stage 2 or 3 had postpartum courses that were not normal, they were assigned to receive modified postpartum surveillance. Postpartum care was continued on labor and delivery for 24 hours for patients successfully treated at stage 2. Laboratory studies were repeated at 1 and 4 hours and vital signs, including urine output, were repeated at higher frequencies for the first 6 hours after bleeding normalized. Patients who were treated at a stage 3 level were all initially monitored in the intensive care unit in
cooperation with critical care, anesthesia, and obstetrics. In some cases where deemed appropriate, and after discussion with the intensivist, care would be carried out on labor and delivery. The rationale for intensive care unit admission was primarily based on concerns related to development of pulmonary edema and renal compromise. The minimal frequency and duration of vital signs and laboratory assessments was outlined by the protocol.

The primary goal of the protocol outlined here was to address the clinical problem of maternal hemorrhage, as well as improve overall patient safety. To determine if hospital personnel and physicians thought that the implementation of the hemorrhage protocol improved patient care, patient safety, and the ability to respond to maternal hemorrhage, a survey was sent to treating physicians (obstetricians and anesthesiologists) and nursing staff. The survey was given 1 year after initiation of the protocol. The survey questions for nursing and physicians are noted in Table 3. The responses were evaluated using a 5-point system.

For data analysis, the time period prior to and after implementation of the hemorrhage protocol were compared. To address the question of whether we reduced the severity of hemorrhage, we compared the number of patients who were activated to each stage of the protocol in the control period vs the intervention period. 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). These time blocks were chosen, because we had established clearly defined hemorrhage stages and data could be prospectively collected. Data were analyzed by analysis of variance for changes in the number of patients treated at each stage. Our second question asked whether aggressive management and a liberal use of replacement blood products reduced the total units of blood transfused on the obstetrical service. Data on the number of patients receiving blood products and the number of units transfused were collected from the blood bank. We compared the 12-month time period prior to protocol initiation and pretraining (preprotocol, 2939 deliveries) and the 12 months after the hemorrhage protocol was initiated (postprotocol, 2874 deliveries). Data were analyzed by t test. Finally, survey results comparing hospital staff and physician perceptions prior to and after initiation of the hemorrhage protocol were compared by paired t test.

**FIGURE 3**

**Protocol algorithm for stage 2**

A. Vaginal delivery. B, Cesarean section. Key components of stage 2 were additional support personnel and A, presence of obstetrician and anesthesiologist to patient’s bedside. OB hemorrhage cart was also brought to A, patient’s bedside or B, OR to facilitate other potential interventions. Patients reaching this level of care also had modified postpartum care.

CBC, complete blood count; EBL, estimated blood loss; IV, intravenous; L&D, labor and delivery; OB, obstetrical; OR, operating room; POC, products of conception; PT, prothrombin time; PTT, partial thromboplastin time; VS, vital signs.

*Hemorrhage panel: CBC with platelet count, PT, PTT, fibrinogen, electrolytes and creatinine. Bold boxes represent personnel with specific assignments.

Results

During the study period there were 5813 deliveries. The overall maternal hemorrhage rate (stages 1-3) was 3.6%. The hemorrhage rate for the combination of stage 2 (i.e., defined as required more than a single dose of a uterogenic) and stage 3 (bleeding >1500 mL) was 1.5%.

During duration of the study, the total number of patients treated at either stage 1 or stage 2 did not differ between the preprotocol and postprotocol time periods. However, after protocol implementation, there was a significant shift in the percentage of patients who were successfully treated at the stage 1 level. Prior to initiation of hospitalwide training, only a third of patients were successfully treated at stage 1, and just >50% of patients required stage 2 level interventions. After training and protocol initiation, this changed, and 82% were successfully treated at stage 1 ($P = .02, R^2 = 0.95$) and only 8% of patients reached stage 2 ($P = .02, R^2 = 0.97$) (Table 4). Thus, consistent with the goals of the protocol, we noted that training and protocol initiation was associated with a significant shift toward patients requiring less intervention and successfully being treated at a lower acuity level.

Of patients categorized as having any blood loss greater than expected (stages 1-3), 10% fell into the severe category, or stage 3. The percentage of patients requiring stage 3 intervention did not change during the duration of the study. However, other indirect goals of the protocol were that early intervention would ultimately reduce the number of units of blood products used and there would be a reduction that the number of patients treated for DIC. We compared the utilization of blood products in the 12 months prior to initiation of the protocol to the 12 months after the protocol was in place. We noted a significant reduction in the total number of blood products transfused and the average number of blood products used per month (16.7 units/month preprotocol and 6.3 units/month postprotocol, $P < .01$). This was primarily a result of significantly less DIC noted in the 12-month postprotocol time period, where the rate of DIC was reduced by 64% ($P = .06$).

One year after the initiation of the hemorrhage protocol, hospital staff and physicians were surveyed to determine if they thought the protocol improved patient care, patient safety, their ability to respond to maternal hemorrhage, and the effectiveness of team communication. The survey was returned by 61% of the physicians and 32% of the nursing staff. There was a significant shift from lower levels of comfort to being mostly comfortable/confident in hemorrhage situations, as well as in team communication (physicians $P < .01$ and nursing staff $P < .01$). These data suggest that physicians and hospital staff favorably viewed the initiation of the protocol with regard to their own ability to respond to a maternal hemorrhage and that this created a culture of improved patient care.

Comment

The primary goal of this study was to assess the effect of initiating a comprehensive protocol for the treatment of postpartum hemorrhage. Consistent with the goals of the protocol, we noted 4 important outcomes. First, patients were successfully treated at a lower stage or degree of hemorrhage and thus experienced less overall blood loss. This allowed care to be maintained at a lower acuity level. Second, we demonstrated that even in the background of promoting early intervention with blood products, fewer blood products were given to patients. This not only reduces the risk for blood-borne illness, but also reduces the burden of obstetrical hemorrhage on local blood banks. Third, early intervention resulted in fewer patients experiencing life-threatening DIC. Fourth, both physicians and nursing staff reported improved clinical knowledge and improved comfort levels when responding
to a maternal hemorrhage. There was uniform agreement that patient care and patient safety were improved.

The results of this study are consistent with the recent Joint Commission Sentinel Alert that recommended adoption of protocols to address maternal mortality and morbidity associated with hemorrhage. Two states (New York and Illinois) have mandated training directed toward treatment for maternal hemorrhage, and recently California developed a comprehensive protocol to address maternal hemorrhage. Excellent Web-based resources are available from both the New York (http://www.health.state.ny.us/professionals/protocols_and_guidelines/maternal_hemorrhage/) and California (http://www.cmqcc.org/ob_hemorrhage) programs. The protocol presented here, and from the California Maternal Quality Care Collaborative, was designed to produce earlier intervention, on-site presence of physician personnel, and prevention of repeated use of unsuccessful interventions. There are very few published data regarding the impact of these interventional programs. Rizvi et al from Ireland reported their results after instituting a labor and delivery hemorrhage policy that included staff education and has many elements that are similar to our stage 1 response. They noted a reduction in the rate of transfusion and were able to demonstrate a reduction in the rate of uterine atony, need for transfusion, and peripartum hysterectomy, and a significant reduction in severe hemorrhage (blood loss of >1500 mL). The major limitation of their study and ours is the relatively small number of deliveries reported. Hopefully, outcome data from other larger patient datasets will be presented and will show similar reductions in blood resource utilization and rates of DIC. If the data presented here and from others were reproduced nationally, there would be a 60% reduction in blood product utilization and similar reduction in the number of patients experiencing DIC as part of childbirth.

The hemorrhage protocol reported here was initiated in a medium-sized, rural facility with slightly less than 3000 deliveries per year. The hospital is part of a larger hospital system with 33 obstetrical facilities and a total delivery service of about 80,000 per year. The obstetrical services in this hospital system vary in size, from a low of about 300 deliveries per year with other facilities having >5000 deliveries per year. At the time this protocol was developed, some type of hemorrhage protocol was in use at all of the hospitals with >3000 deliveries per year. Of the hospitals with services <3000 deliveries per year, only 6 of 21 centers (28%) had a hemorrhage pro-
col in place. After initial development, the protocol outlined here was subsequently rolled out to all of the hospitals with obstetrical delivery services within the Catholic Healthcare West system. Each individual hospital made modifications to meet local staffing needs. In smaller facilities, personnel needs are met through “cross-trained” on-site rapid response teams. Thus, although the algorithms used here were designed in a medium-sized hospital, the overall theme was easily transferred and adopted in a large hospital system where delivery service size varies considerably.

Both physicians and nursing staff reported improved clinical knowledge and an improved comfort level when responding to a maternal hemorrhage after education and protocol adoption. More importantly, there was near uniform agreement among all surveyed that patient care and patient safety were improved after the initiation of the hemorrhage protocol outlined in this report. Although not directly measured, the success of this hospitalwide approach of maternal hemorrhage has facilitated the institution of other patient safety initiatives. 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 a hemorrhage response system that will be tailored to their facility. Based on the success of the system presented here and reported elsewhere,12,19,29-32 the primary goals of those endeavors should include (1) a system that enhances communication between all members of the treatment team; (2) staff education and input regarding protocol development; (3) blood loss assessment training; (4) early standardized treatment and prevention of repeated use of ineffective treatment; (5) early requirement for physician (obstetric and anesthesia) presence; and (6) early intervention with fixed ratios of blood products. These recommendations should facilitate staff and physician acceptance and have been proven to be essential elements of effective interventions.

### REFERENCES


### TABLE 4

<table>
<thead>
<tr>
<th>Stage</th>
<th>Preprotocol</th>
<th>Post-period 1</th>
<th>Post-period 4</th>
<th>Post-period 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>35% (22)</td>
<td>51% (25)</td>
<td>69% (27)</td>
<td>82% (49)</td>
</tr>
<tr>
<td>2</td>
<td>53% (33)</td>
<td>45% (22)</td>
<td>18% (7)</td>
<td>8% (5)</td>
</tr>
<tr>
<td>3</td>
<td>11% (7)</td>
<td>4% (2)</td>
<td>13% (5)</td>
<td>10% (6)</td>
</tr>
</tbody>
</table>

* P = .02; Numbers in parenthesis are total patients at that stage in that time period.


