# Massive Hemorrhage

## *A Report from the Anesthesia Closed Claims Project*

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## ABSTRACT

**Background:** Hemorrhage is a potentially preventable cause of adverse outcomes in surgical and obstetric patients. New understanding of the pathophysiology of hemorrhagic shock, including development of coagulopathy, has led to evolution of recommendations for treatment. However, no recent study has examined the legal outcomes of these claims. The authors reviewed closed anesthesia malpractice claims related to hemorrhage, seeking common factors to guide future management strategies.

**Methods:** The authors analyzed 3,211 closed surgical or obstetric anesthesia malpractice claims from 1995 to 2011 in the Anesthesia Closed Claims Project. Claims where patient injury was attributed to hemorrhage were compared with all other surgical and obstetric claims. Risk factors for hemorrhage and coagulopathy, clinical factors, management, and communication issues were abstracted from claim narratives to identify recurrent patterns.

**Results:** Hemorrhage occurred in 141 (4%) claims. Obstetrics accounted for 30% of hemorrhage claims compared with 13% of nonhemorrhage claims ($P < 0.001$); thoracic or lumbar spine surgery was similarly overrepresented (24 *vs.* 6%, $P < 0.001$). Mortality was higher in hemorrhage than nonhemorrhage claims (77 *vs.* 27%, $P < 0.001$), and anesthesia care was more often judged to be less than appropriate (55 *vs.* 38%, $P < 0.001$). Median payments were higher in hemorrhage *versus* nonhemorrhage claims ($607,750 *vs.* $276,000, $P < 0.001$). Risk factors for hemorrhage and coagulopathy were common, and initiation of transfusion therapy was commonly delayed.

**Conclusions:** Hemorrhage is a rare, but serious, cause of anesthesia malpractice claims. Understanding which patients are at risk can aid in patient referral decisions, design of institutional systems for responding to hemorrhage, and education of surgeons, obstetricians, and anesthesiologists. **(ANESTHESIOLOGY 2014; 121:450-8)**


MASSIVE hemorrhage related to surgical procedures is a rare, but potentially lethal, event that may manifest in the operating room (OR), obstetric suite, intensive care unit (ICU), or postanesthesia care unit (PACU). Anticipating the potential for hemorrhage, and the corresponding requirement for fluid resuscitation and transfusion, is a core requirement of a successful anesthetic.[1] Hemorrhage is expected in certain cases, for example, major peripheral vascular procedures, cardiac and liver surgery, and radical cancer resections. Hemorrhage is less routine, but anticipated, in trauma cases, emergency general surgery procedures, major orthopedics, and obstetrics. Failure by anesthesiologists and surgeons to recognize and appropriately treat hemorrhage in a timely manner may result in significant morbidity and mortality.

Advances in resuscitation have improved patient survival during the last several decades, as techniques developed in combat casualty care have been adopted in civilian hospitals and elective surgery.[2] These techniques include algorithms and scoring systems to anticipate the onset of hemorrhagic shock,[3,4] the surgical concept of "damage control,"[3,5,6] the use of deliberate hypotensive resuscitation,[4–7] early replacement of coagulation factors,[2,4–9] and improved laboratory testing and hemodynamic monitoring.[10] Technological advances include better and more rapid means of obtaining large-bore intravenous access,[4] improved fluid warmers and rapid infusion systems,[6] and the ongoing evolution of surgical

### What We Already Know about This Topic

- Understanding and treatment of hemorrhage has progressed over the past 2 decades, but whether this is reflected in clinical practice is unclear

### What This Article Tells Us That Is New

- In a review of the past 2 decades of closed anesthesia malpractice claims, two areas (obstetrics and spinal surgery) were overrepresented
- Common to many cases were lack of timely diagnosis, timely transfusion, and reoperation, often reflecting poor team communication

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instruments such as staplers and cautery devices. Despite these advances, however, massive hemorrhage remains a life-threatening complication of surgery and obstetrics.

To obtain a perspective on factors associated with patient injury from massive hemorrhage during anesthesia care in the United States, we examined closed malpractice claims from the past 2 decades, comparing claims for massive hemorrhage to other surgical and obstetric malpractice claims. Our hypothesis was that a detailed review of these most serious events could reveal common factors associated with malpractice claims for massive hemorrhage. We also examined the actions and reactions of the providers involved in massive hemorrhage claims in an attempt to identify recurring patterns of patient harm that could inform anesthesia education and system redesign.

## Materials and Methods

### Closed Claims Project Methodology

The Anesthesia Closed Claims Project database is a structured collection of closed anesthesia malpractice claims described in detail elsewhere.[11] In brief, on-site anesthesiologist-reviewers abstracted data from closed anesthesia malpractice claims onto detailed data collection instruments at participating professional liability companies across the United States. The panel of 22 companies (at the time of this study) insured over one third of practicing anesthesiologists in the United States. Information was collected from medical records, consultant evaluations, expert witness reports, claims manager summaries, and legal summaries. Data collected included patient demographics, type of surgery, details regarding anesthesia care, patient outcomes, and legal outcomes. The on-site reviewer evaluated the standard of care, outcome, severity of injury, and cause of injury (*i.e.*, damaging event). The severity of injury score used the National Association of Insurance Commissioners' 10-point scale, which ranges from 0 (no apparent injury) to 9 (death).[12] This scale was collapsed into three categories for this analysis: death (score = 9), permanent disabling injuries (score = 6 to 8), and temporary or minor injuries (score = 0 to 5).

Appropriateness of anesthesia care was assessed by the on-site reviewer as appropriate (based on reasonable or prudent practice at the time of the event), substandard, or impossible to judge. The reliability of these evaluations has been judged acceptable.[13] The on-site reviewer also summarized the claim in a brief narrative, including the sequence of events and causes of injury. The Closed Claims Project Investigator Committee reviewed the claims, and any disagreements in assessments were resolved by Committee members.

For this study, we used the Anesthesia Closed Claims Project database of 9,799 claims. Inclusion criteria were claims for injuries occurring with surgical or obstetric anesthesia care between 1995 and 2011. Of the 3,211 surgical or obstetric claims from this time period, 141 had a primary damaging event of hemorrhage (*hemorrhage claims*) and 3,070 had some other primary damaging event (*other claims*). Background information on the demographics of anesthesia care in the United States was obtained from the National Anesthesia Clinical Outcomes Registry (NACOR) Participant User File of January 2014, by direct query.[14] This information, drawn from approximately 20% of all anesthesia practices in the nation from 2010 to 2013, was used to provide context for case numbers and patient demographics in the Closed Claims Project database.

### Definition of Variables in Hemorrhage Claims

Risk factors for hemorrhage and coagulopathy and the location(s) within the treatment facility where hemorrhage was apparent were abstracted from the claim narratives by two of the authors (R.P.D. and L.A.L.). Obstetric risk factors for hemorrhage were placenta accreta, increta, or percreta; retained placenta; placenta previa; placenta abruption; uterine atony; and uterine rupture. Obstetric risk factors for coagulopathy were amniotic fluid embolus, intrauterine fetal demise of a week or more, and placental abruption. Surgical risk factors for hemorrhage were spine surgery, major vascular surgery, cardiac surgery, liver surgery, large tumor surgery, robotic/laparoscopic/minimally invasive surgery, and surgery after a major trauma event. Surgical risk factors for coagulopathy were preexisting use of anticoagulants or platelet inhibitors, liver disease, and preoperative increased partial thromboplastin time. In addition to these predefined risk factors, other obstetric and surgical risk factors for hemorrhage and coagulopathy were abstracted when present in the claim narratives to assure completeness. The locations within the treatment facility where the hemorrhage was apparent included the OR, the PACU, the ICU, the ward or floor, or other locations.

Two authors (R.P.D. and L.A.L.) judged the following factors based on claim narratives with a third author (K.B.D.) serving as tie breaker for disagreements: whether the hemorrhage was the result of an unexpected organ or vessel injury, whether or not the hemorrhage caused an immediate change in vital signs, and the timeliness of the diagnosis of hemorrhage, transfusion of blood products, or return to the OR if bleeding became apparent postoperatively. These were global assessments of the team (surgeon, anesthesiologist, ICU, *etc.*), not restricted to judgments of anesthesia care. The contribution of anesthesia and surgery to the patient's injury was judged as no contribution, some contribution, or totally responsible for injury. Communication issues contributing to the adverse outcome were identified and grouped into thematic categories.

### Statistical Analysis

Interrater reliability for judgments of factors in hemorrhage claims was measured using kappa ($\kappa$) scores calculated on the initial two author judgments before tie-breaking by the third author. All payments made to the plaintiff were extracted from the database and adjusted to 2012 dollar amounts with the Consumer Price Index.* Median and interquartile range

* Bureau of Labor Statistics, U.S. Department of Labor. Consumer Price Index inflation calculator. Available at: http://www.bls.gov/data/home.htm. Accessed January 2, 2013.

**Table 1.** Presenting Case Characteristics*

| | National Practice Estimate from NACOR (N = 14,259,217) n (%) | Hemorrhage Claims (n = 141) n (%) | All Other OB and Surgical Claims (n = 3,070) n (%) | *P* Value† |
|---|---|---|---|---|
| Category of anesthesia care (NACOR n = 13,769,880) | | | | |
| Obstetric | 1,165,568 (8) | 43 (30) | 404 (13) | 0.000‡ |
| Surgical | 12,604,312 (92) | 98 (70) | 2,666 (87) | |
| Sex (Closed Claims n = 3,202) (NACOR n = 13,680,791) | | | | |
| Male | 5,507,093 (40) | 54 (38) | 1,312 (43) | 0.163‡ |
| Female | 8,173,698 (60) | 87 (62) | 1,749 (57) | |
| Obese (Closed Claims n = 2,310) (NACOR n = 391,580) | 117,193 (30) | 42 (41) | 953 (43) | 0.353‡ |
| Trauma (Closed Claims n = 3,141) | Not available | 5 (4) | 135 (4) | 0.399‡ |
| Emergency (Closed Claims n = 3,145) | 381,399 (3) | 40 (29) | 551 (18) | 0.003‡ |
| ASA physical status (Closed Claims n = 3,008) (NACOR n = 11,561,312) | | | | |
| 1–2 | 7,905,646 (68) | 62 (46) | 1,593 (55) | 0.023‡ |
| 3–5 | 3,655,666 (32) | 72 (54) | 1,281 (45) | |
| Thoracic or lumbar spine procedures (NACOR n = 9,936,047) | 279,309 (3) | 34 (24) | 197 (6) | 0.000‡ |
| Cesarean delivery (NACOR n = 9,936,047) | 187,539 (2) | 23 (16) | 253 (8) | 0.002‡ |
| Type of anesthesia (Closed Claims n = 3,202) (NACOR n = 9,127,845) | | | | |
| General anesthesia | 7,114,117 (78) | 122 (87) | 2,066 (68) | 0.000§ |
| Regional | 204,681 (2) | 16 (11) | 624 (20) | |
| Monitored anesthesia care | 1,718,715 (19) | 1 (1) | 266 (9) | |
| General and regional anesthesia | 90,332 (1) | 1 (1) | 72 (2) | |
| No anesthesia provided | Not available | 1 (1) | 33 (1) | |
| Mean age (Closed Claims n = 3,153) | 49 (SD 22.36) | 44 (SD 17.81) | 47 (SD 18.68) | 0.072‖ |

*n = 3,211 for Closed Claims data and 14,259,217 for NACOR data unless stated otherwise. All events occurred 1995 or later. Chronic and acute pain not included. Missing data excluded. †Statistical tests compare closed hemorrhage claims to all other OB and surgical closed claims. NACOR data were provided for qualitative comparison with claims data without statistical analysis to avoid generating statistical significance of trivial clinical differences. ‡Fisher exact test. §Pearson chi-square test. ‖*t* test for equality of means.

ASA = American Society of Anesthesiologists; NACOR = National Anesthesia Clinical Outcomes Registry; OB = obstetric.

were reported for payments because they were not normally distributed. Claims with no payment were excluded from calculation of median and interquartile range. Demographics and legal outcomes of hemorrhage claims were compared with those in other surgical/obstetric anesthesia claims using Fisher exact test, Pearson chi-square, *t* test for equality of means, or Mann–Whitney U test with *P* value less than 0.05 as the criterion for statistical significance and two-tailed tests. All statistical analysis used SPSS 19 for Windows (IBM Corporation, Armonk, NY). Comparison of Closed Claims cases and NACOR cases did not incorporate a formal statistical analysis because comparison involving 13 million records risks generating statistical significance when the actual clinical differences are trivial. The comparison is therefore presented as qualitative rather than formally quantitative.

## Results

Hemorrhage occurred in 141 (4%) of 3,211 surgical and obstetric anesthesia claims. Hemorrhage was the primary damaging event in 9.6% of claims filed on behalf of obstetric patients *versus* 3.5% of claims filed on behalf of patients undergoing other surgical procedures ($P < 0.001$). The 43 obstetric patients in hemorrhage claims underwent cesarean delivery (n = 23), vaginal delivery (n = 16), dilation and curettage for fetal demise (n = 3), and intrauterо laparoscopic photocoagulation (n = 1). Thoracic or lumbar spine procedures (24% of hemorrhage claims) and cesarean delivery (16% of hemorrhage claims) occurred more frequently in hemorrhage claims than in other claims ($P < 0.001$ and $P = 0.002$, respectively; table 1). Obstetric cases account for 8% of all anesthetics in NACOR, and spine cases account for 3%; both of these proportions are lower than in the Anesthesia Closed Claims Project registry overall and much lower than in hemorrhage claims. Although hemorrhage claims were more likely to involve emergency procedures (29%) compared with other claims (18%, $P = 0.003$; table 1), they were not more likely to occur in association with a traumatic injury (4%; table 1). Patient demographics (age, sex, American Society of Anesthesiologists physical status) were similar between other (nonhemorrhage) claims from the Anesthesia Closed Claims Project and overall national case demographics drawn from NACOR (table 1).

Claims associated with hemorrhage had a greater severity of injury than other claims, with over three fourths resulting in death ($P < 0.001$; table 2). The anesthesia care was more often assessed as less than appropriate and a payment made more often to the plaintiff in hemorrhage claims compared with other claims ($P < 0.001$; table 2). Payments were greater

**Table 2.** Outcomes and Evaluation of Care for Hemorrhage Claims Compared with Other Claims*

| | Hemorrhage Claims (n = 141) n (%) | All Other OB and Surgical Claims (n = 3,070) n (%) | *P* Value |
|---|---|---|---|
| Severity of injury | | | |
| None, temporary, and nondisabling | 8 (6) | 1,563 (51) | 0.000† |
| Permanent and disabling‡ | 24 (17) | 680 (22) | |
| Death | 109 (77) | 827 (27) | |
| Evaluation of anesthetic care (n = 2,821) | | | |
| Less than appropriate | 70 (55) | 1,019 (38) | 0.000§ |
| Appropriate | 58 (45) | 1,674 (62) | |
| Payment made (n = 3,093) | 97 (71) | 1,589 (54) | 0.000§ |
| Median payment (2012 $) | $607,750 | $276,000 | 0.000‖ |
| Interquartile range | | | |
| 25th percentile | $284,440 | $71,500 | |
| 75th percentile | $1,434,050 | $863,500 | |

*n = 3,211 unless stated otherwise. All events occurred 1995 or later. Chronic and acute pain not included. Missing data excluded. †Pearson chi-square test. ‡Two thirds of hemorrhage claims with permanent and disabling injuries were severe brain damage. §Fisher exact test. ‖Independent samples Mann–Whitney U test.

OB = obstetric.

for hemorrhage claims (median $607,750) than for other obstetric and surgical claims ($276,000, $P < 0.001$; table 2).

### Risk Factors for Hemorrhage and Coagulopathy

Most (78%) of the hemorrhage cases had risk factors for hemorrhage and 20% had independent risk factors for coagulopathy. The risk factors varied between obstetric and surgical procedures (table 3). Among the 43 obstetric claims, 74% presented with at least one risk factor for hemorrhage, with the most common risk factors including placenta accreta, increta, or percreta (n = 13); retained placenta (n = 10); and uterine atony (n = 7; table 3). More than one fourth of obstetric patients (28%) had risk factors for coagulopathy, most commonly amniotic fluid embolus (n = 5), placental abruption (n = 3), and intrauterine fetal demise (n = 3; table 3).

Almost 80% of the 98 surgical claims had at least one risk factor for hemorrhage, including thoracic or lumbar spine surgery (n = 35), robotic/laparoscopic/minimally invasive surgery (n = 18), or major vascular or cardiac surgery (n = 16; table 3). Most (77%, n = 27) of the spine procedures were fusions and half the procedures (n = 17) were described as "multi-level." Sixteen percent (n = 16) of the surgical claims had risk factors for coagulopathy, primarily preexisting use of anticoagulants or platelet inhibitors (n = 9; table 3).

### Presentation and Management of Hemorrhage

In most claims, hemorrhage was apparent in the OR (72%) or in the PACU (21%; table 4). In about one third of all of the claims, the hemorrhage was the direct result of an unexpected organ or vessel injury ($\kappa = 0.903$). In about one fourth of all the claims, the hemorrhagic event caused an immediate change in vital signs ($\kappa = 0.763$).

A timely diagnosis of hemorrhage was judged to have occurred in only 31% of the claims ($\kappa = 0.658$; tables 4 and 5). Transfusion did not occur in a timely manner in most of the claims (86%, $\kappa = 0.690$; tables 4 and 5). A timely return to the OR occurred in only 11% of the 52 claims where the hemorrhage was first recognized outside of the OR ($\kappa = 0.945$; table 4). In 88% of claims, the anesthesiologist contributed to some degree to the injury experienced by the patient ($\kappa = 0.515$). In 99%

**Table 3.** Risk Factors for Hemorrhage and Coagulopathy (n = 141)*

| | n (%) |
|---|---|
| Obstetric risk factors (n = 43) | |
| Risk factors for hemorrhage | 32 (74) |
| Placenta accreta/increta/percreta | 13 (30) |
| Retained placenta | 10 (23) |
| Uterine atony | 7 (16) |
| Uterine rupture | 4 (9) |
| Placenta abruption | 3 (7) |
| Placenta previa | 3 (7) |
| Risk factors for coagulopathy | 12 (28) |
| Amniotic fluid embolus | 5 (12) |
| Placenta abruption | 3 (7) |
| Intrauterine fetal demise | 3 (7) |
| Other† | 2 (5) |
| At least one obstetric risk factor for hemorrhage or coagulopathy | 34 (79) |
| Surgical risk factors (n = 98) | |
| Risk factors for hemorrhage | 77 (79) |
| Thoracic or lumbar spine surgery | 35 (36) |
| Robotic/laparoscopic/minimally invasive surgery‡ | 18 (18) |
| Major vascular surgery§ | 8 (8) |
| Cardiac surgery | 8 (8) |
| Large tumor surgery | 5 (5) |
| Major trauma | 5 (5) |
| Liver surgery | 3 (3) |
| Other‖ | 6 (6) |
| Risk factors for coagulopathy | 16 (16) |
| Preexisting use of anticoagulants/platelet inhibitors | 9 (9) |
| Liver disease | 4 (4) |
| Preoperative increased PTT | 2 (2) |
| Other# | 2 (2) |
| At least one surgical risk factor for hemorrhage or coagulopathy | 79 (81) |

*Claims could have more than one risk factor for hemorrhage and/or coagulopathy. †One case of thrombocytopenia and one case where the mother was a Jehovah's Witness who refused blood products. ‡The laparoscopic procedures were cholecystectomy (n = 6), gynecological surgery (n = 3), nephrectomy (n = 1), liver biopsy (n = 1), and gastric band (n = 1). The robotic procedures were colectomy (n = 1), prostatectomy (n = 1), and mitral valve replacement (n = 1). There was one minimally invasive lumbar spine decompression and one obstetric laparoscopic procedure performed on a fetus *in utero*. §In addition, there was one obstetric claim where mother required vascular procedure immediately after delivery. ‖Other risks for hemorrhage included one case each of craniosynostosis, surgical adhesions/tumor location, scalp surgery, splenectomy/portal hypertension, inexperienced surgeon, and impaired surgeon. #Other risks for coagulopathy included one case each of fat embolus and preexisting coagulopathy.

PTT = partial thromboplastin time.

**Table 4.** Assessment of Response to Massive Hemorrhage*

| | n (%) |
|---|---|
| Location where hemorrhage was apparent† | |
| Operating room | 102 (72) |
| Postanesthesia care unit | 30 (21) |
| Intensive care unit | 17 (12) |
| Ward/floor | 17 (12) |
| Emergency department | 3 (2) |
| Radiology | 1 (1) |
| Hemorrhage was the result of unexpected organ/vessel injury (n = 132) | 42 (32) |
| Hemorrhage caused immediate change in vital signs (n = 128) | 33 (26) |
| Timely diagnosis of hemorrhage (n = 130) | |
| Agree | 40 (31) |
| Disagree | 90 (69) |
| Transfusion occurred in a timely manner (n = 125) | |
| Agree | 18 (14) |
| Disagree | 107 (86) |
| Timely return to operating room (n = 52)‡ | |
| Agree | 6 (11) |
| Disagree | 46 (89) |
| Contribution of anesthesia to patient outcome (n = 130) | |
| None | 16 (12) |
| Some contribution | 114 (88) |
| Contribution of surgery to patient outcome (n = 131) | |
| None | 1 (1) |
| Some contribution | 126 (96) |
| Total responsibility | 4 (3) |

*n = 141 unless stated otherwise. Unknown or not applicable data are excluded. †Percentages may total greater than 100% because hemorrhage was apparent in more than one location for some claims. In four claims, there was not enough information to determine whether return was timely. ‡For 85 of the 141 hemorrhage claims, a return to the operating room was not applicable because the hemorrhage was treated in the operating room.

of claims, the surgeon contributed to the patient's injury ($\kappa = 0.472$).

For 12 of the 18 robotic, laparoscopic, or minimally invasive procedures, hemorrhage was the result of unexpected organ (*e.g.*, liver) or vessel (*e.g.*, cystic artery, superior mesenteric artery, portal vein, iliac artery vein, aorta) injury. Bleeding was apparent in the OR in two thirds (n = 12 of 18), in the PACU (n = 4), in the ICU (n = 3), or on the ward (n = 4, some had multiple locations). A timely diagnosis of hemorrhage occurred in only 5 of the 18 cases.

### *Communication*

Sixty percent of the hemorrhage claims (n = 81) had at least one communication breakdown occur (table 6). Over half of the communication problems occurred between the anesthesiologist and the surgeon or obstetrician. The other communication problems were more systematic issues, for example, arising during supervision of cases or with follow-up communication issues with PACU, ICU, or floor personnel.

## Discussion

This review of the Closed Claims Project database identified 141 claims resulting from perioperative hemorrhage. Although claims associated with massive hemorrhage were a small proportion of all surgical and obstetric claims (4%), the high percentage resulting in death or permanent injury raises concern. Analysis of hemorrhage claims reveals several lessons about patient safety (table 7).

### *Clinical Lessons from Study Results*

The most obvious lesson is the type of cases that resulted in malpractice claims. Although hemorrhage is common in certain major surgeries (*e.g.*, liver transplantations, open-heart procedures) and trauma care,[15] these cases were underrepresented in the closed hemorrhage malpractice claims. Hemorrhage claims were most common in obstetrics (30%), thoracic, or lumbar spine surgery (24%). Hemorrhage also occurred in low-risk laparoscopic, robotic, or minimally invasive procedures. Data from the Manufacturer and User Facility Device Experience database corroborates these findings with deaths related to major vascular lacerations during robotic surgical cases. A query limited to the brand name "Da Vinci" or manufacturer name "Intuitive" for 2006 to 2013 identified 135 deaths with 30 (22%) of these associated with intraoperative hemorrhage.†

Failure to immediately recognize ongoing hemorrhage was a common problem in hemorrhage claims. The careful provider must recognize this risk and consider the possibility of hemorrhage whenever a patient exhibits nonroutine clinical signs or symptoms. Warning signs of hemorrhage that might have been recognized earlier were identified in many of the hemorrhage claims. Although hindsight is 20:20 and not all injuries are salvageable, failure to recognize and respond to life-threatening hemorrhage was one of the more common findings in this collection of closed claims.

Delays in recognition and communication of a developing emergency contributed to many of adverse outcomes in the hemorrhage claims. The importance of effective and timely communication between the anesthesia team and the surgeon or obstetrician cannot be overemphasized. Anesthesiologists can be instrumental in calling for reexploring a patient for bleeding. As in disasters in aviation, nuclear power, and other high-risk disciplines, protocols that emphasize interpersonal communications during crisis situations can have a positive impact. Training programs such as Team Strategies and Tools to Enhance Performance and Patient Safety‡ provide multidisciplinary training to improve teamwork skills in healthcare settings with a focus on effective communication.[16]

Timely transfusion did not occur in a majority of these claims. Once life-threatening hemorrhage is recognized, it is important to have an organized response. Both military and civilian trauma education emphasizes team-based care supported by standard practices and well-rehearsed institutional

† Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/results.cfm. Accessed January 30, 2014.

‡ Available at: www.teamstepps.ahrq.gov. Accessed May 12, 2014.

**Table 5.** Examples of Hemorrhage Cases Where Timely Action Did Not Occur

| |
|---|
| Timely Diagnosis of Hemorrhage Did Not Occur |
| Case 1: During total hip replacement, the patient had significant bleeding requiring 4 units packed erythrocyte transfusion. Hypotension persisted, but the surgeon did not see significant bleeding and closed the wound with a drain. The surgeon did not believe the patient was bleeding due to the small amount of blood in the drain. In the PACU, the patient became progressively tachycardic and hypotensive. The anesthesiologist obtained an arterial blood gas, with hematocrit of 11%. A general surgeon was called, who found 4 l of blood in the abdomen after returning to the OR. The patient continued to bleed and was transfused with additional erythrocytes, but not platelets or coagulation products. The patient died in the intensive care unit with ongoing coagulopathy. On autopsy, the right iliac vein was surrounded by blood and perforated by one of the hip screws. |
| Case 2: Thirty minutes after the start of a laparoscopic cholecystectomy, the patient developed hypotension and tachycardia, treated with normal saline and albumen. After the procedure finished, the trachea was extubated and the patient was taken to the PACU with an initial blood pressure of 145/110. Within 30 min, the blood pressure decreased to 70/55. Hypotension was treated with dopamine. No laboratory studies were performed. The surgeon was called and recommended transferring the patient to an intensive care unit. The patient died 4 h later; the last recorded hemoglobin level was 3 g/dl. Autopsy revealed perforation of the inferior vena cava and massive hemoperitoneum. |
| Timely Transfusion Did Not Occur |
| Case 3: The obstetrician stated that blood products had been ordered for D&C for a patient with a deceased 16-week fetus, with evidence of ischemic decay. A 20-gauge intravenous catheter started in the emergency department was used to induce anesthesia. Significant bleeding occurred. The anesthesiologist called for the blood and found out that the order had not been received. The anesthesiologist administered >5 l of crystalloid during resuscitation and gave esmolol to treat sinus tachycardia. The arrival of blood products was delayed for several hours and type O blood was never requested. The patient experienced a cardiac arrest at the conclusion of the procedure and could not be resuscitated. |
| Case 4: During laparoscopic cholecystectomy, the surgeon had difficulty placing an abdominal trocar and converted to an open procedure due to laceration of the superior mesenteric artery. More than 3,000 ml of blood was lost before bleeding was controlled. The anesthesiologist administered 3 l of lactated Ringer's solution and multiple boluses of phenylephrine *via* the preexisting 20-gauge intravenous catheter. Laboratories were not drawn and blood was never ordered or given. The anesthesiologist tried unsuccessfully to start another peripheral intravenous line and then placed a right internal jugular central venous catheter. During this time, the patient became progressively hypotensive and bradycardic and experienced a cardiac arrest. The patient could not be resuscitated. |
| Timely Return to the OR Did Not Occur |
| Case 5: During a two-level lumbar spine fusion, the patient had a sudden decrease in blood pressure and end-tidal carbon dioxide concentration. The differential diagnosis included pulmonary embolism and bleeding. The wound was packed and the patient was turned supine. An ultrasound of the abdomen was negative for intraperitoneal hematoma. Laboratory studies were not obtained. The patient was awakened and extubated. The patient experienced a cardiac arrest in the postanesthesia care unit. The patient was successfully resuscitated and transferred to the intensive care unit. The surgeon insisted that there was no blood loss due to the negative intraperitoneal ultrasound. The patient experienced a second cardiac arrest and could not be resuscitated. Autopsy revealed a perforation of the common iliac artery with a large retroperitoneal hemorrhage. |
| Case 6: After an uneventful Cesarean section with epidural anesthesia and transfer to the recovery room, the patient became hypotensive. Hematocrit was 18%. The obstetrician requested a repeat hematocrit before returning to the OR. While awaiting the laboratory result, the patient experienced a cardiac arrest and could not be resuscitated. A large retroperitoneal hematoma was found on autopsy. |

Many cases exhibited multiple examples where timely action did not occur.

DIC = disseminated intravascular coagulation; D&C = dilation and curettage; OR = operating room; PACU = postanesthesia care unit.

protocols that begin with the ability to call for help, such as a system to notify additional anesthesia personnel and experienced gynecologists, trauma, or vascular surgeons.[4–6] Ensuring an adequate supply, easy ordering, and rapid delivery of blood products are critical components of these protocols. Availability of such resources should be factored into the risk–benefit equation for any surgical plan.

Obstetric claims represented a third of the hemorrhage cases in this study. Throughout the world, postpartum hemorrhage is the most common cause of maternal mortality. In the United States, hemorrhage caused 9.7% of pregnancy-related deaths between 1998 and 2005.[17] Although some obstetric hemorrhage events are unanticipated, identifying patients at risk, such as those with abnormal placentation or with risk factors for uterine atony, can improve earlier recognition and treatment of hemorrhage.[18,19] Preparation for an anticipated postpartum hemorrhage includes development of a multidisciplinary care plan. Consultation between the specialties (including hematology and interventional radiology) regarding patient management can improve communication and reduce maternal mortality.[20] Several initiatives are underway in the United States to improve maternal safety.[21]

In some of the claims reviewed, there were no warning signs of impending hemorrhage in a surgery or delivery that should have been routine. It behooves practitioners in resource-limited settings to have protocols in place for dealing with massive hemorrhage. The most important step might be the drill for rapid consultation outside the facility, with rapid patient transfer to a referral hospital or trauma center. This is one of the core lessons of the Advanced Trauma Life Support curriculum of the American College of Surgeons[22] and might be beneficial in nontraumatic hemorrhage as well. Referral of obstetrics patients with high hemorrhage risk to a tertiary care center for delivery should also be considered for disorders diagnosed on routine ultrasound (*e.g.*, placenta previa; placenta accrete, increta, percreta). These cases represented about a third of the obstetric claims for hemorrhage,

**Table 6.** Types of Communication Issues That Contributed to Problems with Care (n = 136)

| | n (%) |
|---|---|
| Surgeon or obstetrician did not communicate seriousness of problem to anesthesiologist | 17 (13) |
| • Obstetrician knew bleeding was extremely heavy but failed to call anesthesiologist in from home for 2 h. | |
| • Surgeon did not notify anesthesiologist of excessive bleeding during surgery or postoperatively when new bleeding occurred. | |
| • After beginning surgery, the surgeon realized he or she was not removing a Wilm's tumor, but rather a neuroblastoma that involved multiple organs and the aorta but did not inform the anesthesiologist. | |
| Surgeon and anesthesiologist did not communicate seriousness of problem to each other | 12 (9) |
| • Surgeon suspected an organ injury and the anesthesiologist noted changes in vital signs, but they did not inform each other of the problem. | |
| Follow-up communication issues with ICU, PACU, or floor personnel occurred | 12 (9) |
| • Nursing staff did not communicate a patient's deteriorating condition to the supervising physician. | |
| • Nursing staff was confused as to who was managing a patient in the PACU. | |
| Anesthesiologist did not communicate seriousness of problem to surgeon or obstetrician | 10 (7) |
| • Anesthesiologist failed to inform the surgeon of a precipitous drop in hematocrit and need for vasopressors. | |
| • Anesthesiologist delayed alerting the surgeon when serious bleeding occurred in the PACU. | |
| Surgeon did not take blood loss seriously | 10 (7) |
| • Surgeon refused to stop the procedure despite the anesthesiologist's request to stop due to ongoing blood loss. | |
| • Surgeon refused to evaluate a PACU patient who was hypotensive with abdominal distension when requested by the anesthesiologist. | |
| Miscommunication concerning blood availability occurred | 8 (6) |
| • Both physicians assumed the other one had ordered blood products. | |
| • Both physicians failed to check on the supply of blood in the hospital. | |
| Communication issues between anesthesiologist and CRNA/resident occurred | 8 (6) |
| • CRNA delayed calling the attending anesthesiologist when problems occurred. | |
| • Attending anesthesiologist was providing solo anesthesia care in one room although supervising CRNAs in other rooms. | |
| Anesthesiologist failed to call for assistance from a second anesthesiologist | 4 (3) |
| Failure to obtain appropriate informed consent occurred | 3 (2) |
| Anesthesiologist had limited communication skills | 1 (1) |
| At least one communication breakdown occurred | 81 (60) |

Examples of some of the more common communication issues are included in the table. Five claims had obvious delays in hemorrhage treatment, but the narrative did not state whether it was a communication problem or some other type of problem that led to the delay. Four claims had multiple communication issues.

CRNA = certified registered nurse anesthetist; ICU = intensive care unit; PACU = postanesthesia care unit.

emphasizing that hemorrhage cannot always be predicted before labor and delivery.

### Team Communication and Massive Transfusion Protocols

Training of OR and obstetric teams in crew resource management with ongoing practice for hemorrhage emergencies has the potential to improve team coordination and mitigate poor outcomes.[23,24] Training can take various forms. One approach is to set up the simulation in the actual OR with no prior notice to the staff.[25] The Mobile Obstetrics Emergencies Simulator system, which has been aligned with Team Strategies and Tools to Enhance Performance and Patient Safety, demonstrates how simulation training and clinical drills performed in a facility's obstetric unit can improve team performance. Issues specific to each unit can be addressed in the setting in which they occur.[26]

Another key component of communications is the massive transfusion protocol (MTP), now common at many university hospitals, obstetric units, and level 1 trauma centers.[3,27–29] This prearranged order set for the blood bank can be initiated at the point of care with a single phone call. The MTP provides for rapid delivery of blood products to the bedside, beginning with uncrossmatched and emergency-release products if necessary, and plans for continued delivery as the resuscitation progresses. Activation of the MTP is one component of the "crisis checklist" that has been recommended for dealing with intraoperative emergencies.[30] A third of the obstetric hemorrhage cases followed vaginal delivery. Although MTPs specific for obstetric units have been described,[28] there are no data to suggest that a specific obstetric protocol is better than a standardized institutional MTP. Systems factors may need to be optimized to ensure that the MTP functions well in the obstetric environment.

Massive transfusion protocols are designed to facilitate the early replacement of clotting factors if coagulopathy is present or a high risk. A typical MTP calls for the blood bank to send 6 units of erythrocytes, 4 units of plasma, and 1 apheresis pack of platelets to the OR as rapidly as possible, followed with similar "transfusion packs" at regular intervals until the crisis is resolved.[3,27] The optimal ratio of

**Table 7.** Clinical Lessons

Massive hemorrhage is a rare but serious cause of malpractice claims.
- High mortality
- High rate of payment to plaintiff
- Large payment size

Hemorrhage claims were most common in obstetric anesthesia and anesthesia for thoracic or lumbar spine surgery. Massive hemorrhage can also occur in low-risk procedures, *e.g.*, minimally invasive, laparoscopic, or robotic procedures.

Common features:
- Lack of timely diagnosis
- Lack of timely transfusion
- Lack of timely return to the operating room

Anesthesia care contributed to poor outcome in most claims.

Every surgical and obstetric facility should create and practice a plan to address unexpected massive hemorrhage.

erythrocytes, plasma, and platelets is controversial,[31,32] but current recommendations begin with empiric replacement of coagulation factors until hemorrhage has slowed sufficiently to allow for precise assessment of clotting function.[6] Trauma patients, presenting with tissue injury and shock, can become coagulopathic very early after injury.[8] In pregnancy, the placenta is an important source of immune activation that can trigger early, massive coagulopathy.[33] Elective surgical cases with massive hemorrhage may also deteriorate toward the final common pathway of death from hemorrhage: uncorrectable coagulopathy, persistent acidosis, circulatory exhaustion, and eventual cardiac arrest. Frequent laboratory testing and rapid return of results are essential during the dynamic course of hemorrhagic shock.[6]

### *Study Limitations*

The limitations of closed claims analysis have been previously described, including selection bias, nonrandom retrospective data collection, outcome bias, and possible geographic imbalance in data collection.[34] The data are limited to information gathered by insurance companies for claims resolution, and the database lacks a denominator of anesthetics for estimating risk.[34] The NACOR cases used to provide a general context come from a more recently compiled registry (2010 to 2013) and may themselves be subject to selection biases. Comparisons should be interpreted with caution.

Important data on factors in the hemorrhage claims, such as timeliness of diagnosis and treatment, was based on secondary analysis of claim narratives provided by the project on-site reviewer rather than systematic primary data abstraction from the insurance company claim files. Reliability of reviewer judgments in these hemorrhage claims was good to excellent on most items. Inclusion of a third reviewer in such assessments provides improved reliability. The lowest reliability was observed on the assessment of the anesthesiologist and surgeon contribution to the patient's injury. The $\kappa$ value on these assessments reflects the high prevalence of reviewer judgments that these providers contributed to the injury, leaving little room for agreement beyond chance. Our measure of interrater reliability (kappa) calculates agreement beyond that which would be expected by chance, and results in low scores in situations of skewed data distributions such as observed on these judgments.[35] Therefore, the seemingly low reliability on these items, which was still in the acceptable range, reflects the inherent traits of the statistical methodology.

## Conclusions

In summary, the most common types of procedures involved in claims associated with hemorrhage were obstetrics, thoracic or lumbar spine surgery, and robotic/laparoscopic surgery. Lack of communication and absence of organized responses to massive hemorrhage were common and associated with inadequate preparation, delays in diagnosis, and/or effective treatment. Evolving, evidence-based treatment for uncontrolled hemorrhage may lead to a reduction in the frequency and severity of these events.

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## Competing Interests

The authors declare no competing interests.

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