Laboratory Monitoring and Transfusion Guidelines to Influence Care in Patients Undergoing Multilevel Spinal Fusion Surgery

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Purpose: The purpose of this project was to determine whether the use of the modified Northwestern high risk spine protocol in patients undergoing multilevel spinal fusion surgery would result in improved transfusion practices.

Design: Preimplementation and postimplementation design.

Methods: A laboratory monitoring and transfusion guideline protocol was implemented in patients undergoing multilevel spinal fusions. Data were collected via a manual retrospective chart review of the electronic medical record before and after implementation of the protocol.

Findings: Laboratory values were monitored at guided intervals. There was a statistically significant ($P = .004$) decrease in the mean hemoglobin value at which a packed red blood cell transfusion was initiated.

Conclusions: Through the use of the protocol, laboratory value monitoring provided quantitative data to aid and improve clinical decision making for practitioners in the perioperative period.

Keywords: multilevel spine surgery, transfusion guidelines, laboratory monitoring protocols, patient outcomes, postoperative disposition.

The incidence of spinal fusion surgeries has increased by 70% from 2001 to 2011 with approximately 488,300 procedures performed annually in 2011.1 Multilevel lumbar, thoracic, or combined lumbar and thoracic spinal fusion cases are defined as a surgical intervention involving three or more vertebral levels. Patients undergoing multilevel spinal fusion surgery are at increased risk for blood loss. In many instances, these surgeries are associated with extensive blood loss ranging from 1 to 11.5 L,2 the equivalent of more than 200% of a patient’s blood volume. The deleterious effects of blood loss, such as decreased oxygen carrying capacity and hypovolemia can be detrimental to any patient, but even more so if the patient has complex coexisting comorbidities. The development of severe anemia from extensive blood loss increases the risk of mortality from complications such as renal failure, sepsis, myocardial infarction, and respiratory failure.3,4

Blood transfusion, defined as a single unit of packed red blood cells (PRBCs) or massive transfusion of PRBCs, can be lifesaving in certain situations. However, blood transfusions can have negative effects on the patient such as predisposing the patient to multiple organ failure, increased risk of infection, lung injury, coagulation defects, acid-base abnormalities, and increased mortality.5 In fact, patients who received liberal blood
products versus more restrictive guidelines for transfusion therapy experience far greater complications, including an increased in-hospital mortality.\textsuperscript{3} There is expanding evidence, which supports the providers’ use of checklists and protocols to guide blood transfusion practices in effort to improve surgical outcomes.\textsuperscript{2,6}

**Literature Review**

Transfusion may be necessary in multilevel spine surgery because of blood loss, but the goal is to avoid massive transfusion, when possible, to limit deleterious effects.\textsuperscript{5,7} The loss of blood, and specifically red blood cells, decreases the oxygen carrying capacity to the tissues, which may lead to tissue ischemia and damage. Complications of massive transfusion include acidosis, hypothermia, coagulopathy, acute lung injury, multiple organ failure, systemic inflammatory response syndrome, infection, increased mortality, and increased intensive care unit (ICU) and total hospital length of stay.\textsuperscript{5,7} Monitoring of laboratory values perioperatively are crucial in the decision to transfuse. Evidence supports the use of transfusion protocols, like that of the Northwestern high risk spine protocol, which define the intervals and types of laboratory tests to draw in high-risk cases and transfusion triggers.\textsuperscript{2} Safe transfusion thresholds for hemoglobin (Hgb) vary from 6 to 10 g/dL depending on a patient’s associated comorbid conditions. A Hgb of 7 to 8 g/dL is a widely accepted transfusion trigger in the patient without pre-existing cardiovascular comorbidities.\textsuperscript{8,9} A systematic review revealed that restrictive transfusion thresholds are not beneficial for patients who are high risk and scheduled for major surgery.\textsuperscript{6} Some patients may not tolerate the deleterious effects of lower oxygen carrying capacity leading to ischemic events, thus necessitating the need for earlier transfusions triggers. This could be because of comorbidity profiles creating high-risk patients, such as the elderly and those with cardiovascular disease, or select surgical cases, such as cardiac and vascular surgery.\textsuperscript{10} Factors related to surgery and anesthesia such as hypoxia, hypothermia, and acidosis can further increase blood loss because of reduction in platelet (Plt) function and clotting factors.\textsuperscript{11} Excessive intraoperative intravenous fluid administration can lead to a dilutional effect of the coagulation factors, resulting in an increased blood loss instead of the intended increase in blood volume.\textsuperscript{6} Intraoperative coagulopathies are also associated with massive blood loss and vigilance is needed to avoid the untoward effects. The correction of intraoperative coagulopathies requires modalities, which include fresh frozen plasma (FFP), cryoprecipitate, platelets, desmopressin (DDAVP), and Factor VII.\textsuperscript{12} The age of the patient impacts the compensatory mechanisms associated with blood loss leading to the inability to tolerate changes to the decreased circulating blood volume.\textsuperscript{6,10} Increased risk of morbidity and mortality after spinal fusion surgery includes patients older than 65 years, the fusion of nine or more surgical levels, and comorbidities such as cardiac, pulmonary, liver, and renal disease.\textsuperscript{13} Judicious blood loss monitoring and transfusion practice are necessary for those older than 65 years.

Berkow et al investigated continuous noninvasive Hgb monitoring during spine surgery and determined it can lead to a more rapid assessment of blood loss resulting in titrated red blood cell transfusions. Transfusion protocols offer deliberate intervals in laboratory monitoring, which results in early recognition of blood loss and timely transfusions.\textsuperscript{14} However, Miller et al contradicted the accuracy of this method of monitoring Hgb when compared to sending a blood sample to the laboratory for Hgb measurement, limiting its use.\textsuperscript{15} The Northwestern high risk spine protocol recommends monitoring laboratory values every 2 hours for the first 6 hours of surgery, followed by every hour for the remainder of surgery.\textsuperscript{2,16} The implementation of this protocol resulted in a reduction in the total PRBC transfusions by 1 U in spine surgery patients.\textsuperscript{2}

The purpose of this project was to determine whether the use of the modified Northwestern high risk spine protocol in patients undergoing multilevel spinal fusion surgery would result in improved transfusion practices (Figure 1). The specific aims for this project included (1) to evaluate the current state of laboratory monitoring and transfusion practices in patients undergoing multilevel lumbar and/or thoracic spinal fusion cases, (2) to implement an educational intervention with the anesthesia care team regarding the modified Northwestern high risk spine protocol for laboratory monitoring and transfusion practice in patients undergoing multilevel lumbar

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and/or thoracic spinal fusion cases, and (3) to evaluate for a change in practice in laboratory monitoring and transfusion thresholds for patients undergoing multilevel lumbar and/or thoracic spinal fusions.

Methods

Study Design, Sample, and Organizational Setting

This project used a preimplementation and post-implementation design. Data were collected via a manual retrospective chart review. The setting was a 957-bed academic tertiary care facility located in the Southeast United States. More than 1,200 neurosurgical and orthopaedic procedures on the spine, including discectomies, fusions, laminectomies, spinal cord tumor removal, and scoliosis repairs and reconstruction, are performed annually. The convenience sample included 200 patients, 100 in the preimplementation group and 100 in the postimplementation group. The population included all adult patients (aged >18 years) undergoing multilevel lumbar and/or thoracic spinal fusions defined as three or more levels. Patients were excluded if they (1) refused blood products and/or (2) were aged less than

### Labs should be measured:
- Preoperatively
  - The day of surgery if labs are more than 30 days prior to surgery
  - At baseline
  - Before or within 30 minutes of incision
- Every 2 hours for the initial 6 hours of surgery
  - Every 2, 4, and 6
  - Every 1 hour after the initial 6 hours, etc.

### Labs to be drawn:
- ABG, arterial blood gas; ECT, extrinsically-activated test with tissue factor; Hct, hematocrit; Hgb, hemoglobin; INR, international normalized ratio; FDA, US Food and Drug Administration; FFP, fresh frozen plasma; FibTem, tissue factor and the platelet inhibitor cytochalasin D; PRBC, packed red blood cell; PT, prothrombin time; PTT, partial prothrombin time; ROTEM, rotational thromboelastometry. This figure is available in color online at www.jopan.org.
18 years. After the group was identified, criteria for transfusion were based on severity of cardiac disease. Moderate to severe cardiac disease was defined as having a stent or coronary artery bypass graft surgery within 5 years, management for known coronary artery disease, and/or the presence of congestive heart failure or valvular disorders.

**Intervention**

For the current state of practice, the project institution did not have a specific guideline regarding the management of laboratory testing, laboratory value interpretation, and transfusion triggers for the multilevel spinal fusion surgery patient. As a result, the anesthesia providers relied on anecdotal evidence to select intervals to monitor laboratory values and replace blood products. This practice also allowed practitioners to select alternative interventions to transfusion in an attempt to support hemodynamics such as the administration of intravenous fluids and/or medications to support the patient’s hemodynamics. The Northwestern high risk spine protocol used for this project had slight modifications to conform to practices at the current implementation site. The educational intervention included presenting the Northwestern high risk spine protocol during the anesthesia staff meeting, providing laminated handouts of the protocol in the operating room, and reminder e-mails with a PDF attachment of the protocol to anesthesia providers involved in the care of spinal fusion. Through the use of the Northwestern high risk spine protocol designated intervals for the monitoring of Hgb, hematocrit, platelets, arterial blood gases, and coagulation factors were delineated. Providers were given an appropriate decision-making tool to aid in the determination of triggers for blood product transfusion allowing for improved care of the patient undergoing multilevel spinal fusion and their postsurgical outcomes.

**Assessment and Measures**

Data that were collected included patient and surgical demographic variables, laboratory values and time intervals, and information from the anesthesia record to determine intraoperative management of laboratory findings and transfusion practice. Using G*Power software, the sample size was estimated based on 80% power, \( \alpha \) set to 0.017 because of multiple tests, and a medium effect size of 0.50. The estimated sample size necessary to achieve statistical significance is 170 patients total (85 at each time point). Data were analyzed using IBM SPSS v.24 and \( \alpha \) was set to 0.017 to adjust for multiple comparisons. Descriptive statistics (n, %, mean, and SD) were calculated and presented for patient demographics, pre-existing comorbidities, surgical variables, selection and frequency of laboratory tests, transfusions of blood products, and the laboratory value at which transfusions were initiated. Independent \( t \) tests were conducted to compare preimplementation and postimplementation groups.

**Results**

The 100 patients in the preimplementation group and the 100 patients in the postimplementation group were similar in patient demographical and surgical variables.

The preimplementation group was 57% female, with a mean age of 63 years. The mean number of comorbidities per patient was 3.7. Pre-existing cardiac disease was reported in 75% of the patients. There was moderate or severe cardiac disease in 10% of the patients. The mean number of operative vertebral levels fused was 6.3 with a mean surgical duration time of 350 minutes. Postoperatively the patients were sent to the ICU, step-down unit, or floor (Table 1).

The postimplementation group was 51% female, with a mean age of 61 years. The mean number of comorbidities per patient was 3.6. Pre-existing cardiac disease was reported in 77% of the patients. There was moderate or severe cardiac disease in 12% of the patients. The mean number of operative vertebral levels fused was 6.3 with a mean surgical duration time of 380 minutes. Postoperatively the patients were sent to the ICU, step-down unit, or floor (Table 1).

The postoperative disposition of the patients in the preimplementation and the postimplementation groups admitted to the surgical floor after discharge from the postanesthesia care unit (PACU) was 11% and 23%, respectively, 59% and
38% were admitted to the stepdown unit, respectively, and 30% and 39%, respectively, were admitted to the ICU. This reflected a 110% increase in PACU to floor admissions and a 35% decrease in the PACU to stepdown admissions, a statistically significant ($P = .007$) finding (Figure 2).
Preimplementation data revealed 4% of the surgical cases had coagulation laboratory tests drawn at baseline and 1% of cases had coagulation laboratory tests drawn every 2 hours. In the preimplementation group, providers drew a baseline shock panel in 48% of the cases and 34% of cases had a shock panel drawn every 2 hours for the first 6 hours of the case (Table 2). Values for coagulation laboratory monitoring were increased from 4% to 38% at baseline for the preimplementation to postimplementation period, and this was statistically significant at $P < .001$. The 2, 4, and 6-hour laboratory interval was examined and 21% of cases had the appropriate coagulations’ test drawn at the appropriate 2-hour interval ($P < .001$), a statistically significant change. Shock panel laboratory monitoring increased postimplementation to 78% at baseline ($P < .001$) and 42% ($P = .221$) at the appropriate 2-hour interval (Table 2).

In the total population the mean Hgb value at which a PRBC transfusion was initiated decreased from 8.897 g/dL in the preimplementation group to 8.176 g/dL in the postimplementation group, which was statistically significant ($P = .004$). In the mild cardiac disease group, the mean Hgb value at which a PRBC transfusion was initiated decreased from 8.624 g/dL in the preimplementation group to 8.008 g/dL in the postimplementation group, which was statistically significant ($P = .04$) (Table 3). The preimplementation versus postimplementation protocol outcomes for transfusion practice during multilevel spinal fusion cases are reported in Table 4. The mean preoperative Hgb value was 12.82 and 12.99 g/dL and the mean postoperative Hgb value was 9.17 and 9.38 g/dL. There was a reduction in postoperative transfusions given.

Discussion

Checklists and Protocols

Checklists and protocols are beneficial in decreasing error, improving outcomes, and increasing communication. Failure to follow treatment protocols has been identified as a contributing factor for adverse events. Implementing a standardized laboratory value monitoring and blood transfusion practices like the Northwestern high risk spine protocol allows for better management of the patient perioperatively. This provides an improved picture on the state of the patient on transfer out of the operating room to the PACU. It also provides reliable quantitative data to communicate to the PACU nurses during the transition of care. The implementation of this protocol stopped at the end of surgery. The protocol’s components can be maintained in the early postoperative period by the receiving nursing staff allowing for effective transfusion practices in the postoperative period that are based on protocol-driven laboratory values. By continuing the protocol throughout the perioperative period, the patient may experience improved outcomes.
Change in Anesthesia Provider’s Practice

The implementation of the adapted Northwestern high risk spine protocol provided laboratory monitoring and transfusion practice guidelines for multilevel spinal fusion surgery and resulted in a change in practice for anesthesia providers through this guided evidence-based practice. This resulted in increased surveillance of coagulation function as a gauge for appropriate intervention to deter

Table 3. Preimplementation Versus Postimplementation Red Blood Cell (RBC) Transfusion Triggers During Multilevel Spinal Fusion Surgery

<table>
<thead>
<tr>
<th>Average RBC Transfusion Trigger (g/dL)</th>
<th>Group</th>
<th>N</th>
<th>Mean (SD)</th>
<th>Significance (P Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total population</td>
<td>Preimplementation group</td>
<td>38</td>
<td>8.897 (1.029)</td>
<td>.004</td>
</tr>
<tr>
<td></td>
<td>Postimplementation group</td>
<td>37</td>
<td>8.176 (1.059)*</td>
<td>.004</td>
</tr>
<tr>
<td>Minimal/mild cardiac disease</td>
<td>Preimplementation group</td>
<td>25</td>
<td>8.624 (0.833)</td>
<td>.04</td>
</tr>
<tr>
<td></td>
<td>Postimplementation group</td>
<td>25</td>
<td>8.086 (1.196)*</td>
<td>.04</td>
</tr>
<tr>
<td>Moderate/severe cardiac disease</td>
<td>Preimplementation group</td>
<td>3</td>
<td>9.2 (0.954)</td>
<td>.04</td>
</tr>
<tr>
<td></td>
<td>Postimplementation group</td>
<td>4</td>
<td>8.85 (0.768)</td>
<td>.612</td>
</tr>
</tbody>
</table>

*P < .05.
The protocol recommended PRBC transfusions be given to keep the Hgb value greater than 8 g/dL for those with minimal to mild cardiovascular disease and greater than 10 g/dL for patients with moderate to severe cardiac disease. Otherwise, the patient with other cardiac disease, such as hypertension, was defined as having minimal to mild cardiac disease. The protocol positively impacted the practitioner’s decision making on the initiation of the PRBC transfusion trigger for the overall population and specifically in those patients with mild cardiac disease. For those with moderate to severe cardiac disease, the practitioners may have continued concern regarding the need to avoid imbalance in the patient’s oxygen supply and demand, and thus transfusion triggers were not significantly impacted.

Szpila et al\textsuperscript{20} and Trentino et al\textsuperscript{21} report that the practice of PRBC transfusion costs are estimated to be approximately $72 million in the United States and represent 7.8\% of hospital costs. According to Lagerquist et al\textsuperscript{22} the average unit of PRBC has a laboratory cost of $423 and transfusion administration cost of approximately $243. An additional cost found in the Johns Hopkins Hospital cost estimator reveals the practice of blood typing for Rh and ABO compatibility add an additional $515 to transfusion practice costs.\textsuperscript{23} In a study by Shander et al\textsuperscript{24} the costs of FFP are $1,608 per patient after incorporating the laboratory costs and transfusion administrative costs. The costs associated with FFP transfusion practice alone translate into a $2,573 savings per patient in those who underwent multilevel spinal fusion surgery requiring FFP. The theory supporting the use of the protocol was to increase surveillance of coagulation function and intervene at designated triggers so that coagulopathy could be prevented, which would decrease bleeding as measured by estimated blood loss. This would translate into a decreased need for blood product transfusions in the perioperative period. On the basis of our results our patients experienced an increase in PRBC transfusion and estimated blood loss; although both were not statistically significant, the total number of units of FFP decreased from 3.8 to 2.2 U, a 42\% decrease. Practitioners were continuing to give FFP when not indicated, however, less than in the preimplementation period.

### Postoperative Disposition of Multilevel Spinal Surgery Patients

Stepdown beds in hospitals are designed for patients who do not require intensive care and monitoring provided in the ICU but may need more care than can be provided in a traditional hospital bed.\textsuperscript{25} When appropriately assigned, stepdown beds help decrease ICU stays and readmissions and serve as a cost-effective alternative to ICU stays. However, research shows many intermediate care patients are shifted up to the stepdown from the floor, which actually increases hospital costs without improving outcomes.\textsuperscript{30} Through the implementation of this laboratory monitoring and transfusion practice protocol, providers can use quantitative data as criteria for decision making throughout the perioperative period. The data gained from use of the protocol can also be applied by providers

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### Table 4. Preimplementation Versus Postimplementation Protocol Outcomes for Transfusion Practice During Multilevel Spinal Fusion Surgery (N = 200)

<table>
<thead>
<tr>
<th></th>
<th>Preimplementation Group (n = 100)</th>
<th>Postimplementation Group (n = 100)</th>
<th>Significance (P Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td></td>
</tr>
<tr>
<td>Preoperative hemoglobin value</td>
<td>12.82 (2.28)</td>
<td>12.99 (1.67)</td>
<td>.561</td>
</tr>
<tr>
<td>Postoperative hemoglobin value</td>
<td>9.17 (1.44)</td>
<td>9.38 (1.39)</td>
<td>.303</td>
</tr>
<tr>
<td>Total estimated blood loss</td>
<td>1,172.05 (1,093.4)</td>
<td>1,208.45 (1,455.9)</td>
<td>.523</td>
</tr>
<tr>
<td>Total PRBC units transfused</td>
<td>2.47 (1.92)</td>
<td>2.7 (1.77)</td>
<td>.595</td>
</tr>
<tr>
<td>Total platelet units transfused</td>
<td>1.17 (.408)</td>
<td>1.75 (1.75)</td>
<td>.163</td>
</tr>
<tr>
<td>Total cryoprecipitate units transfused</td>
<td>1.43 (.535)</td>
<td>1.67 (1.28)</td>
<td>.639</td>
</tr>
<tr>
<td>Total FFP units transfused</td>
<td>3.38 (2.5)</td>
<td>2.2 (1.75)</td>
<td>.258</td>
</tr>
<tr>
<td>Postoperative transfusion given, N (%)</td>
<td>25 (25%)</td>
<td>19 (19%)</td>
<td>.306</td>
</tr>
</tbody>
</table>

FFP, fresh frozen plasma; PRBC, packed red blood cell.
to aid in the selection of appropriate levels of postoperative care in the patients who underwent multilevel spinal fusions. Compared with the pre-implementation group, there was a 35% decrease in admissions to the stepdown and a 110% increase in admissions to the floor for patients who underwent multilevel spinal fusions. In addition, there was a 30% increase in ICU admissions. Although specific data on variables to determine postoperative disposition was not collected and other confounding variables may be present, the increased quantitative data available served as one level of criteria to aid in the appropriate selection of the need for high acuity admissions and intermediate admissions. As hospital level of care progresses so does expense. The use of data to support the decisions for postoperative care improves outcomes for the patient but it can also translate to cost savings for the health system.

**Limitations**

This study focused on intraoperative laboratory monitoring data and the need for transfusion within the first 24 hours postoperatively for patients undergoing multilevel spinal fusions. The use of an electronic query system from the electronic medical repository would have improved the data collection process. Selectivity of the surgical population that would benefit from the protocol implementation would help decrease protocol fatigue. The use of an electronic query to collect data would have been beneficial.

**Areas for Further Research**

Further research is needed to determine if the implementation of this protocol had effects on the morbidity and mortality after multilevel spinal fusion surgery. The current protocol implementation included all patients undergoing fusion of three or more vertebral levels. The application of the protocol to high-risk patients having high-risk surgery beyond the perioperative period may be valuable to understand the overall impact of the protocol on postoperative patient outcomes.

**Conclusions**

Implementation of the Northwestern high risk spine protocol allowed for improved monitoring of laboratory values through its recommendation of set time intervals for monitoring. It also improved transfusion practices by providing set triggers for the administration of blood products. The use of such a protocol such as the Northwestern high risk spine protocol provides data to anesthesia providers for clinical decision-making. Continued use and refinement of this protocol in high-risk patient populations may lead to improved outcomes for patients.

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**References**