

## The Implementation and Efficacy of the Northwestern High Risk Spine Protocol

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### Key words

- Checklist
- Critical pathways
- Hemostasis
- Patient care team
- Spinal fusion

### Abbreviations and Acronyms

**Cryo:** Cryoprecipitate  
**FFP:** Fresh frozen plasma  
**HRS:** High risk spine  
**PRBC:** Packed red blood cells  
**RBC:** Red blood cells



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Citation: *World Neurosurg.* (2014) 82, 6:e815–e823.

<http://dx.doi.org/10.1016/j.wneu.2014.06.020>

 Supplementary digital content available online.

Journal homepage: [www.WORLDNEUROSURGERY.org](http://www.WORLDNEUROSURGERY.org)

Available online: [www.sciencedirect.com](http://www.sciencedirect.com)

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### INTRODUCTION

Surgical correction of complex adult kyphoscoliosis frequently requires operative times lasting more than 12–16 hours and is often associated with an estimated blood loss ranging between 1200 and 11,500 mL (25%–230% of a patient's estimated blood volume) (11, 41). Not surprisingly, these patients require the coordinated efforts of a variety of health care providers to mitigate perioperative morbidity and mortality (18). In 2005, 1 patient died during a posterior thoracolumbar fusion revision with several major vertebral osteotomies, which was complicated by unanticipated massive surgical hemorrhage. Root-cause analysis of this sentinel event postulated that patient safety for these high risk procedures may be improved with better intraoperative communication and proactive management of anticipated blood loss

■ **OBJECTIVE:** The aims of this study were to determine the efficacy and feasibility of implementation of the intraoperative component of a high risk spine (HRS) protocol for improving perioperative patient safety in complex spine fusion surgery.

■ **METHODS:** In this paired availability study, the total number of red blood cell units transfused was used as a surrogate marker for our management protocol efficacy, and the number of protocol violations was used as a surrogate marker for protocol compliance.

■ **RESULTS:** The 548 patients (284 traditional vs. 264 HRS protocol) were comparable in all demographics, coexisting diseases, preoperative medications, type of surgery, and number of posterior levels instrumented. However, the surgical duration was 70 minutes shorter in the new group (range, 32–108 minutes shorter;  $P < 0.0001$ ) and the new protocol patients received a median of 1.1 units less of total red blood cell units (range, 0–2.4 units less;  $P = 0.006$ ). There were only 7 (2.6%) protocol violations in the new protocol group.

■ **CONCLUSIONS:** The intraoperative component of the HRS protocol, based on two Do-Confirm checklists that focused on 1) organized communication between intraoperative team members and 2) active maintenance of oxygen delivery and hemostasis appears to maintain a safe intraoperative environment and was readily implemented during a 3-year period.

and coagulopathy, as well as aggressive preoperative evaluation, optimization, and coordinated postoperative care. This led to the formation of a multidisciplinary team of physicians who developed a comprehensive perioperative protocol for the evaluation and management of these patients—the high risk spine protocol (HRS Protocol) (18). The intraoperative management of these patients was based on 2 Do-Confirm checklists, which focused on organized communication between intraoperative team members (Table 1) and the active maintenance of oxygen delivery and hemostasis (Table 2).

Medical errors in the highly dynamic perioperative environment result from the complex interplay between intellectual mistakes (e.g., unfamiliarity, imperfect information processing, flawed decision-making, cognitive overload) (21) and communication failures (e.g., occasion, content, audience, or purpose) (32). Adopting a systems-based approach to

medical error analysis and prevention (i.e., Reason's Swiss Cheese model) (34) focuses on developing a series of defenses or safeguards (i.e., the slices of cheese) that either minimize intellectual mistakes and communication failures or alleviate the consequences of these mistakes or errors (i.e., the holes in the cheese) (28, 29, 34, 35). Checklists can provide the intellectual framework for preventing many intellectual mistakes (10, 20) and communication failures (2, 10, 20), and thereby can reduce perioperative morbidity and mortality. Despite the efficacy of checklists, physicians do not readily adopt them, most often because checklists are viewed as Read-Do checklists that impede independent thought, as opposed to Do-Confirm checklists that serve as memory aides to verify that essential tasks have been performed (5, 10, 13, 16, 20, 33, 35).

Despite the growing evidence of utility of checklists in improving surgical outcomes, there has been limited

**Table 1.** Intraoperative Verbal Communication Guidelines

1. Anesthesia Team to Surgical Team
  - a. Vital signs
    - i. Hemodynamics
    - ii. Temperature
    - iii. Cumulative blood loss
  - b. Laboratory data
    - i. Hemoglobin and oxygenation
    - ii. Acid-base status
    - iii. Coagulation
  - c. Any potential issues for balance of case
2. Surgical Team to Anesthesia Team
  - a. Current step in surgical procedure
  - b. Observed blood loss and clotting
  - c. Warning before performing major vertebral osteotomies
    - i. If coagulopathic or anemic, pause for management of administration of appropriate blood products before next step
    - ii. After 6 hours, Go/No-Go decision to proceed based on patient's current physiologic state
3. Neurophysiological Monitoring Team to Anesthesia Team and Surgical Team
  - a. Change in evoked potentials
    - i. >10% increase latency
    - ii. >50% decrease amplitude

Reported hourly or when significant changes occur.

development of checklists specifically targeting neurosurgical procedures (1, 27, 31). The aim of this study was to determine the efficacy of the intraoperative component of the HRS Protocol in improving intraoperative patient safety in complex spine fusion surgery. We used the total number of red blood cell units (total RBCs) transfused as a surrogate marker for efficacy because intraoperative hemostasis should be inversely related to the total RBCs transfused. Convincing data are now being reported that support the shift in paradigm that the transfusion of even 1 unit of RBCs may produce detrimental outcomes in perioperative patients due to damaging systemic immunomodulatory effects (4, 12, 23, 26, 36). A secondary goal of this study was to determine how readily adopted the

**Table 2.** Active Management of Oxygen Delivery & Hemostasis Guidelines

1. Oxygen delivery
  - a. Intravascular volume
    - i. Calculate estimated blood volume
    - ii. Monitor hourly estimated blood loss
    - iii. Monitor hourly urine output
    - iv. Maintain clinical euvolemia with intravascular fluid therapy
  - b. Hemoglobin transfusion trigger
    - i. Moderate/severe cardiovascular disease: Hgb  $\geq 10$  g/dL
    - ii. Mild/minimal cardiovascular disease: Hgb  $\geq 8$  g/dL
  - c. Goal mean arterial pressure
    - i. Moderate/severe cardiovascular disease:  $\pm 10\%$ – $15\%$  baseline
    - ii. Mild/minimal cardiovascular disease:  $\pm 20\%$  baseline
  - d. Laboratory evaluation
    - i. Hemoglobin, hematocrit
    - ii. Arterial blood gas (including ventilator settings, lactate)
    - iii. Electrolytes ( $\text{Na}^+$ ,  $\text{K}^+$ ,  $\text{Ca}^{++}$ , bicarbonate)
2. Hemostasis
  - a. Laboratory evaluation
    - i. Platelet
    - ii. PT, PTT, INR
    - iii. Fibrinogen (Fib)
  - b. Platelet transfusion
    - i. Order platelet dose when  $< 150,000$
    - ii. Transfuse platelet dose when  $< 100,000$
  - c. Fibrinogen maintenance
    - i. Thaw cryoprecipitate when fibrinogen  $< 200$  mg/dL
    - ii. Administer cryoprecipitate when fibrinogen  $< 150$  mg/dL
  - d. If patient is oozing and Fib  $> 200$  mg/dL and Plt  $> 100,000$ 
    - i. Desmopressin (DDAVP)  $0.3 \mu\text{g}/\text{kg}$
  - e. If patient is still oozing after DDAVP and INR  $> 2.0$ 
    - i.  $20 \mu\text{g}/\text{kg}$  activated Factor VII (rVIIa)

Laboratory tests measured every 2 hours for initial 6 hours, then hourly.

Hgb, hemoglobin; Plt, platelet; PT, prothrombin time; PTT, partial thromboplastin time; INR, international normalized ratio; Fib, fibrinogen.

intraoperative component of the HRS Protocol was by the anesthesia providers at our institution.

## METHODS

### Study Setting and Study Sample

This paired availability study was approved by the Institutional Review Board to include a waiver of informed consent

(3, 38). All patients who underwent major spine surgery, defined as instrumented fusion of 3 or more levels and/or vertebral body resections, between January 1, 2003, and May 31, 2009, at Northwestern Memorial Hospital met inclusion criteria. The current procedural terminology codes that were used to determine the eligible surgical procedures were limited to those for arthrodesis of spine deformity (22800, 22802, 22804, 22810, 22812, and 22819),

spinal instrumentation (22842, 22843, 22844, 22846, and 22847), and osteotomy of the spine (22208, 22216, and 22226). In addition, the primary surgeon was limited to 3 of our most experienced surgeons whose practices were predominately focused on the surgical correction of extensive adult spine deformity.

Patients with preexisting bleeding disorders and patients who abstained from receiving blood products were excluded from the database. Patients were not included in the final analysis if they had incomplete perioperative medical records without documentation of the variables under evaluation. To include only 1 surgical procedure for each patient who may have had multiple eligible spine surgeries throughout the 6-year study period, sequential dropout rules were determined to include the procedure that most closely resembled those of the other patients in the database—posterior lumbar spine instrumentation. Multiple surgical procedures were sequentially dropped out in the following order: 1) only anterior surgery, 2) only posterior cervical surgery, and 3) not the earliest by date of the remaining eligible surgical procedures. Of the initial 629 cases identified as eligible, a total of 548 patients were included in the final analysis after exclusion and drop outs (Figure 1).

Initial identification of eligible patients took place between July and August 2009, through queries of the Enterprise Data Warehouse. To control the data accuracy, a subgroup of the investigators extracted all of the data between September 2009 and July 2010. Two investigators entered all of the collected data into a purposely-designed database (PostgreSQL, PostgreSQL Global Development Group, [www.postgresql.org](http://www.postgresql.org)). Scheduled, repetitive checks of the data accuracy were conducted and conflicts resolved after consultation with at least 2 investigators.

### Perioperative Variables

Variables collected included the patients' demographics, preoperative coexisting diseases, preoperative medications, duration of surgery, volume of administered intraoperative fluids and blood products, estimated blood loss, urine output, minimal intraoperative temperature, intraoperative and perioperative laboratory values, and details of the surgical procedure. A full description of the collected variables is reported in Appendix 1.

### Traditional Protocol versus High Risk Spine Protocol

Before September 1, 2006, patients undergoing spine surgery received blood products

at the discretion of the anesthesiologist, according to traditional management strategies (group T). In general, packed red blood cells (PRBCs) were administered to maintain adequate oxygen delivery. Dilutional and consumptive coagulopathies were treated with platelets and fresh frozen plasma (FFP) at the discretion of the anesthesia team.

Starting on September 1, 2006, all patients undergoing major spine fusion of 3 or more levels and/or vertebral body resections were treated according to the HRS Protocol (group HRS). Part of the philosophy of this protocol was that frequent surveillance of "transfusion triggers" would allow the anesthesiologist to avoid moderate-to-severe anemia, thrombocytopenia, and coagulopathy (Table 2) (18). Cryoprecipitate (CRYO) was used in place of FFP to maintain adequate fibrinogen levels (17, 22, 25). Because CRYO contains high levels of factor VIII, von Willebrand factor, and fibrinogen, it serves as an efficient low volume alternative to FFP—100 mL of CRYO (1 pooled unit) is the equivalent of 1000 mL of FFP (4 units) (7). However, because CRYO does not replace all coagulation factors, during massive transfusion (0.7–1 blood volume), the elective administration of a low dose of recombinant activated factor VII (20–40 µg/kg) assists with hemostasis (19).

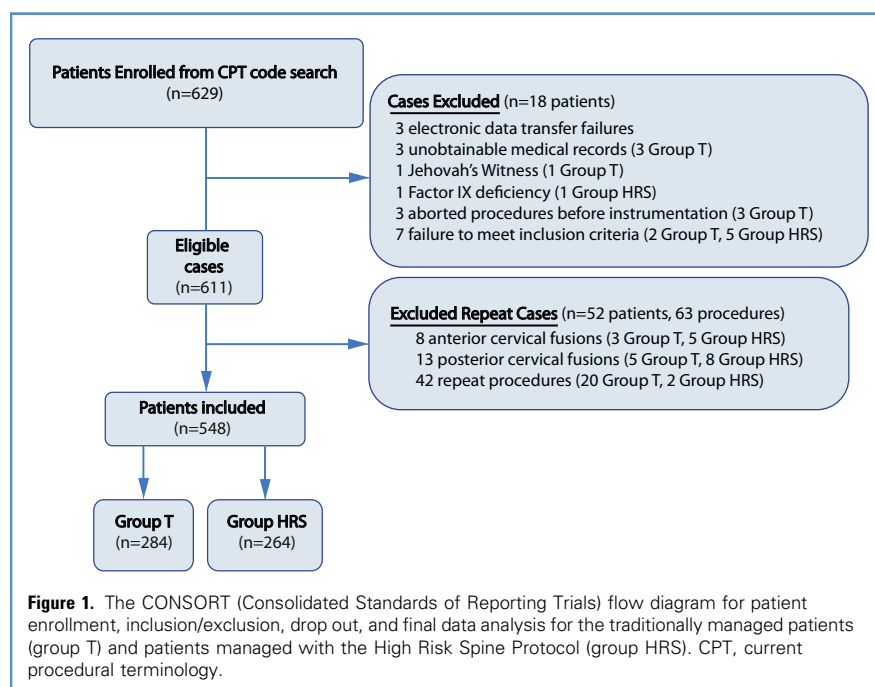
For both protocols, the anesthesiologist could use any intravenous fluid for resuscitation and maintenance of euolemia. Preoperative autologous blood donation, acute normovolemic hemodilution, deliberate moderate hypotension, antifibrinolytic agents, and aprotinin were not used in any patient.

### Statistical Analysis

The aim of this study was to determine the efficacy of the intraoperative component of the HRS Protocol in improving patient safety in complex spine fusion surgery.

We used the total RBCs transfused as a surrogate marker for efficacy because intraoperative hemostasis should be inversely related to the total RBCs transfused. We hypothesized that the intraoperative component of the HRS Protocol (group HRS) would decrease the total RBCs transfused compared with traditional management strategies (group T).

The a priori sample size was determined based on the primary outcome variable, total RBCs administered. This composite outcome variable is the sum of



the number of units of allogeneic PRBCs administered and the units of cell salvage RBCs reinfused (14). Assuming the standard deviation of the number of units of total RBCs transfused was 4.9 units, 2 groups with sample sizes of 300 subjects each achieved 80% power to detect a 1.4 unit difference in the number of units of total RBCs transfused in group HRS with a significance level ( $\alpha$ ) of 0.01 using a 2-sided 2-sample *t*-test (41). We estimated that 6–15 qualifying spine surgical procedures were performed per month. Thirty-three months would be required for each of the treatment groups to accrue 300 patients. Therefore, we examined patients from January 1, 2003, through May 31, 2009, to attempt to accrue 300 patients in each treatment group.

Secondary outcome variables related to the management group efficacy in improving safety included the amount of FFP and CRYO administered (39). A secondary goal of the study was to determine how readily adopted the HRS Protocol was by the anesthesia providers at our institution. The number of protocol violations in group HRS was measured by the use of FFP as a surrogate marker for protocol acceptance by the anesthesia team because FFP is not a treatment option in the HRS Protocol (Table 2).

All patients were analyzed according to their protocol assignment (intention to treat). Discrete data are presented as number (percent) and compared using Fisher's exact test or  $\chi^2$  test. The 99% confidence intervals (CIs) for the differences in percentages were calculated using the Farrington and Manning score. Ordinal data and continuous data that were not normally distributed are presented as median and range. These data were compared between groups using the Mann-Whitney U test and the median differences between groups and the 99% CIs of the differences between groups were calculated. Normally distributed continuous data are presented as mean and standard deviation. These data were compared using the unpaired *t*-test and mean differences between the groups and their 99% CIs were calculated.

Univariate analysis was performed using both NCSS 2004 (Number Cruncher Statistical Systems, Inc., Kaysville, Utah, USA) and StatsDirect statistical software (version 2.6.5, StatsDirect, Ltd., Cheshire,

United Kingdom). Given the large number of comparisons being made, to help minimize the chance of a type I error, the criterion for rejection of the null hypothesis established a priori was  $P < 0.01$ .

## RESULTS

After identifying 629 cases, 18 cases were excluded from eligibility (Figure 1). Of the remaining 611 cases, 63 repeat surgical procedures involving 52 patients were dropped based on the sequential dropout rules. Of the 548 patients included in the final data analysis, 284 patients were in group T and 264 were in group HRS. Seven patients (2.6%) in group HRS received FFP.

The 2 treatment groups were comparable in all patient demographics, coexisting diseases, and preoperative medications (including anticoagulant use) except for the preincision hemoglobin, which differed by a mean of  $-0.4$  g/dL between groups (99% CI  $-0.8$  to  $-0.1$  g/dL;  $P = 0.002$ , group T–group HRS) (Table 3).

Although the type of surgery performed and the number of posterior levels instrumented were similar between groups, the surgical duration was 70 minutes shorter in group HRS (32–108 minutes;  $P < 0.0001$ ) and the minimum core temperature was  $0.3^\circ\text{C}$  lower in group T ( $-0.5^\circ$  to  $-0.2^\circ\text{C}$ ;  $P < 0.0001$ ).

Despite having similar postoperative hemoglobin levels, patients in group T received 1 more unit of PRBCs (0–2 units;  $P < 0.0001$ ) and 1.1 more units of total RBCs (0–2.4;  $P = 0.006$ ) than patients in group HRS (Table 4).

This was consistent with the 400-mL increase in the estimated blood loss in group T compared to group HRS (0–800 mL;  $P < 0.01$ ).

## DISCUSSION

After successfully implementing the intraoperative component of the HRS Protocol, we were able to maintain a safe intraoperative environment, as measured by the decrease in the total RBCs transfused. In addition, we were able to successfully implement these 2 intraoperative Do-Confirm checklists with 30 different faculty anesthesiologists and 100 residents and nurse anesthetists with only 2.6% noncompliance during 35 months, as

measured by our surrogate marker for compliance, the use of FFP in the HRS Protocol patients. Do-Confirm checklists, which can organize complex workloads and simplify conceptualization of complex systems, are aides for team members to have the framework to perform at an exceptional level regardless of their level of clinical experience or the presence of human factors that traditionally will degrade care (i.e., fatigue, unfamiliarity, external distractions) (16, 28, 29). Furthermore, because these checklists incorporate fundamental physiologic principles that are essential for care of patients with anticipated or unanticipated massive surgical hemorrhage, they have served an important role as a more generalizable framework for other cases (i.e., abdominal oncologic surgery, intracranial neurovascular surgery, trauma) (16, 40).

### Primary Outcome—Decrease in Units of RBCs Transfused

The patients in group T received 1 more unit of PRBCs and 1.1 more units of total RBCs than patients in group HRS. One of the possible mechanisms for the decrease in required units of PRBCs and the shorter operative time in the group HRS may be that the active management protocol avoided moderate-to-severe coagulopathy and, therefore, allowed more efficient operations (i.e., better visibility of the surgical field) (24). There are clear animal data, mathematical models, and observational data from surgical patients to support the use of fibrinogen-targeted replacement as the essential component for treatment of dilutional and consumptive coagulopathy (15, 22, 25, 37, 39).

Although it would be tempting to conclude that the HRS Protocol was superior to traditional management strategies, there were differences in other important potential cofactors of blood transfusion requirements between the treatment groups (8, 30). The group HRS patients had higher preincision hemoglobin levels and shorter operations than the group T patients. In addition, by instituting a culture of safety, Do-Confirm checklists often produce changes in the surrounding organization that may produce unanticipated benefits (16, 40). For example, the preoperative optimization of these patients, which is a significant component of the Northwestern HRS

**Table 3.** Patient Demographics, Preoperative Coexisting Disease and Medications, and Surgical Variables

	Traditional Management (Group T)	High Risk Spine Protocol (Group HRS)	P value
Number of patients	284	264	
Women	182 (64.1%)	150 (56.8%)	0.096
Age (years)	56.4 ± 15.4	57.2 ± 14.5	0.553
Weight (kg)	77.8 ± 18.5	77.8 ± 20.0	0.965
Height (cm)	167.2 ± 12.4	168.1 ± 11.0	0.348
Body mass index (kg/m <sup>2</sup> )	27.8 ± 5.5	27.4 ± 6.2	0.528
ASA physical status	2 (1–4)	2 (1–4)	0.952
No tobacco use	189 (66.6%)	166 (62.9%)	0.373
Current tobacco use	246 (86.6%)	237 (89.8%)	0.291
History of coronary artery disease	29 (10.2%)	29 (11.0%)	0.783
Creatinine clearance (mL/min)	57.8 (17.4–417.0)	58.5 (17.4–221.3)	0.884
Steroid use within 6 weeks	26 (9.2%)	23 (8.7%)	0.882
Preoperative anticoagulant use	63 (22.2%)	75 (28.4%)	0.095
Subcutaneous heparin	2 (0.7%)	0 (0)	0.500
Aspirin	47 (16.6%)	63 (23.9%)	0.034
Warfarin	10 (3.5%)	11 (4.2%)	0.825
Clopidogrel	6 (2.1%)	9 (3.4%)	0.436
Low molecular weight heparin	5 (1.8%)	4 (1.5%)	1.000
Infection	11 (3.9%)	7 (2.7%)	0.479
Tumor	12 (4.2%)	19 (7.2%)	0.143
Number posterior of levels instrumented (0–20)	8 (0–20)	8 (0–19)	0.964
Surgical category (0–3)	2 (0–3)	2 (0–3)	0.505
Instrumentation revision	106 (37.3%)	79 (29.9%)	0.071
Simple revision	14 (4.9%)	18 (6.8%)	0.367
Preincision hemoglobin level (g/dL)	11.3 ± 1.66	11.8 ± 1.61	0.002
Operation duration (minutes)	674 ± 164	604 ± 181	< 0.0001
Minimum temperature (°C)	34.8 ± 0.8	35.1 ± 0.7	< 0.0001

Data are mean ± SD, median (range), or number of patients (%).

Protocol, may have produced the observed higher preincisional hemoglobin in group HRS, whereas the increased communication between the operating room and the diagnostic laboratories and blood bank may have decreased the delay time for assay results and blood products (18).

### Secondary Outcome—Implementation of the HRS Protocol

We were able to implement the HRS Protocol in 264 patients during 35 months

with 30 faculty anesthesiologists and 100 residents and nurse anesthetists with a noncompliance rate of 2.6%. Successful widespread adoption of checklists depends on overcoming existing personnel and organizational barriers to adopting a culture of change (5, 13, 16, 35, 40).

The most common barrier that we faced when implementing the HRS Protocol was that many physicians feared that the checklist would replace their clinical judgment. Whereas Read-Do checklists (e.g.,

Surgical Time Out, Advanced Cardiac Life Support) are meant to be closely adhered to, performed sequentially, and checked off as each task is performed, Do-Confirm checklists are meant to be cognitive aides that assist the team members in ensuring that all of the interval steps are performed when predefined checkpoints are reached (16). Although both types of checklists have improved perioperative morbidity and mortality, choosing to create Do-Confirm checklists for the HRS Protocol most likely improved early adoption and long-term compliance of our protocol (5, 13). In addition, basing the Do-Confirm checklists on sound physiologic principles and proven communication guidelines has produced a framework that may be generalizable to other complex perioperative environments (40).

### Limitations of the Study

The major limitation of this study is that the primary outcome, RBCs transfused, is a surrogate marker for the efficacy of the intraoperative component of the HRS Protocol in improving intraoperative patient safety in complex spine fusion surgery. Because the incidence of intraoperative morbidity and mortality is extremely low, it is impractical, if not impossible, to rely on even a composite outcome of total intraoperative morbid events to accurately determine the influence of 2 management protocols (14, 40). The main danger in attempting to study the influence of any checklist on perioperative safety in the case of rare events is that the checklist may produce harm during the study that is not detected until many patients are exposed to potential morbidity (5). Therefore, useful surrogate markers for intraoperative morbidity are essential to screen checklists before its introduction into other centers, or in additional patient populations (16, 21, 35).

The total RBCs transfused was chosen as an outcome, rather than the estimated blood loss or the total cell salvage volume reinfused, because these latter measures are both notoriously poor estimates of actual intraoperative blood loss (6). In addition, the number of transfused units is more clinically relevant after controlling for comorbidities that alter transfusion triggers (9). Convincing data are now being reported that support the shift in paradigm that the transfusion of even 1

**Table 4.** Intraoperative Fluids, Blood Products, and Systemic Hemostatic Medications

	Traditional Management (Group T)	High Risk Spine Protocol (Group HRS)	P value
Estimated blood loss (mL)	2525 (200–15,750)	2000 (50–11,000)	< 0.01
Urine output (mL)	1600 (225–8000)	1137.5 (150–6600)	< 0.0001
3% Hypertonic saline (mL)	0 (0–1000)	0 (0–1000)	0.218
Hetastarch (mL)	0 (0–2000)	1000 (0–1800)	< 0.0001
Crystalloid (mL)	7000 (1000–25,000)	4200 (800–15,000)	< 0.0001
Human albumin 5% (mL)	1000 (0–4500)	1000 (0–6000)	0.013
Human albumin 25% (mL)	0 (0–250)	0 (0–200)	0.418
Total nonred cell colloid (mL)	1970 (0–8010)	1750 (0–6800)	0.839
Packed red blood cells (units)	5 (0–31)	3 (0–33)	< 0.0001
Cell salvage (mL)	479.5 (0–8110)	459 (0–5198)	0.412
Cell salvage (units)	1.6 (0–27.0)	1.5 (0–17.3)	0.416
Total red blood cells (units)	6.4 (0–55.0)	5.1 (0–33.0)	0.006
Fresh frozen plasma	178 (62.7%)	7 (2.6%)	< 0.0001
Initial postoperative hemoglobin (g/dL)	10.9 ± 1.4	10.9 ± 1.5	0.769
Fresh frozen plasma (units)	2 (0–28)	0 (0–6)	< 0.0001
Cryoprecipitate	24 (8.4%)	106 (40.1%)	< 0.0001
Cryoprecipitate (units)	0 (0–5)	0 (0–4)	< 0.0001
Platelets (units)	0 (0–6)	0 (0–8)	0.020
DDAVP	1 (0.4%)	63 (23.9%)	< 0.0001
Recombinant Factor VIIa	1 (0.4%)	13 (4.9%)	< 0.001

Data are mean ± SD, median (range), or number of patients (%).  
DDAVP, desmopressin.

unit of RBCs may produce detrimental outcomes in perioperative patients due to damaging systemic immunomodulatory effects (4, 12, 23, 26, 36).

Another limitation of this data analysis is the inherent weaknesses of retrospective analyses of clinical datasets. The accuracy of retrospective clinical datasets is frequently called into question (3, 14). Fortunately, the data in this analysis are from the common clinical variables recorded in the routine care of these complex surgical patients. Therefore, these data are most likely to be accurately recorded because they are found in redundant parts of the medical record (i.e., preoperative evaluation by internists, preoperative anesthesia note, anesthetic record, and surgical operative note). In addition, we established multiple methods

to confirm the accuracy of the extracted and entered data before beginning this study. Finally, we chose surrogate markers of our primary outcome (total RBCs transfused) and secondary outcome (FFP usage in group HRS) that were based on objective measures that were easily extracted and confirmed. By using these objective measures, we were able to avoid the potential for underreporting, which is especially a concern when examining protocol violations (5, 40).

The lack of randomization of the management groups is often viewed as a limitation of studies examining the effect of new checklists. Unfortunately, a randomized study design is difficult to accurately perform in a single institution because, whether consciously or unconsciously, anesthesia and surgical team members

may still be influenced by the human factors of the alternate protocol (e.g., contamination effect) (34). However, the major concern of any retrospective non-randomized study is that it is prone to learning effects and other uncontrolled and often unmeasured changes related to the date of surgery. We attempted to minimize these temporal variables by only including surgeons that had an extensive history (> 10 years) of training in and/or performing complex adult spine surgery as the majority (> 90%) of their surgical cases. It is possible that having experienced cosurgeons may have biased these results to favor group HRS, which had a 70-minute shorter operative duration. However, we found no relationship between the date of the surgery and the duration of the operation uncorrected and corrected for number of posterior levels instrumented or surgical category ( $P > 0.05$ ; data not shown).

## CONCLUSION

The intraoperative component of the HRS Protocol, based on 2 Do-Confirm checklists that focused on organized communication between intraoperative team members (Table 1) and the active maintenance of oxygen delivery and hemostasis (Table 2), appears to maintain a safe intraoperative environment for patients undergoing complex spine fusion surgery. We were able to successfully implement these intraoperative Do-Confirm checklists with 30 different faculty anesthesiologists and 100 residents and nurse anesthetists with only 2.6% noncompliance during 35 months, thereby confirming that it is feasible to implement a large change in culture in a complex intraoperative environment (5, 10, 16, 20, 40).

## ACKNOWLEDGMENTS

The authors would like to acknowledge the large role that our hospitalists (Peter G. Kallas, M.D., and Anjali J. Desai, M.D.), hematologist (David Green, M.D., Ph.D.), Chief Medical Officer (Gary A. Noskin, M.D.), and process improvement leader (Mary Lou M. Green, M.H.A.) played in developing the Northwestern High Risk Spine Protocol—without their involvement the design and implementation of the complete protocol would have

been much more difficult. The authors would also like to thank the anesthesiologists, nurse anesthetists, anesthesiology residents, hospitalists, and operating room nurses and technicians who supported the implementation of the clinical protocol during the care of these complex patients. Finally, the authors thank J.C. Thomas Rogers, III, M.B.A., and Sara Shaik of the Department of Anesthesiology Information Technology Group for their assistance in database creation and management, and the members of the Enterprise Data Warehouse for their assistance in case identification.

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*Conflict of interest statement: Dr. Carabini has received financial support through a grant from the Department of Anesthesiology of Northwestern University's Feinberg School of Medicine (Melissa Fragen Faculty Development Award), which provided financial support for this author to conduct data acquisition and manuscript preparation. The remaining authors have no conflicts to report.*

Received 10 March 2014; accepted 10 June 2014; published online 17 June 2014

Citation: *World Neurosurg.* (2014) 82, 6:e815-e823.  
<http://dx.doi.org/10.1016/j.wneu.2014.06.020>

Journal homepage: [www.WORLDNEUROSURGERY.org](http://www.WORLDNEUROSURGERY.org)

Available online: [www.sciencedirect.com](http://www.sciencedirect.com)

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Appendix 1. Data Dictionary			
Category	Variables	Definition	Data Source
Demographics	Sex, Age, Weight, Height, BMI, ASA		Admission record or Anesthesia record
Preoperative morbidities and anticoagulation medication	Hx of CAD, Smoking history, etc.	yes or no	Preoperative anesthesia or internal medicine evaluation
	Preoperative anticoagulant medication used	yes or no	Preoperative anesthesia or internal medicine evaluation
Surgical variables	Infection	Evidence of osteomyelitis	Surgical procedure note
	Tumor	Primary or metastatic tumor to the spine	Surgical procedure note
	Number of posterior levels instrumented	0-26: Total number of posterior levels instrumented including corpectomies and vertebrectomies	Surgical procedure note
	Surgical category	0: Any exclusively anterior spine surgery with or without anterior cervical corpectomies (excluding Anterior Lumbar Interbody Fusions ALIFs) 1: Any posterior cervical or thoracic instrumentation with or without anterior cervical corpectomies 2: Any surgery with lumbar posterior instrumentation with or without Smith Peterson osteotomies 3: Any surgery with any combination of posterior corpectomies, pedicle subtraction osteotomies, or vertebral column resections	Surgical procedure note
	Instrumentation revision	yes or no	Surgical procedure note
	Simple revision	yes or no	Surgical procedure note
Intraoperative fluids and blood products	Pre-incision hemoglobin	g · dL <sup>-1</sup>	Anesthesia record
	Operation duration	min	Anesthesia record
	Estimated blood loss	mL	Anesthesia record
	Urine output	mL	Anesthesia record
	Packed red blood cells (PRBC's)	Units	Anesthesia record or transfusion record
	Fresh frozen plasma (FFP)	Units	Anesthesia record or transfusion record
	Cryoprecipitate (CRYO)	Units	Anesthesia record or transfusion record
	Platelets (PLT's)	Units	Anesthesia record or transfusion record
	Cell salvage	Units (mL/300 mL · Unit <sup>-1</sup> )	Anesthesia record or transfusion record
	Crystalloid	mL	Anesthesia record or transfusion record
	3% Hypertonic saline	mL	Anesthesia record or transfusion record
	Hetastarch	mL	Anesthesia record or transfusion record
	5% Human albumin	mL	Anesthesia record or transfusion record
	25% Human albumin	mL	Anesthesia record or transfusion record
	deamino-8-D-arginine vasopressin	yes or no	Anesthesia record
	Recombinant activated factor seven (rFVIIa)	yes or no	Anesthesia record