Patient Blood Management: Improved Decision Making With Real Time Data

Sherri Ozawa, RN
Clinical Director, Institute for Patient Blood Management and Bloodless Medicine and Surgery Englewood Hospital and Medical Center, Englewood, NJ
Director, Society for the Advancement of Blood Management, Houston, Texas
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Learning Objectives

• Address the drivers for change in transfusion practice
• Discuss the importance of modalities for Blood Conservation
• Explain the limitations of invasive hemoglobin measurements
• Introduce the connection between real time hemoglobin data and clinical decision making
• Describe the role of SpHb Monitoring in a comprehensive Patient Blood Management Program
Why do we need to discuss transfusion?

1. Frequency – more than we realize
2. Risks - higher than most believe
3. Costs - large and increasing
4. Behavior - non evidence based
5. Overuse - dangerous
Clinicians’ Perceptions

• Safety of BLOOD - high
• Risk of BLOOD - low
• Risk of Anemia - unknown
• Risk of Surgical Bleeding – low
• Transfusions  rare
Blood Transfusion: Who is at risk?

The 1-3 units of RBC transfused

Lives saved

Questionable or no benefit

Mostly risk

Death

Outcome of transfusion

Patients receiving transfusions

Goodnough LT, Shander A. A&A 2012
Five Drivers for the Paradigm Shift in Transfusion

1. Supply Issues
2. Cost
3. Inherent Risk
4. Adverse Txn Outcome
5. Efficacy
BLOOD TRANSFUSION

• AHRQ: Blood transfusions occurred in 1/10 of all hospital stays that had a procedure
• Most commonly performed procedure in US hospitals
• It is a Liquid Organ Transplant ordered by a physician and performed by a nurse
Blood transfusion rates hovered around 50 units / 1000 members of population from 2001-2008.

Since then, transfusion rates have declined to 40 units / 1000 population by 2013, and experts estimate it may be as low as 35 units today (~30% decline).

Collection rates have fallen, following a supply glut in 2008.

1 Data available for survey years only; 2 ~450-500 mL of whole blood

Blood Centers: A system in Crisis

Medical advances result in a major decline in need for donated blood. Community hospitals use blood and red ink: Hospitals perform fewer transfusions and blood banks feel the pain. Why blood banks are shrinking. New transfusion guidelines, surgical techniques limit need for blood.
The Rising Risk of a Contaminated Blood Supply

Amid new pathogens and cost pressures, efforts are under way to keep patients safe
<table>
<thead>
<tr>
<th>Patient populations in whom adverse outcomes associated with RBC transfusion have been reported</th>
<th>Table 1</th>
<th>Reported adverse outcomes associated with transfusion and populations affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICU patients</td>
<td></td>
<td>Transplantation surgery</td>
</tr>
<tr>
<td>Paediatric patients</td>
<td></td>
<td>Colorectal surgery</td>
</tr>
<tr>
<td>Trauma patients</td>
<td></td>
<td>Gastric surgery</td>
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<tr>
<td>Burn patients</td>
<td></td>
<td>Biliary surgery</td>
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<tr>
<td>Combat casualties</td>
<td></td>
<td>Splenectomy</td>
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<tr>
<td>Acute coronary syndrome patients</td>
<td></td>
<td>General surgery</td>
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<tr>
<td>Oncology patients</td>
<td></td>
<td>Vascular surgery</td>
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<tr>
<td>Population based studies</td>
<td></td>
<td>Orthopaedic surgery</td>
</tr>
<tr>
<td>Obstetrics</td>
<td></td>
<td>Thoracic aneurysm surgery</td>
</tr>
<tr>
<td>Cardiac surgery</td>
<td></td>
<td>Lung surgery</td>
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<tr>
<td>Neurosurgery</td>
<td></td>
<td>Head and neck surgery</td>
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<tr>
<td>Hepatic surgery</td>
<td></td>
<td>Mastectomy and reconstruction</td>
</tr>
<tr>
<td>Pancreatic surgery</td>
<td></td>
<td>Oesophageal surgery</td>
</tr>
</tbody>
</table>
Activity Based Cost of Transfusion from a Provider’s Perspective

![Bar chart showing cost analysis for EHMC, RIH, CHUV, and AKH Linz hospitals]

- **Mean RBC product cost**
- **Mean cost per RBC txn**
- **Mean txn cost per surgical pt txed**
ICCTO

• > 30,000 citations – 494 analyzed – 450 clinical scenarios

• Appropriateness of Allogeneic Blood Transfusion based on improving health outcomes

ALL “appropriately” transfused patients had Hb less than 7.9 g/dL
No one appropriate if Hb > 8.0 g/dL
Who really gets transfused?

97.4% of all transfusions could have been predicted by:

1. Level of anaemia prior to surgery
2. Volume of perioperative blood loss
3. Transfusion trigger
Morphology of RBC’s in Stored Blood
Patient Blood Management

- Optimizing Coagulation
- Interdisciplinary Blood Conservation Modalities
- Patient-Centered Decision Making
- Managing Anemia

IMPROVED PATIENT OUTCOMES
Why do we test for hemoglobin?

• To check overall health
• To diagnose a medical condition
• To monitor a medical condition

Why do we test for hemoglobin?

• It is a predictor of transfusion
• Delta Hg is associated with worse outcomes
• It has the ability to determine if any intervention is required
• Determine that an endpoint has been reached
Delivery of Oxygen to Tissues

\[ \text{DO}_2 = \text{CO} \times \text{CaO}_2 \]

Hemoglobin concentration is a significant factor of oxygen delivery to the tissues.

Decreased levels of hemoglobin can have detrimental effects in a patient due to limited delivery of oxygen to vital organs.\(^1\)

- Hgb: Hemoglobin Concentration
- SaO\(_2\): Oxygen Saturation
- Dissolved Oxygen

\(^1\)Miller's Anesthesia 8th Edition. 2015.
Hemoglobin Levels

• Low hemoglobin values can have multiple causes\(^1\)
  – Diseases that can cause the body to produce fewer red blood cells
  – Diseases that cause the body to destroy red blood cells
  – Procedures or conditions that cause blood loss
    • Examples: a bleeding wound, GI bleeds from ulcers, etc.

> For more severe blood loss, red blood cell (RBC) transfusion is a common method to increase hemoglobin count in the body

- The decision to transfuse is generally based on the value of hemoglobin as well as the clinical condition of the patient\(^2\).

Normal ranges for women and men\(^1\):

12.1-15.1 g/dL
13.8-17.2 g/dL

\(^1\)World Health Organization Global Database on Anaemia. 2008.
\(^2\)Miller's Anesthesia. 8th Edition. 2015.
Different types of Hg measurements

- Lab analysis - Automatic blood analyzer/ CO-Oximeters are the gold standard for Hb measurement
- Capillary blood tube - spun
- POCT – Hemocue - reagent
- Non-invasive Hg monitoring
- Visual color-based POC anemia – pre-investigation
Invasive Hemoglobin Methods

- Cyanmethemoglobin (HiCN)
  - International gold standard - Complex, manual process
- Hematology analyzer
  - Best available measurement in most hospitals and reference labs - Brands: Beckman Coulter, Sysmex, Abbott, Bayer, Siemens
- CO-Oximeter
  - Acceptable measurement, less accurate at higher Hb levels - Brands: include Radiometer, Nova Biomedical
- Point-of-care
  - Least accurate invasive method but benefit is quicker test result - Brands: Hemocue, iStat
Limitations of Traditional Methods

Lab Hb Gives Intermittent and Delayed Results While Transfusion Decisions Are Often Made In Real Time

1 Frank S et al. Anesthesiology. 2012.
Limitations of Current Methods

Lab Hb Gives Intermittent and Delayed Results While Transfusion Decisions Are Often Made In Real Time
Testing vs. monitoring –
What is the difference

• TESTING: A medical test is a kind of medical procedure performed to detect, diagnose, or monitor diseases, disease processes, susceptibility, and determine a course of treatment.

• MONITORING: In medicine, monitoring is the observation of a disease, condition or one or several medical parameters over time.

http://en.wikipedia.org/wiki/Monitoring_(medicine)
http://en.wikipedia.org/wiki/Medical_test
Hemoglobin monitoring vs hemoglobin testing

- Hemoglobin testing:
  - Reliable
  - “spot check”
  - Relatively long turnaround time
- Hemoglobin monitoring:
  - Continuous real-time monitoring and trending
  - Provides early decision ability
Value of SpHb Monitoring

Real-time Visibility to Changes—or Lack of Changes—in Hemoglobin between Invasive Blood Sampling

With SpHb monitoring

Lab Hemoglobin

SpHb

SpHb trend is stable while clinician may otherwise think hemoglobin is dropping

SpHb trend is rising while clinician may otherwise think hemoglobin is not rising fast enough

SpHb trend is dropping while clinician may otherwise think hemoglobin is stable
Advantages of non-invasive continuous monitoring

In a study of 20 spine surgery patients (published in Anesthesia-Analgesia), Ron Miller and colleagues noted that non-invasive and continuous Hb monitoring may:

• “Allow immediate and ongoing changing Hb levels to be displayed”
• “Allow a more rapid detection of clinically significant blood loss”
• “Has the potential to significantly improve perioperative transfusion practices”

Miller RD et al. Anesth Analg 2011
Value of SpHb Monitoring
Real-time Visibility to Changes-or Lack of Changes- in Hemoglobin between Invasive Blood Sampling
SpHb Utility
Orthopedic Surgery

% of Patients Receiving RBC Transfusion

- Retrospective Cohort: 5.7%
- Standard Care Group: 4.5%
- SpHb Group: 0.6%

- Randomized trial
- 327 orthopedic surgery patients
- Massachusetts General Hospital
- Found that availability of SpHb monitoring reduced the rate of transfusions when compared to standard care without SpHb
  - 0.6% of the SpHb group received a transfusion
  - 4.5% of the Standard Care group received a transfusion
  - 5.7% of the Retrospective group received a transfusion

Author Conclusion: “the availability of SpHb decreases inappropriate transfusion (either by preventing an initial transfusion, or the transfusion of additional blood products after a single unit has been delivered).”

Clinical decisions regarding red blood cell transfusions should be based on the clinician’s judgement considering among other factors: patient condition, continuous SpHb monitoring, and laboratory diagnostic tests using blood samples.
Author Conclusion: “The ability to observe the continuous trend in hemoglobin affects transfusion behavior, allowing earlier cessation of RBC transfusion as well as earlier consideration of initiation of RBC transfusion.”

Prospective cohort study
> 106 neurosurgical patients
Adding SpHb monitoring resulted in decreased blood utilization, while also facilitating earlier transfusions
- Fewer units of blood transfused
- Fewer patients receiving more than 3 units
- A shorter time to transfusion after the need was established

The transfusion threshold of 10g/dL was predetermined by the study protocol and may not be appropriate for all patients. Clinical decisions regarding red blood cell transfusions should be based on the clinician’s judgement considering among other factors: patient condition, continuous SpHb monitoring, and laboratory diagnostic tests using blood samples.
Multi-Level Spine

Utilization of Blood

• About 57% (aggregate) of spinal patients receive blood
  – Ranging from 26% to 79% based upon patient pathology\(^1\)

• Clinicians often overestimate the need for blood in spine cases
  – Crossmatch per patient often exceeds amount transfused

<table>
<thead>
<tr>
<th>Pathology Group</th>
<th>Transfused</th>
<th>Crossmatch/ Patient</th>
<th>Transfuse/ Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deformity (scoliosis, kyphosis)</td>
<td>79%</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Fracture (spinal repair and fusion)</td>
<td>65%</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Tumor (tumor removal)</td>
<td>50%</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Painful Spine (reconstruction and fusion)</td>
<td>26%</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>57%</td>
<td>5</td>
<td>3</td>
</tr>
</tbody>
</table>

\(^1\)Kouritas et al. Transfusion Med. 2010.
Multi-Level Spine
Case Example- Pediatric Scoliosis
Study: Berkow et al.¹
- Objective: To evaluate the accuracy of SpHb with tHb during complex spine procedures in patients at high risk for blood loss.
- Sample: 29 patients. Complex spine surgery

Authors’ Conclusions:
- “Continuous, noninvasive hemoglobin measurement via Pulse CO-Oximetry demonstrated clinically acceptable accuracy of hemoglobin measurement within 1.5 g/dL compared with a standard laboratory reference device when used during complex spine surgery.”

Study: Colquhoun et al.²
- Objective: To assess the ability of the Masimo Pulse CO-Oximetry platform to measure changes in Hgb in the intraoperative setting, by comparing SpHb estimates to Hgb from arterial blood gases in major neurosurgical procedures with significant expected blood loss.
- Sample: 20 patients. Major lumbar and low thoracic spine surgery

Authors’ Conclusions:
- “Pulse CO-Oximetry offers an acceptable trend monitor in patients undergoing major spine surgery.”

Multi-Level Spine
Peer Reviewed Studies

> **Study:** Miller et al.¹

- Objective: To compare the accuracy of SpHb and HemoCue® with Lab Hemoglobin Values (Coulter Counter).
- Sample: 20 general spine surgery patients

> **Authors’ Conclusions:**

- “We conclude that SpHb could have frequently been used in many patients to guide clinical decisions regarding the need for blood transfusions.”

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Liver Transplants

Utilization of Blood

• Liver Transplants are the bloodiest surgeries
  – Despite low procedure volumes, fall into top 5 for transfusions¹
  – Procedures are long: ranging from 6 to 12 hours²

• 75% of patients who undergo liver surgery are anemic³
  – Liver disease often causes portal hypertension leading to varices and thus gastrointestinal bleeding
  – Endothelial dysfunction impacts clotting abilities and often leads to coagulopathy
  – Alcohol is toxic to bone marrow, thus impacting the ability to regenerate red blood cells
  – Treatments, such as ribavirin-induced hemolysis for Hep-C patients, may cause anemia as a complication

• The risk of bleeding from coagulopathy and iatrogenic injury is high during the early post-transplantation period⁴
  – Roughly 9% (7-15% per Cleveland Clinic) of patients showed abdominal bleeding occurring at a mean of 6.1 days (range 1-21 days)

¹CMS data - ICD 99.0
²https://my.clevelandclinic.org/health/treatments_and_procedures/hic_Liver_Transplantation
Liver Transplant

Case Example
Liver Transplants

Abstracts

> **Study: Ramsay et al.**
> - **Objective:** To evaluate the trend accuracy of SpHb monitoring in a case series of high blood loss, liver transplant surgery patients.
> - **Sample:** 7 patients (30 points). Liver transplants

> **Authors’ Conclusions:**
> - “SpHb monitoring with spectrophotometric sensor provides continuous, precise real-time data on changes in hemoglobin during dynamic conditions such as high blood loss liver transplantation and therefore may be useful in guiding blood management.”

> **Study: Torp et al.**
> - **Objective:** To determine if noninvasive continuous monitoring of tHb using the rainbow SET™ Pulse CO-Oximeter® is an adequate and reliable detector of the trend and magnitude of hemoglobin changes during liver transplant surgery.
> - **Sample:** 15 patients (89 points). Liver transplants

> **Authors’ Conclusions:**
> - “This monitor has the potential to improve the timeliness and precision of transfusion practices and to help clinicians maintain optimal hemoglobin levels.”

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1Ramsay et al. NYPGA. 2013.
2Torp et al. NYPGA. 2010.
Select cranial and facial procedures (including maxillo) have significant blood loss:
- Glioma Excision - 834mL blood loss¹
- CP Angle Tumors - 568mL blood loss¹
- Decompressive Craniectomy - 338mL blood loss²
- Craniofacial Surgeries - 410mL blood loss³
- Double Jaw Osteotomies - 450mL blood loss⁴

Much of the craniofacial data involves pediatric patients⁵-⁷
Cranial and Facial
Case Example- Craniectomy
Cranial and Facial
Peer Reviewed Studies

> Study: Park et al.¹
  - Objective: To compare noninvasive measurements of SpHb with simultaneous laboratory measurements of total hemoglobin in arterial blood samples taken from children (tHb)
  - Sample: 40 children (130 points). Brain tumor, craniosynostosis, or moyamoya disease

> Study: Patino et al.²
  - Objective: To assess the trending and accuracy of SpHb with Hb concentration obtained with conventional laboratory techniques (Hb) in children undergoing surgical procedures with potential for substantial blood loss
  - Sample: 46 children (158 points). Craniofacial surgery (among others)

> Authors’ Conclusions:
  - “The Radical-7” Pulse CO-Oximeter can be useful as a trend monitor in children during surgery even immediately after intravascular volume expanders are administered.”

> Authors’ Conclusions:
  - “SpHb displayed similar trending and absolute accuracy in pediatric patients undergoing a variety of surgical procedures associated with blood loss as has been found in adult surgical patients.”

SpHb Monitoring Solutions

Root® Monitor

Philips IntelliVue MX800
Conclusion

• Transfusion is complex and costly procedure with clinical and societal implications
• There are multiple drivers for a paradigm shift in transfusion practice
• Traditional Hemoglobin testing has limitations and inefficiencies which can lead to less than optimal clinical decisions
• Non Invasive hemoglobin monitoring (SpHb) provides real time data to clinicians leading to better decision making