

Noninvasive and Continuous Hemoglobin (SpHb®)

BACKGROUND

Blood transfusions are the most common procedure in hospitals today.¹ The Joint Commission has noted that, “while blood transfusions can be life-saving, they also carry risks that range from mild complications to death.”² The Joint Commission and the American Medical Association have listed transfusions among their top five “overuse intervention targets.”²

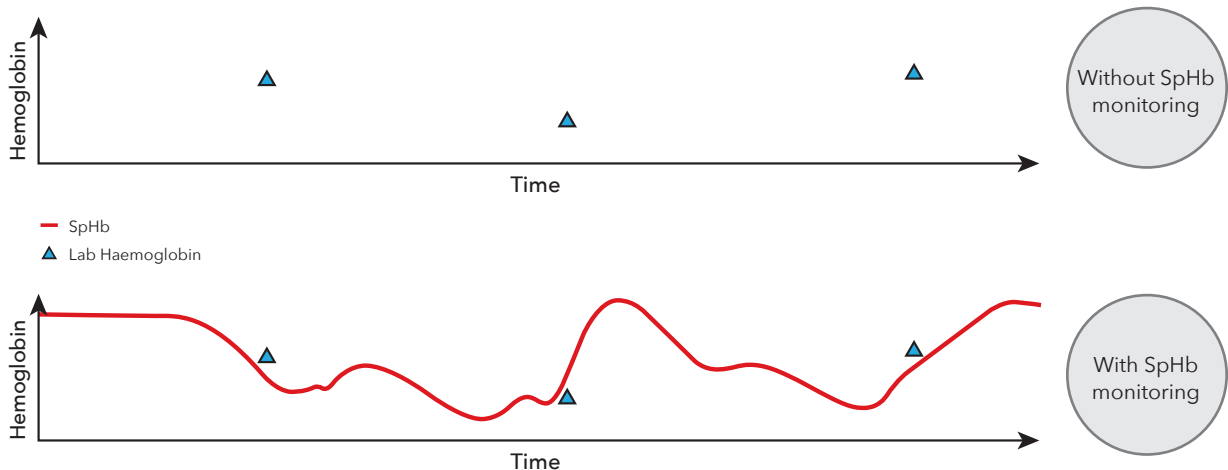
Several clinical studies and meta-analyses also have suggested clinical risk associated with inappropriate transfusions, and some suggest that restrictive blood transfusion practices may improve clinical outcomes.³⁻⁵ Also, given the costs associated with acquiring, storing, and administering blood, a reduction in unneeded transfusions may have an economic benefit.⁶ For these reasons, and others, many institutions are adopting patient blood management protocols and programs.⁷

NONINVASIVE AND CONTINUOUS HEMOGLOBIN MONITORING

Masimo invented noninvasive and continuous hemoglobin monitoring (SpHb), a breakthrough measurement that noninvasively and continuously measures total hemoglobin in the blood.

SpHb provides real-time visibility to changes - or lack of changes - in hemoglobin between invasive blood sampling. SpHb monitoring may provide additional insight between invasive blood sampling when:

- > The SpHb trend is stable and the clinician may otherwise think hemoglobin is decreasing
- > The SpHb trend is rising and the clinician may otherwise think hemoglobin is not rising fast enough
- > The SpHb trend is decreasing and the clinician may otherwise think hemoglobin is stable



**Simulated plots for illustrative purposes*

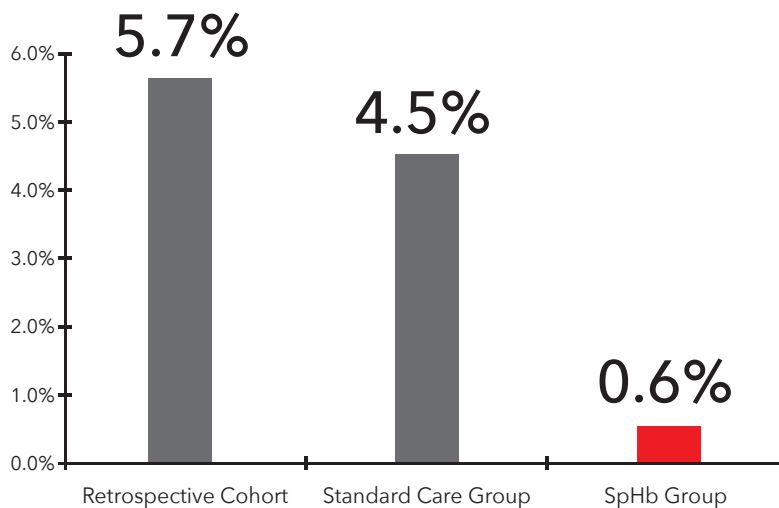
SpHb may help clinicians make more informed and timely decisions. SpHb has been shown to help clinicians reduce blood transfusions in both low and high blood loss surgery.^{8,9} Many hospitals today have adopted SpHb for their patient blood management programs.



SpHb UTILITY IN ORTHOPEDIC SURGERY⁸

A randomized trial, of 327 patients undergoing elective orthopedic surgery, conducted at Massachusetts General Hospital (MGH), found that the use of continuous noninvasive hemoglobin monitoring reduced the rate of transfusions when compared to standard care without continuous noninvasive hemoglobin monitoring. Patients undergoing elective orthopedic surgery were randomized to receive standard care alone or standard care with SpHb monitoring. To determine if transfusion practices matched historical controls, researchers created a retrospective group. The researchers did not standardize transfusion practices or initiate a specific protocol during the study period.

% of Patients Receiving RBC Transfusion



- > 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

STUDY CONCLUSIONS⁸

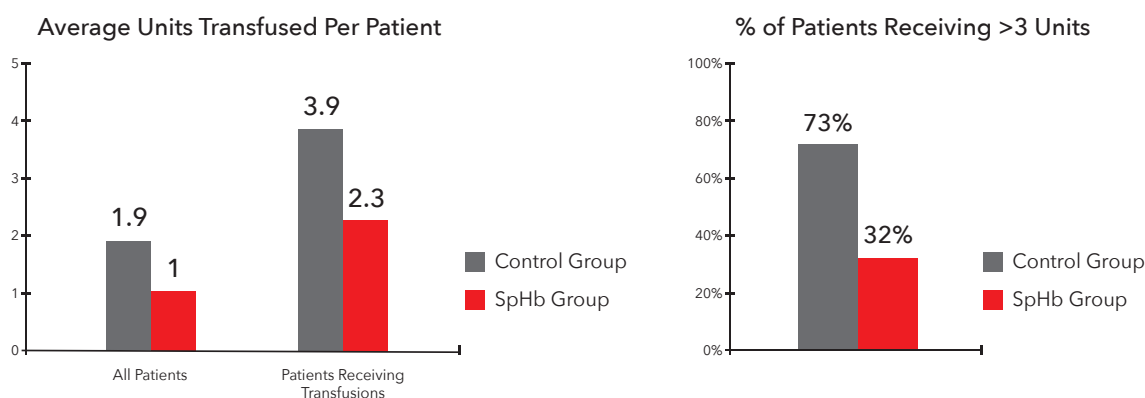
"We conclude that the difference in the rate of intraoperative transfusions was due to the presence of continuous and non-invasive Hb values in the SpHb Group. The reduction in intraoperative transfusion rate was not temporary, as evidenced by the absence of postoperative transfusion rates in the SpHb Group."

"We believe that 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)."

"Given the results of our pilot study, we believe that SpHb shows promise as an adjunct to current perioperative monitoring practice."

SpHb UTILITY IN NEUROSURGERY⁹

A prospective cohort study in 106 neurosurgical patients found that adding SpHb monitoring to standard of care blood management resulted in decreased blood utilization in high blood loss neurosurgery, while also facilitating earlier transfusions. Patients were enrolled into either a Control Group or an intervention group (SpHb Group) where the Control Group received intraoperative hemoglobin monitoring by intermittent blood sampling. In each group, if researchers noted SpHb trended downward, below 10g/dL, a red blood cell transfusion was started and continued until SpHb trended upward, above 10g/dL. The blood sampling technique was the same for patients in both the control and the test group. Arterial blood was drawn from a 20 gauge radial artery cannula into 2mL ethylenediaminetetraacetic acid collection tubes, thoroughly mixed then sent immediately to the central lab for analysis by a hematology analyzer. The reference laboratory device used for hemoglobin measurements in the study was a Coulter GEN-S Hematology Analyzer.



Compared to the Control Group, the SpHb Group demonstrated:

- > Fewer units of blood transfused
 - 1.0 (SpHb) vs 1.9 (Control) units for all patients
 - 2.3 (SpHb) vs 3.9 (Control) units in patients receiving transfusions
- > Fewer patients receiving more than 3 units
 - 32% (SpHb) vs 73% (Control)
- > A shorter time to transfusion after the need was established
 - 9.2 (SpHb) vs 50.2 (Control) min

STUDY CONCLUSIONS⁹

"Adding SpHb monitoring to standard of care blood management resulted in decreased blood utilization in high blood loss neurosurgery, while facilitating earlier transfusions."

"Our results indicate a reduction of 0.9 units of blood per surgery or between \$470 to \$1,065 per patient monitored and \$470,000 to \$1,065,000 per 1,000 surgeries of the same type."

"Post-operatively, continuous hemoglobin trending could provide added benefit by indicating hemorrhage that is otherwise not apparent."

"The real time assessment also affected the initial decision to transfuse, resulting in a quicker decision to initiate a transfusion when needed due to a lack of delay in laboratory Hb values."

"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."

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.

1. CMS data pull: ICD 99
2. Proceedings from the National Summit on Overuse September 24, 2012
3. Rhode (et al.) HealthCare-Associated Infection After Red Blood Cell Transfusion A Systematic Review and Meta-analysis, *Jama*, 5/2014
4. Salpeter (et al.) Impact of More Restrictive Blood Transfusion Strategies on Clinical Outcomes: A Meta-analysis and Systematic Review, *American Journal of Medicine* 2014
5. Villanueva et al., Transfusion Strategies for Acute Upper Gastrointestinal Bleeding, *N Engl J Med* 2013;368:11-21.
6. Shander A (et al.), Activity-based costs of blood transfusions in surgical patients at four hospitals, *Transfusion*. 2010;50(4):753-765.
7. SABM PBM Directory <http://www.sabm.org/programsbystate>
8. Ehrenfeld et al. Continuous Non-invasive Hemoglobin Monitoring during Orthopedic Surgery: A Randomized Trial, *J Blood Disorders Transf* 2014. 5:9.
9. Awada WN et al. *J Clin Monit Comput*, DOI 10.1007/s10877-015-9660-4.

For professional use. See instructions for use for full prescribing information including indications, contraindications, warnings and precautions. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Masimo U.S.
Tel: 1 877 4 Masimo
info-america@masimo.com

Masimo International
Tel: +41 32 720 1111
info-international@masimo.com

