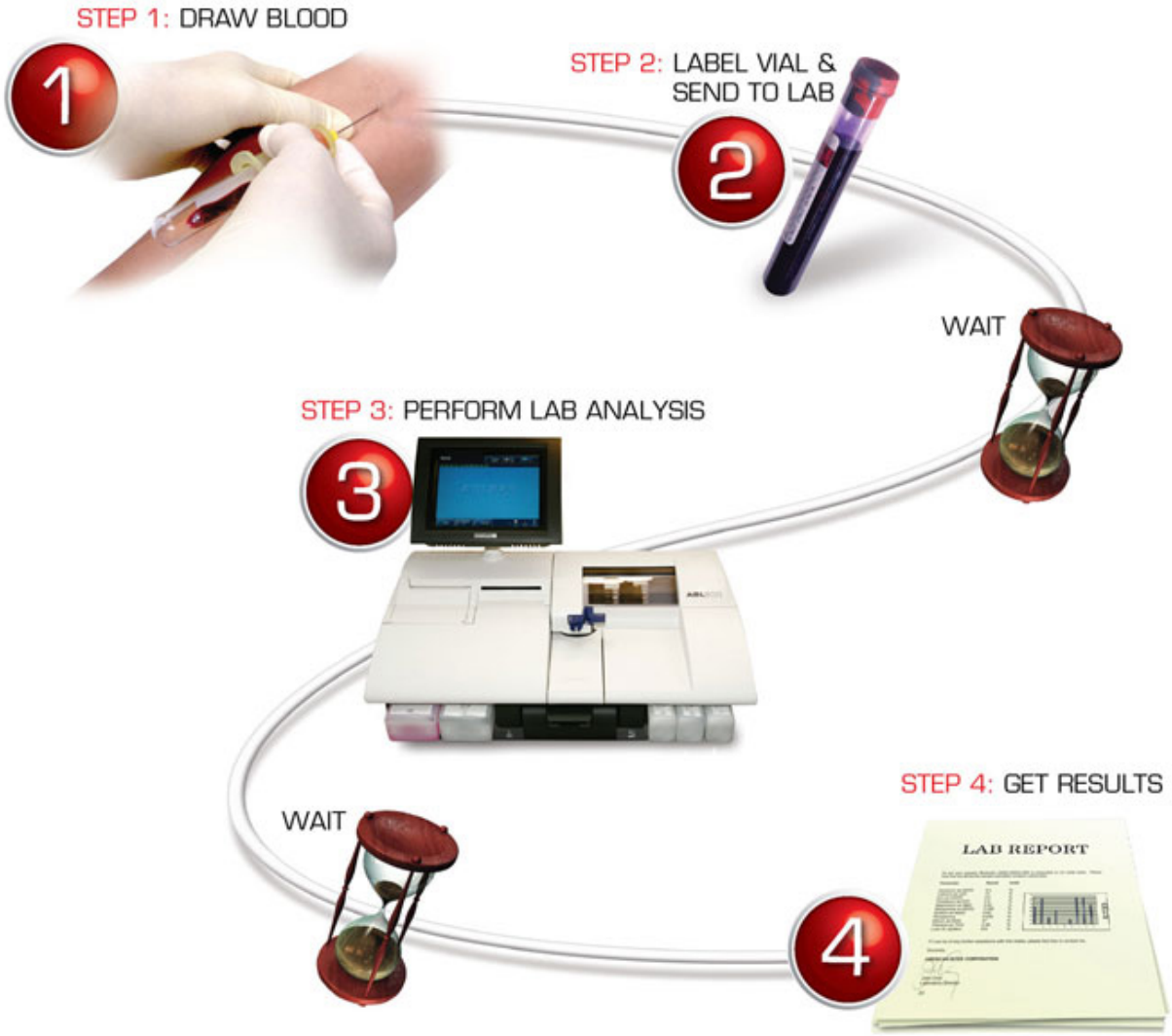
Noninvasive & Continuous Hemoglobin (SpHb®) Monitoring

Lab Hb: Intermittent & Delayed Results While Transfusion Decisions Are Made in Real Time



How is Masimo's Solution Different?

Continuous SpHb provides real-time indication of *changes* in Hb, as well as when Hb is *stable*

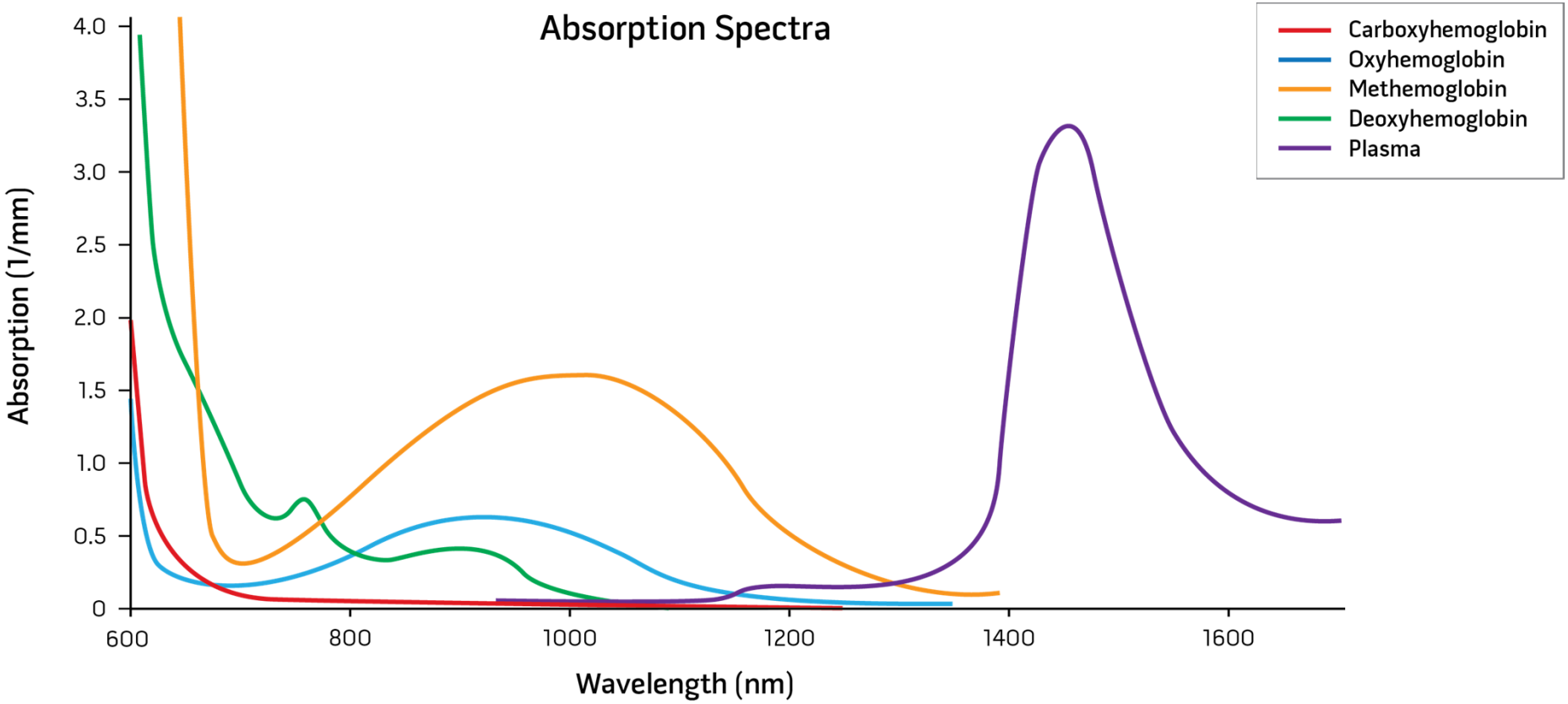
How is Masimo's Solution Different?

With Masimo SpHb:

- Noninvasive
- Continuous

Masimo SpHb permits continuous measurement of hemoglobin between invasive blood samples

rainbow® Multi-wavelength Technology



2 wavelengths of light used to measure oxygen saturation (SpO_2)

7+ wavelengths of light used by rainbow® to measure SpHb, SpCO, SpMet, and SpO_2

rainbow® Technology

SpO2, Pulse Rate plus *Additional Blood Constituents* which previously required a CO-Oximeter… is known as

“Pulse CO-Oximetry”

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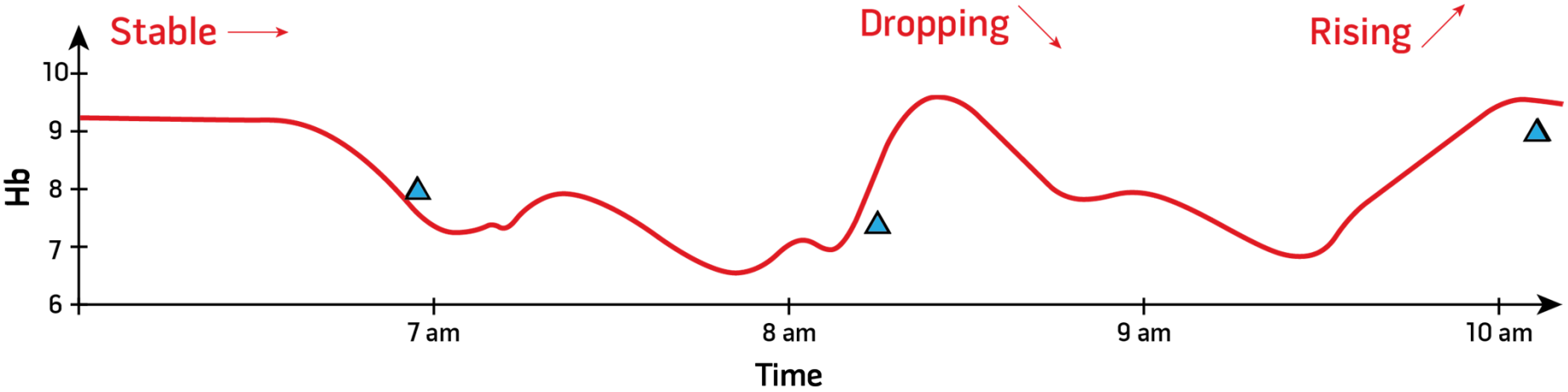
Multi-Parameter Trends of SpHb (*and PVI*) May Facilitate Transfusion Decisions

Intermittent Invasive Hemoglobin Sampling *vs* Real-time SpHb Trending Between Invasive Hb Samples

Intermittent Hb sampling may not provide the **full** picture…



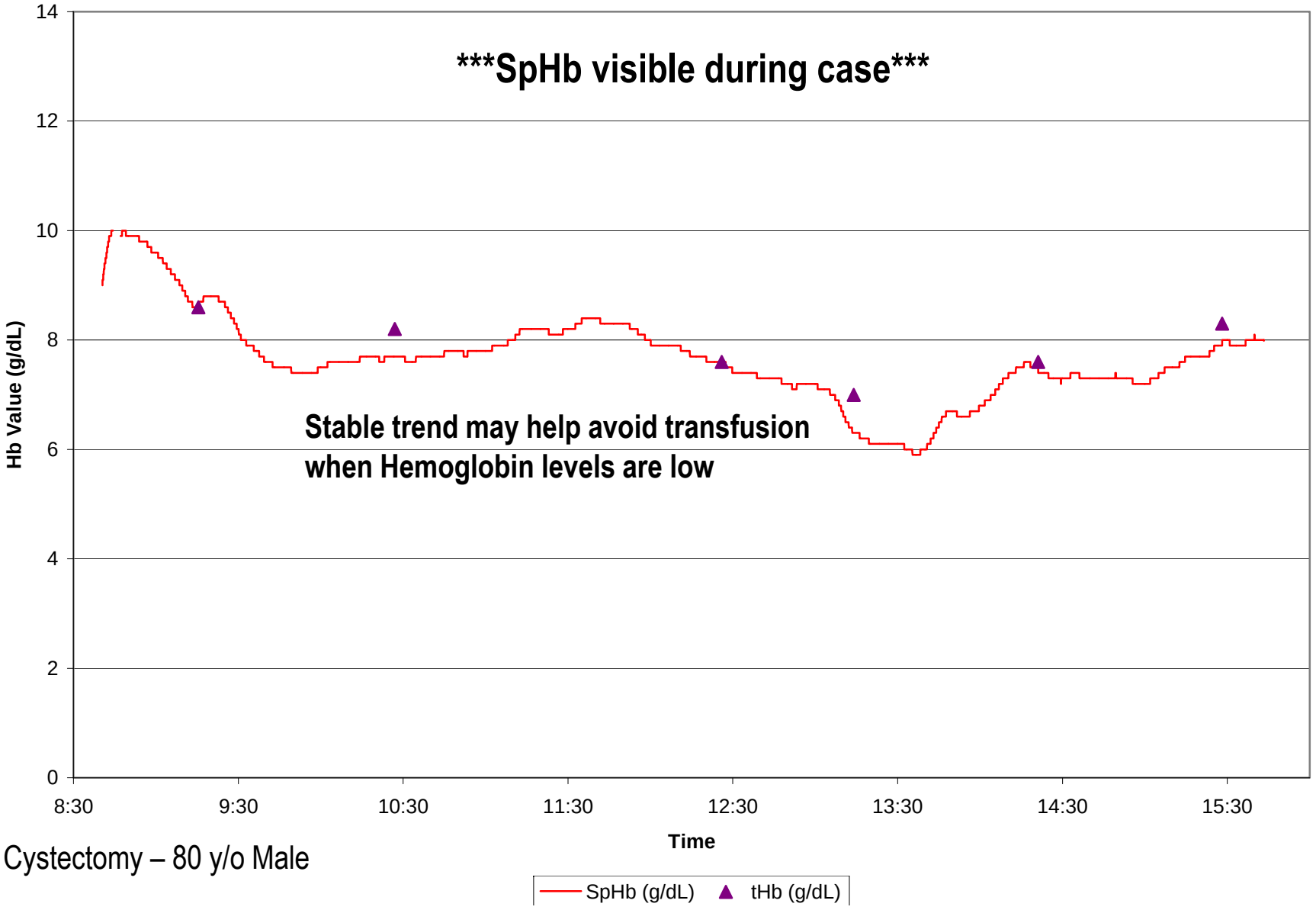
> Continuous SpHb provides real-time indication of whether hemoglobin is *stable*, *dropping*, or *rising*

> Continuous visibility to Hb changes in between lab samples may help avoid unnecessary transfusions…

- When *SpHb is stable* when Hb is perceived to be dropping, **or**
- When *SpHb is rising* when Hb is perceived not to be rising fast enough, **AND…**

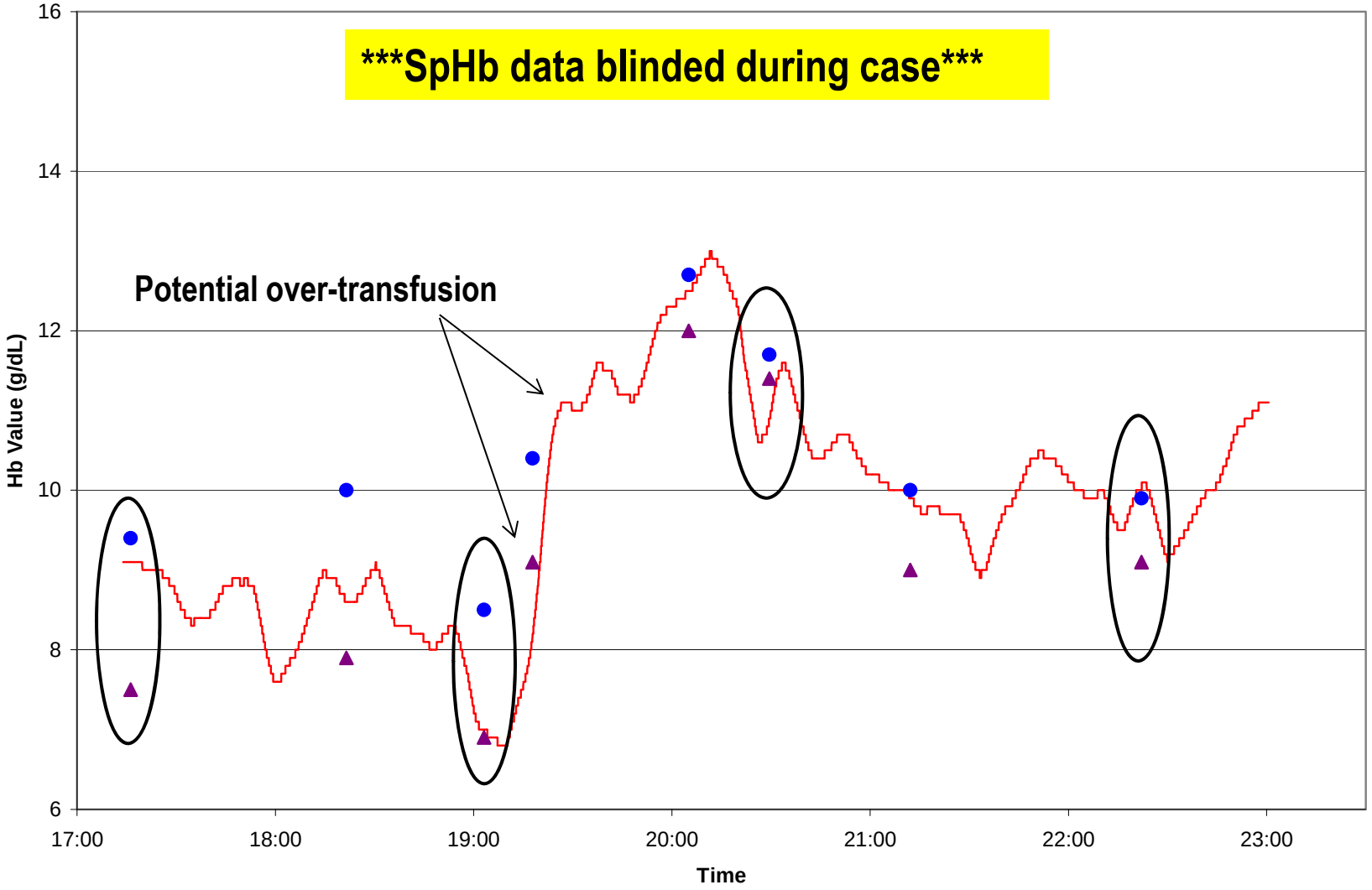
> Detect post-op bleeding **IF** *SpHb is dropping* when Hb should be stable

Continuous SpHb: Stable Trend May Facilitate Delaying Transfusions at Lower Hb Levels



Total Cystectomy – 80 y/o Male

Continuous SpHb: Rising Trend May Facilitate Delaying Transfusion of Additional Units



Liver transplant– 69 y/o female

Hemoglobin Measurement Variability between Two of the Same Model Lab Device

- Two IDENTICAL models of five different types of laboratory CO-Oximeters
- Device A vs. Device B of each model analyzed 72 consecutive blood samples from 12 pts

Manufacturer Model	Radiometer ABL-735	Bayer Rapidlab 860	Nova STP CCX 1	Roche Omni S	Instrumentation 682 CO-Oximeter
Bias (g/dL)	0.0	-0.3	-0.8	-0.4	0.4
1st Standard deviation (g/dL)	0.1	0.2	0.3	0.8	1.2
2nd Standard deviation (g/dL)	0.2	0.4	0.6	1.6	2.4

Two calibrated lab devices of the same model type
1st standard deviation = Avg of 0.5 g/dL; highest 1.2 g/dL

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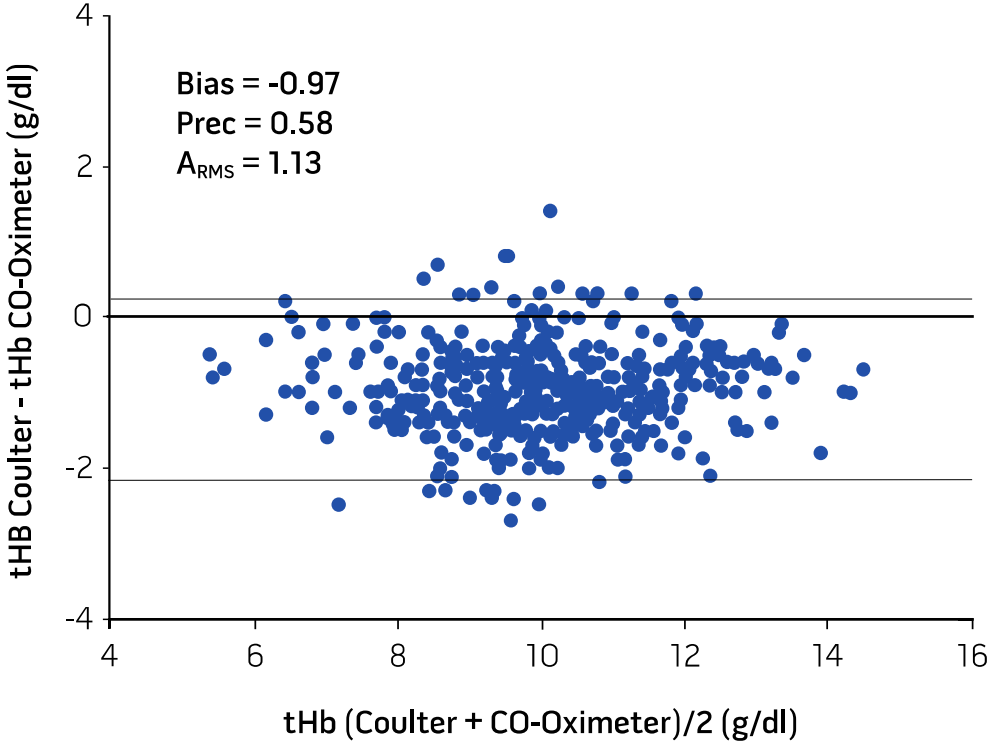
Gehring H et al. Anesth Analg 2007;105:S24 –30.

Hemoglobin Measurement Variability Between Two Different Model Lab Devices

Two different lab devices
- pHOxTM CO-Oximeter (Nova) COULTER® Ac·T diff2™ (Beckman Coulter)
Consecutive blood samples measured on both devices



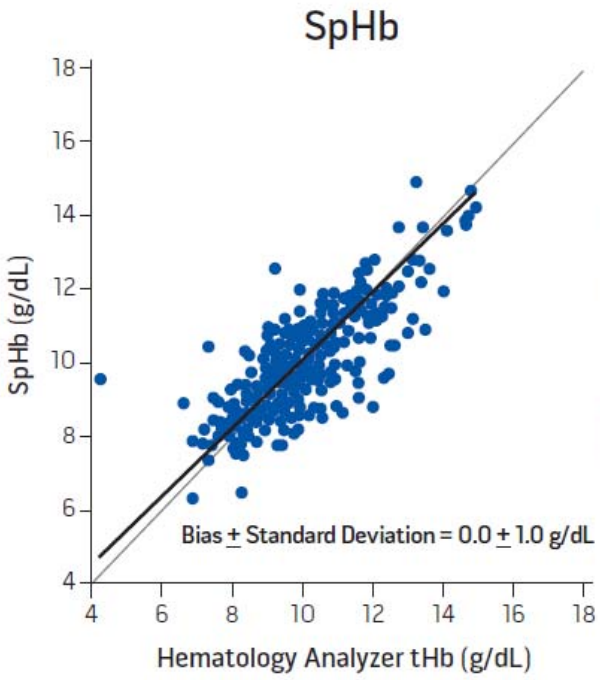
N=471 samples from 33 patients

Two calibrated lab devices analyzing sequential blood draws varied by up to 2 g/dL

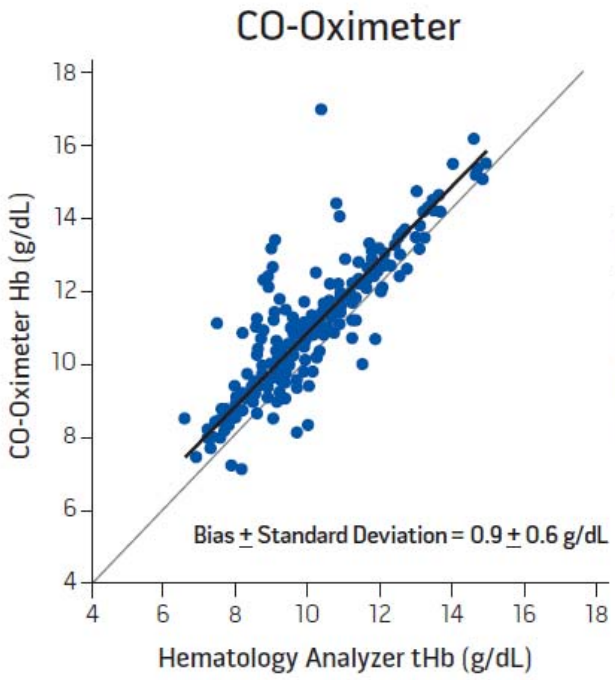
Torp KD et al. Anesthesiology 2009 (ASA abstract): A937.

SpHb, Dept CO-Oximeter, Hemocue
Point-to-Point Accuracy vs Lab CO-Oximeter

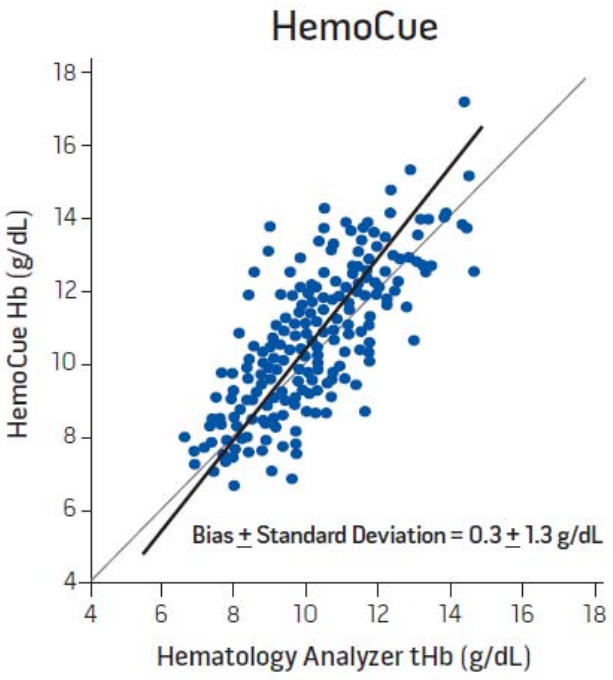
- 471 hemoglobin measurements from 62 Surgical ICU patients
- 3 Hb methods vs. reference Hb (central laboratory hematology analyzer, Sysmex XT2000i)
  - SpHb, satellite CO-Oximeter (Siemens RapidPoint 405), point-of-care device (HemoCue 301)



1.0 g/dL (A_{rms})



1.1 g/dL (A_{rms})

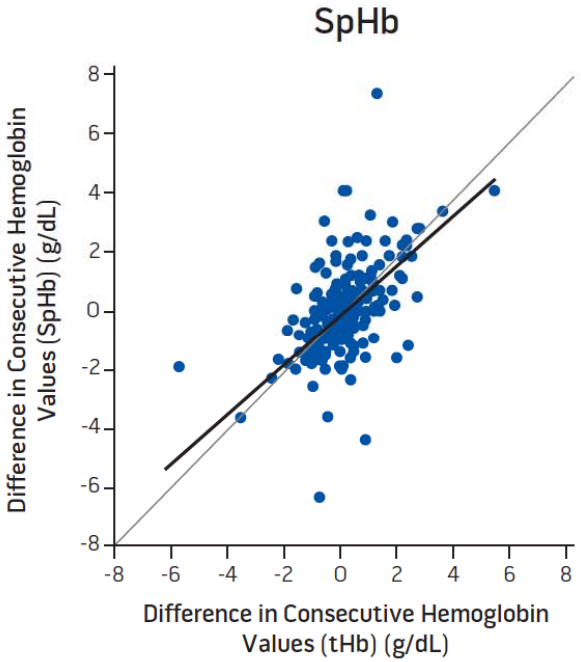


1.3 g/dL (A_{rms})

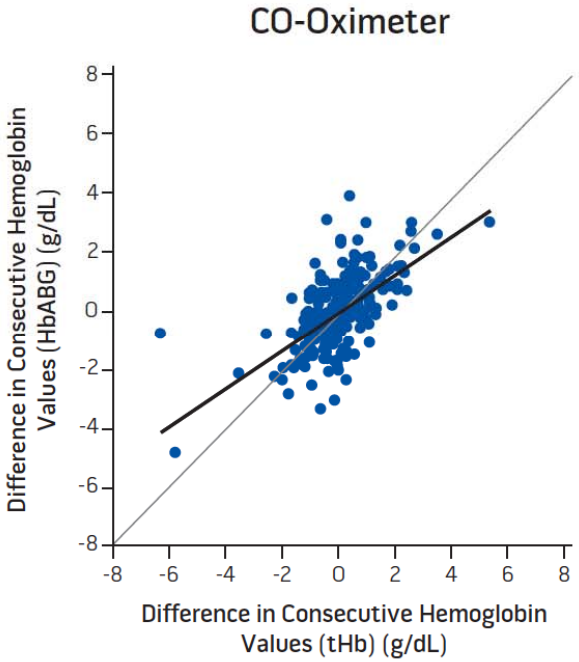
Frasca D et al. Crit Care Med. 39(10); 2011; 2277-2282.

SpHb, Dept CO-Oximeter, Hemocue *TREND Accuracy* vs Lab CO-Oximeter

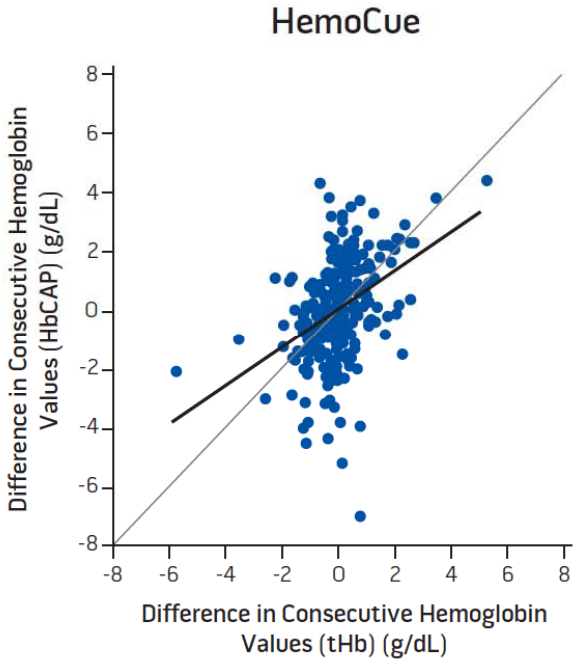
- 471 hemoglobin measurements from 62 Surgical ICU patients
- Changes in 3 Hb methods vs. changes in reference Hb (central laboratory hematology analyzer, Sysmex XT2000i)
  - SpHb, satellite CO-Oximeter (Siemens RapidPoint 405), point-of-care device (HemoCue 301)



R=0.64



R=0.60



R=0.39

Frasca D et al. Crit Care Med. 39(10); 2011; 2277-2282.

Continuous SpHb is shown to help reduce transfusions – without changes in transfusion protocol

Randomized Controlled Trial in Lower Blood Loss Surgery
Objective, Patients, Randomization & Methods

- **Objective**
  - Determine whether Continuous SpHb monitoring helps to reduce surgical transfusion frequency and average amount transfused in lower blood loss surgery
- **Patients**
  - Orthopedic surgery (lower likelihood of transfusion) at academic medical center (Mass General Hospital, Boston, MA)
- **Methods**
  - **Standard Care Group**
    - Treat as normally would
  - **SpHb Group**
    - Treat as normally would but add continuous SpHb
    - **No transfusion protocol changes related to SpHb**

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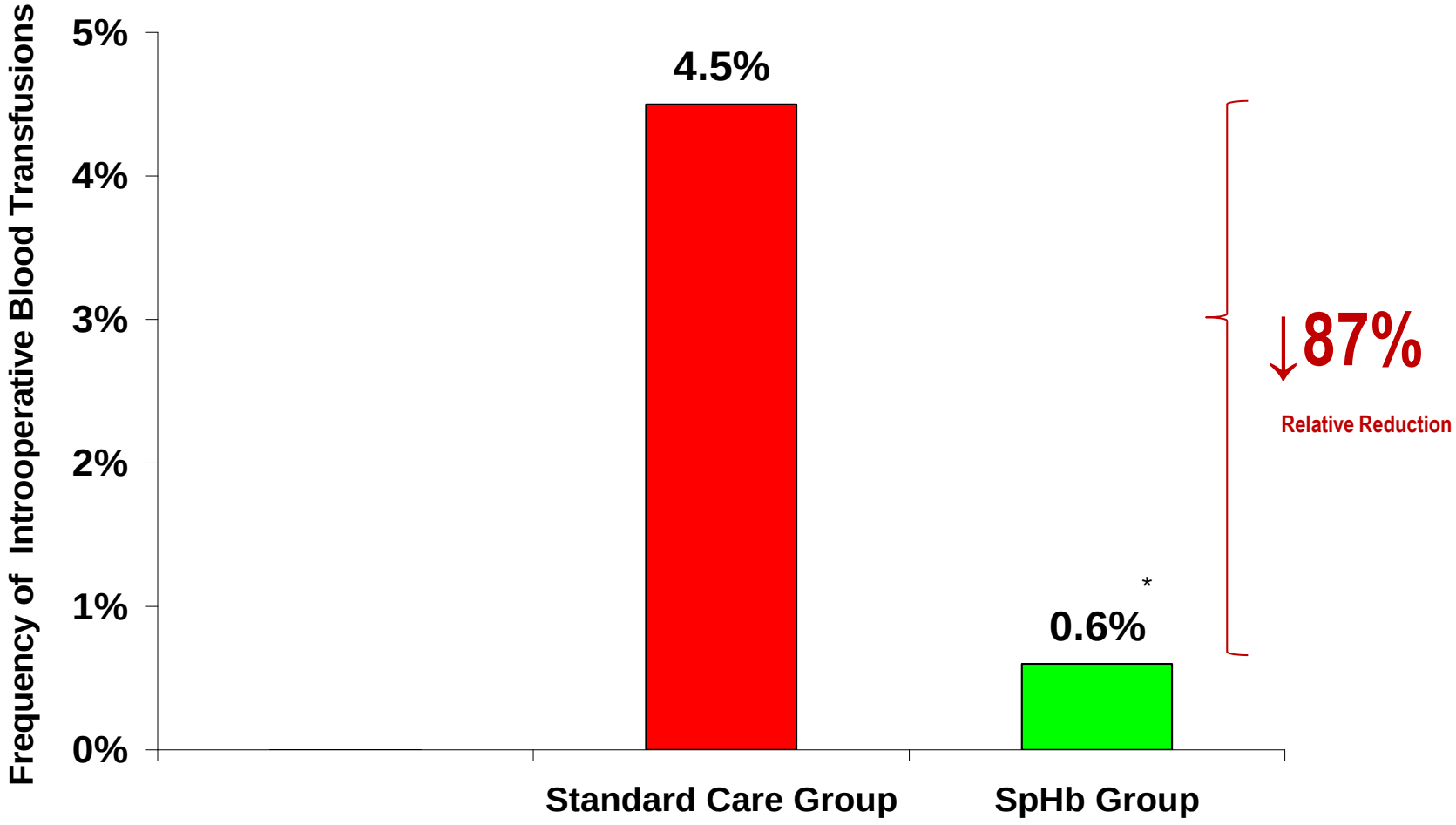
Ehrenfeld JM et al. ASA. 2010. LB05.

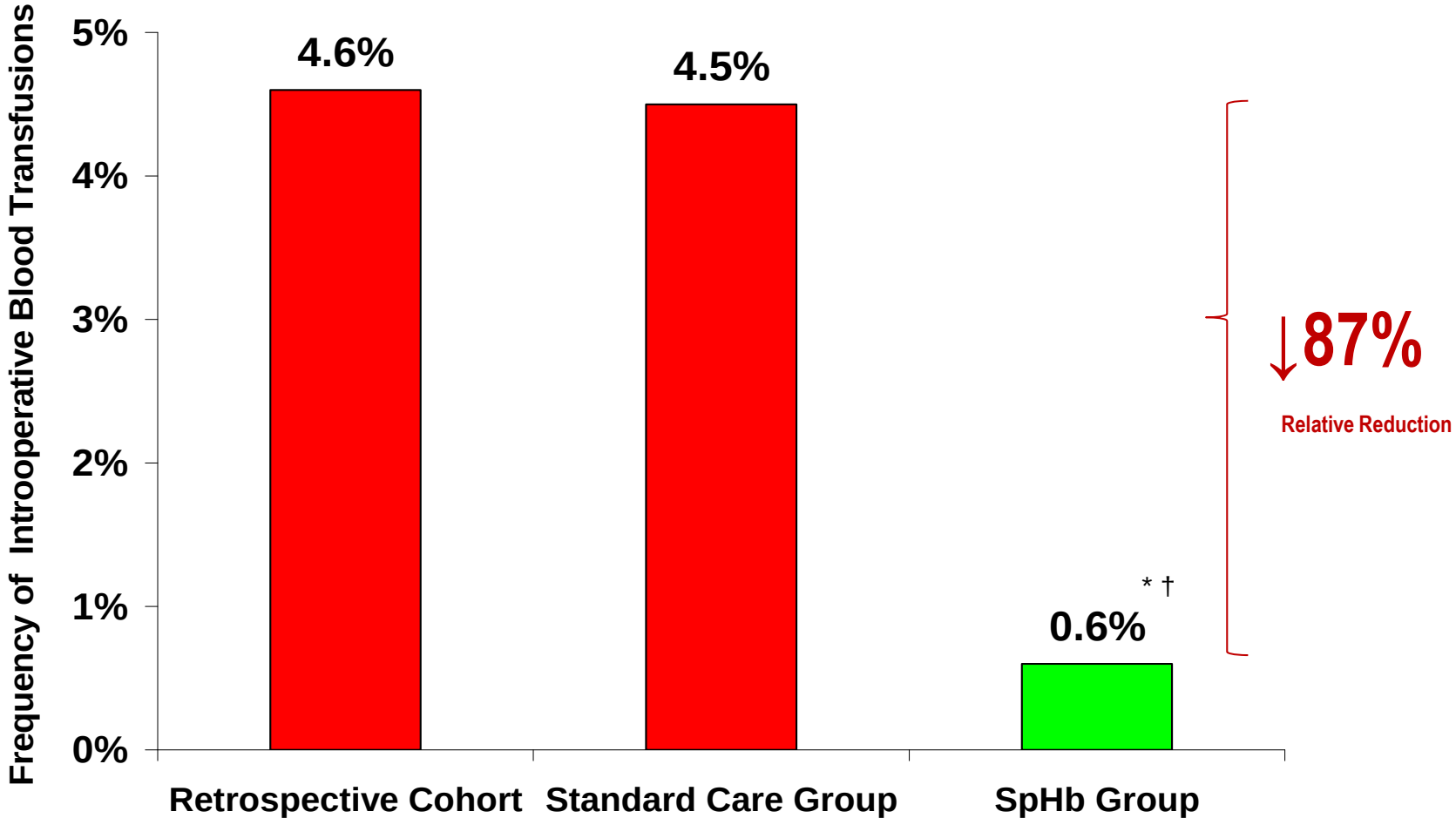
SpHb Monitoring Impact on Frequency of RBC Units Transfusions in Lower Blood Loss Surgery



Randomized controlled trial in 327 orthopedic surgery pts, 157-Standard Care & 170-SpHb
* p=0.03 vs. Standard Care Group;

Ehrenfeld JM et al. ASA. 2010. LB05 (abstract).

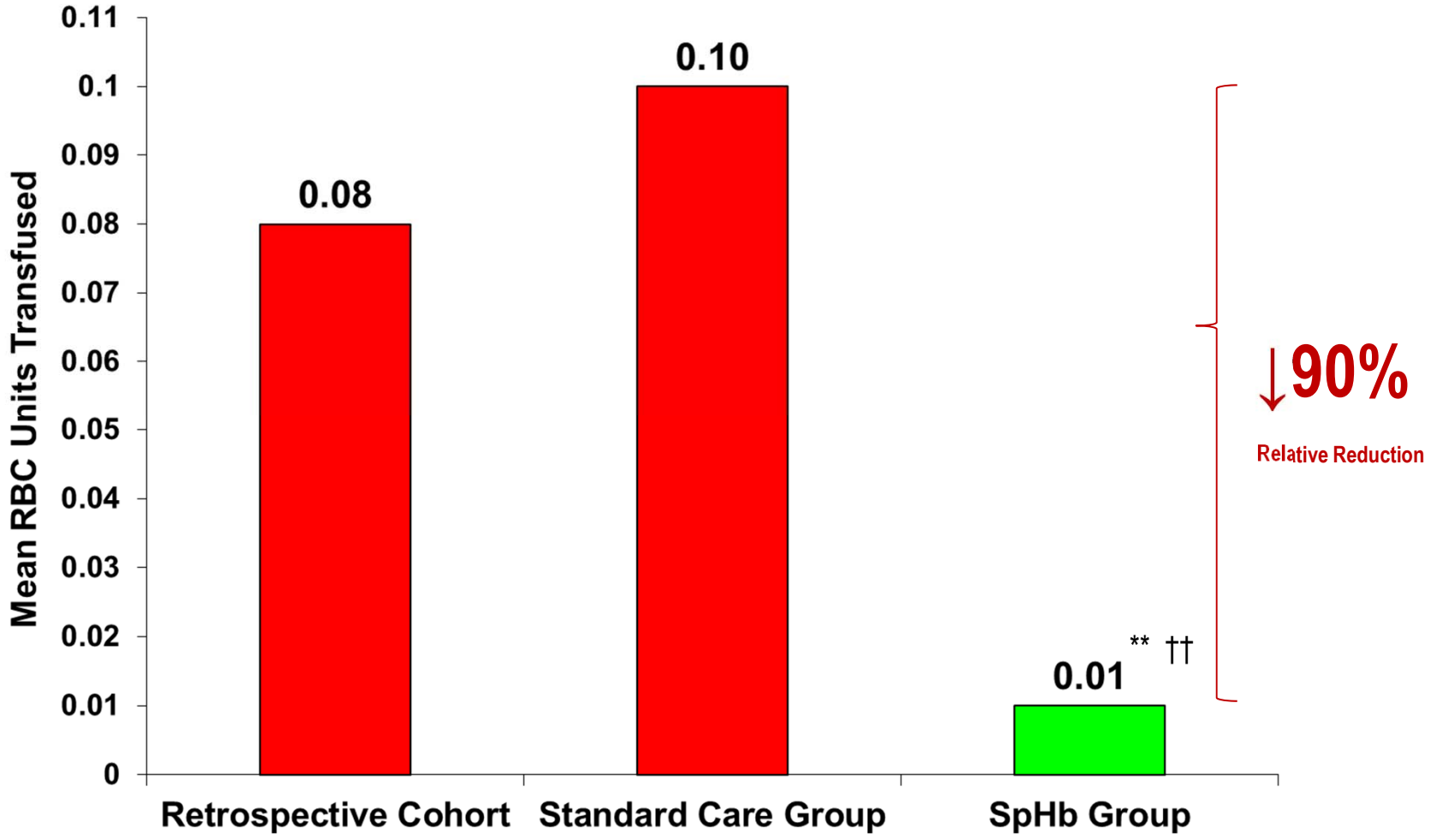
SpHb Monitoring Impact on Average RBC Units Transfused per Patient in Lower Blood Loss Surgery



Randomized controlled trial in 327 orthopedic surgery pts, 157 Standard Care & 170 SpHb
* p=0.03 vs. Standard Care Group; † p=0.02 vs. Matched Retrospective Cohort

Ehrenfeld JM et al. ASA. 2010. LB05 (abstract).

SpHb Monitoring Impact on Average RBC Units Transfused per Patient in Lower Blood Loss Surgery



Randomized controlled trial in 327 orthopedic surgery pts, 157 Standard Care & 170 SpHb
**p<0.0001 vs. Standard Care Group; †† p<0.0001 vs. Matched Retrospective Cohort

Ehrenfeld JM et al. ASA. 2010. LB05 (abstract).

Randomized Controlled Trial

No Differences in Other Variables

- **Frequency of patients receiving intraoperative Hb testing in SpHb and Standard Care Groups**
  - 11.8% vs. 16.3%, p=ns
- **Mean number of Hb tests performed in SpHb and Standard Care Groups**
  - 0.24 vs. 0.21 tests per case, p=ns
- **Safety variables**
  - No patient from either group received a transfusion during the immediate twelve-hour postoperative period
  - No differences at 28 days in the rate of post-operative complications between the SpHb and Standard Care Groups (1.9% vs. 3.0%, p=ns)

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Ehrenfeld JM et al. ASA. 2010. LB05 (abstract).

If SpHb Monitoring Reduces RBC Transfusions in Lower Blood Loss Surgery…

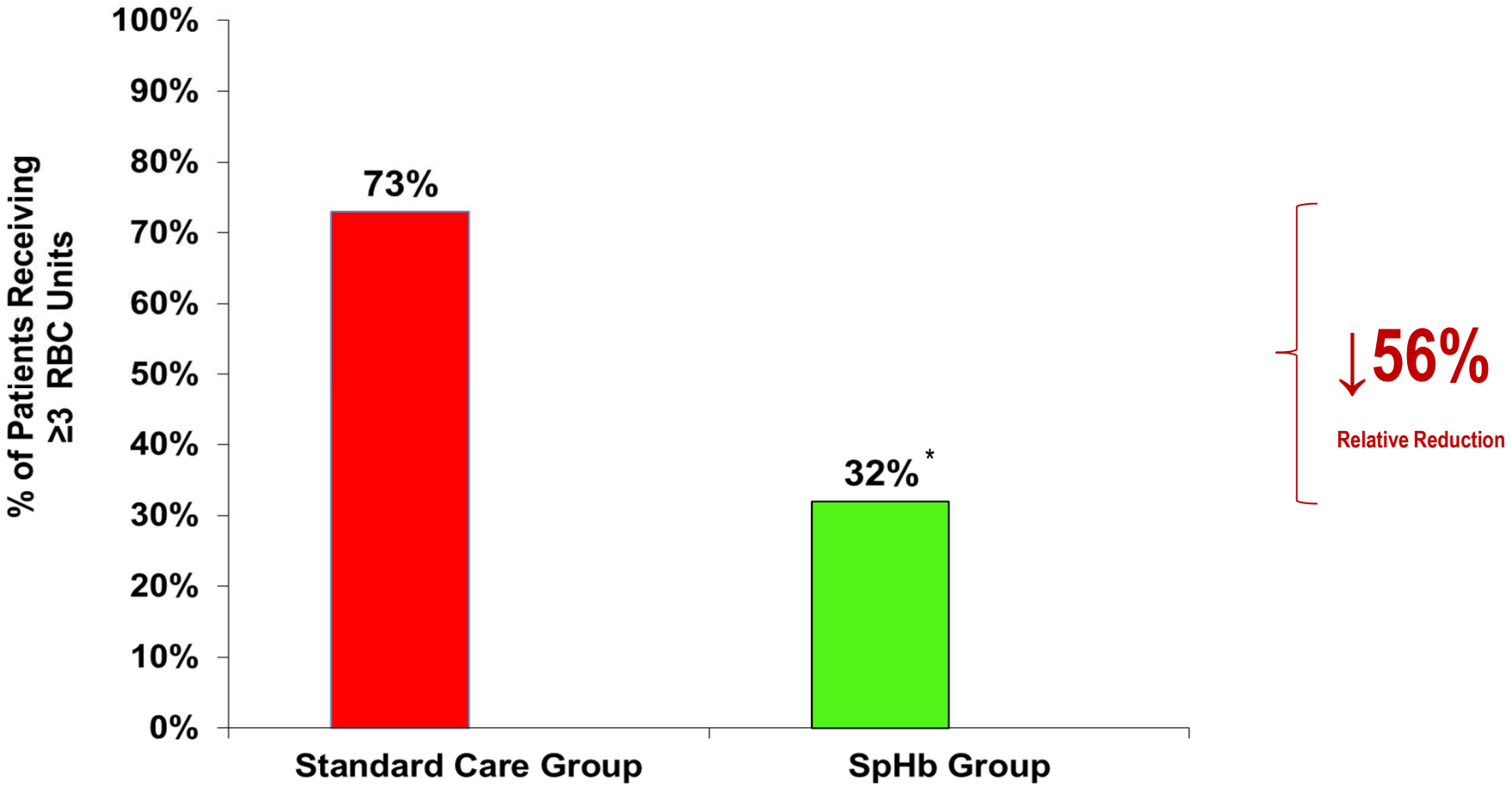
Is it possible that SpHb monitoring could have an even greater impact in high blood loss surgery?

Prospective Cohort Study in High Blood Loss Surgery
Objective, Patients, Randomization & Methods

- **Objective**
  - Determine whether Continuous SpHb monitoring helps to reduce surgical transfusion frequency and average amount transfused in high blood loss surgery
- **Patients**
  - Neurosurgery at academic medical center (Cairo University, Egypt)
- **Methods**
  - **Standard Care Group**
    - Treat as normally would
  - **SpHb Group**
    - Treat as normally would but add continuous SpHb
  - **Both Groups**
    - Blood samples taken at baseline and when EBL was ≥15% of total blood volume
    - RBC transfusion initiated if hemoglobin was ≤10 g/dL and continued until the EBL was replaced and hemoglobin >10g/dL

Awada W et al. STA. 2013 (abstract).

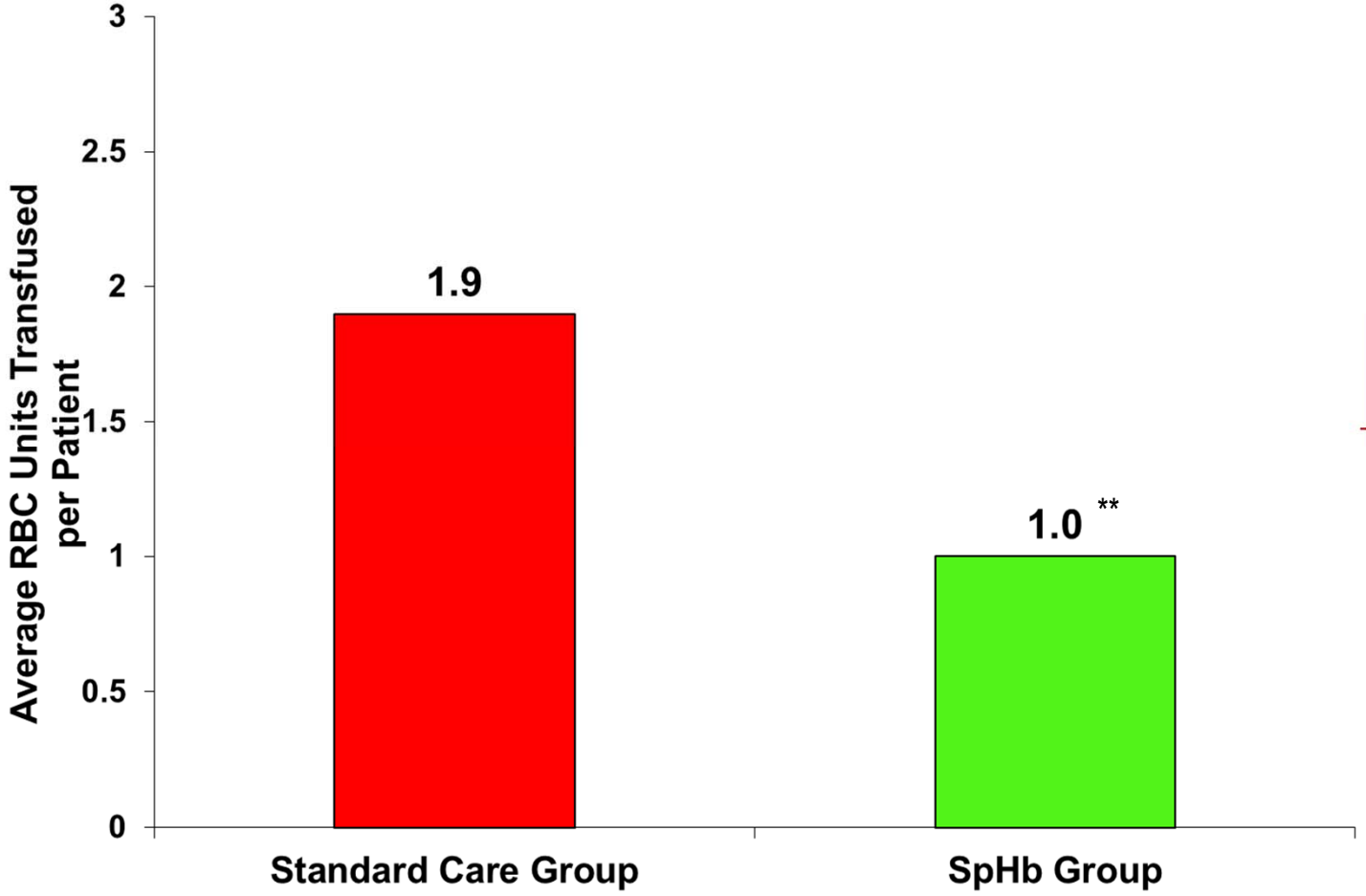
SpHb Monitoring Impact on Frequency of ≥3 RBC Unit Transfusions in High Blood Loss Surgery



Prospective cohort study in 106 neurosurgery surgery pts, 61 Standard Care & 45 SpHb
*p<0.01 vs. Standard Care Group

Awada W et al. STA. 2013 (abstract).

SpHb Monitoring Impact on Average RBC Units Transfused per Patient in High Blood Loss Surgery



Prospective cohort study in 106 neurosurgery surgery pts, 61 Standard Care & 45 SpHb
**p<0.001 vs. Standard Care Group

SpHb Clinical Benefits Extend Beyond Transfusion Decisions…

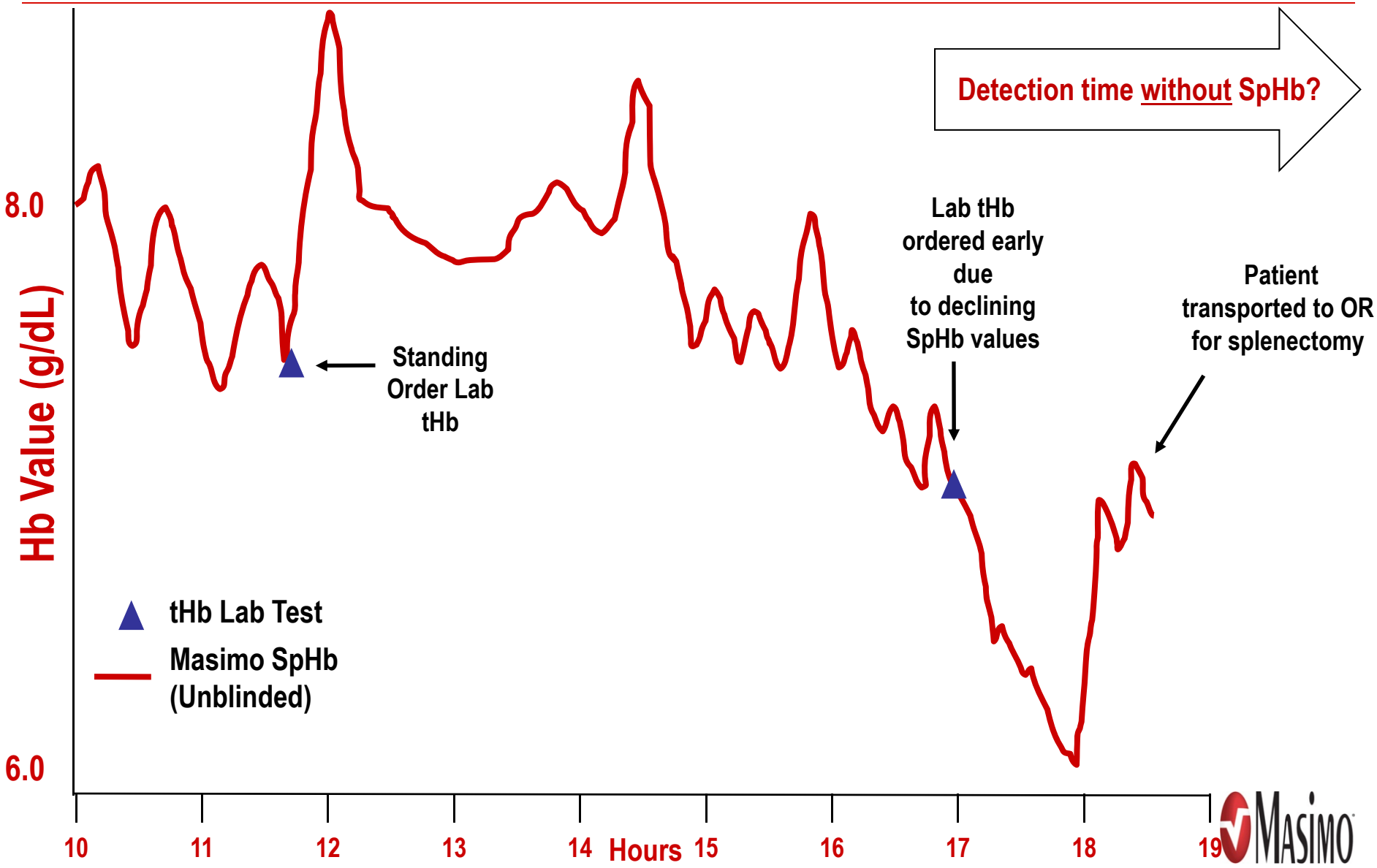
Continuous SpHb can also help identify post-op bleeding

Detecting Post-Op Bleeding

- **Bleeding is frequent in surgery, ICU, OB pts**
  - Up to 35% of patients[1]
- **Bleeding is a significant risk factor**
  - Late detection further increases the risk[2]
  - Responsible for 19% of in-hospital maternal deaths[3]
- **Late bleeding detection impact on patient care**
  - Average hospital has multiple patients per year with serious injury or death due to late detection of bleeding[4]
- **Bleeding significantly increases the total cost of patient treatment**[2]
- **Low Hb identifies almost 90% of patients with bleeding**[5]
  - But traditional lab measurements are infrequent and delayed
- **Joint Commission sentinel event alert for OB patients**
  - Calls for protocols to improve the ability to detect hemorrhage[6]

1 Hebert PC. Crit Care. 1999: 3(2):57-63. 2 Herwaldt LA. Infect Control Hosp Epidemiol. 2003; 24(1):44-50. 3 Bateman BT et al. Anesth Analg May 2010 110:1368-1373. 4 HRA Research of Hospital Executive 2012. 5 Bruns B et al. J Trauma. 2007; 63(2):312-5. 6 The Joint Commission, "Sentinel Event Alert: Preventing Maternal Death" Issue 44, January 26, 2010

Post-trauma Surgery Case Study



rainbow® Technology Clinical Benefits Extend Beyond Transfusion Decisions…

PVI® helps with patient fluid management, which impacts outcomes *and* transfusion decisions

Fluid Administration Challenges

- **Fluid administration is critical**
  - To increase cardiac output and optimize patient status, enabling end organ preservation[1]
- **Unnecessary fluid administration associated with increased morbidity and mortality[2]**
- **Fluid administration causes hemodilution**
  - Which reduces Hb concentration and increases likelihood of transfusion[3]
- **Traditional static measurements not reliable to predict volume responsiveness**
  - CVP, SBP, DBP, Pulse Pressure, Wedge Pressure, Cardiac output[4]
- **New dynamic monitoring technologies are effective**
  - Proven to improve outcomes but are invasive or complex - and costly[5]
    - Pulse pressure variation, stroke volume variation
  - Appropriate for higher-risk patients
- **Opportunity to improve care in moderate to low risk population**
  - Using low cost, noninvasive technology

1 Perel A. Anesth Analg. 2008; 106 (4):1031-33 2 Bundgaard-Nielsen M et al. Acta Anaesthesiol Scand. 2007; 51(3):331-40
3 Huybregts RA et al. Anesth Analg. 2009. 109(2): 331-339. 4 Michard F et al. Chest. 2002; 121(6):2000-08 5 Joshi G et al. Anesth Analg. 2005; 101:601-5 .

Thank You