Patient Blood Management: Improved Decision Making with Real Time Data

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STOP

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

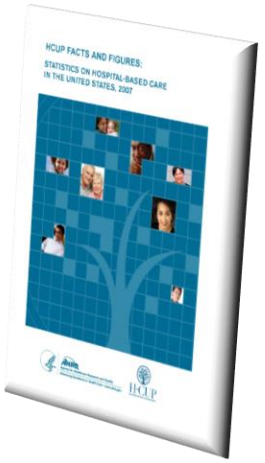
Clinicians' Perceptions

- Safety of BLOOD - high
- Risk of BLOOD - low
- Risk of Anemia - unknown
- Risk of Surgical Bleeding – low
- Transfusions - rare

The Reality…

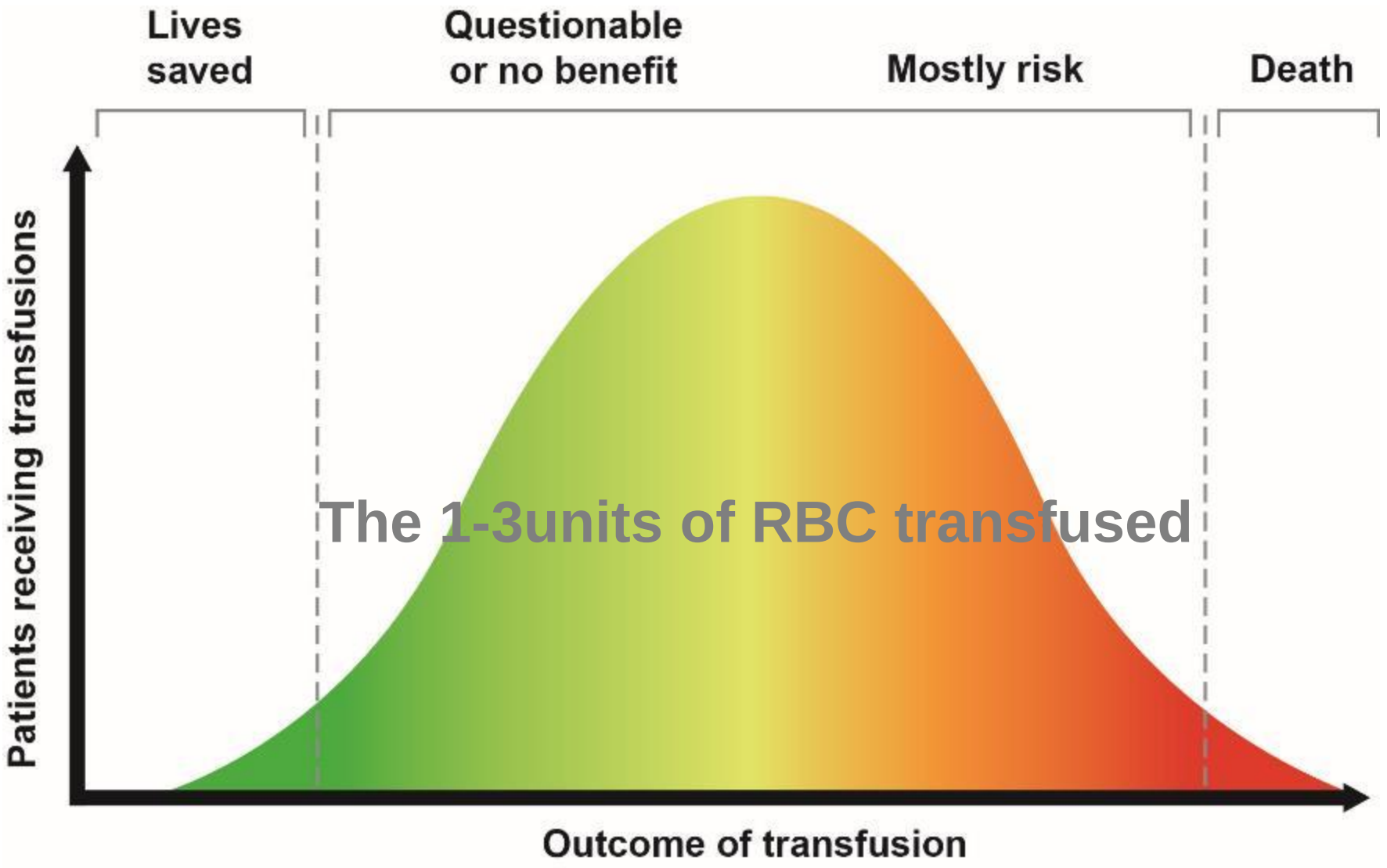
- **Transfusions are often ineffective for the purpose given**
  - **Poor delivery of oxygen at the cellular level due to storage lesion**
- **Transfusions are risky**
  - **A host of infectious and non-infectious risks**
  - **Associated with worse patient outcomes**
- **Transfusions are costly**
  - **A complex process (more tests & processing on the way)**
  - **True cost likely to be significantly higher than what hospitals pay to purchase**
- **Blood supply is inherently always limited**
  - **Constant threat of emerging pathogens**

BLOOD TRANSFUSION



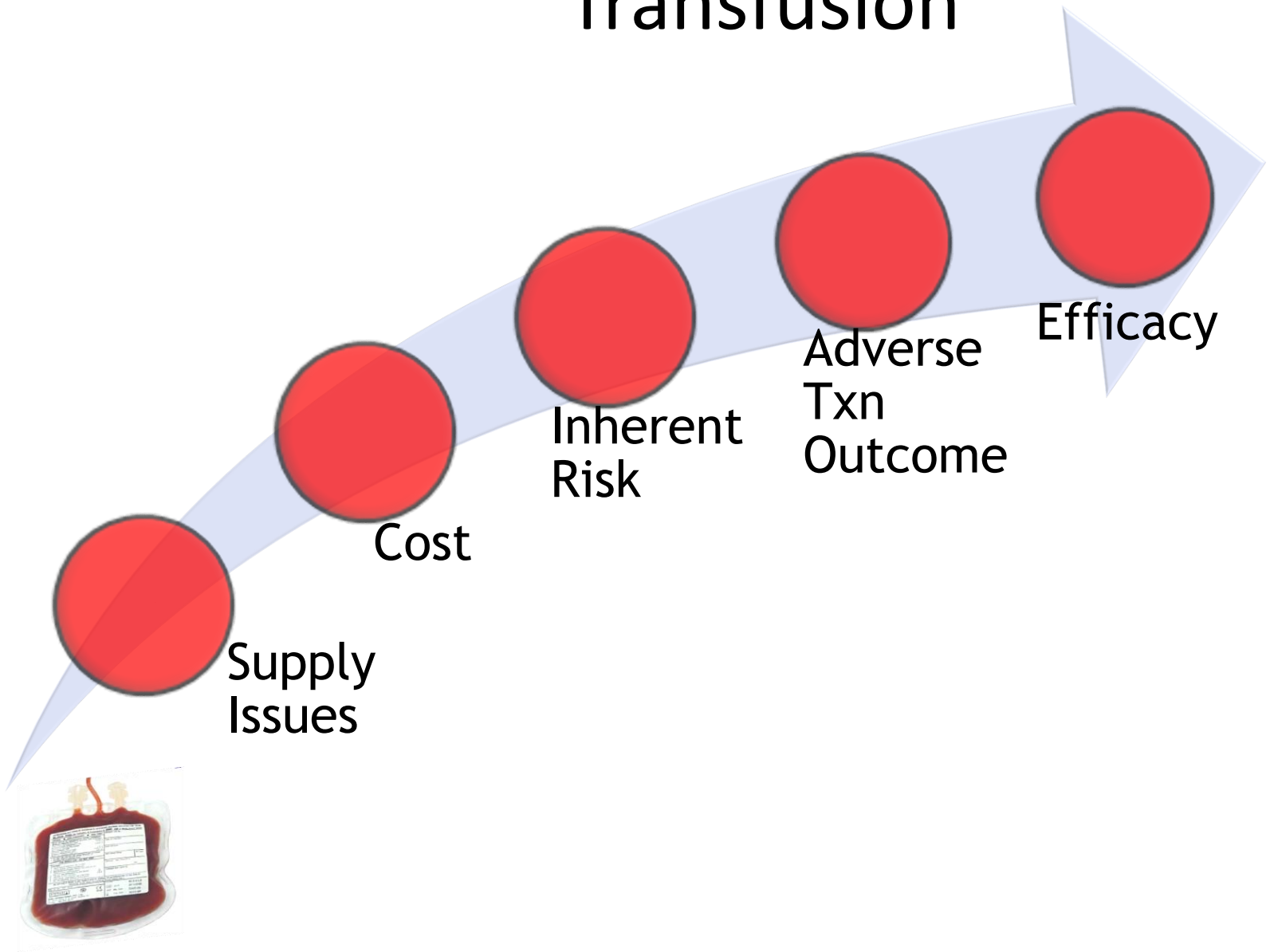
- AHRQ: Blood transfusions occurred in 1/10 of all hospital stays that had a procedure
- Most commonly performed procedure in US hospitals
- It is a Liquid Organ Transplant ordered by a physician and performed by a nurse

Blood Transfusion: Who is at risk?



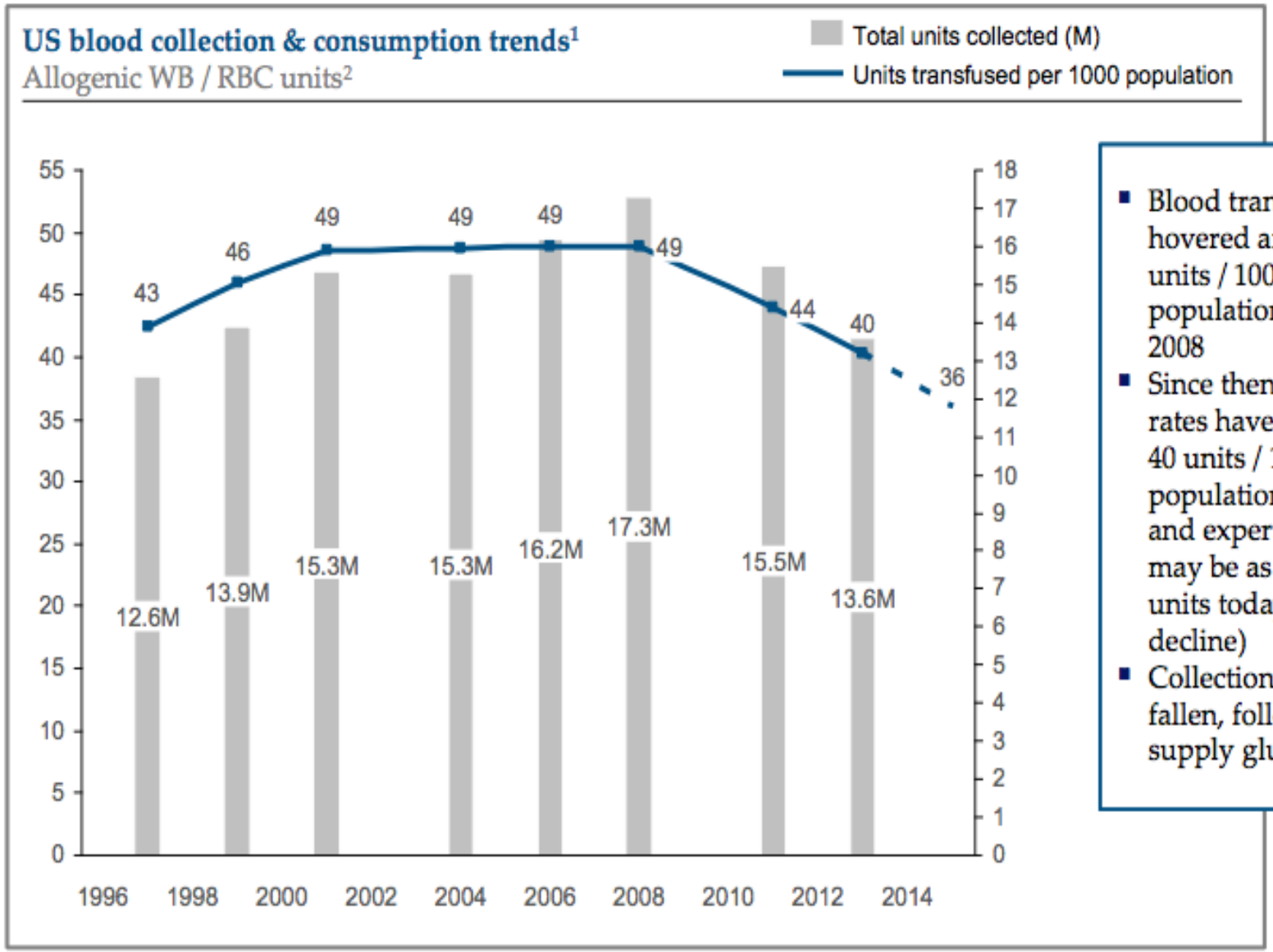
Goodnough LT, Shander A. A&A 2012

Five Drivers for the Paradigm Shift in Transfusion



US blood collection & consumption trends[1]

Allogenic WB / RBC units[2]

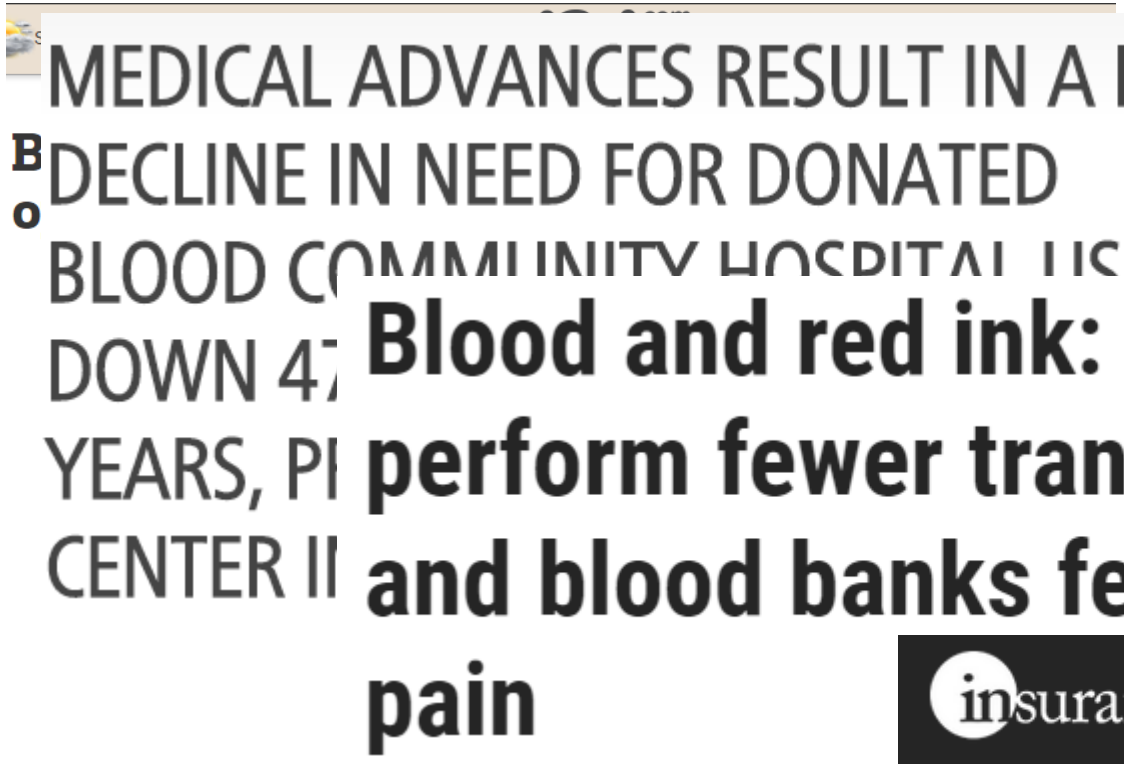


- Blood transfusion rates hovered around 50 units / 1000 members of population from 2001-2008
- Since then, transfusion rates have declined to 40 units / 1000 population by 2013, and experts estimate it may be as low as 35 units today (~30% decline)
- Collection rates have fallen, following a supply glut in 2008

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

SOURCE: DHHS National Blood Collection & Utilization Surveys 1997-2011; AABB Blood Survey 2013

Blood Centers: A system in Crisis



Blood and red ink: Hospitals perform fewer transfusions and blood banks feel the pain

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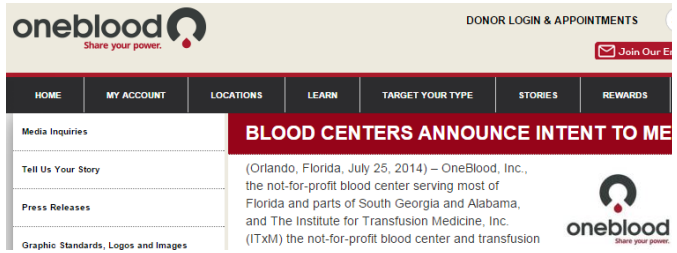
Your industry. One source.

Why blood banks are shrinking



The Advisory Board Company

New transfusion guidelines, surgical techniques limit need for blood

THE WALL STREET JOURNAL.

20 ODD QUESTIONS
Designer Jonathan Adler on Awesome Architecture ...

The Price We Pay for Sitting Too Much

New Devices Take the Pain Out of Hospital Visits

New Sup
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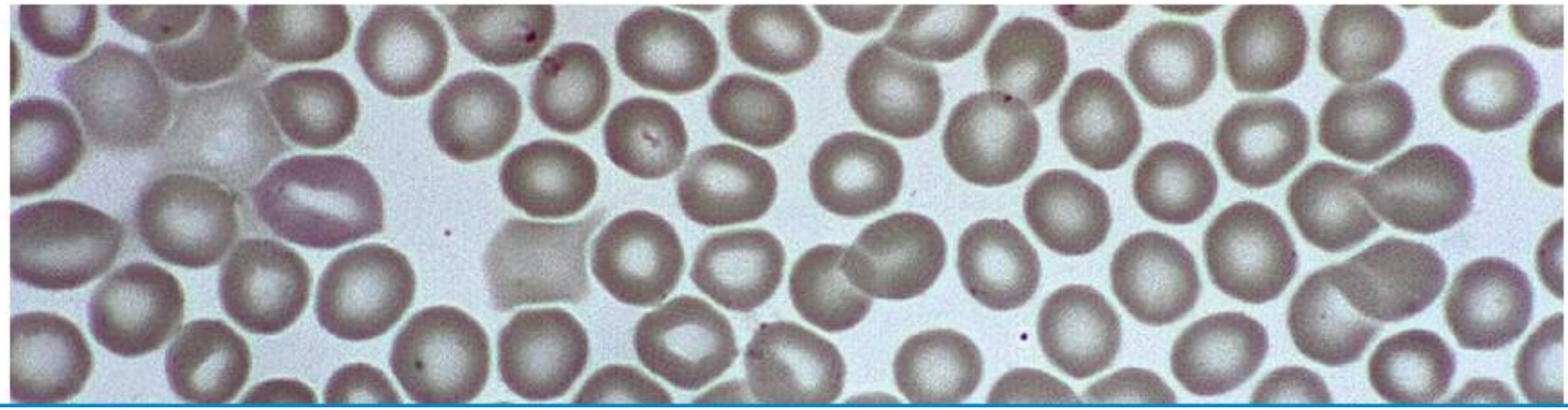
The Rising Risk of a Contaminated Blood Supply

Amid new pathogens and cost pressures, efforts are under way to keep patients safe



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ISBT Science Series
ISBT Science Series (2009) 4, 423–435

REVIEW PAPER

PL5

Patient blood r

Table 1 Reported adverse outcomes associated with transfusion and populations affected

Patient populations in whom adverse outcomes associated with RBC transfusion have been reported	
ICU patients	Transplantation surgery
Paediatric patients	Colorectal surgery
Trauma patients	Gastric surgery
Burn patients	Biliary surgery
Combat casualties	Splenectomy
Acute coronary syndrome patients	General surgery
Oncology patients	Vascular surgery
Population based studies	Orthopaedic surgery
Obstetrics	Thoracic aneurysm surgery
Cardiac surgery	Lung surgery
Neurosurgery	Head and neck surgery
Hepatic surgery	Mastectomy and reconstruction
Pancreatic surgery	Oesophageal surgery

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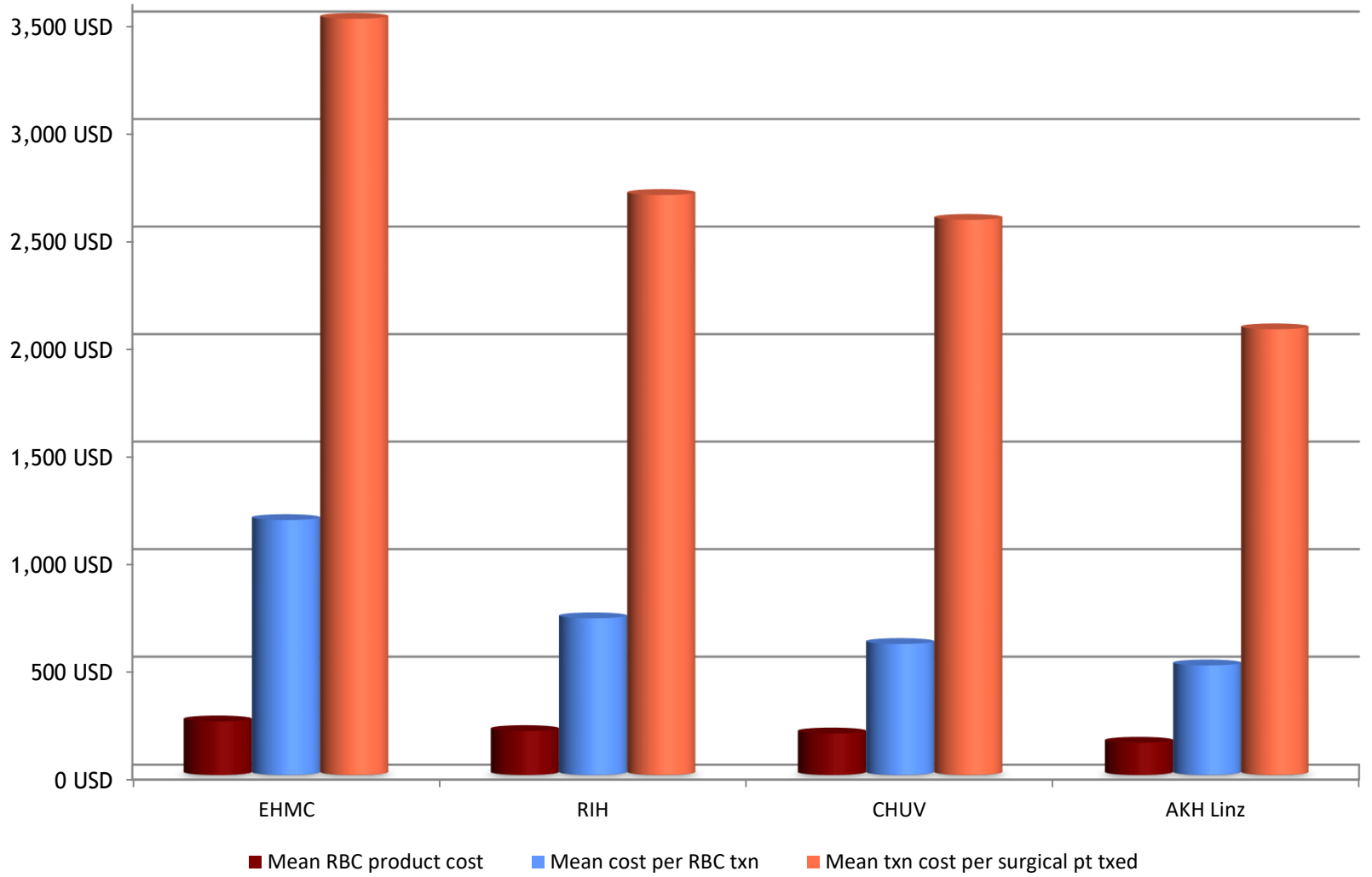
Activity Based Cost of Transfusion from a Provider's Perspective



Blood use in elective surgery: the Austrian benchmark study

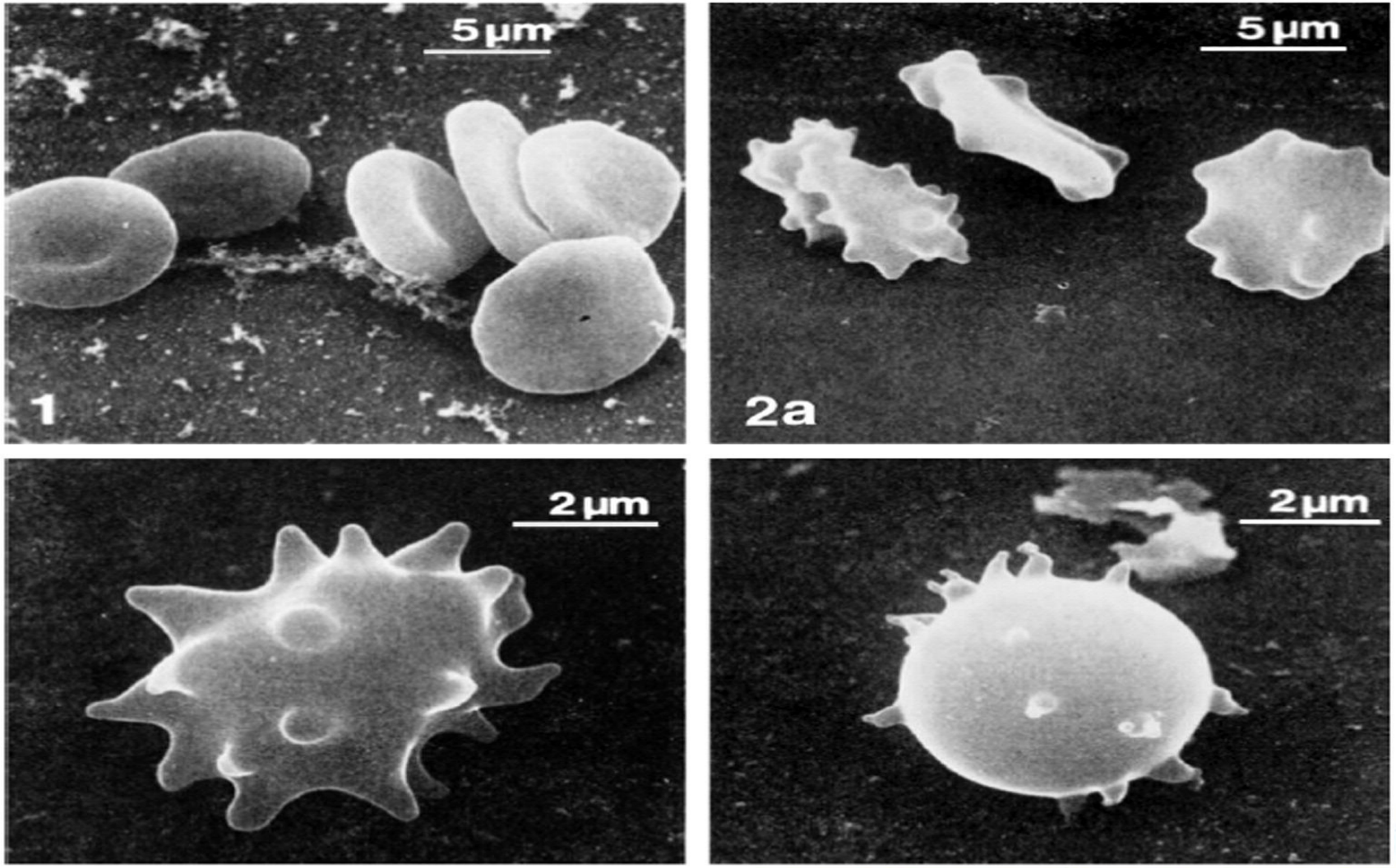
Hans Gombotz, Peter H. Rehak , Aryeh Shander , and Axel Hofmann

Who really gets transfused?

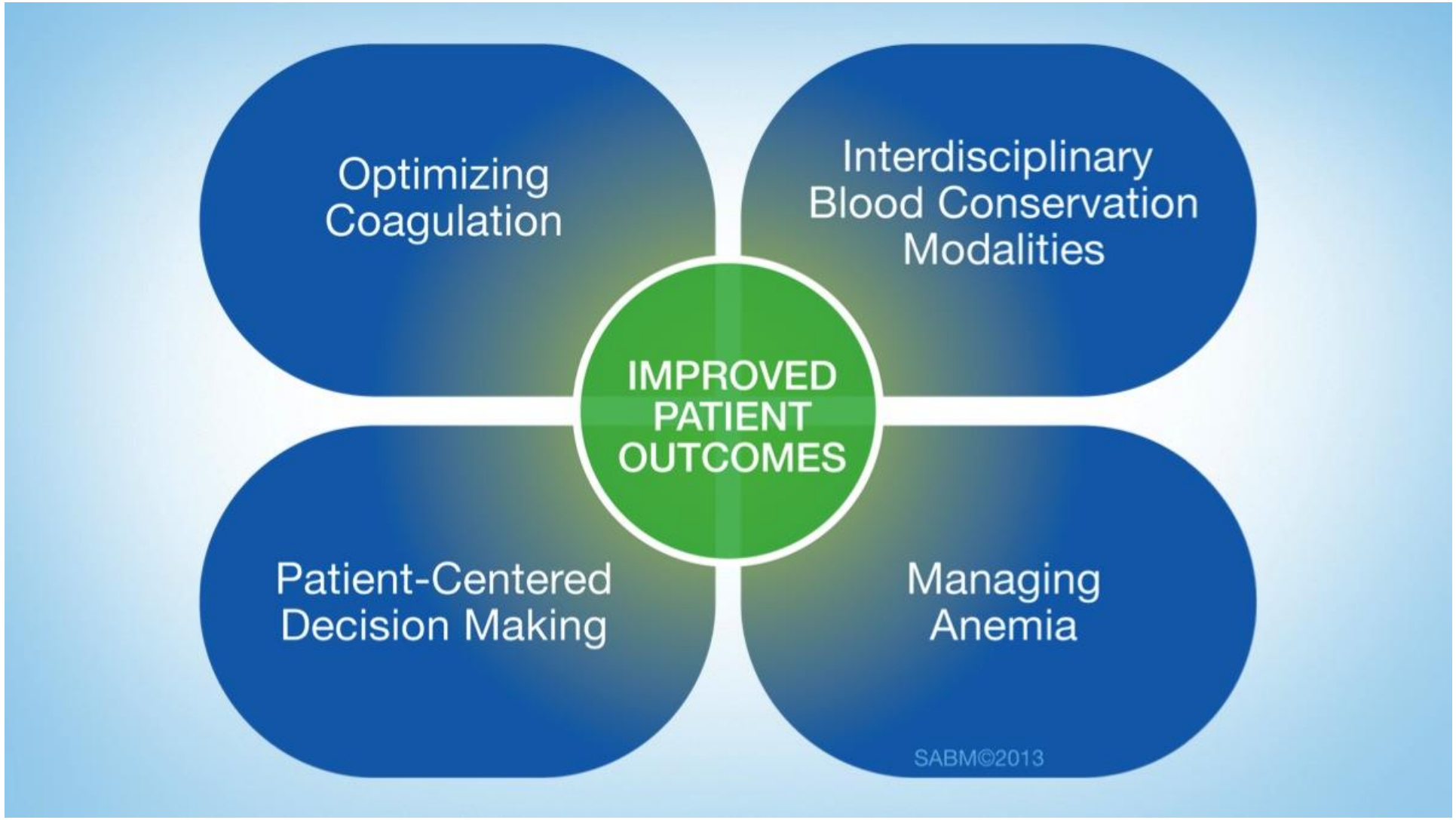
97.4% of all transfusions could have been predicted by:

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



Why do we test for hemoglobin?

- To check your overall health
- To diagnose a medical condition
- To monitor a medical condition

http://www.mayoclinic.org/tests-procedures/hemoglobin-test/basics/why-its-done/prc-20015022

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 or determine that the endpoint has been reached**

Delivery of Oxygen to Tissues

Oxygen Delivery | Cardiac Output | Oxygen Content

$$DO_2 = CO \times CaO_2$$

SV	HR
Stroke Volume	Heart Rate

Hgb	SaO_2	Dissolved Oxygen
Hemoglobin Concentration	Oxygen Saturation	

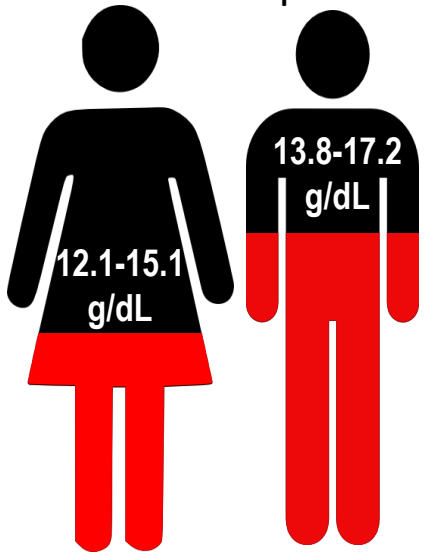
Hemoglobin concentration is a significant factor of oxygen delivery to the tissues.

Decreased levels of hemoglobin can have detrimental effects in a patient due to limited delivery of oxygen to vital organs.[1]

[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.



Normal ranges for women and men[1]

> **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]**

[1]World Health Organization Global Database on Anaemia. 2008.
[2]Miller's Anesthesia. 8th Edition. 2015.

Different types of Hg measurements

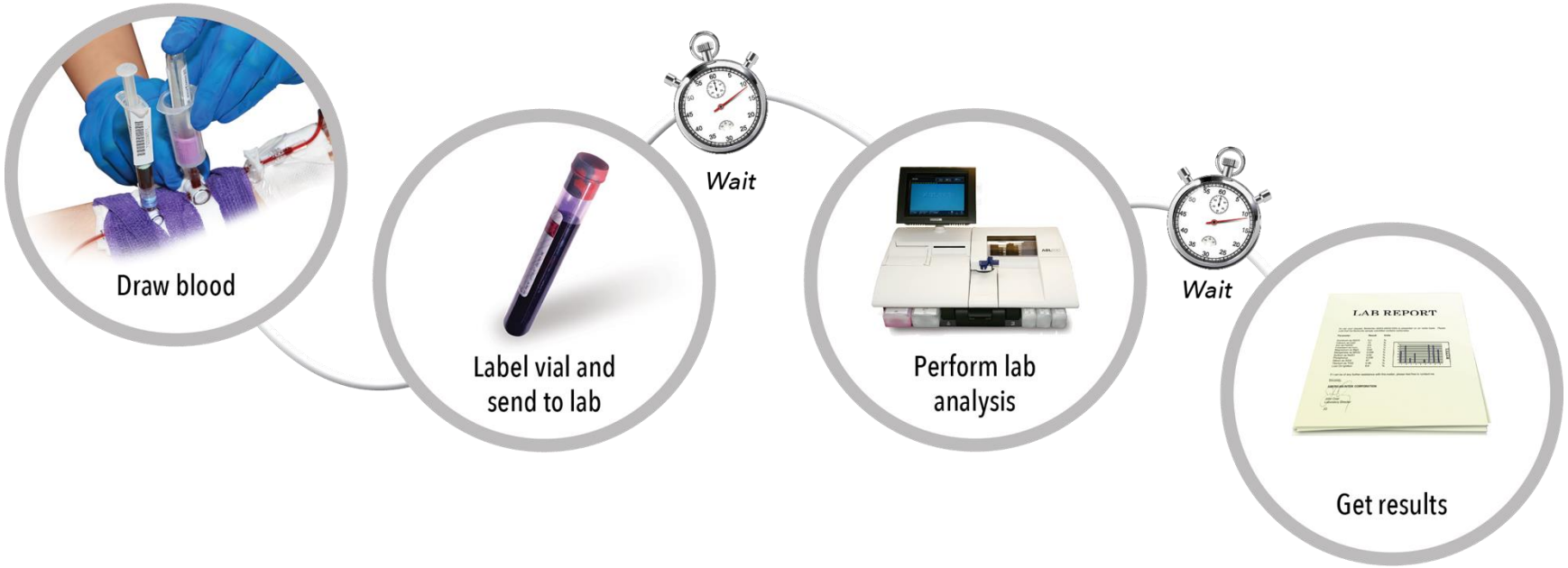
- Lab analysis - Automatic blood analyzer/ CO-Oximeters are the gold standard for Hb measurement
- Capillary blood tube - spun
- POCT – Hemocue - reagent
- Non-invasive Hg monitoring
- Visual color-based POC anemia – pre-investigation

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

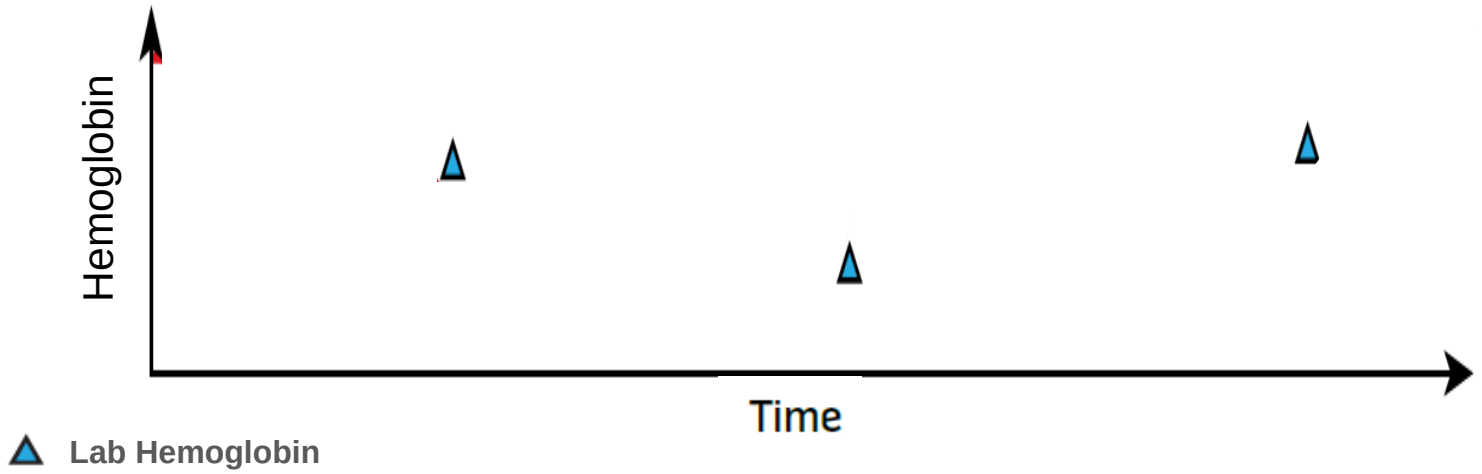
Lab Hb Gives Intermittent and Delayed Results While Transfusion Decisions Are Often Made In Real Time



[1]Frank S et al. Anesthesiology. 2012.
[2]Shander et al. TransMed Rev. 2011.

Limitations of Current Methods

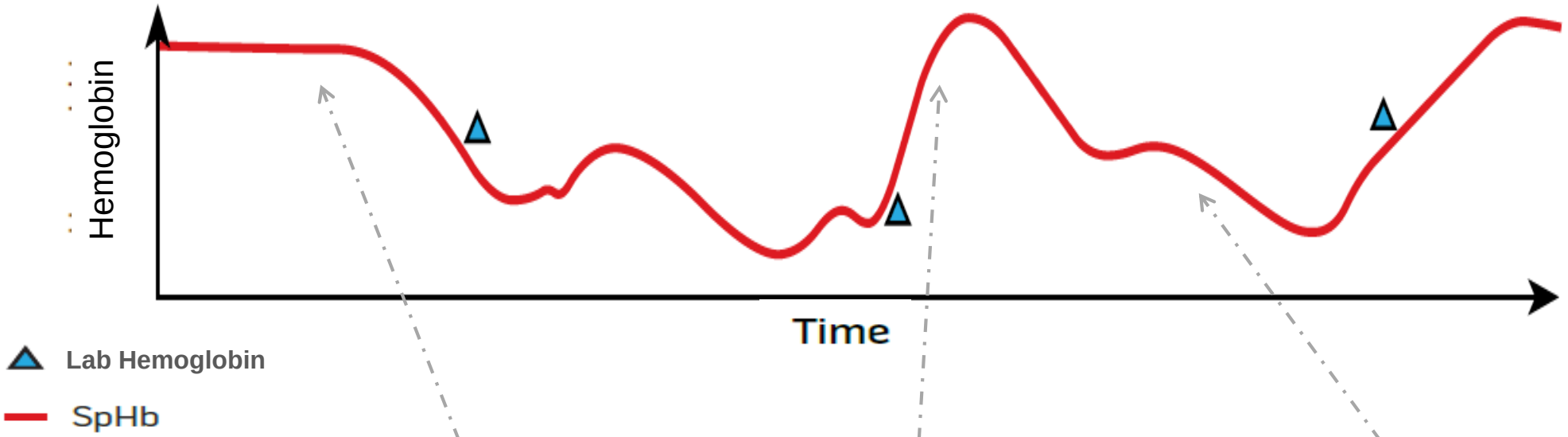
Lab Hb Gives Intermittent and Delayed Results While Transfusion Decisions Are Often Made In Real Time



Without SpHb monitoring

Value of SpHb Monitoring

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



With SpHb monitoring

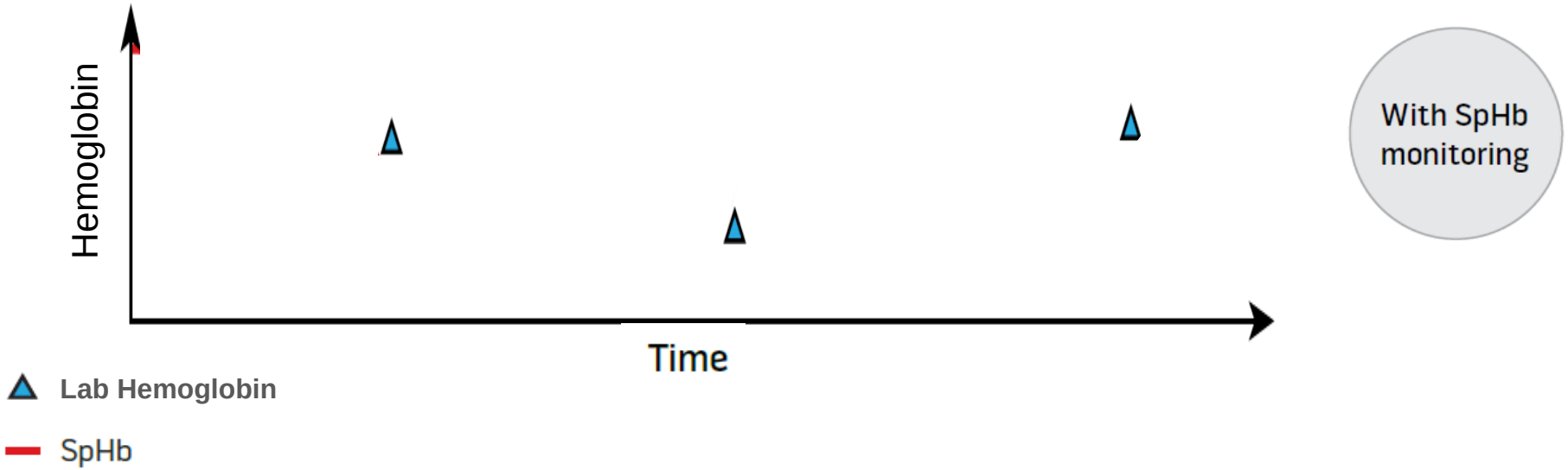
SpHb trend is stable while clinician may otherwise think hemoglobin is dropping

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

Value of SpHb Monitoring

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



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

Advantages of non-invasive continuous monitoring

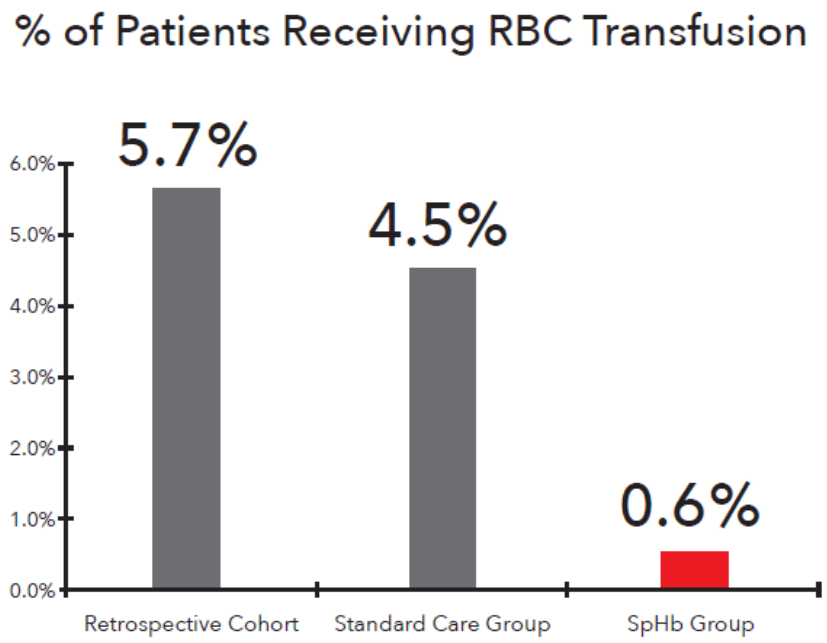
In a study of 20 spine surgery patients (published in Anesthesia-Analgesia), Ron Miller and colleagues noted that non-invasive and continuous Hb monitoring may:

- “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

SpHb Utility

Orthopedic Surgery



- 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

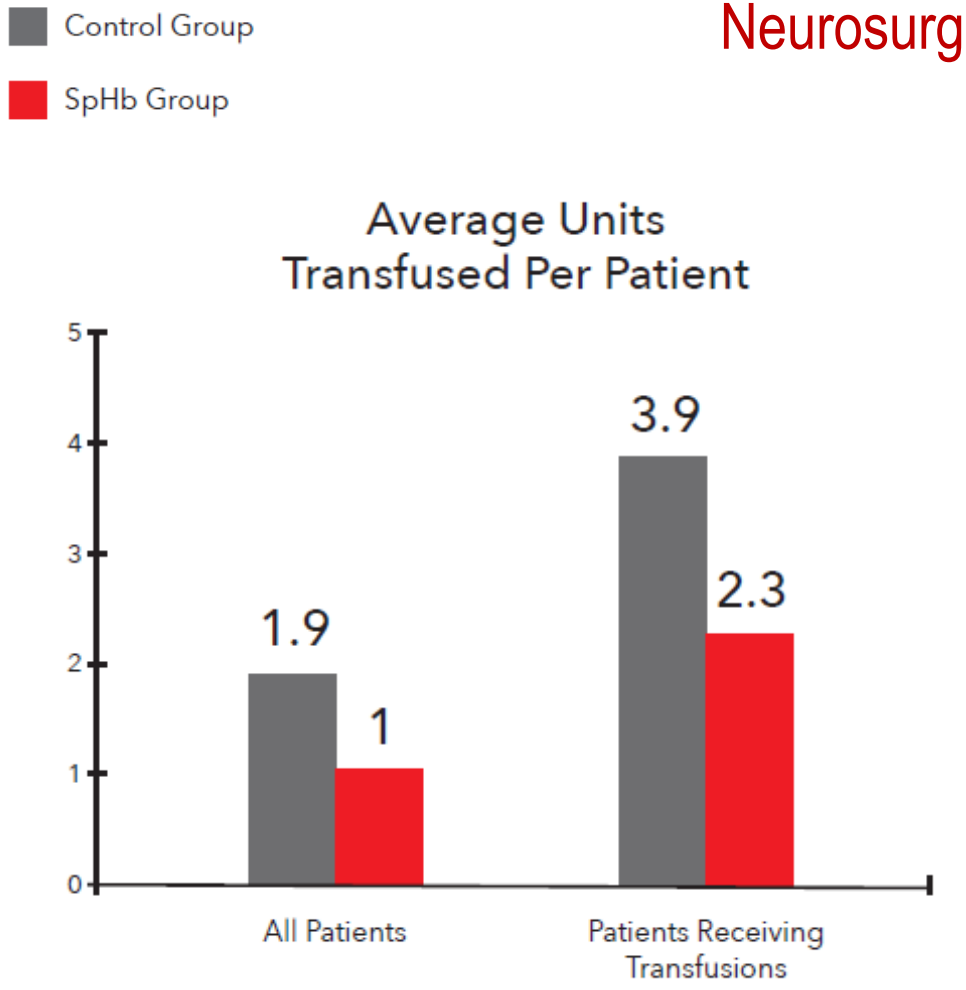
Author Conclusion: "*the availability of SpHb decreases inappropriate transfusion (either by preventing an initial transfusion, or the transfusion of additional blood products after a single unit has been delivered)*."

Ehrenfeld et al. J Blood Disorders Transf. 2014.

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.

SpHb Utility

Neurosurgery



- 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

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.*"

Awada et al. J Clin Monit Comput. 2015.

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

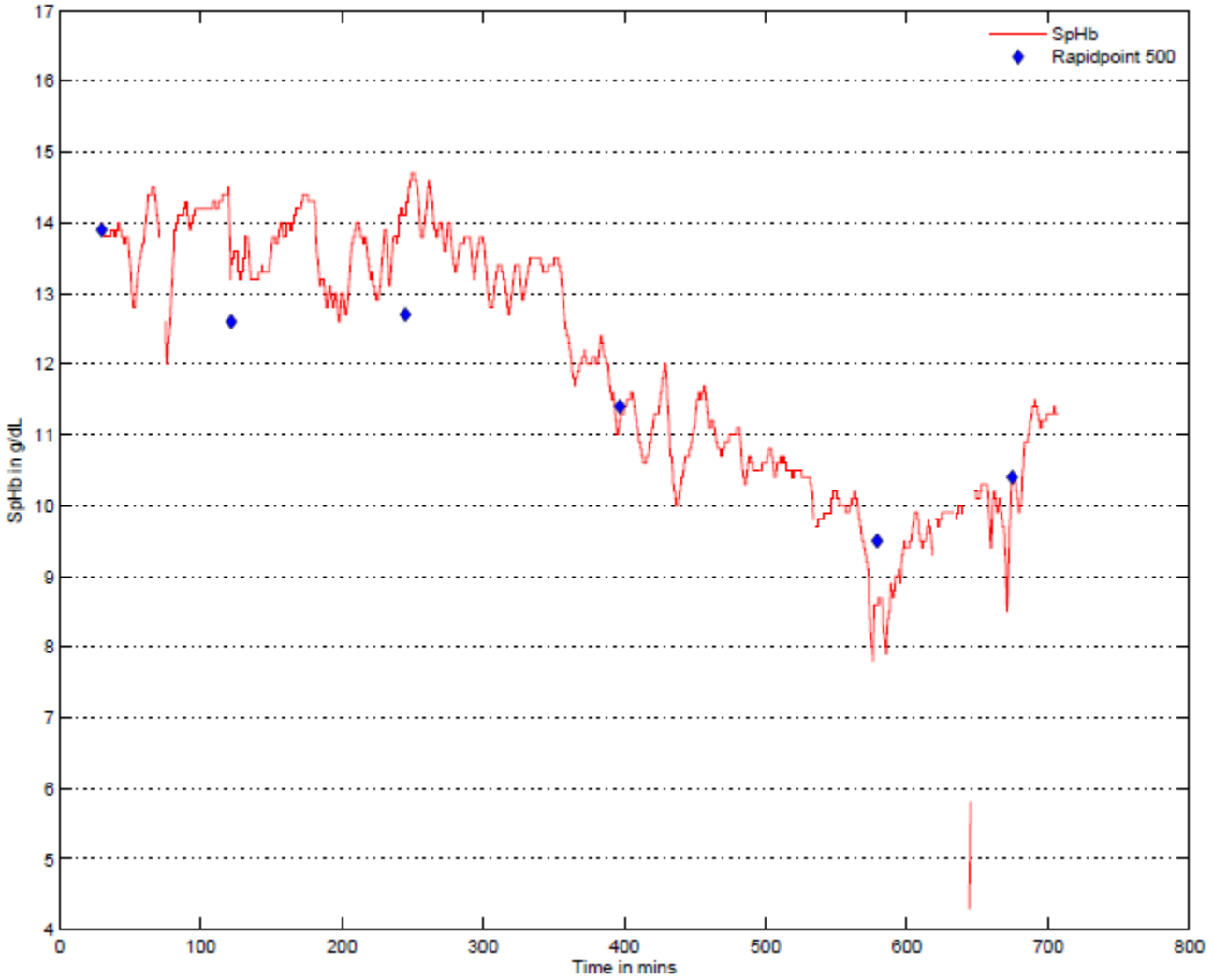
- About 57% (aggregate) of spinal patients receive blood
  - Ranging from 26% to 79% based upon patient pathology[1]
- Clinicians often overestimate the need for blood in spine cases
  - Crossmatch per patient often exceeds amount transfused

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

[1]Kouritas et al. Transfusion Med. 2010.

Multi-Level Spine

Case Example- Pediatric Scoliosis



Multi-Level Spine

Peer Reviewed Studies

> **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."**

[1]Berkow et al. Anesth, & Analg. 2011.
[2]Colquhoun et al. J Clin Monit Comput. 2012.

Multi-Level Spine

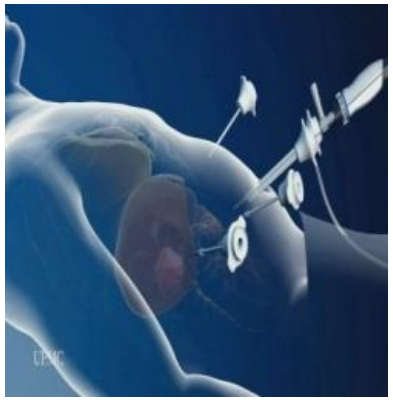
Peer Reviewed Studies

- **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."**

[1] Miller et al. Anesthesia & Analgesia. 2011.

Liver Transplants

Utilization of Blood



- Liver Transplants are the bloodiest surgeries
  - Despite low procedure volumes, fall into top 5 for transfusions[1]
  - Procedures are long: ranging from 6 to 12 hours[2]

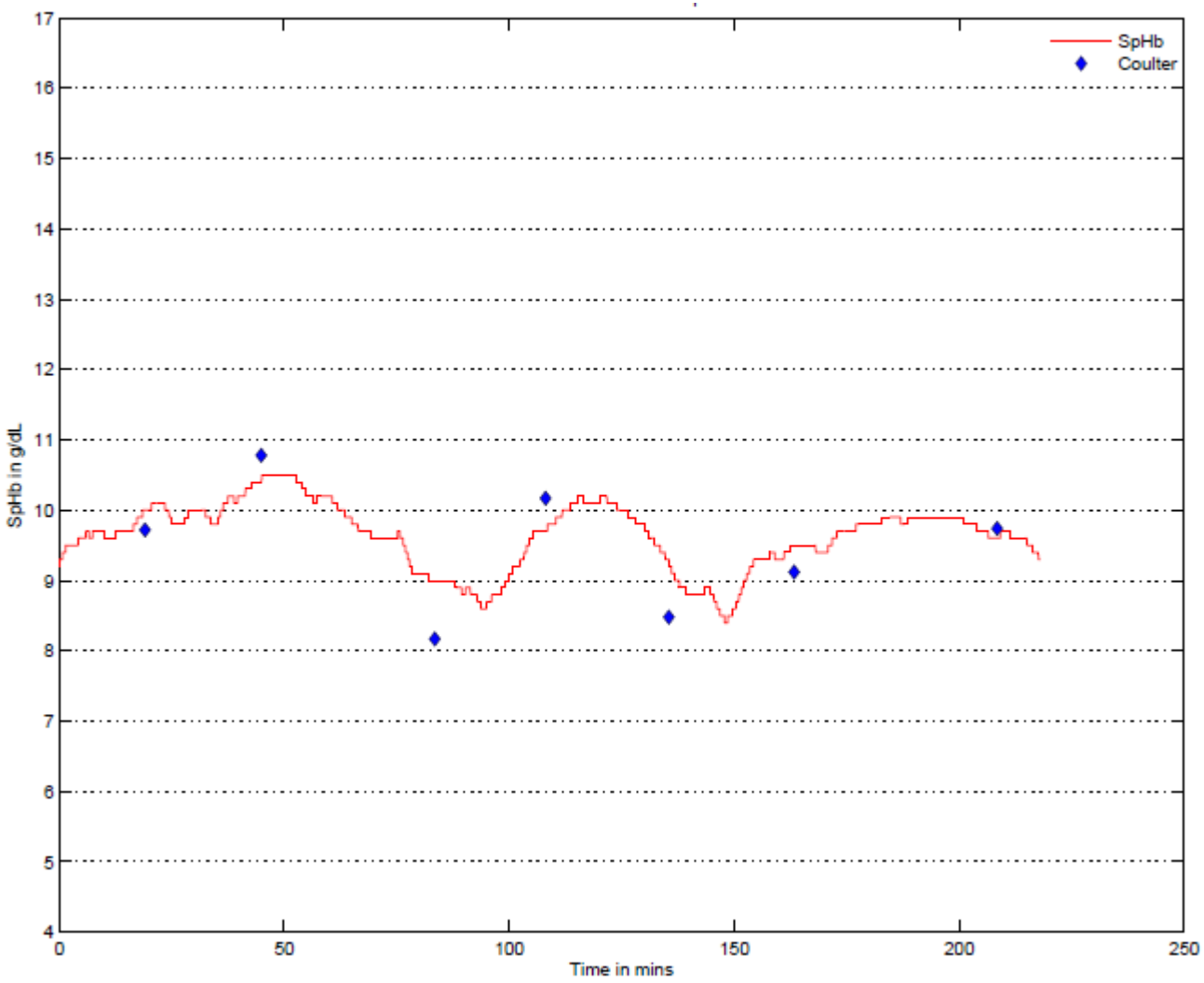
- 75% of patients who undergo liver surgery are anemic[3]
  - Liver disease often causes portal hypertension leading to varices and thus gastrointestinal bleeding
  - Endothelial dysfunction impacts clotting abilities and often leads to coagulopathy
  - Alcohol is toxic to bone marrow, thus impacting 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 period[4]
  - Roughly 9% (7-15% per Cleveland Clinic) of patients showed abdominal bleeding occurring at a mean of 6.1 days (range 1-21 days)

[1]CMS data- ICD 99.0
[2]https://my.clevelandclinic.org/health/treatments_and_procedures/hic_Liver_Transplantation
[3]Gonzalez-Casas et al. World J Gastroenterology. 2009.
[4]Jung et al. Transplant Proc. 2012.

Liver Transplant

Case Example



Liver Transplants

Abstracts

> **Study: Ramsay et al.[1]**
- 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.[2]**
- 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."**

[1]Ramsay et al. NYPGA. 2013.
[2]Torp et al. NYPGA. 2010.

Cranial and Facial

Utilization of Blood

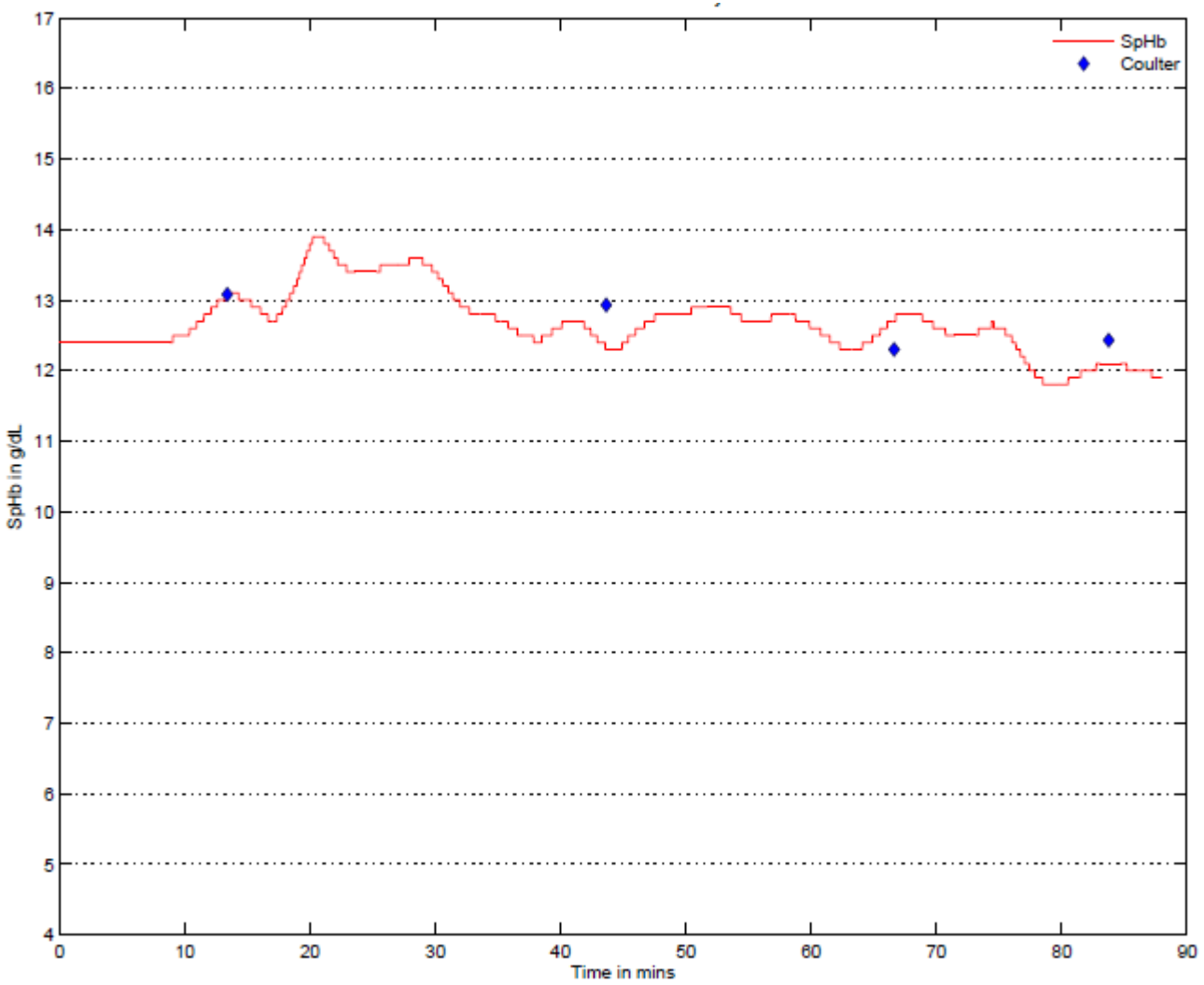
- **Select cranial and facial procedures (including maxillo) have significant blood loss**
  - Glioma Excision - 834mL blood loss[1]
  - CP Angle Tumors - 568mL blood loss[1]
  - Decompressive Craniectomy - 338mL blood loss[2]
  - Craniofacial Surgeries - 410mL blood loss[3]
  - Double Jaw Osteotomies - 450mL blood loss[4]

- **Much of the craniofacial data involves pediatric patients[5-7]**

[1]Bhatnagar et al. Indian Journal of Anaesthesia 2007.
[2]Desgranges et al. Childs Nerv Syst. 2014
[3]Abraham et al. The Internet Journal of Anesthesiology. 2014.
[4]Moenning et al. J Oral Maxillofac Surg.
[5]Park et al. Anesth, & Analg. 2012.
[6]Patino et al. Anesth & Analg. 2014.
[7]Loveland-Baptist et al. Annual Meeting of the ASA. 2011.

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

> **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."**

> **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:**

- **"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."**

[1]Park et al. Anesth, & Analg. 2012.
[2]Patino et al. Anesth & Analg. 2014.

Cranial and Facial

Peer Reviewed Study and Abstract

> **Study: Kim et al.[1]**

- Objective: To evaluate the agreement of the SpHb in patients undergoing orthognathic surgery when using hypotensive anesthesia
- Sample: 51 patients. Osteotomy

> **Authors' Conclusions:**

- **"Continuous monitoring of hemoglobin may *help to determine the appropriate time to perform an invasive measurement of hemoglobin* in patients undergoing double-jaw surgery when using controlled hypotensive anesthesia."**

> **Study: Loveland-Baptist et al.[2]**

- Objective: To study the use of continuous noninvasive hemoglobin (SpHb) assessment in pediatric patients undergoing cranial vault reconstruction
- Sample: 11 children (51 points). Cranial vault reconstruction

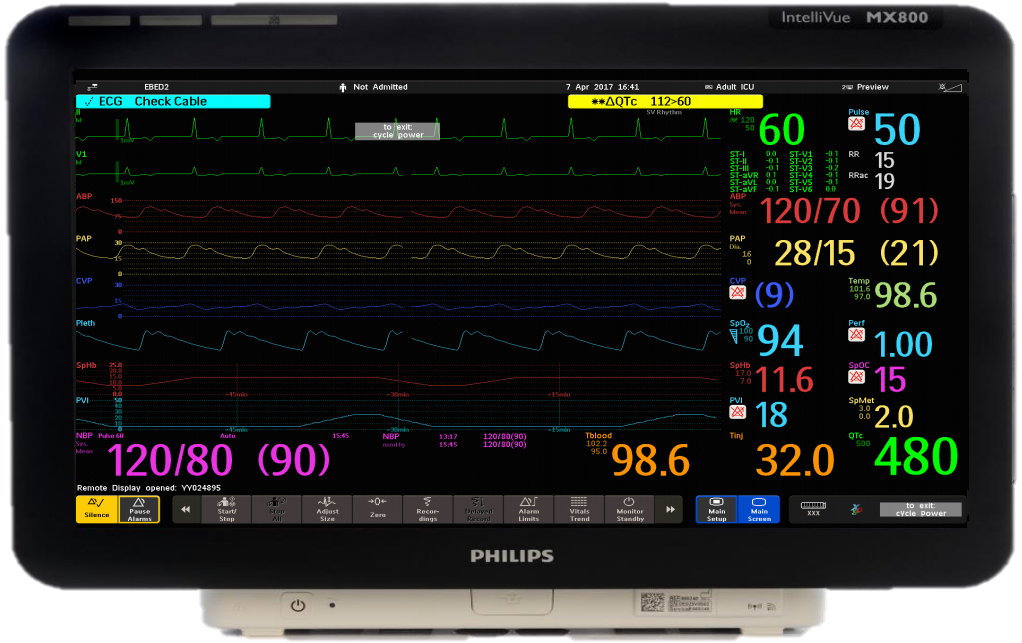
> **Authors' Conclusions:**

- **"The Masimo Radical-7 *provided accurate and timely continuous SpHb measurements* compared with intermittent laboratory methods for pediatric patients undergoing cranial vault remodeling."**

[1]Kim et al. J Oral Maxillofac Surg. 2014.
[2]Loveland-Baptist et al. Annual Meeting of the ASA. 2011.

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 (SbHb) provides real time data to clinicians leading to better decision making