# Feasibility and Validity of a Non-invasive Technology to Measure Hemoglobin

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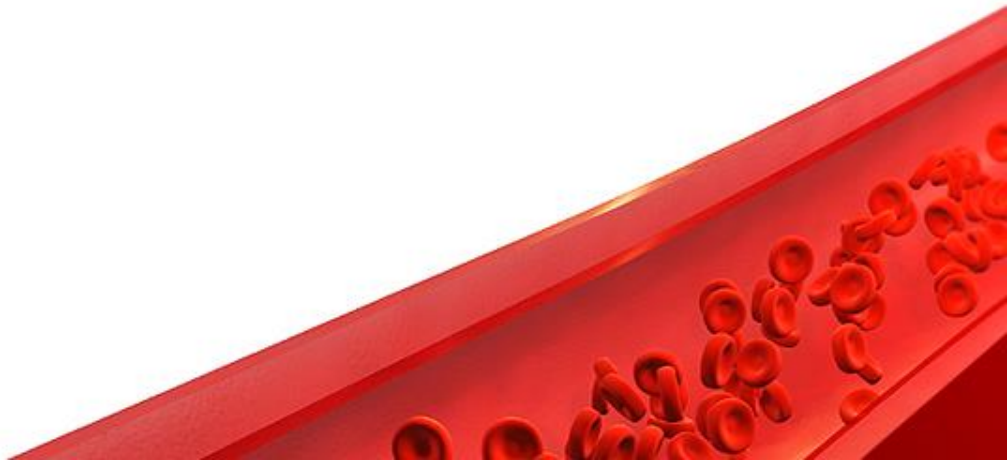
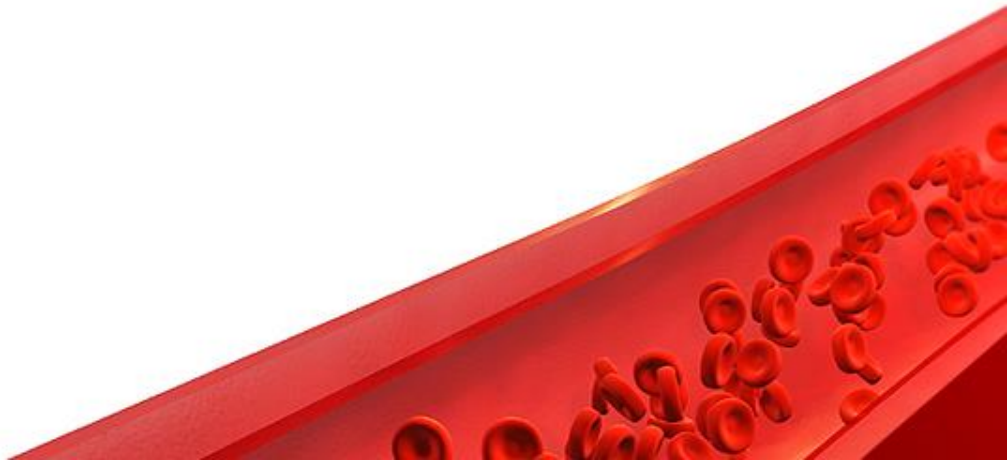
# Disclosures

- None
  - **No financials or incentives associated with Masimo**



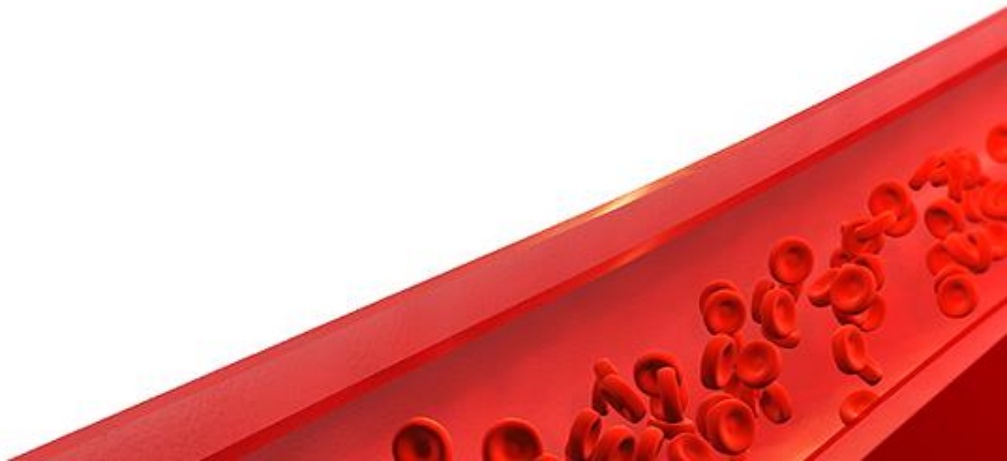
# Objectives

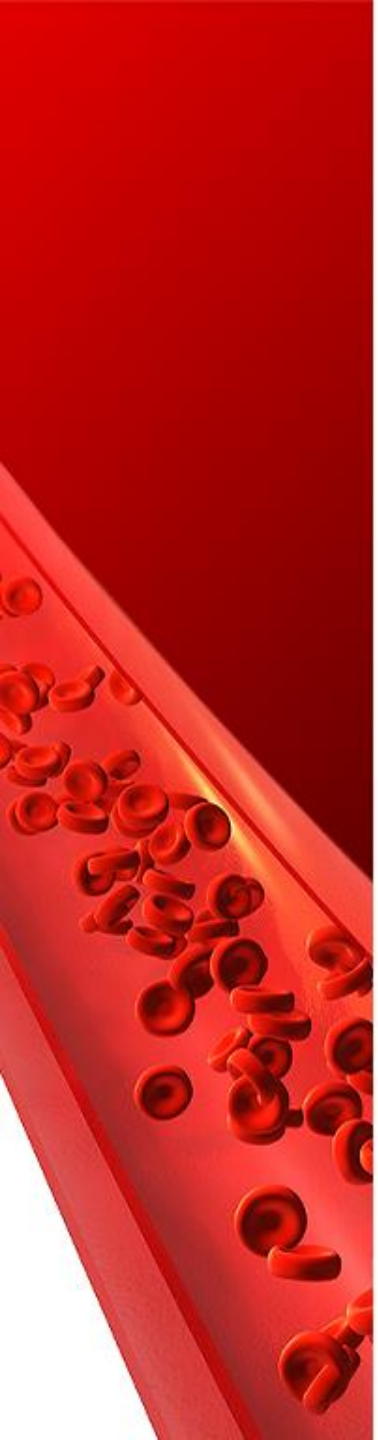
- Describe the issues with redundant lab draws for monitoring anemia.
- Describe the utility and limitations of non-invasive hemoglobin monitoring
- Identify potential uses of non-invasive hemoglobin monitoring



# Background

- The United States spends ~$5 Billion a year on redundant testing alone (Konger et al., 2016).
- Laboratory testing, like daily or multiple CBC, contributes to this expenditure (Konger et al., 2016).
- On average, a person hospitalized for GI bleeding will have 6 CBC blood draws in the first 48 hours and will be transfused on average 2.6 units of PRBCs (Jaben et al., 2020).



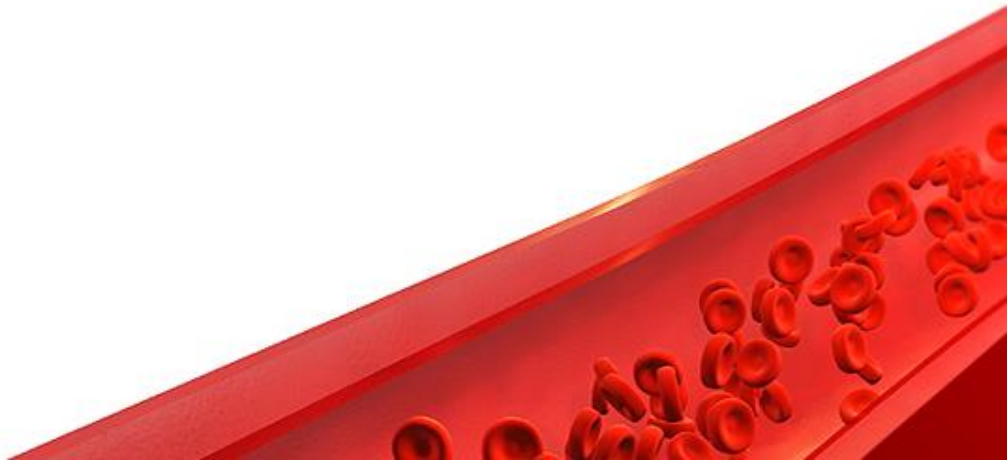


# Background

- Blood Transfusions can cause adverse outcomes and unnecessary costs to patients
- Between 2000 and 2011, there was a 114% increase in blood transfusions for those aged 18 and older.
  - Hospital stays for this age group also increased (West et al., 2016).

# V.H.S.O Background Information

- 10/2020 -8/2021 @ VHSO
  - **154 Veterans admitted for acute anemia**
  - **4,256 CBC blood draws**
  - **543 blood transfusions**



# V.H.S.O. Six-Sigma Project

- **Problem Statement:** The lab turnaround time (TAT) for current performance results in a lag in clinical decision-making time for medical interventions when a Veteran is admitted for Anemia at VHSO.
- **Goal:** The purpose of the proposed action research is to implement a non-invasive hemoglobin monitor to reduce touchpoints for Phlebotomists and decrease multiple blood draws.

| Touchpoints | Time |
|---|---|
| ED MD assessment | 5 mins |
| ED MD places lab order | 2 mins |
| Phlebotomist lab drawing process | 35 mins |
| Clinical Lab TAT for Hemoglobin value | 26 mins |
| ED MD receives results | 10 mins |
| ED MD places Type & Cross order | 2 mins |
| Phlebotomist lab drawing process | 35 mins |
| Clinical Lab TAT for Type and Cross | 38 mins |
| ED MD receives notice Type and Cross is done | 10 mins |
| Total Time: | 2 hours and 43 mins |

# Introducing Non-Invasive Hemoglobin Monitor

## In Scope

- Introduce a non-invasive technology to measure hemoglobin levels to spot-check or surveillance Veterans experiencing or at risk of experiencing anemia.

## Out of Scope

- Traditional monitoring of multiple blood draws sent to the lab to monitor hemoglobin levels of Veterans experiencing Anemia.

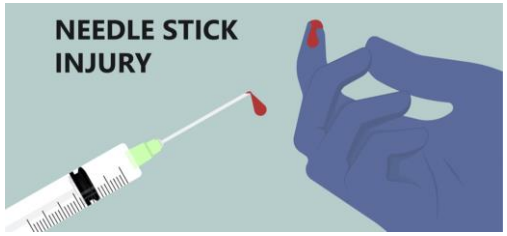
# Costs of Blood Draws

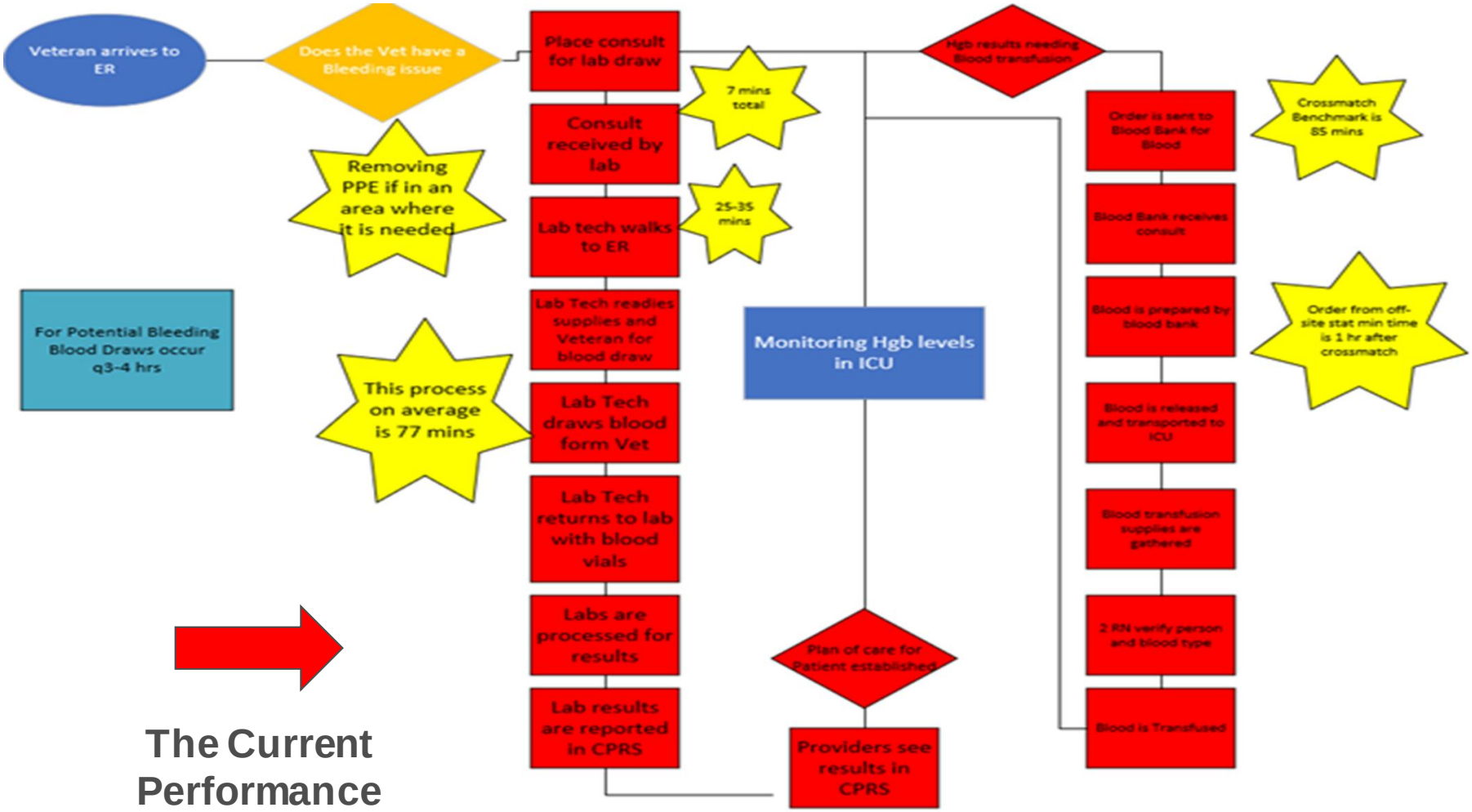
| Description for Drawing a Lab | U/I | Cost |
|---|---|---|
| Gloves (Exam) | 1 | $0.18 |
| Blood tubes (specifically purple top) | 1 | $0.43 |
| Blood tubes (specifically pink top) | 1 | $0.64 |
| Alcohol swabs ($0.01) | 1 | $0.01 |
| Gowns (for use in the COVID unit) ($1.40) | 1 | $1.40 |
| N95 masks ($0.52) | 1 | $0.52 |
| Regular masks ($0.09) | 1 | $0.09 |
| CBC ($2.11) | 1 | $2.11 |
| BD Needles (Preattached tube holder, built-in safety shield) | 1 | $1.10 |
| BD Vacutainer™ Safety-Lok™ Blood Collection Sets with Pre-Attached Holder | 1 | $5.36 |
| Tourniquets | 1 | $0.13 |
| Lab Tech | 1/hr | ~ $24.00 |
| Phelbotomist | 1/hr | ~ $18.00 |
| If transfusing Unit PRBCs | 1 | $205.00 |

| | | **Totals** |
|---|---|---|
| **Cost to Draw a lab:** | | **$48.61 – $52.87** |
| **From 9/1/2020 -8/31/2021,** | **4256 inpatient CBC/H/H** | **$225,014.72** |
| **From 9/1/2020 to 8/31/21,** | **Anemia Surveillance 3 hrs Draws** | **$ 79,516.48** |
| | **or** | |
| **From 9/1/2020 to 8/31/21,** | **Anemia Surveillance 4 hrs Draws** | **$ 59,637.36** |
| **From 10/2020-8/2021,** | **543 blood transfusions** | **$111,315.00** |

# Additional Reasons for Improvement Project

- Decrease multiple blood draws
- Increase Veterans' comfort by decreasing numbers of invasive blood draws
- Decrease iatrogenic blood losses from serial blood draws
- Reduce potential unintentional needle sticks to healthcare workers
- Decrease risks for nosocomial infections
- Reduce blood transfusions if implemented properly.






**The Current Performance**

# Masimo Technology

Masimo Rad-97 continuous SpHb monitoring.

Masimo Rad-67 Spot-check SpHb.

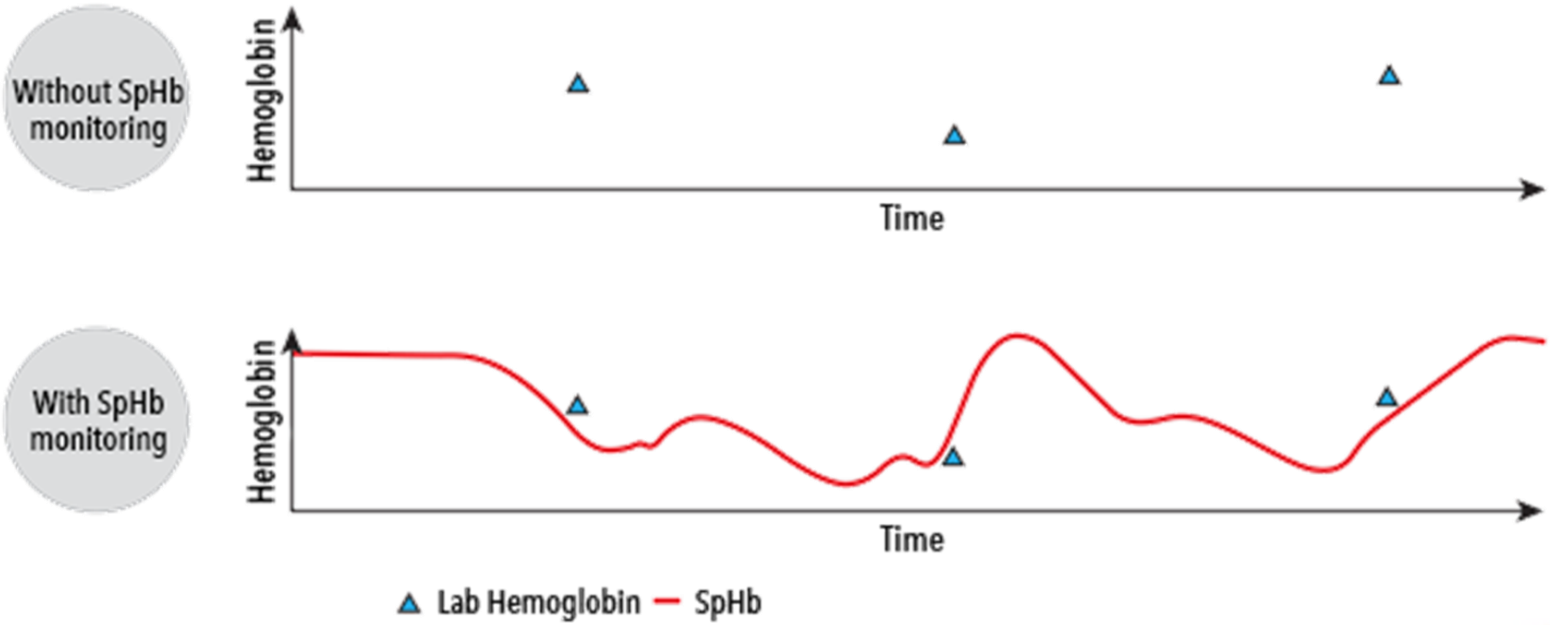
# Historical Insight of pulse oximetry

- Before 1974, oxygen saturation was measured by a painful invasive arterial blood draw
- Took ~20-30 minutes to obtain the result.
  - Delay led to severe brain damage within 5 minutes of low oxygenation.
- 1981 first commercial pulse oximeter.
  - Initially, for respiratory care
  - later expanded into operating rooms.

# Historical Insight cont.

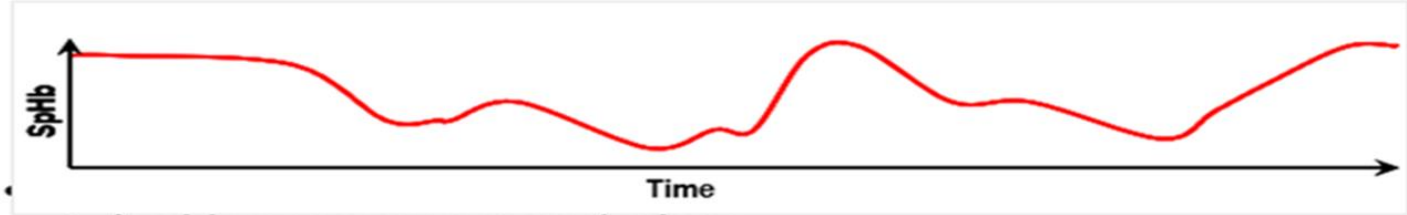
- In 1987 Pulse Oximetry became the standard of care in administrating general anesthetics in the US.
  - The use of Oximetry quickly spread to other hospital units, such as emergency rooms, recovery rooms, neonatal units, and intensive care units.
- 1995 the first finger SpO2 probe appeared on the market.
- Newer finger pulse oximetry units such as Masimo measure more than just pulse and oxygen levels.

# Traditional Monitoring Vs Continuous SpHb Monitoring



# Real-time Hemoglobin Trending Between Invasive Blood Sampling

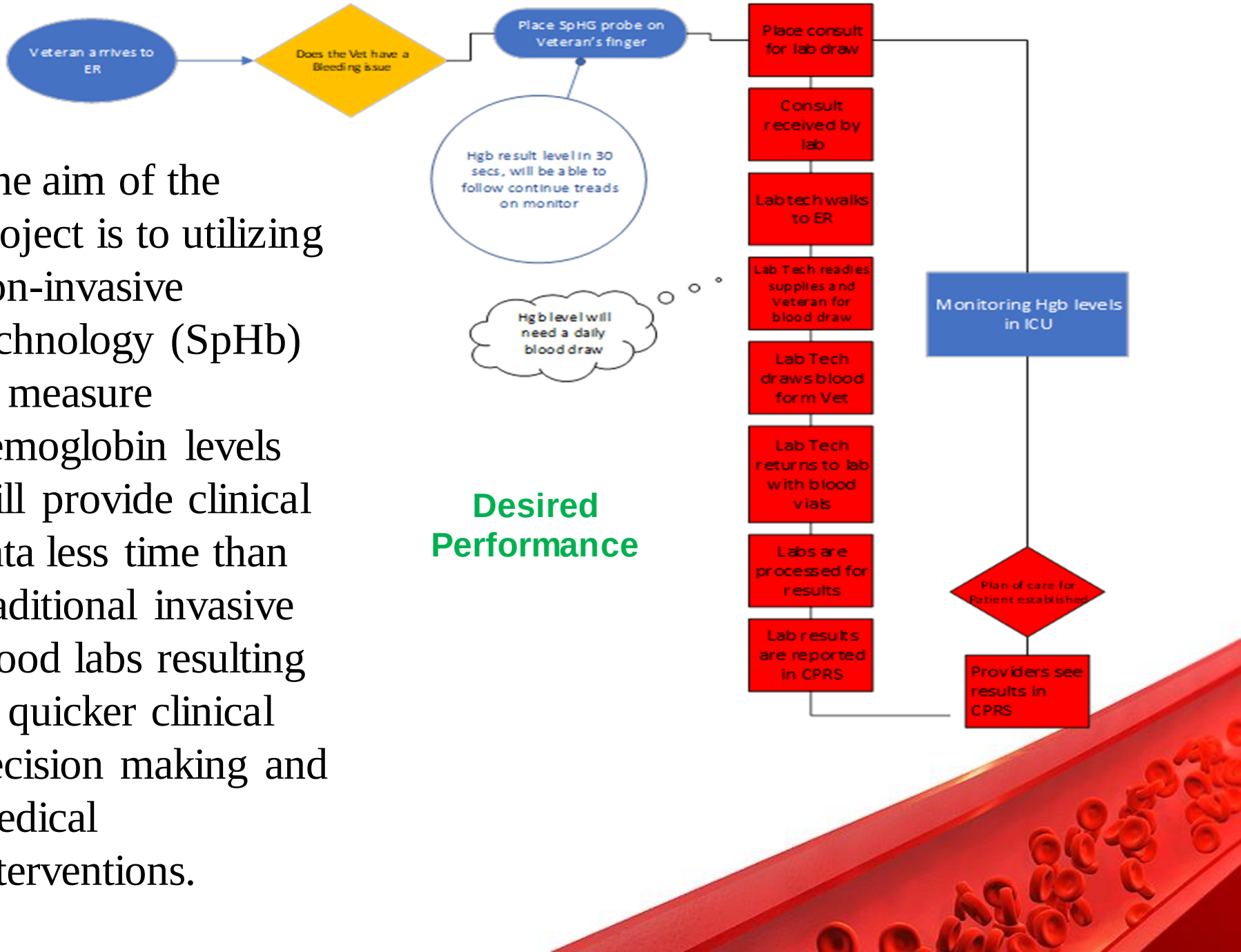
- Continuous indication of whether hemoglobin is:
  - Stable → Dropping ↘ Rising ↗

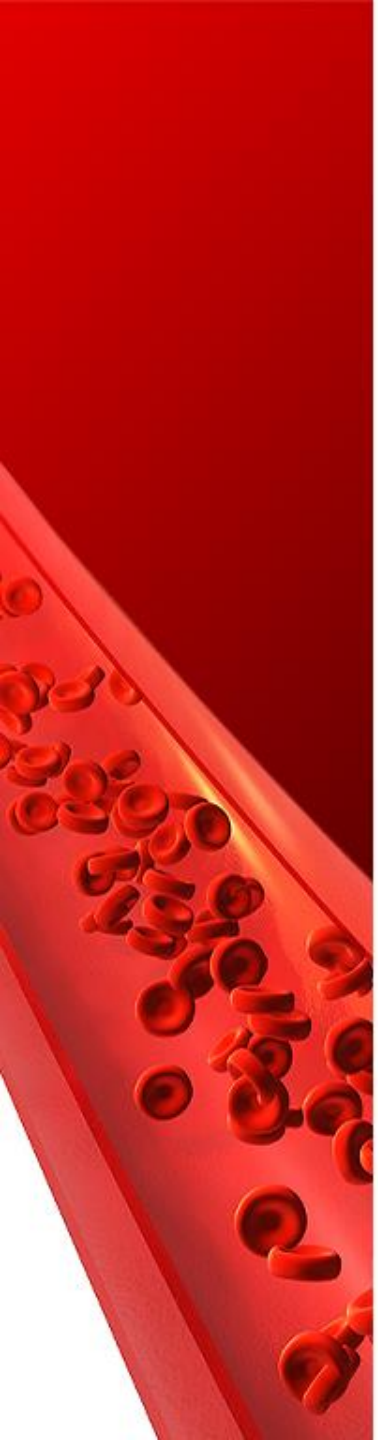



- Avoid unnecessary transfusions
  - SpHb stable when perceived to be dropping
  - SpHb rising when perceived to not be rising fast enough
- Identify post-op bleeding
  - SpHb dropping when perceived to be stable

https://vimeo.com/380128181/111cf4d17c

The aim of the project is to utilizing non-invasive technology (SpHb) to measure hemoglobin levels will provide clinical data less time than traditional invasive blood labs resulting in quicker clinical decision making and medical interventions.



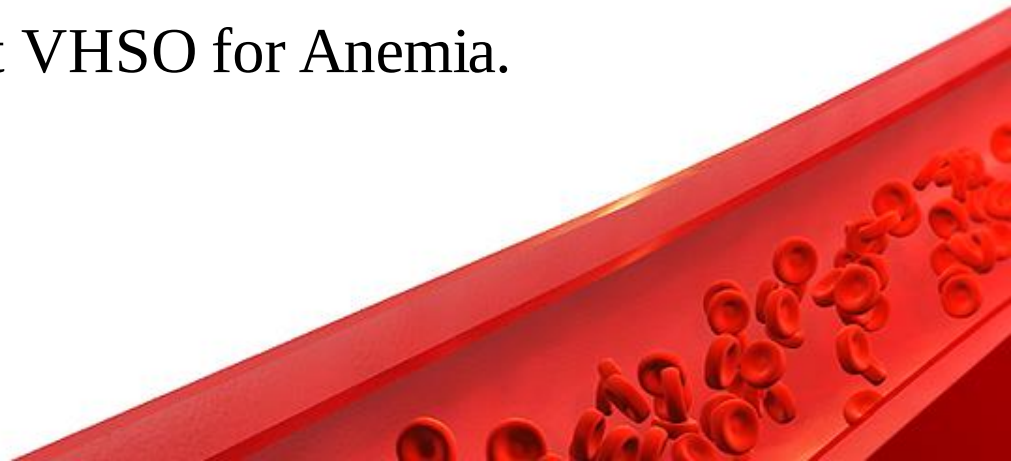


# Gap Analysis

- **How will clinical non-invasive hemoglobin monitoring correlate with invasive hemoglobin blood labs?**
- **WHY?** Will clinical non-invasive hemoglobin monitoring correlate with invasive hemoglobin blood labs
- **Why?** Can a valid tool be introduced to reduce the amount of touchpoints
- **WHY?** Realtime trends for hemoglobin level reduce the amount of blood hemoglobin to be drawn.

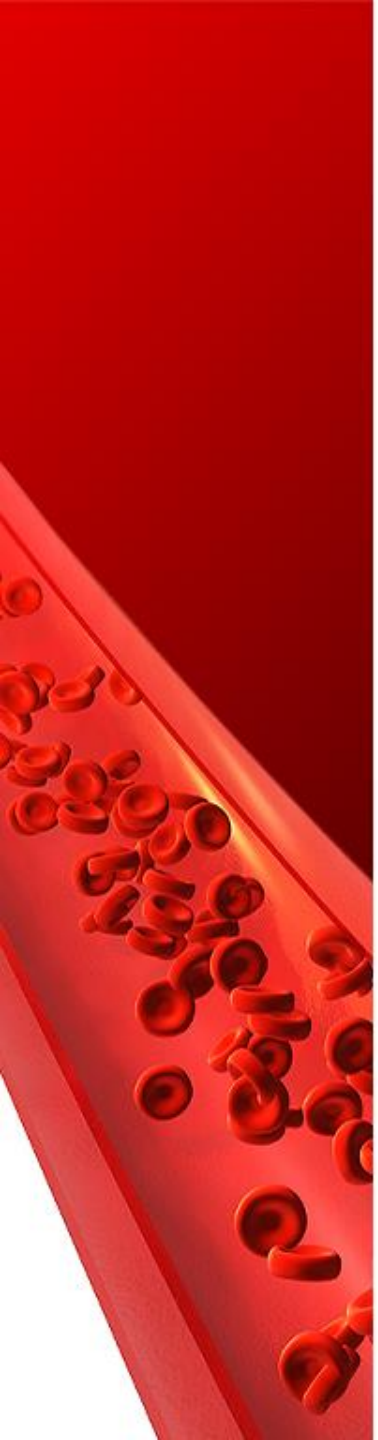
# Gap Analysis

- **To what extent will non-invasive hemoglobin monitors improve Phlebotomists' non-value touchpoints affecting lab TAT?**
- **WHY?** There are many steps between ordering labs and receiving the lab results
- **Why?** Can a tool be introduced to reduce the amount of touchpoints
- **Why?** There has never been non-invasive technology tool used or validated to decrease clinical decision-making intervention time at VHSO for Anemia.



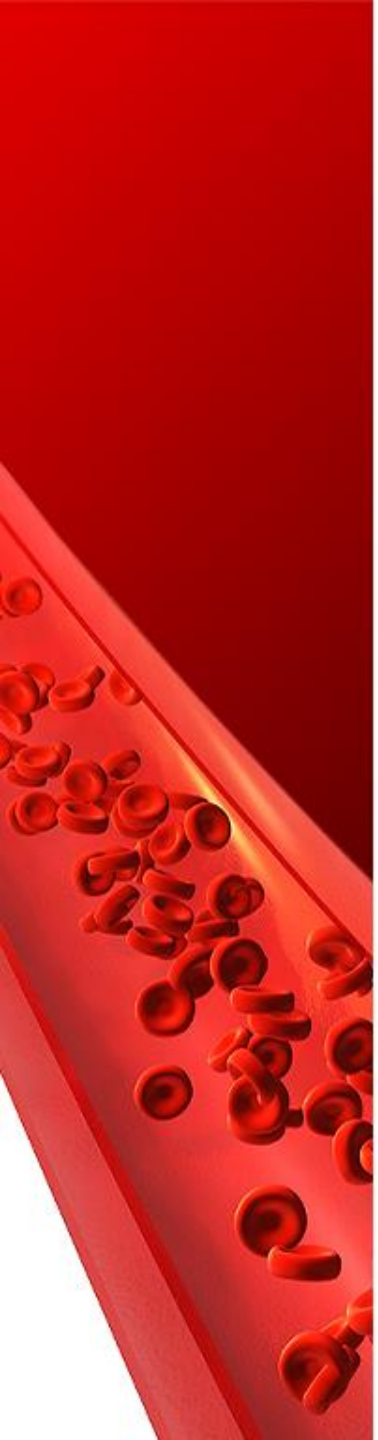
# Literature Review

Continuous SpHb Monitors



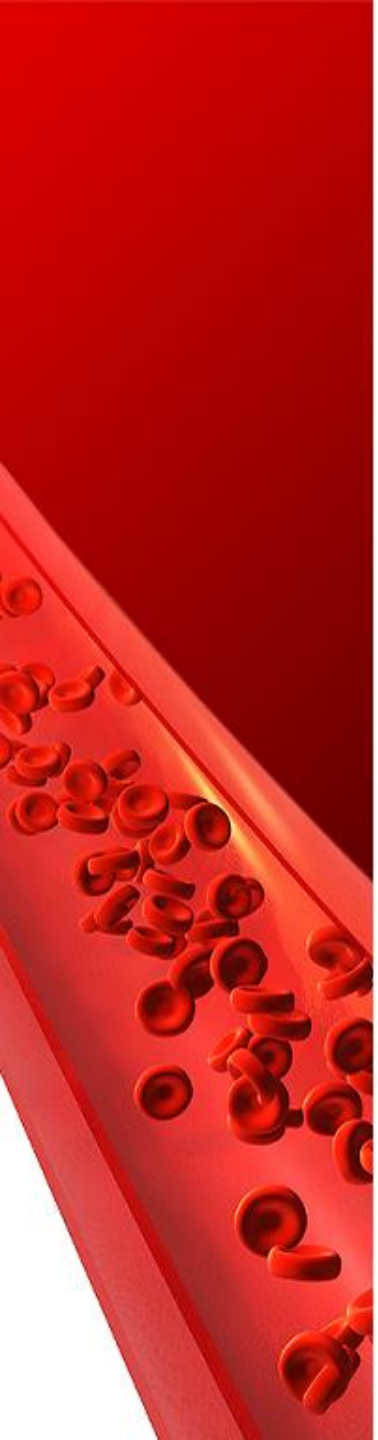
# Continuous Noninvasive Hemoglobin Monitoring Estimates Timing For Detecting Anemia Better Than Clinicians: A Randomized Controlled Trial

- Purpose:
  - Investigate the accuracy of the timing of clinicians' decision-making when they are using non-invasive, continuous, and real-time monitoring to obtain a blood hemoglobin level during a surgical procedure.
- Tang et al. (2019).

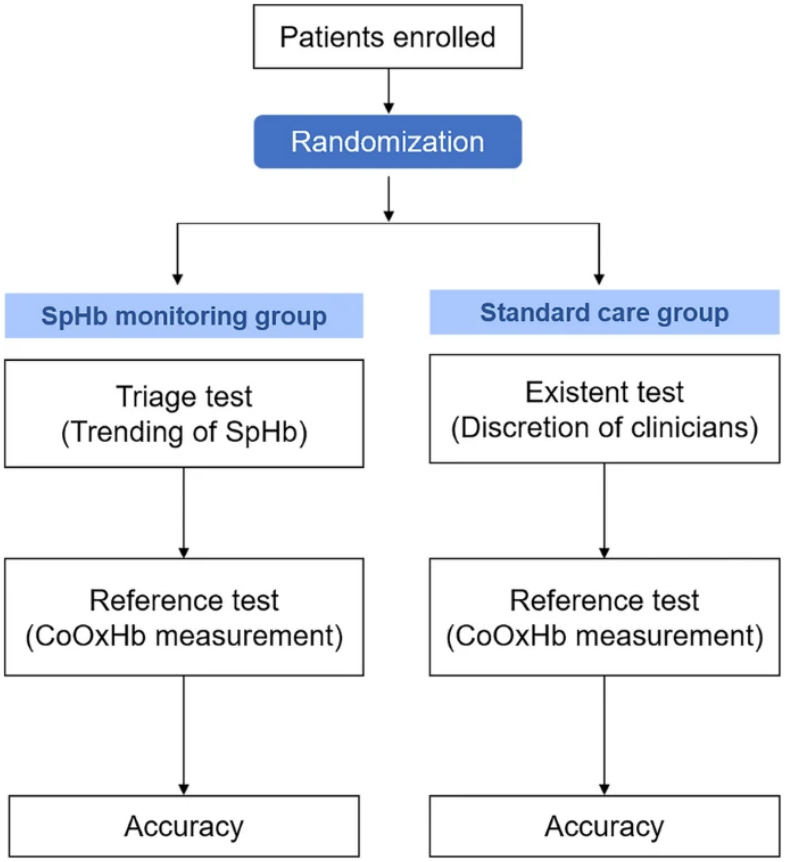


## Continuous Noninvasive Hemoglobin Monitoring Estimates Timing For Detecting Anemia Better Than Clinicians: A Randomized Controlled Trial cont:

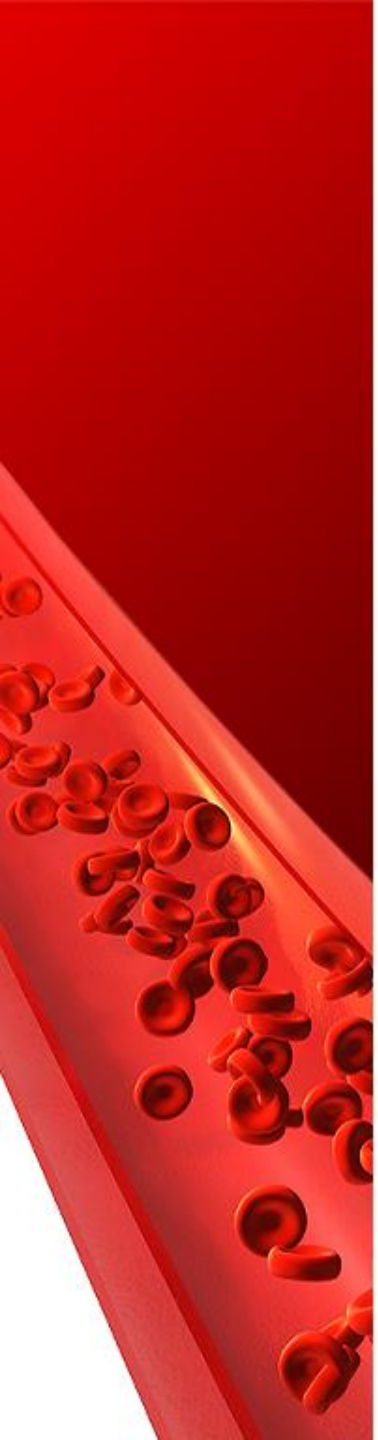
- Methods:
  - Diagnostic randomized controlled trial
  - Patients undergoing spine or cytoreductive surgery were randomly enrolled into SpHb-monitoring and standard-care groups.
  - Diagnostic blood samples were drawn when the SpHb decreased by 1 g/dl or at the clinician's discretion in the standard-care group.
- Tang et al. (2019).



# Method




**Tang et al. (2019).**



# Continuous Noninvasive Hemoglobin Monitoring Estimates Timing For Detecting Anemia Better Than Clinicians: A Randomized Controlled Trial

- Results:
  - 69 patients completed the protocol and were included in the analysis.
  - The incidence of unnecessary Hb measurement was lower in the SpHb monitoring group than in the standard care group.
  - Patient monitored with SpHb detected changes in LabHb >1.0g/dl, 93.3% of the time vs. 54.5% based on Clinicians perception ($p = 0.002$).

- Tang et al. (2019).

**Validity of accuracy and trending ability of non-invasive continuous total hemoglobin measurement in complex spine surgery: a prospective cohort study**

- Purpose:
  - Validate the accuracy and trending ability of SpHb measured using Radical-7™ Pulse CO-Oximeter during major spine surgeries.
  - complex spine surgery present with multilevel spinal associated with major blood loss and hemodynamic changes.
  - Accurate and rapid measurement of hemoglobin concentration is crucial during the decision-making process for fluid and transfusion therapy in complicated surgical procedures.

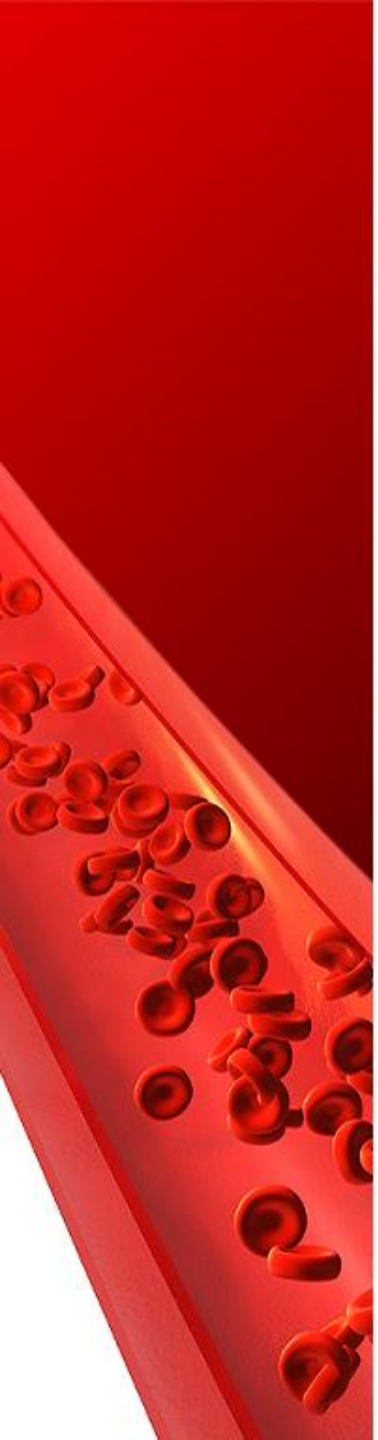
Chang et al. (2019)

**Validity of accuracy and trending ability of non-invasive continuous total hemoglobin measurement in complex spine surgery: a prospective cohort study**

- Method:
  - Forty-nine patients who underwent complex spine surgery.
  - A total of 272 pairs of SpHb-tHb data, divided into two groups based on the perfusion index (PI): PI values $\geq 1.0$ (n = 200) and PI values $< 1.0$ (n = 72).
- Chang et al. (2019)

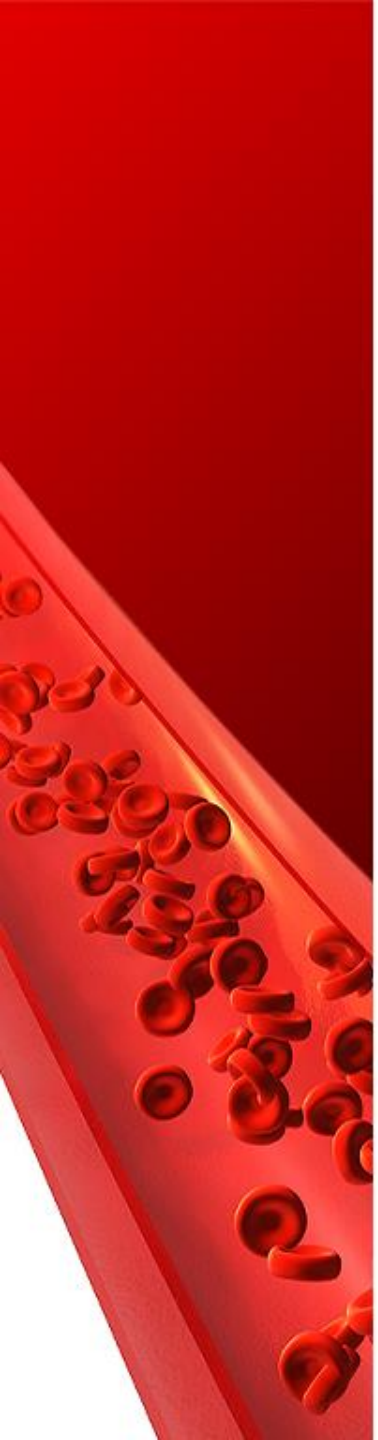
**Validity of accuracy and trending ability of non-invasive continuous total hemoglobin measurement in complex spine surgery: a prospective cohort study cont.**

- Result:
  - The correction coefficients (r) between SpHb and tHb were 0.6946 and 0.6861 in the groups with PI values ≥1.0 and < 1.0, respectively (P < 0000.1).
  - Acceptable accuracy of the Masimo Radical-7™ Pulse CO-Oximeter in measuring the hemoglobin concentration even under low perfusion index levels.
  - Trending ability of this monitor is limited and unsatisfactory, it may be used as a reference for making decisions with regard to transfusion therapy for complex spine surgery.
- Chang et al. (2019)



## Accuracy of a continuous noninvasive hemoglobin monitor in intensive care unit patients

- Purpose:
  - To determine whether noninvasive hemoglobin measurement by Pulse CO-Oximetry could provide clinically acceptable absolute and trend accuracy in critically ill patients, compared to other invasive methods of hemoglobin assessment available at bedside and the gold standard, the laboratory analyzer.
- Frasca et al. (2011)



## Accuracy of a continuous noninvasive hemoglobin monitor in intensive care unit patients

- Method:
  - This prospective, observational study was conducted in a 15-bed surgical ICU at the University Hospital in Poitiers, France.
  - Patients admitted to the ICU and in need of arterial blood draws for standard care were enrolled in the study.
  - Laboratory assessment of hemoglobin was regarded as the gold standard, and the satellite lab CO-Oximeter and pulse CO-Oximeter as methods of comparison.
  - Invasive hemoglobin values were compared to the noninvasive hemoglobin values obtained at the time of the blood draw.
- Frasca et al. (2011)

**Accuracy of a continuous noninvasive hemoglobin monitor in intensive care unit patients cont.**

- Results:
  - 62 subjects were monitored with the SpHb device from 1 to 15 days, with a median monitoring time of 6 days
  - A total of 471 samples were drawn with an average of 8 ± 4 samples taken per patient.

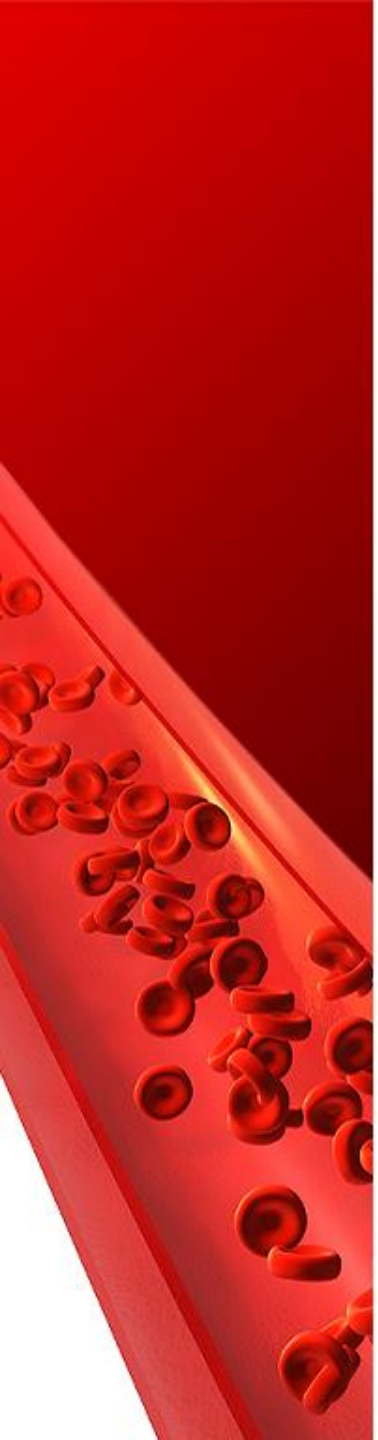
- Frasca et al. (2011)

## Accuracy of a continuous noninvasive hemoglobin monitor in intensive care unit patients cont.

- Results cont:
- Case-to-case variation was assessed, the bias and limits of agreement were
  - 0.0 ± 1.0 g/dL for the Pulse CO-Oximeter,
  - 0.3 ± 1.3g/dL for the point-of-care device
  - 0.9 ± 0.6 g/dL for the satellite lab CO-Oximeter
- Pulse CO-Oximetry showed similar trend accuracy as satellite lab CO-Oximetry.
- SpHb may facilitate hemoglobin monitoring in the intensive care unit.
- Frasca et al. (2011)

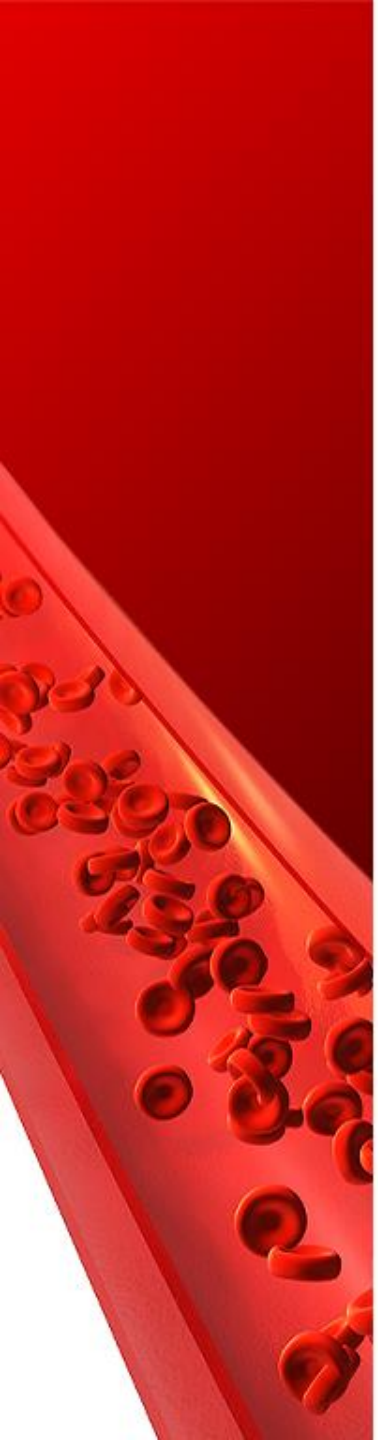
# Masimo Rad-67 Spot-check SpHb

# Literature Review



# The usefulness of non-invasive co-oximetry hemoglobin measurement for screening pre-operative anemia

- Purpose:
  - This study investigated the accuracy of non-invasive hemoglobin measurement using the Masimo Rad-67™ Rainbow compared with formal laboratory testing and its usefulness in detecting pre-operative anemia.
  - Identification of an accurate hemoglobin point-of-care test in pre-operative assessment clinics is crucial to reducing waiting time and improving patient satisfaction.
  - The secondary objective was to investigate the usefulness of the Rad-67 Rainbow in detecting pre-operative anemia (LabHb < 13.0 g.dl−1).
- YH ke et al. (2021).



# The usefulness of non-invasive co-oximetry hemoglobin measurement for screening pre-operative anemia

- Method:
  - This was a prospective, observational study conducted in the pre-operative assessment clinic of a tertiary hospital in Singapore from February to October 2019.
  - A total of 392 patients had measurements taken for non-invasive hemoglobin.
  - Blood collection for LabHb was performed within 1 h of the SpHb reading and analyzed within 4 h.
- YH ke et al. (2021).

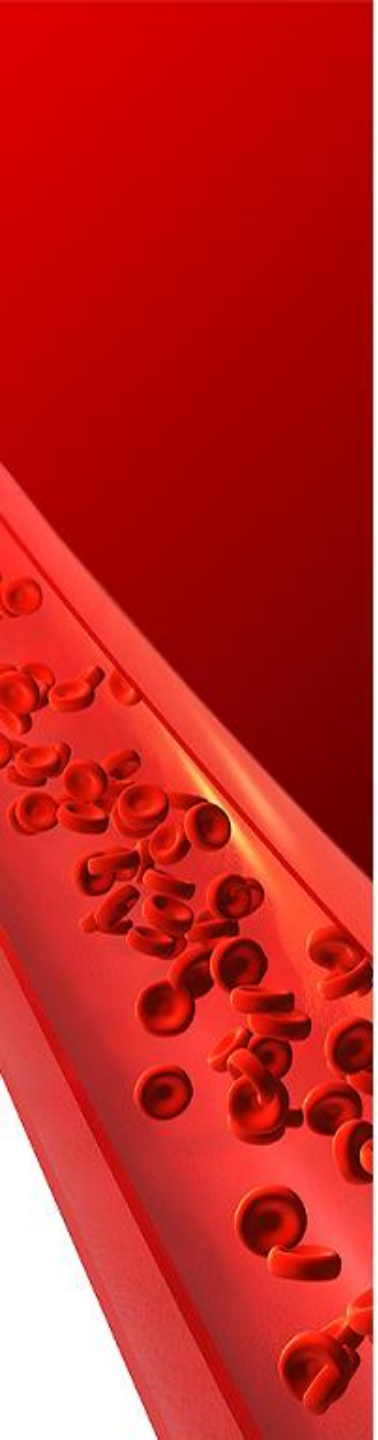
# The usefulness of non-invasive co-oximetry hemoglobin measurement for screening pre-operative anemia cont.

- Result:

**Table 2.** Pearson correlation and Bland–Altman pair-wise comparison analysis of co-oximetry haemoglobin (SpHb; $g.dl^{-1}$) and laboratory haemoglobin (LabHb; $g.dl^{-1}$)

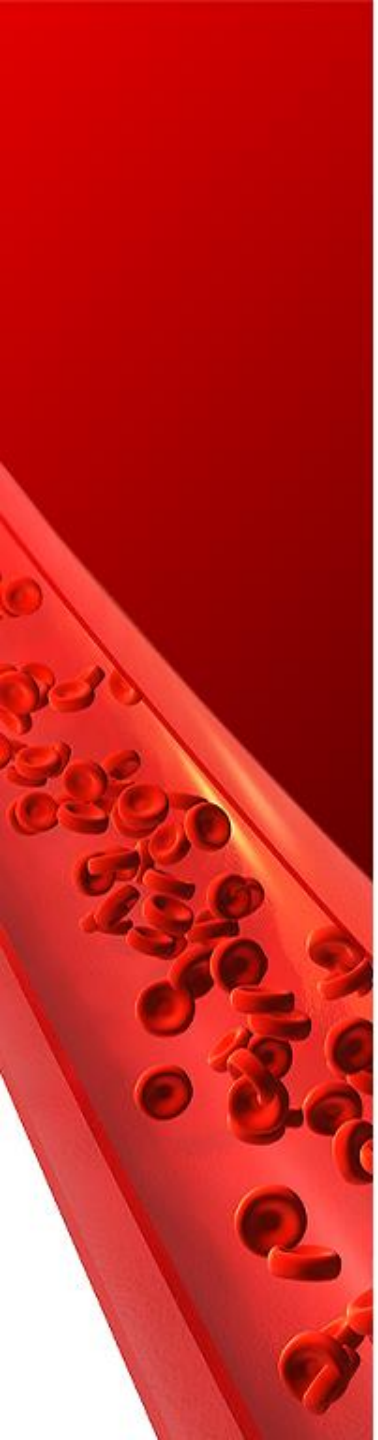
| SpHb | LabHb value mean (SD) | Linear regression SpHb with LabHb (95%CI) | Pearson coefficient | Bland–Altman Analysis | |
|---|---|---|---|---|---|
| | | | | Bias (mean (SD) [95%CI]) | Agreement limits |
| Overall | 13.6 (1.6) | < 0.001 (0.56–0.66) | 0.76 | 0.14 (1.07) [0.04–0.24] | [2.24 to −1.95] |
| Women | 12.6 (1.3) | < 0.001 (0.47–0.63) | 0.68 | 0.38 (0.99) [0.24–0.52] | [2.31 to −1.57] |
| Men | 14.4 (1.4) | < 0.001 (0.44–0.65) | 0.65 | −0.08 (1.09) [−0.23 to 0.07] | [2.06 to −2.23] |

YH ke et al. (2021)



## The usefulness of non-invasive co-oximetry hemoglobin measurement for screening pre-operative anemia cont.

- Result cont:
  - The Rad-67 Rainbow is inadequate for the estimation of formal laboratory hemoglobin and lacks sensitivity for detecting pre-operative anemia, especially in women.
  - The device has also not been tested in other clinical scenarios such as hypovolemia in emergency surgery.
- YH ke et al. (2021).



# Evaluation of the usefulness of non-invasive serum hemoglobin measurement in a perioperative setting in a prospective observational study

- Purpose:
  - The aim of this study was to evaluate the usefulness of hemoglobin (Hb) measured non-invasively (SpHb) in preoperative screening for anemia.
  - Anemia was defined as a LabHb value $< 12$ g $dl^{-1}$ in women and $< 13$ g $dl^{-1}$ in men according to the World Health Organization (WHO).
- Honnef et al. (2022)

**Evaluation of the usefulness of non-invasive serum hemoglobin measurement in a perioperative setting in a prospective observational study cont.**

- Methods:
  - Adult patients undergoing examination for surgery who had their Hb measured by laboratory means also had their Hb measured non-invasively by a trained health care provider.
  - Non-invasive, fast, and inexpensive means of hemoglobin measurement could reduce both these unwanted aspects of testing and the number of non-recognized anemic patients.
- Honnef et al. (2022).

**Evaluation of the usefulness of non-invasive serum hemoglobin measurement in a perioperative setting in a prospective observational study cont.**

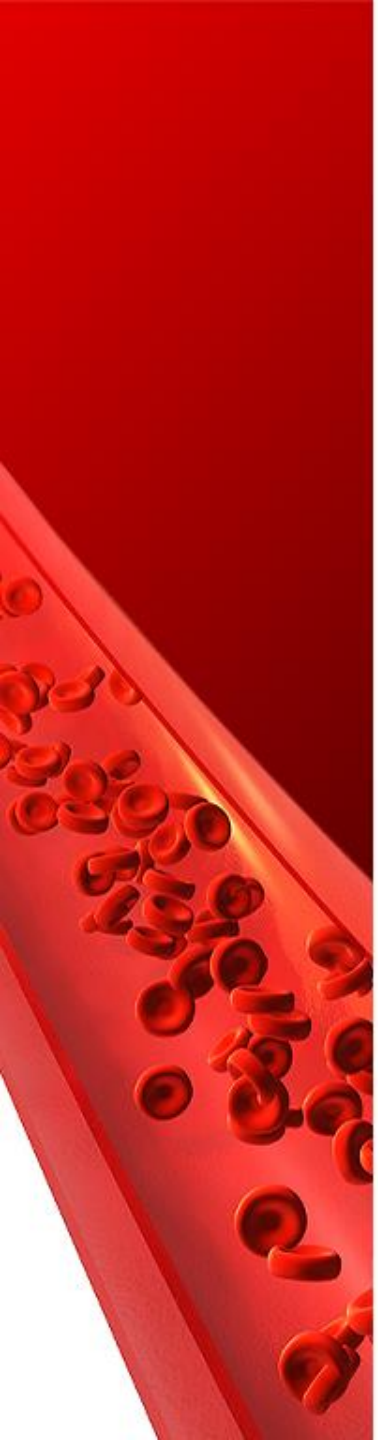
- Methods:
  - Prospective observational study conducted in the preoperative clinic of the Department of General Anesthesiology at the Medical University of Graz, Austria.
  - Blood samples drawn no more than one month before preoperative evaluation, if the patient was in a stable condition
  - Non-invasive Hb measurements were performed with available LabHb values and Rad-67™ Spot-check Pulse CO-Oximeters®
- Honnef et al. (2022).

**Evaluation of the usefulness of non-invasive serum hemoglobin measurement in a perioperative setting in a prospective observational study cont.**

- Result:
  - Mean LabHb was
    - $14.1 \pm 1.5$ g dl−1 overall,
      - $14.9 \pm 1.3$ g dl−1 in men,
      - $13.4 \pm 1.3$ g dl−1 in women.
    - Mean SpHb
      - $14.2 \pm 1.4$ g dl−1 overall
      - $14.7 \pm 1.4$ g dl−1 in men
      - $13.8 \pm 1.5$ g dl−1 in women.
- Honnef et al. (2022).

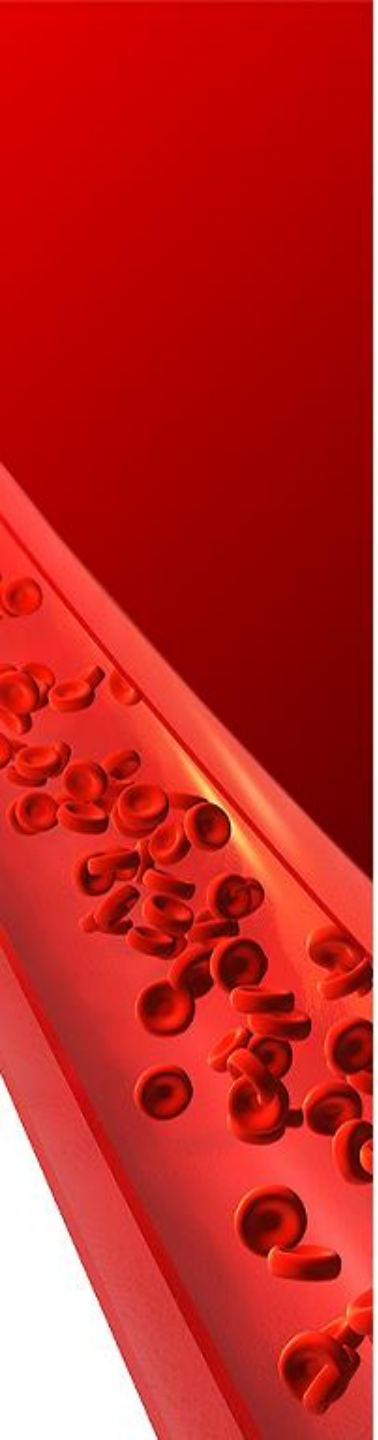
**Evaluation of the usefulness of non-invasive serum hemoglobin measurement in a perioperative setting in a prospective observational study cont.**

- Results:
  - Sensitivity of SpHb to detect anemic patients
    - 0.50 (95% CI 0.37–0.63) in women
    - 0.30 (95% CI 0.18–0.43) in men;
  - Specificity
    - 0.93 (95% CI 0.84–1.0) in women
    - 0.97 (95% CI 0.95–0.98) in men.
- Honnef et al. (2022).



**Evaluation of the usefulness of non-invasive serum hemoglobin measurement in a perioperative setting in a prospective observational study cont.**

- Data suggest that the accuracy of SpHb measurement is insufficient to replace invasive blood sampling in the preoperative evaluation of patients' hemoglobin status. Therefore, we had to reject the hypothesis that SpHb measurement is useful in preoperative screening for anemia.
- Honnef et al. (2022).



# Six Sigma Project

- Purpose:
  - The purpose of this six-sigma lean green belt project was to identify the reliability and feasibility of using an SpHb to identify anemia among at-risk hospitalized Veterans.
- Objective:
  - SpHb may be useful to monitor people for acute anemia, reduce touchpoints for phlebotomists, decrease serial blood draws, increase patient comfort, decrease unnecessary blood transfusions, and improve clinical decision-making time.

# Six Sigma Project cont.

- <u>Method:</u>
  - Masimo rad 67 SpHb was used to identify non-invasive hemoglobin values from a finger probe from 58 Veterans in the emergency department and outpatient lab clinic.
  - Simultaneously, lab-based hemoglobin was gathered via blood draws from the same limb
  - Data were collected on whether patients were fasting or dehydrated during lab draws.
  - The time from lab draw to results (TAT) was recorded

# Six Sigma Project cont.

**What I collected:**

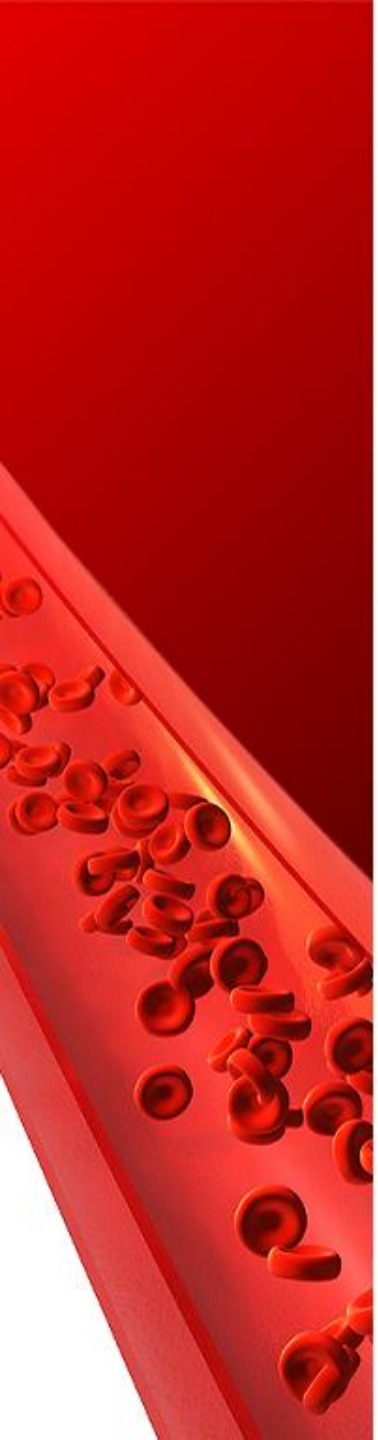
- For ICU SpHb monitor Value: _____ Time: _____
- Blood Hemoglobin Value: _____ Time:_____
- Phlebotomist: Lab Date, SPHB Value and Time
- Lab received time
- Blood hemoglobin result time
- If there was a Type and cross order

# Six Sigma Project cont.

- <u>Results:</u>
  - There was not a significant correlation between fasting hemoglobin levels (n=17, *r*=.16, p =.53) via lab draw [14.86 ±1.25] compared to SpHb [12.67 ± 1.33].
  - There was a significant correlation (n=41, *r*=.78, p <.001) between SpHb [12.84 ± 1.69] and lab hemoglobin [13.20 ± 1.83] among Veterans who were not fasting or dehydrated.

# Six Sigma Project cont.

- <u>Results cont:</u>
  - Lab turnaround time for 24-hour monitoring (blood draws every 3-4 hours) was ~8.5 hours.
  - Average TAT for STAT labs 42 mins.
  - SpHb provides immediate Hgb



# Future Recommended Studies

- The effects of fluid on SpHb
- Capillary blood in natural state.
- Invasive lab values catching up with non-invasive values.

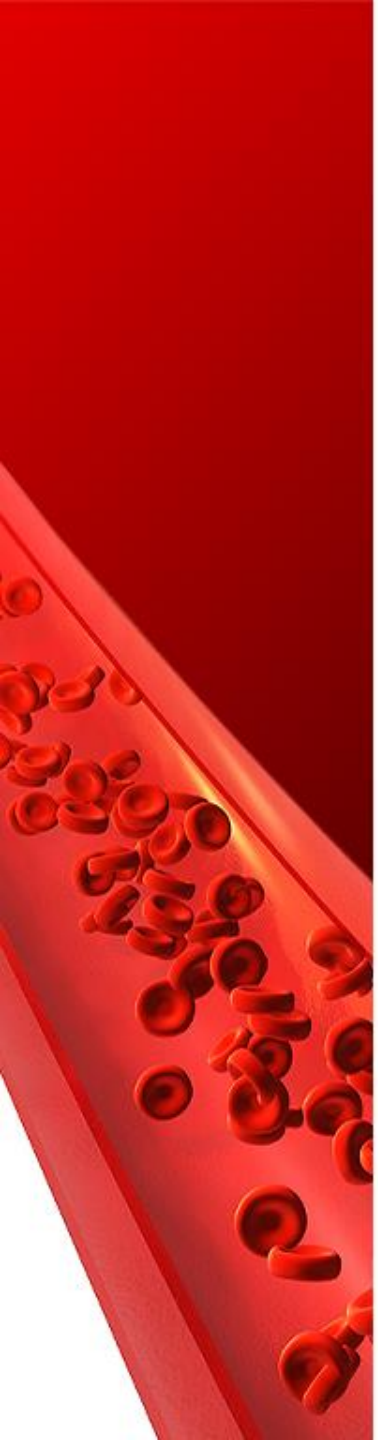
# Examples Blood Loss and Dehydration

**Blood Loss**

| SpHb | LabHb |
|---|---|
| 13.3 | 12.8 |
| 11.1 | 10.1 |
| 10.8 | 9.3 |
| | |
| 11.1 | 9.5 |
| | |
| 11.8 | 9.8 |
| 9.9 | 7.9 |

**Dehydration**

| SpHb | LabHb |
|---|---|
| 13.8 | 15.1 |
| 11.8 | 13.5 |
| 12.4 | 13.9 |
| Baseline | Preop |
| 12.3 | 17.6 |
| | |
| | |
| | |



# Speculation

| Bleeding (Invasive) | True Value Natural Environment (Non-invasive) | Dehydration (Invasive) |
|---|---|---|
| 9.3 | 10.8 | 12.5 |

# Conclusion

- Non-invasive hemoglobin monitoring (SpHb) is feasible and significantly correlated to blood lab hemoglobin values among people without fluid restrictions or dehydration. SpHb can significantly reduce lab turn around time, decrease costs from multiple blood draws, improves patient comfort, decreases biomedical waste, and improve clinical decision-making time.

# Questions

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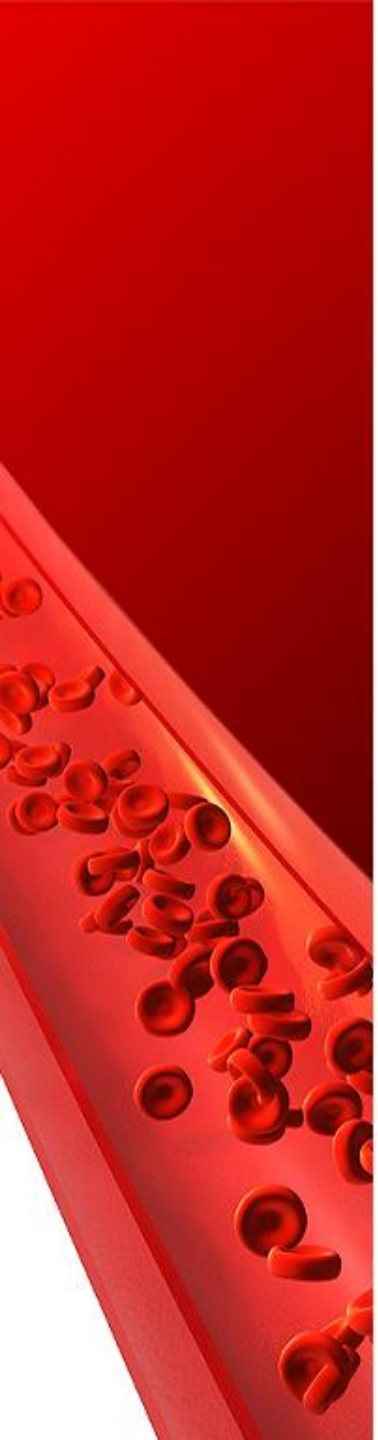

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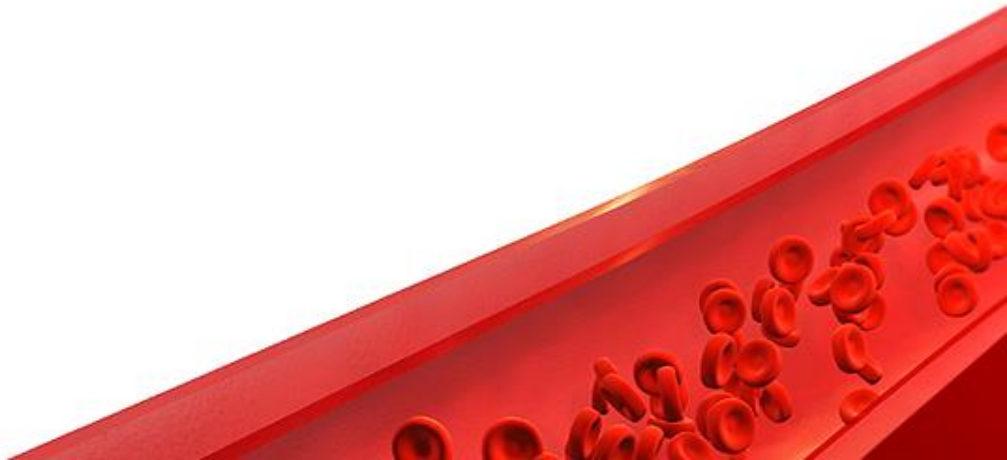
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