Thank You to the Southeastern Area Blood Bankers Association for inviting me to present at your Annual Meeting. An Overview and Perspectives For inviting me to present at your Annual Meeting. Food For Thought
K.C. Roberts, MS, CP, CCA
Founder/CEO VLI
Perioperative Blood Management Consultants - 1978

18 yrs Cardiovascular Perfusion

37 yrs Autologous Blood Salvage / Perioperative Blood Management

14 yrs Autologous Platelet-Leukocyte Enriched Plasma “Platelet Gel”

4 yrs President of the American Board of Clinical Autotransfusion

AABB Activities – Member since 1988
4 yrs Perioperative Standards Cmte. – Co-authored 1st & 2nd Editions + Guidance
3 yrs Perioperative Accreditation – Assessor
3 yrs Perioperative Accreditation Cmte. & Liaison to Quality Systems

31 yrs Allied Health Care Group Co-Owner Contract 3rd Party Provider of Perioperative Services
7 yrs Perioperative Consulting Services – To Hospitals & Private Groups
In the United States, Europe, Australia and Central America

My Avocation
25 yrs Professional Magician
Past “Atlanta Magician of the Year”
& Member of the Order of Merlin
International Brotherhood of Magicians
Personal Observations

“Blood transfusion medicine has to be one of the most important developments in the history of Medicine.

Without the high quality of blood banking, we enjoy today, here in the U.S., much of the progress in Medicine would never have happened, Especially in Surgery.”

I have learned so much through my association with blood bankers and the AABB. As a Clinician, Assessor & Consultant, the most important factors are:
• meeting everyone’s needs and
• how to integrate surgical scenarios with alternative transfusion options, that comply with current AABB Standards.

My observation in the operating room is…
If you choose not to know appropriate transfusion practices…
Then it simply becomes Magic!
Perioperative Blood Management is about…

“Intellectual Coherence”

- The Right Time
- The Right Things
- The Right Reasons.
“Perception is always an opinion…”

“It involves judgment by the observer.”

Believe it or not, these guys are all the same height.
Elements of the Surgical Safety Checklist

**Table 1. Elements of the Surgical Safety Checklist.**

<table>
<thead>
<tr>
<th>Sign in</th>
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<tbody>
<tr>
<td>Before induction of anesthesia, members of the team (at least the nurse and an anesthesia professional) orally confirm that:</td>
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<tr>
<td>The patient has verified his or her identity, the surgical site and procedure, and consent</td>
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<td>The surgical site is marked or site marking is not applicable</td>
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<td>The pulse oximeter is on the patient and functioning</td>
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<td>All members of the team are aware of whether the patient has a known allergy</td>
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<tr>
<td>The patient's airway and risk of aspiration have been evaluated and appropriate equipment and assistance are available</td>
</tr>
<tr>
<td>If there is a risk of blood loss of at least 500 ml (or 7 ml/kg of body weight, in children), appropriate access and fluids are available</td>
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<th>Time out</th>
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<tr>
<td>Before skin incision, the entire team (the surgeon, anesthesia professionals, and any others participating in the care of the patient) orally:</td>
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<tr>
<td>Confirms that all team members are present</td>
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<tr>
<td>Confirms the patient's identity</td>
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<tr>
<td>Reviews the anticipated procedure</td>
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<tr>
<td>Surgeon reviews critical aspects of the procedure</td>
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<tr>
<td>Anesthesia staff reviews critical aspects of the procedure</td>
</tr>
<tr>
<td>Nursing staff reviews critical aspects of the procedure</td>
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<tr>
<td>Confirms that prophylactic antibiotics are not indicated</td>
</tr>
<tr>
<td>Confirms that all essential imaging results for the correct patient are displayed in the operating room</td>
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<tr>
<td>Before the patient leaves the operating room:</td>
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<tr>
<td>Nurse reviews items aloud with the team</td>
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<tr>
<td>Name of the procedure as recorded</td>
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<tr>
<td>That the needle, sponge, and instrument counts are complete (or not applicable)</td>
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<tr>
<td>That the specimen (if any) is correctly labeled, including with the patient's name</td>
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<tr>
<td>Whether there are any issues with equipment to be addressed</td>
</tr>
<tr>
<td>The surgeon, nurse, and anesthesia professional review aloud the key concerns for the recovery and care of the patient</td>
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</tbody>
</table>

* The checklist is based on the first edition of the WHO Guidelines for Safe Surgery. For the complete checklist, see the Supplementary Appendix.

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**How is your facility assessing transfusion risks in the OR?**

*Is it evidence-based?*
The Basics
• What we do in the operating room
• What is driving our profession
• Supply and Demand
• Known & Unknown Risks
• Acceptable Practices

Blood Product Consistency
• Quality Systems
• Regulatory AABB Standards

Improvement Process
• Evidence-Based Outcomes
• Clinical & Cost Comparatives
Blood Flow Through the Cell Saver® System

1. Blood is suctioned from the wound and stored in a reservoir.
2. Waste is separated from red cells in a centrifuge bowl and sent to a bag.
3. Red cells are stored in a bag until transfusion back to the patient.

Blood Cell Separation Device Parameters

- Process Time 30cc to 1 Liter / minute
- Debris Removal 94% - 97%
- Hct. 55% - 65% (No Higher)
- Closed Circuit (Not really)

For Autologous Platelet-Leukocyte Enriched Plasma Closed Circuit
Autologous Blood Cell Separation

Continuous Centrifugation Process
For High or Low Blood Loss Procedures

Packed Red Blood Cells
Hct. 45% - 65%

Buffy Coat Platelet Concentrate
6 to 10 times Patient Plt. Count
The process of moving oxygen from the atmosphere to the inside of a cell is called the “Transport Chain.”
QUESTION
What surgeries currently benefit from Autologous Perioperative Blood Salvage and Blood Component Therapy?

ANSWER
Virtually any surgery where the surgeon feels a “type and screen” or “type and cross” is warranted will benefit from appropriately applied transfusion alternatives.

Or to “Jump Start” the Healing Process for Bone and/or soft tissue. Autologous Platelet-Leukocyte Enriched Plasma

Salvaged Autologous Blood compared to Allogeneic
- Higher 2,3 DPG > Oxygen Delivery – 30% more O² to the myocardium
- Higher ATP levels – Better O² Delivery to the micro-vascular system
- Does not suppress surgical patients’ immune systems
- Fewer Clerical Errors
- Lower use of PostOp Antibiotics
- Few Hospital Days
- Lower PostOp Costs – Tx related infections during postoperative care
Applications & Benefits to Surgeons, Anesthesiologists and Blood Bank

#1 Reducing the need for Pre-Depositing
- CAP Q-Probe 1996
- Immediate Collection
- Lowers Discard Rates for PABD
- Clinically superior approach

#2 May Reduce or Eliminate the need for allogeneic Tx for some surgical procedures

C-Sections (Eliminating Amniotic Fluid)
Gold Standard – Mother’s Blood

Equivalent to Mother's Blood
AABB Standards & Accreditation
“Autologous Perioperative Blood Collection and Administration”

ALL In-House & 3rd Party Providers operating Cell Separation Devices should have programs in place that are in compliance with appropriate Standards for perioperative autologous salvage & blood component therapy.

Am. Society of Extracorporeal Technology
BOARD CERTIFICATION – Device Operators
International Board for Perioperative Blood Management
Info at www.AmSECT.org
Trends That Are Driving Therapy and Clinical Practice

- Less Dependency on Allogeneic Blood and Components
- Inappropriate Use (allogeneic or autologous)
- Improved Patient Outcomes
- Cost Containment (CMS Sentinel Events – No Payment)
- Incorporating New Technology
- Quality Improvement
- Reducing Risks
- Regulatory Issues (AABB, JC, CAP, FDA)
- Information Databases
Supply, Demand, Safety and Costs - What Is Driving Our Profession Forward?
SUPPLY and DEMAND Issues

Aging Population
- >65 yrs 13% of US
- Will use 43% of all blood Tx
- >75% of patients >72 yrs will need Tx

Donor Deferrals
- Deferral Rate 12% - 15%
- New Deferrals – nvCJD, West Nile, SARS

Blood Bank Inventory
- Increased Frequency of < 1 day supply
BLOOD CRISIS

Red Cross Southern Region
Blood Center

DISCOVERY OF
“WHITE PARTICULATE MATTER”
110-120 Units of Donor Blood

Quarantine 75% Blood Supply

75% of Georgia Hospitals

Georgia Hospital Association 185 Hospitals

Quarantine Expands To Northern Florida

Surgery Cancellations Range 15% - 85%
Blood Crisis
Surgery Cancellations
Expands To Other States
Tennessee
North Carolina
Kentucky
Illinois
Missouri
Surgery Cancellations
Over Legal Concerns
Estimated at Greater Than 50%
Total Surgery Schedules Cancelled “No Blood Available”

Even Breast Biopsy Cancellations – Clearly Over Legal Concerns
Surgeons and Anesthesiologists Expectations of the Quality of Blood Transfused to Their Patients

Physicians working in more than one hospitals would rarely question if the blood was better at one hospital verses the other.

WHY?

Confidence in the blood bank’s abilities toward “Quality” and “Consistency.”

Predicting Outcomes
A Practical Demonstration

Welcome to My Magic Show

Predicting Outcomes
Blood Salvage, Processing and Component Therapy

Wouldn’t you expect the same in the operating room?

Today... We can’t make that guarantee.

WHY?

Too few perioperative blood management programs have policies, procedures and protocols for their services. Who’s responsible?

The hospitals’ transfusion services and providers are just now beginning to work together to form Perioperative Blood Management Committees.
Manipulating Outcomes

AVOID

Overlooking Poor Performance

So... What did we learn?

• Educational Programs
• Opportunities for Feedback
• Ability to *Quickly Implement* Change

FOCUS

Inappropriate Agendas

Garbage In... Garbage Out

Appropriate Outcomes

Accountability
Bridging The Gap

With AABB Standards & Accreditation

We are able to build an Observation Platform

Where both Surgery and Hospital Blood Banks can begin to measure Outcomes.
“Sometimes things are not what they seem to be.”

Avoid Trojan Horses

Real or Perceived
Evidence-based data
Tx Criteria

Fundamental Elements
Multi disciplinary by nature
Accountability
Economically Sound
Regulatory Compliance
Clinical information overload may contribute to the long lag time between the availability of evidence and its widespread practice, as discussed in the IOM quality reports To Err is Human (1999) and Crossing the Quality Chasm (2001).

Organizations and clinicians are struggling to stay current with contemporary transfusion practices and research in their fields.

More than 150,000 medical articles are published each month from more than 20,000 biomedical journals.

Avoid Information Overload

150,000 medical articles published each month from 20,000 biomedical journals.
Approaches to Blood Conservation
4 Main Areas

PreOp
- Pharmacology
- Predonation
- Hematologic Analysis
- ABCTherapy
- Transfusion
- Gene Therapy

Operative
- Surgical Technique
- Blood Salvage/Processing
- Synthetic Glue
- Autologous Platelet Gel

Anesthetic
- Pharmacology
- Plasma Expanders/Colloid
- Hypotension
- ANH
- Artificial Blood
- Volume Management

PostOp
- Blood Salvage/Processing
- Leukocyte Depletion
- Micro Blood Vol. Testing
- Hematologic Monitoring
- Ultrafiltration
How Knew Information Can Change Probable Outcomes - Example

What are the Odds and How strange would it seem to walk outside and see...

Until you received additional data... *Circus Music?*

**THE CIRCUS IS IN TOWN**
Sliding Scale – Decision Making Process

Gather & Measuring Data

Define Actionable Tx Pathways

The closer you get to the subject… The clearer the picture becomes.

Finding Optimal Transfusion Pathways

Tx Risks

Tx Alternatives
Background:
There are divergent views on the risks of anemia and the benefits of blood transfusion in critically ill patients.

Blood products - are not without risk, and unnecessary blood transfusion contributes to increased morbidity, costs, and, in some studies, mortality.

In an effort - to promote decision consistency and reduce the number of inappropriate blood transfusions, an evidenced-based transfusion guideline should be employed.

In patients **WITH** acute blood loss, consider RBC Transfusion if…

**Acute Blood Loss Volume?**
- > 20% of total blood volume, regardless of Hct (NV = 70ml/kg in adults)
In patient WITHOUT acute blood loss, consider RBC Transfusion if...

Hematocrit < 24, 26, 28, 30%?
- No: No Transfusion
- Yes: Patients at risk for ischemia?
  - No: No Transfusion
  - Yes: Age and Hematocrit Criteria:
    - No: Age < 40, Hct < 24% (if pt healthy, can tolerate lower hematocrit)
    - Yes: Age 40-65, Hct < 27%
    - Yes: Age > 65, Hct < 30%

Patient with signs/symptoms of acute anemia?
- No
- Yes: Angina/Dyspnea
  - Yes: Pulse Oximetry < 90% or PaO2 < 70mmHg
  - Yes: Mental status change
Government Driven

U.S. Congress acknowledges that bank blood transfusions have a negative *clinical* and *economical* impact on health care in the U.S.

Food and Drug Administration (FDA)

College of American Pathologist (CAP)


for

Perioperative Autologous Collection and Administration

Quality System Essentials (QSE’s)

#1: Organization
#2: Resources
#3: Equipment
#4: Supplier & Customer Issues
#5: Process Control
#6: Documents & Records
#7: Non-conformances
#8: Internal & External Assessments
#9: Process Improvement
#10: Facilities & Safety
ISO 9000 Process Chart

1. Identify your customers
2. Are you meeting customer needs / Expectations?
   - NO: Improve process
   - YES: Are processes well documented?
3. Are processes well documented?
   - NO: Begin documentation
   - YES: Rework into your standard format

Understand your customer needs and improve if necessary

Say what you do

Improvement Process
ISO 9000 Process Chart

- Do What you say
  - Follow procedures and documentation
    - Conduct registration audit
      - Pass?
        - YES: Pass?
          - NO: Perform gap analysis and corrective action
        - NO: Conduct surveillance audits
          - Pass?
            - NO: Perform gap analysis and corrective action
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                                                                - NO: Perform gap analysis and corrective action
                                                            - NO: Follow procedures and documentation
                                                                - NO: Perform gap analysis and corrective action
                                                            - NO: Do What you say
                                                - NO: Prove it
                                                    - NO: Improve it
                                                        - NO: Continue to follow and improve
                                                    - NO: Improve it
                                                - NO: Prove it
                                        - NO: Do What you say
Changing Transfusion Practices

Behavior Modification
2 Degree Course Corrections

Create Attainable Changes

Transfusion Practices are Deeply Engrained In Surgeons & Anesthesiologists Minds

SEND A CLEAR MESSAGE
The PBM Cmte. Exists to Provide Safe Tx Alternatives for Surgeons & Anesthesiologists

Do Not Send Mixed Signals
There are 11 human faces in the picture. Can you find them all?

Normal people find 4 or 5 of them.
If you find 8 of them, you have an extraordinary sense of observation.

If you find 9 of them, you have a sense of observation above the average.
If you find 10 of them, you are very observer.
If you find 11 of them, you are extremely observer.
Any Significantly Advanced Technology Is Indistinguishable From Magic
THANK YOU FOR
THIS OPPORTUNITY

Contact Information or Questions
Office 770-926-8969
bloodsaver@gmail.com