Informatics for the Blood Banker
Faculty Disclosures

The following faculty have no relevant financial relationships to disclose:

– Leana Rahman MPH, MT (ASCP), CQA (ASQ)
– Stephen Sugar
– Ronald Walsh MD

The following faculty have a relevant financial relationship:

– Noah Bentley MS, SBB (ASCP)
  Haemonetics Corporation: Stock Shareholder (self-managed)
Learning Objectives

• Identify the various steps in the implementation of Blood Bank software
• Summarize how Blood Bank software interacts with other clinical systems e.g. interface considerations
• Evaluate the use of informatics in Blood Management
Best Practices in Validation

Noah Bentley
MS, SBB(ASCP)
Overview

- Not a presentation about IQ/OQ/PQ
- Thought challenges in validation philosophy
- Research project findings
- Discuss validation questions that most of us have stopped asking
- Leave you with data-driven analysis to help make validation more meaningful
- Show ways to use validation data to improve your blood bank
What we know

- Validation takes a long time
- There is little consensus about how to validate
- Resources will always be constrained
- No two projects are ever the same
- Worry about audits and inspections is stressful
- Deciding what to validate and how much to test is complicated
What we *don’t* know

- Is more testing better?
- How much is enough?
- What is an acceptable failure rate?
- How do we decide which safety functions should be tested more?
- After validation is complete, what knowledge can I apply to run my blood bank better?
Retrospective research analysis

- 325 Validation projects over six years
- Donor Centers, Transfusion Services and Plasma Centers
- Wide spectrum of organizations
- Very diverse BECS systems
- 35,019 Test case procedures
- 1,013 Failures
Broad and diverse BECS software

**Donor Centers**
- SafeTrace Donor
- EL Dorado Donor
- Donor Doc
- Donor Doc Phlebotomy

**Plasma Centers**
- DMS
- NextGen

**Transfusion Services**
- SafeTrace Tx
- McKesson Blood Bank
- Cerner Millennium PathNet
- HL7 Manager
- Instrument Interface Manager
- BloodTrack
- InstaMatch
Common Findings

- Often not sure how or where to start
- Few blood banks have a validation SOP
- Most want to run test cases right away, without a lot of planning
- Hope that if they run a large number of test cases, then everything will be okay
- Rarely compliant with their validation master plan or even have one
## Details through data

<table>
<thead>
<tr>
<th>Hardware</th>
<th>Labeling</th>
<th>Anomalies</th>
<th>Table Config</th>
<th>Eligibility</th>
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Should every regulated system require similar degree of validation?

- HL7 Interfaces
- Instrument Interfaces
- Remote Blood Storage

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Do all safety functions need the same degree of validation?

- Deferrals
- Test Results
- Reports
- Hardware

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New models to consider

- Very inefficient to try to find bugs. Data indicates time is better spent focusing on configuration settings.
- Many of the functions we think are high safety risk show very few, or zero failures.
- We might better benefit from investing time and resources to design and document configuration settings, and focus on SOPs before starting validation.
Conventional wisdom sometimes isn’t

<table>
<thead>
<tr>
<th>Where we think we should focus</th>
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<tbody>
<tr>
<td>Blood Typing Test Results</td>
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<td>Electronic Crossmatch</td>
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<td>Physical Exam Results</td>
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<td>Collection Types</td>
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<td>Manufacturing Processes</td>
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<td>Recovered Plasma</td>
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<td>Infectious Disease Testing</td>
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<td>Delivery and Shipping</td>
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<th>Where the data says we should focus</th>
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<td>Special Needs Not Met</td>
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<td>Blood Loss Calculations</td>
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<td>Intended Use Factors</td>
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<td>Blood Type/Test History Mismatch</td>
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<td>Component Status Changes</td>
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Take away messages

- More testing isn’t always better
- Take your time to design and plan
- Focus on what matters most… it might not be what you think
- Don’t deviate from your plan
- Follow the chronology of your validation SOPs
- Create and maintain defensible documentation
Where to go for help

- Code of federal regulations
- FDA guidance documents
- Minutes from “Ask the FDA” sessions
- AABB standards
- GAMP
- Software support users group
Questions
What’s the best approach

- Risk assessment
- The right people
  - Expert product knowledge
  - Regulatory/Quality background
- Standardized techniques
- Experience to know what matters and what doesn’t matter
- Detailed process that maps every risk to actions and outcomes
- Consistent documentation to withstand inspections and audits
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
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</table>
| Validation plan                 | • Details of what, how, who, when and why  
                                      • Documented authorization before testing starts |
| Risk analysis                   | • Trace every control function to at least one test scenario  |
| Test case procedures            | • Each with discrete objective, controlled steps and screen output documentation  |
| Test cycle management           | • Controlled investigation, resolution, and reexecution of failed tests  |
| Review affidavits               | • Organized and controlled approvals at every step, exactly as described in Validation Plan  |
| Validation report               | • Details deviations, failures and investigations, summarizes outcome and documents approval for go-live  |
Must do’s

- Name all deliverables and sections within deliverables according to FDA nomenclature
- Ensure that validation plan is approved prior to starting any testing
- Monitor failure rate closely, if suspiciously high then you’re not ready to validate
- Avoid creating any document which is not described in regulations
- Do exactly what your SOP and validation plan states, or revise it
- Follow the risk analysis, avoid under testing and over testing
- Make sure that the validation report covers the full chronology of outcomes, and that it is approved prior to go live
Best practices in an inspection

Don't speculate. Ask your validation resource or ask the validation vendor.

Answer the question asked.

Demonstrate compliance with validation SOP and validation plan.

Unwrap the project from the outside-in:
- Start with Validation Report
- Move backward through test case procedure cycles
- End with risk analysis and validation plan.
Questions
IT section

• System integration
  – What your interface engine can do for you
• Business continuity
System Integration

- BB systems are stand alone (most of the time)
- System requirements
  - Patient data - ADT
  - Orders
  - Results
  - Charges
- All accomplished by industry standard HL7
System integration

- The interface engine brings all systems together.
- It is the U.N. of computer systems.
- It can translate messages between systems so they each understand each other.
- It can filter out unwanted messages.
- It can store data from an order and put it back on the result.
- If you can define the logic, it can be coded.
System Integration

• Three examples of how the interface engine can work for you.
  – Do you need every ADT sent from your HIS?
  – Fix result messages with data from the initial order so they file.
  – Split product results from test results to feed separate HIS interfaces.
Do you need that ADT?

- Do we need every ADT message created by the HIS?
- We have ADT messages being fed by two HIS systems for different hospitals.
- Montefiore sends out about 100,000 messages a day
- Mt Vernon and New Rochelle send 9,000
- Our BB system only processes 60,000
Do you need that ADT?

• An interesting/annoying event occurred a few years ago
• Our HIS started flooding our ADT interface every morning just after 2am.
• Our on-call person complained they were being alerted of interface issues, but found nothing wrong.
  – We have a monitoring job that alerts us if our interface backlog is >500 messages. Runs every 30 minutes
Do you need that ADT?

• Contacted our HIS interface team if anything happened that night.
• They reported no errors, everything was fine
• Problem continued for a couple of days.
• Blood bank started calling about ED and newborn registrations being delayed during the 1.5 hours it took to clear up.
• Rebellion started with the on-call person.
• So we suspended the interface check between 2am and 3am, and escalated our investigation.
Do you need that ADT?

• Turns out we were asking the wrong question.
• Asked if there was an increase in volume during this time frame and could they identify the source.
• Miraculously they were able to tell us that our financial team scheduled an insurance verification job to run at 2am.
  – This would send out between 3000 and 5000 ADT messages to downstream systems in 20 minutes.
Do you need that ADT?

- We learned each of these messages had key identifiers
- Wrote a rule in our engine to drop all ADT messages that have these identifiers.
- Our BB system doesn’t store insurance, so the ADT update to the patient was useless.
- This resolved the delays for ED and newborn registrations.
- Made the blood bank a little happier.
Another interesting use of our engine came to solve a problem with an unknown cause.

Results would fail into the LIS and never get sent to the HIS.

Our old LIS required the same account sent with an order be returned with the result.

We needed to fix result messages to have the correct account that the order was placed on.

Somehow when activating the electronic order in the blood bank the account could get changed.
Result Message Fix

• Our investigation showed orders would go out correctly to the BB.
• When resulting would not have the correct account – sometimes.
• During this investigation we found our LIS was also updating collection date/time to the resulting date/time.
Result Message Fix

• Came up with a why not scenario for the engine.
  – When order sent to BB store the MR, account, order number, collection date to a table in the engine.
  – When result is returned lookup the MR and order in the table. If the account is wrong, put the correct one back.
  – Change the date field the LIS was using to update collection to actual collection date
Product Result Splitting

• Our HIS needs to see product messages differently from test results.
• Our old LIS would bundle all products under the same interface transaction, and looked like block of text.
• The HIS wanted each unit as its own message.
• This allowed the products to be used in the blood administration module.
Devised a simple routing rule to send a copy of each product message directly to the HIS.
The routing rule was based on a table of Blood product order codes.
Added logic on the LIS result outbound to now drop all product messages.
  – Eliminated duplication of the result in the HIS
When we switched to a new LIS the rules were maintained to continue splitting products.
Business Continuity

• Business continuity vs. Disaster recover
• Identical virtual servers in two data centers vs. tape restores at remote data center.
Business Continuity

- Business Continuity is the model we are using to replace our original disaster recovery configuration.
- Original disaster recovery model consisted of:
  - Data center miles away – upstate NY
  - Could take between 24 and 72 hours to complete
  - Data was from your last backup before the system went down.
Business Continuity

• Virtual servers use a site recovery manager tool to migrate to the standby server in less than 15 minutes.

• DB tools have options to keep a standby DB in sync up to the last transaction.
  – Activate the standby DB to become primary. Takes minutes and not hours

• Update logical server names to point to active servers.
Business Continuity

- Our goal is to run 6 months of the year in each of our data centers.
- Confirms functionality for when you need it.
- Nothing worse than having to go to paper.
Using Informatics to Support Patient Blood Management

Ronald Walsh, MD, FASCP
Medical Director, Transfusion Medicine
Health Network Laboratories
Patient Blood Management (PBM)

• SABM definition
  - PBM is the timely application of evidence-based medical and surgical concepts designed to maintain hemoglobin concentration, optimize hemostasis, and minimize blood loss in an effort to improve patient outcome.

• AABB definition
  - PBM an evidence-based approach to optimizing the care of patients who might need transfusion.
PBM
PBM- Why Is It Important

• Supply issue

• Costs

• Risks of transfusions → Patient safety

Slide courtesy of Huy Pham, M.D.
PBM- Why Is It Important?

• 10 studies published in The New England Journal of Medicine have supported restrictive transfusion strategies.

• Aligns with the Choosing Wisely campaign, which is an initiative to reduce unnecessary tests, treatments and procedures.

• Multiple national societies have adopted Choosing Wisely aims to reduce unnecessary red cell transfusions.
Clinical Informatics (CI)

• American Medical Informatics Association definition
  - CI is the application of informatics and information technology to deliver healthcare services.

• Accreditation Council for Graduate Medical Education definition
  - The subspecialty of all medical specialties that transforms health care by analyzing, designing, implementing, and evaluating information and communication systems to improve patient care, enhance access to care, advance individual and population health outcomes, and strengthen the clinician-patient relationship.
Clinical Informatics (CI)

• CI sits at the intersection of information science, information systems, workflow and processes, and leadership and management.

• CI transforms data into useable actionable information.

### Table 3. Blood Utilization by Year for the Five Health System Hospitals Combined

<table>
<thead>
<tr>
<th>Fiscal Year (No. of Inpatients)</th>
<th>2014* (n = 117,444)</th>
<th>2015† (n = 117,690)</th>
<th>2016† (n = 116,741)</th>
<th>2017† (n = 58,732)</th>
<th>P Value</th>
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<tbody>
<tr>
<td><strong>RBCs</strong></td>
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<tr>
<td>Utilization (units/1,000 patients)†‡</td>
<td>455</td>
<td>444</td>
<td>406</td>
<td>365</td>
<td>&lt; 0.0001</td>
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<tr>
<td>No. (%) of patients transfused</td>
<td>13,210 (11.3%)</td>
<td>12,950 (11.0%)</td>
<td>12,093 (10.4%)</td>
<td>6,088 (10.4%)</td>
<td>&lt; 0.0001</td>
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<tr>
<td>No. (%) orders ≥ 2 units</td>
<td>12,038 (39.7%)</td>
<td>9,125 (30.2%)</td>
<td>5,560 (17.7%)</td>
<td>3,513 (20.2%)</td>
<td>&lt; 0.0001</td>
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<tr>
<td>No. (%) orders for Hb ≥ 8 g/dL‡</td>
<td>10,023 (33.9%)</td>
<td>9,120 (30.9%)</td>
<td>7,822 (25.5%)</td>
<td>3,675 (22.1%)</td>
<td>&lt; 0.0001</td>
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<td><strong>Plasma</strong></td>
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<tr>
<td>Utilization (units/1,000 patients)†‡</td>
<td>175</td>
<td>161</td>
<td>162</td>
<td>107</td>
<td>0.0002</td>
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<tr>
<td>No. (%) of patients transfused</td>
<td>3,371 (2.9%)</td>
<td>3,037 (2.6%)</td>
<td>2,705 (2.3%)</td>
<td>1,262 (2.2%)</td>
<td>&lt; 0.0001</td>
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<tr>
<td>No. (%) orders for INR &lt; 1.5**</td>
<td>2,190 (40.6%)</td>
<td>1,888 (39.7%)</td>
<td>1,654 (37.7%)</td>
<td>877 (36.9%)</td>
<td>&lt; 0.0001</td>
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<td><strong>Platelets</strong></td>
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<tr>
<td>Utilization (units/1,000 patients)†‡</td>
<td>167</td>
<td>151</td>
<td>145</td>
<td>141</td>
<td>0.04</td>
</tr>
<tr>
<td>No. (%) of patients transfused</td>
<td>3,610 (3.1%)</td>
<td>3,355 (2.9%)</td>
<td>3,237 (2.8%)</td>
<td>1,572 (2.7%)</td>
<td>&lt; 0.0001</td>
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<tr>
<td>No. (%) orders for PLTS ≥ 50 K††</td>
<td>2,646 (23.5%)</td>
<td>2,514 (22.8%)</td>
<td>3,062 (24.2%)</td>
<td>1,759 (22.7%)</td>
<td>0.02</td>
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Implementing a PBM program


<table>
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<th>Table 1. Steps for Implementation of the Blood Management Clinical Community</th>
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<td>1. Obtain support from health system leadership (business plan)</td>
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<td>2. Assemble multidisciplinary team of stakeholders</td>
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<td>3. Education (with emphasis on the eight randomized controlled trials supporting restrictive transfusion)¹⁸⁻²⁵</td>
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<td>4. Harmonize transfusion guidelines</td>
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<td>5. Decision support for computerized provider order entry (with best practice advisories)</td>
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<td>6. Data acquisition/analytics</td>
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<td>7. Create dashboards</td>
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<td>8. Transfusion guideline compliance audits with feedback (reports) to providers</td>
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<tr>
<td>9. Methods to improve blood utilization</td>
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<tr>
<td>• Evidence-based transfusion triggers</td>
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<tr>
<td>• “Why Give Two When One Will Do?” Choosing Wisely campaign for erythrocytes⁶,³⁴</td>
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<tr>
<td>• Preoperative anemia management</td>
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<tr>
<td>• Antifibrinolytics (e.g., aminocaproic acid, tranexamic acid)</td>
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<tr>
<td>• Intraoperative autologous cell salvage</td>
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<tr>
<td>• Anesthetic management (autologous normovolemic hemodilution, controlled hypotension, normothermia)</td>
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<tr>
<td>• Surgical methods (newer cauteroy methods, topical hemostatics, and sealants)</td>
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<tr>
<td>• Reduce phlebotomy blood loss (smaller tubes, eliminate unnecessary testing)</td>
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<td>• Point-of-care testing (e.g., thromboelastography)</td>
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Using information technology to optimize transfusion practice - related articles


Using information technology to optimize transfusion practice

• Computerized physician order entry (CPOE) with clinical decision support systems can be used to encourage appropriate transfusion practice.

• The impact of CPOE with clinical decision support (CDS) is enhanced when the laboratory information system can be linked to the electronic medical record to enable best practice alerts (BPAs) that query transfusion guidelines against current lab results.
Using information technology to optimize transfusion practice - specific examples

• Pre-op anemia clinical pathway

• Use of CPOE with CDS/BPAs to increase provider compliance with transfusion guidelines

• Healthcare IT provides the ability to acquire and analyze large amounts of transfusion-related data and provide meaningful feedback to clinical departments/individual providers.
CPOE with CDS

Platelet Acknowledgement

1. Platelet count <= 10,000/µL
2. Platelet count <= 20,000/µL and signs of hemorrhagic diathesis
3. Platelet count <= 50,000/µL and active hemorrhage
4. Platelet count <= 50,000/µL with invasive procedure (recent, in-progress, planned)
5. Platelet count <= 100,000/µL with bleeding in a closed anatomical space (eg. CNS, eye, etc)
6. Platelet dysfunction with active or anticipated hemorrhage
7. Other

7 items loaded.

Alert fatigue

Extracting the data

• Maximize the potential of your EMR

• Link your the hospital’s information technology systems, allows data extraction from the blood bank computer system, laboratory medicine computer system, the electronic medical record, the physician order entry portal and the hospital billing computer system.

• Consider outside vendor options
Structuring the data

Fig. 1. Three databases with overlapping but unique information. Each database is used to create a complete overview of RBC transfusions at our hospital.

Dashboards

Using Data to Support Patient Blood Management - Kate Pendry
https://doi.org/10.1111/tme.12223
Individual provider reports

Individual provider reports


Table 3. Intraoperative Blood Product Requirements and Transfusion Hemoglobin Triggers and Targets

<table>
<thead>
<tr>
<th>Surgical Procedure</th>
<th>% of Patients Transfused Erythrocytes</th>
<th>% of Patients Given Cell Salvage Erythrocytes (Volume in ml)</th>
<th>% of Patients Given FFP</th>
<th>% of Patients Given Platelets</th>
<th>Hb Trigger in Patients Transfused (g/dl)</th>
<th>Hb Target in Patients Transfused (g/dl)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary CABG (n = 455)*</td>
<td>42.4†</td>
<td>86.7 (720 ± 240)</td>
<td>19.2†</td>
<td>7.2 ± 0.8</td>
<td>8.9 ± 1.1</td>
<td></td>
</tr>
<tr>
<td>Surgeon A (n = 31)</td>
<td>54.8†</td>
<td>83.3 (650 ± 220)</td>
<td>22.2†</td>
<td>7.2 ± 0.8</td>
<td>9.2 ± 1.3</td>
<td></td>
</tr>
<tr>
<td>Surgeon B (n = 112)</td>
<td>55.4†</td>
<td>84.3 (655 ± 210)</td>
<td>29.9†</td>
<td>7.6 ± 0.6</td>
<td>8.7 ± 0.9</td>
<td></td>
</tr>
<tr>
<td>Surgeon C (n = 193)</td>
<td>40.4†</td>
<td>86.9 (750 ± 260)</td>
<td>19.2†</td>
<td>6.9 ± 0.8</td>
<td>8.9 ± 1.1</td>
<td></td>
</tr>
<tr>
<td>Surgeon D (n = 113)</td>
<td>28.3†</td>
<td>90.4 (750 ± 230)</td>
<td>7.1†</td>
<td>7.3 ± 0.6</td>
<td>8.6 ± 0.9</td>
<td></td>
</tr>
<tr>
<td>Whipple (n = 371)*</td>
<td>27.2†</td>
<td>7.5†</td>
<td>0.8†</td>
<td>9.2 ± 1.5†</td>
<td>11.4 ± 1.4†</td>
<td></td>
</tr>
<tr>
<td>Surgeon A (n = 153)</td>
<td>35.9†</td>
<td>9.8</td>
<td>0.7</td>
<td>9.6 ± 1.5</td>
<td>11.6 ± 1.4</td>
<td></td>
</tr>
<tr>
<td>Surgeon B (n = 31)</td>
<td>12.9†</td>
<td>3.2</td>
<td>3.2</td>
<td>7.8 ± 1.8</td>
<td>9.7 ± 1.8</td>
<td></td>
</tr>
<tr>
<td>Surgeon C (n = 65)</td>
<td>10.8†</td>
<td>3.1</td>
<td>0</td>
<td>8.9 ± 0.7</td>
<td>11.2 ± 0.9</td>
<td></td>
</tr>
<tr>
<td>Surgeon D (n = 54)</td>
<td>27.8†</td>
<td>5.6</td>
<td>0</td>
<td>8.4 ± 1.2</td>
<td>10.2 ± 0.9</td>
<td></td>
</tr>
<tr>
<td>Post. lumbar fusion (n = 346)*</td>
<td>41.6†</td>
<td>20.5 (490 ± 290)</td>
<td>19.9†</td>
<td>9.4 ± 1.1†</td>
<td>11.2 ± 1.0</td>
<td></td>
</tr>
<tr>
<td>Surgeon A (n = 51)</td>
<td>58.8†</td>
<td>31.4 (450 ± 260)</td>
<td>27.4</td>
<td>9.6 ± 1.0</td>
<td>11.1 ± 1.2</td>
<td></td>
</tr>
<tr>
<td>Surgeon B (n = 49)</td>
<td>57.1†</td>
<td>49 (520 ± 330)</td>
<td>20.4</td>
<td>9.2 ± 0.9</td>
<td>10.9 ± 0.8</td>
<td></td>
</tr>
<tr>
<td>Surgeon C (n = 18)</td>
<td>55.6†</td>
<td>11.1</td>
<td>0</td>
<td>10.3 ± 0.3</td>
<td>11.3 ± 0.5</td>
<td></td>
</tr>
<tr>
<td>Surgeon D (n = 38)</td>
<td>52.6†</td>
<td>36.8 (530 ± 250)</td>
<td>39.5</td>
<td>10.1 ± 0.8</td>
<td>11.3 ± 1.1</td>
<td></td>
</tr>
<tr>
<td>Surgeon E (n = 41)</td>
<td>36.6†</td>
<td>12.2 (500 ± 350)</td>
<td>30.6</td>
<td>11.9 ± 1.2</td>
<td>11.6 ± 1.0</td>
<td></td>
</tr>
<tr>
<td>Surgeon F (n = 46)</td>
<td>30.6†</td>
<td>2.2 (500)</td>
<td>30.6</td>
<td>9.7 ± 1.0</td>
<td>11.3 ± 0.8</td>
<td></td>
</tr>
</tbody>
</table>
Summary

• Computer-based clinical decision support improves transfusion practices and patient outcomes

• The challenge is to extract these data and focus on variables that will have the greatest ability to promote evidenced-based practice

• Work with your hospital colleagues to maximize internal systems

• Aim for national standards for transfusion request specification, decision support and PBM performance indicators

• Aim for benchmarking against other institutions
## SABM Blood Utilization Metrics

<table>
<thead>
<tr>
<th>Metric</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Number/Percentage of blood components transfused by Service Line</td>
<td>Identify high blood use Service Lines (Medical and Surgical)</td>
</tr>
<tr>
<td>(all components, broken out by component)</td>
<td></td>
</tr>
<tr>
<td>2. Number/Percentage of blood components transfused by DRG/procedure</td>
<td>Identify top 10 services and top 20 DRGs with high frequency transfusion</td>
</tr>
<tr>
<td>3. Transfusion rates by physician by DRG/procedure</td>
<td>Determine practice variation and identify primary opportunities/ targets for PBM education</td>
</tr>
<tr>
<td>4. Total transfusion of blood products (broken out by component)</td>
<td>Evaluate impact of transfusion guidelines on blood product utilization and identify product specific improvement opportunities</td>
</tr>
<tr>
<td>per 1000 inpatient days or per adjusted patient discharge</td>
<td></td>
</tr>
<tr>
<td>5. Number/Percentage of elective surgery patients admitted with Hgb</td>
<td>Learn prevalence of pre-operative anemia and impact on length of hospital stay and identify opportunities for correction</td>
</tr>
<tr>
<td>&lt;13 g/dL and number of units transfused and LOS</td>
<td></td>
</tr>
</tbody>
</table>
Thank you for your attention

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