Getting Ready for Patient Blood Management Certification

Steve Frank, MD
Eduardo Nunes, MPP, CAE
Stacy Olea, MT(ASCP), FACHE
May 12, 2016
Collaborative Product Offering

- First product to be co-developed with an external organization
- AABB is an established expert in blood management
- Aligns with The Joint Commission’s mission to continuously improve health care for the public
- Based upon AABB’s PBM standards used therein with permission
Objectives

- Learn how to build institutional support for certification
- Introduce AABB’s PBM Standards
- Describe quality management system requirements
- Highlight key aspects of certification readiness
- Learn how to apply for certification and what will happen during the review process
Intro to PBM: Building Institutional Support for Certification

Steven M. Frank, M.D.
Associate Professor
Director, Johns Hopkins Health System Blood Management Program
Department of Anesthesiology/Critical Care Medicine
The Johns Hopkins Medical Institutions
Baltimore, Maryland
Blood transfusion targeted at the **Overuse Summit**.

- Blood transfusion is the most commonly performed procedure in US hospitals

**Five most overused procedures:**

1. **Blood transfusions**
2. Heart vessel stents
3. Ear tubes (tympanostomy tubes)
4. Antibiotics for the common cold (viral upper respiratory infections)
5. Early scheduled births (early induction) without medical need
5 Societies have aims to reduce unnecessary transfusion

- Society of Critical Care Medicine
- American Society of Anesthesiologists
- American Society of Hospital Medicine
- American Society of Hematology
- Am. Assn. Blood Banks
Evidence-based medicine: Save blood, save lives

Transfusions are one of the most overused treatments in modern medicine, at a cost of billions of dollars. Researchers are working out how to cut back.

-Joint Commission
-Choosing Wisely
-Now the #1 scientific journal recognizes overuse
## Eight Landmark Randomized Clinical Trials Supporting Hb Triggers of 7-8 g/dL (Less is More)

### Randomized Trials:
- all supporting Hb triggers of 7 or 8 g/dL

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<td>Murphy GJ, et al: NEJM 2015 – Cardiac surgery patients</td>
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### Higher Triggers
- Same
- Same/Worse
- Same
- Same
- Worse
- Same
- Same/Worse
- Same

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Figure 2
New Study Reveals Wide Variation in Blood Transfusion Practices During Surgery

Published: July 26, 2012

IRVINE, Calif., July 26, 2012 /PRNewswire/ -- According to a new study in the July 2012 print edition of Anesthesiology, blood transfusion, the most common procedure performed in U.S. hospitals\(^1\), has wide variation in frequency by surgical procedure and physician as well as wide variation in the hemoglobin trigger used to help decide whether to transfuse.\(^2\) The study also showed a significant number of transfusion decisions are made without laboratory hemoglobin measurements. The research adds to the growing clinical evidence highlighting the need for improved blood-management strategies. It also underscores the opportunity for noninvasive and continuous total
Surgeon #44 (with permission)

• Next a Whipple case he told the Anesthesiologist:

“If you hang that blood Steve Frank is gonna be all over our case”
Best Practice Advisory
(in EPIC – September, 2015)
When hemoglobin ≥ 7 g/dL or missing

This patient has a last measured hemoglobin result 7 g/dL or greater, or has no measured hemoglobin within the past 24 hours. In hemodynamically stable non-bleeding patients a hemoglobin threshold of 7 g/dL (or 8 g/dL with cardiovascular disease) decreases transfusion requirements and reduces adverse outcomes. ****Single unit transfusions are usually preferable. Please enter the indication for transfusion.****

Citations:

Last HGB=8.0 on 7/15/2015

Acknowledge reason: 
Do not wish to proceed with order
“Efficacy of Education Followed by Computerized Provider Order Entry with Clinician Decision Support to Reduce Red Blood Cell Utilization”

Monthly number of RBC units w/ preceding Hb > 8

Change in RBC Utilization for 10 Surgical Services

- Vascular: -9%
- Transplant: -19%
- Cardiac: -19%
- Thoracic: -23%
- Ortho/Spine: -24%
- OB/GYN: -27%
- General: -29%
- Urology: -30%
- Neurosurgery: -30%
- Pediatrics: -30%

Total Units
Year - Month

54%
14.3%
JHH Orthopedics Dept. - Number and % of RBCs Given by Hb Trigger (Oct-Dec, 2014)

Provider (physician) Level Reports

- Hb < 7 g/dL
- Hb 7-7.9 g/dL
- Hb ≥ 8 g/dL
Why Give Two When One Will Do?

That is the question being asked by the Armstrong Institute for Patient Safety and Quality as it relates to unnecessary blood transfusions, one of the top five most overused medical procedures. Cutting back on excessive blood transfusions could save millions across Johns Hopkins Medicine. More »
≥ 2 RBC Orders Decreased by 48%
FY14 vs. FY15

Johns Hopkins
Bayview

HCGH
Sibley
Suburban
Annualized Cost Avoidance for FY16 vs. FY14

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Joint Commission Certification

• The Joint Commission has an alliance with AABB (formerly American Association of Blood Banks)

• Standards are a “recipe” for a successful program

• Encourages hospital administration support

• PBM has return on investment (ROI) (more than pays for itself)

• Improved blood management can:
  - reduce risk
  - improve outcomes
  - reduce cost

\[ \text{\textbf{= \uparrow Value}} \]
AABB’s Standards for a Patient Blood Management Program

An Introduction to PBM Certification Requirements

Eduardo Nunes, MPP, CAE
Senior Director, Standards, Transfusion Medicine, and PBM

www.aabb.org
PBM Drivers and Benefits

Patient blood management (PBM) is an evidence-based multidisciplinary approach to patient care.

PBM programs recognize the need for transfusions is patient-centric, that some transfusions may not be clinically indicated, that transfusion incurs risk, and that significant resources are utilized to procure, manage, and administer blood and blood components.

PBM program may generate –
• Improved patient outcomes
• Reduced variation in clinical transfusion practice
• Increased transparency re utilization, best practices
• Shorter hospital stays
• Fewer readmissions
• Reduced risk
• Cost savings
Sample PBM Standards

Examples of Standards include:

• **Professional Competency** - Requires a hospital to define the credentials required for individuals who order and/or transfuse blood.

• **Clinical Guidelines** - Requires that the hospital establish and define patient blood management guidelines that are evidence based for hospital population.

• **Perioperative and Pre-intervention Patient Care** – Details the requirements centered around preoperative and pre-intervention patient care such as Maximum Surgical Blood Ordering Schedule, pre-procedure anemia management, interventions intended to reduce need for allogeneic transfusion, etc.

• **Quality Metrics & Reporting** – Requires reporting and feedback to departments/service lines and clinicians
Patient Blood Management Standards

• Certification is based on the *AABB Standards for a Patient Blood Management Program*, which presents requirements in a systematic structure that is tailored to the clinical setting.

• A quality management system (consisting of AABB’s Quality System Essentials) serves as the framework of the *PBM Standards*.

• The program should help to coordinate and integrate practices related to transfusion and patient care throughout the hospital.

• Approach to PBM requires coordinated and cooperative effort in patient management that is a cross-functional program rather than a defined department.
A few thoughts on quality management systems

• AABB framework: Quality System Essentials
• 10 elements:
  – Organization
  – Resources
  – Equipment
  – Supplier and Customer Issues
  – Process Control
  – Documents/Records
  – Nonconformances and Deviations
  – Assessments
  – Preventive and Corrective Action
  – Facilities and Safety
Elements of Quality

• Standardization of practice
• Record-keeping
• In general, your program should have policies, processes, and procedures that describe pathways for decision-making and control/describe the work performed
• For PBM programs, many of these PPP’s already exist (and quality goes by many other names)
• Organized approach to managing multiple complex processes
What is a standard?

• A requirement, often stated as a positive rather than a negative
• A stated goal rather than a method for achieving that goal
• Provides a clear basis for accreditation
• Based on scientific or clinical evidence when available
• Minimal requirements that may be exceeded in practice
The Patient Blood Management Standards Program Unit

John Holcomb, MD, FACS - Chair
Abe DeAnda Jr, MD, FACS, FAHA
John Hess, MD, MPH, FACP, FAAAS
Kathleen Puca, MD
Kathy Frey, MD
Justin Kreuter, MD
Steve Frank, MD
Martin Schreiber, MD
Jeff Riley, CCP
Melanie Jorgenson, RN, BSN
Debbie Tolich, RN, BSN, MSN
Jonathan H. Waters, MD
AABB 2.1.4 / PBMRS.2(6) Facility Defined Credentials

Standard 2.1.4 requires that facilities define the credentials required for individuals who order and/or transfuse blood.

Credentials (facility-defined): Defined requirements for training, education, and experience within each facility that qualify individuals to perform specified procedures.
How do I credential?

- Define requirements (may vary depending on role/position)
- Develop educational tools/resources
  - May be internally developed or not
- Keep records of credentialing
  - Knowledge tests are optional but validated tools exist (eg, see Haspel 2014, TRANSFUSION – “Development of a validated exam to assess physician transfusion medicine knowledge”)
- Initial deployment gradual (eg, plan to credential acceptable in first year acceptable)
BBTS Standards & Periop Standards

• Several times throughout the 1st edition, the Standards for Blood Banks and Transfusion Services and the Standards for Perioperative Autologous Blood Collection and Administration are referenced.

• The PBM SPU suggests that facilities review the current edition of each set of Standards when preparing to implement the 1st edition (see next slide)
Why?

- PBM is by nature interdisciplinary – just ask your TSO or PBM coordinator!
- “Driving from the passenger side”
- As a new or emerging department, PBM may not have complete ownership of many of these activities
Interface between PBM and other departments

- AABB Standards 3.2 and 3.2.1 (PBMEQ.5) address equipment controlled by other departments (e.g., blood bank or perioperative blood management equipment) be managed in accordance with existing AABB Standards.

- AABB Standard 6.2.2.1 [PBMDR.1(3)] reflects the fact some patient blood management programs will not necessarily maintain their own patient records, but that they want to ensure access to them as needed.

- AABB Standard 6.3 (PBMDR.6) addresses policies, processes, and procedures controlled by other departments (e.g., nursing) with goal of PBM program having a place at the table.
AABB Standard 5.1.2 (PBMPC.3) Patient Blood Management Guidelines

- Requires that the facility establish and define patient blood management guidelines that are evidence based for both adults and children.
- This would include a targeted effort to avoid transfusion if not needed and to provide rapid and timely delivery of blood products when they are needed.
- Address major patient groups (based on service lines and care pathways)
AABB Standard 5.3 (PBMPC.8) Pre and Posttransfusion Patient Care

• These standards focus on the review, revision and creation of policies, processes and procedures as they relate to pre- and posttransfusion patient care.
  – This includes measuring transfusion effectiveness, over transfusion vs failure to transfuse and the review of quality indicator data.
  – Requires quarterly review by executive management and department chairs
  – Requires yearly review by the affected quality committees
AABB Standard 5.4 (PBMPC.9)
Preoperative or Preintervention Patient Care

• Are you managing underlying anemia or coagulation disorders?
  – Preoperative/preintervention strategies intended to reduce need for allogeneic transfusion, etc

• Includes identification and management of patients who refuse transfusion.
AABB Standard 5.7 (PBMPC.12) Massive Blood Loss and Management

• Requires that the patient blood management oversee and review the development of a protocol for managing massive blood loss. This would include the timely delivery of blood components to patients.

• Included to ensure that the patient blood management program complies with the existing massive transfusion protocol, or creates one and ensures compliance with it once in place.
AABB Standard 7.1.1 (PBMDN.2)

Nonconformances

What are failures or deviations in PBM?
1) Failure to capture potential candidates for patient blood management interventions.
2) Failure to deliver interventions to patients who have been identified as candidates for those interventions.
3) Failure to report findings to other service lines.
4) Failure of executive management to monitor the program.
5) Failure to follow the existing massive transfusion protocol.
6) Failure to prevent overtransfusion or inappropriate transfusions.
7) Failure to recognize and report suspected transfusion-associated adverse events.
8) Failure to transfuse when indicated.
AABB Standard 8.3 (PBMAM.2) Reporting

Reporting is the PBM program’s most powerful tool to drive behavioral changes. Reports must include:
1) Overall program effectiveness and opportunities for improvement.
2) Allogeneic transfusion rates by service line and/or procedure type.
3) Use and efficacy of preoperative anemia management interventions.
4) Component usage and discard, and cause(s) of waste.
5) Appropriateness of allogeneic transfusion by service line and/or procedure type.
6) Adoption of patient blood management techniques.
7) Effectiveness of the emergency/massive transfusion processes and appropriateness of activation and timeliness of delivery of blood and components.
8) Customer satisfaction (eg, patients, physicians, administrators).
9) Compliance with recommendations made by the program.
10) Suspected transfusion-associated adverse events and adverse events associated with the failure to transfuse when appropriate.
Where to Learn More About PBM

- AABB Annual PBM Workshop (Oct., Orlando)
- eLearning -- PBM Learning Modules, Webinars, etc.
- AABB Publications
- www.aabb.org/pbm
AABB PBM Modules

• Introduction to Patient Blood Management
• Anemia Management
• Informed Consent
• Indications for Transfusion
• Coagulation Management
• Intraoperative Transfusion Strategies and Surgical Techniques
• ICU Strategies and Ancillary Techniques
• Blood Utilization and Review
Patient Blood Management Certification for your Hospital and Patients

Stacy Olea, MT(ASCP), FACHE
Executive Director
Laboratory Accreditation
The Joint Commission
The goal is to assist hospitals in implementing practices in order to:

- Eliminate unnecessary transfusions and adverse outcomes
- Ensure that blood components are available for the patients who need them
- Understand the capability for standardizing processes for blood components and potential for cost savings
Benefits of PBM Certification

- Provides a comprehensive approach to reviewing your PBM program
- Drives hospitals to realize the maximum benefits of establishing a comprehensive patient blood management program
- Coordinates and integrates practices related to transfusion and patient care throughout the hospital to achieve the goal of certification
- Onsite collaboration with reviewers provides opportunities for knowledge transfer and peer-to-peer learning
PBM Certification Process

- Two-year certification with onsite biennial reviews
- Awarded by Joint Commission HCO number
- One day visit
  - If AABB accredited for Blood Bank and/or Transfusion Services then one Joint Commission Reviewer
  - If not AABB accredited then one Joint Commission Reviewer and one AABB reviewer
- Blends the AABB quality systems-based approach and The Joint Commission tracer methodology
- Does not replace or shorten the time spent during the hospital and the laboratory accreditation review of Blood Bank and Transfusion Services
- No Intracycle Monitoring activity
- No direct reporting of Performance Measures
PBM Certification for All Hospitals

- Three activity levels reflect a hospital’s case mix and services
- See Appendix A: Program Activity Levels in the PBM Certification Review Process Guide or the E-app
- There is only one standard that is impacted by the activity level

PBMOR 4 The executive management defines, oversees, and monitors the activities of the program.
- Activity Level 1 must meet elements of performance 2 - 21
- Activity Level 2 must meet elements of performance 2 – 18
- Activity Level 3 must meet elements of performance 2 – 14
Activity Levels

Level 1
- Program for Patients who Refuse Blood
- Compliance with Transfusion Guidelines
- Periop Techniques Consistent with AABB Standards

Level 2
- Periop Blood Loss - Massive Blood Loss
- Rapid Decision-Making for Anemia/Coagulation Management
- Blood Loss, Anemia, and Coagulopathy in Nonoperative Patients

Level 3
- Patient Outcomes - Presurgical Anemia
- Blood Ordering - Institutional Support - Blood Usage
- Patients Refusing Transfusion - Patient Testing/Evaluation
- Wasted Components - Patients Lacking Identification - Budgeting
- Adverse Events - Patient Coagulation Function - Blood Loss due to Lab Testing
PBM Certification Readiness

- Hospital or Critical Access Hospital accredited by The Joint Commission
- PBM Certification manual reviewed
- The right people engaged
- Leadership commitment
- Determine your level of application (1, 2, or 3)
- A minimum of four months of Patient Blood Management data available for review
- Identify your ready date and complete the E-app
- The Joint Commission Review Process Guide reviewed
- Champions at the ready
The Joint Commission

Patient Blood Management Certification

E-dition

Overview

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Standard Introduction and Rationale

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<td>The program shall have a structure that clearly defines and documents the parties responsible for the oversight and review of patient blood management activities and the relationship of individuals responsible for key quality functions.</td>
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<td>The interdisciplinary program shall be patient centered, data driven, and outcomes focused.</td>
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| PBMOR.2 | The program defines the roles and responsibilities of the executive management team. |
| PBMOR.3 | The program defines the roles and responsibilities of the medical director. |
| PBMOR.4 | The executive management defines, oversees, and monitors the activities of the program. |
| PBMOR.5 | The program defines the roles and responsibilities of the program team. |
| PBMOR.6 | The program has a patient-centered quality plan. |
| PBMOR.7 | The program has policies, processes, and procedures for patient blood management. |
| PBMOR.8 | The program has emergency operation policies, processes, and procedures. |
Patient Blood Management Certification

About Patient Blood Management Certification

Patient Blood Management is a voluntary certification that provides a third party evaluation of patient blood management programs. The certification is an evidence-based approach to optimizing care of patients who might need transfusion. It is based on the AABB Standards for a Patient Blood Management Program and can help hospitals and critical access hospitals realize the maximum benefits of establishing a comprehensive patient blood management program.

- Brochure
- FAQs

Resources

For questions about the specific Patient Blood Management Certification standards, email standards@aabb.

- Additional patient blood management resources
Joint Commission Connect & E-app

Notification of Scheduled Events
As of Tuesday, May 03, 2016 no events were available for viewing. Please note that unannounced events are viewable by 7:30 AM on the day of the event.

This is the section of your secure extranet that displays information regarding Joint Commission activity at your organization. For more details, please see your Schedule Information.

An automatic update from Microsoft to all Office365 users has resulted in technical difficulties affecting The Joint Commission's company-wide phone system. As a result, your calls to account executives or other Joint Commission staff may be disconnected without warning. Please be assured we are closely monitoring Microsoft's efforts to fix this issue, but it may be several days before our call system is fully functional again. In the meantime, if your call is disconnected and you need to contact your account executive, please call back or send him or her an email and it will be answered as soon as possible. You can find your account executive's email on your Joint Commission Connect extranet site.

Thank you for your patience.

> Accreditation Certification

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Support available
Monday-Friday 8:30 a.m. - 5:00 p.m. CT
First Certification

Thank you for your patience.

<table>
<thead>
<tr>
<th>Application Description</th>
<th>Completed</th>
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</thead>
<tbody>
<tr>
<td>Launch Certification Application</td>
<td>✔️</td>
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<tr>
<td>Launch Required Org Contacts</td>
<td>✔️</td>
</tr>
<tr>
<td>Launch Contract Signed</td>
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</tbody>
</table>
Already have a Certification
E-Application

Are you seeking certification for Patient Blood Management services?

- [ ] Yes  - [ ] No
Pre-Review Phone Call

- With your Account Executive
- Confirm information reported in the application for certification
- Verify travel planning information and directions to main location for review
- Confirm your access to The Joint Commission Connect extranet site and the certification related information available there (on-site visit agenda, Certification Review Process Guide, etc.)
- Answer any organization questions and address any concerns
Notification of Reviews

- Initial certification onsite review
  - Identify your ready date on your application
  - At least a 30 day advanced notice
  - Joint Commission Connect: review date, reviewer’s name, biographical sketch, and picture

- Re-certification onsite review
  - Seven business day notice to the certification contact identified on your application
  - Joint Commission Connect: 7:30am on the morning of the review
Possible Documents for Review

- Current list of patients receiving blood
- List of discharged patients who received blood
- PBM PI action plans
- Org chart
- Patient centered quality plan
- Supplier evaluations
- Educational materials given to patients
- PBM policies and procedures
- Record retention policies
- Procedures for deviations
Suggested Patient Tracers

- Patients receiving a massive transfusion
- Patients receiving regular transfusions
- Patients that refuse blood products or transfusions
- Patients with chronic anemia
- Patients receiving stem cell transplants
- Patients with elective surgery (preoperative, postoperative)
- Patients from the intensive care, pediatrics, obstetrics, or oncology departments
Possible Personnel Files for Competency Assessment and Credentialing

- PBM medical director
- PBM coordinator
- Midlevel practitioner that orders blood
- Medical technologist in the blood bank
- Perfusionist
- RN from the ICU, ER, or OR
- Anesthesiologist
Sample Agenda – One Reviewer, One Day

- Opening Conference (10 minutes)
- Orientation to the Program (50 minutes)
- System Tracer – Data Use (30 minutes)
- Reviewer Planning Session (30 minutes)
- Individual Tracer Activity (4 hours)
- Competency Assessment and Credentialing (30 minutes)
- Issue Resolution and Report Preparation (1 hour)
- Program Exit Conference (30 minutes)
Sample Agenda – Two Reviewers, One Day

- Opening Conference (10 minutes)
- Orientation to the Program (50 minutes)
- System Tracer – Data Use (30 minutes)
- Reviewer Planning Session (30 minutes)

Split Activities
  - Reviewer 1: Individual Tracer Activity (4 hours)
  - Reviewer 2: Blood Bank Review (2 hours); Perioperative Services Review (2 hours)

- Competency Assessment and Credentialing (30 minutes)
- Issue Resolution and Report Preparation (1 hour)
- Exit Conference (30 minutes)
Certification Decision

- Official certification report is posted on Joint Commission Connect usually two days after the review.

- Final certification decision is made after Joint Commission receives and approves all Evidence of Standards Compliance (ESCs).

- Two decisions possible:
  - **Certified**: Meet all the requirements.
  - **Not Certified**: Fail to meet all the requirements or recognized during the onsite review they will not meet the requirements and requests the review to be changed to an education visit.
Evidence of Standards Compliance (ESC)

- For every Requirement for Improvement (RFI) in the report the organization must submit an ESC
- ESC report is available on Joint Commission Connect
- Acceptable report must detail the actions added to achieve compliance or clarify why the program is in compliance with the standard
- Due at 45 days or 60 days after release of the final report
Next Steps

- Hospital/Critical Access Hospital accredited by The Joint Commission
- PBM Certification manual reviewed
- The right people engaged
- Leadership commitment
- Determine your level of application (1, 2, or 3)
- A minimum of four months of Patient Blood Management data available for review
- Identify your ready date and complete the E-app
- The Joint Commission Review Process Guide reviewed
- Champions at the ready
Be the First!

First hospital to obtain certification will be featured in promotional materials at AABB and The Joint Commission (press release, mention in association newsletters and other communications vehicles)

Invited to participate in AABB's Annual PBM Workshop in Orlando in October
Submit an Application before July 1, 2016

- Receive a 10% Discount on your first year annual fee for PBM Certification
  - Review must be scheduled within 1 year of the application submission date

- Eligible for $200 credit for AABB products
Questions

PBM Certification, applications and incentive: qualityhospitals@jointcommission.org

PBM Standards: standards@aabb.org

PBM resources: pbm@aabb.org
ndamour@aabb.org
eduardo@aabb.org