AmSECT Quality and Outcomes Conference

AABB Standards of Perioperative Autologous Blood Collection and Administration

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8:40am – 9:10am
Introduction
Meaningful Outcome Measures in Cardiac Surgery...

Teamwork, Communication, & Methods

Technology Standards & Guidelines
Perfusion Practice

Change Management & Patient Outcomes
STANDARDS
1958:  
1st ed. of Standards for Blood Banks and Transfusion Services is published

1984:  
AABB develops standards and starts accrediting laboratories in the parentage testing field

1991:  
Requirements for HPCs and bone marrow are introduced in the 14th ed. of BBTS Standards

1996:  
1st ed. of Standards for Hematopoietic Progenitor Cells is published

1999:  
1st ed. of Standards for Immunohematology Reference Laboratories is published

2001:  
1st ed. of Standards for Cord Blood Services is published

2004:  
Standards for HPCs and CB are merged, and the 1st ed. of Standards for Cellular Therapy Product Services is published

2008:  
1st ed. of Standards for Molecular Testing for Red Cell, Platelet, and Neutrophil Antigens is published

2013:  
New content covering clinical activities is added to the 6th ed. of Standards for Cellular Therapy Services

2014:  
1st ed. of Standards for A Patient Blood Management Program is published
Standards: Development & Relevance

- Emerging Science
- Improved Technology
- Evidence Based Practice
- Regulatory Public Health Policy

Current Best Practices

Regulations
Standards Development: Input Framework

- Expert Opinion
- Evidence Based Practice
- Industry & Technology “Know How”
- Stakeholder Engagement

- Science
- Clinical Practice
- Technical Requirements
- Regulations & Policy

- Field Assessment
- Patient Outcomes
- Clinical Research
- Industry Innovation

- Variances
- Non-conformances
- Best Practices
- Active HV
- PSO Findings
- S.A.C.
- Research Agenda
- KOL & Collaborative Engagement
Quality Management System: Why?

- QMS methodology originated in manufacturing, industrial environments, now accepted in clinical settings
- AABB framework consistent with internationally recognized QMS (e.g., ISO)
- Standards form the basis of AABB accreditation
  - Comprehensive assessments of technical and administrative activities
  - No checklists
  - Helps assessors and users of Standards to identify root causes of potential or actual problems
Quality Management System: Why?

• Standards emphasize the goal, not the method

  – Program defines requirements for its products, services
    • Exception: some technical specifications are prescribed in the standards (e.g., product expiration)

  – Program determines method to achieve the desired outcome

  – Provides for autonomy

  – Encourages controlled innovation
Value of QMS in Perioperative Setting

• Quality Management Systems provide:

  – Structure/organization through written policies, processes, and protocols
  – Predictability/reliability
  – Minimizing variation in practices
  – Means to investigate failures and improve for the future
  – Framework for decision-making about quality and safety
  – Model to integrate “up and back” into larger hospital-wide quality management and risk program

www.aabb.org
Two Important Aspects of a QMS

• Validation
  – Critical for introduction of new devices or protocols
  – IQ - was it installed correctly?
  – OQ - does it function as expected?
  – PQ - what are the performance limits?
  – Does it work the way it should before it is put into practice?

• Quality Control
  – Are my methods functioning as expected?
  – Are my processes reliable?
  – Can I see potential problems through trending before they become actual problems?
How are AABB Standards revised?

Does a standard need to be...

**ADDED?**
- In order to...
  - maintain consistency with new regulations
  - specify technical requirements
  - address accepted standards of care
  - reflect new practices with evidence-based support

**CHANGED?**
- In order to...
  - clarify wording or intent
  - enhance document flow
  - reflect any changes in regulations
  - maintain consistency with other standards/guidelines

**REMOVED?**
- In order to...
  - minimize redundancy
  - exclude outdated practices or methodologies
  - delete references to or requirements from outdated regulations or guidance
## Standards Revision Cycle

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<th>ASSEMBLE</th>
<th>REFLECT</th>
<th>DRAFT</th>
<th>COMMENT</th>
<th>FINALIZE</th>
<th>IMPLEMENT</th>
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- **ASSEMBLE**: Form a committee of technical experts, liaisons, and representatives.
- **REFLECT**: Take user feedback about the previous edition of Standards from accredited facilities, assessors, and members.
- **DRAFT**: Committee reviews the Standards and proposes changes.
- **COMMENT**: Proposed version of Standards is sent out for a 60 day public comment period.
- **FINALIZE**: Committee reviews all comments received and finalizes the language for the new edition of Standards.
- **IMPLEMENT**: Standards are published and sent to the membership to be implemented by effective date.
AABB Standards for Perioperative Practice

- First published in 2001
- First AABB Standards re: intraoperative autologous transfusion was in 1978
- Current State:
  - Upcoming 6th edition
  - Incorporation of more clinical practices & products
  - Anchored within PBM Standards
  - 7 SME members: 3 perfusionists
- Recognizes role of independent clinical practitioners
AABB’s PBM Standards - Goals

• Monitor patient outcomes
  – How well do your patients do?
• Use best available evidence
• Timely and appropriate transfusions
• Avoid unnecessary transfusions
• Be prepared for disaster
  – With all components
AABB’s PBM Standards Structure: Activity Based

According to Standard 1.1.2.1, a PBM program can be designated as a program activity level 1, 2 or 3. To be designated as such, the program shall be responsible for or have direct involvement with oversight and monitoring of specific activities. A level 2 program is responsible for activities in levels 2 and 3. A level 1 program is responsible for activities in levels 1, 2 and 3.
U.S. Allogeneic Whole Blood and Red Blood Cell Collections and Transfusions*

* 2011 National Blood Collection and Utilization Survey
### AABB and AmSECT: Two Approaches

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<th>AABB: Quality Systems Essentials</th>
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<td>Development of institutionally based protocols</td>
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AmSECT

- Communication
- Anticoagulation
- Blood Management
- Gas Exchange
- Blood Flow
- Blood Pressure
- Duty Hours

AABB

- Supplier and Customer Issues
- Procedures or Protocols
- Qualification and Competence
- Records
- Process Improvement
- Equipment Maintenance
- Facilities and Safety
- Deviations, Nonconformances, and Adverse Reactions
- Internal & External Assessments
- Processing, Handling, Storage, and Expiration of Perioperatively Collected Blood Products
AmSECT & AABB Standards

• Highly compatible
  – Elements of AABB’s Quality Systems Essentials overlap with AmSECT’s Essentials and Guidelines

• Complementary
  – AmSECT standards have higher degree of technical specificity specifically for perfusionist role
  – AABB standards address a range of activities in the perioperative setting
  – Both play role in larger quality management efforts within the hospital; renewed emphasis on patient-centered care
  – IBBM Certification for Autotransfusionists
6th Edition of AABB Standards: Preview

- Standards upon review demonstrate stability; most of the changes represent minor shifts or fine-tuning

- However, important questions under review:
  - Locating perioperative activities within the PBM spectrum
  - The intersection of perioperative blood management and “point of care” CT (bone marrow aspirate concentrate, platelet gel, “non-homologous use” of perioperatively collected products)
Emerging Issues in Transfusion Medicine

• Red cell storage lesions

• Ongoing supply challenges
  – Emerging infectious diseases (CHIKV, Babesia)
  – TRALI risk reduction measures affect pool of eligible donors

• Adoption of formal risk-based decision making framework
Common Strengths -- Strong Opportunity

• Close alignment between AABB and AmSECT
  
  – Intersection of quality and practice in clinical perioperative setting
  – Transfusion Medicine and PBM specialists have much to learn from perfusionist professionals
  – Relevant research and educational opportunities exist
Thank You

Questions?

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