Overview

• AABB Standards for Cellular Therapy Services
  – Includes cord blood standards
• AABB Accreditation Program
• Collaborations and Partnerships
AABB advances the practice and standards of transfusion medicine and cellular therapies to optimize patient and donor care and safety.

- Professional and standards setting organization since 1947
- 1,800 institutional members
- 8,000 individual members
- Successful history of working with regulatory agencies in various countries
- Proven track record of international technical assistance and close collaborations with government agencies
Standards and Accreditation

• Cellular Therapy Services
• Blood Bank/Transfusion Service
• Relationship Testing
• Immunohematology Reference Laboratories
• Perioperative Autologous Blood Collection
• Molecular Testing for Red Cell, Platelet, and Neutrophil Antigens
# Cellular Therapy Accredited Facilities

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<th>Type of Facility</th>
<th>US</th>
<th>International</th>
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<tbody>
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AABB Standards
Standards Program

- Standards developed by committee of technical and clinical experts, ethicists, public members and external representatives (e.g., CIBMTR and NMDP)
- Public comment period
- Revised on a 24-month cycle
- Process for interim and emergent standards
- Policy to manage conflicts of interest
Milestones in AABB CT Standards

1958
1st edition of *Standards for Blood Banks and Transfusion Services* is published

1991
Requirements relating to HPCs and bone marrow are first introduced in the 14th edition of *Standards for Blood Banks and Transfusion Services*

2001
1st edition of *Standards for Cord Blood Services* is published

2013
The 6th edition of *Standards for Cellular Therapy Services* is published and includes new content covering clinical activities

1996
1st edition of *Standards for Hematopoietic Progenitor Cells* is published

2004
*Standards for HPCs and Standards for Cord Blood Services* are merged, and the 1st edition of *Standards for Cellular Therapy Product Services* is published
Standards

• Chapters match AABB’s 10 Quality System Essentials
  – Begins with high-level quality system requirements
  – Technical requirements cascade from quality system requirements

• Process for interim and emergent standards allows response to emerging issues

• Process for request for clarification from committee

• Variance process allows for differences in regional regulations and recognition of innovative practices while preserving quality and safety
Scope

• AABB Standards are broadly applicable to virtually any cellular therapy product
  – All aspects of procurement, processing, and transplantation
  – International transfer of products

• Continued evolution and expansion to address novel cellular therapies

• New clinical standards also cover clinical use of these products and patient care
Accreditation Program

- Designed to operate in a regulated environment
- Unannounced assessments
- International assessments – coordinated in advance
- 2 year renewal cycle
- Systems approach
  - Reviews objective evidence
  - Verifies operations over time (not snapshot in time)
  - Robust auditing techniques
International Recognition

• **Both** Accreditation program and assessor training program are accredited by ISQua
  – International Society for Quality in Health Care
  – ISQua accredits accrediting organizations worldwide

• AABB is one of only three accredited organizations in North America
  – Assessor training program is one of eleven accredited globally
Translation Requirements

• Only documents sent to AABB as part of pre-assessment and follow up/corrective action must be translated into English

• English translator required during the on-site assessment.
Assessment Team

- Volunteer assessors as content experts
  - Possess technical and clinical expertise
  - Receive training in auditing and assessment process
  - Continuing education requirements
  - Participate in AABB assessor competence program
  - Rigorous conflict of interest policy
    - Facility or assessment team member may decline assignment

- AABB Staff lead assessor serves on each team for consistency and to minimize conflict of interest

*Team size and length of assessment based on facility size and scope of services*
Assessment Summary

- Delivered to key facility representatives at exit session
  - Assessment objective restated
- Acknowledge facility accomplishments
- Nonconformances are based on objective findings – shared and explained during exit session
  - Facility verifies understanding of the issue presented
- Copy of summary report left at facility
- Corrective action due within 30 days
  - Reviewed by AABB staff to determine acceptability
Collaborations and Partnerships
Collaborations and Partnerships

• Work with US HRSA and CMS to add additional assessment verification

• Global Services: International technical assistance programs (e.g. PEPFAR)

• Partner with ABHH (Brazilian Association for Hematology, Hemotherapy and Cellular Therapy) to build joint standards and accreditation program
  – AABB Standards translated and licensed to ABHH
  – Brazil developed mirror accreditation program
    • AABB oversight and shared policies
  – Accreditation certificate issued by AABB/ABHH
  – Applies to transfusion medicine and cellular therapy facilities
Other Options

- Collaborate with health ministries to develop standards for their country in **any** area of AABB standards
  - Used to develop the first cellular products regulations in India

- Collaborate with regional consortiums to accredit multiple centers:
  - Increases value with standardization between centers and offers optimal use of resources
  - Custom packages may include other member services as well
Obrigado
Muchas Gracias
Thank you!

NOVEMBER 3, 2013