AABB Initiatives and Priorities
AABB/FDA Liaison Committee Meeting

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January 31, 2017
Who are we...

...through our vision, mission and core values
AABB Vision

• Making transfusion medicine and cellular therapies safe, available and effective worldwide.
AABB Mission

- AABB is the global leader in standards development, accreditation and implementation of quality systems in transfusion medicine and cellular therapies.
- AABB has an unwavering focus on donor and patient safety. We accomplish it by translating knowledge into solutions that shape the field of transfusion medicine and cellular therapies.
- AABB brings together those engaged in transfusion medicine and cellular therapies. AABB creates a unique learning environment, including our signature Annual Meeting, that inspires and enables research, innovation, discovery and excellence.
AABB Core Values

• **Respect**: Respect for our members, as well as the donors and patients we serve.
• **Integrity**: Dedication to adhering to the highest ethical standards of practice.
• **Transparency**: Maintaining open and honest communication with our membership and the public.
• **Excellence**: Striving to promote best practices for the professional community we serve and for the care of patients and donors.
• **RITE** values deliver **trust**.
A few thoughts for today…
Donor Health and Safety Committee

• AABB has recently established this committee in recognition of critical questions regarding our donors.
• The committee is charged with addressing safety issues affecting both blood and cellular therapy donors.
• Some of the topics discussed today are part of the charges of this Committee.
Regulatory Strategy Committee

• The AABB BOD recognized the need for creation of a committee which could proactively work on issues important to the community we represent.
• This is a Board level committee.
• The actual charges and make up of the committee are being finalized but the report of the exploratory phase has been presented to the BOD.
• Some immediate opportunities include work with legislative and executive branch on the vision for healthcare in the US.
Risk Based Decision Making (RBDM) Framework - AABB/CBS Babesia application

Slides courtesy of Dr. Judie Leach Bennett and Ms. Sheila Ward
Development of the Risk-Based Decision-Making Framework

The Risk-Based Decision-Making Framework was created under the auspices of the ABO. It grew out of a series of activities that began with the International Consensus Conference on Risk-Based Decision-Making for Blood Safety in Toronto in 2010.

The consensus statement that emerged from these discussions acknowledged that risk is...
RBDM Framework

The framework’s objectives are to:

- Optimise the safety of the blood supply while recognising that elimination of all risk is not possible.
- Allocate resources in proportion to the magnitude and seriousness of the risk and the effectiveness of the interventions to reduce risk.
- Assess and incorporate the social, economic, and ethical factors that may affect decisions about risk.

The new decision-making paradigm envisioned for blood safety decision-making

A health sector focus

A consistent, standardised approach to decision-making

Evidence-based decisions using risk assessment tools

Acceptable risk based on societal considerations

Multiple sectors included in the decision-making process
The Decision Making Process

1. Preparation
   - Policy Foundations
     - Risk Management Principles

2. Problem Formulation
   - Risk Communication and Stakeholder Participation

3. Participation Strategy
   - Assessment Principles

4. Assessments

5. Evaluation
   - Risk Tolerability

6. Decision
AABB Babesia Workgroup

- Two face to face meetings
- September 2016 – steps 1-3
- December 2016 – steps 4-6
- Currently working on stakeholder engagement with final report in April 2017
- In house expertise in RBDM
- Possible Future Projects for RBDM:
  - Iron in donors;
  - Geographical deferral
  - Other
In conclusion:

- AABB is committed to patient and donor safety and pursues a variety of approaches to accomplish this goal.
- AABB fully supports RBDM framework to consistently address decision making in highly regulated environments.
- AABB works with all stakeholders to advance its vision.