

AABB Initiatives and Priorities AABB/FDA Liaison Committee Meeting

Zbigniew "Ziggy" M. Szczepiorkowski, MD, PhD President 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.
- <u>Transparency:</u> Maintaining open and honest communication with our membership and the public.
- <u>Excellence</u>: 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

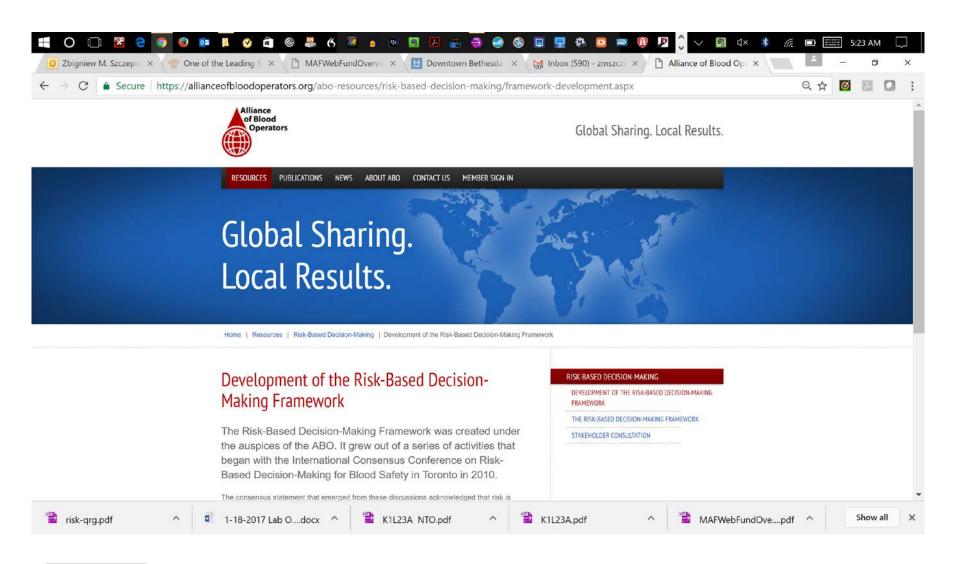
- The AABB BOD recognized the need for creation of a committee which could proactively work on issues important to the community we represent.
- This is a Board level committee.
- The actual charges and make up of the committee are being finalized but the report of the exploratory phase has been presented 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





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







AABB Babesia Workgroup



Risk-Based Decision-Making Framework for Blood Safety

Protecting the blood supply: Babesia microti

Workbook v3 December 09, 2016

- 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.

