

RISK-BASED DECISION-MAKING (RBDM) FRAMEWORK FOR BLOOD SAFETY

Overview: RBDM Framework

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IPFA/PEI 22nd International Workshop on
Surveillance and Screening of
Blood Borne Pathogens

Prague, Czech Republic: 21 May 2015





Decisions about blood safety need to take numerous factors into account, such as risks, benefits, costs, ethical issues, and stakeholder perspectives. The Alliance of Blood Operators (ABO) has developed a unique framework to help blood service operators streamline the process and make responsible decisions that lead to the greatest good, based on the core principles of Risk Tolerability, Expectations for Conduct of Assessments, Risk Communication and Stakeholder Involvement, and Risk Management.



The **Alliance of Blood Operators (ABO)** is a global network of blood operators including:

- American Red Cross
- America's Blood Centers
- Australian Red Cross Blood Service
- Blood Systems Inc.
- Canadian Blood Services
- European Blood Alliance
- National Health Service Blood & Transplant

Project Partners:

- AABB
- Héma-Québec



Approach to Blood Safety Decision Making: Evolution

- Past HIV and HCV tragedies and decision-making legacy
- Adopting interventions that **exceed generally accepted cost-effectiveness thresholds in health and medicine** has come to represent the normative approach to blood operator decision making, even when the safety gained has been marginal



2010 International Consensus Conference on Risk-Based Decision Making for Blood Safety



In 2010, the ABO held an International Consensus Conference on Risk-Based Decision Making for Blood Safety to address the issue. The conclusions were:

- that risk is inherent “vein to vein”
- that zero risk is unattainable
- that the well-being of transfusion recipients must be central to blood safety decision making



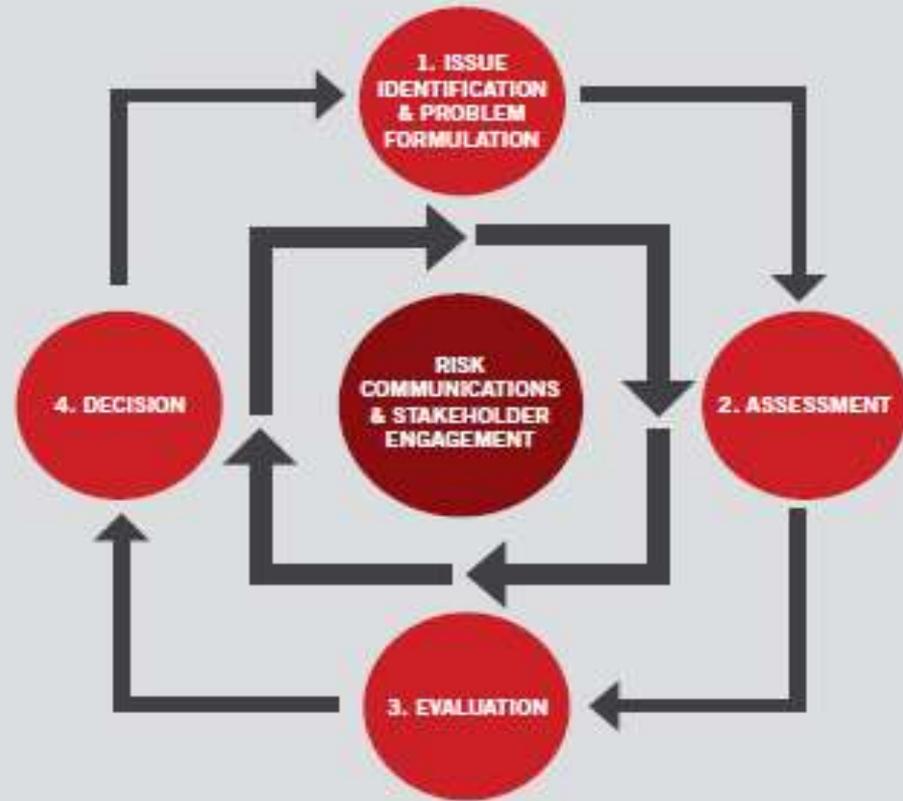
Framework Highlights

- Builds in the ability to gauge both quantitative and qualitative risk, as well as overall **risk acceptability or tolerability** in the context of patient and donor safety.
- Provides guidance regarding the **use of health economics and outcomes assessments** necessary for the evaluation of the cost utility of mitigation options.
- Includes guidelines to enable **stakeholder engagement** on considerations such as risks, opportunities, alternate solutions, unintended consequences, resources, and implementation implications with the ultimate goal of transparency and optimal input.
- Integrates these dimensions into an **overall risk profile** in order to inform the decision-making process.



ABO Risk-Based Decision Making Framework

The framework consists of *risk management policy foundations* and a *risk-based decision-making process*

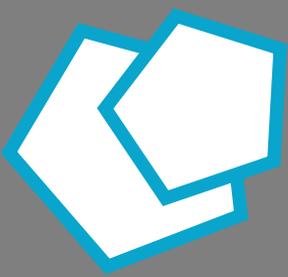


RISK TOLERABILITY

EXPECTATIONS FOR CONDUCT OF ASSESSMENTS

RISK COMMUNICATION & STAKEHOLDER ENGAGEMENT

RISK MANAGEMENT PRINCIPLES



Risk Tolerability

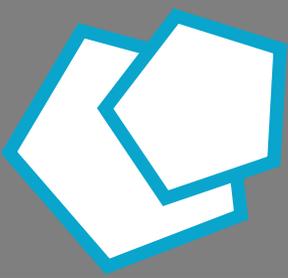
- Each individual has a legitimate expectation of protection from the high risks of societal activity
- Individuals are expected to tolerate reasonable risks for societal benefits of an activity
- Individuals and society should be provided with information on the risks to which they are exposed

INTOLERABLE RISK

TOLERABLE RISK

Risks to be managed to be as low as reasonably achievable (ALARA)

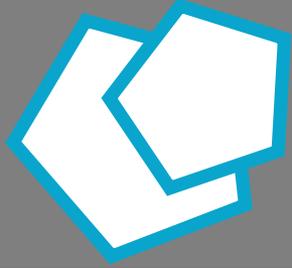
ACCEPTABLE RISK



Expectations for Conduct of Assessments

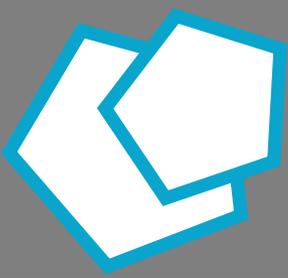
The expectations for the conduct of assessments are:

- Proportionality
- Timeliness
- Judicious use of evidence
- Characterization of uncertainty
- Variability
- Integration with related analyses
- Transparency and confidentiality



Risk Communication & Stakeholder Engagement

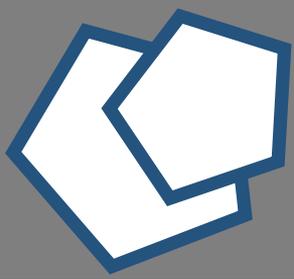
- Blood service operators are accountable for safe, efficient, transparent, ethical decision making.
- Stakeholders need to **understand and contribute to decisions** that affect them.
- Managers of public risks benefit from stakeholder **input**, which enhances the information base for decision making.



Risk Management Principles

The principles of Risk Management are:

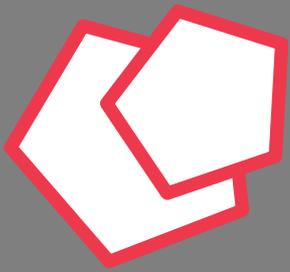
- Beneficence
- Fairness
- Transparency
- Consultation
- Evidence and judgment
- Practicality and proportionality
- Vigilance
- Continuous improvement



Problem Formulation

Purpose

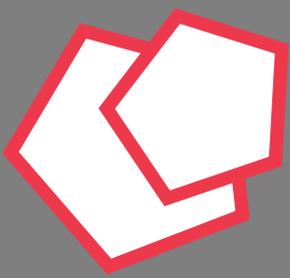
- To generate a **contextual understanding** of the issue and its genesis, and assess which risk management principles are most relevant;
- To consider potential significant **impacts on key stakeholders**;
- To identify **potential risk management options** that should be considered by the assessments and compared in the evaluation stage;
- To develop a clear risk/benefit **assessment question**;
- To identify the **decision support** (information gathering) team and the decision-makers, and declare and resolve any conflicts of interest that could affect assessment, evaluation and decision



Assessments

Purpose

- To provide **credible scientific and technical information for decision-makers** on the nature and significance of the risks in question
- Assessments are **systematic analyses** of relevant information that are conducted to support a decision
- Designed to provide the information and analyses that **decision-makers** require to address the issue
- Conducted according to the **methods and standards** of the specific **discipline**

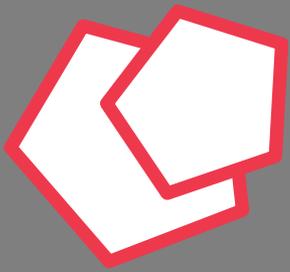


Assessment Principles

Various types of assessments are used to help make decisions about risks. These assessments must be conducted so they serve as useful inputs for the decision-making process.

To ensure the value of the assessments, the risk management policy should provide a set of expectations for these assessments, such as:

- *Proportionality*
- *Timeliness*
- *Judicious use of evidence*
- *Characterization of uncertainty*
- *Variability*
- *Transparency and confidentiality*



Assessments

An **initial screening assessment** helps you:

- assess the level of risk, relevant ethical concerns, and the urgency of taking action
- shed light on the quality of information on a subject
- assess the information and resources needed for full assessments and confirm which specific assessments would be most useful.

Specific assessments may include, among others:

Blood safety risk assessment [generally considered essential]

Health economic and outcomes assessment [generally considered essential]

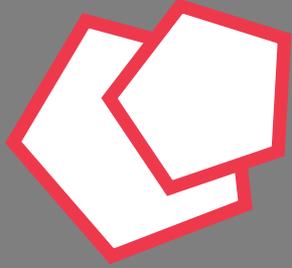
Operational risk assessment

Equity assessment

Trust assessment

Social concern and risk perception assessment

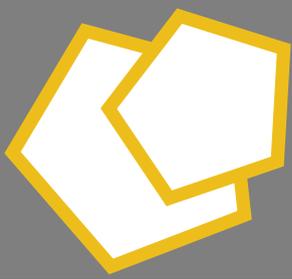
Legal and jurisdictional assessment



Health Economics and Outcomes Assessment

- Are a means to quantify the cost of a risk response at various levels of precaution
- Inform the selection of risk management options for optimal patient outcomes
- Provide an understanding of inherent opportunity costs

Economic analyses of blood safety interventions do not conform to broadly accepted cost-effectiveness thresholds.

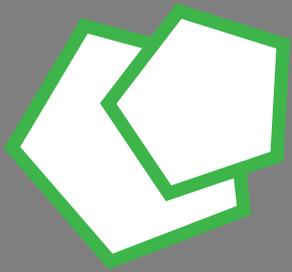


Evaluation

Purpose:

- To **gather, integrate and analyze** the inputs and assessments completed during the Assessment step
- To summarize broader cost-of each

RISK MANAGEMENT OPTIONS	Status Quo	Option 1	Option 2	Option 3	Option 4
ASSESSMENTS					
Blood safety risk					
Health economics and outcomes					
Social Concerns/Risk Perception					



Decision

Purpose

- To select a risk management option based on the results of the Evaluation step using the **Options Rating Scale**
- To develop an **implementation plan** which minimizes risk
- To develop a **monitoring plan** to:
 - enable the tracking and evaluation of the **effectiveness** of the risk management plan and support the **re-evaluation of precautionary decisions** in the face of new information, and
 - identify the elements to be monitored, the frequency of monitoring, and any reporting or communications requirements
- To develop a ongoing **stakeholder plan**
- To **document** the decision and the decision rationale, and the plan for implementing, monitoring and communicating the decision



RBDM Achievements

Deliverables have been achieved

- Framework delivered – Steering Committee and subject matter experts satisfied with content - but it will continually improve
- Blood sector awareness raised
- Positive relationships established with key stakeholders - patient groups, regulators, blood operators, industry organizations
- New knowledge/methodologies introduced, e.g. health economics methodology for blood sector decision making

Well positioned for the crucial next step – sector adoption of risk-based decision-making



Implementation Recommendations

Proposed approach to ensure ongoing improvement and management of the Framework

Promote Framework use:

1. ABO members will lead the industry by committing to use the Framework
2. Establish metrics to evaluate effectiveness
3. Use the online tool to promote use, educate, collaborate
4. Establish a library of RBDM knowledge
5. Broadly communicate successes

Promote system integration:

6. Undertake an outreach program to blood regulators
7. Establish an ongoing communications program

Ensure appropriate governance/management:

8. Establish a standing ABO RBDM working group; administration by Secretariat



RBDM Publications

VOL 25, NO 4

OC

Proceedings of a Consensus Conference: Risk-Based for Blood Safety

Judie Leach Bennett, Morris A. Blajchman, Gilles Delage, Margaret Fear

Blood safety decision making has become increasingly complex, and making is, it consensus confer experts in ar such a fram

FROM safety d

How safe is safe enough, paradigm to risk-v

Jay E. Menitove,¹ Judie Leach Bennett,² Peter Tomas...

Screening for babesiosis: where is the policy? EDITORIAL a zero-risk

REVIEW

Health economics and outcomes methods in risk-based decision-making for blood safety

Les

Brian Custer^{1,2} and Mart P. Janssen,^{3,4}

for the Alliance of Blood Operators Risk-Based Decision-Making (RBDM) Initiative

Trypanos become transmis

and blood transfusion. An estimated 300,000 people in the United States and Canada are infected; most infections occur in those emigrating from South America but a small number of autochthonous cases have also emerged in the United States. Once infected, low-level parasitemia per-

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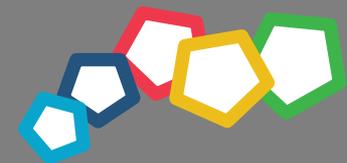
R. Steiner,¹ P. van Aken¹¹ & D. Devine¹²
¹University of Toronto, Toronto, ON, Canada

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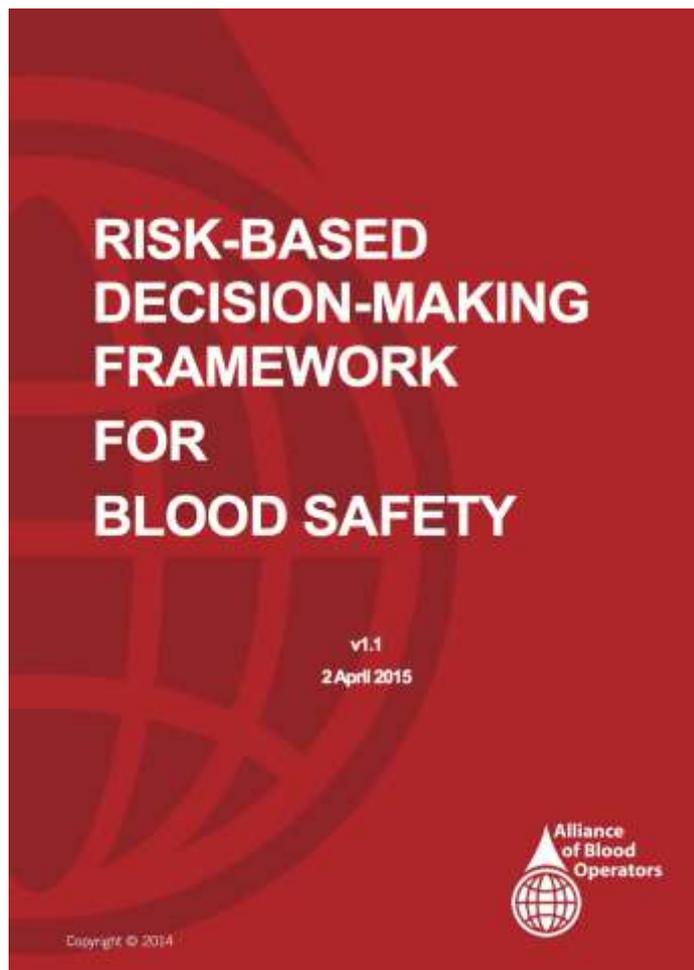
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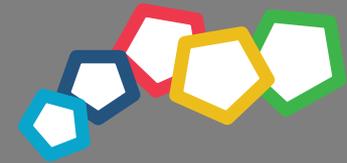




RBDM Documents

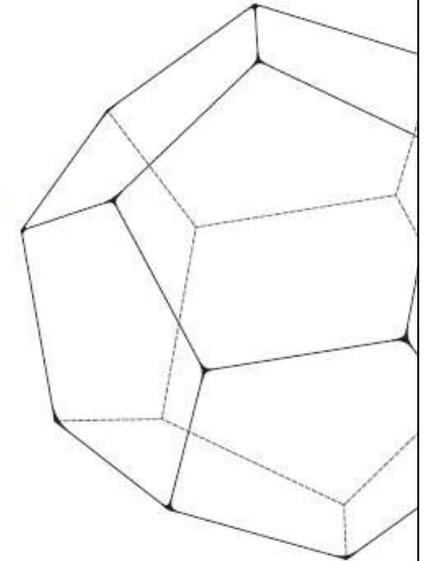


- Full Framework (114 pages) www.allianceofbloodoperators.org
- Short executive summary version soon
- Online interactive tool from August 2015: responding to feedback for a user friendly way to apply the decision making process
- PDF version of the online content



RBDM Online Tool

Making decisions about blood safety can be a complex task. This Framework can help you organize the process and lead you to the best decision for your situation.



Why use this framework?

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Guidance

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