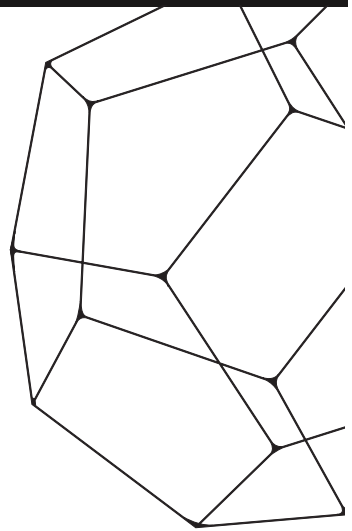


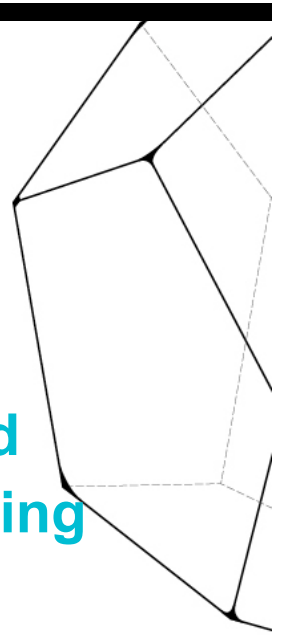
ALLIANCE OF
BLOOD OPERATORS'



Risk-Based Decision-Making Framework for Blood Safety: Update

www.allianceofbloodoperators.org

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

Tolerable risk based on societal considerations

Multiple sectors included in the decision-making process

Summary


The Decision Making Process
1
Preparation
2
Problem Formulation
3
Participation Strategy
4
Assessments
5
Evaluation
6
Decision
Policy Foundations
Risk Management Principles
Risk Communication and Stakeholder Participation
Assessment Principles
Risk Tolerability

Policy Foundation

Assessment Principles

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

- Proportionality
- Timeliness
- Quality of evidence
- Characterisation of uncertainty
- Variability, Integration with related analyses
- Transparency and confidentiality

Stage 4

Assessments

Core:

- Blood Safety Risk
- Health Economics and Outcomes
- Stakeholder
- Operational Risk

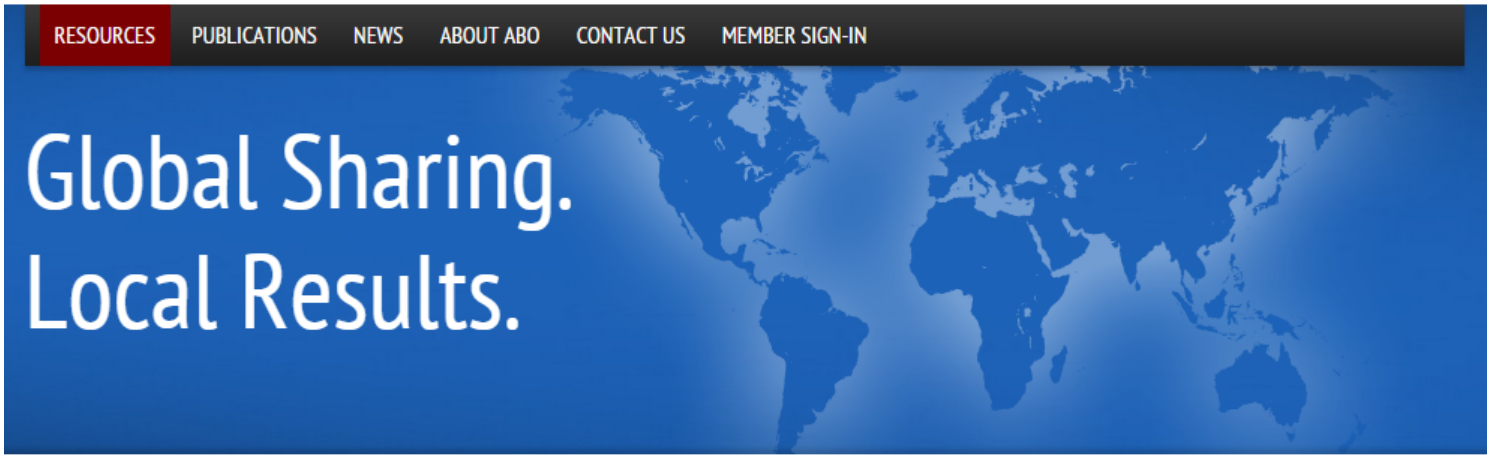
Contextual:

- Social Concern & Perception
- Equity, Trust, Legal & Jurisdictional

Alliance of Blood Operators

Global Sharing. Local Results.

RESOURCES | PUBLICATIONS | NEWS | ABOUT ABO | CONTACT US | MEMBER SIGN-IN

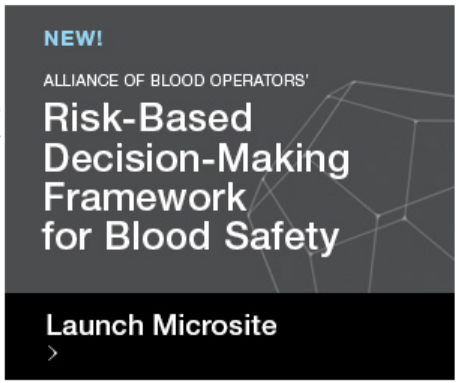


Risk-Based Decision-Making

Decisions about blood safety need to take numerous factors into account, such as risks, benefits, costs, ethical issues, and stakeholder perspectives.

ABO has developed a unique framework to help blood service operators streamline the process and make responsible decisions that lead to the greatest good. Whether the blood safety decision to be made is small or large in scale, this framework can help to organize the process and to assure the quality of the information used to make the decision.

More information about the Framework can be found by launching the microsite.



RISK-BASED DECISION-MAKING
DEVELOPMENT OF THE RISK-BASED DECISION-MAKING FRAMEWORK
THE RISK-BASED DECISION-MAKING FRAMEWORK
STAKEHOLDER CONSULTATION



ALLIANCE OF BLOOD OPERATORS

Risk-Based Decision-Making Framework for Blood Safety

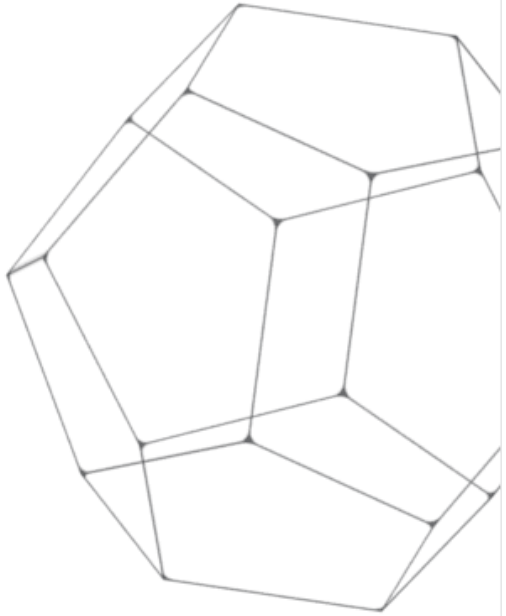
Welcome to the Alliance of Blood Operators' Risk-Based Decision-Making Framework for Blood Safety. Please sign in below, or register for an account. Please note that this site has been optimized for browsers above IE7.

Username or Email

Password

Remember Me

Log In



While blood safety decisions vary widely in scope, the decision-making process follows common principles. This framework can help organise the process and assure the quality of the decision.

Let's get started >

Return to any stage >

Why use this framework?

Streamline the process of assessing blood safety risk and make informed blood safety decisions. The framework helps simplify the decision-making process by breaking it down into a logical sequence.

>

Guidance

Learn about the risk-management policy foundations that will guide your work at every stage of the decision-making process. This foundational knowledge will help you use the framework more effectively.

>

Stage 1 Preparation

Review the basics of risk management so you can carry out the other stages efficiently and effectively

Get Started >

Stage 2 Problem Formulation

Stage 3 Participation Strategy

Stage 4 Assessment

Stage 5 Evaluation

Stage 6 Decision

Why use this framework?

Streamline the process of assessing blood safety risk and make informed blood safety decisions. The framework helps simplify the decision-making process by breaking it down into a logical sequence.

Guidance

Learn about the risk-management policy foundations that will guide your work at every stage of the decision-making process. This foundational knowledge will help you use the framework more effectively.

- Use descriptions as specific as possible. Avoid generic statements like “a significant reduction,” “reduces the risk to safe levels.”

Stage 4
Task 3

Step 6
Integrate the results into the framework

OBJECTIVE

Integrate the results of this analysis with the results of other assessments.

ACTIONS

- Retrieve the Risk Management Options and Assessment
- Fill in the blood safety risk assessment results for each risk management option in the table.

Example of a blood safety risk assessment summary

NEXT: Stage 4 Task 4 ›

Task 1 | Task 2 | Task 3 | Task 4 | Task 5 | Task 6 | Task 7

Appendix 5

Blood Safety Risk Assessment

Option	Virus X Risk	Non-Virus X risks modified by interventions
Status Quo	*Autochthonous:* Most likely estimate: chosen as 10th percentile of the distribution; 1.6 per 10,000 (16 per 100,000). *Travel-related:* Most likely estimate: midrange of 6.5 per 100,000. *Total risk:* Most likely estimate: sum of the most likely estimate for each risk component: 22.5 per 100,000.	We will use data in Custer et al, page 2464, Table 3* with the following modifications: · Adjust bacterial risk from platelets from 1 in 47,000 to 1 in 2,000. · Adjust bacterial risk from other components from 1 in 50,000 to 1 in 500,000. · Adjust HBV risk from 1 in 153,000 to 1 in 750,000. · Eliminate CMV, FNHTR, and TRIM from the model.
Option A: Defer donation for travellers to regions where Virus X is thought to be endemic.	100% effective for travel-related cases; no effect on autochthonous case risk.	· No effect on any of these variables.
Option B: Implement PRT without modification of existing procedures.	50-fold risk reduction for each risk component; i.e., risk is 2% of the baseline total risk.	· Retain risk reduction factors.

*Custer, B., Agapova, M. and Martinez, R.H. (2010), The cost-effectiveness of pathogen reduction technology as assessed using a multiple risk reduction model. Transfusion, 50: 2461-2473. doi: 10.1111/j.1537-2995.2010.02704.x

Acknowledgements

Commissioned & sponsored by:

The Alliance of Blood Operators:

- 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

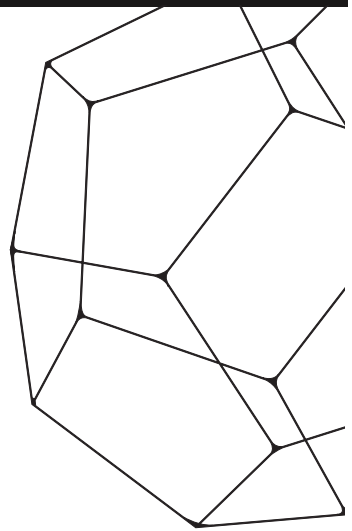
With additional support from:

AABB and Héma-Québec.

Developed by:

- Brian Custer *(Blood Systems Research Institute)*
- Smaranda Ghibu *(Héma-Québec)*
- Michel Giroux *(Institut de consultation et de recherche en éthique et en droit (ICRED), Québec)*
- Matt Granato *(America's Blood Centers)*
- Mart Janssen *(University of Utrecht/Sanquin)*
- Lou Katz *(America's Blood Centers)*
- Andy Kelly *(Irish Blood Transfusion Service/European Blood Alliance)*
- Stephanie Kelly *(Canadian Blood Services)*
- Judie Leach Bennett *(Canadian Blood Services) (Project Chair)*
- Lorna Lemay *(LL Concord Consultation & Mediation Services)*
- Peter McDonald *(Australian Red Cross Blood Service)*
- Jay Menitove *(AABB)*
- Greg Paoli *(Risk Sciences International)*
- Mark Skinner *(World Federation of Hemophilia, USA)*
- Peter Tomasulo *(Blood Systems Inc.)*
- Ralph Vassallo *(American Red Cross/Blood Systems Inc.)*
- Tina Viner *(Canadian Blood Services)*
- Sheila Ward *(Canadian Blood Services) (Project Manager)*
- Anne Wiles *(Risk Sciences International)*
- Lorna Williamson *(National Health Service Blood & Transplant)*

ALLIANCE OF
BLOOD OPERATORS'



Risk-Based Decision-Making Framework for Blood Safety

www.allianceofbloodoperators.org