

# Improving blood safety through a risk-informed approach to complex decision-making

## What was achieved?

Risk-based decision-making is an approach to decision-making that estimates risk, prioritizes risk management options and communicates risk to all stakeholders. It is a structured process that assists decision-makers faced with high-impact, complex decisions involving multiple objectives and an uncertain environment. The aim of risk-based decision-making is to ensure that decisions between competing alternatives are considered with an awareness of the risks associated with each option, and that all attributes of a decision are considered in an integrated way. The Alliance of Blood Operators, through the leadership of Canadian Blood Services, adapted this approach to the needs of blood operators and developed the *Risk-Based Decision-Making Framework for Blood Safety*.

The Risk-Based Decision-Making Framework for Blood Safety provides blood operators with an approach for making decisions about blood safety in the context of emerging risks, evolving technology, societal issues, and economic realities.

It moves away from an unsustainable zero-risk approach to one that balances risks against benefits and acknowledges that some level of risk may be tolerable to achieve the anticipated benefits. By using this framework, Canadian Blood Services has been able to implement increasingly balanced and effective policies that continue to meet the needs of Canadians.

## How was this achieved?

Historically, decisions about the safety of blood and blood products were based on the concepts of “zero-risk” and “safety at any cost.” This approach was in reaction to system failures in relation to infectious threats to blood systems in the 1980s and 1990s. Moving to a balanced approach with a framework to characterize and prioritize risk encourages consistency in decision-making practices across the blood sector for situations that pose similar risks.

With Canadian Blood Services' leadership, the International Consensus Conference on Risk-Based Decision-Making for Blood Safety (Toronto, 2010) convened international scholars and experts to seek recommendations and guidance on creating a framework for risk-based decision-making. During the conference, based on presentations and after reviewing information on various issues related to risk practices, a draft consensus statement was developed and later finalized (Stein et al., 2011). The statement acknowledged the inherent risks in blood transfusion, the impossibility of achieving zero risk, and the responsibilities of blood operators to protect the safety and supply of blood products.

Canadian Blood Services, with support from the Alliance of Blood Operators, led the research and coordination efforts to produce a risk-based framework for supporting complex decision-making. The framework offers a structured approach for setting the best course of action under uncertainty by identifying, assessing, communicating, and mitigating risk to inform decision-making. Specifically, the framework outlines six stages to help blood operators systematically consider risk: preparation, problem formulation, participation strategy, assessments, evaluation and decision. The framework also includes deliberate engagement of stakeholders as a central element of decision-making — underscoring the importance of effective, two-way risk communication.



## What was the impact and outcome?

The Alliance of Blood Operators' risk-based decision-making framework provides an approach to making blood safety decisions, allowing for the consideration of inherent risk and societal values. This approach is reflected in the framework's key impacts:

**Holistic decisions:** The framework accounts for all aspects of blood safety: product safety, process safety, sufficiency of supply, patient safety, donor safety and recipient safety. This comprehensive view ensures that all factors are considered in decision-making.

**Effective policies:** The framework has informed policy decisions for blood operators around the world. Recommendations from the framework have played a key role in setting guidelines and protocols, ensuring safer blood practices.

**Simpler decision-making:** The framework's structured approach helps blood operators organize and simplify complex decision-making processes. It guides operators through a sequence of stages, which helps them assess and manage risks more efficiently.

Since the publication of the framework in 2015 and subsequent iterations, blood operators have used the framework to make decisions and assess the risk of new and emerging pathogens, as well as assess risks to the security and supply of blood products. At Canadian Blood Services, the framework has been used to assess:

- the risk of *Babesia microti* to the Canadian blood supply.
- the risk reduction capabilities of current cytomegalovirus (CMV) testing.
- the risk of hepatitis E virus to the Canadian blood supply.
- the security of the immunoglobulin supply for patients in Canada.
- the security of the plasma supply for patients in Canada.

The framework has also been used outside of Canadian Blood Services. For example:

- The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) in the United Kingdom used the framework to assess donor eligibility criteria.
- The Association for the Advancement of Blood & Biotherapies (AABB) in the United States used the framework to assess the risks of iron deficiency among blood donors.
- Australian Red Cross Lifeblood used the framework to examine the risks of human T-lymphotropic virus (HTLV) to the Australian blood supply.

By embracing a structured methodology for assessing and managing risk, blood operators are not only improving safety practices but also allocating resources more effectively and improving their decision-making processes.

## Bibliographies

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