



ALLIANCE OF  
BLOOD OPERATORS'

# Risk-Based Decision-Making Framework for Blood Safety

## **Workbook**

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Version: August 2018

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## The aim of the Risk-Based Decision-Making Framework is 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 framework consists of six stages. In the first stage, you review foundational material and gain understanding of how the framework is organised. The remaining stages — problem formulation, participation strategy, assessment, evaluation, and decision — are common to many decision frameworks. Each stage has a purpose and a process and includes several decision-support tools.

## How to use the Risk-Based Decision-Making Workbook

This workbook is designed to assist with completion of assessments using the Risk-Based Decision-Making (RBDM) Framework.

It is designed to enable application of the RBDM process in a scalable manner. Depending on the complexity of the risk situation you are dealing with or the urgency with which a decision needs to be made, the guidance and the tools provided can be easily applied.

Judgement by the risk management team is required before the process begins. They must ask themselves:

- Is this a complex decision that requires in-depth assessment of a series of factors?
- Is it a blood safety decision where time is critical and a quick decision is required?
- Is the risk small or contained and a full assessment would be out of proportion to the risk?

The answers to these questions will determine the depth and extent of the assessments.

The workbook should be used from beginning to end and should be completed in conjunction with the instructions provided in the RBDM Framework.

For complex decisions, it may be most helpful to have the RBDM process facilitated by someone familiar with use of the Framework. As an additional aid, a Facilitator's Guide has been developed and can be found in the "Resources" section of the Framework.

### A note for Associations, alliances or networks

Associations, alliances or networks have uniquely complex internal communication requirements compared to unitary blood operators and need to address them in the plan at the outset very clearly.

# Key Definitions



## Blood Safety

Blood safety encompasses product safety, process safety, sufficiency of supply, donor safety, and recipient safety.

## Risk

The impact of exposure to a hazard, combining the probability or frequency of exposure outcomes with the seriousness of those outcomes.

## Risk Assessment

A formal, systematic process for estimating the level of risk that considers both the consequences of exposure to a hazard and the probability or frequency of these exposures. While risk assessments use discipline-specific methods, a core set of steps and quality expectations apply to most processes.

## Risk Management

A systematic approach to setting the best course of action by identifying, assessing, understanding, acting on, and communicating risk. While distinct from risk assessment, risk management interacts with risk assessment processes at several points, particularly at the problem formulation stage, when the scope and urgency of a risk determine the assessments needed for the risk management decision.

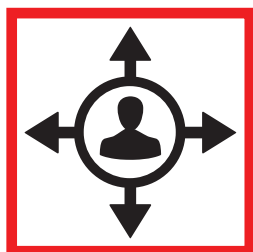
## Risk Tolerability

The degree to which people can be expected to tolerate a risk. Tolerable risks are those that individuals and groups can be expected to tolerate for the benefit of society. Intolerable risks are too high for individuals or groups to tolerate.

## Stakeholder

Any individual or group that is affected by, or has an interest in, an issue.

# Summary of the Framework and Workbook



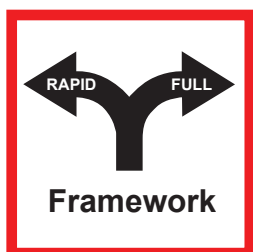
The RBDM Framework is best completed by someone who has an understanding of or has undergone training on risk management



The workbook can be completed fully, or when quick decisions are required a more succinct approach can be used

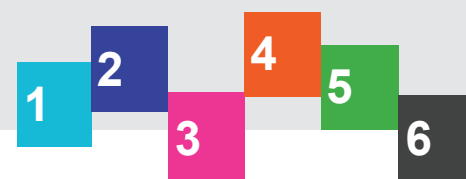


You may utilise a more rapid approach of the version if using the full framework would be disproportionate to the size of the risk



If a rapid approach is used due to time constraints for a decision it should always be followed up with the completion of the full RBDM process to validate that the initial decision was appropriate

# Summary of the Framework and Workbook



## STAGE 1

### Briefly Review the Foundations of Risk Management

Stage 1 is the foundation of the framework and contains the underlying principles. An understanding of these foundations and risk management principles is considered crucial to completion of the risk-based decision-making process. If you do not possess this level of understanding it is recommended that you read the resources available prior to commencement.

## STAGE 2

### Characterise the problem to generate risk management options

At this stage you will gather information about the risk issue you are facing to determine which assessments are required and the risk management options that might be feasible. The issue characterisation checklist helps you gather key pieces of information by asking a series of questions. For the best results, obtain input from subject matter experts. In a more rapid scenario or a smaller risk decision it may be just a few people identifying the issues and options.

## STAGE 3

### Consult with necessary stakeholders

This stage involves clarifying the need to involve stakeholders and the roles they may play, identifying and prioritising stakeholder groups, and develop a consultation or communication plan. It is recognised that, depending on the issue, there may not be time for full consultations with all stakeholders. However, some form of assessment and planning is necessary. When a decision is not required in a short time frame or more complex decisions are required there is an expectation that full stakeholder consultation would be undertaken.

## STAGE 4

### Assessments

Typical assessments conducted at this stage include a blood safety assessment, health economic assessment, operational risk assessment and contextual assessments appropriate to the issue such as ethical, legal or regulatory. How in-depth these are will depend on the risk problem and the time frame required.

## STAGE 5

### Evaluate the risk management options based on completed assessments, stakeholder input, and risk tolerability

At this stage all the work that has been done so far is gathered together and used to evaluate the risk management options. Using the quantitative and qualitative information gathered, the risk tolerability of each option is also evaluated and the options are rated and ranked.

## STAGE 6

### Decide on the best risk management option

Stage 6 involves making and sharing the decision about the best risk management option and writing a report justifying the recommended approach.

# Preparation

Stage 1 is the foundation of the framework and contains the underlying principles. Understanding these foundations is considered crucial to completion of the risk-based decision-making process. (For further information refer to Stage 1 in the Risk-Based Decision-Making Framework)

## Risk Management Principles

The purpose of risk management is not to eliminate risk but to use resources appropriately to minimise risk. Principles such as those suggested below govern the process and the actions that follow from the decisions.

- **Beneficence:** Decision must do more good than harm. Decision must focus on the safety of donors and patients.
- **Fairness:** Safety decisions must be timely, fair, independent and sensitive to cultural values. Risks unacceptable to society are not imposed, and the risk is distributed as equitably as possible.
- **Transparency:** The process must be transparent and accessible to stakeholders and members of the public. People involved in making decisions must declare all relevant conflicts of interest.
- **Consultation:** Stakeholders must be consulted on relevant issues that affect them or present a significant social concern. The consultation process must give stakeholders an opportunity to provide input.
- **Evidence and Judgement:** Decisions should include an analysis of the risk, possible mitigation options, expected benefits of the intervention and impact of costs of achieving them. This analysis should encompass the best available evidence, coupled with sound judgement.
- **Practicality and Proportionality:** Managing the risk should be proportional to the level of risk and potential for risk reduction.
- **Vigilance:** Evolving risk situations must be monitored to identify the need for interventions, understand stakeholder concerns, and assess the effectiveness of risk management measures.
- **Continuous Improvement:** All aspects of blood safety risk and management must undergo periodic review and improvement.

## Risk Tolerability

- Risk tolerability is a public risk management principle, concerned with a judgement of the appropriate level of risk to the public from a managed activity.
- Risk tolerability may be applied as an evaluation of a quantitative risk level against the cost-effectiveness of potential risk reduction activities or it may be a more complex judgement that includes a qualitative judgement of a range of contextual factors associated with the societal perspective of risk.

## Risk Tolerability Principles

- Individuals should be protected from high risks.
- Individuals are expected to tolerate reasonable risks in exchange for the societal benefits gained.
- The tolerability of a risk depends on the nature of the risk.
- Tolerated risks are fairly distributed.
- People should be informed and updated about the risks they are assuming for the benefit of society.

## Specific Assessments as part of the Framework

- **Blood safety risk assessment**
- **Health economics and outcomes assessment**
- **Stakeholder assessment**
- **Operational risk assessment**
- **Contextual assessments** - risk perception, ethical concerns, trust, equity, legal issues and jurisdictional factors, among others.

## Expectations of the assessments:

To ensure the value of the assessments it is expected that they will incorporate:

- **Proportionality:** Scope and level of detail of assessments are proportional to the significance of the risk and the decision to be made.
- **Timeliness:** Assessment information is provided in a timely manner.
- **Quality of Evidence:** Assessments use established methods of assessing data.
- **Characterisation of uncertainty:** Assessments should describe the types and sources of uncertainty and their impact on the assessment results.
- **Variability:** Assessments must consider how the risk varies within relevant populations.
- **Integration with related analyses:** Individuals responsible for different assessments should communicate to ensure all relevant areas are covered while minimising duplication of effort.
- **Transparency and confidentiality:** Assessments that support decisions of primary importance to the public should include consultations with stakeholders and the public.

# Problem Formulation

In this stage you will

- Define the characteristics of the issue you are addressing
- Identify the decision driver
- Formulate the assessment question
- Identify options
- Determine the required assessments

*(For further information refer to Stage 2 in the Risk-Based Decision-Making Framework)*

## Issue Characterisation Checklist

Answer the following questions:

Q1. Does the issue involve a threat to the safety or quality of the blood supply?			
<input type="checkbox"/> YES	If YES, answer the following:	<input type="checkbox"/> NO	If NO, Provide rationale below ✍
What is the threat? Who is at risk? a) Blood recipients b) Donors c) Others			
Briefly describe the estimated severity, probability of the threat and severity of consequences			
Q2. Does the issue involve a threat to the availability of blood and blood products?			
<input type="checkbox"/> YES	If YES, answer the following:	<input type="checkbox"/> NO	If NO, Provide rationale below ✍
How is the blood supply threatened?			
Q3. Does this issue have the potential for a significant impact on blood donors?			
<input type="checkbox"/> YES	If YES, answer the following:	<input type="checkbox"/> NO	If NO, Provide rationale below ✍
a) What is the risk?			
b) What is the impact?			



**Q4. Does the issue involve the implementation of a new test and/or technology?**

YES If YES, answer the following:  NO If NO, go to next question →Q5

→ What will test/technology achieve?

→ What tests could be implemented?

→ What technology options have been considered?

→ Are there significant financial implications?

**Q5. Does the issue involve the withdrawal of an existing process, safety step, technology or test?**

YES If YES, answer the following:  NO If NO, go to next question →Q6

→ What is the rationale for withdrawing the procedure or test?

→ What outcomes are expected?

→ Are there any related options of alternatives other than withdrawal?

**Q6. Is there a high level of risk communication required on the issue?**

YES If YES, answer the following:  NO If NO, Provide rationale below

→ Describe the potential impacts of this concern.



**Q7. Is there a concern in society or the media about a serious health risk associated with the issue?**

YES If YES, answer the following:  NO If NO, Provide rationale below

→ Describe how the issue (or related issues) has been covered by the media.



**Q8. Does the risk affect a particular group more than others? Identify the group and its relevant features.**

<input type="checkbox"/> YES	If YES, answer the following:	<input type="checkbox"/> NO	If NO, Provide rationale below
→ Identify the group and its relevant features.		✍	
→ How is the group impacted?			
→ Is there disproportion or inequity in the distribution of risks and benefits?			

**Q9. Do you have positive, supportive relationships with key stakeholders?**

<input type="checkbox"/> YES	If YES, answer the following:	<input type="checkbox"/> NO	If NO, answer the following:
→ Identify the stakeholders and consider how these relationships can be leveraged.		→ Identify the stakeholders and explain the issue.	

**Q10. Could the issue involve ethical, legal, political, regulatory factors? Describe the contextual aspects that could influence a risk management option’s usefulness, e.g. giving iron to donors in some states would be considered the “practice of medicine”.**

<input type="checkbox"/> YES	If YES, answer the following:	<input type="checkbox"/> NO	If NO, answer the following:
→ Describe the potential legal, political or regulatory issue.		→	

**Summarise the issue:**

**Risk Management Principles**

What are the risk management principles involved:

- |              |                          |                                  |                          |                        |                          |
|--------------|--------------------------|----------------------------------|--------------------------|------------------------|--------------------------|
| Benevolence  | <input type="checkbox"/> | Consultation                     | <input type="checkbox"/> | Vigilance              | <input type="checkbox"/> |
| Fairness     | <input type="checkbox"/> | Evidence and Judgement           | <input type="checkbox"/> | Continuous Improvement | <input type="checkbox"/> |
| Transparency | <input type="checkbox"/> | Practicality and proportionality | <input type="checkbox"/> |                        |                          |

**Decision Drivers**

Based on the information gathered in the Issue Characterisation Checklist and taking the relevant risk principles into account, note the main reasons a decision is required. Examples may be threat to the blood supply, a social or ethical concern, a safety issue.

**What are the decision drivers?**

**Assessment Question**

Develop a question that will guide the primary decision to be made and the types of assessments required to make the decision. Think about the answers you need to make the decision; this will guide the assessment teams.

**What is the assessment question?**

## Risk Management Options and Assessment table

From the Issue Characterisation Checklist generate the risk management options and assessments required. Note the risks and benefits associated with each option under the headings below. EXAMPLE BELOW:

Risk Management Options	Blood Safety Risk	Operational Risk <small>Assess the risks from impacts on internal procedures, people and systems</small>	Health Economic/ Budget Impact/Cost Utility	Contextual factors	Security of Supply (Adequate inventory)	Assessments Required	
<b>OPTION A</b> Status Quo <i>example</i>	<i>Significant risk to recipients</i>	<i>None since no change</i>	<i>No implementation costs associated with transfusion-transmitted infection</i>	<ul style="list-style-type: none"> <li>• <i>Breach of ethical principles as a risk to patient safety has been identified</i></li> <li>• <i>Erosion of trust – patients and other stakeholders</i></li> </ul>	<i>None</i>	<input checked="" type="checkbox"/> Blood Safety <input type="checkbox"/> Budget Impact <input type="checkbox"/> Health Economics <input type="checkbox"/> Operational	<input checked="" type="checkbox"/> Ethical <input type="checkbox"/> Legal/regulatory <input type="checkbox"/> Contextual <input checked="" type="checkbox"/> Social concern/trust <input type="checkbox"/> Other
<b>Expected Benefits of Option A</b> <i>example</i>	<i>No benefit to patient safety</i>	<i>Blood operator does not have to make operational changes</i>	<i>Blood operator does not incur new or additional costs</i>	<i>Negative benefit to trust and ethical practices</i>	<i>Not applicable</i>		
<b>OPTION A</b> Status Quo						<input type="checkbox"/> Blood Safety <input type="checkbox"/> Budget Impact <input type="checkbox"/> Health Economics <input type="checkbox"/> Operational	<input type="checkbox"/> Ethical <input type="checkbox"/> Legal/regulatory <input type="checkbox"/> Contextual <input type="checkbox"/> Social concern/trust <input type="checkbox"/> Other
<b>Expected Benefits of Option A</b>							
<b>OPTION B</b>						<input type="checkbox"/> Blood Safety <input type="checkbox"/> Budget Impact <input type="checkbox"/> Health Economics <input type="checkbox"/> Operational	<input type="checkbox"/> Ethical <input type="checkbox"/> Legal/regulatory <input type="checkbox"/> Contextual <input type="checkbox"/> Social concern/trust <input type="checkbox"/> Other
<b>Expected Benefits of Option B</b>							

### Risk Management Options and Assessment table

From the Issue Characterisation Checklist generate the risk management options and assessments required. Note the risks and benefits associated with each option under the headings below.

Risk Management Options	Blood Safety Risk	Operational Risk <small>Assess the risks from impacts on internal procedures, people and systems</small>	Health Economic/ Budget Impact/Cost Utility	Contextual factors	Security of Supply (Adequate inventory)	Assessments Required	
OPTION C						<input type="checkbox"/> Blood Safety <input type="checkbox"/> Budget Impact <input type="checkbox"/> Health Economics <input type="checkbox"/> Operational	<input type="checkbox"/> Ethical <input type="checkbox"/> Legal/regulatory <input type="checkbox"/> Contextual <input type="checkbox"/> Social concern/trust <input type="checkbox"/> Other
Expected Benefits of Option C							
ADDITIONAL OPTIONS						<input type="checkbox"/> Blood Safety <input type="checkbox"/> Budget Impact <input type="checkbox"/> Health Economics <input type="checkbox"/> Operational	<input type="checkbox"/> Ethical <input type="checkbox"/> Legal/regulatory <input type="checkbox"/> Contextual <input type="checkbox"/> Social concern/trust <input type="checkbox"/> Other
Expected Benefits of Additional Options							

Note specialised expertise required for the following assessments

Blood Safety  \_\_\_\_\_ Budget impact  \_\_\_\_\_ Ethical  \_\_\_\_\_ Contextual  \_\_\_\_\_  
 Health Economics  \_\_\_\_\_ Operational  \_\_\_\_\_ Legal regulatory  \_\_\_\_\_

Stakeholders are people or groups with an interest (stake) in an issue. Stakeholders' concerns about a risk issue may significantly affect public perception, which in turn can affect blood supply. This stage involves assessment and development of a management plan for stakeholders. It is recognised that when a quick decision is required there may not be time for a full consultation with stakeholders, however, full consultation should be the preferred option wherever possible.

*(For detailed information on stakeholder participation, refer to Stage 3 in the Risk-Based Decision-Making Framework)*

## Create a plan for consulting and communicating with stakeholders

### Task 1 : Review best-practice considerations



Consultation with selected stakeholders improves the quality of the decision by creating a shared understanding and building trust.



Remember stakeholders have a right to be consulted about decisions that affect them and issues in which they have a significant interest. The extent of stakeholder involvement depends on the situation.



You may have to communicate with the general public in order for society to understand and embrace important decisions. When communicating the risk to a broader audience of stakeholders be sure to think about the reason and urgency for communicating about the issue, the intended outcome, time frame, and form of communication (persuasive or informative).

### DO's of Stakeholder Consultation



- Be clear about which aspects of an issue are open to stakeholder input
- Let stakeholders know how their input was used
- Keep a positive relationship with stakeholders and the organisation

### DON'Ts of Stakeholder Consultation




- Do not stop engaging with stakeholders if they happen to disagree with the decision. Engaging with them even if they disagree will help them to accept the decision as valid.

### Decide on the best form of communication, which may be:



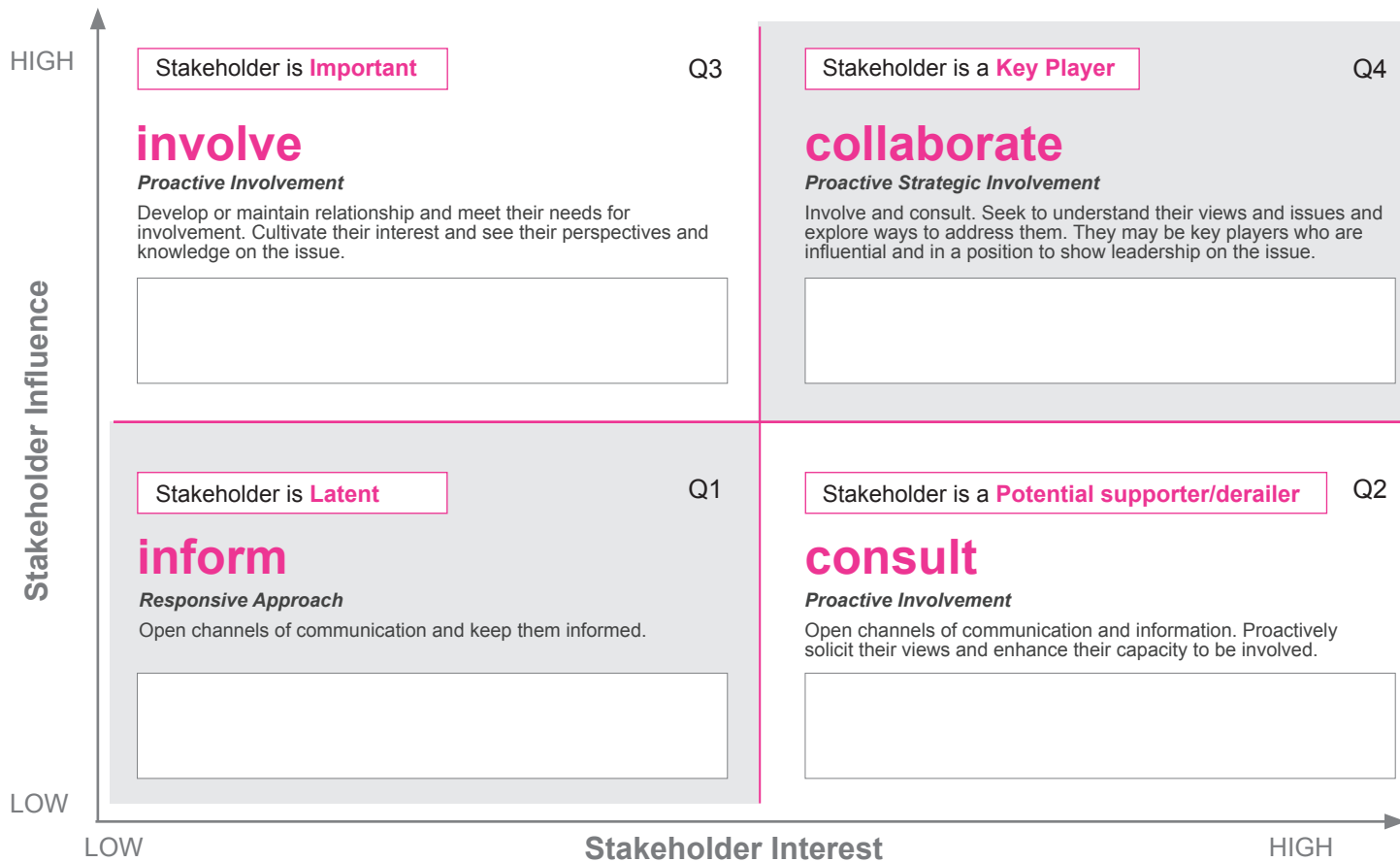
**PERSUASIVE:** Communicating in a persuasive tone would be useful when reinforcing a recommendation and its rationale to elicit a specific behaviour; it is used in urgent situations when the audience needs to understand and follow protective measures, or to encourage adoption of health behaviours.

**INFORMATIONAL:** Enhancing public understanding of an issue without making recommendations to enable people to make informed decisions.

Define the need for participation			
Answer the following questions:			
→ Why do the stakeholders have to be involved? Do they expect to be involved? If so how?			
→ What roles will stakeholders play? Will their involvement have an impact on the decision?			
→ Why do people need to know about the situation? Might public perception have an impact on the decision or ability to carry it out?			
Identify and assess stakeholder groups	Positive/Constructive relationship 	Neutral/non-existent relationship 	Challenging/negative/adversarial 
Identify the stakeholders you wish to engage with based on the following categories:			
Professional associations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Health institutions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Health professionals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Thought leaders	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Funders	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Regulators	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Industry partners	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Suppliers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patient advocacy groups	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Affected patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Donors	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
General public	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Use the map quadrants (below) to determine the appropriate levels of interaction with the stakeholders you identified (previous page)

**Stakeholder Identification Tool**



**Stakeholder Participation Plan**

Complete the plan for all relevant stakeholder groups.

Group	Interest (Int) & Influence (Inf) (based on quadrant above)	Issues	Plan

(For tips on developing messaging refer to Stage 3 in the Risk-Based Decision-Making Framework)

At this stage you complete the assessments that were identified as required in Stage 2

## Review Assessment Principles

Review the assessment principles described earlier in Stage 1 before conducting the assessments.

## Assessment Methods

Consider which assessment methods will be used. Assessments may use quantitative methods, qualitative methods, or both. As far as possible, assessments should capture:

- Sources of variability
- Extremes of risk
- Probabilities (numerical or estimated) of different risk scenarios

## Assessment Teams

It is recommended that you consider obtaining specialised expertise for certain assessments, e.g. health economics.

*(For detailed information on conducting the various assessments, refer to Stage 4 in the Risk-Based Decision-Making Framework)*



**APPLY ASSESSMENTS TO EACH  
RISK MANAGEMENT OPTION  
IDENTIFIED IN STAGE 2**



## Blood Safety Assessment

Determine the risk to blood safety and the impact of the risk management options on the risk.

The following steps are performed when completing a blood safety risk assessment. It is likely that you will have specialised expertise available to complete this assessment.

*(For detailed information on conducting blood safety risk assessments, refer to Stage 4 in the Risk-Based Decision-Making Framework)*



### Step 1: Frame the problem



### Step 2: Identify the hazard



### Step 3: Assess hazard exposure



### Step 4: Characterise the blood safety risk



### Step 5: Assess the impact of the risk management options

Transfer a summary of the completed blood safety risk assessment into the Blood Safety Summary Table.

***Briefly evaluate how effectively each risk management option will address the blood safety risk.***

## Blood Safety Summary Table

Briefly evaluate how effectively each risk management option will address the blood safety risk.

Blood Safety Risk	Status Quo	Option A	Option B	Option C
Option description				
Estimate the level of risk reduction achieved by the risk management options				
How will it reduce the probability of adverse outcomes?				
Will it reduce the severity of adverse outcomes?				
What are the advantages of this option?				
Can you see disadvantages to this option?				



## Operational Risk Assessment

*This assessment requires you to identify operational risks associated with implementing the risk management options. Your organisation's risk manager should be able to assist with this assessment. You may also use the risk identification tool to assist you identifying risks. A sample risk rating tool is provided on page 22 however if your organisation has a risk matrix this is what should be used.*

**Describe your options below. If you need to, add more option boxes.**

Status Quo	Option A	Option B	Option C

## Risk Management Option A

Risk Description	Causes	Controls	Likelihood	Impact	Risk Rating

**Risk Management Option B**

Risk Description	Causes	Controls	Likelihood	Impact	Risk Rating



**Risk Management Option C**

Risk Description	Causes	Controls	Likelihood	Impact	Risk Rating

**Summary**

*Provide a summary of the Operational Risk Assessment:*



## Risk Assessment Tool - Sample risk matrix

This is a sample risk matrix. The recommendation is that your organisation's tool be used for assessing operational risks and/or this one be modified to reflect your organisation's risk appetite using appropriate examples of impact and thresholds and likelihood definitions.

		Likelihood of risk occurring...						
		Almost Certain	Likely	Possible	Unlikely	Rare		
<b>Very High</b> • Financial: Material deviation from approved budget. • Reputation: National or sustained negative media exposure; Extreme degradation in relationship with governments, customers and/or stakeholders. • Customer: Material deviation in meeting demand.	<b>5</b>	<b>High (25)</b>	<b>High (20)</b>	<b>High (15)</b>	<b>Medium (10)</b>	<b>Medium (5)</b>		
	<b>High</b>	<b>4</b>	<b>High (20)</b>	<b>High (16)</b>	<b>Medium (12)</b>	<b>Medium (8)</b>	<b>Medium (4)</b>	
		<b>Moderate</b>	<b>3</b>	<b>High (15)</b>	<b>Medium (12)</b>	<b>Medium (9)</b>	<b>Medium (6)</b>	<b>Low (4)</b>
	<b>Minor</b>		<b>2</b>	<b>Medium (10)</b>	<b>Medium (8)</b>	<b>Medium (6)</b>	<b>Low (4)</b>	<b>Low (2)</b>
			<b>1</b>	<b>Medium (5)</b>	<b>Medium (4)</b>	<b>Low (3)</b>	<b>Low (2)</b>	<b>Low (1)</b>
<b>Negligible</b>								

## Health Economic Assessment

Because blood is a donated good, the RBDM framework recommends taking a societal perspective when conducting an economic assessment, that is the impact on the health care system rather than solely blood operator economic impact. If a risk is deemed significant enough to be assessed, it calls for a budget impact analysis at a minimum. The risk management team can then decide whether a full economic assessment (budget impact and cost utility assessment) is needed. A full economic assessment requires specialised expertise and financial literacy. Depending on the complexity of the assessment, blood establishments may wish to hire a health economist to conduct the analysis.

*(For further information refer to Stage 4 in the Risk-Based Decision-Making Framework)*

### Budget Impact Analysis

#### Description

- Addresses the ability to afford a particular action
- Addresses not only the financial resources required by the operator, but the financial impact of the action on local, regional or national budgets

#### Primary Outcome

- Numerical figures reflecting the cost differences between risk management options

#### Primary Limitation

- Does not measure effectiveness or benefit of interventions beyond the costs saved from preventing adverse events or use of health service

### Cost Utility Analysis

#### Description

- Assesses value for money in terms of costs versus benefits
- The use of quality-adjusted life year (QALY) as common outcomes enables comparison of different interventions

#### Primary Outcome

- For a pair of interventions: cost difference divided by effectiveness difference, usually in QALY's

#### Primary Limitation

- Provides an average ratio for all people
- Requires weighting of disease or illness health states prevented or caused by each intervention

### Summary

*Provide a summary of the findings from the Health Economic Assessment.*

## Contextual Assessments

In this section you will review contextual issues such as social, legal or ethical concerns associated with the issue. Conducting a contextual assessment enables you to gauge their possible impact on the decision.

Complete the table below to determine if a full contextual assessment is required in one of the identified areas (ethical, legal, regulatory, social concern).

**For more information on contextual assessments, refer to Stage 4 in the Risk-Based Decision-Making Framework)**

Issue	Description	Further assessment required	
<b>Ethical:</b>		YES ✓	NO ✕
Does the situation involve an ethical issue?			
Has the ethical issue affected public policy in the recent past?			
Is the risk seen as unfair?			
Are the risks distributed unfairly within society?			
Does the issue involve vulnerable groups?			
Has there been a lack of consent or access to information?			
<b>Legal /regulatory:</b>		YES ✓	NO ✕
Are there legal/regulatory/ political issues?			
Does this affect the various options?			
<b>Social concern, risk perception, trust:</b>		YES ✓	NO ✕
Does the issue involve a lot of media coverage, high profile people or controversy?			
Is the hazard unfamiliar/ transmission unclear?			
Are the effects potentially serious?			
Is the risk perceived as involuntary?			
Is perceived risk higher than actual?			



Issue	Description	Further assessment required	
		YES ✓	NO ✕
<b>Social concern, risk perception, trust:</b>			
Does the risk outweigh the benefits?			
Is the situation linked to previous controversy?			
Is there a perception that the blood operator has contributed to the risk?			
Is the issue significant enough to threaten any aspect of the system?			
Could the issue affect the credibility and reputation of the blood operator?			

### Summary

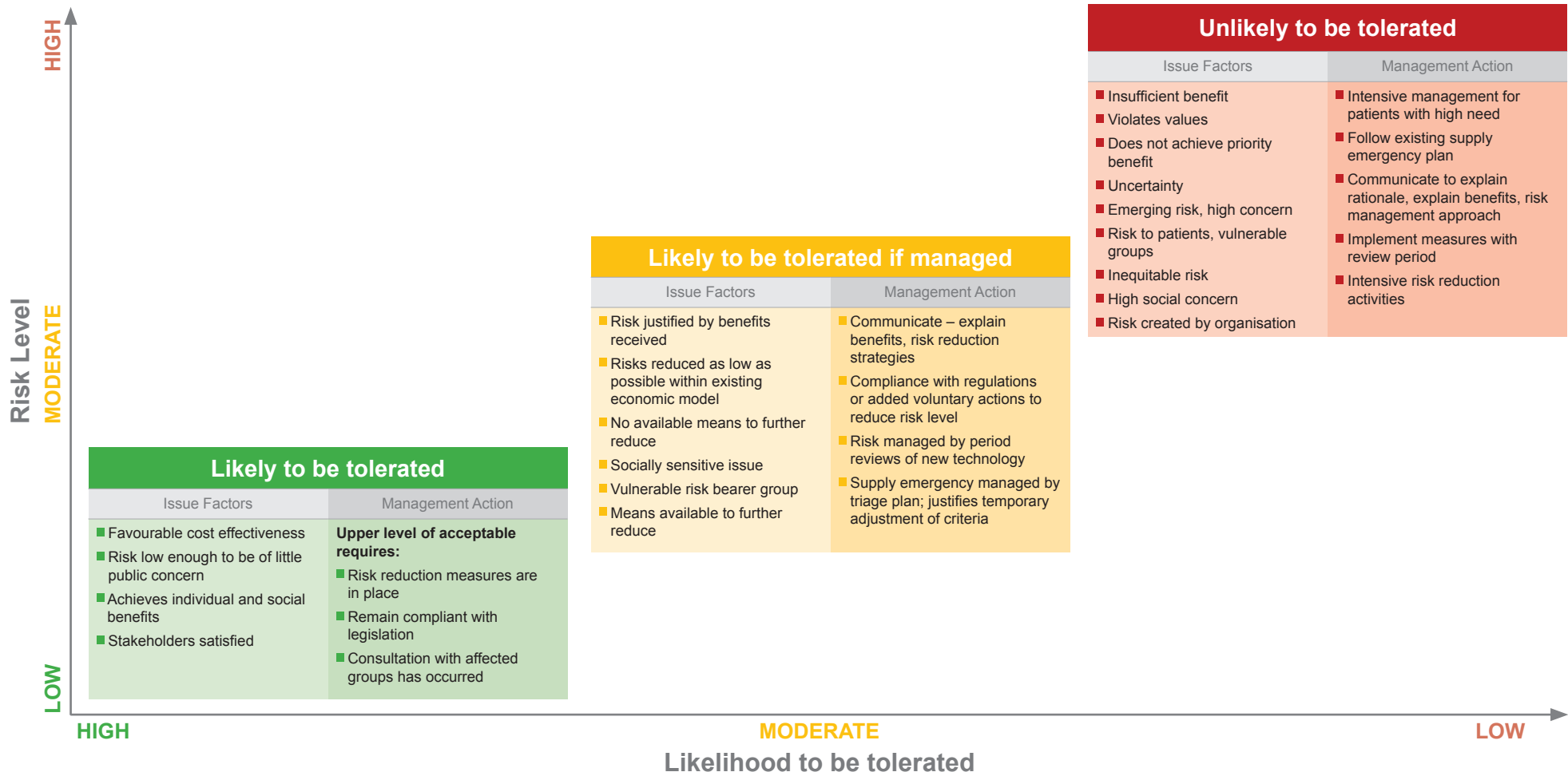
*Provide a summary of Contextual Issues.*



**SUMMARISE ALL  
ASSESSMENTS IN A CONCISE  
HIGH LEVEL DOCUMENT**

## Risk Tolerability Concept Map

The Risk Tolerability Concept Map illustrates the influence of risk management context on tolerability of basic risk levels. It also illustrates the influence of certain management actions on the risk levels and the risk management contextual factors. Use this concept map in conjunction with the Risk Tolerability Worktable to help assess the tolerability level of your risk management options.



## Risk Tolerability Worktable

Using assessment results and tolerability concept map, please complete the following table for each option. The risk tolerability concept map will assist you with completing this.

Risk Management Option \_\_\_\_\_

Assessment Information	Findings	Tolerability Level		
		Tolerable	Tolerable if Managed	Intolerable
<b>Section 1. Risks, benefits, costs</b>				
<b>Risk level for patients and/or donors</b> This information should be sourced from the Blood Safety Risk Assessment				
<b>Risk reduction achieved Compared to status quo</b> This information should be sourced from the Blood Safety Risk Assessment				
<b>Benefits achieved Compared to status quo</b> This information should be sourced from the Risk Assessment				
<b>Budget impact Costs to health care system</b> This information should be sourced from the Health Economic Assessment				
<b>Cost effectiveness - QALY's</b> This information should be sourced from the Health Economic Assessment				
<b>Implementation factors</b> This information should be sourced from the Operational Risk Assessment				



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<b>Public concern</b> Should be accessed through Contextual Assessment				
<b>Ethical considerations</b> Should be accessed through Contextual Assessment				
<b>Legal/Regulatory issues</b> Should be accessed through Contextual Assessment				

Summarise above table into tolerability estimate

### TOLERABILITY ESTIMATE:

#### Section 2. Societal and contextual factors

<b>Risk/Benefit Balance</b>	
<b>Cost/Cost Effectiveness</b>	
<b>Stakeholder Risks/ Concerns</b>	
<b>Implementation Issues</b>	
<b>Overall Risk Tolerability</b>	
<b>Tolerability of residual risk with option implemented</b>	<input type="checkbox"/> Tolerable <input type="checkbox"/> Tolerable if managed <input type="checkbox"/> Intolerable

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#### Section 2. Societal and contextual factors

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Rate the options (out of three) according to efficacy, cost and residual concerns associated with each option. Rank the options from best to worst. Use the tolerability estimate to assist you with the rating.

Risks	Risk Management Option				
	Status Quo	Option A	Option B	Option C	Option D
Safety/Efficacy	/3	/3	/3	/3	/3
Financial/Operational	/3	/3	/3	/3	/3
Social/Contextual (ethics, trust, stakeholder tolerability)	/3	/3	/3	/3	/3
Total					
Tolerable					
Tolerable if managed					
Intolerable					
Rank					

Rating	Risk Scale	Rank Scale
1	Low	Best option
2	Medium	Acceptable
3	High	Unacceptable

## Decision and Implementation Plan

Now the risk management option has been selected:

- Prepare a report summarising the assessment results and analysing the impact of the results on the risk management options.
- Present the recommendations to the decision-makers within your organisation.
- Determine how the decision should be communicated to all stakeholders.
- Prepare the message to communicate.
- Create a plan to implement the risk management option and monitor effectiveness of it.
- Will you need to conduct a more comprehensive assessment if the decision was completed within a short time frame? If so when?
- Continue to gather and assess new evidence that may lead to a review of the current decision and possibly to a new decision-making process.

## Risk Tolerability Worktable

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Risk Management Option \_\_\_\_\_

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Summarise above table into tolerability estimate

TOLERABILITY ESTIMATE:	
Section 2. Societal and contextual factors	
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