

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?