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EXECUTIVE SUMMARY

Operators of blood services are responsible for providing an adequate supply of blood to meet the needs of medical practice, and for optimizing blood safety. They make decisions about blood safety in the context of emerging risks, evolving technology, societal issues, and economic constraints. These decisions are aimed at managing risks in a process that extends from blood donation to blood transfusion and beyond.

This Risk-Based Decision-Making Framework provides a structured and systematic process for considering all relevant factors in decisions on blood safety, and for ensuring that finite resources are allocated to the most significant blood safety risks. The Framework consists of a structured approach to blood safety risk management—a systematic methodology for setting the best course of action under uncertainty by identifying, assessing, acting on, and communicating risk—that is tailored to the specific needs of blood service operators.

The Framework has been developed to help blood service operators achieve two main objectives. The first is to optimize the safety of the blood supply by enabling the proportional allocation of finite resources to mitigate the most serious risks, recognizing that the elimination of all risk is not possible. The Framework provides a set of approaches to help users identify and prioritize risks to blood safety, and to evaluate the effectiveness of potential risk management options, such as introducing a new intervention or withdrawing an existing one. The second purpose of the Framework is to analyze and account for a series of contextual, often qualitative factors that affect decision making in the management of blood risks. The Framework takes a societal perspective, enabling consideration of social, economic, and ethical perspectives that go beyond quantitative calculations of risk, and that can alter risk tolerability.

The Framework facilitates the gathering and consideration of information on health risk, economic factors, and broader societal factors in an integrated approach to decision making. It does so by outlining policy foundations needed for risk-based decision making, as well as procedural guidance on risk assessment, health economics and outcomes, stakeholder involvement and consultation, risk communication, and evaluation of risk tolerability.
CHAPTER ONE – OVERVIEW OF FRAMEWORK

Scope and application of the framework

This Framework was created under the auspices of the Alliance of Blood Operators (ABO) for application in blood service organizations. It is the outcome of a series of activities that began with the International Consensus Conference on Risk-Based Decision Making for Blood Safety in Toronto in 2010. Led by an ABO Risk-Based Decision-Making Steering Committee, these activities include research on a variety of public-health oriented risk decision-making Frameworks and health economics methodologies, stakeholder consultations, and peer review by experts in blood risk and public health risk management generally. The overarching structure of the Framework, the general intent of the Framework elements, and the decision-making processes and tools were developed to support risk-based decision making on issues of blood safety management and the optimum use of resources. Implementation is expected to be organization-specific, since each blood services operator will adapt elements of the Framework to its own operational context and regulatory structure. By applying a risk-based approach to blood safety decision making in their day to day operations, blood operators are making a commitment to stakeholders that they will carefully weigh the critical factors impacted by their decisions. It is important to note, however, that jurisdictional differences may result in blood operators in different countries arriving at different decisions; using a common framework does not mean all blood operators will arrive at a common result.

The Framework consists of risk management policy foundations and a risk-based decision-making process outlined below. Risk management policy foundations are required for effective decision making and provide guidance on establishing an organization’s tolerance for risk, on communicating and involving stakeholders in the decision-making process, and on the nature of assessments required to make an informed risk-based decision. These policy foundations, together with a set of risk principles, are used to govern the risk-based decision-making process designed for the management of blood safety risks.
Risk management policy foundations

Risk management policy foundations are stable background elements that express the values and risk management priorities and policies of an organization. They are also important underpinnings to the risk-based decision-making process because they will guide how decisions are made. They must be put in place by the organization before the risk-based decision-making process is undertaken, and in support of transparency be made available to stakeholders and to the public. These foundations, while stable, are revisited periodically in the spirit of continuous improvement.

One way to establish these risk-based decision making foundations is to develop an overarching, organization-specific risk management policy that addresses the following elements: risk management principles, guidance for risk communication and stakeholder engagement, expectations for the conduct
of assessments, and the application of judgment on risk tolerability. Guidance on these foundational elements is provided throughout the framework. Some aspects of the guidance that follows, such as the risk principles, can be built directly into an operator's risk management program, while others, such as risk tolerability, will need to be customized for each operator. This is because risk tolerability is impacted by many individual factors such as jurisdictional expectations, organizational culture, and the business environment.

**Risk-based decision-making process**

The four stages of the decision-making process are intuitive and common to many decision Frameworks: issue identification and problem formulation, assessment, evaluation, and decision. Each step in the decision-making process is designed to ensure that all relevant information is considered in a systematic manner. As such, for each step, several elements are described: the step’s purpose, the key functions it entails, the decision support tools provided, and the expected outputs. Links to outlines or templates for recording and organizing the information that results from each step are also included. Generally, each step is meant to prepare decision-makers with the information and analysis necessary to undertake the decision stage that follows. It should also be noted, however, that the decision-making process will not always be linear. It may instead be iterative, involving a return to a previous step if more information is required, or if new information suggests the need for a different or more detailed assessment.

In keeping with core risk management principles, the effort and resources allocated to the conduct of the process will be proportional to the significance of the decision to be made, in terms of health risk, cost, public interest in the issue, or other factors. However, all decisions should follow the same fundamental structure to ensure that all key elements are considered. The decision-making process may be conducted with different degrees of effort and detail depending on the magnitude and tolerability of the risk in question. The basic process calls for the systematic determination and documentation of a decision with a rationale based on the core considerations included in the Framework. The number of options considered, the number and extent of the assessments conducted, and the detail of the issue profile and risk characterization may be as minimal or extensive as is appropriate.

The assessment stage is deliberately composed of two levels: a screening assessment, in which existing information is gathered and reviewed for an initial overview of the issue and a determination of further information and resource requirements; and a full assessment, which involves a series of more intensive, specialized assessments conducted as required for certain aspects of the issue. This flexibility allows the risk-based decision-making process to be applied in a way that is proportional to the risk.

Similarly, with respect to recording the decision-making process for a given risk, it is recommended that each decision be recorded in a document that notes the consideration of all the basic elements of the Framework and the rationale for the decision, at a scale that is commensurate with the significance of the issue or decision. The more significant and complex a decision, the more detailed the issue characterization, assessment and evaluation should be, and the more extensive the document which accompanies the decision.
Risk management principles
The first element of a risk management policy is a set of principles, such as those suggested below, to govern the risk-based decision-making process, the decisions made using the process, and the actions that flow from those decisions. Although individual decisions would be expected to respect all principles, some principles will be more or less pertinent, or have a different weight, depending on the issue.

1. Beneficence
Decisions will do more good than harm. Decision making is focused on the safety of patients and donors. A cautious approach is taken to the management of the blood supply.

2. Fairness
Safety decisions are timely, fair, independent, and sensitive to cultural values. Risks that are unacceptable to society are not imposed; however the tolerability of the risk depends on the nature of the risk. The distribution of risk is as equitable as possible.

3. Transparency
Decisions are made via a transparent process. Information on risk issues and decisions is accessible to interested stakeholders and members of the public. Decision-making participants will declare any and all conflicts of interest relevant to the issue.

4. Consultation
Stakeholders will be consulted on issues that affect them, and / or which are the subject of significant social concern. Conducting high quality consultation processes helps ensure that stakeholders understand the issue and have an opportunity to provide input, and that decision-makers have all available information in making and implementing decisions.

5. Practicability and proportionality
The allocation of effort and resources to assess and control risk is proportional to the level of risk and the level of risk reduction that can be expected. The goal of this allocation is to achieve optimal use of society’s limited resources for risk management. Risk management decisions include an analysis of the risk, possible mitigation options, expected benefits of those interventions, and the impacts and costs of achieving them. This analysis is based on the best available evidence and sound judgment and, to the extent possible, adopts a societal perspective in terms of risk prioritization and allocation of resources. The purpose of risk management is not the complete elimination of risk but rather the appropriate application of resources to minimize risk.

6. Vigilance
Management of risks related to the blood supply is an evidence-based activity requiring constant vigilance and knowledge generation. Risk management is based on generating and acquiring knowledge, surveillance of established and emerging risks, and the application of lessons learned from the
management of previous blood safety risk issues. Evolving risk situations are monitored in order to identify the need for interventions, to understand stakeholders’ concerns, and to assess the effectiveness of risk management measures.

7. **Continuous improvement**
Continuous improvement is applied in evaluating and implementing cost-effective interventions and in the day-to-day management of the blood supply. Periodic review and improvement are applied to all aspects of blood safety risk management, including risk-reduction strategies, stakeholder engagement, operational efficiencies, cost reduction, and decision-making processes and policies.
CHAPTER TWO – PROBLEM FORMULATION AND IDENTIFICATION (STAGE TWO)

Purpose
The purpose of this stage is to characterize the issue in order to identify the fact-finding and analysis required, which in turn will enable effective evaluation of risk management options. The objectives of Stage 2 are to:

- generate a contextual understanding of the issue and its genesis, and assess which risk management principles are most relevant;
- consider potential significant impacts on key stakeholders;
- identify potential risk management options that should be considered by the assessments (Stage 3) and compared in the evaluation stage (Stage 4);
- develop a problem-formulation statement with a clear risk/benefit assessment question, including impacts on key stakeholders; and
- 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 making.

Tasks and tools
The following tasks support the objectives of Stage 2.

Task 1: Characterize the issue
Gathering preliminary information about the issue helps to determine what further investigations and assessments are required, and what risk management options might be feasible. The Issue Characterization Checklist poses several questions covering key risk and issue attributes. The checklist probes the main aspects of the issue and the decision type involved. It also helps to highlight which risk management principles are salient to the issue, and identifies contextual concerns that may require stakeholder involvement or risk communication. Through documentation and tracking, the checklist provides a record of the onset of the issue to facilitate understanding of the management context when the decision is revisited in the future.

CASE STUDY - THE ISSUE

A new virus is emerging for which there is no test. Pathogen reduction (PR) technology is effective in killing this virus and others, and a neighbouring jurisdiction has indicated it will implement the technology. The public is very concerned about this new disease, and there are questions in the media whether your products are less safe than other blood operators’. You know that this technology is very expensive and, while it is effective, you are not sure it is cost effective. However, the regulator has approved this technology and has even indicated a willingness to remove some required tests based on post-implementation studies that would support such a move. What should you do?
Task 2: Identify the Decision Driver
The questions in the Issue Characterization Checklist also help identify the primary decision. The decision driver is important because it will influence the focus of the assessment question; the assessment question in turn drives the kinds of assessments that will be called for and the kind of information that will be provided to the decision makers. A description of decision drivers is provided in the Toolkit.

Based on the information collected in the Issue Characterization Checklist, the risk-benefit dynamic—that is, the potential for harm to specific risk bearers in relation to the benefits derived from the implementation of a measure—will become apparent. Each issue will have a particular risk-benefit dynamic.
Task 3: Formulate the assessment question

The goal of this task is to identify clearly the primary decision to be made, the areas on which assessments must focus in order to support the decision, and the level of investigation required. The assessment question consists of the overall information needs of the decision-maker (e.g. the relative cost-effectiveness of interventions), as well as specific charge questions for individual assessment components (e.g., efficacy of interventions, health risk reduction estimates, and cost estimates). A well thought-out, carefully articulated question will provide guidance on the type and depth of assessments that will be required. Various scenarios may be developed in order to compare risk management options, and expectations may be set in terms of level of benefit, risk reduction, and cost.

CASE STUDY – ASSESSMENT QUESTION

What is the effect, in terms of risks and benefits to blood recipients and donors, as well as costs to the blood operator, of the proposed risk management strategies, particularly implementation of pathogen reduction with and without modification of existing blood safety procedures, to reduce the risk of Virus X?

CASE STUDY – RISK MANAGEMENT OPTIONS

1) Maintain status quo and continue to monitor for new data
2) Fund and conduct a study to determine the prevalence of the agent in blood donors in your own jurisdiction
3) Institute a deferral for travelers to regions where Virus X is now thought to be endemic – will need to determine timeframe of deferral (probably 28 days after leaving the affected region) and specifics of the countries that would be included in the deferral
4) Implement the regulator-approved pathogen reduction methodology without modification of any existing safety procedures
   a. Implement the pathogen reduction methodology with modification of:
      b. Existing donor deferral criteria for some travel and behaviour-based deferrals
      c. one or more donor screening (i.e., laboratory) tests
      d. irradiation of blood components
      e. some combination of options a-c

Record the assessment question on the Assessment Question and Decision Requirements worksheet (located in the Toolkit Chapter).

Task 4: Identify preliminary risk management options

Based on a preliminary understanding of the risk and associated issues gained from the Issue Characterization Checklist task, an initial list of potential risk management options is generated in order to focus the assessments and analyses to be conducted in Stage 3.
**Task 5: Determine the required assessments to be conducted in Stage 3**

Using the results of the **Issue Characterization Checklist**, identify the assessments and analyses that will be conducted. The list of required assessments includes:

- Blood safety risk assessment;
- Health economics and outcomes assessment—budget impact, cost effectiveness;
- Contextual assessment—legal, jurisdictional issues;
- Stakeholder assessment—stakeholder impact, trust, equity concerns, risk perception;
- Operational impact assessment; and
- Risk communication is required.

**NOTE:** Further assessments may also be required (see **Risk Management Options and Assessment Table** for other possible assessments).

This exercise will also provide guidance on the resource intensity required for any given assessment. The decisions made here are key to maintaining proportionality between the level of effort in risk assessment and risk control and the magnitude of the risk. Planning as to who will provide the subject-matter expertise needed for the identified assessments is also triggered during this task, with careful attention to any potential conflicts of interest. These decisions will also be recorded on the **Risk Management Options and Assessment Table**.

**CASE STUDY – ADDITIONAL INFORMATION**

- Travel survey to assess percentage of donors that would be deferred, if this information is not already known.
- New study regarding the prevalence of Virus X in our geographic region may be required.
- The regulatory file indicates that several of the components have different in-vitro characteristics upon storage than do their non-PR treated counterparts, leading some scientists to question whether the PR components have equivalent quality. Consideration should be given to further assessing this through product quality assessments for each component type.
- Comparison of PR risk reduction versus test(s) proposed to be withdrawn. Blood safety assessment with the PR technology applied, and with and without those screening tests that could be eliminated.

**Outputs**

Step 1 is intended to yield the following outputs:

- identification of a preliminary list of risk management options and required assessments;
• formulation of the assessment question;
• high level direction on the types of assessments that will be required to deliver on the decision makers' information needs; and
• identification of human resources and expertise to complete assessment activities.
CHAPTER THREE – CONDUCTING ASSESSMENTS (STAGE THREE)

Expectations for conduct of assessments

A risk management policy should also address specific expectations for the conduct of assessments, including medical and scientific risk assessments, health economics and outcomes assessments, social concern assessments, ethical and legal analyses, and any other assessments of evidence that are relevant to the decision-making process. These assessments must be conducted such that they serve as credible inputs to risk decisions. They are domain-specific, and are conducted according to the methods and standards of the appropriate discipline. Additionally, they are functionally separate from risk management and decision making to ensure that they are not subject to undue pressures stemming from other aspects of the process. Guidance on conducting different types of assessments is provided in the Assessment step of the decision-making process. All assessments are ultimately integrated to create a comprehensive profile of the risk and available options.

General expectations for assessments

To ensure optimal input for the risk-based decision-making process, the risk management policy should provide a set of general quality and process expectations for these assessments, such as those set out below.

Proportionality

The scope and level of detail of assessments are proportional to the estimated significance of the risk and the decision to be made.

Timeliness

Assessment information is provided in a timely manner to decision-makers to maximize the utility of the assessment to risk management.

Evidence-informed and quality-assured

Assessments are based on established domain-specific methods of assessing the quality of data, the appropriateness of the methods used, and the conclusions drawn, with consideration of scientific and technical uncertainty.

Openness and transparency while respecting confidentiality

Assessments supporting decisions that have important consequences for the health and safety of the public should include consultation with stakeholders and the public, as appropriate to the nature of the issue and the level of stakeholder interest. Information on the objectives, process, evidence, and conclusions of assessments should be made available to the public, subject to confidentiality obligations.
Appropriate consideration of variability

Appropriate processes and methods are in place for the systematic consideration and description of the impact of variability within the populations considered in assessments.

Characterization of key uncertainties

The type and source of uncertainty in an assessment, and the impact of that uncertainty on the conclusions of the assessment, are explicitly described.

Integration with related analyses

Assessments are designed, conducted and communicated with the aim of contributing to an integrated assessment of an issue.

Two main types of assessments will provide key information and analysis in support of decisions: the health risk or blood safety risk assessment and the health economics and outcomes assessment. Both are specialist assessments carried out according to their own disciplinary methods and standards. They will be conducted at a level of detail and intensity that is proportional to the significance of the risk. The results of both assessments will facilitate risk communication and stakeholder consultation processes.

Purpose

The purpose of this stage is to provide credible scientific and technical information for decision-makers on the nature and significance of the risks in question, the benefits of risk mitigation measures and their distribution, the economic factors associated with the addition or withdrawal of interventions, and other risk management options. In addition, assessments of contextual issues, such as social or ethical concerns about the risk or its management, or legal, regulatory, political or jurisdictional considerations, may provide more complete information on these issues when they are significant. Assessments are systematic analyses of relevant information that are conducted to support a decision. They are designed to provide the information and analyses that decision-makers require to address the issue, but are conducted according to the methods and standards of the specific discipline. In addition, they all observe the expectations for the conduct of assessments set out in the section on policy foundations above.

The process includes a tiered approach to assessments. It sets out an initial screening assessment step that provides an overview of the issue, and then a series of more detailed assessments that may be conducted at a level of detail proportional to the risk. The more detailed assessments would be formal assessments conducted according to disciplinary standards. They would produce new information on the threat or proposed intervention, including more detailed and quantitative information on the possible consequences of exposure to the threat, and an expression of their seriousness, the
probability or frequency of the threat’s occurrence, and the number within the risk-bearer populations that could be affected. Such information would be presented in common terms to enable the comparison of the risks, costs and benefits of alternative scenarios.

**Tasks and tools**
A variety of assessment types may be required. Some of these are described briefly below.

**Task 1: Conduct initial screening assessment**
An *initial screening assessment* will help assess levels of risk, the ethical profile of the issue to be decided, and the urgency of taking action. It will also help to identify additional assessments that are required to address the fundamental question for decision. Screening assessments are conducted to gain an early understanding of the nature and significance of the issue and decision. They are not full assessments with detailed quantitative risk data. Rather, they gather existing information on a hazard or an intervention to identify the likelihood and magnitude of risks and benefits associated with identified management alternatives, using conservative assumptions. The results of such “desktop” assessments can confirm that there are risks to be managed, or that the benefit in a proposed management approach justifies the risks. A screening assessment may also reveal the populations that may experience the risks and benefits of a proposed measure. Some insight may be gained on the quality of the information that is available on the subject and the adequacy of information available on the issue for decision making. An initial screening assessment can point to the further, specific information in full assessments that will be necessary to address the overall risk question, as well as the degree of intensity that would be proportional to the significance of the risk and the timeline for their preparation.

*Complete an initial screening assessment to help estimate the level of risk and the urgency of taking action (a sample template is located in the Toolkit Chapter).*

- Using the results of the work completed in Stage 2, determine the main categories of risk associated with the issue at hand, e.g., patient risk, legal risk, reputational risk.
- Name these risk categories in the **Risk Management Options – Initial Screening Assessment Table**, and provide a short description why these are considered important risks for each risk management option.
- Using the risk rating scale embedded in the **Initial Screening Assessment Table**; estimate the level of risk for each category against each risk management option.
- **NOTE:** Depending on the issue and the environment in which your blood service operates, it may be necessary to apply weightings to the risk categories. The level of weight given to various risk categories must be determined by each blood service to reflect its operating reality; this should be done before the screening exercise begins.
Assess the level of urgency to take action by using a risk magnitude/likelihood matrix. Ideally, blood services will already have developed their own risk matrix, customized for their operation, which can be used. If you do not, it is strongly recommended that one be developed; an example matrix is provided in the toolkit chapter.

Use a spider plot to obtain a visual picture of the highest areas of risk. Seeing the level of risk this way will help confirm the screening assessments required (an example of a sample spider plot is located in the Toolkit Chapter).

Task 2: Conduct core assessments
Depending on the outcomes of the screening assessment, additional, more detailed assessments may be required for some aspects of the issue. In all cases, the level of detail and amount of information and analysis required should be appropriate to the information needed by decision-makers and proportional to the significance of the risk or the broader issue. Guidance on these types of assessment can be found in the chapters below.

Blood safety risk assessment
The core of the assessment process will be the blood safety risk assessment. A risk assessment is conducted to identify, characterize and estimate the consequences of exposure to a hazard in order to select the most effective and appropriate mitigation strategy.
Health economics and outcomes assessment

Health economics and outcomes assessments, particularly the budget impact analysis and cost utility analysis, provide information on the cost-effectiveness of interventions and other risk management measures. The type of health economics assessment should be appropriate to the issue to be decided.

Stakeholder assessment

This assessment provides decision makers with critical information on key stakeholders’ perspectives, concerns, insights, preferences and advice on the risk issue under scrutiny. Following a flexible but principles-based process, stakeholder assessment identifies who needs to be involved, offers guidance on how to involve them and produces results that support blood operators’ evaluation and decision-making options to address the risk being addressed. The process is designed to be adaptable – blood operators will tailor its stakeholder assessment as required, taking into account their context, capacity, resources, and needs, and the nature and scale of the risk being addressed.

Operational risk assessment

A feasibility and supply-impact assessment will usually be required to evaluate the effects of different risk management options on the blood system, such as a potential reduction of the blood donor pool, impact of financial costs, operational complications or human resource demands. These types of assessments may be more effective if performed when the list of management options has been narrowed, so that the specific details of each have been elaborated. A generic tool (see toolkit chapter) can be adapted to conduct a general risk assessment and by adapting the questions can be used to suit the needs of the contextual assessments as further detailed below.

Task 3: Conduct contextual assessments

Contextual assessments

Some issues involve contextual factors that need to be more fully understood so that they can be addressed appropriately, through such measures as risk communication, stakeholder involvement, or adjusting risk management actions. These issues may relate to elevated perceptions of risk, concerns about the distribution of risks and benefits, public or stakeholder trust in the risk manager, or more specific considerations such as legal factors or differences among jurisdictions in the approach to managing a risk. If one or more contextual issues are identified in the Issue Characterization Checklist and deemed significant, the relevant assessment may be conducted. The major areas that could require dedicated analyses include: social concern and risk perception, equity, trust, legal requirements, political considerations and jurisdictional differences.

Social concern and risk perception

This analysis studies the level of awareness and concern about an issue in society, which is often indicated by elevated media attention to the issue, and the tone of public discussion. Concern may relate to a perception that the risk involved is particularly high or the outcome is very serious, or that there is high degree of uncertainty. Understanding these concerns is important for developing the appropriate risk communication and stakeholder involvement plans and activities.
Equity
Concerns with the equity of risk distribution or the impacts of a risk management measure relate to the allocation of risks and benefits within society and among recipient groups and society in general. An assessment should also explore whether there are risks to particularly vulnerable groups, or ethical implications of actions that affect a specific group, as may occur with a donor deferral action. An analysis of these issues should focus on the implications of uneven impacts of a risk within society, as well as the impacts of a management action on a particular group, including the possible stigmatization or other adverse social impacts to a group.

Trust
Trust in the management of blood safety, and in the blood service operators, relates to a general social attitude toward the competence and ethical behaviour of the blood operator based on past policies and activities and an interpretation of present activities. It also relates to relationships with stakeholder groups on specific issues. In addition, trust is premised on the provision of adequate information (on risks and risk management measures) which enables users of the blood system to make informed decisions.

Legal and jurisdictional
Although the relevance of legal and jurisdictional issues may relate to public and stakeholder trust, assessments of these issues will be specific to the technical matter identified. They may involve specific considerations such as the potential for liability on a certain risk management action, or to concerns that another jurisdiction has adopted different risk control expectations or implemented different tests. An issue may involve one or more of the areas identified. The assessment should address the areas that are relevant, as required for a full understanding of the issue to be decided.

Contextual assessments entail gathering information on the relevant concerns and related matters, and analyzing the way in which the concern shapes the risk management decision and affects the selection of a management measure. They should be conducted at the level of detail that is appropriate to the nature and significance of the issue. The output of these assessments is a written description and analysis of the relevant factors.

At a general level, most of the information that is needed for these assessments is readily accessible, through reference to data on the risk decision to be made and records of the blood operator’s previous decisions on related matters, including stakeholder involvement activities, as well as searches of media coverage of the issue. Assessments that require a higher level of detail and analysis may require the advice or participation of subject-matter experts, on such issues as risk perception, media analysis, legal and jurisdictional considerations or stakeholder relations.

An outline of the questions to address in each of the four main areas in which a contextual assessment may be carried out is provided below. The subject areas can be addressed in greater or lesser degrees of detail as is appropriate to the issue. In all cases the following factors should be considered:
- How significant is the contextual issue in relation to the technical aspects of health risk assessment and management?
- Is the concern significant enough to threaten any aspect of the blood system?
- How does the contextual issue or concern affect the tolerability of the risk?
- Can the issue or concern be addressed or resolved through risk communication or stakeholder involvement activities?
- Does the issue or concern require adjustments to be made to risk management actions?
- Does the issue or concern have implications for the credibility and reputation of the blood operator?

**Salience:** Is there high attention given to the issue?
- a. High levels of media coverage
- b. Involvement of high-profile individuals, cases
- c. Involvement of controversial elements

**Risk perception:** Is the risk perceived to be serious?
- a. Are the effects serious, severe or long-term?
- b. Is the hazard unfamiliar? Is there emerging risk or new effects? Is transmission unclear?
- c. Is the risk perceived to be involuntary?
- d. Is the perception of the risk disproportionate to the technically assessed level of the risk?

**Equity:** Is there perceived unfairness in the risk?
- a. Is the risk disproportionately borne by a specific group in society?
- b. Is the risk disproportionate to the benefits?
- c. Are the risks and benefits distributed unfairly?
- d. Is a vulnerable group involved?
  - i. Children
  - ii. Seriously ill, immunocompromised, frequent blood recipients
  - iii. Donor group
- e. Has there been lack of consent or risk information?
- f. Are there differences among jurisdictions with respect to risk levels, tests performed or donor-deferral strategies?

**Trust**
- a. Is the issue associated with or linked to a previous event, issue or controversy, such as a deferral policy, attention to emerging risk, or a risk management strategy?
- b. Is there a perception that the risk management organization has contributed to the risk?
- c. Are there poor relationships with stakeholders due to inadequate consultation, a lack of transparency, or another information provision?
- d. Are there issues of liability or other legal considerations?
- e. Are there considerations of different risk management provisions in other jurisdictions?

**Task 4: Conduct contextual assessments**
With the benefit of the initial screening assessment and any additional contextual assessments, it is appropriate to determine the nature and timing of risk communication that may be required as the
issue progresses through the decision steps. The chapter on Risk Communication provides detailed guidance on preparing a risk communication plan.

**Outputs**
Stage 3 will produce the following outputs:
- a completed initial screening assessment;
- for some issues, completed full assessments for technical and social factors;
- results of stakeholder assessment;
- preparation of a stakeholder involvement plan; and
- identification of an appropriate risk communication strategy.
CHAPTER FOUR – EVALUATION (STAGE FOUR)

Purpose
The Evaluation step is focused on gathering, integrating and analyzing the inputs and assessments completed during the Assessment step. Its ultimate task is to summarize risk management options and consider the broader cost-effectiveness, and societal and ethical implications of each.

It should also be noted, however, that some issues may involve an apparently high risk and urgency for risk management action, yet the amount and quality of information that is usually required as the basis for a decision is lacking. In such cases, a decision may be made to implement precautionary risk reduction measures for a specified period of time, while additional information is gathered and considered in a planned review of the issue.

Tasks and tools
The following tasks support the objectives of Stage 4. For each task, a decision support tool is provided in the Toolkit chapter.

Task 1: Acquire and array Stage 3 output against the risk management options
Recording the results of all the assessments conducted in Stage 3 against the risk management options helps to depict the strengths and weaknesses of each option. This exercise may also reveal gaps in the evidence needed to evaluate an option. In such cases, a return to Stage 3 for an additional assessment may be necessary. Depending on the number and type of assessments conducted, the amount of information could be quite substantial. It is recommended that material be presented in a simple and consistent manner for each risk management option.

Task 2: Integrate the results of stakeholder assessment
Incorporate the Stakeholder Assessment and Consultation results and options into Stage 4 Evaluation (assuming that Stage 3 is done well, a good set of recommendations will emerge). The results of the consultation activities are provided to the stakeholders to affirm their contribution, and to the decision-makers for consideration in rendering a decision.
### CASE STUDY - SUMMARY OF ASSESSMENT RESULTS

<table>
<thead>
<tr>
<th>Option</th>
<th>Blood Safety Risk</th>
<th>Health Economics</th>
<th>Operational</th>
<th>Stakeholder</th>
<th>Social Concern/Trust</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Status Quo</strong></td>
<td>16/100,000 (endemic)</td>
<td>$127,922,078</td>
<td>No impact</td>
<td>Not acceptable</td>
<td></td>
</tr>
<tr>
<td></td>
<td>22.5/100,000 (travel)</td>
<td>138.6 QALY loss</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Deferral</strong></td>
<td>16/100,000 (endemic)</td>
<td>$129,519,697</td>
<td>Medium risk</td>
<td>Acceptable</td>
<td>May not be considered sufficient protection.</td>
</tr>
<tr>
<td></td>
<td>0/100,000 (travel)</td>
<td>133.0 QALY loss</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PR plus existing</strong></td>
<td>50 fold risk reduction; risk is 2% of baseline total</td>
<td>$270,061,319</td>
<td>Medium to extreme</td>
<td>Acceptable, requires risk communication re PR effects on product</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.0 QALY loss</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PR only</strong></td>
<td>50 fold risk reduction; risk is 2% of baseline total</td>
<td>$201,372,000</td>
<td>Low to medium</td>
<td>Acceptable, requires risk communication re PR effects on product</td>
<td>Positive but will require risk communication about technology/safety</td>
</tr>
<tr>
<td></td>
<td></td>
<td>135.3 QALY gain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PR partial</strong></td>
<td>Not quantified</td>
<td>Not quantified</td>
<td>Low to medium</td>
<td>Confusing</td>
<td>Negative</td>
</tr>
</tbody>
</table>

**Task 3: Evaluate the risk tolerability of risk management options**

Referring back to the risk tolerability evaluation, situate the outcomes of that evaluation on the Risk Tolerability Evaluation Tree. Final determination of tolerability of the risk given the various risk management options requires application of judgment; it is rare that the tolerability levels of a risk are so straightforward that they will clearly fit within one region or another. However, the point is to use all of the information that has been gained from each assessment and to overlay them in an explicit and transparent way so that the logic of the decision is clear and defensible.
Risk tolerability evaluation tree

The diagram illustrates three regions: a region of acceptable risk levels, a region of intolerable risk levels, and an intermediate region where risks are managed to be as low as reasonably achievable (ALARA).

Figure 2: Risk tolerability evaluation tree

Compare risk management options

Use the Options Rating Scale, or a similar kind of tool to compare the risk management options (see toolkit chapter).
CHAPTER FIVE – DECISION (STAGE FIVE)

Purpose
The purpose of this stage is to:

- select a risk management option based on the results of the Evaluation step using the Option Rating Scale;
- optimize the risk management options in order to balance residual risks and costs;
- consider the steps required to implement the risk management action.

Tasks and tools
The following tasks support the objectives of Stage 4.

Task 1: Describe and rank the selected risk management options
Based on all the data gathered, it is necessary to describe in detail the risk management options according to:

- change or intervention proposed, such as technology implemented or withdrawn;
- effectiveness expected;
- procedural or operational components;
- cost and budget; and
- residual concerns or considerations associated with residual risk (safety, ethics, trust, cost) and mitigation measures.

The risk management options are then ranked based on the data and analysis output of the Evaluation step.

Task 2: Develop a recommendation and present the risk assessment to the decision makers
Based on the application of this risk Framework, a recommendation document should provide:

- an issue profile, including risk management principles in play;
- a fundamental question that requires a decision;
- the risk level, including the need for risk reduction, change or intervention;
- all risk management options considered;
- any results of assessments and subject matter expertise engaged;
- the outcomes of any additional processes, such as stakeholder consultations;
- an evaluation of risk management options, including a review of contextual considerations such as risk tolerability;
- a ranking of options with rationale; and
- a review date and triggers if applicable.
Task 4: Post-Decision: Create decision implementation plan
Once the decision makers have selected the risk management response, the decision and the decision rationale should be documented, and the plan for implementing, monitoring and communicating the decision should be developed. In addition to an operational implementation plan, it is important to develop a plan that will permit ongoing monitoring of the decision impact on key stakeholders and the decision’s effectiveness in terms of risk reduction, clinical outcomes, costs and social considerations. Ongoing monitoring of the implementation impact may lead to an iteration of the current decision, while monitoring of new evidence and new sources of risk may lead to a renewed decision-making process. The implementation plan should also address communications to ensure appropriate communication of the decision, its rationale and implementation.

As well as revisiting individual decisions as necessary, it will also be necessary to continue to monitor and evaluate the risk-based decision-making processes themselves, in order to achieve continuous improvement of the Framework and how it is applied.

<table>
<thead>
<tr>
<th>CASE STUDY – THE ASSESSMENT REPORT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suggested report format:</td>
</tr>
<tr>
<td>Table of contents, including list of tables and figures</td>
</tr>
<tr>
<td>Executive Summary</td>
</tr>
<tr>
<td>Composition of the team</td>
</tr>
<tr>
<td>Overview of the issue</td>
</tr>
<tr>
<td>Risk assessment question</td>
</tr>
<tr>
<td>Risk assessment approach used</td>
</tr>
<tr>
<td>Assessments undertaken and techniques used</td>
</tr>
<tr>
<td>Specific risk assessment issues</td>
</tr>
<tr>
<td>Assessment results</td>
</tr>
<tr>
<td>Recommendation</td>
</tr>
<tr>
<td>Include all assessment documentation as appendices</td>
</tr>
</tbody>
</table>
CHAPTER SIX – BLOOD SAFETY RISK ASSESSMENT

Guidance on Conducting a Blood Safety Risk Assessment

There are several general and procedural expectations that blood safety risk assessments should meet, including the use of a formal assessment process as well as certain technical and scientific analytic procedures. Processes that apply to most risk assessments are:

- Applying formal methods to review evidence
- Use of “weight of evidence” methods to draw conclusions
- Using mathematical methods to estimate variability of inputs and probability of risk and uncertainty
- Being explicit about assumptions behind the risk assessment and decision-making process.

The risk assessment proceeds through a set of standard steps that are conducted according to the relevant discipline.

Step 1: Frame the problem

Purpose

Characterize the scope of the assessment and level of detail required to produce the information needed by decision-makers.

Outputs

- Objectives and scope of the risk assessment;
- Risk measures to determine the potential risk reduction; and
- Information required and level of detail.

Process

1. Establish the scope of the blood safety risk assessment and describe its interaction with other assessments such as health economics assessment. This ensures that any elements not addressed by the risk assessment are addressed in another assessment.
2. Clearly state the objective of the risk assessment. A risk or hazard can be explained in terms of specific characteristics, such as potential to cause an adverse outcome to a blood recipient, or in terms of policy objectives, such as improving the efficiency of a process. Understanding the desired outcomes at the outset of the risk assessment will ensure risk measures are selected using the best available information.
3. Select risk measures; consider scientific factors, economic analysis, or societal factors, depending on the assessment objectives.
4. Determine the kind of information required and the level of detail.

Considerations

- Regularly communicate with the risk manager and other assessors (e.g., health economics) to ensure problem formulation continues to capture the necessary information.
- Revisit the conclusions of this step as part of the iterative process when new information may justify modifying the scope or the level of detail required to be compatible with other analyses.
Step 2: Identify the hazard

**Purpose**
Identify and characterize the ways in which adverse events can arise of the hazard.

**Outputs**
- Description of the possible adverse outcomes;
- Evidence of a causal relationship between a hazard and the adverse outcomes; and
- Summary of the properties of the hazard.

**Process**
1. Systematically gather and review relevant evidence such as hemovigilance data and surveillance information.
2. Identify the hazards causing the adverse event and determine the possible adverse outcomes.
3. Examine scientific data or evidence of a relationship between the threat and the adverse outcome.

**Considerations**
- Risk assessors must pay careful attention to the process for inclusion, exclusion and weighing of evidence. The transparency with which causality is determined is one of the most important elements of the risk assessment.
- Formal and systematic methods, combined with information technology, can improve the efficiency of updating information related to the risk assessment process.
- Consider the weight of different types of studies and studies having different results; consider the sources of uncertainty and how these may impact the hazard identification.

Step 3: Describe the hazard and assess exposure

**Purpose**
To estimate the frequency and extent of potential harm to the risk bearer from the hazard.

**Outputs**
- Description of risk sources and pathways;
- An estimate of the probability and extent of exposure to risk bearers; and
- A description of the consequences of hazard exposure and the severity.

**Process**
1. Decide how in-depth the investigation of risk sources and pathways will be (e.g. all risk bearers, all sources, all pathways or a more constrained scope).
2. Use scientific and technical arguments to determine the most important combinations of hazard sources and risk bearers. These combinations constitute the system to be analyzed in the risk assessment.

3. Estimate the probability and extent of exposure by using a combination of qualitative and quantitative methods. The choice of method is generally determined by the type of assessment and the way in which the assessment will be used (see below for additional information on quantitative and qualitative methods), or it may be a function of the amount of data available.

4. Estimate the consequences, in several stages if necessary (e.g., introduction of an infectious agent, with a spectrum of consequences of varying probability, ranging from minor, reversible effects to more serious, irreversible impacts such as fatalities or chronic disability).

5. Estimate the probability, rate and extent of damage to the risk bearer given a level or type of exposure.

6. Merge the relationship between exposure to a hazard and the consequences with the estimates of the frequency and extent of exposure to generate estimates of risk.

Considerations

- A clear statement explaining why the scope was chosen, including limitations, should be provided along with scientific or technical arguments or risk management considerations.
- Where distinct populations are expected to incur greater or less severe consequences than the general population, these factors should be computed and described separately and be appropriately weighted in population-level risk estimates. The specific differences in vulnerability, given the same degree of exposure, may be driven by a variety of risk factors, including age, genetic differences or pre-existing conditions.

Quantitative methods

The probability of key events (for event-driven risks) or of various degrees of exposure (e.g., for chronic exposures that vary in their level), can be assessed quantitatively using deterministic or probabilistic methods. The choice of methods can depend on the amount of data available, the complexity of the system and the levels of uncertainty and variability that can be assessed. Probabilistic assessments provide more information on the range of the risks within a population and can address uncertainty more effectively. Greater amounts of data and resources are required to conduct probabilistic assessments and are critical to the assessment of risks: that arise from highly non-linear phenomena; that arise from the combination of a set of events and pathways of exposure; and whose levels are highly variable. Additional data and resources may also be required when there is a need for decision-makers to make trade-offs between levels of risk.

It is important to describe the most important sources of variability that influence estimates of risk and the resulting variability in the level of risk faced by different groups of individuals in different regions or other appropriate groupings. In order to adequately capture the importance of variability and properly calculate risk, the extremes of risk must be appropriately characterized. Such extremes may result from the simultaneous variation in several quantities toward extreme values that yield high-risk scenarios. Estimating the probability of these events requires careful use of mathematical or computational
methods to ensure that these risks (in particular, the probability components) are neither systematically underestimated nor systematically overestimated.

In specific contexts, risks are purposefully and systematically overestimated, such as in screening-level assessments to detect the potential for high risk and prompt further analysis. While deliberately overestimating risks is useful in screening issues on the basis of potential risk, their use as input into a cost-benefit analysis is generally inappropriate. Overestimates lead to estimates of benefit that cannot be reasonably compared with the estimates of the societal costs of risk management actions. The deliberate overestimation of risk and its implications should be a critical component of the communication of the results.

Numerical estimates of risk that result from propagation of either averages or “normal” values (often tending to underestimate risk) or from propagation of a series of “worst-case” values (tending to overestimate risk) should be computed and characterized with considerable care. Moreover, they should be avoided through use of appropriate established techniques to propagate variation (i.e., to compute the probability of extreme risk scenarios) to generate risk estimates in a more reliable, reproducible and defensible manner. Analytical methods to propagate variation can be applied for simple risk models, while computational methods to propagate variation (e.g., Monte Carlo simulation) may be required for complex models that have non-linear relationships.

**Qualitative methods**

Qualitative methods and measures are often used in conjunction with, or as a precursor to, the application of quantitative methods. Purely verbal expressions of probability (e.g., “unlikely,” “remote,” “often,” “rare”) are not considered to be appropriate, except where these labels are predetermined, in consultation with the risk management function (e.g., “rare” has been predetermined to mean “the event has a mean return period of more than 1,000 years, and “unlikely” is understood to mean a “mean return period between 200 and 1,000 years”). These terms should be used consistently and described transparently. The application of simple ordinal labels is preferred (such as I, II, III or A, B, C), and these should be linked explicitly to quantitative ranges. The use of ordinal labels avoids the value-laden nature of words such as “negligible,” “low,” “high” or “catastrophic” and the ambiguity and unreliability of verbal descriptions of probability. This approach helps to avoid inconsistent communication of risk and avoid the potential for, or perception of, any manipulation of the verbal characterization of risks. It will also facilitate more consistent communication of risk in multiple languages and to international audiences.
Step 4: Characterize the risk

**Purpose**
To integrate the information generated from the risk assessment into a summary conclusion of the risk in a manner that is relevant and useful for decision-makers.

**Outputs**
- Summary risk measures for the magnitude and probabilities of risk for the risk bearers.
- Estimate of risks for identified individuals and/or populations and an explanation of the nature and significance of uncertainty and variability in the risks to individuals.
- Evaluation of other risk measures and an evaluation of the significance of those risks to the larger risk-decision context (e.g. risks to availability of blood or capacity of the blood service to carry out its full range of responsibilities).
- Distribution of the burden of risk; the effects of a risk can vary within a population according to factors such as geographic location, age or life stage, or income level.

**Process**
1. Combine estimates of the frequency and extent of exposure with exposure consequences to yield estimates of the magnitude of consequences with estimates of their probabilities.
2. Estimate the level of risk and characterize the extent of uncertainty.
3. Characterize uncertainty in any of the components or the results of the risk assessment.
4. Use the combined information to inform the process for selecting the risk management option.

**Considerations**
- Various methods can be chosen to combine probability and consequence to simplify the characterization of risk. Examples include the average population risk, a specific percentile of the distribution of individual risks to demonstrate the expected variation in risk faced by members of the public, or a number of separate scenarios to demonstrate the extent of uncertainty.
- The results often include a baseline scenario (e.g. status quo without additional risk management action) and a set of alternative scenarios corresponding to alternative assumptions. Some of the alternative scenarios will represent alternative interpretations of scientific evidence in order to demonstrate and make transparent the level of uncertainty.
- Where there is uncertainty in the data or analysis, the source, type and significance of uncertainty should be specified. Approaches to the characterization of uncertainty range in sophistication and time requirements, and more detailed characterization methods should be applied when significant uncertainty of parameters can affect critical risk calculations.
- There are different methods for assessing and expressing uncertainty, such as bounding values, interval analysis, sensitivity analysis and importance analysis. The rationale for employing these techniques, and the processes, data sets or inferences to which they were applied should be described. Scenario analysis can be used to characterize uncertainties in models in order to make the impacts of specific scientific assumptions transparent.
Step 5: Assess the risk reduction impact of the risk management options

**Purpose**
To estimate the benefits of specific decision options.

**Outputs**
- An estimate of the change in risk levels for each option (avoid use of labels like “a significant reduction”, “reduces the risk to safe levels”).

**Process**
1. Select a range of risk management options for comparison against each other and the baseline scenario.
2. Repeat the risk characterization step of risk assessment; focus attention on the differences in the level of risk among the options and the baseline scenario (e.g. status quo).
3. Evaluate the effectiveness of the risk management option to reduce risk (through reductions in probability or severity, or both), the possible creation of new risks through measures to control the baseline risk, and any other known side effects of each option.
4. Identify and characterize the risk trade-offs created by the risk management options (e.g., trade-off between the risks of an activity or foregoing the activity, or weighing the significance of ancillary risks or the adverse effects generated by the risk management option.

**Considerations**
- This part of the risk assessment process informs the Evaluation step in the decision-making process, providing the data on risk estimates under the scenarios reviewed. These risk estimates need to be compatible with the economic analysis, since the change in risk constitutes the “effect” in a cost-effectiveness analysis.
- This process may be an iterative one in which the objectives of the risk assessment are revised if additional information is required, or if other risk management options must to be evaluated.
<table>
<thead>
<tr>
<th>STEP</th>
<th>CONSIDER</th>
<th>DECIDE</th>
</tr>
</thead>
</table>
| 1. Frame the problem | **What is it?**  
- Infectious disease  
- Contamination (non-infectious)  
- Supply shortage – loss of facility, staff shortage (pandemic, strike)  
**Is the threat imminent – requires urgent assessment action? Or is it longer term?**  
**How much/what kind of information is required?**  
**How will we measure risk reduction?** | **Determine expertise required to conduct the risk assessment (dependson issue) e.g.**  
- infectious disease  
- public health  
- transfusion medicine  
- technical,  
- financial  
- health economics  
**Decide on the objective of the assessment.**  
**Determine what kind of information is required and where to get it.** |
| 2. Identify the hazard | **What are the properties of the hazard?**  
**What are the adverse outcomes?**  
**Is there a causal relationship between the hazard and the adverse outcomes?** | **Review available data/information about the threat and potential adverse effects – use surveillance, public health information, publications, case reports, and expert opinion.**  
**Decide if scientific data provides evidence of a causal relationship.** |
| 3. Describe the hazard and assess exposure | **How severe is the threat? Life threatening? Health threatening?**  
**How likely is it to happen?**  
**Which individuals are at risk from the hazard? What are the consequences?**  
**Will the threat result in blood shortage?** | **Evaluate the adverse effects that may be experienced under expected levels of exposure to the hazard.**  
**Estimate the probability and extent of exposure by using qualitative and quantitative methods.**  
**Estimate the consequences.** |
| 4. Characterize the risks | **Does the hazard pose significant risk?**  
**How serious?**  
**How will it impact?**  
**Who will it impact?** | **Integrate the information from the first three steps into a risk characterization.** |
<p>| 5. Assess the risk | <strong>What is the impact of doing nothing?</strong> | <strong>Estimate the effectiveness of risk management strategies.</strong> |</p>
<table>
<thead>
<tr>
<th>STEP</th>
<th>CONSIDER</th>
<th>DECIDE</th>
</tr>
</thead>
</table>
| reduction impact of the risk management options | What actions are available and how quickly can they be implemented e.g., donor deferral, donor testing for infectious disease risk?  
What impact will the actions have on blood supply, if any?  
What is the cost of risk mitigation strategies?  
How effective is the strategy at mitigating risk? | mitigations to determine whether an action will decrease the risk, and by how much. |
CHAPTER SEVEN – HEALTH ECONOMICS and OUTCOMES ASSESSMENT

Expectations for health economics and outcomes assessments

Health economics and outcomes assessments are premised on a set of fundamental concepts. Chief among these is the notion that decision-makers operate with limited budgets and are not able to implement all interventions. They must therefore choose among competing alternative actions and be aware that the choice to use a resource in one way implies foregoing its use in another way. The purpose of a health economics and outcomes assessment, therefore, is to help decision-makers understand the cost-effectiveness of introducing a blood safety measure, and to optimize the use of limited health care resources.

The type of health economics study must be appropriate to the decision to be made. There are many different types and models of health economics studies. Each addresses a certain type of question, employs a specific outcome measure, and carries particular limitations. The two main types that are relevant to the blood safety decision-making Framework are budget impact analysis, which addresses the ability to afford a particular action; and cost utility analysis, which addresses the extent to which an option provides a reasonable relationship between cost and benefit.

The conduct of health economics and outcomes assessments is guided by a set of principles. For example, since donated blood is a societal good that involves costs, risks and benefits that accrue to different groups, health economics and outcomes assessments of blood safety decisions must take a societal perspective and encompass all costs and effects incurred by all stakeholders. Decisions on blood safety benefit from the results of health economics and outcomes assessments along with those of other assessments. Cost-effectiveness will not always be the determining factor in a decision, as the prevention of some types of risk may be a more important objective.

There are some general processes that should be considered in all health economics analyses. They include framing the question and selecting the perspective; choosing the evaluation method, conducting the decision analysis and assessing uncertainty; selecting data and addressing data scarcity; critiquing the analysis; and presenting, interpreting and integrating the results.

Introduction

These guidelines present the principles and recommended methods for completing health economic and outcomes evaluations of blood safety interventions. They help answer two questions:

- Can we afford a particular action or intervention?
- Does the action or intervention offer value for money?

Part of the rationale for evidence-based decision making is to optimize the use of limited health care resources across the entire health care sector; in the case of blood transfusion, this means seeking efficiency and effectiveness in safety interventions from donors to recipients and beyond. The use of
health economic analyses will therefore help decision-makers understand the cost and cost-effectiveness of introducing a blood safety measure. Economics alone cannot be used to prioritize interventions, but when combined with risk assessment and stakeholder engagement can create a strong foundation for rationale decision making.

The guidelines are based on the deliberations of the Health Economics and Outcomes Committee and formally presented in the manuscript Overview of Health Economic and Outcomes Methods in Risk Based Decision Making for Blood Safety. The manuscript can be downloaded from the ABO website.

These guidelines should help blood services understand what is involved in economic assessments, and to decide whether or not specialist expertise must be recruited. There are also several internet resources available. To determine if local health economic evaluation guidelines have been established for your country, consult the International Society for Pharmacoeconomics and Outcomes Research website: http://www.ispor.org/PEguidelines/index.asp. Note that nearly all guidelines have been developed for the broader context of health technology assessment. They are not specific to blood-safety evaluation.

Part I – Guiding Principles

Three core concepts underpin applied economics. The first is that scarcity exists and there are insufficient financial and other resources (human capital, infrastructure, etc.) to support all possible activities. Scarcity is another way of saying that budgets are limited and so not all interventions can be implemented. As a result the second concept, choice, becomes necessary. Choice is the recognition that decisions between competing alternatives will be made. However, choice itself is not without consequences. The third concept is opportunity cost. By choosing to use resources in one way, the benefits of using those resources in other ways are wiling forgone.

Awareness of the need to apply health economic and outcomes analyses is relatively new to the field of transfusion medicine. As such, considering the following “guiding principles” should help the user.

1. **Health economic analysis is not static.** Decisions should be reviewed and re-analyzed as better or more data becomes available. This practice is a form of due diligence that is necessary in blood safety, and equally applicable to all aspects of risk-based decision making.

2. **Societal perspective.** Donated blood and derived components are societal goods with substantial costs, risks and benefits accruing to different stakeholder groups. For this reason, the societal perspective is the unifying analysis principle to be applied in health economic and outcomes evaluations. This perspective includes the entire set of costs and effects that are incurred by all stakeholders. When more limited perspectives are used justification for not conducting an analysis from the societal perspective is necessary.
3. **Context.** Acceptable economic thresholds for implementing (or not implementing) a given intervention must be placed in the context of blood transfusion risk. Prevention of some risks are considered more important than prevention of others. Even when the cost-effectiveness (efficiency) for mitigating one risk is better, it may not be considered the most important risk to avoid.

4. **Transparency and best practice.** Enhancing transparency and adhering to established best practices in modelling the intervention options, conducting and reporting analyses are required.

5. **Estimation.** Although health economic analyses depend on data, when empirical data are not available, other means may be used to aid in decision making, such as estimation of input parameters by expert opinion. In such cases, the use of experts and their recommended assumptions must be clearly documented.

6. **Precaution.** While precaution remains a strong force in blood safety, health economic analyses support concepts of proportionality and consideration of the impact of actions to reduce risk and increase overall safety because of the presence of a wide diversity of risks.

7. **Other assessments.** Health economic and outcomes assessments are only one part of the Risk-Based Decision-Making Framework. Other assessments or priorities may take precedence over health economic evaluation results.

**Part II - Completing the health economic and outcomes assessment**

Health economic and outcomes analysis is one of several specialist assessments that may be undertaken as part of the decision-making process. A screening assessment is conducted at Step 2 of the risk-based decision making process to identify the magnitude and significance of the risk. If a risk is deemed significant enough to be assessed, there will be a budget impact analysis at a minimum. A judgment may be made at this point as to whether the health economic evaluation should include a partial assessment (budget impact only) or full economic assessment (budget impact and cost utility assessment). If the screening assessment does not make a recommendation about the scope of the health economic and outcomes assessment, documentation of the reasoning is recommended.

Undertaking a full economic assessment is a complex task. Health economic analyses require subject matter expertise and a substantial level of numerical literacy in order to interpret the analysis results and their implications. Depending on the complexity of the assessment, blood establishments may wish to retain the services of a health economist to conduct the analysis.

Once the scope of the assessment has been determined, the health economic and outcomes assessment can begin. Recommended reference material on conducting health economic and outcomes analyses for each step is provided at the end of this chapter.
Step #1: Frame the question and select the perspective

**Purpose**
The aim is to clearly state the health economic questions that need to be answered and select the analysis perspective, or “viewpoint”, from which the analysis is conducted.

**Outputs**
- A clear and concise study question that will guide the analysis;
- The analysis perspective; and
- Develop an outline of the analysis structure.

**Process**
- Agree on the evaluation question(s) by defining: what is the problem, why is it important, what do we want to know, what is the focus?
- Select an analysis perspective. Generally, the societal perspective should be the standard used for blood safety health economic evaluations. This is because donated blood is a societal good with substantial costs, risks, and benefits accruing to different constituencies.
  - **NOTE:** If the societal perspective is not used, justification for selecting a more limited perspective should be clearly documented.
- Structure the analysis to consider the impact on specific groups, such as blood services, donors, hospitals or patients, and the overall impact on society.
  - The **stakeholder identification tools** included in the Framework can be used to help identify the groups that need to be considered in the economic analysis.
  - Plan for the health economic outcomes report to include combined summary results as well as individual results for specific stakeholder groups.

**Considerations**
- The clarity of the study question will have a direct impact on the approaches that will be taken and the amount of time, effort and resources that devoted to the assessment. Take the time at the beginning to make sure the question is clear and captures the issue or scope of the problem.
- Analysis perspectives range from very narrow to very broad. For example:
  - a blood centre or hospital perspective where only the costs incurred by the implementing organization;
  - a health care system or third-party payer perspective that would include the direct costs (and effects) that accrue to both the providers and consumers of health care services;
  - society as a whole, considering all the costs and impacts that are incurred by all stakeholders in the healthcare system, including patients and donors (i.e. societal perspective).
- Although the societal perspective is most appropriate for most blood safety interventions, when dealing with a new and unknown threat, it may be difficult to achieve. Alternatively, a known risk may be well defined and the affected stakeholders obvious. In both cases a more limited perspective may be appropriate.
Step #2: Choose the health economic evaluation method

Purpose
Decide which economic evaluation method is most appropriate to address the problem. For risk-based decision making in blood safety, two methods have been selected as being most appropriate: budget impact and cost utility. Each answers a different question and together the results are complementary, creating a strong base of economic evidence for decision-makers.

Outputs
- A decision about the economic evaluation methods that will be used: Budget Impact Analysis (BIA), Cost Utility Analysis (CUA), or both.

Process
- Refer to the screening assessment to determine if guidance was provided defining the required health economic and outcomes evaluation results.
- If no guidance was provided, using the options below as a guide, select the appropriate evaluation method that will provide results suitable to answer the framework questions in Step 1.

**NOTE:** At a minimum a budget impact analysis should be conducted.

**Budget impact analysis** answers whether an intervention is affordable and where the costs to implement will be incurred. It assesses the financial consequences of adopting a new intervention for local, regional or national budgets. It is not simply a cost accounting of resources required to implement an intervention by the blood operator. Budget impact analysis provides results from the standpoint of the budgeting authority or health care decision maker. This means that it will include costs that cut across different budget silos.

<table>
<thead>
<tr>
<th>Relevant to what question?</th>
<th>Primary outcome measure</th>
<th>Primary limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>The balance sheet between the cost of implementing an intervention and the costs of adverse events prevented or other clinical services/interventions avoided</td>
<td>Single overall summary numerical monetary amount reflecting cost difference</td>
<td>Does not measure effectiveness or benefit of an intervention beyond the cost saved from preventing adverse events or use of other clinical services/interventions</td>
</tr>
</tbody>
</table>

**Cost utility analysis** assesses value for money in terms of cost per quality-adjusted life year gained (QALY). It provides insight into whether an intervention is worth implementing based on the improvement in health or prevention of sickness or death that can be achieved per unit of currency spent. The use of QALY as the measure of health benefit is critical because it establishes a common denominator that enables comparison of interventions across different diseases or conditions.
A description of additional evaluation methods can be found in the Table 1 Summary Description of Health Economic and Outcomes Designs Relevant to Blood Safety.

**Considerations**

- In the blood safety context, cost utility analysis allows for the comparison of different interventions from transfusion-transmissible infections to non-infectious threats attributable to transfusion, some of which may primarily result in injury while others in death. If outcomes can be defined in terms of comparable metrics such as QALYs, a range of interventions—from donor selection to long-term recipient outcomes—can be evaluated through CUA. Without a comparable metric (common denominator) of the costs and effects of interventions, it is nearly impossible to understand which interventions maximize the health of the population.
- The use of BIA as a complement to CUA is increasingly common. Instructions on how to apply budget impact and cost utility analysis methods are described in several publications listed in the toolkit chapter.

**NOTE:** Actual analyses may require the help of specialist expertise.

**Step #3: Conduct the analysis**

**Purpose**

Build the economic model(s) that will allow you to conduct the analysis. For example, for Budget Impact Analysis you would develop a cost model; for Cost Utility Analysis you would build a cost and effects model.

**Outputs**

- A model or models that adequately represent reality and that present relevant outcomes; and considered important for the implementation decision.

**Process**

- Select an appropriate economic model to analyze the results for decision-making. The choice of model will depend on the specifics of the process or technology to be analyzed, the nature of the hazard, and the evaluation method used (i.e. BIA or CUA). Table 2, Types of Models Used in Health Economics and Outcomes, summarizes common models that can be used.
• Construct and enter data into the model, following established best practice.
• Developing and entering data into the model are separate activities with different guiding principles.
• **NOTE:** This is an area where the help of specialist expertise may be considered.

**Considerations**

• Models are simplified representations of a broad range of possible outcomes. The best model for a given question should be only as complex as is necessary to answer the question it was designed to address. Overly complex models are difficult to work with and even more difficult to find appropriate data for entering into the model.

  *The use of these techniques can lead to insights that may support precaution. In situations where uncertainty is very high, it may be appropriate to adopt an intervention that favours precaution rather than a proportional intervention.*

• It is important to ensure transparency and adherence to established best practices in modeling. Substantial effort has been made to codify best practices in recent years and several reports by large consensus bodies have been published to help improve reporting and transparency in analyses.

**Step #4: Assess uncertainty and sensitivity**

**Purpose**

Obtain insight into the uncertainty and sensitivity of outcomes and subsequent decisions based on the data entered into the model. Provide insight into the magnitude and likelihood of potential outcomes.

**Outputs**

• A deterministic sensitivity analysis, which highlights model parameters with the most influence on the results of the analysis.
• A probabilistic sensitivity analysis, which provides an indication of the overall uncertainty around various model outcomes, and the contribution of individual model input values to this uncertainty.
  
  **NOTE:** Both deterministic and probabilistic sensitivity analyses should be conducted as part of health economic evaluations in blood safety. This is an area where the help of specialist expertise may be considered.

**Process**

• Assessment of the relationship between model inputs and model outputs.

  **NOTE:** Various methods can be applied to obtain insight into the uncertainty and sensitivity of model outcomes and subsequent decisions. Choosing the most appropriate sensitivity analysis method depends on the level of uncertainty in the underlying data available for the decision that has to be made.
Although data are essential, the conceptual structure should be driven by the decision problem or research question and not determined by data availability.

- As new information becomes available, it is critical that re-evaluation of both the risk and the health economics of the earlier decision takes place.

Considerations

- For most health economic models, uncertainty is related to availability or reliability of data rather than a lack of knowledge or understanding of causal relationships. In other words, the outcomes are known but their magnitude and likelihood are not.
- Historical examples have shown clearly that health economic evidence only fulfills part of the total evidence in determining the outcome of the decision-making process.

Further reference material on data uncertainty and sensitivity can be found in the toolkit chapter.

Step #5: Manage data and data scarcity

Purpose

Identify ways of conducting health economic and outcome assessments when data is unreliable or not available.

Outputs

- Selection of methods that can be used in the absence of complete data.

Process

- Health economic analyses are data-intensive exercises but sometimes empirical data will not be available, especially in the early emergence of a risk. When empirical data are not available, consider using:
  - a consensus method (e.g., used for early-days vCJD risk assessment) to define input values
  - estimation of specific model parameters by expert opinion elicitation
- Use of these kinds of techniques in health economic analyses requires that reports clearly state the source of data used and assumptions made.
Considerations

- Estimation of model parameters by expert opinion is sometimes viewed as flawed. In practice, however, such approaches are sometimes unavoidable. As long as the use of expert opinion is clearly documented there is no valid reason to discount such an approach. Moreover, structured expert-elicitation exercises can provide highly acceptable sources of information. These alternate approaches may not be ideal, but will support the decision making process, and contribute to overall transparency in the RBDM process.

Further reference material on consensus methods and expert opinion can be found in the toolkit chapter.

Step #6: Present and interpret results

Purpose
Provide a report to decision-makers that clearly present the analyses and allows interpretation of the results within the context of the evaluation question(s).

Outputs
Report BIA and CUA results with interpretation of the meaning for each risk management option.

Process
Present results as Costs and Consequences tables where:

- Report BIA results as disaggregated costs incurred by specific groups or organizations and then as aggregated total costs of implementing an intervention,
- Present CUA results as separate costs and effects for each intervention and then in the form of the ratio of costs to effects when comparing two or more interventions, and

\[
\text{The formula for the incremental cost-effectiveness ratio (ICER) is:}
\]
\[
\frac{(\text{Cost of Intervention 1} - \text{Cost of Intervention 2})}{(\text{Effectiveness of Intervention 1} - \text{Effectiveness of Intervention 2})}
\]

- Present CUA results graphically in a cost-effectiveness plane where the difference in cost is plotted against the difference in effects for each of the alternative interventions included in the analysis:
  - Each intervention will fall into one of the quadrants of the cost-effectiveness plane. Simplistically, interventions that are less costly and more effective should be adopted; those that are more costly and less effective should not. However, the merits and implications of an intervention need to be considered before a decision can be reached.
An advantage of displaying results as a cost-effectiveness plane is that the uncertainty in costs and effects as well as their association (e.g. higher when costs imply higher health effects) can be shown in a graphical manner in the form of confidence ellipses.

Figure 3: Cost-effectiveness plane with rule of thumb decision guides.

- Determine whether a cost-effectiveness threshold is applicable for interpreting the results.
- Interpret results.

Considerations
- What are the threshold considerations in the context of blood safety?
  - Depending on local expectations from health authorities and established health-technology assessment guidelines, the results of analysis can be compared to existing thresholds considered acceptable in your country. For example:
    - In the U.S. the threshold of $US 50,000/QALY has significant traction as a ratio at which or below which interventions may be classified as cost-effective. Similarly, a ratio of £20,000/QALY has been suggested for the U.K. However, there are significant challenges and problems with using these ratios to define cost-effective interventions in blood safety.
    - For health care interventions and preventative measures, a cost-effectiveness ratio of less than three times the gross domestic product per capita in a given country is another measure of cost-effectiveness (Tan-Torres Edejer, T. et al).

NOTE: this value is applicable to care and cure interventions. The cost-effectiveness ratios for interventions implemented for risk prevention are usually much higher. This is a clear illustration of societal preference for risk aversion. People are generally willing to pay more to avoid unintended or undesired side effects or risks outside of the individual’s control.
For many interventions in health care, a cost-effectiveness threshold is appropriate. For analyses in which interventions are both more costly and more effective, the concept of the acceptable threshold becomes relevant. This relates to an established maximum value for acceptable ratio of costs to health effects (the cost-effectiveness ratio). See the discussion on threshold considerations in the Considerations section below.

- Threshold considerations should be placed in the context of the nature of the adverse events for blood transfusion because prevention of some events is considered more important than prevention of other events, even when the latter have lower cost-effectiveness ratios. For example, the cost-effectiveness of infectious disease screening of donations rarely conforms to the threshold of three times the per-capita GDP in a given country. Interventions that have been adopted in blood safety in most developed and developing countries do not conform to WHO-CHOICE or other thresholds. Moreover, within a country a single threshold may not be defined. For some interventions these thresholds may be considered appropriate, but for other interventions the acceptable threshold ratio may be much higher. Implementation of blood safety interventions is sometimes political. Governments may mandate priorities, and political decisions may override the use of health economic and risk-assessment methods. Consistent generation of health economic results, nonetheless, is important to help inform the decision-making process by establishing a body of health economic and outcomes information for the range of blood safety concerns that blood operators must address.

Further reference material on results interpretation can be found in the toolkit chapter.

Step #7: Critique the Analysis

**Purpose**
Evaluate the quality of the work and verify the completeness of the study. Assess the robustness of the model outcomes; check whether the outcomes of the health economic model are valid.

**Outputs**
- Expert opinion on the strengths and weaknesses of the analyses;
- Completed checklists to evaluate the quality of the work (these are readily available, see below); and
- Verified sensitivity and uncertainty of model outcomes.

**Process**
- Have the health economic assessment reviewed by subject matter experts (who are able to judge the sensibility of the outcomes) and health economic experts (who can judge the methodology of the work performed).
- Ensure the reviews include:
  - a review of use of all evidence and data available;
- an assessment of the model and outcome face validity;
- an assessment of adherence to best practices; and
- a comparison of results to similar studies.

- Use independent experts to avoid biased critiques.

**Considerations**

- For most analyses, it will not be possible to formally validate the model. Formal validation would require what is most likely to be lacking: robust data sets and outcomes following implementation of a strategy. However, a peer review of the model can help to establish face validity.
- The development of checklist approaches to review health economic and outcomes studies is useful for both subject matter experts and non-experts. The recently developed Consolidated Health Economic Evaluation Reporting Standards (CHEERS) are not intended to serve as a critiquing tool, but can be used to assess if key aspects of the analysis are described in sufficient detail to help build confidence in the analysis and findings. An older checklist published in the 1990s remains relevant. See the *Checklist of Evaluation Factors* at the end of this chapter.

**Step #8: Integrate the health economic analysis into the framework**

No formal process has been developed to integrate health economic and outcomes analyses into RBDM because the relatively weight each part of the framework should contribute to a given decision is specific to the decision being evaluated.

**Purpose**

Integrate the results of the health economic and outcomes analysis with other framework findings.

**Outputs**

- A more complete overview of risk management options.

**Process**

- Map the health economic assessment results against the risk management options identified at the beginning of the process, along with the other assessments that were identified as important to the decision at hand. Use the *Risk Management Options and Assessments Table*.

**Considerations**

- How health economics and outcomes results are included will depend on whether this information is considered necessary or optional in a given setting and with respect to given issue.
## Summary of Health Economic and Outcomes Designs Relevant to Blood Safety

<table>
<thead>
<tr>
<th>Health economic study type</th>
<th>Relevant to what question?</th>
<th>Primary outcome measure</th>
<th>Primary limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Budget Impact Analysis</td>
<td>The balance sheet between the cost of implementing an intervention and the costs of adverse events prevented</td>
<td>Single overall summary numerical monetary amount reflecting cost difference</td>
<td>Does not measure effectiveness or benefit of an intervention beyond the cost saved from preventing adverse events or use of other healthcare services</td>
</tr>
<tr>
<td>Cost Minimization</td>
<td>An analysis where the effects of an intervention lead to identical outcomes</td>
<td>Total cost of implementing each intervention</td>
<td>Exact equivalence of different interventions is rare</td>
</tr>
<tr>
<td>Cost Effectiveness</td>
<td>Effectiveness is assessed in natural units, such as infections prevented, adverse donation reactions avoided, adverse transfusion reactions avoided</td>
<td>A ratio of the difference in the costs of two interventions divided by the difference in the effectiveness of two interventions; life years gained may be used as the outcome measure</td>
<td>The ratio has meaning for the specific outcome but cannot be easily compared to the effectiveness of interventions to prevent other adverse events</td>
</tr>
<tr>
<td>Cost Utility</td>
<td>Effectiveness assessed in terms of quality adjusted life years (QALYs), or other outcomes such as disability adjusted life years (DALYs)</td>
<td>A ratio of the difference in the costs of two interventions divided by the difference in the effectiveness expressed as QALYs or DALYs of two interventions</td>
<td>Results in a summary average ratio of all persons, and requires preference weights for health states associated with each intervention</td>
</tr>
<tr>
<td>Cost Benefit</td>
<td>Costs and outcomes with results of both expressed in monetary units</td>
<td>A ratio of costs to implement an intervention compared to costs saved or averted by preventing adverse outcomes</td>
<td>The value of human life (outcomes) are expressed in monetary units</td>
</tr>
</tbody>
</table>

*Table 1: Summary Description of Health Economic and Outcomes designs relevant to blood Safety including primary outcomes and limitations of each design*
<table>
<thead>
<tr>
<th>Health economic study type</th>
<th>Relevant to what question?</th>
<th>Primary outcome measure</th>
<th>Primary limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cohort</td>
<td>Overall impact on static (finite) single group or population</td>
<td>Average population experience</td>
<td>May oversimplify individual experiences and disease outcomes</td>
</tr>
<tr>
<td>Markov Process</td>
<td>Overall impact on static (finite) single group or population as persons transition from one health state to the next</td>
<td>Average population experience and progression and final health state of a cohort</td>
<td>Simplifies disease progression into repeating cycles of a limited number of health states</td>
</tr>
<tr>
<td>Transmission or Epidemic; SIR (Susceptibles, Infecteds and Removed)</td>
<td>Spread or dispersion of disease in a population</td>
<td>Transmission rate of disease based on SIR structure of the population</td>
<td>Infectious processes only; not easily amenable to inclusion of resource allocation</td>
</tr>
<tr>
<td>Discrete Event Simulation</td>
<td>Assessment of processes, procedures or outcomes by imitating complex systems and decisions over time</td>
<td>Occurrence of conditions, progression of disease, resource allocation (i.e. anything that can conceptualized as events)</td>
<td>Requires more data and can be difficult to explain and validate</td>
</tr>
<tr>
<td>Microsimulation</td>
<td>Specific clinical progression routes for persons or populations using different interventions or algorithms</td>
<td>Direct comparison of competing interventions at the individual or aggregated population level</td>
<td>Extremely data intensive; requires complete clinical histories for individual patients</td>
</tr>
</tbody>
</table>

Table 2: Types of Models Used in Health Economics and Outcomes
# Checklist of Evaluation Factors

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Was a well-defined question posed in answerable form?</td>
</tr>
<tr>
<td>1.1</td>
<td>Did the study examine both costs and effects of the services or programs?</td>
</tr>
<tr>
<td>1.2</td>
<td>Did the study involve a comparison of alternatives?</td>
</tr>
<tr>
<td>1.3</td>
<td>Was a viewpoint for the analysis stated and was the study placed in any particular decision-making context?</td>
</tr>
<tr>
<td>2</td>
<td>Was a comprehensive description of the competing alternatives given (i.e. can you tell who did what to whom, where and how often)?</td>
</tr>
<tr>
<td>2.1</td>
<td>Were there any important alternatives omitted?</td>
</tr>
<tr>
<td>2.2</td>
<td>Was a do-nothing alternative considered? Should one be?</td>
</tr>
<tr>
<td>3</td>
<td>Was the effectiveness of the programs or services established?</td>
</tr>
<tr>
<td>3.1</td>
<td>Was this done through a randomized, controlled clinical trial? If so, did the trial protocol reflect what would happen in regular practice?</td>
</tr>
<tr>
<td>3.2</td>
<td>Was effectiveness established through an overview of clinical studies?</td>
</tr>
<tr>
<td>3.3</td>
<td>Were observational data or assumptions used to establish effectiveness? If so, what are the potential biases in results?</td>
</tr>
<tr>
<td>4</td>
<td>Were all the important and relevant costs and consequences for each alternative identified?</td>
</tr>
<tr>
<td>4.1</td>
<td>Was the range wide enough for the research question at hand?</td>
</tr>
<tr>
<td>4.2</td>
<td>Did it cover all relevant viewpoints? (Possible viewpoints include the community or social viewpoint, and those of patients and third-party payers. Other viewpoints may also be relevant depending upon the particular analysis.)</td>
</tr>
<tr>
<td>4.3</td>
<td>Were the capital costs, as well as operating costs, included?</td>
</tr>
<tr>
<td>5</td>
<td>Were costs and consequences measured accurately in appropriate physical units (e.g. hours of nursing time, number of physician visits, lost work-days, gained life years)?</td>
</tr>
<tr>
<td>5.1</td>
<td>Were any of the identified items omitted from measurement? If so, does this mean that they carried no weight in the subsequent analysis?</td>
</tr>
<tr>
<td>5.2</td>
<td>Were there any special circumstances (e.g., joint use of resources) that made measurement difficult?</td>
</tr>
<tr>
<td>5.3</td>
<td>Were these circumstances handled appropriately?</td>
</tr>
<tr>
<td></td>
<td>Were the cost and consequences valued credibly?</td>
</tr>
<tr>
<td>---</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>6</td>
<td>Were the sources of all values clearly identified? (Possible sources include market values, patient or client preferences and views, policy-makers’ views and health professionals’ judgments)</td>
</tr>
<tr>
<td>6.1</td>
<td>Were market values employed for changes involving resources gained or depleted?</td>
</tr>
<tr>
<td>6.2</td>
<td>Where market values were absent (e.g. volunteer labour), or market values did not reflect actual values (such as clinic space donated at a reduced rate), were adjustments made to approximate market values?</td>
</tr>
<tr>
<td>6.3</td>
<td>Was the valuation of consequences appropriate for the question posed (i.e. was the appropriate type of analysis selected)?</td>
</tr>
<tr>
<td>6.4</td>
<td>Were costs and consequences adjusted for differential timing?</td>
</tr>
<tr>
<td>7</td>
<td>Were costs and consequences that occur in the future adjusted to their present values?</td>
</tr>
<tr>
<td>7.1</td>
<td>Was there any justification given for the discount rate used?</td>
</tr>
<tr>
<td>8</td>
<td>Was an incremental analysis of costs and consequences of alternatives performed?</td>
</tr>
<tr>
<td>8.1</td>
<td>Were the additional (incremental) costs generated by one alternative over another compared to the additional effects, benefits or utilities generated?</td>
</tr>
<tr>
<td>9</td>
<td>Was allowance made for uncertainty in the estimates of costs and consequences?</td>
</tr>
<tr>
<td>9.1</td>
<td>If data on costs and consequences were stochastic (randomly determined sequence of observations), were appropriate statistical analyses performed?</td>
</tr>
<tr>
<td>9.2</td>
<td>If a sensitivity analysis was employed, was justification provided for the range of values (or for key study parameters)?</td>
</tr>
<tr>
<td>9.3</td>
<td>Were the study results sensitive to changes in the values (within the assumed range for sensitivity analysis, or within the confidence interval around the ratio of costs to consequences)?</td>
</tr>
<tr>
<td>10</td>
<td>Did the presentation and discussion of study results include all issues of concern to users?</td>
</tr>
<tr>
<td>10.1</td>
<td>Were the conclusions of the analysis based on some overall index or ratio of costs to consequences (e.g. cost-effectiveness ratio)? If so, was the index interpreted intelligently or in a mechanistic fashion?</td>
</tr>
<tr>
<td>10.2</td>
<td>Were the results compared with those of others who have investigated the same question? If so, were allowances made for potential differences in study methodology?</td>
</tr>
<tr>
<td>10.3</td>
<td>Did the study discuss the generalizability of the results to other settings and patient/client groups?</td>
</tr>
<tr>
<td>10.4</td>
<td>Did the study allude to, or take account of, other important factors in the choice or decision under consideration (e.g. distribution of costs and consequences, or relevant ethical issues)?</td>
</tr>
<tr>
<td>10.5</td>
<td>Did the study discuss issues of implementation, such as the feasibility of adopting the preferred program given existing financial or other constraints, and whether any freed resources could be redeployed to other worthwhile programs?</td>
</tr>
</tbody>
</table>
Health Economic & Outcomes Guidelines Map

Guiding Principles

Consider the Guiding Principles when planning, conducting and completing the HE&O assessment.
1. HE not static
2. Societal perspective
3. Context
4. Transparency and best practice
5. Estimation
6. Precaution
7. Other assessments

Step 1: Frame the question and select perspectives

Clearly state the HE&O question:
- What is the problem
- Why is it important
- What do we want to know

Select the analysis perspective:
- Societal is gold standard for blood safety
- Selecting an alternative perspective needs to be justified and documented

Step 2: Choose HE & O evaluation method

Budget Impact Analysis
- Is it affordable?
- Where will costs be incurred
- Include costs that cut across budget siloes (budget authority perspective)

Cost Utility Analysis
- Assesses value for money
- Uses QALYs as measure of health benefit

Step 3: Conduct the analysis

Select analysis
Model scope and structure should be consistent with and adequate to address decision problem
Structure should be driven by decision problem, not data availability

Step 4: Assess uncertainty and sensitivity

Contributes to decision when there is large uncertainty in model parameters:
- Sensitivity analysis
  - Deterministic
  - Probabilistic
- Uncertainty analysis
  - Related to data availability or reliability

See Table 1

See Table 2
Present the data:
- Costs and consequences table
- Cost-effectiveness plane

Results interpretation:
- Threshold considerations
- Established threshold options
- Non-threshold considerations:
  - risk tolerance
  - political issues

Use checklists to evaluate quality of the work
- Review use of data available
- Assess model and outcome face validity
- Assess adherence to best practice
  - Compare results to similar studies

Incorporate results of HE&O assessment into RBDM Framework decision support tool, “Assessment Findings/Risk Management Options Mapping”

- Techniques to deal with data scarcity
  - Consensus methods
  - Real data vs assumptions
  - Estimation by expert opinion
  - Expert elicitation by a panel process

See Table 3
Overview of stakeholder involvement

A risk management policy describes expectations for stakeholder involvement and risk communication to inform the risk-based decision-making process. These activities may collectively be referred to as risk issue management. A risk issue has become, or has the potential to become, particularly salient in the public mind. Often risk issues will involve one or several stakeholder groups, with the potential for wider public interest, often through media attention. Concern may focus on contextual factors associated with a risk issue, and the level of concern may not correspond with the health risk as technically assessed. Such issues may impact the organization’s ability to implement risk management strategies or undermine its credibility and authority as an effective risk manager.

Stakeholder consultation processes are used to help blood operators understand the perspectives and perceptions held by stakeholders to determine their expectations for the management of risk, and to bring all relevant information before the decision-makers prior to making a decision. This policy also contemplates the use of communication practices to provide information about a risk management decision, once made, to the broader public.

Involving stakeholders helps the organization to shape and/or validate decision options—it is not abdicating decision making authority. Consultation, when done well, improves the quality of decisions by informing decision-makers of stakeholders’ views, concerns and ideas, and offers the opportunity to provide input into decisions on issues that interest or affect them. It also helps develop relationships between stakeholders and the organization, builds trust in the organization as a risk manager, and facilitates the development of a shared understanding of risk management priorities. Stakeholder consultation can be an important means of risk issue management, through providing opportunities for all perspectives to be heard and acknowledged and for risk management options to be explored.

Preparing for and conducting effective consultation lays the foundation for trust. Providing stakeholders with the consultation outcomes and how their input informed the decision contributes to legitimacy and sustainability.

Why is it critical to consult stakeholders?

Ideally, stakeholder consultation is proactive, meaningful and proportional to the context, timelines and resources available.

These steps propose a sequential process for identifying and involving stakeholders in a risk-based decision. Stakeholder consultation serves to inform the decision-makers of possible gaps, problems, and risks as well as opportunities and alternate solutions; enables understanding of all interests; identifies unintended consequences; points out additional resources, sources of information and linkages; and can facilitate implementation.
This input is combined with other forms of evidence throughout the decision-making process. Stakeholder involvement contributes to achieving a robust, well-informed and socially tolerable decision.

The following five-step process is intended to help blood operators effectively involve key stakeholders in risk-based decision making:

1. Define need for stakeholder involvement in the risk being assessed
2. Stakeholder Identification & Assessment; (what categories of stakeholders need to be at the table and who are they?)
4. Stakeholder Consultation Implementation and documenting the results
5. Decision Implementation and reporting back to stakeholders (share decision including how their input was used and ongoing involvement)

Best Practice Considerations

- Stakeholders have a right to be invited to share their views on decisions that will affect them and/or on issues in which they have a significant interest
- Genuine consultation demonstrates accountability for safe, efficient and ethical decision making.
- Blood operators will want to be clear about the aspects of the issue that are open to stakeholder input
- Blood operators will also want to report back to stakeholders on how their input was used when sharing their decision
- If meaningfully engaged in a genuine and effective process, stakeholders who disagree with the decision may still support the process and accept the decision as legitimate
- Blood operators can use this process at varying levels of involvement and intensity depending on their context, capacity and need
- All pertinent information should be made available to stakeholders to ensure they can participate in a meaningful way.

Step #1: Define need for stakeholder involvement

Purpose
The purpose of Step 1 is to clearly identify the roles stakeholders play in contributing to the decision at hand.

Output
Determination of how stakeholder involvement will:
a) Inform the decision (knowledge, ideas, advice); and
b) Establish legitimacy and aid in implementation.
Process
- Clearly define the problem to be resolved (Step 1 of the Framework).
- Preliminary identification of the key stakeholder categories - aligned with the problem definition.
- Identification of the aspects of the issue benefitting from and/or requiring stakeholder involvement.

Considerations
- What issues do stakeholders have in relation to the issue?
- Do stakeholders expect to be involved and if so, how?
- How might stakeholders aid or impact implementation?
- What is known and what is unknown and can stakeholder input fill the gaps?
- Where might there be opportunities to leverage stakeholders in influencing others?
- What are the regulatory expectations or requirements related to involving stakeholders?

Step #2: Identify and assess stakeholders

Purpose
To identify, assess and prioritize key stakeholders who should be involved in the decision.

Outputs
- A stakeholder map;
- A list of stakeholders for consultation;
- A list of stakeholders for risk communications and monitoring; and
- A strategy for addressing negative stakeholders.

Process
1. Determine the categories of stakeholders who are interested in or affected by the issue. Stakeholders could be, but are not limited to, any of the following categories: patient groups, funders, regulators, professional associations, researchers, health institutions, industry partners, thought leaders, health care professionals, suppliers, general public.

2. Using the template below, place each stakeholder (individuals or groups) on the stakeholder map, in the appropriate quadrant, according to their level of interest and influence in relation to the issue:
   a. Interest – the level of attention and importance a stakeholder gives to the issue; and
   b. Influence – the extent of influence (resources and power) the stakeholder brings to the issue.
### Considerations
- Stakeholders mapped to quadrant 1 ("low interest/low influence") will require an open channel of communication/information sharing.
Stakeholders mapped to quadrant 2 (“high interest/low influence”) should be kept informed and their views should be solicited.

Stakeholders mapped to quadrant 3 (high influence) should be invited to contribute their perspectives and knowledge on the issue.

Some stakeholders in quadrant 3 whose influence you will benefit from may have to be encouraged to participate as their interest is lower than stakeholders in Q4.

More challenging relationships may require a tailored and more intensive approach that addresses their specific issues.

You may want to leverage the stakeholders with whom you have more positive relationships to help influence others.

Step #3: Stakeholder involvement plan

**Purpose**

Guided by the identified problem/risk and the results of the stakeholder assessment, develop a stakeholder involvement plan.

**Outputs**

- Detailed stakeholder involvement plan
- Critical path
- Critical documentation for stakeholders
- Calendar for stakeholder involvement activities

**Process**

1. Clarify the purpose, objectives and desired outcomes/goals of stakeholder involvement.

2. Using the stakeholder map, identify and prioritize activities related to each quadrant, focusing attention on quadrants 3 and 4. For example, activities for quadrant 1 and 2 could include web updates, e-mails, phone calls, and conference calls. Activities for quadrants 3 and 4 could include face-to-face meetings, video conferencing, webinars, web-based consultation, key informant interviews, and surveys.

3. Design a structured consultation process that maximizes open questions and encourages participation.
   - Match the consultation method with the key objectives.
   - There are many different consultation methodologies to draw on.
   - There are excellent online sources, such as: IAP2 ([www.iap2.org](http://www.iap2.org)), NCDD ([www.ncdd.org](http://www.ncdd.org)), and Participedia ([www.participedia.net](http://www.participedia.net)).

4. Develop a critical path (including data analysis and reporting) with identified resources and timelines matched to the deliverable dates associated with the decision process.

5. Prepare and support stakeholders for meaningful participation by:
   - Providing critical documentation in advance of the consultation
   - Encouraging them to solicit input from their networks in advance of the consultation

6. Plan and schedule a calendar of stakeholder involvement activities.

**Considerations**
- Blood operators may wish to tap into external expertise if this capacity does not exist in-house or resources are stretched.
- Some stakeholders may recommend the inclusion of others in the consultation. Consider their recommendations as it will ensure broad input.

**Step #4: Consulting stakeholders and capturing results**

**Purpose**
Implement the consultation plan and deliver the consultation results to support the Evaluation step in the decision-making framework.

**Outputs**
- Detailed report on the consultation results, including preferred options; and
- Stakeholder evaluation on the consultation.

**Process**
1. Conduct the consultations.
   - Plan for a consistent means of accurately recording / capturing stakeholder input.

2. Undertake analysis and drafting of report.
   - Validate draft report with stakeholders.

   - Blood operator may request follow-up consultation on emergent options or considerations.

4. At the end of the consultation, provide stakeholders with the opportunity to give feedback on their experience. An evaluation form can be completed at the session or provided electronically following...
the consultation. For example, you may wish to inquire about the following: stakeholders’ feedback on: sufficient opportunity to offer their views and discuss the issue; openness and transparency; if their knowledge of the issue increased; increased trust of the operator or decision-makers.

5. Blood operators will also want to advise participants on how their input will be used to ensure transparency and improve future opportunities).

**Considerations**

In conducting the consultations, allow for sufficient time for questions and discussions, access to subject matter experts for points of clarification, assemble the resources required (staff, technical or other expertise, communications support, travel support, venues), and establish ground rules for dialogue.

**Step #5: Decision implementation**

**Purpose**

Share decision with stakeholders, providing rationale on how their input was considered and used in decision-making (how did it inform the decision?)

**Outputs**

- Briefing note from decision-makers to stakeholders;
- Thank you letter to stakeholders; and
- Identification of next steps and any additional involvement opportunities related to the decision.

**Process**

Following the consultation:

1. Blood operator provides a briefing note to share with stakeholders on how the input was considered and what the final decision/next steps are in the process prior to being made public.
2. Inform stakeholders of ways to stay connected with the issue (include in risk communications planning).
CHAPTER NINE – RISK TOLERABILITY

Risk tolerability

As part of a risk management policy, risk tolerability guidelines should be developed in a manner that is consistent with the risk management principles described earlier. The tolerability of the risk of a given intervention or decision is a risk management judgment made with awareness of concerns and priorities of the public and affected or interested stakeholders.

A tolerable risk is a risk that is justified by the benefits gained, is managed at a level that is proportional to the risk and the benefits which accompany it, is fairly distributed to the extent possible, and is borne knowingly. It is distinguished from an acceptable risk, which is one that is low enough that no management is needed. These guidelines describe a process for evaluating the tolerability of a risk, taking into account various contextual factors.

The concept of risk tolerability is generally applied to the risks of societal activities, which are undertaken for their benefits to society. Adverse outcomes of these activities are minimized through risk management measures, but these add a cost to the activity. Risk tolerability is a judgment that the level of risk of an activity is reasonable, given both the benefits of the activity and the additional resources required for further risk reduction. The tolerability of a risk is affected by a number of factors related to the source of the risk and the risk bearer. Risk sources associated with lower tolerance include activities without evident benefits; risks that are imposed without adequate consultation or consent; risks expected to be managed by an institution; and risks resulting from incompetent or negligent behaviour. Risk bearers associated with lower risk tolerance include vulnerable individuals or groups (e.g., children, those with serious health problems or socio-economically disadvantaged). Lower risk tolerance is also associated with an inequitable distribution of risk and benefit, especially where risks are borne disproportionately by an identifiable group.

A widely used approach to incorporating risk tolerability into risk management uses is a principle called ALARA (“as low as reasonably achievable”) which considers the degree of risk reduction that is necessary or warranted, taking into account scientific, social and economic factors. It is an approach that attempts to achieve the lowest possible risk level with attention to practicality and costs. Note: A similar concept to ALARA is called ALARP (“as low as reasonably practicable”); sometimes the terms are used interchangeably.

The ALARA principle is applied where two fundamental conditions are present. First, there is an explicit recognition that there is a risk in the activity; second, it is acknowledged that the level of risk is weighed against benefits and risk reduction costs, based on information produced by case-specific assessments. In the context of blood safety, these conditions are present in society’s tolerance of risk to individuals from the use of blood products, based on the societal requirement for readily available and affordable blood products. An integral aspect of the ALARA principle is that there is an expectation of continual improvement as management methods, technologies and costs change.
The evaluation of risk tolerability using the ALARA principle establishes a continuum of risk levels and divides them into acceptable, tolerable and intolerable regions, as represented in Figure 4 below.

The ALARA principle is applied in risk based decision making, facilitating the allocation of risk management measures and effort in proportion to the risk and other contextual factors; it primarily applies this approach in a ‘tolerable risk region’ that is bounded by lower and upper risk thresholds, usually defined by quantitative risk levels. At one end of the continuum there is a broadly acceptable region of very low risks, in which the status quo is deemed acceptable: individuals are expected to accept the risks and no risk management is required. At the opposite end of the continuum there is an intolerable region of high risks, in which the risk to health (or another valued component of the blood system) is intolerable regardless of benefits elsewhere. Exceptions may be made in some cases, where very high risks are tolerated if the activity is required to reduce a serious competing risk.

Risks that are assessed as falling in the tolerable risk, or ALARA, region between the lower and upper thresholds, are weighed against benefits, the potential for further risk reduction, and a range of contextual and concern factors. In this region risks are deemed to be tolerable in view of the benefits gained and based on the assumption that management is applied to reduce the risk to be as low as reasonably achievable. Even after management effort has been applied to reduce risks within the tolerable region, they may remain above the level of broadly acceptable risk. Barriers to further reduction of risks include insufficient scientific or technical understanding (i.e. for emerging risks), the potential for other risks to be increased as a consequence of risk mitigation, or considerations of the relative cost-effectiveness of further risk mitigation in the context of other priorities competing for limited resources.

The evaluation of risk tolerability, particularly for risks that remain in the ALARA region where risks may be tolerable, is informed by an analysis that considers a variety of evidence (gathered through the Assessment step of the decision-making process) including the blood safety risk assessment, health economics assessments, input from consultations and other assessments. The use of these factors to locate a risk within acceptable, tolerable or intolerable regions is illustrated in the Risk Tolerability Evaluation Tree, provided in the Evaluation step. The evaluation of risk tolerability also draws heavily on the risk management principles described above.
Figure 4: An illustration of the ALARA concept applied to risk tolerability

Introduction and basic principles

It is implicit in risk-based approaches that risk managers and regulators no longer suggest that they attempt to reduce all risks as far as possible, without consideration of other factors. Instead, information about the risk supports the proportional allocation of resources, enabling risk managers to address certain risks before others, and to reduce a risk as far as is warranted by the acceptability of its level in relation to a number of factors including benefits achieved, existing management, and the additional costs that would be required to reduce the risk further.

The challenge in risk-based management is to determine which risks should be given priority, and how much cost is appropriate to reduce a risk. It is perhaps more difficult to decide, for any given risk, at what level it is considered to be high enough that it must be reduced, or low enough that further reduction is not warranted.

Who determines the tolerability of a risk?

Risk tolerability refers rather imprecisely to a societal judgment on the acceptability of a risk in relation to the benefits of the activity and the costs of managing the risk. The judgment is meant to protect the public and reflect social values, but it is not made by members of the public or stakeholder groups. Instead, it is made by the risk management institution, usually with consideration of public and stakeholder concerns informed by stakeholder engagement and public concern assessments.
The tolerability of a risk is a judgment made by risk managers on behalf of the public, in terms of standards or criteria that represent the ‘public good’. Therefore, blood system operators must interpret and apply principles of societal tolerability of risk to an ongoing series of decisions, in consultation with the public and specific stakeholders when appropriate.

**Risk management approaches to determining risk tolerability**

Assessing societal tolerability requires a process that establishes criteria and principles that are taken to express broader social values, so that the evaluation and management of the social impacts of a large range of risks can reflect those values.

**Application of relevant risk thresholds in health care decision-making**

The ALARA principle has been applied to risk tolerability in a number of risk management contexts in which relatively crude risk measures are relevant (such as fatalities per year, in major industrial settings). It has not generally been applied to health care settings, where it is more difficult to define the ‘harm’ of concern in a risk decision unambiguously, with a wide range in the type and severity of outcomes that will be defined and considered against benefits and costs of an intervention. The approach is flexible, however, and offers to some health care decision-making a structure for making case-specific risk-benefit and cost trade-offs within broader established risk thresholds. It is expected that the risk manager will adapt the approach, integrating the scientific, clinical and social contextual specificities of the situation.

The application of the ALARA principle requires the characterization of risks, benefits and costs, as well as a consideration of contextual factors. The RBDM Framework provides for a blood safety assessment and a health economics and outcomes assessment, as well as a set of contextual assessments, providing the information needed to evaluate risk tolerability based on the ALARA principle of evaluating trade-offs. The level of detail of the assessments, and the information they produce, will vary with the extent and intensity of the overall decision-making process, in proportion to the significance of the risk and the decision to be made. In some cases a screening assessment that results in qualitative assessments may be sufficient, while others may require more intensive assessments that produce quantitative risk characterizations.

**Step 1: Establish broad threshold risk levels for the organization’s risk tolerability evaluations**

**Purpose**

To establish quantitative or qualitative risk levels that can serve as broad thresholds, for the lower boundary of tolerable risk – the acceptable risk threshold - and the upper boundary, the intolerable risk threshold. These thresholds guide the identification of the tolerability zone within which the level of the specific risk to be managed, along with contextual and ethical factors, are considered, enabling a risk-informed approach.
To support risk-benefit tradeoffs that apply in some clinical contexts it may be necessary to establish several sets of thresholds for application to different types of risk decisions; separate thresholds could be established for application in situations and outcome severities, such as once-in-a lifetime infusions, or chronic infusions, or particular risk-risk tradeoffs.

These general upper and lower thresholds will express the organization’s determination of appropriate public risk thresholds: these are unique to each organization and should be established as part of the risk management policy. Because risk management decisions will be made at varying levels of detail and intensity, risk thresholds should be established in both qualitative and quantitative terms to provide support for evaluations using either type of measure. An example of risk thresholds that are applicable for a blood operator context (found in the Toolkit Chapter): is in the form of a matrix that includes both qualitative and quantitative measures of the expected frequency of an outcome, and qualitative descriptions of different levels of outcome severity, resulting in the definition of acceptable, tolerable and intolerable risk levels.

Because cost-effectiveness is also an important organizational criterion the organization should also establish broadly applicable guidelines on upper and lower benchmarks for cost-effectiveness for consideration in Step 4.

**Outputs**

- Upper and lower levels of tolerable risk and cost-effectiveness that may apply to a range of risk management situations.

**Process**

- Establish quantitative thresholds for the acceptable, tolerable, and unacceptable risk regions. Sets of thresholds applicable to specific types of situations may be developed.
- Use comparative benchmarks to help establish the thresholds
- Establish quantitative acceptable, tolerable and intolerable cost-effectiveness thresholds, using existing blood safety or health economics benchmarks as comparators.

**Considerations**

A number of industries, and regulators of industries, employ an ALARA or ALARP method that establishes a lower level of tolerable risk and a high level of intolerable risk (usually in terms of annual fatalities). The greatest progress on this approach has been made by the UK Health and Safety Executive (HSE), which has developed guidance on a Tolerability of Risk Framework (*see additional information below for a brief description*).
The Tolerability of Risk Framework begins with the assumption that many societal risks are often not unconditionally or universally accepted, but are worth taking in view of their careful management and the benefits that are gained from the activity. This is a risk-based approach that views risk tolerability as a problem of trade-offs. The framework includes a structure and process for a case-by-case evaluation of the risk to be managed in relation to both a set of fundamental risk criteria and a range of ethical and contextual factors that are relevant to the risk. The risk tolerability approach requires information on the risk, from several assessments:

- **Assessment of the risk posed by the activity**, which is then compared to established thresholds of lower (‘acceptable’) and upper (‘intolerable’) quantitative risk levels. In between is a ‘tolerable risk’ zone in which risks are accepted if it can be shown that they have been reduced “as low as reasonably practicable (ALARP)” when other considerations are taken into account.

- **Estimation of the costs and benefits of management options**. In the UK a cost-benefit assessment is required, as the framework fits into a legal context that demands that the ‘sacrifice’ (economic and other costs) involved in measures to reduce a risk should not be ‘disproportionate’ to the benefit of reducing the risk; this information is needed in order to assess the ‘practicability’ of further risk reduction. This is an assessment that the risk reduction is ‘achievable’ (a variation on ‘practicable’ yielding the equivalent acronym ALARA), including assessment of the costs and other resources that would need to be allocated in order to reduce the risk, or to confirm that its control meets these conditions. Technological, ethical and utility considerations are applied in the evaluation of the need to reduce the risk further.

- **Consideration of social concern and other contextual factors** that may suggest, for example, that the risk should be more strictly controlled than other risks at a comparable quantitative level.
Step 2: Define contextual factors that affect tolerability

**Purpose**
As described in the Policy Foundation part of this section, factors related to the source of the risk and the risk bearer affect risk tolerability. It is necessary right at the beginning of this exercise to clearly articulate what the source of the risk is, the potential harm that can be caused, and who primarily bears the risk.

**Outputs**
- Understand the nature of the risk;
- Identify the harm that can be caused by the risk;
- Identify who primarily bears the risk; and
- Understand the distribution of risks and benefits.

**Process**
Steps 1 and 2 of the blood safety risk assessment will provide information on the nature and source of the risk, the harm that may be caused (both severity and frequency of occurrence, expressed either qualitatively or quantitatively), and who is at risk from the hazard.

The issue characterization checklist, and any contextual assessments that have been conducted, will provide information on broader contextual factors such as the involvement of vulnerable populations or risk-benefit distribution, that decision-makers should be aware of when evaluating risk tolerability.

Step 3: Establish case-specific risk levels for determining tolerability

**Purpose**
Identify a risk level that captures the significance of the risks, in the qualitative or quantitative terms as the threshold risks established by the organization in Step 1. The risk levels of the issue under consideration are compared to these broader risk thresholds and benchmarks. This will locate the risk within the acceptable, tolerable or intolerable range as a starting point for consideration of contextual factors in the risk under consideration.

**Outputs**
- A summary of the existing risk levels applicable to the risk under consideration.

**Process**
- Identify the risk levels in the issue under consideration, using the information obtained in the blood safety risk assessment, for example, rates of adverse effects from the intervention considered, or in closely analogous interventions; or prevalence of existing or previous infectious agents in blood.
- Include in the summary levels that are prevalent, with a lower boundary of risk levels (or incidences) that are tolerated within that field, the range of generally accepted levels of severity or incidence and the level that is considered intolerable.
• Indicate whether the existing levels are considered acceptable or if there is pressure to reduce them when this becomes technically possible or economically feasible.

**Considerations**
This approach will ensure that the following factors are relevant to the blood safety decision to be made:

- The risk can be defined as transfusion events or procedures, blood processing factors, blood quality, or others as relevant.
- The effect of concern
  - the severity can be defined and categorized as necessary.
- The incidence can be defined within relevant populations of blood recipients or donors, or the entire population.
- Levels can be established that are considered acceptable for different exposures (one time or chronic transfusion, for example) that are standard for the intervention.
- Challenges and costs for reducing these levels.

**Step 4: Evaluating the risk-benefit tradeoffs for determining tolerability**

**Purpose**
The results of the health economics and outcomes assessment should be considered as part of the risk tolerability evaluation, in order to assess the value of expending resources to reduce the risk; or to compare the cost-effectiveness of several risk mitigation options along with other contextual aspects of the risk situation.

**Outputs**
- Ensures adequate consideration of costs and other risks in the interests of societal need for cost-effectiveness in health care resource allocations

**Process**
- Use the outputs from the budget impact analysis and the health economics and outcomes analysis (if available) to inform the risk tolerability evaluation.
- Apply or consider organizational criteria for cost-effectiveness.

**Considerations**
- Although quantitative information is being used to inform the risk tolerability evaluation, the outcome of this step requires judgment and cannot rely solely on data.
Step 5: Considering ethical and concern factors affecting the societal tolerability of a risk

**Purpose**

Review risk and risk management options in terms of ethical principles underlying risk tolerability as well as organization’s risk management principles, and understand public and stakeholder concerns and priorities that could affect their risk tolerability judgments.

**Outputs**

- Review and consideration of ethical concerns affecting tolerability of risk and risk management options;
- Awareness of public and stakeholder concerns with respect to the risk and management measures;
- Determination of need for additional stakeholder involvement to assess concerns; and
- Determination of need for risk communication to address outstanding public or stakeholder concerns.

**Process of applying ethical principles**

- Evaluate the ethical implications of the risk using a set of principles that set out the conditions under which members of the public should expect to be protected from a risk; under which they are expected to tolerate a risk; and how much they are expected to pay to protect everyone from a risk. Examples of principles that could be used are:
  - Individuals have a legitimate expectation of protection from high risks of societal activity, by competent authority acting in the public interest. It is by virtue of this ‘rights-based’ principle that very high risks from any societal activity are not tolerated.
  - Individuals are expected to tolerate reasonable risks for societal benefits of activity. This ‘utility-based’ principle is the basis for the expectation that all members of society will tolerate reasonable risks from societal activities that provide benefits to society.
  - Individuals and society should be informed on the risks they are assuming for broader social benefit (an ‘informed consent’ principle).
  - Risks tolerated are:
    - justified by the benefits gained
    - managed relative to risk and cost
    - fairly distributed.

**Considerations**

Organizations may integrate these tolerability principles with the Risk Management Principles they adopted as guidance and commitments for their own risk management decision-making process, as several of these converge in their overall intent. Reviewing the risk–benefit and cost dynamics of the risk under consideration in terms of these principles for risk tolerability and risk management will help decision-makers ensure that the primary ethical concerns and obligations are addressed in making the risk management decision.
<table>
<thead>
<tr>
<th>Risk Tolerability Principle</th>
<th>Convergent Organizational Risk Management Principle</th>
</tr>
</thead>
</table>
| Individuals should be protected from high risks of societal activities | **Beneficence**: do more good than harm  
**Fairness**: risks that are unacceptable to society are not imposed |
| Individuals are expected to tolerate reasonable risks for societal benefits of the activity | **Practicality and Proportionality**: The purpose of risk management is not the complete elimination of risk but the appropriate allocation of resources to minimize risk. The goal is optimal use of society’s limited resources for risk management. A societal perspective is adopted in terms of risk prioritization and allocation of resources. |
| Tolerated risks are justified by the benefits gained | **Beneficence**: Decision-making is focussed on the safety of patients and donors.  
**Vigilance**: risk management decisions include an analysis of the expected benefits of interventions. |
| Tolerated risk are managed relative to risk posed | **Practicality and Proportionality**: allocation of effort and resources to assess and control risk is proportional to the level of risk and the level of risk reduction that can be expected.  
**Continuous Improvement**: periodic review and improvement are applied to all aspects of blood safety management, including risk-reduction strategies.  
**Fairness**: tolerability of risk depends on nature of risk |
| Tolerated risks are fairly distributed | **Fairness**: the distribution of risk is as equitable as possible |
| Individuals and society should be informed on the risks they are assuming for societal benefit | **Transparency**: information on risk issues and decisions is accessible to interested stakeholders and members of the public.  
**Consultation**: stakeholders will be consulted on issues that affect them |

Table 4: Principles for risk tolerability and for blood safety risk management.

**Public tolerance of a risk**

Consider the relevant contextual factors about the risk that may raise concern within the public and reduce the tolerance of the risk, such as factors relating to the source or bearers of the risk, and to any special concerns or sensitivities about the risk. This will ensure that decision-makers are aware of any factors related to the issue that may contribute to public tolerance judgments. Several sources of information may be used in this review, including the results of the contextual assessments, as well as research on related risk contexts and industries.

**Stakeholder tolerance of a risk or risk management options**

An understanding of the concerns about the risk held in relevant stakeholder communities, including specific perceptions of the tolerability of the risk and of different management options, can be gained from a review of outcomes of stakeholder consultations held throughout the decision-making process. In addition, any documentation produced by the group or proceedings or outcomes of meetings of conversations may express relevant concerns and positions.

If there are significant public or stakeholder concerns that are not addressed in the tolerability assessment or risk management approach, it may be advisable to prepare risk communication material.
to explain the risks, and the organization’s rationale for adopting the risk management approach. The risk communication guidelines [in Chapter Ten] can be consulted for the preparation of this material.

In some, likely exceptional, situations in which stakeholders’ concerns may alter the organization’s risk tolerability judgment, further information of stakeholders’ views may be elicited. This may be a situation in which, for example, a stakeholder group is particularly affected by, or interested in, a risk decision, or there are significant ethical implications or trust considerations. The factors included in such a consultation will depend on the risk issue to be decided, the degree of controversy anticipated, and the area of interest and extent of knowledge of the group.

**Process for elicitation of stakeholder attitudes on tolerability of a risk**

If initial screening and concern assessments suggest that stakeholder concern will be high, engagement activities that are undertaken as a regular part of the decision-making process should include discussion of the tolerability of the risk and of risk management options. Only in exceptional circumstances should it be necessary to conduct separate consultations or engagement activities as part of the risk tolerability evaluation. In either case, the following activities can be used to gain an understanding of stakeholders’ views on risk tolerability.

- Use questions answered on a scale, for example the degree of agreement with a statement, or the position of the risk according to certain tolerability factors, to capture tolerability perspectives.
- Information gathered from stakeholder consultations held throughout the decision-making process, including documentation provided by stakeholder groups, or outcomes of meetings or conversations.

**Considerations**

- A sample risk tolerance questionnaire, below, suggests questions that elicit stakeholders’ opinions on each of the contextual public risk concern factors. The sample questionnaire is generic and hypothetical; to be applied, it would be tailored to the risk or decision context under consideration.
- The response scale gives all high, risk-low tolerance opinions, as the low numeric choice, while the higher number choices represent the lower risk – greater tolerance opinions.
- Risk decision-makers can create a questionnaire that elicits opinion on factors that are relevant to the decision at hand, including items that are specific to that issue and not among standard risk perception or concern factors.
Risk tolerability worksheet

<table>
<thead>
<tr>
<th>Contextual Factors</th>
<th>Concern</th>
<th>Question and Rating Scale</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Groups or individuals at risk</td>
<td>Inequitable risk burden</td>
<td>The distribution of risk within the public is fair 1 (very inequitable) -&gt; 7 (very equitable)</td>
<td></td>
</tr>
<tr>
<td>Vulnerable risk bearers</td>
<td>Those at risk are vulnerable members of society 1 (yes, most affected are very vulnerable) -&gt; 7 (no; most of those affected are not particularly vulnerable)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk source</td>
<td>Risk perception</td>
<td>The source of risk is well understood by science: 1 (not at all) -&gt; 7 (well understood)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>There is a risk to patients from this intervention 1 (yes) -&gt; 7 (no)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Snapshot of risk tolerability worksheet (see Toolkit Chapter for complete worksheet)

Step 6: Summarize tolerability evaluation

Purpose
Integrate the results of the previous steps.

Outputs
- The risk tolerability evaluation.

Process
- Summarize the tolerability of the risk in terms of the following factors:
  - assessed level of risk relative to the relevant risk thresholds
  - whether benefits justify the risk
  - whether risks and benefits are distributed fairly and other ethical principles are satisfied
  - whether cost-effectiveness estimates justify the costs of implementing intervention or options for risk management
  - whether further reduction of the risk is justified by risk, benefit and cost-benefit levels (where relevant).
- determine the need for risk communication or further stakeholder involvement on the issue.
Risk communication involves the sharing of information about risks that takes place among experts, stakeholders and the general public. Its primary goal is to raise awareness of the issue, enhance technical understanding of a complex matter, and ensure transparency with stakeholders. Such communication prepares affected individuals to contribute effectively to the decision-making process. Risk communication will likely be highly organization-specific, adapted to the functions of the organization and the stakeholders with which it interacts. Detailed below is the process involved in developing a risk communication program. Further information on the subject of risk communication has also been provided in the Toolkit Chapter.

**Setting overall goals and objectives**

This is a definition of the risk communicator’s intentions for carrying out risk communication on a matter. While there are many specific goals an organization may have for communicating about a risk it manages with a range of audiences, there is an important distinction between persuasive and non-persuasive communications.

Non-persuasive communications aim to enhance understanding of an issue and any relevant tradeoffs, and make no recommendations, so that recipients are informed enough to make their own decision on the matter. This type of communication is used to inform an audience of a decision or a policy where it is inappropriate to attempt to persuade, and particularly when recipients need to make their own decisions based on a sound understanding of the important factors involved, such as in choices of medical treatments.

Persuasive communications make recommendations, in such a way that the recipients feel the recommended option is the best one. The intended outcome of the communication is a specific behaviour, or in some applications changed behaviour. Persuasive communications are used in emergency situations when it is important that the audience understand and comply with protective actions, or in public health communications that encourage healthy behaviours such as giving up smoking or eating a healthy diet. As risk communication is not public relations or advertising, it is important that the recommended option have a valid rationale and be clearly in the best interests of the audience, as is the case in health and safety emergencies.

Goals for the risk communication program should specify:

- the reason the risk communication is needed, such as an emerging risk to blood safety, public notification of a recent risk management decision, or consultation with stakeholders on selected options for managing a risk as part of a risk decision process.
- the persuasive or non-persuasive intent of the communication, such as increased public awareness of a new threat, improved understanding of a risk trade-off or improved public health behaviour in a specific population (such as avoiding activities or locations that increase the risk of infections that can be transmitted by blood).
the basic message that is to be communicated, or options that are to be considered.

The urgency and expected scale of the risk communication program should also be identified. Management agreements for the program should be secured if necessary, including the purpose, main messages and intended outcomes, time frame and necessary budget.

Finally, the evidence base for the message to be conveyed should be summarized so that it can be referenced as a sufficient rationale for a decision or choice made, or policy decided.

Step 1: Audience identification and assessment

Purpose
Identify the audience and ascertain their level of interest and understanding.

Outputs
- A precise list of the intended audience.

Process
This step involves identifying the audience to which the communication will be directed, understanding their need for information on the risk matter and their level of interest and understanding. Because it is difficult for risk managers to know the values, concerns and preferences of many diverse stakeholder and public groups, it is important that the social concern assessments and stakeholder engagement processes gather information on the understanding of the risk and relevant contextual issues so that communications can be designed appropriately. Important questions to answer include the following:

1. What audience(s) need to receive the information, and why (scale)?
   - entire population or regions;
   - patient interest group;
   - sub group of patients affected;
   - some donors; and/or
   - travellers to a certain region; groups who have visited that region.

2. What need do they have for the information?

3. What is the outcome that is valued by the audience, which the communication is meant to help them achieve?

4. If persuasive, why is the audience encouraged to take the recommended action?

5. In non-persuasive, why does the audience need information on or greater understanding of the issue (awareness of and protection from a risk; awareness of a risk management decision that affects their health, or interested in policy developments)?

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6. What is their level of comprehension? This is easier to determine for smaller groups, especially stakeholder groups with a demonstrated interest in the subject.

7. Identification of existing attitudes that might affect risk communications. The social concern assessment(s) should provide information on some or all of the following, as well as other relevant factors:

a. the general level of awareness in society of the issue (extent and tone of media coverage);
b. any particular concerns about the risk – severity of outcome, nature of risk source;
c. important gaps in information or understanding, incomplete understanding of the issue or inaccuracies
   NOTE: use of mental models approach, if time and other resources permit, can help focus information;
d. expectations for its identification and control, and whether these expectations have been met or there is concern that proper control is lacking;
e. existing attitudes towards risk managers, programs or other institutions that were formed on historic events and may shape the reception of the new information; challenges in lack of trust or confidence; and
f. any preferences or priorities for risk management that are evident in media or other expressions of public or stakeholder opinion.

Considerations
- Environmental factors will affect how a particular risk communication program is presented and will affect the reception of the message and the response to it.

Step 2: Methods of communication and channels of distribution

Purpose
Identify the appropriate methods of communication and channels of distribution for the risk message.

Outputs
- List of the different channels that will be utilized for the distribution of the risk message; and
- Detailed list of type of message format.

Process
This will depend on the size of the audience and its diversity; reaching the general public is different, in both message format and distribution channel, from reaching a stakeholder group with which the organization has established connections.

The urgency of the communication is also a factor; emergency communications should be disseminated over major broadcast news organizations and directly through media, while non-urgent
communications should be formatted for distribution through channels that are most likely to reach the intended audience.

a. For important risk information needed to alert the general public of a risk, notices in major media outlets such as television, websites and radio are generally recommended in order to gain the broadest reach with a consistent message.

b. To inform the general (or interested) public of a decision or other routine matter, for transparency purposes, it may be sufficient to post the information on the organization’s web site. Blogs and other social media associated with the organization can also include the information; these can tailor the information further to the particular audience reached through that medium, and link to the primary notice on the website.

c. Reaching a specific group can be done either directly, such as through sending information to a stakeholder group, holding meetings, sending emails to key contacts with links to more complete information; or consulting through larger scale engagement processes. It can also be done indirectly, by sending notices to health care offices at which the intended audience may attend, or community centres, or travel agents. Physicians can be reached through notices in professional journals or networks.

d. Determine the most appropriate format, or mix of formats:
   - text, such as notices in print media or on websites;
   - video – television, posted on website or blogs;
   - audio – radio, posted on websites, blogs; and
   - interactive, such as small programs on computers that the audience can link to from a website and that can show risk levels, regions of concern, etc.

At the end of the needs assessment, it should be possible to describe the proposed risk communication program in terms of the following details:
   - the risk information that needs to be communicated
   - the audience(s) to which it needs to be communicated
     - their need for the information;
     - the desired and expected effect of the provision of information to the audience;
     - the level of information and understanding of the issue;
     - the channels and methods that are most appropriate for these audiences;
     - any existing challenges in message reception, such as comprehension, trust in risk managers, opposition to risk management measures; and
     - type of message format that is most appropriate.

Considerations
   - urgency of risk communication will determine type of distribution.
Step 3: Message preparation and delivery

**Purpose**

Prepare a clear and concise message regarding the risk.

**Outputs**

- risk information message.

**Process**

From risk communication design, information is prepared to address the key elements: the information that is to be conveyed; the audience(s) to whom it is to be conveyed, and their current beliefs on and understanding of the issue; the format and style in which the information is presented in order to provide the necessary information in the form that is most likely to be attended to and understood.

**Develop message content**

Determine the information that is important to convey: this will include both key facts about the risk and any other information that is necessary for understanding and perspective, based on information gathered on the audience(s) to be addressed. While drafting the information it is important to keep in mind three main considerations that will influence the information that is presented to the audience:

- What knowledge and information about the risk itself does the audience already have? What background knowledge needs to be supplied so the key risk information can be understood?
- How will the audience use the information? What recipient decision needs to be supported? Information meant to persuade people to take protective actions will be different, and presented differently, from information that is meant to enhance independent decision-making.
- What special concerns about the risk, pre-existing beliefs or attitudes about background situations, institutions or past decisions may affect the reception of the information and the key messages?

The information presented, and the way it is prepared, will be specific to the purpose of the communication and the audience. One major application of risk communication, and one that may be particularly important to do well, is communication of blood safety risks and risk management options. The following is a list of general considerations for drafting the content of risk communication meant to inform an audience of a threat to blood safety; specific information and advice will of course be determined for each case.

**What is the risk?**

- What is the hazard; what is the outcome of concern?
- Where does it come from?
- How does it affect blood?
- How does one become exposed?
- What is the link between exposure and outcome (does everyone exposed get the disease?); time periods of exposure, infection, symptoms, infectiousness, etc.
Who is at risk (how to know if you are at risk)?

- Any specific populations exposed
- Any specific groups more vulnerable/susceptible
- Any specific locations, activities that increase likelihood of exposure
- Who is NOT at risk, if this is clear and relevant

What people should do?

- If they are at risk, or care for someone at risk
- Further information on protective actions, if needed
  - Diagnostic tests needed/not needed
- Signs that direct assistance should be sought; when to go for help

Risk management

- What is being done
  - What you are doing that protects from threat, supports recommended actions
- If there is a level of reduction of risk, explain level and rationale

Where people can get more information or support

- General information
- Medical information or advice

**Message preparation and information format**

Once the key messages and supporting information that are to be included in the risk communication have been determined, it should be prepared, formatted and delivered in a way that will reach the intended audience, catch their attention and consideration, and help them understand the information so that it can achieve the goal of the communication program.

There are many factors that should be considered in this, from general communications practice to recommended approaches to communicating technical and quantitative information. The following are the most common and important guidelines for preparing information material.

**Message Factors**

- Simplify the information, while ensuring accuracy and completeness:
  - Start with essential information; include key points in headings to aid memory;
  - Be clear on essential information that directly addresses key messages and objectives;
  - If the goal is persuasion, be clear on recommended actions, their rationale and any necessary practical guidance;
  - Add specifics or more complex information later in the document, if it is necessary for the understanding of the intended audience; and
Avoid including supplementary information that may be confusing or not relevant.

- Directly address known concerns, misunderstandings, or important expectations for risk management:
  - Anticipate ‘risk perception’ response to certain risks and address these concerns (e.g. lack of control, involuntary, inequitably distributed); mention the way these are addressed in risk management.
  - Address known misunderstandings and knowledge gaps, explaining why they are inaccurate, especially if accurate information is counter-intuitive or very different from widespread assumptions.

- Framing: the context in which an issue is defined and presented will affect recipients’ response
  - Message recipients may already have a frame for understanding the issue, such as an overall risk or benefit perspective. If a goal is to balance or reverse an existing frame this will need to be addressed explicitly, and the factor that has been downplayed described. It is important to acknowledge and not discount the existing frame.
  - Care should be taken in the framing of an issue, particularly one that is to support a decision on risks and benefits. Both the risks and the benefits of an intervention should be described in order to provide a balanced perspective.

- Note/describe the evidence base to validate, give confidence, and make people feel they’re responding to evidence not just doing what they’re told.
- Monitor responses to the message to learn of & correct inaccuracies and misunderstandings.

**Expressing technical risk information**

- Avoid technical jargon.
- Avoid ambiguity and inconsistency.
  - If there are messages in more than one format or on several channels, ensure that they are consistent.
- When using risk terminology use the most common terms, defining them if necessary, and be consistent in their use.
- Distinguish hazard from exposure
  - Clearly identify hazard, source of risk
  - Clearly identify exposure to hazard, scenarios and types of exposure
  - Clarify severity of consequence from likelihood of occurrence
  - Clarify risk measure: is probability of occurrence frequency in population, or some measure of individual risk
  - Clarify which exposures are of concern
  - Relative vs. absolute risk: risk reduction seems larger expressed as relative risk; ensure that the most appropriate measure is used for the context
- Use numbers only when necessary to convey the critical information.
  - Quantitative information is often used in clinical settings to help patients understand and decide on treatment options, and is less essential to understanding of health policy decisions.
(see Fischhoff et al., 2011 for guidance on communicating technical and quantitative information).

− If it is important to express a level of risk, use broad qualitative categories. Report numerical risks if they are known and part of risk assessment/management, but explain with verbal explanation to help comprehension and context.
− Address uncertainty only when it is a relevant factor, and do not use quantitative uncertainty measures.
− If probability or frequency is a key factor, try using graphic representations of proportions rather than quantitative measures; use basic fractions, charts, etc.

Step 4: Implement the risk communication program

Purpose
Develop an effective risk communication program

Outputs
- risk communication plan; and
- monitoring plan.

Process
There are three stages to implementing a risk communication program. Before the risk communication program is implemented, the message content and its delivery with a representative group should be tested. After the risk communication program has been implemented, the communication must be monitored for its reception.

Risk communication program testing
It is important to test the suitability of the risk communication message content, format and preparation, and distribution channels before the material is distributed to the full audience. The test group should be representative of the intended audience in terms of relationship to the risk (at risk from a blood safety threat, a potential donor group), familiarity with the issue and level of comprehension of technical material; depending on the scale of the program, the test groups could include co-workers in non-technical areas, friends or family members; or representative members of stakeholder groups with whom the organization has developed a positive relationship.

The test group should review the material and revise the content, format and channels as needed. Testers should be asked to report on:

- their understanding of the health risk message (verified for accuracy, as appropriate) or policy decision;
- their interest in reading or attending to the entire message (to test for interest, appropriate level of detail and amount of information);
Their response to the risk management measures proposed, if relevant, in terms of their apparent effectiveness and practicality;
Their intention to carry out any risk management or other actions recommended, and reasons why not, if relevant;
Their response to the tone, reflecting the concern and competence of the communicating and risk management agencies; and
any other challenges in understanding and receiving the information.

Monitor, evaluate, adjust and correct
Once the risk communication program has been implemented, it is important to monitor the receipt of, and response to, the information among the audience that was to be reached. This can be done through established media monitoring processes, contacting key informants in relevant communities, or monitoring access to websites and blogs, as well as comments left on them. The following aspects should be monitored:

■ Have the channels of message distribution reached the intended audience(s)?
■ What is the level of awareness of the message and its content?
■ Are there misconceptions, inaccuracies or misinterpretations in the material evident in the response?
■ Serious inaccuracies should be corrected, in serious or emergency situations promptly, through issuing of statements clarifying the information. In other cases it may be sufficient to address the inaccuracy in the next release of information.

Considerations
■ It is important to be aware of and consider any existing societal concern or other contextual factors in developing a risk communication plan.
■ It is imperative that decision-makers are presented with complete and accurate information about the risk to enable the decision-making process. A risk communication plan will take into account, the technical background of the decision-makers so that the key elements that are needed to make a decision are made clear.
Glossary

Acceptable risk: a risk that is generally agreed to be low enough that no management is required.

ALARA: As Low as Reasonably Achievable (social and economic factors taken into account); in the UK the phrase used is As Low as Reasonably Practicable (ALARP). The basic concept illustrates the progression of risk levels from very low risks, which are acceptable without management, to high risks that are intolerable except in extraordinary circumstances. In the middle region are risk levels that should be reduced to be as low as is economically feasible (even if lower than a regulated standard), and reduced further as new technologies and improving economics permit.

Levels of risk can be elaborated to serve as an operational guide, showing pre-determined risk thresholds and levels, such as an acceptable risk threshold, below which no risk management is required, and an upper threshold of risk to which no one should be exposed. In between are risk levels that are tolerable with specified benefits gained and risk management measures applied.

Blood safety: Blood safety encompasses product safety, sufficiency of supply, patient safety and donor safety. It includes the safety of blood and blood products as experienced by recipients. Blood safety also includes the safety of blood-donation processes and the adequacy of the supply of blood products.

Decision driver: A factor of primary concern in an issue that defines the type of decision to be made, and orients the risk-based decision-making process towards certain types of assessments and decision-support and risk management activities. A decision driver may also highlight the significance, urgency or level of social concern inherent in the issue, such as may be present in a hazard-driven decision but not in a priority-setting exercise.

Hazard: A source of harm. The inherent potential of a substance, activity, condition or situation to cause harm.

Health economic and outcomes assessment: A systematic analysis to inform decision-makers regarding the cost implications and the cost-effectiveness of introducing a blood safety measure, and to optimize the use of limited health care resources.

Risk: The impact of exposure to a hazard, combining the probability or frequency of occurrence of possible outcomes of exposure 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 their occurrence. Risk assessments follow the methodology established by the discipline in which the assessment is conducted, although a core set of steps and quality expectations have been developed that apply to most processes.

Risk bearers: The person, group or other entity that experiences the adverse outcomes associated with exposure to a hazard. A risk bearer may be a blood recipient or donor, in the context of a blood safety
matter, or it may be the health system or society in general for a matter of resource allocation or public health outcomes. In many cases, there will be more than one risk bearer, or bearers of different types of risk involved in an issue.

**Risk-benefit dynamic:** The relation of the risks borne—from exposure to a hazard or as a result of an intervention—to the benefits gained, with consideration of those who bear the risks and those who gain the benefits. In some cases, the risk bearer and the beneficiary are the same person. In other cases they may be quite different. Risks and benefits may also be different in kind, such as risks to individual blood recipients, risks to the availability of blood products and risks to the health care system in general.

**Risk communication:** An exchange of information about risk among interested parties, including experts, stakeholders and members of the general public. A primary goal of risk communication is to prepare and disseminate risk information in a manner that maximizes the comprehension of the audience and supports decision making. Risk communication is designed with an awareness of the concerns of the target audience about the risk and the information that is relevant to them. Although the process is not as interactive as stakeholder engagement, risk communicators are attentive and responsive to feedback on the effectiveness of the information flow and to shifting or evolving understanding of the issue.

**Risk control:** The measures put in place to manage a risk to a level that has been identified as tolerable.

**Risk issue:** A matter related to a risk that is, or has the potential to become, highly salient among the public or specific stakeholders. A risk issue may emerge from factors that are inherent in the larger risk situation, such as the involvement of a vulnerable population. It may also emerge from contextual factors such as ethical concerns with the characterization of a risk source, costs or inequities in proposed risk management measures, or concerns with past management or regulatory practices. Media attention may drive or escalate social concern in risk issues.

**Risk management:** A systematic approach to setting the best course of action under uncertainty by identifying, assessing, understanding, acting on and communicating risk. Risk management is the broader policy-setting and decision-making function that is related to, but functionally separate from, risk assessment. Risk management and risk assessment functions must interact at several points in decision processes, particularly at the problem formulation stage when the scope, level of detail and urgency of an assessment are determined to ensure that the assessment provides the information needed for the risk management decision.

**Risk policy:** General policy positions of the organization that express the values and priorities of the organization, and apply to all aspects of the organization including risk assessment and risk management. As outlined in this Framework, the broader risk policy elements are a set of broad risk management principles, a position on the role and importance of risk communication and stakeholder engagement, risk tolerability guidelines, and expectations for the conduct of risk assessments.
**Risk source:** An agent, activity, substance or process that has the potential to cause harm. The risk source incorporates the hazard with types of exposure to it and means by which it causes harm. It does not include the consequences of exposure or the probability that they will occur. A risk source may be the overall focus of risk assessment.

**Risk tolerability:** The determination that a level of risk is provisionally acceptable in view of the benefits gained by the activity (source of the risk) and the application of appropriate measures to reduce the risk from higher levels.

**Risk tolerability threshold:** A point (usually quantitative) that signals a predetermined risk management response. Several risk tolerability thresholds can be established. A lower risk threshold is a level that is low enough that no risk management is required. An upper risk threshold may designate the level of health risk at which an intervention is required, or the level of risk that may be permitted from an activity.

**Social concern:** The level of interest among members of the public or a particular social group or sector in an issue or an event, or the inherent sensitivity of an issue due to the potential for harm, the nature of a risk or the population affected. The amount and tone of media interest and coverage often drives social concern and reflects its presence within the public.

**Societal perspective:** Consideration is given to all risks, benefits and costs incurred by all of society, rather than only those that are borne by the blood system or the health-care system. In practical terms, this means that the risks and benefits of blood safety decisions consider health impacts on blood donors, blood recipients and society more generally. Risks, costs and benefits to the blood operator or hospital, health care system and consumers are also considered.

**Stakeholder:** Any individual or group that is affected by, or has an interest in, the blood risk issue being considered.

**Stakeholder involvement:** Interactions with stakeholders to share information about an issue and approaches to its management. Involvement may consist primarily of consultation or it may be a fuller process in which stakeholders are invited and engaged to contribute to the decision that is made.

**Variability:** Diversity or heterogeneity within the population of concern or being assessed that is related to a range of factors such as individual characteristics or behaviours, and social, economic or geographic circumstances. Variability is an inherent property of the system or population. Although it may be better understood through research or data gathering, it cannot be reduced.

**Uncertainty:** A lack of knowledge or precision in measurements of properties of a system that result in an inability to estimate the level of risk precisely. The knowledge gap may lie in incomplete data, such as information on a population or its behaviour; in a fundamental scientific uncertainty, such as the mechanism of transmission of an emerging disease; or the inherent difficulty in predicting frequencies or probabilities of events or outcomes in complex situations. Some types of uncertainty may be reduced through data gathering or further research.
**Issue characterization checklist**

To complete this checklist:

1. Select the applicable response to indicate the presence of each factor in the issue.
2. Enter the information requested.
3. Record the assessments that will be required in order to provide the information and analysis necessary to make the decision.

**NOTE:** the completed checklist will be used to complete subsequent tasks in the issue identification and problem formulation step, and will serve as a basic issue-profile document)

**SECTION 1 - RISK**

1. **Does the issue involve a threat to the safety or quality of the blood supply?**

   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________

   **What is the threat?**

   **Who is at risk from this threat (blood recipients, donors, other stakeholders)?**

   **Describe estimated severity, probability of infection and severity of consequences.**

   *(If information not readily available, complete the screening level risk assessment (Step 2, Assessments) and return to complete this question)*

   **List potential management options, including donor deferral.**

   **List assessments needed for evaluation of threat.**

2. **Does the issue involve a threat to the availability of blood and blood products?**

   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
3. Does this issue have the potential for a significant impact on donors?

____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________

SECTION TWO - INTERVENTIONS

4. What is the intervention?

____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________

5. What benefit is intended from the intervention?

a) Reduced risk *(from threat to blood supply/other)*

Identify the aspect of blood supply that is threatened.

Who could be at risk from a lack of availability of these blood products?

*(certain blood recipients, general public, emergency/accident)*

Describe risk management options.

List assessments required.

Risk

What impact?

Which donors?

Tolerability of risk estimated?

Assessments required?
b) cost saving or resource reallocation

What group is expected to benefit (*blood recipients, donors, society in general, blood service*)?

6. Does this issue involve the implementation of a new test?

For what purpose is a test to be implemented?

List sensitivities or specifications

What tests could be implemented?

What assessments are needed?

7. Does this issue involve the implementation of a new technology?

Describe the intention in implementing the new technology and list expected outcomes.

List which technology options have been considered.

What assessments are required?

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

What is the rationale for withdrawing the procedure or test? What outcomes are expected?

What assessments are required?

List other related options or alternatives.

9. Does the intervention considered have significant financial implications?

What is the cost of the intervention? (*financial, other resource or burden on part of blood service*)

Refer to screening assessment - Step 2
10. Is there conflict among potential risk interventions?

Which interventions?

a. What risks?

b. What populations are affected?

What assessments are required?

11. Does the decision to be made involve prioritization of issues for attention?

What is the purpose of the prioritization exercise?

What assessments are required?

SECTION THREE – SOCIAL AND ETHICAL CONCERN

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

Describe the nature of coverage and aspects of the issue focused on by the media or through other forums.

List required assessments and risk communications requirements.

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

Describe the potential impacts of concern and contextual associations.

List other options (*communications, stakeholder involvement*).

14. Does the risk affect a particular recipient group more than others? Identify the group and its relevant factors
15. Is there disproportion or inequity in the distribution of risks and benefits?

Which groups get risks and which get benefits?

How significant is the discrepancy?

Do the benefits justify asking a particular group or entity to accept risks?

Identify those groups receiving benefits and the type of benefit received.

16. Is a particular donor group affected more than others?

Is donor deferral considered as an option for managing the issue? List specific options considered and identify groups affected.

What assessments are required?

17. Do you have challenging, problematic relationships with key stakeholder(s)? What group? Describe all relationship challenges and previous associations on particular issues.

18. Do you have positive, supportive relationships with key stakeholder(s)? (Note: You could leverage the bad with the good)

19. Are there potential legal, political, regulatory or jurisdictional considerations associated with the issue?
Describe potential legal (e.g. liability) or jurisdictional (e.g. policy or actions on issue in other jurisdictions) issues.

What assessments are required?

SECTION FOUR – RISK MANAGEMENT PRINCIPLES

20. Which risk management principles predominantly apply to this matter?

Beneficence ______ Practicality & Proportionality ______
Fairness ______ Vigilance ______
Transparency ______ Continuous Improvement ______
Consultation ______
# Types of Decisions and Decision Drivers

<table>
<thead>
<tr>
<th>Decision Driver</th>
<th>Attributes and Examples</th>
</tr>
</thead>
</table>
| **Threat**      | - An identified or emerging risk to blood quality that affects blood recipients  
                  - A threat to donor safety  
                  - A threat to the blood supply, through a demand surge or a reduction of supply or withdrawal of products  
                  - May involve high levels of uncertainty  
                  - Likely to require risk assessment, economics assessments and technology evaluations  
                  - May require options analysis, comparative assessments, trade-off of risks, benefits and costs |
| **Intervention**| - *New intervention*  
                  - Consideration of effectiveness, cost and residual risks of a new intervention, (such as a new test or procedure) in some cases in the context of comparing several interventions  
                  - May require consideration of regulatory approvals and time required, and risk of associated delay in implementation  
                  - *Withdrawal of intervention*  
                  - Consideration of withdrawing use of a current intervention (such as a test, procedure or protocol) in light of an alternative intervention (such as one new test replacing several existing tests) |
| **Priority setting** | - Prioritization for risk assessments, interventions, policies |
| **Social concern** | - Consideration of intervention with a major ethical component or particular social sensitivity |
| **Ethics**       | - Legal or jurisdictional issues may be relevant |
| **Law/regulation**| - May include stakeholder consultation or similar processes to gain understanding of perceptions and preferred intervention options |
Assessment question and decision requirements

To answer this question:

1. Clearly state the primary decision to be made so that it provides guidance on:
   - Areas where the assessments must focus to support a decision
   - Types of assessments required
   - Level of investigation required

2. Be specific about what information is needed from each assessment.

3. Be specific about expectations from the assessments, e.g. level of benefit, risk reduction, cost.
To complete the table:

1. From the results of the issue characterization checklist, generate the risk management options and enter them below.
2. Using the results of the Initial Screening Assessment, note the required assessments.

**NOTE:** For the Social Concern section, an assessment may be recommended if sufficient concern has been identified under one or more heading.

<table>
<thead>
<tr>
<th>RISK MANAGEMENT OPTIONS</th>
<th>Status Quo</th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
<th>Option 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASSESSMENTS</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Blood safety risk</td>
<td></td>
<td></td>
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<tr>
<td>Health economics and outcomes</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Social Concerns/Risk Perception</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Equity concerns</td>
<td></td>
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<tr>
<td>Trust Concerns</td>
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<tr>
<td>Legal or jurisdictional</td>
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<tr>
<td>Operational risk</td>
<td></td>
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<tr>
<td>Regulatory</td>
<td></td>
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<tr>
<td>Political</td>
<td></td>
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<tr>
<td>Expertise required</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Effort estimate</td>
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<td>------------------------</td>
<td>------------------------</td>
<td>------------------------</td>
<td>------------------------</td>
<td></td>
</tr>
<tr>
<td>Links between assessments</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decision support team</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
**Risk management options – initial screening assessment**

To complete the table:

1) Use the results of the work completed in Step 1, to determine the main categories of risk associated with the issue at hand, e.g. patient risk, legal risk, reputational risk, etc.
2) Provide a short description why these are considered important risks for each risk management option.
3) Use the risk rating scale to estimate the level of risk for each category against each risk management option.

**NOTE**: Risk Tolerability is unique to each organization and should be determined by the blood operator as part of their risk management policy.

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Risk Management Option</th>
<th>Risk Category</th>
<th>Risk Category</th>
<th>Risk Category</th>
<th>Risk Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status Quo</td>
<td>Maintain Status Quo</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Status Quo: Risk Rating**

<table>
<thead>
<tr>
<th>Option A</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>

**Option A: Risk Rating**

<table>
<thead>
<tr>
<th>Option B</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>

**Option B: Risk Rating**

<table>
<thead>
<tr>
<th>Option C</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>

**Option C: Risk Rating**

**LEGEND**

<table>
<thead>
<tr>
<th>Level of Risk</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>None to Minimal</td>
<td>1</td>
</tr>
<tr>
<td>Between Minimal and Medium</td>
<td>2</td>
</tr>
<tr>
<td>Medium</td>
<td>3</td>
</tr>
<tr>
<td>Between Medium and High</td>
<td>4</td>
</tr>
<tr>
<td>High</td>
<td>5</td>
</tr>
</tbody>
</table>
Sample Spiderplot

<table>
<thead>
<tr>
<th>Status Quo</th>
<th>Option A</th>
<th>Option B</th>
<th>Option C</th>
<th>Option D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score (1-5)</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

- **Patient Risk**
- **Social Concern**
- **Operational Risk**
- **Cost**

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### Example risk matrix

**RECIPIENTS RISKS**

<table>
<thead>
<tr>
<th>FREQUENCY</th>
<th>Very Low</th>
<th>Less than 1:5,000,000</th>
<th>Low</th>
<th>1:1,000,000 to 1:5,000,000</th>
<th>Moderate</th>
<th>1:250,000 to 1:1,000,000</th>
<th>High</th>
<th>1:1 to 1:250,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEVERITY</td>
<td>Low</td>
<td>Acceptable</td>
<td>Acceptable</td>
<td>Tolerable</td>
<td>Tolerable</td>
<td>Intolerable</td>
<td>Intolerable</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>Acceptable</td>
<td>Tolerable</td>
<td>Tolerable</td>
<td>Intolerable</td>
<td>Intolerable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>Tolerable</td>
<td>Tolerable</td>
<td>Intolerable</td>
<td>Intolerable</td>
<td>Intolerable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Catastrophic</td>
<td>Intolerable</td>
<td>Intolerable</td>
<td>Intolerable</td>
<td>Intolerable</td>
<td>Intolerable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**DONORS RISKS**

<table>
<thead>
<tr>
<th>FREQUENCY</th>
<th>Very Low</th>
<th>Less than 1:5,000,000</th>
<th>Low</th>
<th>1:1,000,000 to 1:5,000,000</th>
<th>Moderate</th>
<th>1:250,000 to 1:1,000,000</th>
<th>High</th>
<th>1:1 to 1:250,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEVERITY</td>
<td>Low</td>
<td>Acceptable</td>
<td>Tolerable</td>
<td>Tolerable</td>
<td>Tolerable</td>
<td>Intolerable</td>
<td>Intolerable</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>Tolerable</td>
<td>Tolerable</td>
<td>Intolerable</td>
<td>Intolerable</td>
<td>Intolerable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>Intolerable</td>
<td>Intolerable</td>
<td>Intolerable</td>
<td>Intolerable</td>
<td>Intolerable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Catastrophic</td>
<td>Intolerable</td>
<td>Intolerable</td>
<td>Intolerable</td>
<td>Intolerable</td>
<td>Intolerable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
European Up-Front Risk Assessment Tool (EUFRAT)

This online tool can be used to generate quantitative transmission risk estimates of emerging infectious diseases. It guides the user through five steps to estimate the infection risk in blood transfusion: 1) the prevalence of infection in the donor population, 2) the risk of obtaining infected donations, 3) infected components, 4) infected blood products, and 5) the risk of transmitting the infection to recipients. The tool can be found at http://eufrattool.ecdc.europa.eu/.
<table>
<thead>
<tr>
<th><strong>RISK STATEMENT:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>VULNERABILITY:</strong></td>
</tr>
<tr>
<td><strong>SCENARIO:</strong></td>
</tr>
<tr>
<td><strong>CURRENT MITIGATION:</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>CURRENT RISK MAGNITUDE</strong></td>
</tr>
<tr>
<td><strong>LIKELIHOOD:</strong></td>
</tr>
<tr>
<td><strong>IMPACT:</strong></td>
</tr>
<tr>
<td><strong>BUSINESS IMPACT AREA:</strong></td>
</tr>
<tr>
<td><strong>RISK MAGNITUDE:</strong></td>
</tr>
<tr>
<td><strong>ADDITIONAL MITIGATION:</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>RESIDUAL RISK MAGNITUDE</strong></td>
</tr>
<tr>
<td><strong>LIKELIHOOD:</strong></td>
</tr>
<tr>
<td><strong>IMPACT:</strong></td>
</tr>
<tr>
<td><strong>BUSINESS IMPACT AREA:</strong></td>
</tr>
<tr>
<td><strong>RISK MAGNITUDE:</strong></td>
</tr>
<tr>
<td><strong>KEY RISK INDICATORS:</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>RISK OWNER</strong></td>
</tr>
</tbody>
</table>
**Risk Communication**

**Identification of options for risk communication**

Provide a description of the recommended communication tools that will be followed for each of the following:

<table>
<thead>
<tr>
<th>OPTIONS FOR RISK COMMUNICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk issue management</td>
</tr>
<tr>
<td>-------------------------</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

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Complete one per risk management option.

<table>
<thead>
<tr>
<th>Contextual Factors</th>
<th>Concern</th>
<th>Question and Rating Scale</th>
<th>Score</th>
</tr>
</thead>
</table>
| Groups or individuals at risk | Inequitable risk burden | The distribution of risk within the public is fair  
1 (very inequitable) -> 7 (very equitable) |       |
| Vulnerable risk bearers | | Those at risk are vulnerable members of society  
1 (yes, most affected are very vulnerable) -> 7 (no; most of those affected are not particularly vulnerable) |       |
| Risk source | Risk perception | The source of risk is well understood by science:  
1 (not at all) -> 7 (well understood) |       |
| | | There is a risk to patients from this intervention  
1 (yes) -> 7 (no) |       |
| | | The consequences of this risk are:  
1 (very severe) -> 7 (mild) |       |
| | | The risk is caused by an action/ failure to act by the risk manager  
1 (yes caused by organization) -> 7 (no not caused by organization) |       |
| | | There are social concerns associated with the use of this intervention  
1 (serious concerns) -> 7 (no concerns) |       |
| Risk management measures | Risk-benefit balance | The outcome of this intervention has proven to be effective  
1 (not all) -> 7 (very effective) |       |
| | | The intervention will protect the public:  
1 (not at all) -> 7 (will protect everyone) |       |
| | | The risk of the intervention is justified by its benefits  
1 (not at all) -> 7 (completely justified) |       |
| | | Those benefitting from the intervention bear the risks  
1 (not at all) -> 7 (beneficiaries bear all of the risk) |       |
<table>
<thead>
<tr>
<th>Risk management organization</th>
<th>Appropriateness of management option and its rationale</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Those bearing the risks from the intervention receive its benefits</td>
<td>The level of risk to health posed by the intervention, in light of the benefits gained through its use</td>
<td>*low number = high risk</td>
</tr>
<tr>
<td>1 (not at all) -&gt; 7 (all risk bearers gain benefits)</td>
<td>1 (unacceptably high) -&gt; 7 (completely acceptable)</td>
<td></td>
</tr>
<tr>
<td>The priority that should be given to the management of this risk</td>
<td>Members of the public should pay more in taxes to enable the adoption of this intervention</td>
<td></td>
</tr>
<tr>
<td>1 (very low) -&gt; 7 (top priority, urgent)</td>
<td>1 (no/none at all) -&gt; 7 (yes, substantial)</td>
<td></td>
</tr>
<tr>
<td>The organization has taken all the necessary steps to identify and manage this risk</td>
<td>The organization has provided information on the risk and on the options being considered for its management</td>
<td></td>
</tr>
<tr>
<td>1 (not at all) -&gt; 7 (yes, all expected actions have been taken)</td>
<td>1 (not at all) -&gt; 7 (complete, timely and adequate information)</td>
<td></td>
</tr>
<tr>
<td>The organization that is deciding on the management of this risk and will implement the risk management is competent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (not at all) -&gt; 7 (very competent)</td>
<td></td>
<td></td>
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</tbody>
</table>

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Advantages and disadvantages of options

<table>
<thead>
<tr>
<th>RISK OPTION:</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>
Use this template to first rate the options according to efficacy, cost, and residual concerns associated with each option. Then, rank them from best to worst.

### OPTIONS RATING SCALE

<table>
<thead>
<tr>
<th>Risk management options</th>
<th>Residual Safety Risk</th>
<th>Infrastructure and costs required</th>
<th>Expected residual concerns (ethics, trust, stakeholder tolerability)</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H</td>
<td>M</td>
<td>L</td>
<td>H</td>
</tr>
<tr>
<td>Option 1</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Option 2</td>
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</tr>
<tr>
<td>Option 3</td>
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<tr>
<td>TOTAL</td>
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</tbody>
</table>
CHAPTER TWELVE – BIBLIOGRAPHY

Health Economic Evaluation Methods (Step #2)


Conduct Analysis (Step #3)


Assess Uncertainty and Sensitivity (Step #4)


Present and interpret results (Step #5)


Critique Results (Step #6)

Kacker, S., K.D. Frick, and A.A. Tobian, Data and interpretation: economic evaluations in transfusion medicine, Part 4. Transfusion, 2013
Incorporate Results (Step #7)


Risk Communication


EFSA 2012. When food is cooking up a storm: proven recipes for risk communications. Risk Communications Guidelines.


Available at: http://www.fda.gov/ScienceResearch/SpecialTopics/RiskCommunication/ default.htm


Risk Tolerability


