RISK-BASED DECISION-MAKING FRAMEWORK FOR BLOOD SAFETY
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1 INTRODUCTION

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 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 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 engagement and consultation, risk communication and evaluation of risk tolerability.

Figure 1: Risk-Based Decision-Making Framework for blood safety
The Framework consists of risk management policy foundations and a risk-based decision-making process.

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 to its own operational context and regulatory structure.

The Framework outlines the risk management policy foundations (Section II) required for effective decision making and a risk-based decision-making process (Section III) designed for the management of blood safety.
The Framework is illustrated in Figure 1. A Glossary which defines significant terms (signified in green) used in the Framework appears at Appendix A. Templates and decision support tools are found in Appendix B. Guidance documents on risk communication, stakeholder engagement, health risk assessments, health economics and outcomes assessments, and contextual assessments are included as Appendices C, D, E, F, and G. Finally, a case study applying each of the steps is found at Appendix H.

The Framework is illustrated in Figure 1.

2 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, and inform the process of risk-based decision making. They must be put in place by the organization before the risk-based decision-making process is undertaken, and be made available to stakeholders and the public in support of transparency. 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 in the section below.

A RISK MANAGEMENT PRINCIPLES

The first element of a risk management policy is a set of principles, as 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 Beneﬁciency

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, or which are subject of significant social concern. Stakeholder engagement processes help 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 Practicality 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 applying 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.

B RISK COMMUNICATION AND STAKEHOLDER ENGAGEMENT

A risk management policy describes expectations for risk communication and stakeholder engagement to inform the risk-based decision-making process. (See Appendices C and D.) 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.

As risk issues evolve, a risk communication strategy will support risk management efforts, especially where there is significant public concern. A risk communication strategy is an important tool for informing stakeholders of the issue, creating an environment of transparency and expressing the intention to engage them in the decision-making process. Stakeholder engagement processes should be used to 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.

1 Risk communication

Risk communication involves the sharing of information about risks that take 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 through stakeholder engagement. Technical information should be presented in a manner that takes into account stakeholders’ information needs and their perceptions, concerns and values. Risk communication can include one-way, two-way and multi-stakeholder communication processes.

2 Stakeholder engagement

Stakeholders are engaged in risk-based decision making as part of the organization’s commitment to transparency and accountability. Engagement improves the quality of decisions by informing decision-makers of stakeholder perspectives, concerns and ideas, and offers stakeholders the opportunity to provide input into decisions. 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.
C EXPECTATIONS FOR CONDUCT OF ASSESSMENTS

A risk management policy should also address specific expectations for the conduct of assessments, including medical and scientific 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.

1 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.

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

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

c 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.

d 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.

e 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.

f 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.

g 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 engagement processes.

2 EXPECTATIONS FOR HEALTH RISK ASSESSMENTS

Health risk assessments focused on blood safety are conducted to provide information on the nature and magnitude of a risk, and the value of potential risk management options. There are a number of general and procedural expectations that health risk assessments should meet, including the use of a formal assessment process as well as certain technical and scientific analytic procedures. The first step in a risk assessment is problem formulation, in which risk managers and risk assessors establish the objectives and scope of the risk assessment required to provide the information needed for a decision. The units of risk measurement that will be used in the assessment are determined based on the information that is to be provided.

The risk assessment then proceeds through a set of standard steps that are conducted according to the relevant discipline. The steps include hazard identification and causal analysis, which can be conducted through hemovigilance and surveillance; exposure assessment, which may include an identification of risk sources and pathways; and an estimate of the probability and extent of exposure to risk bearers such as patients and donors. The assessment integrates all of these factors and characterizes uncertainty in any of the components or results of the risk assessment.

If the risk management decision involves the selection of a risk management option, the risk assessment should assess the degree of risk reduction that is achieved by each of the options under consideration, and identify any risk trade-offs entailed in any of the management options. 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 be evaluated.

More detailed guidance on the conduct of blood safety risk assessments is provided in the guidelines on risk assessment, found in Appendix E.
3 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 within 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 output 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.

Detailed guidance on how to conduct health economics and outcomes assessments, including the production and analysis of data within different types of assessments, is found in Appendix F.

D RISK TOLERABILITY

As part of a risk management policy, risk tolerability guidelines should be developed in consultation with stakeholders and in a manner that is consistent with the risk management principles described above. Risk tolerability is based on the following key concepts, which operate in tension with one another.

- Individuals are expected to tolerate reasonable risks for societal benefits of activity. This concept is utility-based: the optimal decision should maximize the total expected net benefit to society.
- At the same time, each individual has a legitimate expectation of protection from high risks of societal activity. All members of society have an equal right to life and security, and no individual or group can be put at undue risk to benefit others.
- Individuals and society should be provided with information on the risks to which they are exposed, for their own and for broader societal benefit. This is a contract-based premise in which individuals accept a risk to which they have consented. It is impractical to acquire explicit consent from all who may be affected by a societal risk, but the provision of information and opportunities for consultation is considered to qualify as the basis of consent to such societal risks.

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 for which no management is needed. The Framework provides a tool with which to evaluate the tolerability of a risk, taking into account various contextual factors.

For example, a number of factors related to the source of the risk and the risk bearer affect risk tolerability. 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.

The general approach to incorporating risk tolerability into risk management is the ALARA (as low as reasonably achievable) concept, which takes into account scientific, social and economic factors. It is a precautionary approach that attempts to achieve the lowest possible risk level with attention to practicality and costs.

The ALARA approach is premised on two fundamental assumptions. First, the societal requirement for readily available and affordable blood products is the basis for society’s tolerance of risk to individuals. Second, there is continual improvement as management methods, technologies and costs change.

This approach describes a continuum of risks and divides them into acceptable, tolerable and unacceptable risk regions, as represented in Figure 2 below. For some types of risks, quantitative thresholds may be established for each of these risk regions. There is first a broadly acceptable region of very low risks, in which individuals are expected to accept risks and in which no risk management is required and the status quo is deemed acceptable. At the opposite end of the continuum, there is an intoleraable region of high risks, in which the risk to health (or another valued component of the blood system) is intolerable regardless of benefits elsewhere. In some cases, very high risks may be tolerated if the risk is unavoidable and is required to reduce a serious competing risk.

In between, there is a tolerable region, in which 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 tolerable region of the ALARA approach, is informed by an ethical analysis that considers a variety of evidence (accumulated during the Assessment step of the decision-making process) including risk assessment, health economics assessments, input from consultations and other assessments. The evaluation of risk tolerability draws heavily on the risk management principles described in Section II A, above. Guidance on the application of risk tolerability factors in risk decision-making is provided in the Evaluation step.
information is gathered and reviewed for an initial overview of the issue and a determination of further information. The assessment stage is deliberately composed of two levels: a screening assessment, in which existing assessments conducted, and the detail of the issue profile and risk characterization may be minimal or extensive. The number of options considered, the number and extent of the processes calls for the systematic determination and documentation of a decision with a rationale based on the degrees of effort and detail depending on the magnitude and tolerability of the risk in question. The basic decision steps and their sub-components and tools are described below. 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 minimal or extensive as 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.

The basic decision steps and their sub-components and tools are described below.

## 3 RISK-BASED DECISION-MAKING PROCESS

### A GENERAL CONSIDERATIONS

The following tasks support the objectives of Step 1. For each task, decision support is provided in the Issue Characterization and Problem Formulation Template located in Appendix B.

#### 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 engagement 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.

At this stage, it is also helpful to identify the decision driver (as exemplified in the Table 1 below) in order to specify the type of decision to be made.
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—can also be described. Each issue will have a particular risk-benefit dynamic.

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 Step 2. The risk management options can be recorded on the Risk Management Options and Assessments Table.

Determine the required assessments to be conducted in Step 2

Using the results of the Issue Characterization Checklist, it is necessary in Step 1 to identify the assessments and analyses that will be conducted in Step 2. The list of required assessments could include one or more of the following: a health risk assessment, a risk-benefit comparison, a health economics and outcomes assessment, a contextual assessment or others as required. The Issue Characterization Checklist exercise will also provide guidance on the resource intensity required for any given assessment. The decisions made as part of this step are key to maintaining proportionality between the level of effort in risk assessment and risk control and the magnitude of the risk. The identified assessments can be recorded in the Risk Management Options and Assessments Table. 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.

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, the specific types of assessment needed, 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). 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.

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; and
- identification of human resources and expertise to complete assessment activities

STEP 2: ASSESSMENTS

Purpose

The purpose of this step 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 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 risks, costs and benefits of alternative scenarios.

Tasks and Tools
A variety of assessment types may be called for in Step 1. Some of these are described briefly below. Guidance and tools are provided in the appropriate Appendices C, D, E, and F.

Conduct initial screening assessment
An initial screening assessment will help estimate the blood safety 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.

The following information may be contained in an initial screening assessment:

- health (or social or ethical) effect - type of effect considered;
- change - type of change in health effect that results from the implementation of intervention or alternative;
- quality of evidence - high, moderate or low; convincing, probable, possible or insufficient;
- magnitude of effect - qualitative (strong, moderate or low); quantitative estimates if available;
- population affected - blood recipients, blood donors, blood operators or the health care system; and
- health outcomes (beneficial, adverse or none).

Conduct required core assessments at level of detail required
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 analyses required should be appropriate to the information needed by decision-makers and proportional to the significance of the risk or the broader issue.

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.

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 engagement, 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 Guidance on Conducting Contextual Assessments (Appendix G) provides general direction on the factors that should be considered in the scope and conduct of these assessments. The major areas that could require dedicated analyses include: social concern and risk perception, equity, trust, legal requirements and jurisdictional differences.

Conduct other required assessments
Several other types of assessments may be conducted, as needed, on the impacts of potential risk management options on the blood system and blood supply. A feasibility and supply-impact assessment may 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. An assessment of the impact of financial costs, operational complications or human resource demands may also be required. 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.

Prepare a risk communication plan
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, as further described in Appendix C.

Prepare a stakeholder engagement assessment and plan
Using the Stakeholder Engagement Guidelines in Appendix D, stakeholder identification and analysis (Guideline 1) is conducted, with attention to laying the foundations for any consultations which are required (Guideline 2) and framing the consultation issues (Guideline 3).

Outputs
Step 2 will produce the following outputs:

- a completed initial screening assessment;
- for some issues, completed full assessments for technical and social factors;
- identification of an appropriate risk communication strategy; and
- preparation of a stakeholder engagement, assessment and plan.

STEP 3: EVALUATION

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 Step 3. For each task, a decision support tool is provided.

**Acquire and array Step 2 output against the risk management options**
Mapping the results of the assessments conducted in Step 2 against the risk management options helps to depict the strengths and weaknesses of each option. This exercise may also reveal gaps in the evidentiary base needed to evaluate an option. In such cases, a return to Step 2 for an additional assessment may be necessary. An Assessment Findings/Risk Management Options Mapping tool is provided in Appendix B.

**Evaluate the risk tolerability of risk management options**
Use the Risk Tolerability Evaluation Tree in Appendix B to review the potential contextual factors that affect risk tolerability and the overall evaluation of the risk management options. This analysis varies according to whether the risk output from Step 2 puts the risk in the broadly acceptable range or in the tolerable or intolerable range.

**Compare risk management options**
Develop a context-specific options rating tool. A sample Options Rating Scale is provided in Appendix B.

**Conduct stakeholder engagement**
Using the Guidance on Stakeholder Engagement (Guidelines 4 and 5), in Appendix D, engage stakeholders in the decision-making process. The results of the consultation are provided to the stakeholders to affirm their contribution, and to the decision-makers for consideration in rendering a decision.

**STEP 4: DECISION**

**Purpose**
The purpose of this stage is to:

- select a risk management option based on the results of the Evaluation step using the Options 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, including the development of new procedures and training, and the acquisition of materials;
- determine a timeline for the implementation of the different components of the risk management plan;
- develop a monitoring plan to:
  - enable the tracking and evaluation of the effectiveness of the risk management plan and support the re-evaluation of precautionary decisions in the face of new information, and
  - identify the elements to be monitored, the frequency of monitoring, and any reporting requirements;
- prepare communications materials required to inform stakeholders of the decision, or of changes in policy or procedures entailed in the decision; and
- document the decision and the decision rationale, and the plan for implementing, monitoring and communicating the decision.

**Tasks and Tools**
The following tasks support the objectives of Step 4. Decision support tools are provided in Appendix B.

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

- 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. The Options Rating Scale in Appendix B can be used for this purpose.

**Develop a recommendation**
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.

**Create decision implementation plan**
In addition to accounting for operational implementation details, it is important to develop a plan that will permit ongoing monitoring of the decision impact 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.

In addition to 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.
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 pre-determined 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, an issue being considered.

Stakeholder engagement: Interactions with stakeholders to share information about an issue and approaches to its management. Engagement may consist primarily of consultation or it may be a fuller process in which stakeholders are invited to contribute to the decision that is made.
APPENDIX B: DECISION-SUPPORT TOOLS

Decision-support tool: Issue characterization and problem formulation template
The issue characterization and problem formulation template consists of:

1. An issue characterization checklist
2. A risk management options and assessments table
3. A risk communication and stakeholder engagement option identification table
4. A table to record key challenges and trade-offs to be expected

1 ISSUE CHARACTERIZATION CHECKLIST

To complete this checklist, select the applicable response to indicate the presence of each factor in the issue, then enter the information requested. Finally, note the assessments that will be required in order to provide the information and analysis necessary to make the decision. 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.

ISSUE CHARACTERIZATION CHECKLIST

<table>
<thead>
<tr>
<th>SECTION 1: RISKS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Answer the following questions:</td>
<td></td>
</tr>
<tr>
<td>1. Does the issue involve a threat to the safety or quality of the blood supply?</td>
<td>NO If NO, provide rationale. YES If YES, answer the following.</td>
</tr>
<tr>
<td></td>
<td>What is the threat?</td>
</tr>
<tr>
<td></td>
<td>Who is at risk from this threat?</td>
</tr>
<tr>
<td></td>
<td>a. Blood recipients</td>
</tr>
<tr>
<td></td>
<td>b. Blood donors</td>
</tr>
<tr>
<td></td>
<td>c. Other</td>
</tr>
<tr>
<td></td>
<td>Describe estimated severity, probability of infection and severity of consequences.</td>
</tr>
<tr>
<td></td>
<td>(If information not readily available, complete the screening level risk assessment (Step 2, Assessments) and return to complete this question)</td>
</tr>
<tr>
<td></td>
<td>List potential management options, including donor deferral.</td>
</tr>
<tr>
<td></td>
<td>List assessments needed for evaluation of threat.</td>
</tr>
<tr>
<td>2. Does the issue involve a threat to the availability of blood and blood products?</td>
<td>NO If NO, provide rationale. YES If YES, answer the following.</td>
</tr>
<tr>
<td></td>
<td>Identify the aspect of blood supply that is threatened.</td>
</tr>
</tbody>
</table>
| 3. Does this issue have the potential for a significant impact on donors? | NO | If NO, provide rationale.  
| YES | If YES, answer the following. |

<table>
<thead>
<tr>
<th>4. What is the intervention?</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. What benefit is intended from the intervention?</td>
</tr>
<tr>
<td>a) Reduced risk</td>
</tr>
</tbody>
</table>
| i. Reduced risk from threat to blood supply  
ii. reduced cost to blood service  
iii. other |
| b) cost saving or resource reallocation |

| 6. Does this issue involve the implementation of a new test? | NO | If YES, answer the following.  
| YES | |

| 7. Does this issue involve the implementation of a new technology? | NO | If YES, answer the following.  
| YES | |

**SECTION 2: INTERVENTIONS**

| 8. Does the issue involve the withdrawal of an existing process, safety step or test? | NO | |
| YES | If YES, answer the following. |

| 9. Does the intervention considered have significant financial implications? | NO | If YES, answer the following.  
| YES | |

| 10. Is there conflict among potential risk interventions? | NO | |
| YES | If YES, answer the following. |

| 11. Does the decision to be made involve prioritization of issues for attention? | NO | |
| YES | If YES, answer the following. |

**SECTION 3: SOCIAL AND ETHICAL CONCERN**

| 12. Is there a high level of media coverage on the issue? | NO | If NO, provide rationale.  
| YES | If YES, answer the following. |

| 13. Is there concern in society or media about a serious health risk associated with the issue? | NO | If YES, answer the following.  
| YES | |

---

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.

**SECTION 2: INTERVENTIONS**

<table>
<thead>
<tr>
<th>4. What is the intervention?</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. What benefit is intended from the intervention?</td>
</tr>
<tr>
<td>a) Reduced risk</td>
</tr>
</tbody>
</table>
| i. Reduced risk from threat to blood supply  
ii. reduced cost to blood service  
iii. other |
| b) cost saving or resource reallocation |

What group is expected to benefit?  
- blood recipients  
- donors  
- society in general  
- blood service  
- other

| 6. Does this issue involve the implementation of a new test? | NO | If YES, answer the following.  
| YES | |

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? | NO | If YES, answer the following.  
| YES | |

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 or test? | NO | |
| YES | If YES, answer the following. |

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? | NO | If YES, answer the following.  
| YES | |

What is the cost of the intervention (financial, other resource or burden on part of blood service)?  
a. Refer to screening assessment - Step 2 outcomes are expected?  
Describe the associated resource reallocation.  
a. Functions involved, intended outcomes  
What assessments are required?

| 10. Is there conflict among potential risk interventions? | NO | |
| YES | If YES, answer the following. |

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? | NO | |
| YES | If YES, answer the following. |

What is the purpose of the prioritization exercise?  
What assessments are required?

**SECTION 3: SOCIAL AND ETHICAL CONCERN**

| 12. Is there a high level of media coverage on the issue? | NO | If NO, provide rationale.  
| YES | If YES, answer the following. |

Describe the nature of coverage and aspects of the issue focused on by the media.  
List required assessments.

| 13. Is there concern in society or media about a serious health risk associated with the issue? | NO | If YES, answer the following.  
| YES | |

Describe the potential impacts of concern and contextual associations.  
List other options (communications, stakeholder engagement).
2. RISK MANAGEMENT OPTIONS AND ASSESSMENTS TABLE

From the results of the issue characterization checklist, enter the assessments that have been identified as required for each factor in the table below. For the Social Concern section, an assessment may be recommended if sufficient concern has been identified under one or more headings. These assessments should be entered in the appropriate spaces in the table.

### RISK MANAGEMENT OPTIONS AND ASSESSMENTS TABLE

<table>
<thead>
<tr>
<th>RISK MANAGEMENT OPTIONS</th>
<th>ASSESSMENTS AND ANALYSES REQUIRED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health risk assessment</td>
<td>Health economics and outcomes</td>
</tr>
<tr>
<td>Contextual assessment and focus areas</td>
<td>Other feasibility and system impact</td>
</tr>
<tr>
<td>Social concern and risk perception</td>
<td>Equity concerns</td>
</tr>
<tr>
<td>Baseline</td>
<td></td>
</tr>
</tbody>
</table>

### 3 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>
<th>Stakeholder concerns and management discussions</th>
<th>Public understanding of new policy or intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk issue management</td>
<td>Stacketor concerns and management discussions</td>
<td>Public understanding of new policy or intervention</td>
</tr>
</tbody>
</table>

### 4 IDENTIFICATION OF POTENTIAL CHALLENGES AND TRADE-OFFS

Provide detailed responses to each of the sections.

| IDENTIFICATION OF POTENTIAL CHALLENGES AND TRADE-OFFS |  |
|-------------------------------------------------------|  |
| Risk control challenges: costs, availability and effectiveness of tests |  |
| Risk-benefit distribution inequities or imbalances |  |
| Impacts of differential perception of hazard by distinct stakeholders |  |
| Impacts of ethical or social concerns |  |
| Cost/risk – benefit trade-offs |  |
### Decision-support tool: Assessment findings and risk management options mapping

**RISK MANAGEMENT OPTIONS AND ASSESSMENTS TABLE**

<table>
<thead>
<tr>
<th>RISK MANAGEMENT OPTIONS</th>
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<td>Social concern and risk perception</td>
</tr>
<tr>
<td></td>
<td>Equity concerns</td>
</tr>
<tr>
<td></td>
<td>Trust in management</td>
</tr>
<tr>
<td></td>
<td>Legal or jurisdictional</td>
</tr>
</tbody>
</table>

Baseline

Option 1

Option 2

Option 3

Option 4

### Decision-support tool: Options rating scale

**OPTIONS RATING SCALE**

<table>
<thead>
<tr>
<th>Risk management options</th>
<th>Expected efficacy of option</th>
<th>Infrastructure and costs needed for option</th>
<th>Expected residual concerns (ethics trust)</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPTION1</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medium</td>
<td>Medium</td>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td></td>
</tr>
</tbody>
</table>

| OPTION1                 | RANK # | |
|-------------------------|--------|
| High                    | High   |
| Medium                  | Medium |
| Low                     | Low    |

---

### Risk tolerability evaluation tree

**ABOVE TOLERABLE THRESHOLD**
- High health risk
- Uncertainty
- Emerging risk
- High social concern

**RISK UNLIKELY TO BE TOLERABLE**
- Base risk at high end of tolerable range
- Uncertainty
- Potential for higher risk
- No clear benefits to justify risk

**RISK TOLERABLE ONLY IN EXCEPTIONAL CIRCUMSTANCES:**
- Blood supply emergency
- Tolerable with actions
- Stakeholder consultation
- Intensive risk reduction

**TOLERABLE REGION**
- Above acceptable threshold
- Justified by benefits received
- Managed to be as low as possible with existing economical methods
- No available means of further reduction

**ACCEPTABLE REGION**
- At or below de minimus level
- Low enough to be of little concern
- Justified by benefits received
- Does not warrant costs of further reduction

**ACCEPTABLE RISK**
- No serious concerns

**RISK TOLERABLE IF QUALIFIED**
- Socially sensitive issue
- Vulnerable risk bearer
- Means available to reduce risk
- Adverse impacts on donors

**RISK TOLERABLE IF QUALIFIED**
- Risk management incomplete
- High profile legacy issue

**RISK TOLERABLE IF QUALIFIED**
- Existing risk justified by supply or demand emergency

**RISK TOLERABLE IF QUALIFIED**
- Intensive risk reduction

**RISK TOLERABLE IF QUALIFIED**
- Risk socially intolerable

Figure 3: Risk tolerability evaluation tree
APPENDIX C: GUIDANCE ON RISK COMMUNICATION

Risk communication consists of a range of activities carried out both as a sub-type of routine communication and as a risk control measure.

For example, in an emergency, authorities must ensure that an affected population receives accurate information on the nature and significance of the emerging risk (such as a health or safety risk posed by a product or substance) and of the protective actions they should take. The goals of this type of risk communication are to instill an appropriate sense of personal risk in those who are at risk, and encourage compliance with emergency recommendations.

More routine risk communication activities involve the preparation of information on a risk to enhance comprehension in order to enable stakeholders to make more informed decisions. Activities of this type include issuing educational information or launching larger campaigns about health risks, or delivering information about risk management programs and policy decisions. Risk communicators also monitor reception of the information in order to respond to information needs and comprehension.

Risk communication will likely be highly organization-specific, adapted to the functions of the organization and the stakeholders with which it interacts. However, organizational policies generally address two main types of activity that underlie most risk communication programs and activities.

The first is the preparatory work required to understand the risk situation and the audiences that may require the information. Even in its most routine applications, risk communication requires a prior understanding of the information needs and comprehension levels of the intended audiences.

The second type of activity concerns the more applied aspects of the risk communication strategy, such as the message design and the distribution channels that are most appropriate to the specific risk situation and audience. The design of the methods and content of a risk communication program will be determined in large part by the urgency of the risk and the targeted population. The channels over which the message is delivered and the preparation of the message itself should be tailored to the information needs and preferences of the audience. The response of the targeted audience is monitored and revisions made as required.

APPENDIX D: GUIDANCE ON STAKEHOLDER ENGAGEMENT

INTRODUCTION: WHY IS IT CRITICAL TO ENGAGE STAKEHOLDERS?

These guidelines provide step-by-step advice for identifying and engaging 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 facilitates implementation. This input is supplemented with other forms of evidence throughout the decision-making process. The results are robust, well informed decisions, particularly as they relate to weighing and mitigating risk, while enabling blood agencies to build credibility, trust and capacity. When issues are not urgent, it is the most opportune time to map, assess and build relationships with key stakeholders to facilitate engaging them when the need arises.

Consider the following six elements to ensure consultation is proactive, appropriate, meaningful and proportional to the context, timelines and resources available:

1. Stakeholder Identification & Analysis;
2. Foundation for Consultation;
3. Framing the Issue;
4. Consultation Methodologies;
5. Reporting; and
6. Resources.

Considerations

- Genuine consultation demonstrates accountability for safe, efficient and ethical decision making.
- Engaging stakeholders in decision making is not equivalent to relinquishing decision-making authority.
- It is important that stakeholders understand the aspects of the issue that are open to input and the final decision-making sources.
- While not all stakeholders will agree with the outputs of consultation, they will refer to a genuine process constructively and positively.
- Consultation must seek out and facilitate the involvement of all relevant stakeholders in the decision-making process.
- All pertinent information should be made available to stakeholders to ensure they can participate in a meaningful way.
- Stakeholders must be advised of the impact of their input.
GUIDELINE #1: STAKEHOLDER IDENTIFICATION & ANALYSIS – WHO DO WE CONSULT?

Steps

1. Determine the categories of stakeholders who are interested in or affected by the issue. It is suggested to consult internal and external subject matter experts for this step. 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. Determine the individual stakeholder that best represents each category identified in Step 1.

3. Using the template below, conduct an exercise in which you place the individual stakeholders 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 quantity, resources and power the stakeholder brings to the issue.

   ![Stakeholder Map](image)

   **Figure 5: Stakeholder Map**

   4. Assess the status of the current relationship with each of the stakeholders.
      a. Green – positive/constructive;
      b. Yellow – neutral/ambivalent or non-existent; and
      c. Red – challenging/negative or adversarial.

   5. Analyze the map quadrant to determine the level of consultation required (see considerations below).

   Considerations
   - Stakeholders who are mapped into Q1 on the stakeholder map (“low interest/low influence”) will require an open channel of communication/information sharing that should be set up for them (email, regular meetings, conference calls, etc.). If their interest or influence changes, you will be aware and can adjust the level of consultation as needed.
   - Stakeholders who are mapped into Q2 on the stakeholder map (“high interest/low influence”) should be treated the same as those in Q1. In addition their concerns, views and perceptions should be proactively addressed. Monitor this group carefully.
   - Stakeholders who fall into Q3 & Q4 on the stakeholder map (high influence) should be provided an opportunity to engage in the decision-making process (face-to-face when possible to build relationships).
   - Some stakeholders in Q3 (whose influence you will benefit from), may have to be encouraged to participate as their interest is lower than stakeholders in Q4.
   - You may also want to consider building a relationship with stakeholders in Q3 and Q4 who are yellow to benefit from their interest and influence.
   - Stakeholders with whom the status of the relationship is red, should be addressed via an individual strategy to determine their issues and move the relationship to a more positive stance prior to bringing them into a consultation.
   - You may choose to leverage stakeholders who are green to influence those who are red or yellow.

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

GUIDELINE #2: FOUNDATION FOR CONSULTATION - HOW DO WE PREPARE TO CONSULT?

Steps

1. Establish an agency-wide commitment to stakeholder consultation that:
   - Reflects organizational values;
   - Keeps the engagement focused and productive;
   - Sets clear expectations for all involved;
   - Ensures the integrity and transparency of the process;
   - Considers relevant input; and
   - Cultivates trust and builds sustainable relationships.
2 Prior to the stakeholder consultation, you should:
   • Articulate what kind of input you need from stakeholders (information, experiences, suggestions, concerns, priorities, or advice).
   • Clearly define the decisions to be made or issues for consultation (eg ‘a summary of stakeholders’ priorities will be presented to the Decision committee to help them establish the selection criteria).
   • Determine how you will follow up with stakeholders.
   • Prepare background information/data/research for stakeholders.
   • Prepare an agenda for distribution.
   • Prepare a list of participants, drawn from Q3 and Q4 of the mapping process, for distribution.

Considerations
   • Some stakeholders may recommend the inclusion of others in the consultation. Consider their recommendations as it will serve to build trust and ensure broad input.

Outputs
   • Organizational commitment to consultation.
   • Agenda.
   • Discussion paper/background information.
   • Template for consultation report to decision-makers.
   • Invitation/participant list for stakeholders.

GUIDELINE #3: FRAMING THE ISSUE – HOW DO WE GATHER INPUT/ADVICE?

Steps
1 It is important to frame the issue that is being put forth for consultation in such a way as to ensure focus and manage expectations, without limiting the discussion. Start by describing the issue/decision to be resolved (what does the decision-maker need to move forward?), and then develop a question or series of questions based on this.
2 The question(s) must also identify the opportunity for stakeholders to genuinely influence the outcome by specifying things like: understanding the issue, formulating the plan, sharing experiences, providing advice, developing/weighing options, identifying gaps, facilitating implementation, etc.
3 For example, the decision-maker may require help weighing the options. A question could be, “In determining the optimal approach to recommend to our regulator on [decision/issue], what are the pros and cons of each option that should be considered?” A secondary question could be, “Are there any other options that should be considered and why?”

4 Once you have the question(s) designed, send the participant list the following, via email: invitation with details as to the decision/issue to be discussed, the question(s) being asked, agenda, participant list, background information/data/research and aspects that are open to/not open to input. Consider involving other stakeholders that are put forward by stakeholders.

5 It is important to request that the stakeholders prepare for the engagement by:
   • Reviewing materials provided;
   • Consulting with their respective groups;
   • Seeking to understand the context of the issue;
   • Listening to the perspectives of others;
   • Understanding where the final decision making authority lies;
   • Indicating their willingness to consult;
   • Defining what else they need to participate;
   • Revealing any conflicts of interest that could exist in terms of the decision at hand; and
   • Declaring their authority to participate.

6 Follow up via telephone may be necessary or preferable for certain stakeholders with whom you need to gauge their interest or build trust before the consultation.

Considerations
   • A generative question will frame the issue while allowing for adequate answers to complex issues, permit creativity, provide richness of detail and reveal a respondent’s logic, thinking process, and frame of reference.
   • It is important to develop a complementary risk communications strategy and information sharing plan to ensure consistency and continuity (this will also keep the stakeholders in Q1 and Q2 informed).

Outputs
   • Generative question(s) for consultation

GUIDELINE #4: CONSULTATION METHODOLOGIES – HOW DO WE CONSULT?

Steps
1 There are many consultation methodologies, the most effective of which are done face-to-face. In bringing the stakeholders from Q3 & Q4 together, you should ensure:
   • a comfortable setting for the consultation;
   • a professional facilitator is used whenever feasible (ensures neutrality);
GUIDELINE #5: REPORTING - WHAT ARE THE OUTCOMES OF CONSULTATION?

STEPS

Following the consultation:

1. Produce a draft consultation report and share with stakeholders, prior to sending to the decision-makers, to ensure accuracy. This may consist of questions, concerns, priorities, experiences, advice, mitigating steps, or proposals.

2. Provide the final consultation report to the decision-makers and advise stakeholders of date.

3. Ask decision-makers to provide a briefing note to share with stakeholders as to how the input was considered and what the final decision/next steps in the process are.

4. Share any further updates with stakeholders prior to them being made public.

5. Advise the stakeholders of any additional engagement opportunities.

Considerations

As the process moves forward, it is important to be responsive to questions from stakeholders. The consultation outputs should be positioned as one source of input into the decision-making process.

Considerations

There are many different methodologies for engaging in consultation with stakeholders depending on your goals such as: developing partnerships, deliberating over options, dialoguing, providing input, reaching consensus or obtaining information.

Other items to consider when planning engagements are:

- Accessibility to stakeholders: online, face-to-face, bilateral, or multilateral approaches be most acceptable?
- Resources available: staff, technical or other expertise, communications support, travel support, venues.
- Timelines for the decision-making process.

Outputs

- Consultation report
- Briefing note from decision-makers
- Stakeholder communication updates
- Evaluation Results.
GUIDELINE #6: RESOURCES – HOW DO WE BUILD OUR CAPACITY TO CONSULT?

<table>
<thead>
<tr>
<th>GUIDELINE</th>
<th>RESOURCES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triggers: Recognize the need for engagement</td>
<td>Build the assessment of stakeholder engagement triggers into corporate decision-making processes (i.e. business planning, priority setting)</td>
</tr>
<tr>
<td>Foundation: Develop a commitment to the stakeholders</td>
<td>Develop a corporate set of principles to guide stakeholder engagement and build capacity across the organization</td>
</tr>
<tr>
<td>Framing the Issue: Clarify the intent of consulting and the input needed from stakeholders</td>
<td>Seek advice from internal experts (communications, operations, leadership, etc.) to ensure the issue is framed clearly, accurately, and consistently</td>
</tr>
<tr>
<td>Stakeholders: Identify and analyze stakeholders</td>
<td>Outside of urgent issues, when possible take time to map, assess and build relationships with key stakeholders</td>
</tr>
<tr>
<td>Methodologies: Conduct appropriate engagement activities</td>
<td>Develop familiarity with a range of facilitation and engagement methodologies</td>
</tr>
<tr>
<td>Genuine Engagement: Follow up on input and incorporate learning</td>
<td>Create an ongoing engagement mechanism to facilitate rapid, trusted feedback when needed Measure against corporate values and principles to assess whether the engagement process reflects the organization’s values.</td>
</tr>
</tbody>
</table>

Learn more about the rationale and benefits of stakeholder Engagement with the International Association for Public Participation at www.iap2.org

See examples of values and principles from other organizations:
- www.phac-aspc.gc.ca/ph-sp/collab/collab2-eng.php#public
- www.saplan.org.au/better_together/principles

Ensure the issue is framed in a format that offers stakeholders a genuine opportunity to provide input. Here is a link to examples:
- www.motivcoach.wordpress.com/2011/03/03/25-powerful-generative-questions/

A more in-depth process for identifying and analyzing stakeholders:
- Stakeholder Discovery Workshop

Tools and tip-sheets:

WORKING WITH STAKEHOLDERS

Stakeholder engagement:
The practice of presenting parties who may affect or be affected by a decision with genuine opportunities to participate in shaping a way forward that is well informed and openly supported.

Stakeholder discovery:
Identification and analysis of interested or affected parties specific to a project or issue.

Why engage stakeholders?
- They want to have a say
- They often have a right to do so
- They can strengthen the project: influence, improvements, contributions, networks, resources, etc.
- If engaged, they can become strong allies
- If not engaged, they can damage the organization’s reputation, trust, and ability to operate
**STAKEHOLDER IDENTIFICATION: WHO IS A STAKEHOLDER?**

Stakeholders are individuals or groups who:

- **Who have something to contribute to the project or issue?**
- **Who are affected by the project or issue?**
- **Who are involved in the project or issue?**
- **Who can affect the successful roll-out of the initiative?**
- **Who needs to:**
  - Be informed?
  - Be consulted?
  - Be brought on board?
  - Contribute?

**A:** Generate a list of all stakeholders who may be interested in or affected by the decision using the following categories to guide you.

- Patient organizations
- Regulators
- Funders
- Donors / volunteers
- Health care practitioners
- Professional associations
- Health Institutions
- Blood Operators
- Suppliers
- Thought leaders:
  - health policy
- stakeholder engagement
- academics / researchers
- Others?

**B:** Review your stakeholder list for potential gaps using the following parameters:

- Operational perspective
  - Who’s involved “from vein-to-vein”?
- Implementation perspective
  - Who can AFFECT the successful roll-out of the initiative?
    - Block / Influence
    - Implement / Fund
    - Reach others
    - Support / Promote
    - Provide expertise
    - Contribute / Approve
- Change perspective
  - Who’s AFFECTED by the initiative?
    - Past experience
    - Change in:
      - Services
      - Budget
      - Direction
      - Workload
      - Skills needed
- Relationship perspective
  - Who needs to:
    - Be informed?
    - Be consulted?
    - Be brought on board?
    - Contribute?

**C:** In this step, we assess each stakeholder based on their level interest in the issue and their potential influence over the issue to determine the appropriate level of involvement required in the decision.

*2 variables affect the level of involvement:*

- **Influence:** the quantity and type of resources and power that the stakeholder brings to bear on the issue.
- **Interest:** the level of attention and importance the stakeholder gives to the issue.
C: Assessing Stakeholders

<table>
<thead>
<tr>
<th>HIGH Influence</th>
<th>LOW Influence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q3 – Involve Important Players</td>
<td>Q4 – Collaborate Prominent Players</td>
</tr>
<tr>
<td>When activated can move things forward.</td>
<td>Can advance or derail the initiative, draw others in, show leadership.</td>
</tr>
<tr>
<td>Q1 – Inform Dormant Stakeholders</td>
<td>Q2 – Consult Potential Players</td>
</tr>
<tr>
<td>Controversy can turn them into an interested group.</td>
<td>Want involvement when affected by initiatives. Could support or hinder.</td>
</tr>
</tbody>
</table>

LOW ↔ Interest ↔ HIGH

2 additional factors can affect the type of involvement required:

> Status of the relationship:
  - Tone
  - Maturity
  - Resource intensity
  - Position on the issue
  - Role of the stakeholder:
  - What type of contribution can they make to the initiative? (influence, resources, expertise, perspective etc.)

C: Assessing Relationships

We can indicate the current status or quality of the relationship by colour:

- **Green** indicates a positive, constructive, helpful working relationship.
- **Yellow** indicates a neutral, ambivalent, or shifting relationship.
- **Red** indicates a challenging, adversarial or nonexistent relationship that may hinder our work.

D: The next step is to determine the appropriate strategy for each stakeholder, considering the following:

a) What are your goals of engagement?

b) How can stakeholders affect the decision?

c) What additional information or input is required to help shape the decision?

d) What is needed to create buy-in to support implementation of the decision?

e) Do we need raise awareness of the issue or decision?

f) Which stakeholders have networks that can be leveraged through engagement to support our decision?

g) Who should we engage to ensure all stakeholder perspectives are represented in the decision?

D: Developing a Stakeholder Engagement Strategy

What, if anything, needs to change in the relationship with each stakeholder?

- Increase or decrease the stakeholder’s level of interest or influence?
- Establish, strengthen, or improve the relationship?
- Simply maintain (steward) the relationship?

What stakeholder needs should be addressed?

- Allay a particular concern from the beginning?
- Engage them in a particular way (e.g. one-on-one vs. publicly)?
APPENDIX E: GUIDANCE ON HEALTH RISK ASSESSMENT

General

Formal processes should be established and followed for the conduct and documentation of risk assessments. In addition to the general quality expectations that apply to all assessments found in Section II C, there are a number of scientific and technical procedures required to prepare a sound risk assessment. Risk assessments are domain-specific, but a number of processes that may apply within the conduct of most types of risk assessments. These include:

• using formal methods of systematic evidence review to ensure that all the relevant information has been captured in a defensible and reproducible manner, allowing for more efficient iteration;
• applying weight-of-evidence methods to draw conclusions on the causal relationship between a potential hazard and an adverse outcome;
• using approaches and methods for the propagation of variability in inputs to estimate the variability in the level of risk and the probability of extreme values in the level of risk;
• using approaches and methods for the propagation of uncertainty in inputs to estimate the level of uncertainty in the level of risk;
• applying multiple measures of risk to describe different dimensions and possible interpretations of the risk situation;
• being explicit about the assumptions behind risk assessment and decision-making processes; and
• preparing information in a form that is readily accessible for risk communication and stakeholder engagement functions.

THE RISK ASSESSMENT PROCESS

Problem formulation

As is done at the outset of the overall risk-based decision-making process, risk assessments should begin with problem formulation. This involves characterizing the scope and level of detail required in the risk assessment to produce the information needed by decision-makers. This step is important to:

• structure the risk assessment to measure the potential risk reduction associated with potential intervention and to maximize the capacity to integrate risk assessment information with other analyses that will be conducted to inform the same decision;
• determine the appropriate level of detail required in the assessment; and
• establish timelines for completion.

What do we need each stakeholder to do to help with this project?

• Offer approval publicly?
• Refrain from an action?
• Leverage their networks?
• Share how the initiative would affect them?
• Provide funds?

D: Developing a Stakeholder Engagement Strategy

What is proposed for priority stakeholders to achieve our engagement goals?

1. By quadrant, list each stakeholder from the map (Q1, Q2, Q3, Q4)
2. Briefly describe how the project will impact the stakeholder
3. Identify the Current and Desired Relationship Status
4. Brainstorm the Actions/Opportunities/Activities to achieve our Desired Relationship Status for each stakeholder
5. Assign who would be Responsible to deliver the action or activity (specify position or person)
6. List any Considerations/Barriers that must be taken into account as part of the activity/action or opportunity.

Sample worksheet you could use to capture strategy suggestions:

<table>
<thead>
<tr>
<th>Stakeholder (Name, Org.)</th>
<th>How will the project impact the stakeholder?</th>
<th>Current Status</th>
<th>Desired Status</th>
<th>Action/Opportunity/Activity - Project phase/when?</th>
<th>Who Resp.?</th>
<th>Considerations/Barriers</th>
</tr>
</thead>
<tbody>
<tr>
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</table>
Risk assessments will often have a more limited scope than the overall scope of the problem discussed at this stage. The limitations to the scope and their interactions with other assessments that may be conducted as part of a risk management decision should be clearly described in the risk assessment products. Such an approach will ensure understanding, particularly to ensure that any elements not addressed by the risk assessment are addressed in another assessment.

Risk assessors should regularly communicate with the risk manager and other relevant analytical units (e.g., health economics, technologic, legal) to ensure that the problem formulation and the scope of the assessment continue to capture the necessary information. Stakeholders can participate at this stage if desired or deemed necessary by the risk manager.

Although problem formulation is a critical first step in risk assessment, it is also important to revisit the conclusions of this step as part of the iterative process when new information (e.g., new technology, the establishment of new international standards, information from stakeholder consultations, new scientific studies, etc.) may justify modifying the scope or the level of detail required to be compatible with other analyses.

Selecting risk measures
Consider risk measures carefully during problem formulation. The choice of specific measures is based not only on technical factors, but also on a consideration of different societal values (i.e., value-laden judgments) related to risk management options. These could include, among others, the following risk measures:

- measures of individual and population health;
- impacts on quality of life; and
- measures of equity in the burden of disease among groups.

The appropriate measures of risk should be selected considering scientific factors, integration with economic analysis, and other key elements of the risk management process, such as cost-effectiveness, and in consultation with the risk management function. This is important because 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 process will help ensure that decision-makers have the best available information to facilitate selecting risk measures.

Hazard identification
All risk assessments share a common requirement to identify and characterize the ways in which adverse events can arise. Hazard identification involves recognition that a hazard (e.g., a specific pathogen) can cause a specific adverse health outcome. The conclusions at this step of risk assessment are limited to describing the possibility of adverse outcomes, including a characterization of the evidence for a causal relationship between a hazard and the adverse outcomes. The step can also be used to summarize fundamental properties of the hazard.

Causal analysis
Causal analysis involves recognition that a hazard can cause a specific adverse health outcome. The conclusions at this step of risk assessment are limited to describing the possibility of adverse outcomes, including a characterization of the evidence for a causal relationship between a hazard and the adverse outcomes. The step can also be used to summarize fundamental properties of the hazard.

In some risk domains, the causal analysis component of hazard identification can be a relatively simple task, such as in the case of an infectious agent that is known to cause infections in humans through blood products.

In other cases, the attribution of causality can be a complex aspect of the risk assessment, for example, when determining the risks of various processing factors.

Where the underlying causal relationship is in question, 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. Using formal methods of systematic review can help ensure transparency and reproducibility of the evidence base. Moreover, formal and systematic methods, combined with information technology, can improve the efficiency of updating information related to the risk assessment process.

Exposure assessment
Exposure assessment consists of converting the possibility of harm associated with a hazard into estimates of the frequency and extent of the interaction between the hazard and the risk bearers. The following discusses the key aspects of exposure assessment.

Identifying sources, pathways and targets or receptors
In an ideal analysis, all potential hazards or failures, all pathways of exposure, and all potential risk bearers are considered. In practical terms, the scope of a risk assessment may be significantly reduced as a result of, for example, deliberation in the problem-formulation stage where risk managers, risk assessors and stakeholders have arrived at a decision on an appropriate scope; or by scientific and technical arguments that determine the most important combinations of hazard sources and risk bearers. The scope of these combinations constitutes the system to be analyzed in the risk assessment.

A clear statement explaining why the scope was chosen, including associated limitations, should be provided. Where the scope has been determined by scientific or technical arguments, these arguments should be provided in the exposure assessment stage. If the scope is largely determined by various risk management considerations, these considerations should be described in the problem formulation stage.

Estimating probability and extent of exposure
The estimate of probability can be assessed and reported 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, or it may be a function of the amount of data available.

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.

**Exposure-consequence assessment**

In this step, the consequences of exposure to the hazard and their severity are described and expressed as appropriate for the hazard and the evidence available to estimate risk. In many cases, the consequences may need to be estimated in several stages, where the damage is best described as having several cascading steps, for example as further consequences of the introduction of an infectious agent, with a unique spectrum of further consequences of varying probability, ranging from minor, reversible effects to more serious, irreversible impacts such as fatalities or chronic disability.

Different levels of susceptibility as well as simultaneous exposures to the same or related hazards may lead to variations in the probability or severity of consequences among individuals or groups for a variety of reasons. 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.

This process derives estimates for the probability, rate and extent of damage to the risk bearer given a level of exposure or a specific type of exposure event. This relationship between exposures and the associated consequences is then merged with the estimates of the frequency and the extent of exposure to generate estimates of risk in the risk characterization step.

**Risk characterization**

Risk characterization, which contains computational and narrative components, is the final step in the estimation process. The estimation task combines estimates of the frequency and extent of exposure (resulting from the exposure assessment stage) with the relationship between exposure and consequences to yield estimates of the magnitude of consequences with corresponding estimates of their probabilities. 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 principal results of risk assessment are the estimates of the level of risk and the characterization of the extent of uncertainty. The results often include a baseline scenario (which is often the 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.

Other outputs of a risk assessment process (such as intermediate calculations, the results of validation exercises, and the results of peer review) may be provided for context and to ensure the quality of the results. These outputs provide further background evidence in the decision-making process and foster the appropriate levels of confidence in the decision-making process among stakeholders.

The following are some key components of risk characterization.

- Summary measures of risk: Key risk measures are presented for the magnitude and probabilities of the risks for the populations of risk bearers of particular concern or bearers that were identified in the scoping process.

- Individual risk estimates: Where appropriate, the estimation of risks for individuals in identified populations of targets or receptors is presented. The nature and significance of uncertainty and variability in the risks to individuals should be explained.

- Population risk estimates: Population estimates or distributions should identify the populations or sensitive members of subpopulations to which they apply. Uncertainty or confidence levels should be specified.

- Complementary measures of risk: Measures of risks other than, or in addition to, the key risks of interest should be evaluated and reported, along with the terms used for measurement and the significance of those risks to the larger risk-decision context. This could include risks to the availability of blood, or to the capacity of the blood service to carry out its full range of responsibilities.

- Distribution of risk burden: The distribution of the burden of risk is a key factor in the consideration of equity in relation to the risk assessment and the management options selected for evaluation. The effects of a risk can vary within a population according to factors such as geographic location, age or life stage, or income level.

Risk characterization integrates 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. Multiple measures of risk that demonstrate different conceptual aspects of the estimated risk should be presented. The information provided by the risk assessment will be used in combination with other parallel assessments (i.e., health economics,
legal, technological, social and political) to inform the process for selecting the risk management option. These parallel analytical tasks may be identified during the problem formulation phase or may emerge during iterations of the risk assessment and risk management processes.

Characterization 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. (This is particularly salient when characterization leads to uncertainty with regard to determining the preferred risk management option.)

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.

Assessing the risk reduction impact of risk management options
To estimate the benefits of specific decision options, select a range of risk management options for evaluation and comparison against each other and the baseline scenario. This part of the risk assessment process informs the evaluation step in the decision-making process, and provides the data on risk estimates under the scenarios reviewed.

This step repeats the risk characterization step of risk assessment and focuses attention on the differences in the level of risk among the various options and as compared with a baseline scenario (for example, the status quo). Depending on the context, a selection of risk management options may be known in advance and can be evaluated throughout the risk assessment process. In many cases, options may be identified as a result of the primary risk assessment and subsequently evaluated in further iterations of the risk assessment and risk management processes. The evaluation and comparison should include 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. Risk trade-offs created by the risk management options should be identified and characterized. These may include a trade-off between the risks of an activity and those of foregoing the risk activity, or weighing the significance of ancillary risks or the adverse effects generated by the risk management option intended to reduce a target risk.

The specification of the risk management options, including the timing, the scope and other details must be coordinated with other analytical efforts in order to ensure that an integrated decision-support product is available to decision-makers.

APPENDIX F: GUIDANCE ON CONDUCTING HEALTH ECONOMICS & OUTCOMES ASSESSMENTS

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 medicine, resources must be optimized from donor to recipient and beyond. The use of health economic analysis as part of risk-based decision making will help decision-makers understand the cost-effectiveness of introducing a blood safety measure and enable them to link this information to other results generated by the Framework.

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

PART I - GUIDING PRINCIPLES

Three core concepts underpin applied economics. The first is that scarcity exists and there are insufficient financial and other resources 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, we willingly forego using the same resources in other ways.

The application of health economic and outcomes analyses is relatively new to the field of transfusion medicine. As such the following principles have been developed to help guide the user.

1. Health economic analysis is not static. Decisions must 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 is a societal good 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 sets of costs and effects that are incurred by all stakeholders. Justification for not conducting an analysis from the societal perspective is necessary when other perspectives are used.

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 may be considered more important than prevention of others. Even when the cost-effectiveness 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 conducting, modelling and reporting analyses is 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 model parameters by experts. In such cases, the use of experts and their assumptions must be clearly documented.

6. Precaution remains a strong force in blood safety. Health economic considerations 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 override health economic considerations.

**PART II - COMPLETING THE HEALTH ECONOMIC AND OUTCOMES ASSESSMENT**

The process of undertaking a health economic assessment will be guided by the steps in the Framework. A depiction of the Framework is provided below.
The guidelines that follow describe the various factors that need to be considered when carrying out a health economic analysis:

- framing the question and selecting the perspective;
- choosing the evaluation method;
- conducting the decision analysis;
- assessing uncertainty and sensitivity;
- evaluating data and data scarcity;
- presenting and interpreting the results;
- critiquing the analysis; and
- integrating the health economic analysis into the Framework.

Detailed instructions on producing and analyzing data when undertaking a health economic assessment are outlined at the end of each of the following sections, and an overall bibliography is provided at the end of the document. A brief description of common analysis methods and primary characteristics of these methods as used in health economic and outcomes assessment are provided in Table 1.

It is important to observe that health economic analyses require a substantial level of numerical literacy in order to properly understand some of the outcomes presented and their implications. Depending on the complexity of the health economic assessment at hand, blood establishments may wish to retain the services of a health economist to conduct the analysis.

GUIDELINE #1: FRAMING THE QUESTION AND SELECTING THE PERSPECTIVE

The first step in conducting an economic assessment is to clearly state the health economic questions that need to be answered. Some include what is the problem, why is it important, and what do we want to know? Clearly stating 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.

Next, select a unifying analysis perspective that links health economics to other information necessary for evaluation and decision making. In applied economics, the analysis perspective describes the viewpoint from which an analysis is conducted. 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;
- the societal perspective which includes the entire sets of costs and effects that are incurred by all stakeholders in the healthcare system, including patients and donors.

For blood-safety interventions, the societal perspective should be the standard used for health economic evaluations. This is because donated blood is a societal good with substantial costs, risks, and benefits accruing to different constituencies. Because the costs and effects of transfusion are borne by different groups, any analysis that does not account for the impact at a societal level cannot be considered to have fully assessed the health economics of an intervention.

An analysis conducted from the societal perspective should be structured to allow for consideration of the impact on specific groups, such as blood centres 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. The reporting of health economic outcomes should include combined summary results as well as individual results for specific stakeholder groups.

Although the societal perspective is most appropriate for blood safety, 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 have to be taken. In such instances, the justification for not conducting an analysis from the societal perspective should be clearly documented.

GUIDELINE #2: CHOOSING THE HEALTH ECONOMIC EVALUATION METHOD

There are several economic evaluation methods that can be used to perform a health economic analysis. An overview of common health economic study designs, the questions each answers, and the limitations of each is provided in Table 1.

For risk-based decision making in blood safety, two approaches have been selected as being the most appropriate: budget impact and cost utility. Both answer different questions and are complementary. Their combined outcomes create a strong base of economic evidence for decision-makers.

- Budget impact analysis (BIA) answers the question of 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 even 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.

- Cost utility analysis (CUA) 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 people to compare interventions across different diseases or conditions.

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 QALY, a range of interventions—from donor selection to long-term recipient outcomes—can be evaluated through CUA. Without a comparable metric 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, some of which are suggested below.
Recommended reading on evaluation methods:


GUIDELINE #3: CONDUCTING THE DECISION ANALYSIS

After selecting the appropriate type of economic evaluation method for an economic assessment, select a technique to analyze the resulting decision. There are many techniques to choose from but they almost always include the development of a model (a cost model for BIA or a cost and effects model for CUA). The choice of model will depend on the specifics of the system or process to be analyzed, the nature of the hazard, and the evaluation method used. Table 2 summarizes the various models that can be used.

A model will need to adequately represent reality, but it does not need to be as complex as the real world. Models are simplified representations of a 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 to enter into the model.

Important guiding principles when developing a model:

1. A model's scope and structure should be consistent with, and adequate to address, the decision problem and policy context.

2. Although data are essential, the conceptual structure should be driven by the decision problem or research question and not determined by data availability.

A way to increase confidence in models that are used to guide decision making is to improve the consistency of the modeling and the reporting of outcomes. Likewise, 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.

Recommended reference materials on evaluation methods:


GUIDELINE #4: ASSESSING UNCERTAINTY AND SENSITIVITY

Where there are large uncertainties as to the actual value most appropriate for use in model parameters, and therefore the possible outcomes, both sensitivity and uncertainty analyses can help to contribute to the decision. In this regard, there is considerable value in using two types of sensitivity analysis: deterministic analysis (which studies the key factors that influence an outcome) and probabilistic analysis (which considers the likelihood and uncertainty that these factors will influence an outcome). Deterministic analyses highlight which model parameters influence the results of the analysis. Probabilistic sensitivity analysis provides an indication of the overall parameter uncertainty around various model outcomes. Both analyses should be conducted as part of health economic evaluations in blood safety.

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. Various statistical methods can be applied to obtain insight into the uncertainty and sensitivity of model outcomes and subsequent decisions. Choosing the most appropriate one depends on the level of uncertainty in the underlying evidence for the decision that has to be made.

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 a proportional intervention that favours precaution. However, 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.

An example of how our understanding of a blood safety threat advanced over the years is found in variant Creutzfeldt-Jakob disease (vCJD). When vCJD first emerged, highly precautionary measures were appropriately adopted because of lack of knowledge. While today knowledge is far from complete, the understanding of the risk of vCJD and the role that precautionary measures played to limit transfusion-transmission are supported by scientific evidence. Moreover, health economic analyses of interventions to reduce the risk of transfusion transmission have not supported the adoption of specific targeted interventions. This clearly underlines the fact that health economic evidence only fulfils part of the total evidence in determining the outcome of the decision-making process. It also demonstrates that as the evidence of the scope of vCJD risk has been better defined, proportionality in response and resource expenditure has led to a level of risk tolerance that might have seemed unimaginable when vCJD first emerged.

Recommended reference material on uncertainty and sensitivity analysis:


GUIDELINE #5: DATA AND DATA SCARCITY

Health economic analyses are data-intensive exercises. Sometimes empirical data will not be available, especially in the early emergence of a risk. Such a case makes analyses more challenging to conduct. For unknown risks, little can be done other than to use consensus methods, as was done when assessing some aspects of vCJD risk. Use of such techniques in health economic analyses requires that reports clearly state which analysis parameters draw on real data and which on assumptions.
Another approach that can be taken when data is scarce is estimation of model parameters by expert opinion. Frequently casual readers view this approach as flawed. In reality, however, such assumptions are sometimes necessary. As long as the use of expert opinion is clearly documented, especially for new or novel threats, there is no valid reason to discount such analyses. Moreover, structured expert-elicitation exercises can provide highly acceptable sources of information. These alternate approaches when data are scarce may not be ideal but will still help with the decision making.

Recommended reference material on consensus methods and expert opinion:


GUIDELINE #6: PRESENTING AND INTERPRETING RESULTS

There are various ways to present health economic analysis results. A minimum standard is to present results as costs and consequences tables where:

- BIA results are reported as disaggregated costs incurred by specific groups or organizations and then as aggregated total costs of implementing an intervention,
- CUA results are presented 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

- the formula for the incremental cost-effectiveness ratio is:

\[
\text{ICER} = \frac{\Delta C}{\Delta E}
\]

Where ICER is the incremental cost-effectiveness ratio, \(\Delta C\) is the difference in cost, and \(\Delta E\) is the difference in effectiveness. This ratio can be used to determine the cost-effectiveness of one intervention over another.

There are four possible outcomes when comparing two interventions:

1. **Less costly and More effective**
2. **More costly and More effective**
3. **More costly and Less effective**
4. **Less costly and Less effective**

The ICER is positive if the intervention is more costly and more effective, indicating cost-effectiveness. If the intervention is less costly and more effective, it is considered cost-saving. If the intervention is more costly and less effective, it is considered a cost-wasting intervention. If the intervention is less costly and less effective, there is no reason to adopt it.

Threshold considerations should also be placed in the context of the nature of the adverse events for blood safety. Interventions that have been adopted in blood safety in most developed and developing countries do not conform to WHO-CHOICE or other thresholds. Some interventions to prevent blood-safety threats are considered more important to mitigate than others, despite lower cost-effectiveness ratios. Moreover, even in the same country for some interventions these thresholds may be considered appropriate, but for other interventions the acceptable threshold ratio may be much higher. 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.

Another common presentation is the cost-effectiveness plane, where the difference in cost is plotted against the difference in effects. Each intervention will then fall into one of the quadrants of the cost-effectiveness plane. Interventions that are less costly and more effective should be adopted; those that are more costly and less effective should not. Few interventions fall into either of these quadrants. Typically, the merits and implications of an intervention need to be considered before a decision can be reached. A further 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 costs imply higher health effects) can be shown in an easily interpretable graphical manner in the form of confidence ellipses.

Results interpretation – threshold considerations

For many health care applications, a cost-effectiveness threshold is applicable. 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 the ratio of costs over health effects (the cost-effectiveness ratio).

What are the threshold considerations in the context of blood safety?

Two common questions many decision-makers would like answered are whether an intervention is cost-effective, and among potential interventions, which are more cost-effective? Health economics cannot answer this first question because there is no single threshold in any country that will define a cost-effective versus not cost-effective intervention. Threshold considerations therefore need to be further developed in the context of blood safety and transfusion medicine.

Depending on local expectations from health authorities and established health-technology assessment guidelines, the results of analysis can be compared to established thresholds that are considered acceptable. 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 as defining 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 that 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.)

Threshold considerations should also be placed in the context of the nature of the adverse events for blood transfusion because prevention of some events, such as transfusion-transmission of HIV or HCV, is considered more important than prevention of other events. Interventions that have been adopted in blood safety in most developed and developing countries do not conform to WHO-CHOICE or other thresholds. Some interventions to prevent blood-safety threats are considered more important to mitigate than others, despite lower cost-effectiveness ratios. Moreover, even in the same country for some interventions these thresholds may be considered appropriate, but for other interventions the acceptable threshold ratio may be much higher. 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.
Guideline #7: Critiquing the Analysis

Checklists that help to evaluate the quality of the work are readily available (see below). These can be used to easily verify the completeness of the study. A next step—which should also be part of the assessment itself—is to verify the sensitivity and uncertainty of model outcomes. This assessment not only provides insight into the robustness of the model outcomes, but also extends the means of checking whether the outcomes of the health economic model are correct.

The health economic assessment should preferably be 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). Generally the checks 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.

To avoid biased critiques, the review should preferably be performed by independent experts.

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. Face validity is not true validation, but provides the opportunity for peers to comment on whether aspects of the analysis (and particularly the model) are sufficient. This is an opportunity for persons outside the analysis to challenge and critique the work. However, it is not expected to include additional modeling or analysis.

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 Table 3.

Recommended reference material on critiquing analysis:


GUIDELINE #8: INTEGRATING THE HEALTH ECONOMIC ANALYSIS INTO THE FRAMEWORK

In the Assessments step of the Framework, all inputs and assessments to support decision making are gathered and assimilated. The results of the health economic assessment should be integrated into the assessment findings and risk management options mapping tool. In so doing, the findings of the health economic assessment are mapped 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.

Integration of health economics and outcomes findings into the Framework will depend on the specific threat or set of interventions being evaluated. How health economics and outcomes results are included in the Assessments phase will depend on whether this information is considered necessary or optional in a given setting and with respect to given issue.

Use this quick reference guide to help you step through the Health Economic & Outcomes assessment process.

<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>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>
<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</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health economic study type</th>
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<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 1: Summary Description of Health Economic and Outcomes Designs Relevant to Blood Safety Including Primary Outcomes and Limitations of Each Design

Table 2: Types of Models Used in Health Economics and Outcomes
CHECKLIST OF EVALUATION FACTORS

1. Was a well defined question posed in answerable form?
   1.1 Did the study examine both costs and effects of the services or programs?
   1.2 Did the study involve a comparison of alternatives?
   1.3 Was a viewpoint for the analysis stated and was the study placed in any particular decision-making context?

2. Was a comprehensive description of the competing alternatives given (i.e. can you tell who did what to whom, where and how often)?
   2.1 Were there any important alternatives omitted?
   2.2 Was a do-nothing alternative considered? Should one be?
   2.3 Was the effectiveness of the programs or services established?

3. Were all the important and relevant costs and consequences for each alternative identified?
   3.1 Was this done through a randomized, controlled clinical trial? If so, did the trial protocol reflect what would happen in regular practice?
   3.2 Was effectiveness established through an overview of clinical studies?
   3.3 Were observational data or assumptions used to establish effectiveness? If so, what are the potential biases in results?

4. Were all the important and relevant costs and consequences for each alternative identified?
   4.1 Was the range wide enough for the research question at hand?
   4.2 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.)
   4.3 Were the capital costs, as well as operating costs, included?

5. 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)?
   5.1 Were any of the identified items omitted from measurement? If so, does this mean that they carried no weight in the subsequent analysis?
   5.2 Were there any special circumstances (e.g., joint use of resources) that made measurement difficult?
   5.3 Were these circumstances handled appropriately?

6. Were the cost and consequences valued credibly?
   6.1 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)
   6.2 Were market values employed for changes involving resources gained or depleted?
   6.3 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?
   6.4 Was the valuation of consequences appropriate for the question posed (i.e. was the appropriate type of analysis selected)?

7. Were costs and consequences adjusted for differential timing?
   7.1 Were costs and consequences that occur in the future adjusted to their present values?
   7.2 Was there any justification given for the discount rate used?

8. Was an incremental analysis of costs and consequences of alternatives performed?
HEALTH ECONOMIC EVALUATION METHODS (GUIDELINE 2)

Budget Impact Analysis


Cost Utility Analysis


Decision Analysis (Guideline 3)


Uncertainty and Sensitivity Analyses (Guideline 4)


Dealing with Data Scarcity (Guideline 5)


Table 3: Checklist of evaluation factors from Drummond et al. Oxford University Press
APPENDIX G: GUIDANCE ON CONDUCTING CONTEXTUAL ASSESSMENTS

This guidance may be used to determine the information to be gathered and the analysis conducted in a contextual assessment. The following are examples of contextual factors that may be pertinent.

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 engagement 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 assessment 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 engagement 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 or legal and jurisdictional considerations.

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 engagement 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?
1. 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

2. 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?

3. 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?

4. 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?