



# **Rapid Risk Assessment of Acute Public Health Events**



**World Health  
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## Introduction to the manual

This manual has been developed to guide rapid risk assessment of acute public health risks from any type of hazard in response to requests from Member States of the World Health Organization (WHO). The manual is aimed primarily at national departments with health-protection responsibilities, National Focal Points (NFPs) for the International Health Regulations (IHR) and WHO staff. It should also be useful to others who join multidisciplinary risk assessment teams, such as clinicians, field epidemiologists, veterinarians, chemists, food-safety specialists.

The manual will assist rapid and defensible decision-making about acute public health events that pose a risk to human health through application of a systematic process from event detection and risk assessment to communication with key stakeholders and the public.

The manual complements existing hazard-specific risk assessment guidance (see Appendices 1 and 2), including:

- *WHO Human Health Risk Assessment Toolkit: Chemical Hazards*<sup>1</sup>
- *Application of Risk Analysis to Food Standards Issues*, a Joint FAO/WHO Expert Consultation, Geneva, Switzerland, 13–17 March 1995<sup>2</sup>.

As the process is incorporated into routine practice during acute public health events we hope that users will suggest improvements for this manual as well as provide additional case studies that will improve it and assist training.

## Purpose of the manual

Rapid risk management of acute public health events reduces or prevents disease in affected populations and reduces negative social and economic consequences. Additional benefits include:

- defensible decision-making
- implementation of appropriate and timely control measures
- more effective operational communication
- more effective risk communication
- improved preparedness.

## Defensible decision-making

Risk assessment takes into account and documents all relevant information available at the time of the assessment. This supports and directs decision-making and provides a record of the process including:

- which risks and control measures were assessed
- the methods used to assess them
- why they were considered important
- their order of priority.

<sup>1</sup> <http://www.who.int/ipcs/publications/methods/harmonization/toolkit.pdf>

<sup>2</sup> <http://www.who.int/foodsafety/publications/micro/march1995/en/index.html>

If documented consistently, risk assessment provides a record of the rationale for changes over the course of the event including the:

- assessed level of risk
- recommended control measures
- key decisions and actions.

Evaluation of the risk assessment – based on systematic documentation – provides an important means of identifying where improvements can be made and provides an evidence base for future risk assessments and responses to events.

## Implementation of appropriate and timely control measures

The **systematic approach** to collecting and analyzing information about the hazard, exposures and context in which the event is occurring helps to:

- **identify evidence-based control measures**
- **rank the suitability and feasibility of control measures**
- ensure that control measures are proportional to the risk posed to public health.

In addition, because the risk is assessed repeatedly during an event, risk assessment offers authorities an opportunity to adapt control measures as new information becomes available.

## More effective operational communication

Using a **common risk terminology** can greatly improve the **operational communication between different levels of an organization** and with other sectors and institutions involved in the assessment and response to the event.

## More effective risk communication

The aim of public risk communication is to enable the **target population to make informed decisions about recommended personal and community-based prevention and mitigation measures**. Effective risk communication relies on the **timely and transparent sharing of all relevant information, and the building of trust and empathy**. A systematic approach to the assessment of acute public health events supports effective risk communication through the rapid dissemination of information and the identification of key prevention and mitigation measures.

## Improved preparedness

Although the manual focuses primarily on the use of **risk assessment during acute public health events** the approach is equally applicable to preparedness activities, especially to seasonal and recurrent outbreaks (e.g. annual cholera outbreaks in Africa and the dengue season in the Americas and Asia). To aid preparedness planning, **risk assessment can be used to identify at-risk areas or populations, rank preparedness activities, and engage key policy and operational partners**.

## How the manual was developed

A working group first met in Geneva, November, 2010 consisting of staff from WHO Country Offices, Regional Offices and Headquarters who were:

- responsible for event-based surveillance
- responsible for public-health event risk assessment across multiple hazards or specifically food safety or chemical hazards risk assessment
- experienced in leading outbreak responses
- experienced in delivering risk assessment training courses.

In addition, an animal health expert was involved in developing the manual and WHO risk communication and International Health Regulations (IHR) specialists were consulted.

A list of people who participated in the working group and subsequent telephone conferences is provided in Appendix 6.

## Terminology

In the context of this manual, an acute public health event is **any outbreak or rapidly evolving situation that may have negative consequences for human health and requires immediate assessment and action**. The term includes events that have not yet led to disease in humans but have the potential to cause disease through exposure to infected or contaminated food, water, animals, manufactured products or environments.

Terms used to describe risk differ between disciplines. In this manual, **risk is the likelihood of the occurrence and the likely magnitude of the consequences of an adverse event during a specified period**. A comparison of 'risk' terms used in important sectors and disciplines relevant to public health is provided in Appendix 1.

There are historical reasons why different disciplines use different terms when considering risk. As this manual focuses on acute public health events, where multidisciplinary and multisectoral inputs into the risk assessment may be needed, the terms used are a practical compromise that have been proven to work across disciplines and are defined in Appendix 2.

## The all-hazards approach and the International Health Regulations

An all-hazards approach has been used for many years in emergency and disaster management to describe natural, technological, or man-made events that require action to protect life, property, environment, and public health or safety, and to minimize social disruption.

It is applied to public health events that require **an immediate response and are potentially caused by more than one hazard** — **including biological, chemical and radionuclear hazards, whether naturally occurring** or as a result of an accident or deliberate release — and natural disasters such as fires, floods, other extreme weather events, volcanic eruptions, earthquakes and tsunamis.

This approach has been **driven by the International Health Regulations (IHR)**, which were revised in 2005 to reflect growth in international travel and trade, emergence or re-emergence of international disease risks, and threats posed by chemicals, toxins and radiation.

The IHR requires all States Parties to the Regulations to develop a set of core capacities in surveillance and response covering any “illness or medical condition, irrespective of origin or source that presents or could present significant harm to humans”.

Following a risk assessment, the Annex 2 decision instrument of the IHR are used by Member States to decide whether an acute public health event requires formal notification to WHO. The effective use of Annex 2 depends on each national authority and its IHR National Focal Point (NFP) carrying out risk assessments on public health events occurring within their territories.

**The IHR core capacity requirements for surveillance and response require Member States to develop a national (and, where possible, a sub-national) risk assessment capacity that is recognized as an integral part of the prevention, surveillance and response system.** The structure and location of this capacity, which may be a dedicated team or embedded into the existing prevention, surveillance and response system, will be country-specific.

Despite differences in how Member States might structure and locate their risk assessment capacity, WHO and all Member States should use a consistent, structured approach to the risk assessment of acute public health events. Recommended steps in such a structured risk assessment are outlined in the following sections.

## Detection and confirmation of a public health event

All Member States have surveillance systems that detect outbreaks of infectious diseases. As a result of the emphasis in the IHR on strengthening this core capacity, many Member States have expanded these systems to include public health events caused by other hazards. Surveillance systems detect public health events through:

- **Indicator-based surveillance:** The routine collection of pre-defined information about diseases<sup>3</sup> using case definitions (e.g. weekly surveillance of cases of acute flaccid paralysis). Predetermined outbreak thresholds are often set for alert and response.
- **Event-based surveillance:** The rapid collection of ad hoc information about acute public health events. Event-based surveillance uses a variety of official and unofficial information sources to detect clusters of cases with similar clinical signs and symptoms that may not match the presentation of readily identifiable diseases. Official sources include national authorities and other agencies such as the UN system. Unofficial sources include media reports, other unofficial public information (e.g. internet sites), reports from the public

Not all event reports and alerts generated through indicator and event-based surveillance systems describe real events, nor are all real events of public health importance. The number of 'false positives' (i.e. reported events that cannot be confirmed as real or when alert thresholds of indicator-based surveillance systems are exceeded but an outbreak does not result) depends on the objectives and design of the surveillance system and the organizational level at which the event is assessed.

Guidance should be developed to assist staff in the triage and assessment of newly detected events (see Box 1). Event triage uses the same principles for assessing the risk an event may pose to public health as the more formal risk assessment described in this manual.

### Box 1: Example of guidance to surveillance staff for triaging incoming signals from surveillance activities

Question	Answer
Has the event been reported by an official source (e.g. local health-care centre or clinic, public health authorities, animal health workers)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Has the event been reported by multiple independent sources (e.g. residents, news media, health-care workers, animal health staff)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Does the event description include details about time, place and people involved (e.g. six people are sick and two died three days after attending a local celebration in community X)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is the clinical presentation of the cases described (e.g. a cluster of seven people admitted to hospital with atypical pneumonia, of whom two have died)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Has a similar event been reported previously (e.g. with a similar presentation, affecting a similar population and geographical area, over the same time period)?	Yes <input type="checkbox"/> No <input type="checkbox"/>

Incoming signals are more likely to describe real events if there are one or more 'yes' answers to the questions tabled above.

3 The term 'disease' is used in its broadest sense, including syndromes.



If the event is detected quickly, initial information may be limited and non-specific. The initial triage process focuses on assessing the credibility of the incoming signal(s) and whether the event described is a potential risk to public health that warrants investigation. **The accuracy of the reporting of the event may be assessed at the same time. Confirmation of an event does not automatically mean that it presents a risk to public health.** Some events may have little or no effect on human health or may be related to chronic diseases or issues that do not pose an acute public health risk. As a result, different actions may result from the initial risk assessment (see Table 1).

**Table 1: Example of action taken as a result of triage and confirmation of an event**

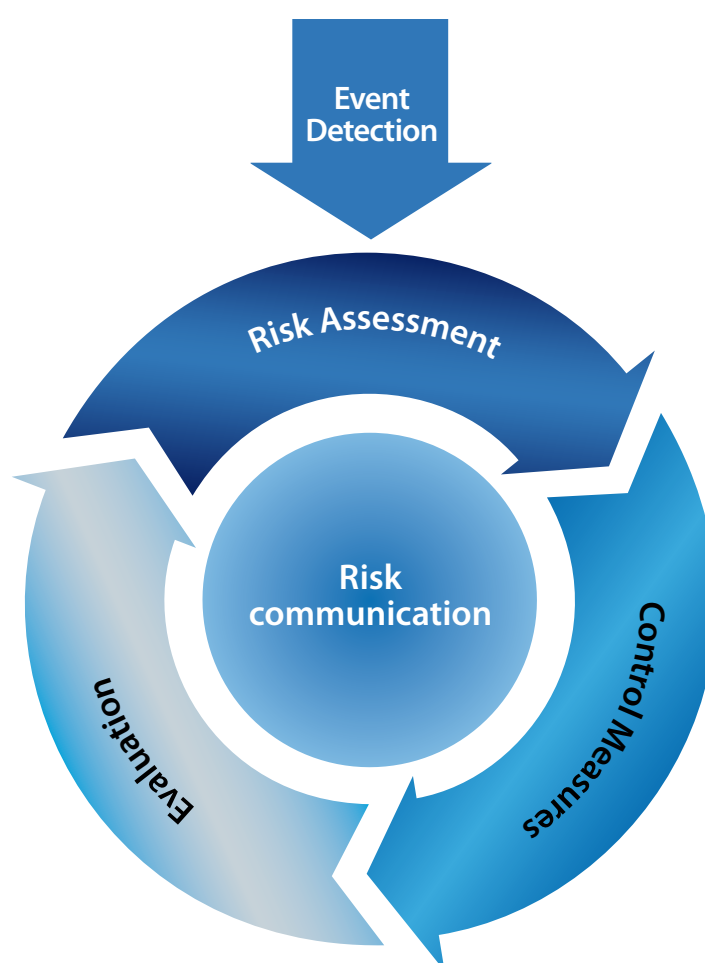
Outcome of triage and confirmation	Action
<b>Reported event is proved to be a false rumour</b>	<p>Discard the event</p> <p>Risk communication and media communication about the event may be needed to address the public perception of risk (e.g. smallpox rumours)</p>
<b>Event is confirmed but is not an immediate public health risk</b>	<p>Monitor the event and undertake risk assessments as new information becomes available</p> <p>Risk communication and media communication about the event may be needed to address the public perception of risk</p>
<b>Event is confirmed and may be considered an immediate public health risk</b>	<p>Undertake a full risk assessment and state the level of confidence in the assessment</p> <p>Provide recommendations for decision-makers, including which actions should be taken and which should have the highest priority (e.g. recommended control measures, key communication messages)</p> <p>Undertake additional risk assessments and modify recommendations for decision-makers as new information becomes available. The actions taken as a result of the risk assessments will differ at different organizational levels</p>

## Introduction to risk assessment

Risk assessment is a systematic process for gathering, assessing and documenting information to assign a level of risk. It provides the basis for taking action to manage and reduce the negative consequences of acute public health risks (see Figure 1). The risk management cycle includes:

- risk assessment — hazard, exposure and context assessment and risk characterization in which the level of risk is assigned to the event
- identification of potential control measures — ranked by priority, taking into account likelihood of success, feasibility of implementation and unintended consequences for the affected population and society more broadly
- continuous monitoring and evaluation as the event unfolds
- effective ongoing communication to ensure that risk managers, other stakeholders and affected communities understand and support the control measures that are implemented
- an evaluation of lessons learned at the end of the response.

**Figure 1: The risk management cycle**



## Steps in the risk assessment of public health events

### Assembling the risk assessment team

After confirming that a reported event is real and may be considered an immediate public health risk, its public health importance must be determined. **Depending on the quality and completeness of the information available to assess the risk, a risk assessment team may be assembled.** Deciding on the disciplines that should make up the risk assessment team is a critical step that is often overlooked. Additional expertise (e.g. in toxicology, animal health, food safety or radiation protection) can be brought in at any time but may be needed at the beginning of the risk assessment if:

- the hazard is unknown
- the event is unlikely to be caused by an infectious agent
- an event is associated with disease or deaths in animals, and/or is otherwise identified as a suspected zoonosis
- the event is related to a food or product recall, known chemical accident, or radionuclear incident with or without reports of human disease.

Operational communication and risk communication are integral parts of risk management. At a minimum, links should be established between the risk assessment team and communication specialists. If possible, a communication specialist should be included in the risk assessment team. Ensuring that there is good communication between decision-makers and the affected population from the start of the process will increase the likelihood of effective implementation of control measures, especially those requiring behavioural change.

The knowledge and expertise of the team greatly influence the risk assessment. Local knowledge about the environment in which the event is occurring is a critical component of risk assessment. The level of risk of an acute public health event depends on the social, economic, environmental and political conditions in the affected area and the effectiveness of local health services (e.g. curative and public health services). For some hazards, the effectiveness of links between health services and other responsible sectors and agencies (e.g. with the animal health sector for zoonotic diseases) may also affect the risk and must be assessed.

### Formulating risk questions

The risk assessment team should decide on the key questions to be answered. This helps to define the scope of the assessment and ensures that all the relevant information is collected. **Clearly defined questions help identify priority activities to be conducted** as part of the risk assessment. This may include literature reviews, epidemiological investigations, enhanced surveillance, consultation with disease experts, surveys and research.

A risk question is similar to a research question and typically focuses on:

- who is likely to be affected
- the likely exposure to a hazard
- when, why and how a population might be adversely affected by exposure to a hazard.

The questions asked by the risk assessment team will be influenced by factors including:

- the population at risk
- the level at which the risk assessment is taking place – local, sub-national, national, international (e.g. cross-border), or global
- the technical and policy disciplines and agencies that are included in the risk assessment team and their collective experience with the type of event they are assessing (e.g. a well-characterized disease compared to a public health event of unknown cause (unknown etiology))
- the level of risk accepted by decision-makers, other stakeholders and society (i.e. the acceptable risk)
- the timing of the risk assessment during the course of the event
- the outcome of previous risk assessments carried out for the event and similar situations in the past
- the level of perceived external (e.g. international community) interest or awareness of the event.

The team should not try to answer all the possible risk questions at once. Instead, critical questions should be identified and ranked by priority for immediate response. Less time-critical questions can be addressed later or by other teams.

The main question asked during acute public health events is, ‘what is the public health risk of the event’ (i.e. what is the risk related to exposure to a particular hazard in a particular location, or to a particular population at a particular time)?

This question often leads to others, such as:

- What is the likelihood of exposure to the hazard if no action is taken?
- What are the consequences (type and magnitude) to public health if the event were to occur?

Risk questions may be framed as a series of scenarios, such as:

- What is the public health risk of the event in the current situation?
- What is the public health risk of spread to a major city?
- What is the public health risk of the event affecting more than one area (province/state, country)?

Other examples of risk questions in response to different scenarios are shown in Table 2.

**Table 2: Examples of risk questions**

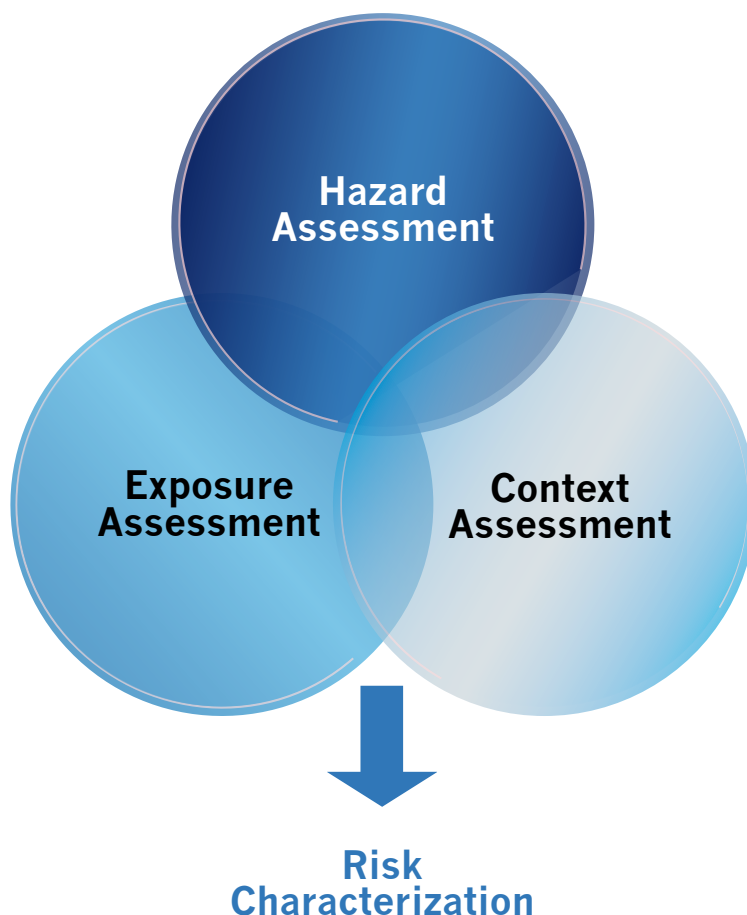
Example of event report	Risk question
<b>52 pigs died in two neighbouring farms over one to two days.</b>	Could this be a risk to human health?
<b>Clusters of people living with HIV/AIDS have suddenly become unresponsive to treatment.</b>	Which hazards could cause this event? For example: <ul style="list-style-type: none"> <li>• secondary infection</li> <li>• substandard medication (e.g. counterfeit drugs or loss of potency due to expired drugs)</li> <li>• drug resistance</li> <li>• availability of the drug (e.g. that leads to sharing medications or patients unable to access the medications)</li> <li>• patient adherence with treatment.</li> </ul>
<b>Pneumonia of unknown cause linked to deaths among health-care workers.</b>	What is the likely cause (etiology) of the pneumonia? What are the possible public health consequences?
<b>Two deaths and 16 suspected cases of cholera in a camp for internally displaced persons in a particular district.</b>	What is the likelihood of further spread of cholera? What would be the consequences if this occurred?
<b>Paediatric analgesic syrup formulated with diethylene glycol is identified after a cluster of deaths in children.</b>	Is this product marketed abroad, either formally or informally? What would be the consequences if this occurred?
<b>An outbreak of hand, foot and mouth disease (HFMD) in nursery school children in one of 14 regions in a country.</b>	What would be the effect on disease transmission of implementing quarantine in the affected region? How would implementing quarantine measures affect disease transmission? What would be the consequences of implementing quarantine in the affected region?

Based on the characteristics of the event, the risk assessment team should decide how frequently the risk assessment should be updated. The team should also agree on the priority questions and decide the time needed to complete each assessment. The time available between assessments may help to direct the number and scope of risk questions considered.

## Undertaking the risk assessment

The level of risk assigned to an event is based on the suspected (or known) hazard, the possible exposure to the hazard, and the context in which the event is occurring. Risk assessment includes three components — hazard, exposure, and context assessments. The outcome of these three assessments is used to characterize the overall level of risk (see Figure 2).

**Figure 2: The risk assessment process**



Completing a risk assessment is not always a sequential process with hazard, exposure and context usually assessed at the same time. Although each is assessed separately, there is overlap in the information required to assess each domain.

## Hazard assessment

Hazard assessment is the identification of a hazard (or number of potential hazards) causing the event and of the associated adverse health effects.

Public health hazards can include biological, chemical, physical and radionuclear hazards. Hazard assessment includes:

- identifying the hazard(s) that could be causing the event
- reviewing key information about the potential hazard(s) (i.e. characterizing the hazard)
- ranking potential hazards when more than one is considered a possible cause of the event (equivalent to a differential diagnosis in clinical medicine).

When there is a laboratory confirmation of the causative agent or the event is easily characterized on clinical and epidemiological features, hazard identification can be straightforward. In such cases the hazard assessment would start with a known or strongly suspected hazard. However, in all other cases hazard assessment starts with listing possible causes based on the initial description of the event (e.g. the clinical and epidemiological features), known burden of disease in the affected community, and type and distribution of existing hazards (e.g. the number and location of chemical plants and the chemicals they use).

Medical practitioners, nurses, veterinarians and others working in clinical settings will be familiar with the importance of the differential diagnosis in the process of assessing a patient; hazard assessment is similar.

The less specific the information reported about an acute public health event, the broader the list of possible hazards becomes. However, as more information becomes available, the number of potential hazards is reduced and they can be ranked in order of the likelihood of being the cause.

The relative likelihood of a hazard can be determined by:

- the clinical features and natural history of the disease in humans or animals
- timing of the event and the speed with which the event evolves
- geographical area and settings affected
- the persons and populations affected.

Table 3: Examples of questions to assess the likelihood of a specific hazard

Sample questions
<ul style="list-style-type: none"><li>• Does the suspected hazard (pathogen, toxin, contaminant etc.) cause the clinical signs and symptoms observed?</li><li>• Is the suspected hazard known to cause disease in humans or animals?</li><li>• Are the age group(s), sex or occupational group(s) affected typical for exposure to any hazards?</li><li>• Has the case(s) reported a history of recent travel?</li><li>• Is the time from presumed exposure to the onset of clinical signs and symptoms typical of a particular hazard or type of hazard?</li><li>• Is the severity of disease typical of a particular hazard or type of hazard?</li><li>• Does the disease respond to particular treatments (e.g. antibiotics)?</li><li>• Has the suspected hazard been diagnosed previously as the cause of disease at the same time of year, place or population?</li><li>• Have there been any associated or preceding events (e.g. disease or deaths in animals, food or product recalls, known accidental or deliberate releases of chemical, biological or radionuclear agents, similar events in neighbouring countries, etc.)?</li><li>• Do laboratory test results confirm a specific cause or are they consistent with a particular type of hazard?</li></ul>

Exposure assessment

Exposure assessment is the evaluation of the exposure of individuals and populations to likely hazards. The key output of the assessment is an estimate of the:

- number of people or group known or likely to have been exposed.
- number of exposed people or groups who are likely to be susceptible (i.e. capable of getting a disease because they not immune)

Information required to answer these questions includes:

- modes of transmission (e.g. human-to-human transmission by droplet spread or direct contact transmission; animal-to-human transmission)
- dose-response (e.g. some infectious agents, toxins, chemicals)
- incubation period (known or suspected)
- case fatality rate (CFR)
- estimation of the potential for transmission (e.g. R0, the basic reproduction number).
- Vaccine status of the exposed population

For some hazards a dose-response relationship is an important determinant of the magnitude of exposure. Examples include the inhalation or ingestion of heavy metals such as lead, the number of salmonella bacteria ingested or the amount of a radionuclear isotope ingested or absorbed. For such hazards, in addition to assessing the exposure, the duration of exposure may also be important. With infectious diseases, differences in exposure can occur within households (e.g. measles), among close contacts (e.g. SARS) and other social networks (e.g. sexually transmitted diseases), in occupational risk groups (e.g. hepatitis B, Rift Valley fever, Q fever), and among travellers (e.g. malaria).



For vector-borne diseases (see Table 5) and other zoonoses, information about the vectors and their animal hosts is needed to assess exposure. This might include the species, distribution and density of vectors of disease, and the species, distribution and population density of animal hosts. The exposure assessment will provide an estimate of the likelihood that a particular area is vulnerable to the transmission of a zoonotic disease.

## Context assessment

Context assessment is an evaluation of the environment in which the event is taking place. This may include the physical environment such as climate, vegetation, land use (e.g. farming, industry) and water systems and sources as well as the health of the population (e.g. nutrition, disease burden and previous outbreaks), infrastructure (e.g. transport links, health care and public health infrastructure), cultural practices and beliefs.

Those who are trained in scientific disciplines, such as medicine, food safety and veterinary science, tend to approach risk assessment from a relatively narrow scientific perspective (e.g. of identifying the hazard) and may not consider other factors that affect risk.

Context assessment should consider all factors – social, technical and scientific, economic, environmental, ethical, and policy and political – that affect risk. These factors, summarized in the term STEEEP<sup>4</sup>, can affect the level of risk by increasing or decreasing the likelihood of exposure or its consequences (Appendix 3).

Information (see Table 4) that helps to answer the following types of questions is a critical component of context assessment.

- What are the factors associated with the environment, health status, behaviours, social or cultural practices, health infrastructure and legal and policy frameworks that increase a population's vulnerability?
- Do any factors associated with the environment, health status, and social or cultural practices reduce the population's risk of exposure?
- What is the likelihood that all suspect cases can be identified?
- What is the availability and acceptability of effective preventive measures and of treatment or supportive therapies?

<sup>4</sup> Some authors express STEEEP as 'PEST analysis' (omitting the 'E' for environmental and for ethical); others add an 'E' for environment and an 'L' for legal and speak of PESTLE; while others add an 'E' for ethics to this and speak of STEEPLE.

**Table 4: Examples of the type of information that could be collected during a context assessment**

Source	Type of information	Output from the assessment
Surveillance system	<ul style="list-style-type: none"> <li>• Number of functioning reporting sites in the affected area</li> <li>• How suspected cases are identified</li> </ul>	The likelihood that cases will be identified
Health-care infrastructure assessments or reports	<ul style="list-style-type: none"> <li>• The number, location and quality of health-care facilities in the affected area</li> <li>• Health-seeking behaviour in the affected population</li> </ul>	The likelihood that cases will seek and receive medical care that results in good clinical outcomes
Nutrition surveys from NGO or government reports	<ul style="list-style-type: none"> <li>• Level of malnutrition in the affected area or among specific risk groups</li> </ul>	The likelihood of severe disease
Information on animals and vectors	<ul style="list-style-type: none"> <li>• Information on environmental conditions that might be favourable to population explosions of potential vectors of disease</li> <li>• Information on the number and distribution of potential animal hosts</li> </ul>	The likelihood of outbreaks in humans or animals

The vector-borne disease, Japanese encephalitis, has been used to illustrate possible sources of information for assessment of the hazard, exposure and context (Table 5).

**Table 5: Information sources used in assessing hazard, exposure and context of Japanese encephalitis**

Characteristic being assessed		Information sources
<b>Hazard assessment</b>		
<b>Viral factors</b>	Genotypes	Published literature on research in humans and animals
	Neurovirulence	E.g. Database of nucleotide sequences (Genbank)
	Antigenicity	Reference laboratory data
	Proliferation	
<b>Clinical factors</b>	Clinical presentation	Medical records (ICD-10 <sup>5</sup> ), hospital-based sentinel surveillance systems, laboratory surveillance systems
	Clinical progression	
	Severity	
<b>Exposure assessment</b>		
<b>Vector factors</b>	Distribution, density and host preference of competent mosquito vectors	Published data (e.g. entomological surveys), vector control programme data (e.g. entomological surveillance systems including mosquito trapping, detection methods for JE virus in pooled mosquitoes, pesticide susceptibility data)
<b>Host factors</b>	Epidemiology of infection and disease in humans and other mammals (dead-end hosts)	Published research, including seroepidemiological studies and outbreak investigations Indicator-based and event-based surveillance systems in endemic and epidemic-prone areas (human and animal) Medical records, hospital-based sentinel surveillance systems, laboratory surveillance systems International event-based surveillance systems, including the media aggregators Biocaster, GIDEON, GPHIN, HealthMap, EMM MediSys, ProMED Mail, RSOE EDIS, among others. Surveys of permanent neurological impairment in endemic areas Official data and reports from WHO, FAO and OIE, other UN agencies, non-governmental organizations (e.g. PATH), foundations, charities (e.g. SciDevNet), national government websites of endemic countries. WHO sites reporting outbreaks include the Disease Outbreak News, Weekly Epidemiological Record and the password protected Event Information Site for IHR National Focal Points and ShareGOARN Participatory epidemiology systems Case reports of illness in returning travellers
	Distribution and susceptibility of amplifying hosts (pigs and aquatic birds)	Aquatic bird population, density and distribution of domesticated and feral pigs close to human populations Sentinel pig surveillance data
	Susceptibility (age, population immunity, vaccination status, protection from cross-reacting antibodies e.g. dengue)	Medical records and chart audits (ICD-10 <sup>5</sup> , acute neurological syndrome, etc.)

Table 5 *continued*

Characteristic being assessed		Information sources
<b>CONTEXT ASSESSMENT</b>		
<b>Socio-economic factors</b>	Size of population at risk Agriculture and livestock management	Vital statistics Demographic data including household income data (e.g. census) – access to personal protective equipment to prevent mosquito bites Maps of population density Economic analyses of pig farming in endemic areas
	Human behaviour	Surveys and studies on community awareness of Japanese encephalitis virus transmission; prevention and control; cultural practices regarding pig farming; acceptability and uptake of Japanese encephalitis vaccination etc. International transport (vectors, live pigs)
<b>Ecological factors</b>	Climate	Meteorological data (rainfall, temperature, wind) Modelling data on climate variability, climate change (e.g. World Meteorological Organization)
	Mosquito breeding sites	Entomological surveys; maps of standing water sources; town plans, reports on environmental engineering controls of breeding sites Remote sensing data of vegetation coverage, e.g. NASA Earth Observatory, Global Observing Systems Information Center (GOSIC )
	Amplifying bird hosts	Mapping data on bird migration patterns, seasonality and size of wetlands
	Feral pigs	Wildlife monitoring systems; data from culling programmes etc.
<b>Program-matic factors</b>	Strength of the health system (access to acute care services, intensive care units, diagnostic capacity, surveillance systems, Japanese encephalitis vaccination programme, vector control programme, financial and human resources, political support for control programmes including coordination with agriculture, livestock and wildlife sectors etc.)	National health indicator data Routine programmatic data, annual reports, programme evaluation reports etc. Vaccination coverage data (published and rapid assessment, public and private health-care facility data etc.)

## Risk characterization

Once the risk assessment team has carried out the hazard, exposure and context assessments, a level of risk should be assigned. This process is called risk characterization. If there is no mathematical output from a quantitative model or comparison with a guidance value (e.g. in food safety risk assessments), the process is based on the expert opinion of the team.

A useful tool to assist the team is a risk matrix (Figures 3a and 3b) where estimates of the likelihood (see Table 6) are combined with estimates of the consequences (see Table 7).

As the majority of acute public health event risk assessments are qualitative, the categories used in the matrix are not based on numerical values but on broad descriptive definitions of likelihood and consequences (see Tables 6 and 7 and the legend for Figures 3a and 3b, which explains how to read the risk matrices).

When applying the matrix, the definitions of likelihood and consequence can be refined to fit with the national or sub-national context in each country.

Two styles of presenting the risk matrices are shown in Figures 3a and 3b. The choice of style of matrix depends on the team's preference; both styles serve as a visual tool to stimulate discussion and to help team members agree on a level of risk.

During discussions, team members should consider all types of consequences in addition to the expected morbidity, mortality, and direct long-term health consequences of the event (e.g. disability). This includes consideration of the STEEEP consequences (Appendix 3).

The risk matrix also helps to assess and document changes in risk before and after control measures are implemented. For some events, where information is limited and when the overall level of risk is obvious, the matrix may not be needed.

Figure 3a: A risk matrix showing clearly delimited boundaries between categories

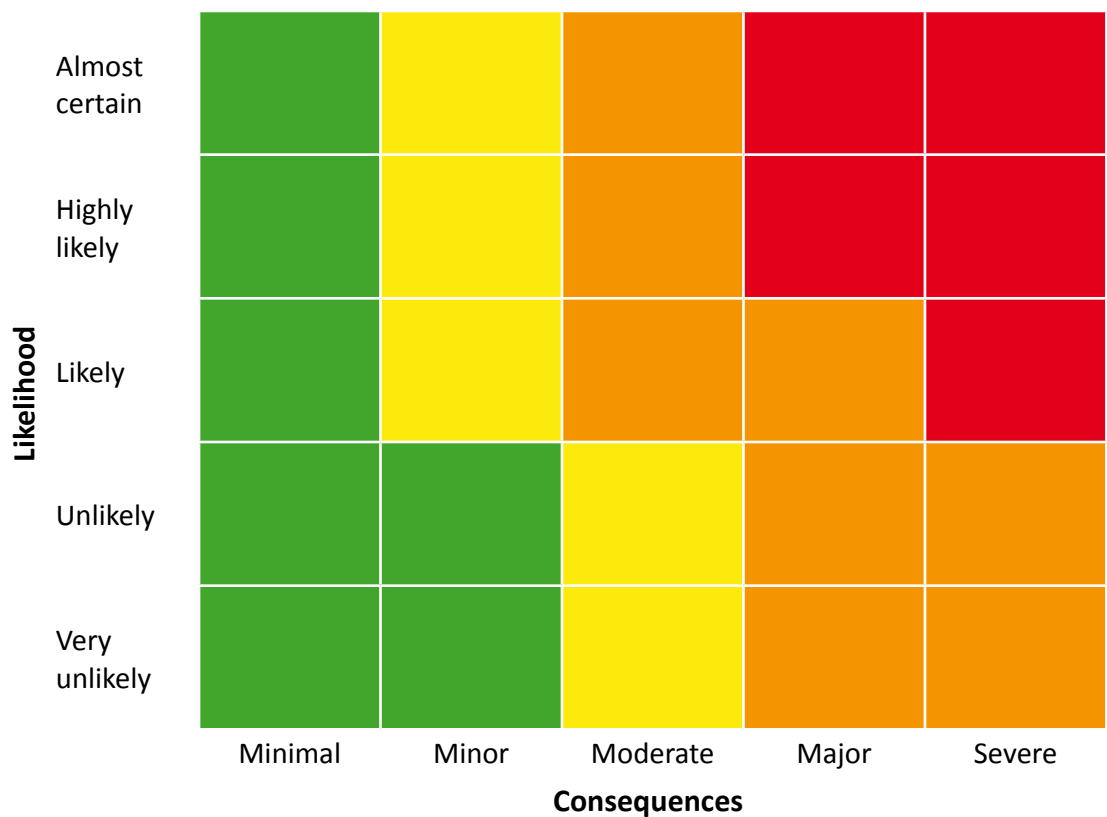


Figure 3b: A risk matrix without clearly delimited boundaries between categories

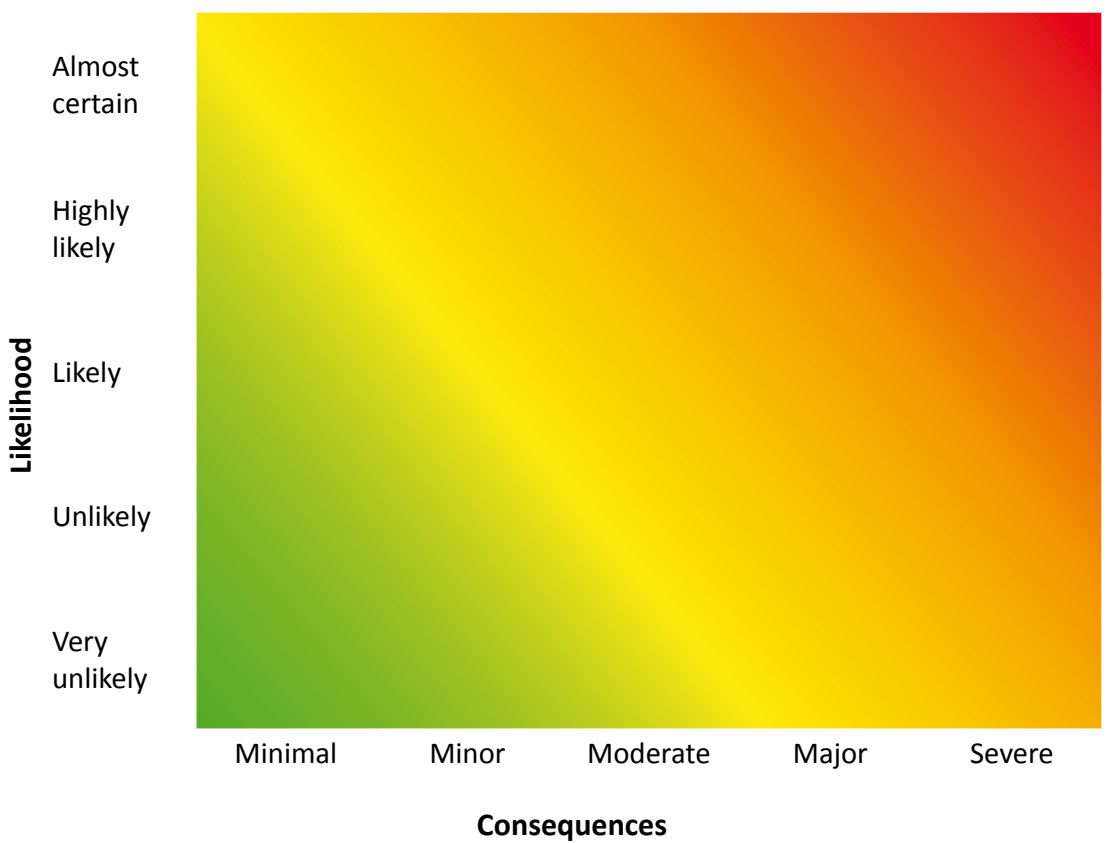


Table 6: How to read Figures 3a and 3b<sup>6</sup>

	Level of overall risk	Actions
	<b>Low risk</b>	Managed according to standard response protocols, routine control programmes and regulation (e.g. monitoring through routine surveillance systems)
	<b>Moderate risk</b>	Roles and responsibility for the response must be specified. Specific monitoring or control measures required (e.g. enhanced surveillance, additional vaccination campaigns)
	<b>High risk</b>	Senior management attention needed: there may be a need to establish command and control structures; a range of additional control measures will be required some of which may have significant consequences
	<b>Very high risk</b>	Immediate response required even if the event is reported out of normal working hours. Immediate senior management attention needed (e.g. the command and control structure should be established within hours); the implementation of control measures with serious consequences is highly likely

Table 7: Estimates of likelihood definitions<sup>7</sup>

Level	Definition
<b>Almost certain</b>	Is expected to occur in most circumstances (e.g. probability of 95% or more)
<b>Highly likely</b>	Will probably occur in most circumstances (e.g. a probability of between 70% and 94%)
<b>Likely</b>	Will occur some of the time (e.g. a probability of between 30% and 69%)
<b>Unlikely</b>	Could occur some of the time (e.g. a probability of between 5% and 29%)
<b>Very unlikely</b>	Could occur under exceptional circumstances (e.g. a probability of less than 5%)

<sup>6</sup> Adapted from WHO and FAO. *Risk Characterization of Microbiological Hazards in Food*. Microbiological Risk Assessment Series 17, World Health Organization and Food and Agriculture Organization, 1999. (<http://www.who.int/foodsafety/publications/micro/MRA17.pdf>).

<sup>7</sup> Adapted from WHO and FAO. *Risk Characterization of Microbiological Hazards in Food*. Microbiological Risk Assessment Series 17, World Health Organization and Food and Agriculture Organization, 1999. (<http://www.who.int/foodsafety/publications/micro/MRA17.pdf>).

**Table 8: Estimates of consequences definitions<sup>8</sup>**

Level	Consequences
<b>Minimal</b>	<p>Limited impact on the affected population</p> <p>Little disruption to normal activities and services</p> <p>Routine responses are adequate and there is no need to implement additional control measures</p> <p>Few extra costs for authorities and stakeholders</p>
<b>Minor</b>	<p>Minor impact for a small population or at-risk group</p> <p>Limited disruption to normal activities and services</p> <p>A small number of additional control measures will be needed that require minimal resources</p> <p>Some increase in costs for authorities and stakeholders.</p>
<b>Moderate</b>	<p>Moderate impact as a large population or at-risk group is affected</p> <p>Moderate disruption to normal activities and services</p> <p>Some additional control measures will be needed and some of these require moderate resources to implement</p> <p>Moderate increase in costs for authorities and stakeholders</p>
<b>Major</b>	<p>Major impact for a small population or at-risk group</p> <p>Major disruption to normal activities and services</p> <p>A large number of additional control measures will be needed and some of these require significant resources to implement</p> <p>Significant increase in costs for authorities and stakeholders</p>
<b>Severe</b>	<p>Severe impact for a large population or at-risk group</p> <p>Severe disruption to normal activities and services</p> <p>A large number of additional control measures will be needed and most of these require significant resources to implement</p> <p>Serious increase in costs for authorities and stakeholders</p>

<sup>8</sup> Adapted from WHO and FAO. *Risk Characterization of Microbiological Hazards in Food*. Microbiological Risk Assessment Series 17, World Health Organization and Food and Agriculture Organization, 1999. (<http://www.who.int/foodsafety/publications/micro/MRA17.pdf>)



## Level of confidence in the risk assessment

It is important to document the risk assessment team's level of confidence<sup>9</sup> in the assessment and the reasons for any limitations. This will depend on the reliability, completeness and quality of the information used, and the underlying assumptions made with respect to the hazard, exposure and context.

The more evidence there is to inform the hazard, exposure and context assessments, the greater confidence the team can have in the results. The degree of confidence can be expressed using a descriptive scale that ranges from very low to very high.

Table 9 shows two scenarios that illustrate how levels of confidence can be estimated. Example A describes detailed information based on a variety of sources, including first-hand reports from clinicians, sources with local knowledge, historical records and peer-reviewed articles. A risk assessment based on these data would have a medium-to-high confidence score. In contrast, example B describes an event reported in a newspaper article that has not been confirmed by any other source. Any risk assessment based on this information alone would have a very low or low confidence score.

**Table 9: Level of confidence in two risk assessments**

Example A - High level of confidence	Example B - Low level of confidence
Hazard assessment based on: <ul style="list-style-type: none"> <li>• a detailed clinical description of cases provided by hospital-based physicians</li> <li>• etiological (i.e. causative) agents known to have caused similar outbreaks in the previous two years</li> <li>• surveillance data</li> </ul>	Hazard assessment based on: <ul style="list-style-type: none"> <li>• a non-specific clinical description of cases reported in newspaper article</li> <li>• no historical data included in the report</li> </ul>
Exposure assessment based on: <ul style="list-style-type: none"> <li>• epidemiological investigation of the rapid response team</li> <li>• peer-reviewed articles and evidence from previous outbreaks</li> </ul>	Exposure assessment based on: <ul style="list-style-type: none"> <li>• the likely routes of transmission consistent with the clinical features reported in the media report (e.g. food- or water-borne transmission causing an acute disease with nausea, vomiting and diarrhoea)</li> </ul>
Context assessment based on: <ul style="list-style-type: none"> <li>• health-care system performance during previous outbreaks</li> <li>• external reviews</li> <li>• local sources: detailed information from local leaders and health authorities</li> </ul>	Context assessment based on: <ul style="list-style-type: none"> <li>• the knowledge and experience of a staff member in the risk assessment team</li> </ul>

<sup>9</sup> In some disciplines, the 'confidence' (or 'certainty') of an estimate is described as its reverse: its 'uncertainty' (see glossary of terms in Appendix 2).

## Box 2: Example of risk characterization — severe respiratory disease

**Event:** A cluster of 22 cases of severe respiratory disease with seven deaths in country X were admitted to hospital over the past 17 days. The event is occurring 8 km from the border and cases have been reported from three villages by a local health-care worker (HCW). The area is the poorest in country X and health infrastructure is limited. Many of the health care facilities charge a consultation fee and consequently the local population self-medicates during mild illness. There are also strong beliefs that ‘strange diseases’ are caused by sorcery.

**Risk question:** What is the likelihood of further spread of severe cases of respiratory disease and what would be the consequences (type and magnitude) to public health if this were to occur?

### Information used to assess the likelihood of further spread:

- cases are still being reported 17 days after the first known cases were detected
- the specific hazard and mode(s) of transmission have not been identified
- it is also likely that some cases are not being detected (e.g. mild cases are less likely to seek care from health services and are therefore not included in the official reports).

Therefore it is highly likely that further cases will occur if nothing is done.

### Information used to assess the consequences of further spread:

- the disease has a high case fatality ratio (even when under-reporting is taken into account)
- the health-care system is poor and the ability to treat the cases is already limited; new admissions will further stress acute care services and lead to worse clinical outcomes for hospitalized patients
- negative economic and social impact of the cases and deaths in the affected communities
- there is potential for unrest in communities because of cultural beliefs that sorcery is causing the deaths
- the event is occurring in a border area and could affect the neighbouring country.

Therefore the consequences if further cases occur will be **severe**.

Using the risk matrix to combine the estimate of the likelihood and the estimate of consequences leads to an estimate of the overall risk; in this case, the overall level of risk is **high**.

The confidence in the risk assessment is **low-medium**.

Although the report is from a local HCW, the information is limited and it is not clear if the HCW has examined the suspect cases or is reporting a rumour.

Often at the start of a series of assessments, the risk assessment team will face the type of scenario outlined in Example B. The risk assessment will then rely on the opinion of the team and the interpretation of the limited information available.

It should be emphasized that a risk assessment with very low or low confidence does not indicate a poor risk assessment; rather it reflects the information available when the risk assessment was undertaken and the limitations of the data. It is important to include the confidence level in any conclusions and recommendations of a risk assessment (see Box 2).

## Quantification in risk assessment

The degree of quantification that is possible in a risk assessment depends on factors such as the data available, how quickly the assessment is required and the complexity of the issues.

In some disciplines such as engineering, highly quantitative assessments are feasible. However, in the assessment of acute public health events a qualitative approach may be the only option, particularly early in an event when data are often limited or unavailable.

Even with biological risk assessments that might take much longer (e.g. in international trade, where major import risk analyses using large multidisciplinary teams might extend over several years), it is unlikely that reliable quantitative data are available for all steps in the risk assessment. In practice, many assessments use a mix of methods, using quantitative methods when numerical data are available and qualitative methods when they are not.

It should be emphasized that a quantitative risk assessment that uses poor data or inappropriate quantitative techniques can be far less scientific and defensible than a well-structured, more qualitative assessment. Appendix 4 provides some further information on issues related to quantification in risk assessment.

## Control measures

The outcome of a risk assessment should be used to direct proportionate control measures that reflect the risk. The overall level of risk assigned to the event helps identify the urgency and extent of the control measures needed.

Both risk matrices can also be used to rank control measures according to their effectiveness. For example, they can be used to rank the likelihood that a control measure will prevent further spread or dissemination of a hazard (see Table 10) and the consequences of applying each control measure (see Table 11).

**Table 10: The likelihood that a control measure will prevent further spread**

Level	Definition
Almost certain	Is expected to prevent additional cases in most circumstances
Highly likely	Will probably prevent additional cases in most circumstances
Likely	Will prevent additional cases some of the time
Unlikely	Could prevent additional cases some of the time
Very unlikely	Could prevent additional cases under exceptional circumstances

**Table 11: Consequences of implementing each control measure**

Level	Definition
<b>Minimal</b>	Limited social impact No ethical considerations No or very little economic impact No or very little political impact
<b>Minor</b>	Minor social impact Limited ethical considerations Limited economic costs Some political impact
<b>Moderate</b>	Moderate social impact Some ethical considerations Moderate economic costs Moderate political impact
<b>Major</b>	Major social impact Significant ethical considerations Major economic costs Major political impact
<b>Severe</b>	Severe social impact Considerable ethical considerations Considerable economic costs Severe political impact

The risk assessment team should consider the **STEEEP consequences** of each control measure (Appendix 3). In doing so, the team should be careful to consider all aspects of STEEEP and not just one set of consequences (e.g. limiting the assessment to only the technical and scientific or biomedical effects of a control measure).

Assessing the likely effectiveness and consequences of control measures helps to ensure that they are appropriate to the risk of harm. This type of assessment can help the team convince decision-makers of the most appropriate set of control measures and to assist in deciding on the level of acceptable risk.

**Generally, the control measures that are most likely to prevent spread or reduce adverse health and other STEEEP consequences** and that have minor to moderate negative consequences are the most acceptable. However, in exceptional circumstances where the event is determined as high risk (i.e. almost certain to happen with serious consequences) and/or there is a low level of confidence (i.e. a high level of uncertainty) requiring a cautious or precautionary approach, control measures that may have only a limited chance of preventing additional cases or spread of the hazard may be acceptable.

## Risk communication

Risk communication is an integral part of the risk management process and is described in more detail in Appendix 5. There are two equally important components to risk communication:

- **Operational communication:** The structured communication that organizations use to meet their work goals and strategic objectives, including coordination internally and with people and groups outside the organization. Operational communication occurs between the risk assessment team and relevant stakeholders (technical specialists and policy-makers at the relevant levels of government, other response agencies, the private sector etc.).
- **Communication with the public:** Communication to provide key findings from risk assessments at regular intervals. Regular communication helps to ensure that the public is informed of the nature and level of risks and the desired behavioural changes that can minimize them.

At the start of the risk assessment, the team should identify stakeholders. The communication strategy for each public health event should be agreed as soon as possible to ensure that there is two-way communication between the risk management team and stakeholders.

The strategy should include:

- how the team will provide regular feedback on the risk assessment, and in what format;
- clearly defined roles and responsibilities (e.g. focal points) for communications functions;
- how and in what format the information should be presented to stakeholders and the public.

## Monitoring and evaluation

A risk assessment should be repeated as new information becomes available. It may also be repeated on a regular timetable (e.g. daily in the early stages of an event, perhaps driven by a Minister who agrees to provide an update to other Ministers or to the media at a specific time each day).

Each time a risk assessment is undertaken for an event it builds on the previous assessment. Each risk assessment (including the data and information available at the time it was undertaken) should be documented. Such documentation is an important part of monitoring and evaluation of the process.

Depending on the size and complexity of a public health event, many risk assessments may be needed to address new and different risk questions as the event progresses. For some events, different risk assessment teams may be required to work collaboratively to assemble the information for a composite picture of the risk (e.g. clinical severity, transmission dynamics, and control measures).

At the conclusion of the event, all of the risk assessments should be formally reviewed. The systematic analysis of well-documented risk assessments identifies where improvements can be made in the management of acute public health events.

# APPENDIX 1:

## Glossary of terms used in this manual

<b>Acceptable risk</b>	The level of risk that is tolerated or accepted. Hazards must be monitored to identify changes that could increase the level of risk. Defining acceptable risk should take into account informed consent and that 'acceptability' is likely to vary markedly between different stakeholders, populations and locations, and may be culturally specific.
<b>Acute public health event</b>	Any event that may have negative consequences for human health. The term includes events that have not yet lead to disease in humans but have the potential to cause human disease through exposure to infected or contaminated food, water, animals, manufactured products or environments.
<b>Acute public health risk</b>	The risk of an acute event resulting in negative consequences for public health.
<b>Alert</b>	The first notification that a public health event with adverse consequences may occur or may be occurring.
<b>All-hazards approach</b>	An approach to emergency management that takes into consideration all possible hazards — including biological, chemical, and radionuclear, hazards and natural disasters (e.g. fires, floods, other extreme weather events, volcanic eruptions, earthquakes and tsunamis).
<b>Bias</b>	The systematic deviation of results or inferences that distort the view of what is actually occurring.
<b>Confidence</b>	Confidence describes how sure the assessment team is of an estimate. It reflects what some disciplines call the certainty or uncertainty around an estimate. Even with perfect information (i.e. no 'uncertainty'), natural variation ('variability') still exists.
<b>Confirmation</b>	The process of seeking evidence to confirm the accuracy of information. Also, the conclusion of such a process (i.e. the state when information has been verified).
<b>Consequences</b>	The downstream effects that result from an action or condition that may be negative or positive. A negative public health consequence causes or contributes to ill health. Consequences may include social, technical and scientific, economic, environmental, ethical, or policy and political effects.
<b>Context assessment</b>	Assessing the environment in which the event is taking place.
<b>Control measures</b>	Interventions put into place to reduce the effect of a hazard on the exposed population.
<b>Detection</b>	Finding through systematic means.
<b>Differential diagnosis</b>	A systematic method for attaining a diagnosis through consideration of health and vital statistics according to age, sex, or some other factor.

<b>Event-based surveillance</b>	The organized and rapid capture of information about events that are a potential risk to public health.
<b>Event report</b>	A report that systematically documents the time, person(s) and place (including context) associated with an event.
<b>Exposure assessment</b>	The evaluation of the potential exposures of individuals and populations to the hazards identified in the hazard assessment.
<b>False positive</b>	A positive test result in an individual who does not have the disease for which the test was undertaken.
<b>Hazard</b>	An agent that has potential to cause adverse health effects in exposed populations.
<b>Hazard assessment</b>	Identification of the hazard (or list of potential hazards) causing the event and of the associated adverse health effects.
<b>IHR</b>	The International Health Regulations (2005).
<b>IHR Contact Point</b>	WHO points of contact for communication from Member State IHR National Focal Points.
<b>IHR National Focal Point</b>	The national agency or institution designated to liaise with, and be accessible to, WHO and Member States at all times for the purposes of giving effect to the IHR.
<b>IHR reports</b>	Reports that are generated from or to Member States to comply with IHR for assessment and notification of events that may constitute a public health emergency of international concern.
<b>Indicator-based surveillance</b>	The routine collection of pre-defined information about diseases <sup>10</sup> using case definitions (e.g. weekly surveillance of cases of acute flaccid paralysis). There are often predetermined outbreak thresholds for alert and response.
<b>Infectious disease</b>	A disease caused by a specific infectious agent or its toxic products that arises through transmission of that agent or its products from an infected person, animal, or reservoir to a susceptible host.
<b>Likelihood</b>	The probability of an event occurring.
<b>NGO</b>	Nongovernmental organization.
<b>Outbreak</b>	An epidemic limited to localized increase in the incidence of a disease.
<b>Public health</b>	Health programmes and services characterized by planning and intervening for better health in populations, including understanding and reducing the risks of disease, disability and death.
<b>Precautionary approach</b>	Principle 15 of the Rio Declaration produced at the UN Conference on Environment and Development (UNCED 1992) codified the 'precautionary approach' for the first time at the global level. This approach indicates that lack of scientific certainty is no reason to postpone action to avoid potentially serious or irreversible harm to the environment. This principle has been adopted by some other sectors, including public health. Note that the term is not used in other sectors (e.g. import risk analysis, in which one may adopt a cautious or conservative approach but not a 'precautionary' one).

<sup>10</sup> The term 'disease' is used in its broadest sense, including syndromes.

<b>Reliability</b>	The degree of stability of results exhibited when a measurement is repeated under identical conditions.
<b>Risk</b>	The likelihood of the occurrence and the likely magnitude of the consequences of an adverse event during a specified period.
<b>Risk assessment</b>	A systematic process for gathering, assessing and documenting information to assign a level of risk. Risk assessment includes three components — hazard assessment, exposure assessment and context assessment.
<b>Risk communication</b>	Risk communication is the range of communication principles, activities and exchange of information required through the preparedness, response and recovery phases of a serious public health event between responsible authorities, partner organizations and communities at risk to encourage informed decision-making, positive behaviour change and the maintenance of trust.
<b>Risk management</b>	The process of weighing policy options in the light of a risk assessment and, if required, selecting and implementing appropriate intervention options, including regulatory measures. With respect to acute public health events, risk management is the process by which appropriate actions are taken to manage and reduce the negative consequences of acute public health risks.
<b>Risk statement</b>	A statement assigning the level of risk associated with the potential of an acute public health event. This statement should be accompanied by a statement of confidence in the level of risk.
<b>Sensitivity</b>	The proportion of actual positives that are correctly identified by a test (e.g. the percentage of sick people who are correctly identified as having a condition).
<b>Syndrome</b>	A group of clinical signs and symptoms that consistently occur together, or a condition characterized by a set of associated clinical signs and symptoms.
<b>Triage</b>	The process of determining if an event or alert detected by a surveillance system is a potential risk to public health and prioritizing it for action.
<b>Vulnerability</b>	A position of relative disadvantage. The extent to which an individual or population is unable or unlikely to prevent or respond to hazards.
<b>Zoonosis (plural: zoonoses)</b>	A disease transmissible between animals and humans.



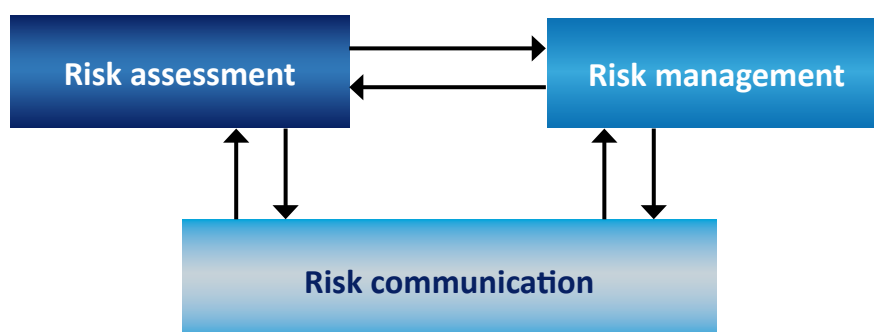
## APPENDIX 2: Definitions used by different sectors and disciplines

### Terms used in food safety risk analysis

The Codex Alimentarius Commission (or 'Codex') defines three components for food safety risk analysis (see figure below):

- risk assessment
- risk management
- risk communication

The three components of the Codex approach to food safety risk analysis



Codex uses the following definitions of terms in food safety risk analysis:

- **Hazard:** A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.
- **Risk:** A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard (or hazards) in food.
- **Risk analysis:** A process consisting of three components: risk assessment, risk management, and risk communication.
- **Risk assessment:** A scientifically based process consisting of the following steps: (i) hazard identification; (ii) hazard characterization; (iii) exposure assessment; and (iv) risk characterization.
- **Hazard identification:** The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.
- **Hazard characterization:** The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents that may be present in food. For chemical agents, a dose–response assessment should be performed. For biological or physical agents, a dose–response assessment should be performed if the data are obtainable.

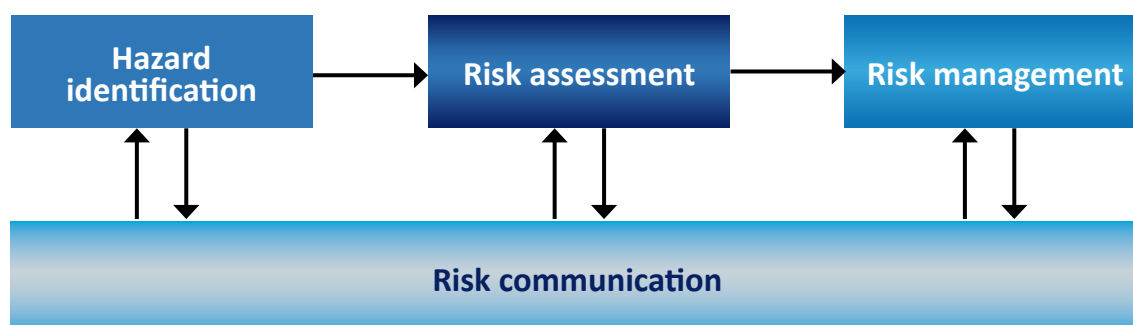
- *Exposure assessment*: The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.
- *Risk characterization*: The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.
- *Risk management*: The process, distinct from risk assessment, of weighing policy alternatives in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.
- *Risk communication*: The interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

## Terms used in import risk analysis

The Terrestrial Animal Health Code and the Aquatic Animal Health Code ('the Code(s)') of the World Organisation for Animal Health (OIE) describe four components in import risk analysis (see figure below):

- hazard identification
- risk assessment
- risk management
- risk communication

The four components of OIE's approach to import risk analysis



OIE uses the following definitions of terms in import risk analysis:

- *Hazard*: Any pathogenic agent that could produce adverse consequences on the importation of a commodity.
- *Risk*: The likelihood of the occurrence and the likely magnitude of the consequences of an adverse event to animal or human health in the importing country during a specified time period.

- *Risk analysis*: The process composed of hazard identification, risk assessment, risk management and risk communication.
- *Hazard identification*: The process of identifying the pathogenic agents that could potentially be introduced in the commodity considered for import.
- *Risk assessment*: The evaluation of the likelihood and the biological and economic consequences of entry, establishment or spread of a pathogenic agent within the territory of an importing country.
- *Risk management*: The process of identifying, selecting and implementing measures that can be applied to reduce the level of risk.
- *Risk communication*: Risk communication is the interactive exchange of information on risk among risk assessors, risk managers and other interested parties.

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## APPENDIX 3: Examples of the STEEEP consequences of an acute public health event and associated control measures

### Social

- Effects on individual cases placed in isolation, especially when hospitalized at a distance from their community
- Effects of restricted contact (e.g. for families visiting infected and seriously ill patients)
- Changes to important social or religious events (e.g. social distancing policies)
- Impact on lifestyle (e.g. changes to child care arrangements)
- Acceptability of the control measures by the affected community
- Social stigma from being a case of an infectious disease
- Psychological impacts

### Technical and scientific

- Morbidity, mortality and long-term disability
- Effectiveness of control measures
- Ability to implement control measures in a timely manner
- Side effects of treatment or prophylaxis

### Economic

- Direct financial costs for the preparedness and response agencies
- Direct financial costs of the response activities for the affected individual/families/communities (e.g. cost of treatments, health-care fees, loss of domestic and farmed animals)
- Indirect costs:
  - effect on individual and family ability to work (e.g. closure of schools, home isolation, hospitalization)
  - effect on household income
  - effect on the community income
  - effect on national economy
- The following should be considered at the local, national and international levels:
  - effect on travel and trade
  - effect on tourism

### Environmental

- Negative effects of control measures on the natural environment (e.g. contamination or residues)
- Positive effects on the natural environment (e.g. simultaneous control of other diseases such as might occur with vector control)

## Ethical

- Individual liberty (e.g. restricted movement)
- Unintended consequences (e.g. the removal of primary food sources for families when livestock is culled or contaminated crops destroyed and no alternative can be provided)
- Privacy
- Protection of the public from harm
- Use of unlicensed or unregistered drugs and vaccines
- Informed consent (i.e. that people understand what they are asked to accept or permit)
- Protection of communities and individuals from stigmatization (i.e. being regarded as unworthy or treated with disapproval)
- Proportionality (i.e. that control measures correspond to or reflect the risk)
- Duty to provide care (i.e. an obligation to provide safe, competent and ethical care to individuals or populations)
- Equity (i.e. being fair or impartial)
- Transparency (i.e. being open, obvious or evident)
- Unequal burden of risk (e.g. health-care workers, other first responders)

## Policy and political

- Views of senior management in a response or supporting organization (e.g. compatibility with other programmes and policies)<sup>11</sup>
- Diversion of resources from other programmes and projects to support the response
- Views of the Minister of Health and other Ministers
- Views of Opposition parties
- Imminent elections and other politically charged situations
- Likely response of the media and key stakeholder groups
- Governments unwilling or incapable to respond effectively (e.g. political oppression or armed conflict; provision of access to care of internally displaced people or refugees)

<sup>11</sup> These are sometimes called 'programmatic' risks.

## APPENDIX 4: Quantification in risk assessment

The degree of quantification used in a risk assessment depends on factors such as the information available, how quickly the assessment is required and the complexity of the issues.

Some literature implies that there are two methods for risk assessment: 'qualitative' (using no or few numerical data) and 'quantitative' (using numerical data and computer modelling). However, even the most quantitative methods rely on qualitative, subjective judgement to formulate models and estimate parameters. Equally, even the most qualitative methods involve an ordering of risks and outcomes that is quantitative in the sense that they reflect the rules of the mathematics of probability and formal logic.

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Structured formal risk assessment can use methods ranging from subjective reasoning based on descriptions of biological systems, to point-scoring systems, logical rules and Monte-Carlo simulation. Risk assessment can include methods that express inputs and results with varying degrees of numerical representation — that is, with varying degrees of quantification.

In some disciplines such as engineering, highly quantitative risk assessments are widely undertaken. Even in biological risk assessments that extend two or more years (e.g. in international trade, where major import risk analyses use large multidisciplinary teams), reliable quantitative data are unlikely to be available for all stages of the assessment. In practice, many assessments employ a mix of methods, using more quantitative methods when data are available and qualitative methods where they are not. In acute public health events a qualitative approach may be the only option, particularly early in an event when limited data are available.

Some methods use sensitivity analysis to determine if a particular parameter for which data are not available has a major effect on the overall risk. Such sensitivity analyses often show that there are only a few critical points in a pathway that have a significant effect on the overall risk. If good data are available on these points, the analyst can be confident that the assessment is robust. However, if good data are not available on these critical points, the analyst may use a less quantitative approach until appropriate research is conducted to obtain the data needed to undertake a more quantitative risk assessment.

Quantitative approaches are not necessarily better than qualitative approaches. A quantitative risk assessment that uses poor data or inappropriate techniques can be far less scientific and defensible than a more qualitative assessment. A well-structured and timely qualitative assessment is better than an incomplete and late attempt at a more 'quantitative' approach.

With respect to trade, all degrees of quantification are acceptable under the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), and the World Trade Organization (WTO) recognises the validity of even the most qualitative risk assessments when they are appropriate to the circumstances.

## Further reading:

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# APPENDIX 5: Risk communication

Risk communication is the range of communication principles, activities and exchange of information required through the preparedness, response and recovery phases of a serious public health event between responsible authorities, partner organizations and communities at risk to encourage informed decision-making, positive behaviour change and the maintenance of trust.

Risk communication is often listed last when it comes to risk management, which is not an accurate reflection of its importance. To be effective, risk communication needs to be planned and initiated early in a risk assessment and to continue as an iterative process throughout all phases of the assessment. If this does not happen, risk assessment is easily perceived as a process of expert risk assessors advising stakeholders of the result of their assessment and their proposed management strategies. This top-down approach implies that communication is largely one-way and ignores the need for consultation throughout the whole process. Poor risk communication can provoke outrage among stakeholders.

Problems in risk communication often arise because of the differences in world view between specialists and the public. These differences are reflected in the scientific and statistical language of specialists and the intuitive language of the public. The approaches are compared in the following table (adapted from Powell and Leiss, 1997)<sup>12</sup>.

## Expert and public assessments of risk

'Expert' assessment of risk	'Public' assessment of risk
Scientific	Intuitive
Focused on 'acceptable risk'	Focused on safety ('no risk')
Changes with new information	Tends to be fixed
Compares risks	Focuses on discrete events
Uses population averages	Focuses on personal consequences
'A death is a death'	'It matters how we die'

Good risk communication seeks to 'translate' these languages to achieve cooperative understanding between all parties.

12 Powell D and Leiss W. *Mad Cows and Mother's Milk: the perils of poor risk communication*. McGill-Queen's University Press, Montreal, 1997.



## Risk perception

Perceptions of risk by stakeholders and the public often align poorly with those held by expert assessors. A number of factors determine individual and group perceptions of risk. For example, analysis has shown that hazards perceived as unfamiliar or which provoke dread are assigned a higher risk than can be demonstrated statistically. Hazards with a low probability, which are regarded as having potentially catastrophic effects, are perceived as high risk and provoke strong public demands for government regulation and protection. Examples include a nuclear accident or the introduction of an unfamiliar disease that might be a zoonosis (e.g. ebola or nipah viruses), or the introduction of a known disease that might decimate native species. Risk assessors need to take account of these reactions in their communications with stakeholders and understand what provokes the feelings of these groups.

Even when good information is available on a hazard (i.e. where it is 'familiar'), the degree of trust given to the source of that information influences the perception of the risk. For example, surveys show that the public trust information from environmental groups or consumer organizations much more than that from government sources (and experts). Similarly, information provided by the media is trusted more than official government statements.

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## Lessons for good risk communication

The results of poor risk communication have been documented in a number of case studies such as the epidemic of bovine spongiform encephalopathy (BSE or 'mad cow disease'). Risk assessors, particularly those working on highly technical risk assessments, tend to focus on technical details. They may therefore be surprised to find their dedicated work on a risk assessment and their carefully reasoned recommendations for risk management provoke strong opposition. Leaving consideration of risk communication until late in the process, rather than involving stakeholders and the public early and often throughout the process, only increases the likelihood of such unfavourable reactions.

Powell and Leis (1997) defined 10 lessons in risk communication based on analysis of case studies of a range of animal health, food safety and public health issues:

- a vacuum in information on risk is a primary factor in the social amplification of risk
- regulators are responsible for effective risk communication
- industry is responsible for effective risk communication
- if you are responsible, act early and often
- there is always more to a risk issue than what the science says
- always put the science in a policy context
- 'educating the public' is no substitute for good risk communication practice
- banish 'no risk' messages
- risk messages should address directly the 'contest of opinion'
- communicating well has benefits for risk management.

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## **Rapid Risk Assessment of Acute Public Health Events**