EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

TECHNICAL REPORT

Operational tool on rapid risk assessment methodology

ECDC 2019

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Definition of terms

Epidemic intelligence	The process of detecting, verifying, analysing, assessing and investigating public health events that may represent a threat to public health. It encompasses activities related to early warning functions, integrating event and indicator-based surveillance and also signal assessments and outbreak investigation. Providing early warning signals is a main objective of public health surveillance systems.
Event-based surveillance	The organised and rapid capture of information about events that are a potential risk to public health. Information can be rumours and other ad hoc reports transmitted through formal channels (i.e. established routine reporting systems) and informal channels (i.e. media, health workers and nongovernmental organisations reports).
Evidence-based medicine (EBM)	The process of systematically reviewing, appraising and using clinical research findings to aid the delivery of optimum clinical care to patients.
Evidence-based practice (EBP)	Advocating for clinical decisions based on the best available evidence and emphasising well-conducted systematic research to inform decisions.
Hazard	Anything with the potential to cause harm. Note that the presence of a hazard does not automatically imply a threat.
Horizon scanning	The detection of incidents/events of potential threat to public health via systematic review of informal and formal reports.
Indicator-based surveillance	The routine reporting of cases of disease, including notifications of disease, sentinel surveillance, laboratory-based surveillance and syndromic surveillance.
Incident	A single case of a serious unusual illness that is of concern for public health, but since this cannot be technically termed an outbreak, it is instead referred to as an incident.
Outbreak	Said to occur when the number of cases observed is greater than the number expected over a given time period or two or more cases are linked by epidemiological, toxicological, microbiological or radiological features.
Public health threat	The occurrence of a hazard to human health.
Prevention	Measures aimed at reducing the likelihood of event occurrence.
Preparedness	Measures aimed at reducing the impact of event occurrence.
Response	Measures aimed at mitigating the public health impact resulting from the occurrence of an event.
Risk	Combination of the consequences (impact) of an event or incident (hazard/threat) and the associated likelihood (probability) of a harmful effect to individuals or populations.
Risk assessment	The overall process of risk identification, risk analysis and risk evaluation.
Risk identification	The process of finding, recognising and describing risks.
Risk analysis	The process of comprehending the nature of the risk and determining the level of risk.
Risk evaluation	The process of comparing the results of risk analysis with risk criteria to determine whether the risk and/or its magnitude is acceptable or tolerable.
Risk communication	The interactive transmission and exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and perceptions among assessors, managers, communicators, the general public and other interested parties (OIE - World Organisation for Animal Health definition).
Risk management	The process of identifying, selecting and implementing measures that can be applied to reduce the level of risk.
Threat	A potentially damaging event or incident.
Validation	Confirming the authenticity of an event or incident when reported by an informal source (professional communication, media blogs). Formal communication from national authorities is considered to be already validated.

1 Introduction to purpose and scope of document

Rapid risk assessments (RRA) are undertaken in the initial stages of an event or incident of potential public health concern while more comprehensive risk assessments, which often include the conduct of full systematic reviews, are produced at a later stage of an event, usually when more time and information are available. The operational goal for ECDC is that an RRA should be produced within a limited time frame.

The aim of this document is to provide an operational tool to facilitate the structured and reproducible development of rapid risk assessments for communicable disease incidents. The target audience is primarily experts responsible for the rapid assessment of communicable disease threats at the European level, although the document may also serve as a useful reference for experts with similar responsibilities at a national or subnational level.

The initial assessments of potential communicable disease threats can be complex and challenging as they must be produced within a short time period when information is often limited and circumstances can evolve rapidly. However, RRAs should still be based on the structured identification of key information from all readily available sources at the time in order to provide a clear estimate of the scale of the health threat while documenting the level of uncertainty.

A good RRA should be:

- consistent and transparent to ensure fairness and rationality
- easily understood by the intended target audience
- reproducible
- based on the best scientific evidence available at the time, well-documented and supported with references to scientific literature and other sources, including expert opinions
- regularly reviewed (may be done at preset intervals) and updated if needed when additional new information becomes available
- complemented by a log for decisions and actions based on available information; and
- contain a record of uncertainties (gaps in knowledge) and assumptions made in order to evaluate the effect of these on the final risk estimate and priorities for future research (dated and with version control).

2 Operational tool

The first step within ECDC after the decision to produce an RRA is to set up a response team. This team is in charge of producing the RRA and carries out all the different stages described in this chapter.

Box 1: Stages of rapid risk assessment

- Stage 1: Define the risk questions
- Stage 2: Collect and validate event information
- Stage 3: Literature search and extraction of evidence
- Stage 4: Appraise evidence
- Stage 5: Estimate risk.

Stage 1: Defining risk questions

It is important to clearly define risk questions before any further steps are taken. Prior definition of the scope of the assessment will ensure that all relevant information is collected and identifies priority activities to be conducted as part of the risk assessment.

The risk assessment should be performed separately for all specific population groups and geographical areas and should be considered in questions such as:

- What is the risk for specific population groups (e.g. migrants, immunocompromised people)?
- What is the risk of spread at the local, subnational, national, regional, EU and worldwide levels?

Stage 2: Collecting and validating event information

- Collating incident information is an essential first step in determining what further disease-specific information and evidence is needed for assessing risk.
- Ensure that detailed information on the incident is gathered, preferably from those responsible for investigating the incident at the local or national level. See Checklist 1 for relevant information to be collected.
- Incident information should be critically assessed and summarised for the risk assessment information table (Table 1). The type of information required may vary between incidents, but will generally include the items listed in Checklist 1.

Checklist 1: Incident/event information (this may vary or need supplementing according to incident)

- Who reported the incident/event?
  - name
  - organisation
  - contact details
- How has the incident/event been detected?
- What is the primary diagnosis?
- Has the aetiological agent been confirmed?
- Is this illness endemic in this country?
- What is known about exposure (means/mode of transmission)?
- Where have cases occurred? Are the cases clustered in time and/or space?
- Over what time period have cases been detected?
- Who are the cases? Are they from a particular social group or setting?
- How many cases have been detected?
- What are the symptoms experienced by the cases?
- Have any of the cases been seen by a specialist clinician? What is the working diagnosis and clinical findings? Case definition?
- Have specimens been taken? Where have they been sent for analysis? Which tests have been performed? Which tests are planned? When will results be available? What are the limitations of test results that need to be considered?
- Have there been any deaths? Are autopsy results available?
- Have the ambulance service, local hospitals and doctors (including private practice) been informed?
- Where are the cases being managed?
- What is being done to manage cases at the moment?
  - Which treatment if any has been instituted?
- Who else has possibly been exposed and may be at risk of developing this illness? Has a list of these persons been made?
- Are there any conditions occurring that may increase risks to others, e.g. healthcare workers exposed, ongoing incident, weather forecasts? What is being done to prevent the development of new cases at the moment? For example:
  - protection of emergency and healthcare staff
  - quarantine
  - prophylactic treatment
- Which agencies are involved at the moment? Obtain contact details. Has any agency declared a major incident? Who else has been informed?
- What measures have already been taken to address the situation?

Stage 3a: Performing structured literature search/systematically collecting information

Identify basic facts about the disease and the aetiological agent from a standard reference text. Refer to Checklist 2 for basic disease information that should be collected.

Checklist 2: Basic disease information/determinants

- Occurrence: time, place and person
  - geographical distribution – is the disease endemic in the country?
  - if not, what are the routes of introduction (food/vector/animal/human)?
  - seasonal/temporal trends
- Reservoir – if zoonotic, which species are affected and will animals be symptomatic?
- Susceptibility: specific risk groups at increased risk of exposure/infection
  - specific age groups (children, the elderly)
  - occupational groups
  - travellers
  - those with impaired immunity, (immunosuppressed/chronic disease, pregnant women); and
  - others (as a result of specific recreational or other activities)
- Infectiousness
  - mode of transmission
  - incubation period
  - period of communicability
  - length of asymptomatic infection
  - reproductive rate
- Clinical presentation and outcome
  - disease severity: morbidity, mortality, case fatality
  - complications/sequelae
  - specific risk groups at increased risk of severe disease/complications (children, the elderly, those with immunosuppression/chronic disease, pregnant women, occupational/recreational risks)
- Laboratory investigation and diagnosis
  - laboratory tests available
  - test specifications (sensitivity, specificity, positive predictive value, quality assurance) and limitations (cross-reactivity, biosafety concern)
- Treatment and control measures
  - treatment (efficacy)
  - prophylaxis (vaccination/other)
  - other control measures (quarantine, withdrawal of food product, culling animals)
- Previous outbreaks/incidents
  - novel transmission routes

Basic disease information from standard textbooks should be supplemented by searching published and grey literature (including outbreak reports and surveillance data, guidelines and disease fact sheets – it is particularly important to ensure consistency with any up-to-date ECDC fact sheets). When time and resources are limited, a preliminary literature search should be undertaken to identify key literature in the subject area, but there will inevitably be a trade-off between time and sensitivity. Particular attention should be given to filtering results, i.e. choice of subjects, time frame and restricting to 'review' articles – most citation databases can filter searches this way. A trained information specialist or librarian can identify the best way to use these options in databases and retrieve appropriate records according to the questions. It should be acknowledged that a comprehensive systematic review will not be possible in the early stages of an RRA, but the need for such a review should be considered at a later stage when time and resources permit.

Stage 3b: Extracting relevant evidence

Complete the information table (Table 1) that provides supporting evidence underpinning the RRA. If there are high-risk groups identified, an information table should be completed for the general population and each of the groups identified as being at increased risk of exposure, infection or adverse outcome. This is because the risks are likely to be very different in various groups. The information table also acts as a template (log record) for recording the evidence and its quality and documents sources, gaps and uncertainties, which are an integral part of the assessment process.

Where gaps in knowledge are identified and further information is required, formulate key questions and seek an expert assessment of the conclusions from the evidence if possible.

- Identify and seek advice from key experts, including public health, microbiology, infectious disease and other disease-specific experts or specialists:
  - within country – previously identified national experts or through personal contacts/national public health body websites; and
  - internationally – through reports of previous outbreaks (ProMED, EWRS, IHR, websites), disease-specific networks (e.g. ECDC Food- and Waterborne Diseases and Zoonoses network, NoroNet, European Influenza Surveillance Network), through ECDC's candidate expert database or through other national or international public health bodies, e.g. CDC and WHO).
- Responses to key questions should be sought ('unpack' the expert knowledge) and where possible distinguishing where this is based on:
  - previous experience
  - opinion; and
  - knowledge of evidence base (ask for key references and sources in published and grey literature).

If necessary, ask the expert to identify other experts from outside their group they would recommend to be consulted (with contact details if possible). The information table should be updated as further information becomes available, ensuring document control.

Stage 4: Appraising evidence

The quality of evidence is assessed as the level of confidence in the veracity of the information or data that has been used and depends on the source, design and quality of each study or piece of information. Unlike evidence-based medicine, where a systematic review of (usually) large bodies of evidence is undertaken using established frameworks for assessing quality, evidence may be limited in RRA, particularly those related to emerging infectious diseases, and there may be a need for greater reliance on observational studies, including outbreak/case series and reports and specialist expert knowledge. Even for many well known infectious disease threats, observational data are often the main or only available body of evidence.

While there are extensive frameworks for assessing the quality of scientific evidence that are used in the production of more comprehensive evidence-based risk assessments and guidance, it is not often practicable to apply these in full in the time frame available for producing an RRA. However, a minimum level of quality assessment should consider at least the following factors:

- method of generating data and study design (analytical epidemiology vs. descriptive)
- strength of association
- evidence of a dose-response relationship; and
- consistency with other studies/expert opinion.

Ideally, an RRA should not rely on a single study or piece of evidence. There should be a cautious approach to the interpretation of information if only one research group reports on an infection or disease association in multiple publications. Poor evidence or information should not be used for the RRA unless this is the only data available. In any case, uncertainties should be documented in the information table.

Triangulation is a widely used technique in qualitative research to address internal validity by using more than one method of data collection to answer a research question. The body of evidence should be considered as a whole and the triangulation of evidence should confirm or refute the internal validity of findings. Triangulation of evidence, including specialist expert knowledge, may be important to reach a consensus. Ensure a minimum of two to three data sources and agreement between them (i.e. two experts or an expert and literature). Sources of evidence and agreement between these (or their absence thereof) should be clearly stated in the information table.

Based on consistency, relevance and external validity of the available and relevant information, it is the responsibility of the designated lead expert in the response team to grade the evidence used according to the following categorisation:

- good – further research is unlikely to change confidence in the information.
- satisfactory – further research may have an impact on confidence in the information and change the assessment.
- unsatisfactory – further research is very likely to have an impact on confidence in the information and likely to change the assessment.

Stage 5: Estimating risk

Once the quality of evidence has been assessed, the completed information table is then used to assess the risk posed by the threat with the risk assessment algorithms. The overall risk is defined as a combination of the probability and impact of the health threat (Figure 1). Therefore, the probability and impact is first assessed separately (Figures 2.1–3, Table 1), then combined to assess the overall risk (Figure 4).

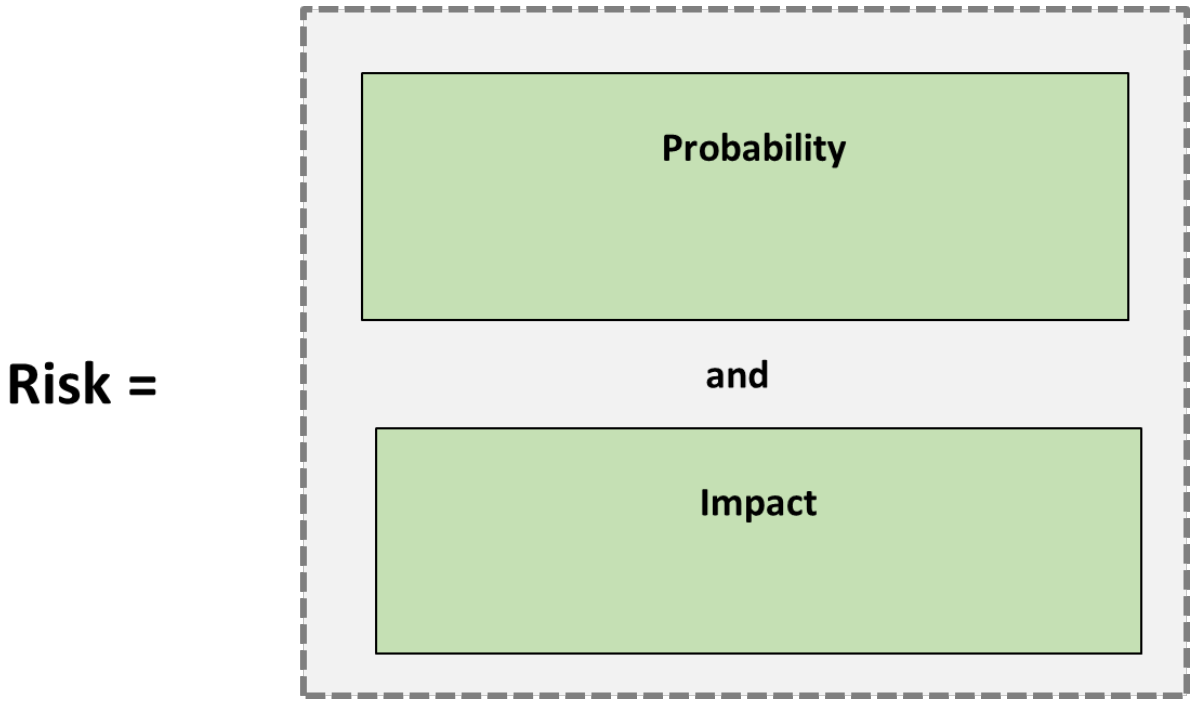
This approach makes use of all available information collected in the respective table to assess the level of risk and also aids the identification of gaps in knowledge. It may be difficult to rapidly assess a potential threat when certain information necessary to inform the risk process is unknown. This uncertainty is documented and managed in the algorithms by adopting a precautionary approach, a proportionality principle and moving through the algorithm to a higher level of risk.

Assessing the probability and impact separately avoids oversimplification and provides a more accurate assessment in situations where there is a high-probability low-impact disease or a low-probability high-impact disease, while the resulting individual risk levels can be combined into a single overall risk level using the risk ranking matrix (Figure 4).

The approach should be applied to the general population, then repeated for groups at increased risk of exposure, infection or adverse outcome in which risk may be very different or for geographical areas where the risk may be different.

It should be noted that the RRA may change over time in light of new information or events and should be updated accordingly.

Figure 1: Risk=probability and impact



Algorithms for assessing probability and impact

This approach uses three separate algorithms (the probability of infection in the EU, the probability of infection of EU citizens outside the EU and the likely impact) of infection together with the risk ranking matrix to produce an overall risk level (Figures 2–4) to be used with reference to information from Table 1. The algorithms are described below:

- The probability of infection in the EU (Figure 2.1) depends on the availability of routes of introduction, probability of exposure, population susceptibility and probability of transmission.
- The probability of infection of EU citizens outside of the EU (Figure 2.2) depends on the probability of exposure, susceptibility and probability of transmission.
- The impact of infection (Figure 3) depends on several factors including the:
  - severity of disease in the population/risk group; includes morbidity, mortality and burden of disease
  - number of people affected; and

  - availability of interventions that may alter the course and influence the outcome of the event in terms of containing, reducing or eliminating the transmission of the organism; includes treatment, prophylaxis and other control measures.
- The risk ranking matrix (Figure 4) combines the individual levels of risk to produce an overall score.

Contextual factors such as public concerns and expectations, the media and political pressures should also be considered in risk assessments. They may be difficult to assess and are therefore better considered separately. While they do not necessarily alter risk in absolute terms, they may alter the perception of risk and should be mentioned in the RRA.

The final step for both options is to consider the level of confidence in assigning risk (Box 2). This is based on the quality of evidence (i.e. good, satisfactory, or unsatisfactory) assigned to each question in the information tables. Confidence in assigning risk should be documented as follows:

Box 2: Level of confidence

Quality of evidence	**Confidence**
Mostly unsatisfactory	Unsatisfactory (little poor quality evidence, uncertainty/conflicting views among experts, no experience with previous similar incidents)
Mostly satisfactory	Satisfactory (adequate quality evidence, including consistent results published only in grey literature; reliable source(s), assumptions made on analogy and agreement between experts or opinion of two trusted experts)
Mostly good	Good (good quality evidence, multiple reliable sources, verified, expert opinion concurs, experience of previous similar incidents)

Table for probability and impact algorithms

Table 1: Information table for rapid risk assessment to support risk ranking algorithm

If high-risk groups are identified, a separate information table should be completed for the general population and each of the groups identified as at increased risk because the risks are likely different in various groups.

Probability and impact algorithms To be completed if the evaluation of initial information necessitates a rapid risk assessment	
Public health issue: Risk being assessed: Date of rapid risk assessment: DD/MM/YYYY Scope of rapid risk assessment: Summary of incident:	Probability: refer to assessment risk ranking tools (Figures 2.1,2.2) Impact: refer to assessment risk ranking tools (Figure 3) Outcome of risk assessment: refer to risk matrix (Figure 4)
	Confidence: (Good/satisfactory/unsatisfactory)

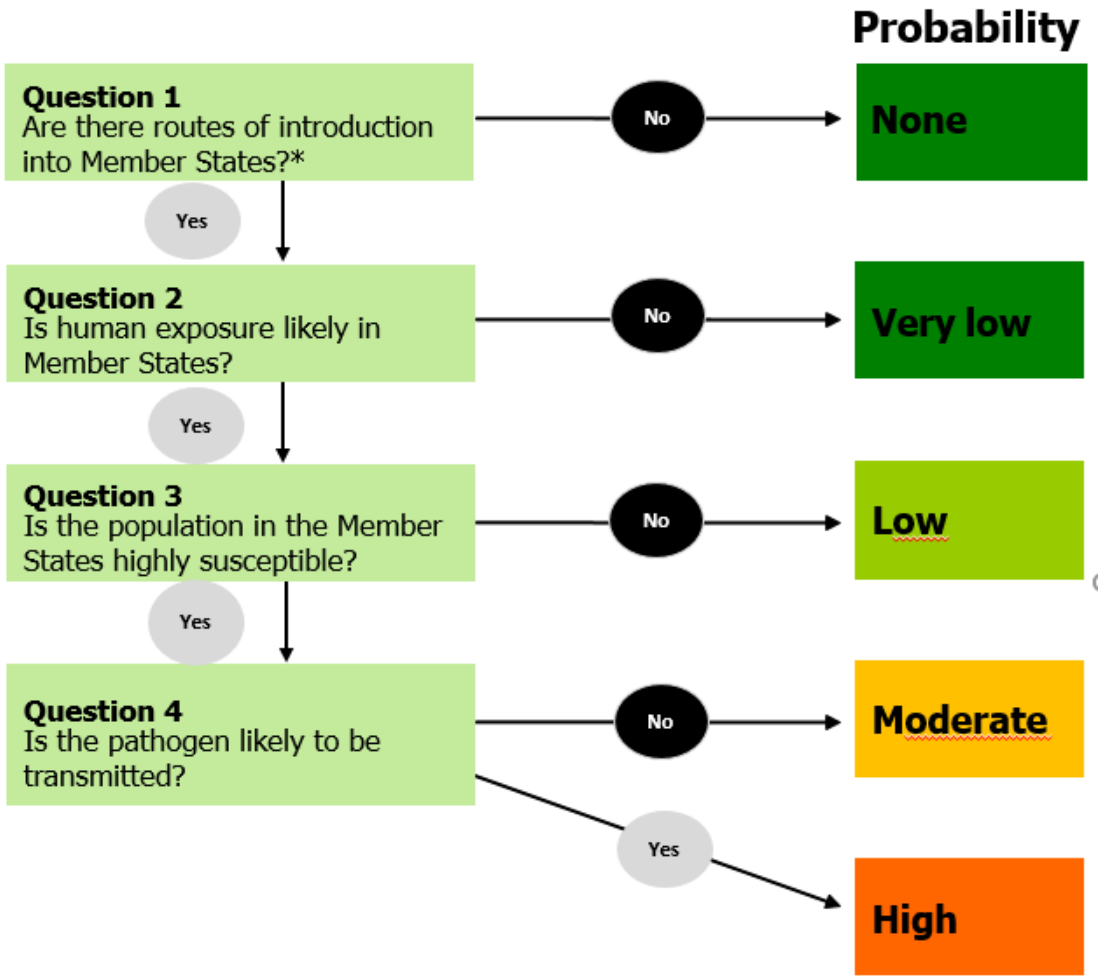
Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence	Quality of evidence	Comments (including gaps, doubts and uncertainties)
Probability of infection (probability of transmission) within the EU or for EU citizens abroad					
1. Are there routes of introduction into Member States? Categorisation as: Yes/No	• Consider availability of route of introduction/ spread, size of susceptible population and likely number of cases. • Routes of introduction may include humans, animals (bird/insect vectors), food or other trade products.				
2. Is human exposure likely in Member States? (Or in case of EU citizens outside of the EU, are they likely to be exposed?) Categorisation as: Yes/No	• Consider infectivity and infectiousness • Examples include widely distributed and consumed food products or a vector-borne disease with a high population density of competent vectors.				
3. Is the population in the Member States highly susceptible? (Or is the exposed individual/group/community highly susceptible in case of EU citizens outside of the EU?) Categorisation as: Yes/No	• Consider the size of the susceptible population (immunity) and likely number of cases. • Examples include the emergence of a novel influenza strain or hepatitis A in an unvaccinated community in a non-endemic country.				
4. Is the pathogen likely to be transmitted? Categorisation as: Yes/No	• Consider factors relating to infectivity and infectiousness, e.g. mode of transmission, period of communicability, reproductive rate. • Examples include measles, influenza and chickenpox (diseases for which the categorisation is likely to be "yes".				
Impact (severity of disease in population/group)					
5. Is severe disease likely in this population/group? Categorisation as: Yes/No	• Consider morbidity, mortality, case fatality, and burden of disease. • Examples of severe disease include those with long-term sequelae and/or high case fatality ratio, e.g. rabies, Ebola, meningococcal disease, MDR-TB, diphtheria or polio.				

Question/parameter	Parameters to consider	Evidence for categorisation	Source of evidence	Quality of evidence	Comments (including gaps, doubts and uncertainties)
6. Will a significant number of people be affected? Categorisation as: Yes/No	• Consider specific risk groups, direct and indirect risk, mode of transmission, reproductive rate, size of susceptible population and likely number of cases. • Examples include diseases where large numbers are exposed and infected, e.g. a novel influenza strain, or chickenpox in a non-immune population.				
7. Are effective treatments and control measures available? Consider other factors that may affect these (feasibility, acceptability). Categorisation as: Yes/No	• Consider effective treatment, prophylaxis and whether logistics are in place to deliver. • Examples of effective treatment and control measures include those where intervention is of clear benefit and relatively easy to implement, e.g. withdrawal of contaminated food product in closed institution, chemoprophylaxis for close family contacts of meningococcal disease.				

Probability and impact algorithms with risk matrix

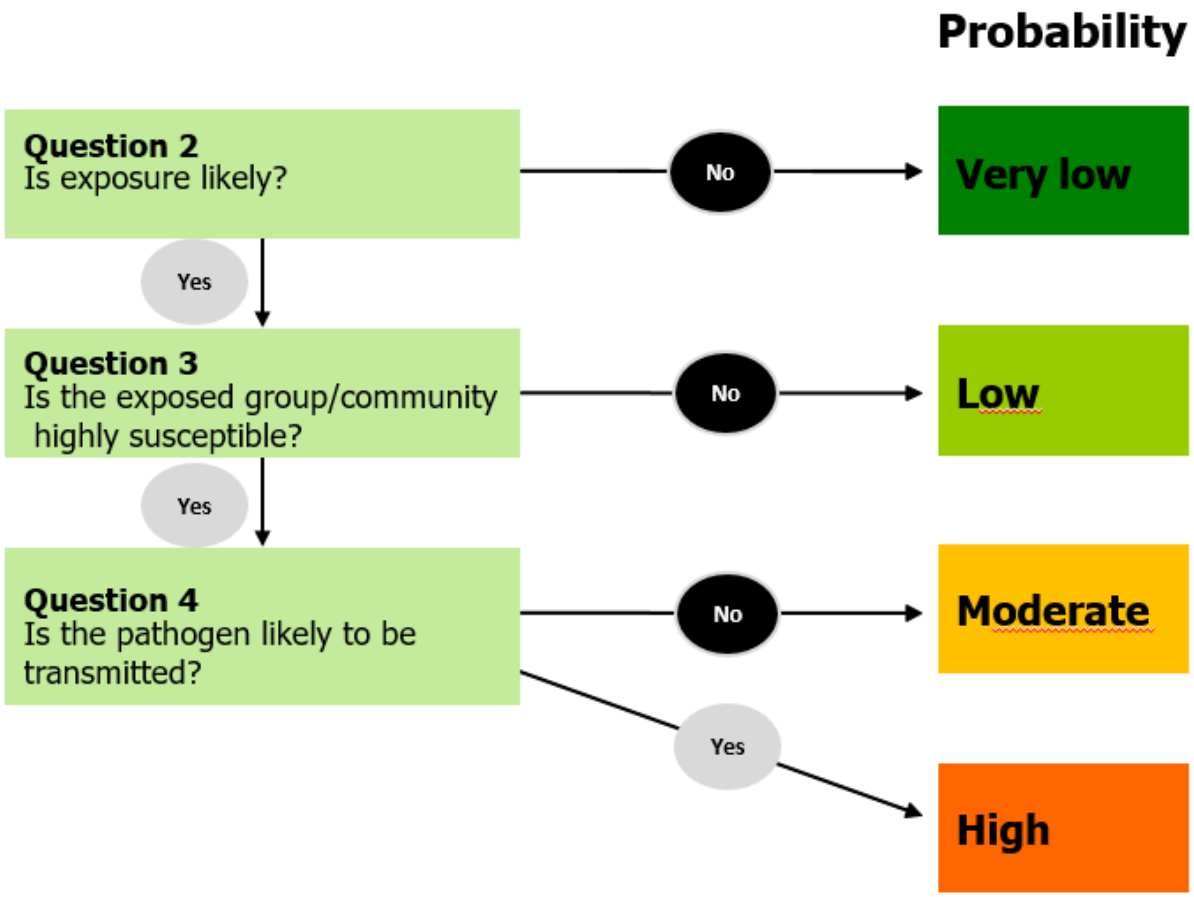
The following algorithms are based on the questions in Table 1. If there are specific groups at increased risk of infection or different risks for different geographical areas, conduct separate risk assessments: one for the general population and one for each risk group or different geographical area.

Figure 2.1: Probability of infection/transmission in the EU



**: If the event is already in an EU Member State, the question refers to introduction into other Member States. If the event is outside of the EU, the question refers to introduction into one or more Member States.*

Figure 2.2: Probability of infection/transmission to EU citizens outside the EU[1]



[1] Question 1 is irrelevant since this algorithm is for EU citizens outside of the EU, so no routes of introduction into the EU are needed.

Figure 3: Impact (severity of disease in population/group)

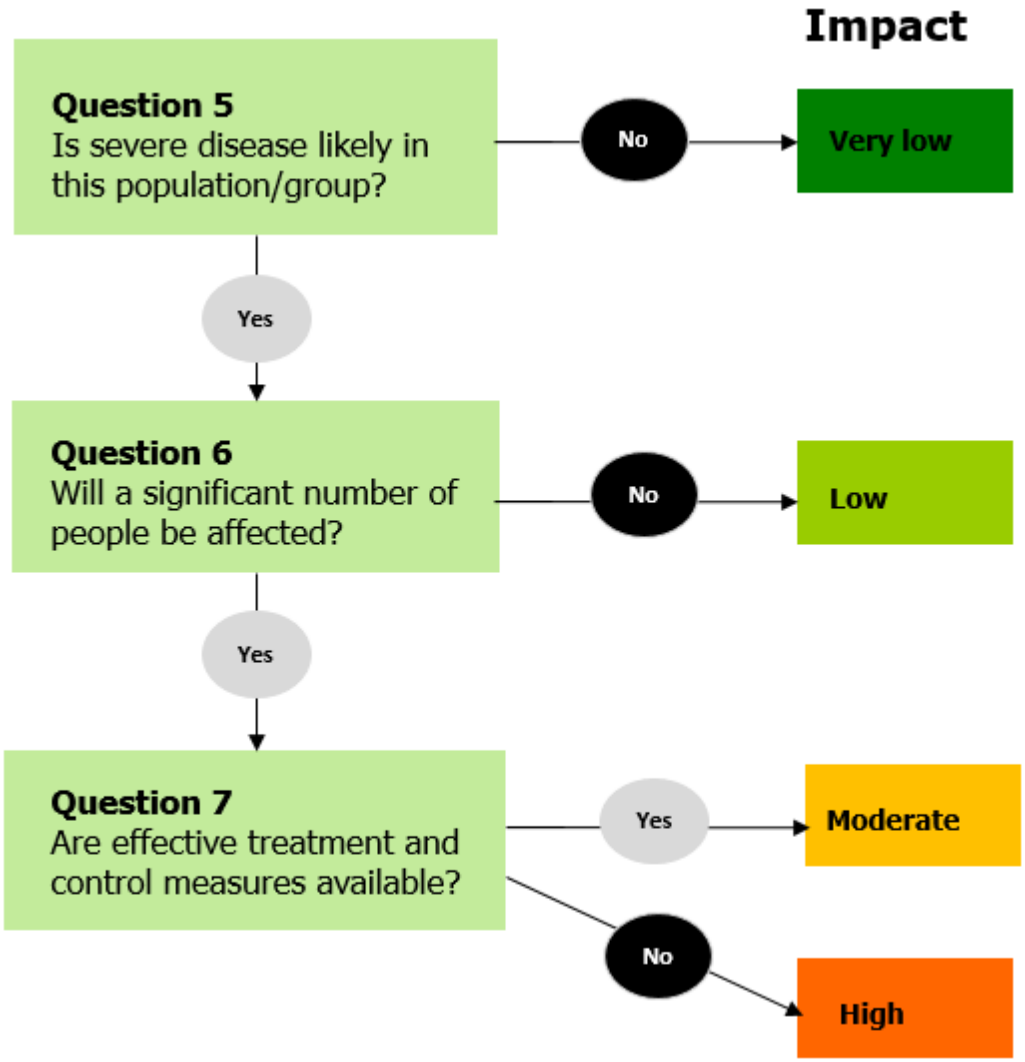


Figure 4: Risk-ranking matrix

Impact \ Probability	None	Very low	Low	Moderate	High
Very low	None	Very low risk	Low risk	Low risk	Moderate risk
Low	None	Low risk	Low risk	Moderate risk	Moderate risk
Moderate	None	Low risk	Moderate risk	Moderate risk	High risk
High	None	Moderate risk	Moderate risk	High risk	Very high risk

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