Human Animal Infections and Risk Surveillance (HAIRS) group

Processes of risk assessment

Date: 19 November 2018
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About the Human Animal Infections and Risk Surveillance group

This document was prepared by Public Health England (PHE) on behalf of the joint Human Animal Infections and Risk Surveillance (HAIRS) group.

This cross-government group is chaired by the PHE Emerging and Zoonotic Infections section. The HAIRS group acts as a forum to identify and discuss infections with potential for interspecies transfer (particularly zoonotic infections).

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Introduction

Since the Human Animal Infections and Risk Surveillance (HAIRS) group was established in early 2004, there has been a steady evolution and development of the risk assessment processes used by the group. The initial methods and sources used for identifying, assessing and reporting potential threats were developed to fulfil the functions of the Chief Medical Officer’s National Expert panel on New and Emerging Infections (NEPNEI). Thus, all activities were agreed and approved by the NEPNEI panel. NEPNEI was disbanded in 2012 and HAIRS now reports to the Advisory Committee on Dangerous Pathogens (ACDP). HAIRS members also report to their Government Ministries and Agencies.

This paper summarises the multi-step processes (Figure 1) used by the group in the assessment of new and emerging threats of potential significance to the health of the UK public.

Figure 1. Overview of steps taken as part of a HAIRS risk assessment process

1. Hazard identification
2. Hazard review
   - Information assimilation
   - Preliminary review
   - Determination of action(s) required
3. Risk assessment
   - Evidence gathering
   - Assessment of the zoonotic risk or probability of infection in the UK population
   - Assessment of the UK human health impact
4. Risk management options
5. Risk communication
Hazard identification

Potential hazards (either potential zoonotic agents/syndromes or emerging infections) are identified by members of the HAIRS group. These can include incidents or reports identified through epidemic intelligence activities, acute clusters and outbreaks or increasing trends of known infections/syndromes and reports of new infections or undiagnosed syndromes.

Members of the group also act as a focus through which concerns of their respective agencies or organisations can be considered by the group. Epidemic intelligence activities undertaken by individual agencies and organisations will vary depending on individual remit; however, they will incorporate monitoring of a wide range of official reports, scientific publications and unofficial sources (such as grey literature and media reports).

Depending on the perceived urgency of the situation, issues highlighted by members or significant results of epidemic intelligence activities are either disseminated within the group via email for immediate consideration, or are distributed with meeting papers and discussed as a standing agenda item at the next monthly meeting.

All potential hazards discussed by the HAIRS group are recorded by the secretariat in the “Issues Discussed Log” and are reviewed at the face-to-face meetings.
Hazard review

A three-step process is used by the group to review newly identified hazards:

**Step 1 – Initial information gathering**

A brief overview of all currently available information on the identified hazard is assembled by the secretariat with the assistance of appropriate members. This summary of assimilated information is provided to all members for consideration ahead of further discussions (see following steps). For novel or emerging agents there is usually limited information so parallels with related agents and/or expert opinion are often important at this early stage to ensure that the most appropriate information is considered.

**Step 2 – Preliminary review**

The group reviews the summary information and discusses further actions as required. This may be done by email or by teleconference or if it can wait, at a scheduled monthly meeting. If required, external subject matter experts can be consulted at this, and further stages (see below). If the initial review suggests that there may be major implications from the hazard, then this is immediately summarised and escalated and an expert group may be convened.

**Step 3 – Determination of actions required**

Following the initial review, a consensus decision is reached by members on the most appropriate action required:

a) Only record hazard in log

If the identified hazard is not considered a significant risk to public health, the hazard is recorded in the issues discussed log. The group may decide to take no further action and “sign off” the hazard, or the group may continue to monitor the situation and literature on the agent to ensure there are no emerging issues.

b) Risk review statement

A risk review statement is undertaken when:

- the information available is insufficient for a formal risk assessment or
- a comprehensive risk assessment was not deemed necessary at the time
HAIRS risk assessment processes

- an urgent assessment of the risk is required before a formal assessment can be carried out. In this case, an interim risk review statement may be produced while the full risk assessment is completed. See appendix A for HAIRS risk review statement template

c) Formal risk assessment

If a risk assessment is deemed necessary, it is carried out by the most appropriate member(s) of the group in consultation with the rest of the HAIRS group and, if appropriate, recognised external experts. Agreed algorithms to assist in the risk assessment have been developed to provide uniformity to the process. These are the Zoonotic Potential and Emerging Infections algorithms. The most appropriate algorithm is used for the hazard under assessment.

If neither of the above algorithms are considered appropriate for the hazard under review, a descriptive qualitative risk assessment can be undertaken.
Risk assessment

Gathering evidence

A full systematic review of the scientific literature is undertaken for each risk assessment, guided by questions within each of the respective algorithms. All sources used in determining the risk are recorded and included in the document.

For assessments for which there is insufficient information from traditional sources (e.g., peer-reviewed literature), expert opinion is sought at an early stage. Personal experience and expert opinion may be included in the risk assessment document but the source is very clearly documented.

Case reports, non-peer reviewed studies and other grey literature may be included, but this is clearly distinguished from other evidence sources.

An assessment of the quality of evidence (above) is undertaken for all risk assessments (see appendix B), and this allows for a degree of confidence in the estimation of risk to be clearly stated.

Risk assessment algorithms

The risk assessment algorithm used for each identified hazard is circumstance dependent (see below). A fixed set of questions is applied to risk assess identified hazards. Using the guidance of the algorithm, the evidence to support answers to each question is recorded in information tables with full referencing. For both sets of algorithms the probability of either zoonotic risk or infection in the UK population, as well as the potential impact on the UK public health, are reported separately to offer greater clarity of the nature of the risk.

Zoonotic potential and UK threat assessment algorithms

The zoonotic potential risk assessment algorithms are used for either (a) newly identified animal pathogens or (b) animal syndromes for which an aetiological agent has not yet been identified.

a) Qualitative assessment of the zoonotic potential of an identified animal pathogen

This algorithm is used for assessing the risk of newly described, emerging or re-emerging animal diseases for which the aetiological agent has been identified as infectious.
b) Qualitative assessment of the zoonotic potential of a novel animal syndrome of unknown aetiology

This algorithm is used for assessing the risk of newly described, emerging or re-emerging animal syndromes for which the aetiological agent has not yet been determined. If, following initial assessment, the aetiological agent is determined as infectious in nature, the risk assessment is repeated using the algorithm determining the zoonotic potential of an identified animal pathogen.

For both algorithms, if the agent or syndrome is regarded as potentially zoonotic (level 2 or above), a qualitative UK public health threat assessment is also completed to assist in determining further actions required.

These algorithms were implemented in October 2018 (see appendix C for full details). Prior to this, the algorithm described in the scientific literature by Palmer and colleagues in 2005 was used (1).

Emerging infection and UK impact assessment algorithm

The emerging infections risk assessment algorithm is used for recognised emerging zoonotic or other emerging infections. The algorithm assesses the likelihood of the agent causing infection in the UK human population, as well as its potential impact on the health of the UK population. The requirement for this risk assessment is normally triggered by a change in either the epidemiology of the disease (eg emergence, re-emergence or increased incidence), the pathogenesis of the agent (eg increases in associated human morbidity and/or mortality), or host specific factors (eg newly recognised host or increasing geographical range).

The algorithm have been in use since 2005 (see appendix D for full details) and has been described in the scientific literature by Morgan and colleagues in 2009 (2).

Conveying uncertainty

If a question in an algorithm cannot be conclusively answered by a yes/no response, then evidence for both answers should be provided in the information tables and following precautionary principles, the algorithm should be continued until a decisive answer is attained. Uncertainty in the response is differentiated from a conclusive answer by the use of hatching in the algorithm.

Assessing the level of confidence in the assessment

Once the algorithm has been completed, the level of confidence in the assessment of risk is assessed by examining the quality of evidence in the information tables which
HAIRS risk assessment processes

underpin the risk assessment (appendix B). The level of confidence in the assessment is presented on the front cover of each risk assessment document.
**Risk management options**

The actions taken following the completion of a risk assessment will be proportionate to the level of risk (appendix E).

For issues assessed as low risk or for which direct action is not warranted, the group may “sign off” or “risk manage” the incident, eg through alerting at risk groups or developing and issuing guidance, or continue to monitor the situation and reassess the risk at appropriate intervals.

For incidents assessed as being of a higher potential threat to public health, the group will alert policy makers and other cross-government groups to the need for risk management action.

In circumstances in which the evidence used to assess the risk is deemed unsatisfactory, the output is reviewed by the group and management decisions are made on a case-by-case basis.

Members of the group will act as points of contact for the agencies and departments responsible for risk management. Thus, the HAIRS group may not act directly as risk managers but may contribute advice and expertise to the risk management process.
Risk communication

Communication of risk assessments may take various forms dependent upon how the potential risk was raised, the determined risk or the context surrounding the situation/incident. Risks assessed as high are immediately escalated and communicated.

All risk assessments and risk statements are agreed and signed off by HAIRS members.

HAIRS members are responsible for the distribution and alerting of risk assessments and statements within their respective agencies or organisations. In certain circumstances, an abridged version of the full risk assessment may be deemed most appropriate for wider distribution.

Risk assessments for which there is good enough evidence to support the outcome are placed in the public domain on the HAIRS group webpage on the GOV.UK website.

Completed risk assessments are communicated to ACDP and the UK Zoonoses, Animal Diseases and Infections Group (UKZADI), and the UK Public Health Network for Zoonoses as appropriate. For specific situations, a narrative risk statement or summary may be appropriate.

In addition, summary versions of risk assessments are also published in the public domain in the HAIRS group annual reports.
Risk review and revision

If significant changes in the epidemiology or knowledge base affecting the risk rating are reported, the risk assessment will be reviewed by HAIRS members. If appropriate, the choice of algorithm used reviewed.

Otherwise, to ensure the information in the risk assessments remains current, all assessments are reviewed at annually, and updated using any new information and evidence.

The date the risk assessment was completed (or the most recent review and update), the version, and if appropriate, the reason for the update, is clearly noted on all risk assessment documents.
Bibliography

Appendix A: Risk review statement template

HAIRS risk review

Topic

Note: a risk review is undertaken in circumstances where (a) insufficient information is currently available to perform a comprehensive risk assessment or (b) a comprehensive risk assessment was not deemed necessary at this time.

Date of review by HAIRS group:
Version:
Prepared by:

<table>
<thead>
<tr>
<th>SUMMARY OF RISK STATEMENT FOR xxxxxxx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overview</td>
</tr>
<tr>
<td>Assessment of the risk</td>
</tr>
<tr>
<td>Level of confidence in assessment of risk</td>
</tr>
<tr>
<td>Action(s)/Recommendation(s):</td>
</tr>
</tbody>
</table>

Background

Possibility of human exposure

Risk to human health

The probability of human infection in the UK is therefore considered xxxxxxx.

The potential impact on human health is therefore regarded as xxx.

Recommendations

References
Appendix B: Assessing the quality of evidence and confidence in the risk

Table 1. Determining the quality of evidence used to estimate the risk

<table>
<thead>
<tr>
<th>Quality of evidence</th>
<th>Examples of types of information or evidence</th>
</tr>
</thead>
</table>
| **Good**            | ▪ peer reviewed published studies where design and analysis reduce bias e.g. systematic reviews, randomised control trials, outbreak reports using analytical epidemiology  
▪ text books regarded as definitive sources  
▪ expert group risk assessments, or specialised expert knowledge, or consensus opinion of experts  
▪ established surveillance systems by recognised authoritative institutions |
| **Satisfactory**    | ▪ non peer reviewed published studies/reports  
▪ observational studies/ surveillance reports/outbreak reports  
▪ individual (expert) opinion |
| **Unsatisfactory**  | ▪ individual case reports  
▪ grey literature  
▪ individual (non-expert) opinion |

Table 2. Determining the confidence of the risk assessment output using the quality of assessment score

<table>
<thead>
<tr>
<th>Quality of evidence</th>
<th>Confidence</th>
</tr>
</thead>
</table>
| Mostly ‘unsatisfactory’ | **Unsatisfactory**  
(little poor quality evidence, uncertainty/conflicting views amongst 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 2 trusted experts) |
| Mostly ‘good’ | **Good**  
(good quality evidence, multiple reliable sources, verified, expert opinion concurs, experience of previous similar incidents) |
Appendix C: Zoonotic risk algorithms

Identified animal pathogen

Zoonotic risk algorithm

Threat assessment for UK public table

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>OUTCOME</th>
<th>QUALITY OF EVIDENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the animal host or vector present in the UK?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has the syndrome been detected in animals and/or humans in the UK?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the UK population susceptible? (consider immunity and innate resistance)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Would a significant number of individuals be exposed or affected?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are effective interventions available?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Summary of threat assessment

-
Novel animal syndrome of unknown aetiology

Zoonotic risk algorithm

Threat assessment for UK public table

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>OUTCOME</th>
<th>QUALITY OF EVIDENCE</th>
</tr>
</thead>
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<tr>
<td>Is the animal host or vector present in the UK?</td>
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<tr>
<td>Has the syndrome been detected in animals and/or humans in the UK?</td>
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<td></td>
</tr>
<tr>
<td>Is the UK population susceptible? <em>(consider immunity and innate resistance)</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Would a significant number of individuals be exposed or affected?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are effective interventions available?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of threat assessment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- If a pathogen is identified at any stage, use risk assessment algorithm for known pathogens

- Level 0: Non human syndrome
- Level 1: Comparable human syndrome with no apparent epidemiological evidence of zoonotic association
- Level 2: Syndrome with potential zoonotic association
- Level 3A: Syndrome with zoonotic association
- Level 3B: Significant syndrome with zoonotic association
- Level 4: Significant syndrome zoonotic link
Appendix D: Emerging infection algorithm

Probability algorithm

Impact algorithm

*This question has been added to differentiate between those infections causing severe disease in a handful of people and those causing severe disease in larger numbers of people. "Significant" is not quantified in the algorithm but has been left open for discussion and definition within the context of the risk being assessed.*
## Appendix E: Risk management options

Table 3. Expected action following assessment of the Zoonotic Risk of an Identified Animal Pathogen

<table>
<thead>
<tr>
<th>Level</th>
<th>Descriptor</th>
<th>Considerations</th>
<th>Actions</th>
</tr>
</thead>
</table>
| 0     | Non-human pathogen | At this stage, consider microbiology investigations to establish:  
- RNA/DNA stability  
- risk of reassortment  
- virulence factor  
- phylogenetic relationship  
- cross-species spread | Share collated information and output of risk assessment with the UK Veterinary Risk Group |
| 1     | Human infection with no zoonotic risk | At this stage, assess the ability of the surveillance system to detect evidence of infection. Consider expanding the system of detection if necessary. If evidence of infection present but no obvious zoonotic link, consider setting up studies to ascertain exposure risk factors | Share collated information and output from risk assessment with appropriate public health bodies |
| 2     | Zoonotic infection | After zoonotic infection identified, establish how it manifests in humans. | Assess threat to UK population. Revisit risk assessment if further clinical information becomes available. Share collated information and output of risk assessment with relevant government agencies. |
| 3A    | Zoonotic pathogen | Assess the severity of infection in humans and establish appropriate clinical disease surveillance | Assess threat to the UK population. Consider risk communication and methods of reducing exposure of humans to affected animals and potential environmental sources. Share collated information and output of risk assessment with relevant government agencies. |
| 3B    | Significant zoonotic pathogen without person-to-person transmission | Assess the risk of person-to-person transmission | |
| 4     | Significant zoonotic pathogen with person-to-person transmission | Assess threat to UK population. Consider risk communication and methods of reducing person-to-person transmission and exposure of humans to affected animals and potential environmental sources. Share collated information and output of risk assessment with relevant government agencies. |
Table 4. Expected action following assessment of the Zoonotic Risk of a Novel Animal Syndrome of Unknown Aetiology

<table>
<thead>
<tr>
<th>Level</th>
<th>Descriptor</th>
<th>Considerations</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Non-human syndrome</td>
<td>At this stage, explore whether there is any disease in humans that would produce a similar clinical picture to this novel disease.</td>
<td>Share collated information and output of risk assessment with the UK Veterinary Risk Group so other aspects associated with this threat that need specific risk assessment and/or management are appropriately pursued.</td>
</tr>
<tr>
<td>1</td>
<td>Comparable human syndrome with no apparent epidemiological evidence of zoonotic association</td>
<td>At this stage, assess the ability of the surveillance system to detect any increase of cases. Consider expanding the system of detection if necessary and set up enhanced surveillance.</td>
<td>Share collated information and output of risk assessment with the UK Veterinary Risk Group and appropriate UK public health bodies so other aspects associated with this threat that need specific risk assessment and/or management are appropriately pursued.</td>
</tr>
<tr>
<td>2</td>
<td>Syndrome with potential zoonotic association</td>
<td>Establish any zoonotic link with the disease</td>
<td>Assess threat to UK population. Revisit risk assessment if further clinical information becomes available. Share collated information and output of risk assessment with relevant government agencies.</td>
</tr>
<tr>
<td>3A</td>
<td>Syndrome with zoonotic association</td>
<td>Assess the severity of disease in human</td>
<td>Assess threat to the UK population. Consider risk communication and methods of reducing exposure of humans to affected animals and potential environmental sources. Share collated information and output of risk assessment with relevant government agencies.</td>
</tr>
<tr>
<td>3B</td>
<td>Significant syndrome with zoonotic association</td>
<td>Assess the risk of person-to-person transmission</td>
<td>Assess threat to UK population. Consider risk communication and methods of reducing person-to-person transmission and exposure of humans to affected animals and potential environmental sources. Share collated information and output of risk assessment with relevant government agencies.</td>
</tr>
<tr>
<td>4</td>
<td>Significant syndrome with zoonotic association and person-to-person transmission</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 5. Expected actions following assessment of the risk to the UK population from a New or Emerging Pathogen

<table>
<thead>
<tr>
<th>Probability/impact</th>
<th>Expected actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very low</td>
<td>The risk of such an event is often deemed acceptable without the implementation of mitigation strategies. If appropriate, consider communications with relevant at-risk groups.</td>
</tr>
<tr>
<td>Low</td>
<td>Implementation of mitigation strategies should be considered in terms of the efficacy, impact and practicability of potential measures. Continue to monitor. If appropriate, consider communications with relevant at-risk groups.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Mitigation strategies must be reviewed immediately and escalation should be considered. Share collated information and output of risk assessment with relevant government agencies. If appropriate, consider communications with relevant at-risk groups.</td>
</tr>
<tr>
<td>High</td>
<td>Control measures and escalation must be implemented without delay and multi-agency action groups formed. Share collated information and output of risk assessment with relevant government agencies. If appropriate, consider communications with relevant at-risk groups.</td>
</tr>
<tr>
<td>Very high</td>
<td>Public health emergency. Considerable and immediate effort to reduce the impact and/or prevent the event is required. Urgent escalation is essential.</td>
</tr>
</tbody>
</table>