

HEALTH PROTECTION AGENCY  
LOCAL AND REGIONAL SERVICES



# FIELD EPIDEMIOLOGY TOOLKIT

NORTH EAST, NORTH WEST, YORKSHIRE AND HUMBER  
REGIONAL EPIDEMIOLOGY UNITS

Copyright © 2010 Health Protection Agency  
Local and Regional Services

PUBLISHED BY NORTH EAST, NORTH WEST, YORKSHIRE AND HUMBER  
REGIONAL EPIDEMIOLOGY UNITS

*Version 1.0, July 2010*

# Contents

|  |    |
|--|----|
| <i>Introduction to the toolkit</i>                                 | 5  |
| <i>Guidance sections</i>   | 7  |
| <i>Train and maintain investigative capacity</i>                   | 7  |
| <i>Analyse descriptive epidemiological data early and often</i>    | 8  |
| <i>Form a hypothesis of agent, source, pathway or transmission</i> | 10 |
| <i>Make a decision about conducting an analytical study</i>        | 10 |
| <i>Access the required resources</i>                               | 11 |
| <i>Select an appropriate study design</i>                          | 12 |
| <i>Draft a study protocol</i>                                      | 14 |
| <i>Develop a study-specific questionnaire and database</i>         | 15 |
| <i>Collect data</i>  | 15 |
| <i>Enter the data into a suitable database</i>                     | 18 |
| <i>Clean and validate the data</i>                                 | 18 |
| <i>Analyse and interpret the data</i>                              | 18 |
| <i>Write a report and disseminate it</i>                           | 20 |
| <i>Learn from the outbreak</i>                                     | 21 |
| <i>Additional considerations for specific circumstances</i>        | 23 |
| <i>Outbreaks in health or social care settings</i>                 | 23 |
| <i>Environmental epidemiology</i>                                  | 24 |
| <i>Questionnaire, analysis and report templates</i>                | 25 |
| <i>EpiData Entry and Analysis</i>                                  | 25 |
| <i>Food and water borne disease questionnaire</i>                  | 27 |
| <i>Health care associated infection questionnaire</i>              | 32 |

|   |    |
|---|----|
| <i>Environmental questionnaire</i>                              | 36 |
| <i>Analysis template</i>  | 39 |
| <i>Report template</i>  | 42 |
| <br>  |    |
| <i>Audit standards</i>  | 45 |
| <i>Health Protection Agency Incident and Outbreak standards</i> | 45 |
| <i>IRIS audit standards</i>                                     | 47 |
| <i>Possible additional audit standards</i>                      | 47 |
| <br>  |    |
| <i>References and further reading</i>                           | 53 |
| <br>  |    |
| <i>Index</i>  | 55 |

# *Introduction to the toolkit*

The aim of this field epidemiology toolkit is to provide step-by-step guidance and other resources to support consistent, timely and appropriate investigation of infectious disease outbreaks and other incidents which may require a field epidemiology approach. The guidance outlines the issues that need to be considered in planning or conducting an epidemiological investigation. The guidance is generic and is intended to be applicable in a range of situations, including food or water borne outbreaks, outbreaks in institutional settings or outbreaks in the community, as well as incidents related to environmental agents. It is mainly aimed at Health Protection Agency staff, working in health protection units or regional epidemiology units, who may be involved in leading or contributing to outbreak investigations.

In addition to guidance, the toolkit also includes templates for data collection, data entry and analysis to be modified for use as required. Links to templates are marked by a symbol.<sup>1</sup> Templates are collated in the appendix of this document.

Existing HPA standards for outbreak and incident management are listed in the appendix and linked to at appropriate points in the guidance.<sup>2</sup> Audit standards are collated in the appendix on page 45.

Where applicable, links to reference documents or further reading are marked by a symbol<sup>3</sup> in the margin. Web links to reference documents and further reading are collated in the appendix.

We hope that the toolkit will support hardpressed frontline health protection workers in using field epidemiology, and we would welcome feedback to improve the guidance and templates contained herein.

The Development Team, July 2010

HPA North West REU: Paul Cleary, Caoimhe McKerr, Catherine Quigley

HPA Yorkshire & Humber REU: Louise Coole, Leena Inamdar, Adrian Wensley

HPA North East REU: Russell Gorton

<sup>1</sup>  See templates on page 26. Page numbers are hyperlinked in the electronic version - use the key combination Alt-← to return.

<sup>2</sup> Marked by the symbol  in the margin

<sup>3</sup>  Further reading: Clicking on the note in the margin will usually open the relevant Web link.



## Guidance sections

### *Train and maintain investigative capacity*

All staff within HPUs and Regional Epidemiology Units should receive adequate training appropriate for their role in the investigation of outbreaks.<sup>4</sup>

<sup>4</sup>  $\Delta$  Audit standard: Relevant key staff should be trained and updated in their outbreak and incident plans and their roles and responsibilities and public health/epidemiology skills.

---

|   |  |
|---|--|
| <b>Data collection</b>                    | Questionnaire development<br>Data entry and validation<br>Consent<br>Telephone Interviewing skills   |
| <b>Descriptive epidemiology</b>           | Line listing<br>Construction and interpretation of epidemic curves<br>Mapping the geographical distribution of cases   |
| <b>Epidemiological reasoning</b>          | Formulating a hypothesis of aetiology, source of infection, mode of transmission or pathway, or risk factors<br>Testing hypotheses   |
| <b>Planning an analytical study</b>       | Choosing an appropriate study design<br>Sample size calculation<br>Selection of a comparison group<br>Developing a study protocol  |
| <b>Data analysis</b>                      | Understanding measures of association, such as the odds ratio<br>Stratified and multivariable analysis (especially logistic regression)<br>Use of statistical software (Epidata, STATA, R) |
| <b>Data interpretation</b>                | Causality<br>The play of chance<br>Minimising bias<br>Accounting for confounding and interaction<br>Small numbers  |
| <b>Communication skills</b>               | Writing an outbreak report<br>Media management   |
| <b>Influencing and Negotiation skills</b> | Using information to influence public health outcomes<br>Managing a multiagency outbreak team  |

---

Table 1: Key competencies and knowledge areas

The technical skills required to support outbreak and incident investigation will depend upon an individual's role. The incident lead for an outbreak or other investigation should have access to the skills and knowledge areas in table 1, within the HPU or from the REU or national centres of expertise as appropriate. The overall management of an outbreak demands a comprehensive range of skills and competencies. Some of these represent leadership skills which, whilst of critical importance, are not discussed further in this document, which concentrates on the epidemiological aspects of investigation.

### *Analyse descriptive epidemiological data early and often*

Basic descriptive analysis of epidemiological data may by itself identify the cause, source or mode of transmission of a communicable disease and obviate the need for more complex epidemiological investigation.<sup>5 6</sup> The basic data collected on cases should include the information in the table below, where this is available. For ease of reference and information sharing, this information is best collated in a line listing.

A **line listing** is a table that summarizes information about persons associated with an outbreak. It includes basic descriptive epidemiological information on time, place and person. Information often includes identifying information (name, phone number, county of residence), demographic information (date of birth, sex, occupation); date and time of onset and recovery; symptoms experienced (bloody or watery diarrhoea, nausea, vomiting, abdominal cramping); and other important factors (specimens submitted, medical visits, hospitalizations, diagnosis, potential exposures). It is a unique record for each individual with a unique identifier and helps to avoid confusion with multiple versions. It can be updated as the investigation develops and allows regular, automated, computerized analysis.

<sup>5</sup>  $\triangle$  Audit standard: For Level 1 incidents, there should be a clear risk assessment process with a record of actions agreed based upon the assessment, along with good basic descriptive epidemiology.

<sup>6</sup>  $\triangle$  Audit standard: Level 2 or above incidents should also have good quality epidemiology carried out.

| Name | DOB | Sex | Job | Onset date | Onset time | Diarr | Nausea | Vomiting | Abdo cramps | Attended event |
|------|-----|-----|-----|------------|------------|-------|--------|----------|-------------|----------------|
|      |     |     |     |            |            |       |        |          |             |                |
|      |     |     |     |            |            |       |        |          |             |                |

Table 2: Example of line listing

A line listing could usefully include information on:

- **Case definitions:** Clear case definitions allow consistency in the counting of cases. Case definitions may evolve in the course of an outbreak investigation, from a broad initial definition to a more specific one when more is known about possible risk factors.

Using more than one case definition may be useful and they may need to be reviewed during the investigation as new information comes to light.

- A **confirmed** case usually refers to a person with laboratory confirmation of the diagnosis.

- A **probable** case usually lacks laboratory confirmation but has suggestive clinical features, or may be linked to a confirmed case.<sup>7</sup>
  - In outbreak investigations, case definitions are usually based on clinical features and/or the results of diagnostic tests and may also specify the time and place of the putative exposure.
- **Case finding:**<sup>8</sup> Further cases may be identified through routine surveillance data, or by raising awareness of the outbreak through communications with the general public.
  - Number of cases (or less commonly incidence/prevalence where the population at risk can be quantified)
  - Patient details (including age, gender, occupation)
  - Patient and GP/hospital contact details (if required for case management only)
  - Basic clinical features (can include markers of severity such as hospitalisation or fatality)
  - Indicators of particular susceptibility to infection/severe disease (*e.g.* immunisation status, pregnancy, immunosuppression)
  - Laboratory results
  - Key dates (such as disease onset, taking of diagnostic sample or reporting of case)
  - Location (*e.g.* postcode of residence)
  - Possible common exposures as ascertained from routine screening questionnaires
  - Information on contacts (for diseases which may spread from person to person)

Time (epidemic curves), place (spot maps) and person based (summary tables of possible risk factors) analyses should be produced at the earliest opportunity from a line listing and updated as new cases are found. Timelines of significant exposures and disease onset may also be useful.

An **epidemic curve**<sup>9</sup> is a special type of histogram that provides a visual depiction of the outbreak and offers information related to time. An epidemic curve provides information about the extent of the outbreak, the potential period of exposure, and the possible mode of transmission. The shape of the epidemic curve can also be very instructive, suggesting a point-source epidemic, ongoing transmission, or a combination of the two. By reviewing the epidemic curve and by examining the characteristics (*e.g.* age, sex, ethnicity, residence, occupation, recent travel, or attendance at events) of the cases, investigators can often generate hypotheses concerning the cause(s) or source(s) of the outbreak, for testing in an analytical study. The spread of disease, especially infectious disease is unavoidably spatial. Infection moves from individual to individual following a network of contacts within a population through local or even global transmission. **Maps** and diagrams are helpful in showing the geographical location or layout of the place in which an outbreak has occurred.<sup>10</sup> This spatial information may be crucial to the outbreak investigation and may provide

<sup>7</sup> Having a probable case definition is useful for including cases of disease which may not have sought medical attention to be tested, or which presented too late for testing. In addition, where there are large numbers of people affected, it may not be feasible or desirable to test all potential cases.

<sup>8</sup>  Further reading: Case Finding and Line Listing: A Guide for Investigators.

<sup>9</sup>  Further reading: Epidemic Curves Ahead.

<sup>10</sup>  Further reading: Mapping for Surveillance and Outbreak Investigation.

clues about the source of the outbreak. The spot map is a well-used pictorial of the spatial distribution of illness within a specific setting or area. Where person to person spread is considered a possibility, social networks can usefully be presented as a diagram.

### *Form a hypothesis of agent, source, pathway or transmission*

Based on previous knowledge of the disease and the descriptive epidemiological and/or microbiological information from the current outbreak, a **hypothesis** explaining the observations about the outbreak can be developed.<sup>11</sup> Hypotheses should address the source of the agent, the mode and vehicle of transmission, and the specific exposure that caused the disease. They should also be plausible, supported by the facts established during the epidemiological, laboratory and food investigations and able to explain most of the cases. An analytical study serves to test the hypothesis arrived at in this way. It may, for example, be observed from the descriptive epidemiology that a particular exposure (such as a foodstuff or a visit to a particular place) is commonly seen among cases, which leads to a hypothesis that this exposure is associated with the disease. An analytical study can provide evidence for or against this hypothesis. If no hypothesis can be arrived at from the descriptive epidemiological data after consulting relevant expertise, an analytical study may not be appropriate.

At this stage of the investigation the data need to be summarized and hypotheses formulated to explain the outbreak. The source(s) and route(s) of exposure must be determined to understand why an outbreak occurred, how to prevent similar outbreaks in the future, and, if the outbreak is ongoing, how to prevent others from being exposed to the source(s) of infection. Using the information gathered so far, consider the possible source from which the disease may have been contracted. Quite often, by knowing the descriptive aspects and the diagnosis and by plotting an epidemic curve, the source, mode of transmission and population at risk can be determined. Once the population at risk has been determined, appropriate control measures can be targeted. The descriptive aspect of the analytical investigation is most often carried out at the local level.

### *Make a decision about conducting an analytical study*

**Analytical epidemiological studies**, where groups with different exposure or disease status are compared, are required to test hypotheses of an association between a disease and a risk factor. The decision whether to conduct an analytical study should be considered by an outbreak control team at the initial meeting, irrespective of delays in the collection of basic descriptive epidemiological data.<sup>12</sup> The decision (and its rationale) should be recorded clearly in the meeting notes or incident log. The fundamental criterion for deciding to conduct an analytical study is the possibility of detecting a common source of disease which would enable appropriate action to protect the health of the public. In addition, the following considerations may also indicate a need for an analytical study in relation to an outbreak or incident:

<sup>11</sup>  Further reading: Hypothesis Generation During Outbreaks.

<sup>12</sup>  Audit standard: For all outbreaks and incidents, analytic epidemiology should routinely be considered and decisions recorded on whether to undertake such studies or not.

- A large number of affected persons
- An outbreak of disease with significant morbidity or mortality
- A high level of public or media concern
- An absence of known effective control measures
- A disease from an unknown source, or with an unknown mode of transmission
- Where risk factors for a disease may have changed
- A new or unknown pathogen or hazard
- Where there is uncertainty and a need for new knowledge
- An outbreak linked to a nationally distributed product
- An outbreak linked to a disease not normally occurring in the United Kingdom
- An outbreak linked to an event of national or international significance
- An outbreak of particular interest to national surveillance
- An outbreak which may be related to standards of institutional care

As a secondary consideration, analytical studies should also be considered training opportunities for junior staff.

### *Access the required resources*

Where an analytical study is thought necessary, the necessary **resources** must be discussed and agreed at an early stage. The availability of resources is an important constraint on the design, and it is best if this is explicitly considered in the study protocol. The impact upon critical functions and arrangements for maintaining resilience should also be considered and planned for. Consultation or collaboration with specialist divisions or with external centres of expertise is also advisable where information on microbiological, toxicological, environmental or other highly technical matters is sought.<sup>13</sup>

All level 2 and above and significant Level 1 incidents should be discussed with the REU. Significant Level 1 incidents include those which are large, complex, or cross HPU or regional boundaries. Features which should prompt discussion with the REU include incidents with significant (actual or potential) morbidity or mortality, and where the incident fulfils any of the following criteria:

- Has the potential of exposing a large number of (more than 50) people
- Is linked to a nationally distributed product
- Is linked to an event of national or international significance
- Is unusual or likely to generate media or public interest
- May require an analytical study to identify an aetiological agent, source, pathway or means of transmission.

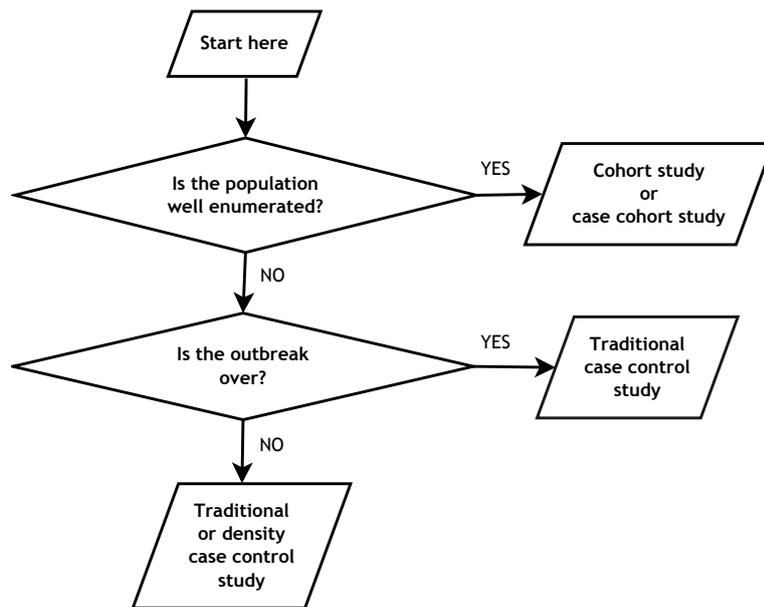
#### <sup>13</sup> **Access to advice and support**

Regional Epidemiology Units (REUs) can provide advice and active practical support in the design and implementation of analytical studies, including sample size calculation, development of study protocols, questionnaire design and basic statistical analysis. More sophisticated epidemiological or statistical issues may require the involvement of epidemiologists or statisticians in one of the specialist divisions of the Health Protection Agency.

| Activity                      | Potential staff involved  |
|-------------------------------|---|
| Study design / planning       | CCDC/ RE / epidemiological scientist / analyst  |
| Data collection               | CCDC / HP practitioner / administrative staff / IT support / environmental health officers  |
| Data entry                    | HP practitioner / analyst / administrative and surveillance staff   |
| Data analysis                 | CCDC / RE / epidemiological scientist / analyst   |
| Data interpretation           | CCDC / RE / epidemiological scientist / analyst   |
| Report writing                | CCDC / RE / epidemiological scientist / analyst / administrative staff  |
| HPA specialist expertise      | HPA CfI epidemiologists, statisticians or microbiology staff; expertise from Centre for Radiation, Chemical and Environmental Hazards |
| External specialist expertise | Veterinary expertise from Veterinary Laboratory Agency; other agencies, <i>e.g.</i> Environment Agency                                |

### Select an appropriate study design

A number of possible **study designs** can be used to investigate outbreaks and incidents.<sup>14</sup> The most common study designs used are **cohort studies**, **case control studies** and **case cohort studies**. Their strengths and weaknesses are summarised in the table below.<sup>15</sup> See figure 1 for further guidance.



A **matched design** may occasionally be required where a major potential confounder is thought to exist. It is generally preferable to adjust for confounding at the analysis stage, but if the sample size is small this may not be possible and matching may need to be considered. For these reasons the decision to match should be carefully considered.

Table 3: Human resource requirements

<sup>14</sup> Audit standard: Investigating HPA staff should be competent either to undertake local analytical studies (simple cohort or case control studies) or should easily be able to access practical and active HPA epidemiological support to do so.

Figure 1: Choosing a study design

#### Cohort studies

Cohort studies identify groups of persons with different exposure status and follow them up over time to compare the occurrence of diseases of interest in the different groups and identify associations. This can be done prospectively, where subjects are recruited before the onset of disease, but in the context of the investigation of outbreaks and incidents, it is more commonly done retrospectively, collecting information on exposure and occurrence of disease during or following the incident or outbreak.

Further reading: Cohort Studies for Outbreak Investigations.

#### Case control studies

Case control studies compare the exposures of groups of persons with different disease outcomes to identify associations. Cases are all or a sample of those patients identified as having the outcome of interest, whereas controls are sampled in a number of possible ways from the non cases in the population. In “traditional” case control studies, controls are selected from those disease free at the end of the study period. Occasionally “density” or “risk set sampling” case control studies may be selected where controls are sampled concurrently with cases (i.e. each time a case is identified, a control must also be identified).

Further reading: Case-Control Studies for Outbreak Investigations.

<sup>15</sup> Further reading: Selecting a Study Design.

| Type of study        | Strengths   | Weaknesses  |
|----------------------|---|---|
| Cohort studies       | Design of choice for well defined populations (i.e. where a complete list exists), such as outbreaks related to social events, or in settings such as cruise ships or care homes<br>Allow direct estimation of incidence rates and of relative risk | Not feasible when population at risk is not well defined.                                 |
| Case control studies | Useful when population at risk is not well enumerated<br><br>May be less resource intensive than a study on the whole cohort (e.g. nested case control studies)   | Incidence rates and relative risk cannot be directly calculated from case control studies |
| Case cohort studies  | More efficient alternative to a cohort design - only a sample of non-cases need to be recruited   |   |

Matching can complicate study design and interpretation in a number of ways:

- Complicating the identification of controls
- Case data may need to be excluded where data is missing from the control in a matched pair
- Masking of true effects through overmatching

Selection of suitable controls for a case control study may be difficult. If no suitable sampling frame for controls exists, they can be nominated by cases from among friends or neighbours, or recruited by using random-digit dialling.

### *Draft a study protocol*

A draft study **protocol** should be drafted and circulated to members of the outbreak control team for discussion soon after the decision is made to proceed to an analytical study. A large sample size is not always necessary, as effect sizes may be large, particularly in food borne outbreaks.<sup>16</sup> Input from the Regional Epidemiology Unit or national centres may be helpful at this point. The protocol should include the following information:

- Brief notes on the background to the investigation
- Aims and objectives of the investigation
- Study design
- Case definitions and inclusion and exclusion criteria
- **Sample size estimations** based on the main study hypothesis.<sup>17</sup>
- Case control ratio<sup>18</sup>

Table 4: Strengths and weaknesses of study designs

#### **Case cohort studies**

A further possible variant on the case control design is to sample controls from all those disease-free at the beginning of the study period ie before the outbreak started. This is referred to as a case cohort design. Cases are compared to controls which are a defined sample of the total cohort which may include individuals which are both affected and unaffected by the end of the study period.

<sup>16</sup> For example, to detect a risk ratio of 9 (90% of cases and 10% of controls exposed) with 80% power, complete exposure information on only 6 cases and 12 controls is required. The potential sample size is not always known when undertaking a study in a timely fashion. A study may be started with the intention of adding new cases and sets of controls as they arise.

<sup>17</sup> **Sample size:** A number of other factors, such as response rates or the need to adjust for confounding at the analysis stage, may also influence the estimated sample size. If the estimated sample size required to identify an odds ratio of 3 is not thought to be feasible, then a study may not be worthwhile. However, it should be considered that a non significant result may sometimes be helpful for focussing further microbiological or environmental investigations.

<sup>18</sup> Where the number of cases is small, consideration should be given to increasing the ratio of controls to cases, up to 4 controls per case. Increasing the ratio above 4 controls per case is unlikely to increase power substantially.

- Methods of data collection and plan for management of non-responders
- Hypothesis and theme of enquiry
- Draft questionnaire
- Data management plan
- Ethical considerations<sup>19 20</sup>
- Analytical strategy, outlining process and intended outputs
- Action plan with timeline, identifying roles and responsibilities
- Specification of resources
- Dissemination plan (internal and external feedback)

Whichever study design is selected, there should be clear case and control **inclusion and exclusion criteria**. In the investigation of outbreaks of possible food borne disease it is common to exclude those with a history of foreign travel or contact with a known case.<sup>21</sup>

### *Develop a study-specific questionnaire and database*

Preparing generic epidemiological interview instruments<sup>22</sup> that can be tailored to the particular scenario is an important step in preparing for managing outbreak investigations. The **questionnaire** should be as short as possible, while collecting information on important inclusion/exclusion and exposure variables as accurately as possible. Question wording should be simple and clear, and should give clear time references where required. Closed questions should be matched with responses that are mutually exclusive and exhaustive.<sup>23</sup> It may be necessary to define codes (*e.g.* “999”) for missing values. Any other codes used (*e.g.* 1=present, 0=absent) should be used consistently.

The questionnaire should be formatted to aid navigation and completion. It is preferable for responses to be circled rather than ticked, as ticks can lead to ambiguity. Formatting responses in a single vertical column can also aid data entry.<sup>24</sup>

### *Collect data*

When the questionnaire has been developed and the study design has been selected, the logistics of carrying out the investigation should be further considered, including the following:

- If possible, the questionnaire should be tested for clarity prior to administration.
- The personnel assigned to the study should become familiar with the questionnaire and any potential questions that may arise.
- Training interviewers to collect epidemiological data is crucial in ensuring standardisation and a high quality of collected data.
- A feasible method for administering and distributing the questionnaire should be discussed: self-administered/personal interview; in person/by phone/by mail/by electronic mail/via the Internet.

<sup>19</sup> Formal ethical review of non research public health activities such as outbreak investigations is not required, but due consideration should be given to ethical issues such as obtaining informed consent from participants and maintaining data confidentiality.

<sup>20</sup>  Audit standard: There should be documented consideration of ethical and research governance issues.

<sup>21</sup>  Further reading: Statistics review 4: Sample size calculations.

<sup>22</sup>  Questionnaire and other templates can be found beginning on page 26.

<sup>23</sup> An “Other” or “Don’t know” category may be required.

<sup>24</sup>  Further reading: Database setup and EpiData.

- The data entry program or spreadsheet and method of entering data into the program should be considered.
- Data collection should begin at the earliest opportunity.

Although outbreak investigations are time critical, interviewer training is a crucial component that should not be left out, especially in a situation where there are inexperienced interviewers or several interviewers are involved. Interviewing is an important, though sometimes difficult task. There are several things to be covered in interviewer training:

- Interviewers should be provided with an overview of the outbreak situation and review the purpose of the questionnaire.
- Interviewers should also be aware of the respondent selection process. Respondents will often ask the interviewer how they got their contact information.
- A majority of the training should focus on the questionnaire - how to use it, the intent and meaning of each question, and how to record or code responses.
- Discuss how the interviewer should respond to questions from the respondents.
- Questions should always be asked in the same way for each participant. The interviewer should not prompt or lead the respondent to answers, which could introduce bias into the study.

The logistics of conducting the interviews should be agreed at the start of the outbreak investigation. This includes the hours during which it is acceptable to call, how to track the calls, how many times should the interviewers call a prospective respondent, whether they should leave a message if they get an answering machine, and what to do with completed questionnaires. Finally, and most importantly, discuss confidentiality of the interviews and questionnaires. At the interviewer training, it is good practice to provide materials to the interviewers in a manual (what exactly is included in a manual will depend on the outbreak situation). You might include a calendar to help track dates, a map of a facility, or guidelines related to but not directly associated with the outbreak (for example, a copy of vaccination guidelines if you are investigating an influenza outbreak) that might be useful if there are questions. Also, you might create a list of frequently asked questions and answers that can be used by interviewers as a quick reference tool. Interviewers might also find it useful to have some background information available on the outbreak - the organism, an epidemic curve, etc. Depending on each outbreak scenario, decide which **interview method** would be most appropriate (face to face, postal or telephone) and why. The relative strengths and weaknesses of these approaches are summarised in table 5:

| Method                   | Advantages  | Disadvantages  |
|--------------------------|---|--|
| Face to face interview   | Generally achieves the highest response rates<br>May allow collection of more complex data  | May be time consuming and resource intensive   |
| Postal questionnaire     | Least resource requirements   | Generally achieves the lowest overall and item response rates<br>Slower data collection  |
| Telephone interviews     | Can achieve high response rates<br><br>May allow collection of more complex data<br>May be the quickest method of data collection | Respondent must be contactable by telephone; may also be resource intensive  |
| Online self administered | May be the quickest method of data collection especially if appropriate for the sample  | Dependent on respondents having access to the appropriate technology; may achieve low response rates<br>Data security principles must be respected |

Table 5: Strengths and weakness of interview methods

Based on the above, where resources allow, telephone interviews are often the optimal method of data collection. The questionnaire templates are designed on the assumption that telephone interviews are the chosen method of data collection, and so will require further adaptation if another method is chosen.

If data is to be collected by a postal questionnaire, particular attention will need to be given to the design of the questionnaire. Clear instructions and formatting are important to aid the navigation and completion of postal questionnaires. The questionnaire will need to be short and avoid open or complex questions. Unlike in research studies, there may not be time for a thorough pretesting or piloting of the questionnaire before it is used to collect data. However, where possible the questionnaire should be at least completed by a convenience sample of colleagues or others before use to identify issues with presentation, wording, navigability or content.

Whichever method is chosen, data collection should be preceded by an interviewer script (or cover letter for postal questionnaires) explaining who is conducting the investigation and why the investigation is taking place, giving assurances on data confidentiality and security, and thanking respondents for their participation. The completed questionnaire should be checked after completion, as this is the best time to clarify anything with the respondent. In phone interviews, a courteous and knowledgeable interviewer can be the difference between a hang-up and a completed questionnaire. By maintaining a professional but friendly approach throughout an interview, an interviewer can obtain important information that will help investigators identify the cause of an outbreak.

### *Enter the data into a suitable database*

Errors may be introduced into the data at any stage of data collection, data entry or data analysis, and **checking** should take place at each stage. There are three main ways of reducing data entry errors and maintaining data quality at the data entry stage: interactive checking, double data entry and batch checking. None of these approaches can guarantee the identification of all data entry errors.<sup>25</sup>

**Double data entry** (where the data is entered twice, ideally by two different people, with the two data sets then compared using verification software) is the gold standard, but may be impractical in an incident or outbreak setting. **Interactive checking** identifies errors or anomalies in the data as it is entered, and can detect range errors (*e.g.* an age of 176) or consistency errors (*e.g.* a pregnant male). Interactive checking is best used when data collection proceeds in parallel with data entry, and anomalies in the data can quickly be queried from the data source. However, interactive checking interrupts data entry, and so **batch checking**, where checks are made on the data after all the data is entered, or periodically during data entry, may be preferred.<sup>26</sup>

It is important that every record entered into the database has a unique identifier, which must be entered with the record. Personal identifying information (PID) such as name or address does not need to be entered into the study database (although names can alternatively be anonymised using Soundex codes) but should be stored separately and securely along with the linking database identifier to allow subjects to be linked with their records if required to correct errors.

Data should be stored securely, with backups made at appropriate intervals.<sup>27</sup>

### *Clean and validate the data*

Maintaining quality control during data collection and data entry will prevent many, but not all common errors in the data, and further checking and “**cleaning**” will usually be required. As discussed above, batch checks can be run once the data has been entered to avoid interrupting data entry to correct errors. Interim analyses of the data, such as basic tabulations and plots, can identify further errors in the data. Where errors are corrected, it is important to maintain an audit trail of changes made to the data. One way of doing this is to leave the original data untouched and to correct errors programmatically at the time of analysis. If it is not possible to correct these errors, then it may be necessary to set their values to missing.

### *Analyse and interpret the data*

Once the data is entered and cleaned, the analytical strategy will usually aim to answer some or all of the following questions.

- What was the size and time course of the outbreak?
- What were the demographics and other characteristics of the cases, and

<sup>25</sup>  Questionnaire templates can be found on page 26.

<sup>26</sup>  Further reading: Data management for surveys and trials (EpiData).

<sup>27</sup>  Audit standard: Data should be stored and transferred using an appropriate secure method that is compliant with Caldicott principles, the Data Protection Act and other HPA guidance on confidentiality and security of data and information.

what does this suggest about the population at risk?

- What were the clinical features and the outcomes of the cases?
- What do the above suggest about the likely agent?
- What factors are associated with disease?
  - Are any associations real, artefactual, confounded or due to the play of chance?
  - What do the findings suggest about the likely source or mode of transmission of the agent?
  - Are the data consistent with the hypothesis developed from the descriptive epidemiology?

Important steps to consider in analysing incident or outbreak data include:<sup>28</sup>

- Re-evaluate the case definition and ensure that persons classified as cases or controls are eligible for inclusion.
- Familiarise yourself with the data by examining the distribution of each individual variable.
  - Categorical variables can be examined as frequency tables or bar charts.
  - Quantitative variables can be examined by computing numerical summaries (such as mean and standard deviation, or median and interquartile range) or by histograms and box plots.
  - Identify how much data is missing for each variable.
- Orient the data in time.
  - Update any epidemic curves previously plotted.
  - Compute the median and range for the estimated incubation and recovery periods.
- Orient the data in terms of person characteristics.
  - Demographics of cases and controls
  - Clinical features of cases and controls
  - Outcomes of cases
- Univariate analyses<sup>29</sup>
  - If the study design was a retrospective cohort study, calculate the overall attack rate, risk factor specific attack rates, and relative risks.
  - If the study design was a case control study, calculate the risk factor specific odds ratios.
  - If possible, examine the dose-response relationship between a risk factor and outcome.
  - Test the null hypothesis of no association for each relationship of interest.<sup>30</sup>

<sup>28</sup> See the example analysis in EpiData Analysis on page 39 in the appendix.

<sup>29</sup> The term “univariate analysis” is commonly used to refer to steps in the analysis where each risk factor is examined individually for a possible association with outcome. The term “bivariate analysis” is sometimes preferred. Given that there is a 5% chance of each univariate analysis falsely demonstrating an association with a  $p$  value of less than 0.05, the more risk factors that are studied, the less likely it is that any associations observed are real.

<sup>30</sup> The chi square test (or Fisher's exact test) are commonly used methods. Further reading: 2-way Contingency Table Analysis.

- Where evidence is found for an association, calculate 95% confidence intervals for the observed measure of effect.
- Consider adjusting for the effect of confounding or related issues.<sup>31</sup> Methods which can be used include:
  - Stratified analysis, which examines the outcome in relation to two possible risk factors
  - Multivariate regression, which examines the outcome in relation to several possible risk factors (examples include logistic regression, Poisson regression, Cox regression)

The measures of effect (relative risks or odds ratios), after adjustment for confounding if required, then need to be interpreted for the support they give to the hypothesis or hypotheses under investigation. If, for a possible risk factor, the measure of effect is not significant at the 5% level,<sup>32</sup> then we conclude that the data does not provide evidence of an association. If the measure of effect is significant at the 5% level, we conclude that the data does provide evidence of an association between this risk factor and disease. To judge whether this association may be a *causal* association, we need further information. The stronger the association,<sup>33</sup> the more likely the association is to be causal. Demonstrating a dose-response relationship adds further evidence towards a causal explanation for the association.<sup>34</sup>

The term “epidemiological **bias**”, or simply “bias”, refers to a whole range of possible weaknesses in the design or conduct of the investigation which may lead to an incorrect conclusion being drawn. Observational study designs such as case control studies are prone to particular types of bias, and bias should always be considered in the interpretation of the results of the investigation of an outbreak or incident.

The results of the epidemiological study should also be considered in the light of the results of the microbiological and environmental parts of the investigation. Careful development of epidemiological inferences combined with environmental and clinical evidence may provide convincing evidence of the source and mode of spread of a disease.

### *Write a report and disseminate it*

Every outbreak should have a report prepared.<sup>35 36</sup> For some incidents this will be a very brief document but for more significant outbreaks this will be more substantial. Using a template report can facilitate this process.<sup>37</sup> The production of the outbreak report is the overall responsibility of the Incident Lead (often the Consultant in Communicable Disease Control (CCDC) within whose area the outbreak occurred). However all agencies involved in the outbreak investigation will be required to contribute to appropriate sections.

Consideration needs to be given to target audience for the report and how it may be used. Outbreak reports should be completed within 3 months of outbreak or incident closure. Preliminary findings to enable public health action should be available within 4 weeks of closure of the incident. It is important at the outset of the incident to agree responsibility for the writing or preparation of different sections of the report. It is also essential

<sup>31</sup> Confounding refers to the influence of a third “lurking” variable on the observed association. Specialist advice may be required to account for this in the analysis.  Further reading: Advanced Data Analysis: Methods to Control for Confounding (Matching and Logistic Regression).

<sup>32</sup> In other words, if the *p* value is not less than 0.05, and/or the 95% confidence interval of the measure of effect includes 1.

<sup>33</sup> In other words, the larger the measure of effect.

<sup>34</sup>  Further reading: Statistics review 3: Hypothesis testing and P values.

<sup>35</sup>  Audit standard: All Level 1 incidents should be well documented using a template capturing standard information

<sup>36</sup>  Audit standard: For all Level 2 and above incidents there should be a report on the results of investigation and action points which is disseminated to partners in a timely way.

<sup>37</sup>  A report template can be found on page 42.

to be clear which is the lead organisation for the investigation and where ownership of the data rests to avoid unnecessary dispute. Similarly it is good practice to agree the sign off process for the report and the distribution plan at an early stage.

Preparation of reports for publication should follow the STROBE guidance<sup>38</sup> or equivalent for reporting observational studies such as outbreak investigations.

<sup>38</sup> See references section.

Outbreak reports should be made available to stakeholder agencies and OCT members. Reports should also be made available to the Regional Epidemiology Unit to provide a regional resource. Where possible investigated outbreaks should be presented as posters or presentations at appropriate level conferences. Submission for publication in public health journals should also be considered.

### *Learn from the outbreak*

Learning the lessons which have been identified through the investigation of an outbreak both about public health risks and effective working in the control of an incident is essential. Local mechanisms may exist for multi-agency fora to review lessons and recommendations from local incidents. Within each Region there may be various mechanisms in place to both: Share the learning with other colleagues e.g. audit meetings,<sup>39</sup> Regional CCDC/ Health Protection Practitioner meetings etc and to Review progress with addressing the issues identified which the HPA can influence e.g. public health issues, HPA process and performance issues, e.g. audit meetings, Regional Executive Group Meetings etc.

<sup>39</sup>  Audit standard: Incidents and outbreak investigations should be routinely audited against the HPA Incident and Outbreak standards.

Regular audit of the management of outbreaks and incidents may be beneficial for organisational learning. A number of suggested audit standards are included at the end of this document. Audits can assess structure (were adequate resources available?), process (were actions and decisions appropriate?) and outcome (was the cause/source/mode of transmission identified? Was the response effective?)

## *Additional considerations for specific circumstances*

### *Outbreaks in health or social care settings*

Health protection staff have long been involved in the response to community-based outbreaks, such as those occurring in care homes, and are now increasingly involved in the investigation of outbreaks or incidents occurring in acute and other hospital settings, which this section will briefly focus on. Health care associated infections are common, and the organisms involved are diverse and may include *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus*, or other pathogens which may be notable for their potential for nosocomial transmission, virulence or resistance to multiple antibiotics. In health care settings, the population at risk may be particularly susceptible to infection with certain pathogens by virtue of their underlying medical conditions.

The basic principles of investigation in a health or social care setting are similar to the general principles outlined above. Good descriptive epidemiology is a key part of the early investigation, and may be sufficient to demonstrate potential sources of infection or transmission pathways between cases of diseases, the institutional environment and health care workers (or other vectors). Where a common source of infection is hypothesised to exist, or other possible individual-level risk factors are of interest, a field epidemiology analytical study may be of value and can identify risk factors, for example the use of intravascular devices in cases of bacteraemia with certain organisms, or the use of high risk antibiotics in cases of *Clostridium difficile* associated disease.<sup>40</sup> As an alternative or complementary approach, where numbers allow, rates of infection can be compared at ward level and correlated with indicators such as hand hygiene scores.

Investigation of outbreaks and incidents in institutions may be facilitated by use of existing data sources, such as medical case notes, hospital information systems (for administrative and prescribing data), information from surveillance systems for health care associated infection and the results of internal investigations, such as “root cause analyses”. Infection control teams are often a source of informal local intelligence. Case definitions used in the investigation may need to take account of existing case or outbreak definitions, for example in mandatory surveillance data. For example, a widely used definition of an outbreak of *Clostridium difficile* on a hospital ward is two or more cases of the same strain which are related in time and place.

New forms of molecular typing<sup>41</sup> may be very useful for demonstrating

<sup>40</sup>  A template questionnaire for the investigation of a hospital *Clostridium difficile* outbreak can be found on page 26.

<sup>41</sup> Such as multiple locus variable repeat analysis, or MLVA, for distinguishing between different strains of *Clostridium difficile* with the same PCR ribotype.

nosocomial transmission, and it is best to ensure access to such specialised laboratory resources at an early stage. Studying transmission of certain pathogens, where infection may be preceded by a period of colonisation of indeterminate length, may be complex. The Health Protection Agency is developing its health care epidemiology expertise and has health care epidemiologists who can provide advice on investigation.

There should be a clear understanding about the relative contribution of resources from the health protection unit and the Trust. In general, the Trust should provide information in an analysable form and clerical tasks such as data collection or data entry should not fall to the health protection unit.

The investigation may also be complicated by media interest or medico-legal consequences for the Trust and it is especially important that the investigation is of the highest possible standard.

### *Environmental epidemiology*

Frontline health protection staff are less often required to investigate possible acute health effects of physical or chemical hazards. This section will briefly outline certain relevant principles of environmental epidemiology. Expert advice should be sought from the HPA Centre for Chemical, Radiation and Environmental Hazards.

Good descriptive epidemiology is again important for generating hypotheses. Mapping may be particularly important in studying possible environmental exposures. Physical and chemical hazards are often best conceptualised using a source-pathway-receptor model, rather than the agent-host-environment model often used for communicable diseases.

For an incident occurring within a short time scale, a field epidemiology study such as a case control study may be appropriate. However, more ambitious studies, such as retrospectively studying the possible chronic health effects of a long term chemical, physical or other environmental exposure; prospectively studying the possible future health effects of a defined episode of exposure to such as hazard; or investigating a geographical or temporal cluster of health outcomes with a putative environmental cause, all raise other epidemiological issues<sup>42</sup> which it is outwith the scope of this document to address.

Just as the investigation of communicable disease outbreaks may be complemented by microbiological typing data, environmental epidemiological investigations may be complemented by chemical or physical measurements on individuals or on the environment. Environmental investigations are often multidisciplinary, involving partners such as the Environment Agency.

<sup>42</sup> Such as taking account of spatial or temporal factors in the analysis, or of studying variables at both individual and area level.

# *Questionnaire, analysis and report templates*

## *EpiData Entry and Analysis*

Epidata Entry and Analysis are two programmes based on the venerable Epi Info software developed by the Centres for Disease Control in the United States, and provide a suite of software tools for entering and checking data, as well as analysis. Unlike Epi Info, this software is under active development, partly by volunteers, and partly funded by organisations such as the World Health Organisation. A new version is under development which will supersede the current version, but the qes-chk-rec principles of the current EpiData software will be applicable to the new version.

Microsoft Excel and similar programmes were not designed for epidemiology, but primarily for book keeping and financial purposes. Some common epidemiological tasks, such as plotting an epidemic curve or calculating an odds ratio, are difficult in Excel. In contrast, EpiData is designed by epidemiologists to use for epidemiology. It does well the 20% of things epidemiologists do 80% of the time. It is easy to learn, and tasks such as plotting an epidemic curve or calculating an odds ratio are easy.

EpiData has a particular focus on questionnaire design, data entry, data checking and data management. It has simple database capabilities and can handle data in several formats. It has minimal computing requirements and will run on almost any Windows computer from the last decade. It has a number of useful security and confidentiality features, including strong encryption and automatic backups of data. EpiData is also programmable to allow automated analyses and reporting. Data is also easy to export from EpiData in formats suitable for analysis in more sophisticated software packages, such as STATA. It is also free.

The basic principles of how EpiData works are simple. Epidata Entry creates a minimum of three files, which are created in the following sequence.<sup>43</sup>

- The .qes file is the questionnaire.
- The .rec file is the database of records entered.
- The .chk file is a list of the errors you have told Epidata Entry to watch out for either when data is being entered or after data has been entered.

There are sometimes any of three other files (.not for notes, .log for logging, and .eix for an index of your data) but use of these is optional.

EpiData encourages good data management practice, and forces the epidemiologist to think in detail about the types of data required. For each

<sup>43</sup> The three files (.qes, .rec and .chk) should be kept in the same folder, ideally along with other files related to the outbreak.

of the variables that comprise the data, Epidata needs to know the type of variable, the permissible values (*e.g.* for sex, male or female), the size of the variable, for text whether it is upper or lower case, for dates what format (British or American) they are in, for numbers how many decimal places there are, etc.

This is recorded in the questionnaire (.qes) file, using a simple coding system. This is one of the ways Epidata Entry prevents errors - for example, if a variable for age should only contain two-digit numbers, then Epidata Entry will not allow text to be entered. See table 6 for the main codes that are used. The supplied questionnaire templates show how this can be formatted.

| Type of data    | Epidata Entry code |
|-----------------|--------------------|
| Discrete        | ##                 |
| Continuous      | ##.#               |
| Binary          | <Y>, #             |
| Nominal/ordinal | _____, <A >, #     |

Table 6: EpiData Entry variable coding

For binary (“Boolean”) variables, the yes/no variable <Y> can be used, but it is preferable to use a single digit number, as we have done, which allows use of the numeric keypad to aid data entry. It also allows the addition of other categories (such as “Don’t know”) and uses memory more efficiently. A useful convention is to use 0=No and 1=Yes. This avoids having to recode to perform logistic regression. It is also useful to use 0=Male and 1=Female.

For nominal or ordinal variables, the code used depends on the number of categories. If all the possible responses are known, and there are not a huge number of them, use numeric codes. It is possible to tell Epidata what each code stands for, using “labels”. For variables with many possible values, *e.g.* occupation, a free text variable may be preferred.

Each non-comment line in the .qes file tells Epidata what the question is, what the variable should be called when it is recorded in the database, and what type of data to expect.<sup>44</sup> It is possible to use curly brackets to use part of the question as the variable name. Epidata Entry can also be set to use the first word of the question as the variable name if preferred.

When the data entry screen is created from the .qes file, the data codes turn into empty fields that can be navigated using the Tab key.<sup>45</sup>

Interactive checks are defined in a check (.chk) file of the same name as the questionnaire and database files. The provided questionnaire templates have associated check files set up with a number of interactive checks. For numeric values, one can specify a “legal range” of ages from *e.g.* 2–99. For categorical variables, one can specify “legal values”, i.e. which codes are allowable. A check can be set to ensure that important information, such as a unique identifier field, must be entered.

<sup>44</sup> Variable names should be ideally be meaningful to reduce errors during data analysis.

<sup>45</sup> Tip: Use the “Align Fields” facility in EpiData to line up the data entry fields into a single column if possible.

*Food and water borne disease questionnaire*

Template questionnaire for use in the investigation of suspected food or water borne outbreaks of infectious disease

\*\*\*\*\*

The following template and associated files can be modified for use in any suspected food or water borne outbreak, whether data collection is by telephone interview or respondents complete the questionnaire themselves. Many of the questions will not be relevant to a particular outbreak and can be deleted.

To print this questionnaire, use File/Print Data Form in Epidata. Set Automatic Field Naming in Epidata options if not already done.

It may be necessary to have a calendar and a copy of any relevant menus to hand when completing this questionnaire.

\*\*\*\*\*

Preamble - suggested script

\*\*\*\*\*

Hello, this is ..... from the Health Protection Agency. You may have heard that a number of people became unwell after attending .....

We are conducting an investigation to try and find out what caused the outbreak.

As part of that we need to compare the kinds of foods or drinks consumed by people who were unwell with those consumed by people who were not unwell.

Could I ask you a few questions about this?

Any information you provide will be completely confidential.

```

                Unique sequential {ID}   <IDNUM>
                    {Case} {stat}us #
(Confirmed case=2, probable case=1, control=0)
                {Match} code (if matched study) ###
                    Interviewee   #
                (1=self, 2=parent, 3=spouse, 4=other)
                    Date of interview <dd/mm/yy>
    
```

PID should be recorded separately but linked to the above ID

What is your surname?

What is your first name

What is your DOB?

\*\*\*\*\*

Demographic data

\*\*\*\*\*

What is your {age}? ### year  
(Will need additional age field if outbreak affects under-ones)  
Male or female {sex}? <A> (M/F)

\*\*\*\*\*  
Disease history - skip this section for controls  
\*\*\*\*\*

Let me ask you about any symptoms you have had since the (date and time of suspected exposure).

On what {date} did you first feel {unwell}? <dd/mm/yy>  
At what {time} of day did you first feel {unwell}? ##.##  
(24 hour clock)

Are you {still} {ill} now? #  
For how many {days} were you {unwell}? ##

Were you {admitted} to hospital with this illness? #

Did you have any of the following symptoms between -dates-?

{Diarrhoea} (three or more loose stools per day) #  
    {Blood} in your {stools} #  
            {Vomiting} #  
            {Nausea} #  
    {Abdo}minal {pain} or cramps #  
    Were you {feverish}? #

[Add other symptoms if not GI illness under investigation]

\*\*\*\*\*  
Exposures  
\*\*\*\*\*

Let me ask you about the different foods that you ate or tasted while at .....

- Foodstuff1 #
- Foodstuff2 #
- Foodstuff3 #
- Foodstuff4 #
- Foodstuff5 #
- Foodstuff6 #
- Foodstuff7 #
- Foodstuff8 #
- Foodstuff9 #
- Foodstuff10 #
- Foodstuff11 #

Foodstuff12 #  
 Foodstuff13 #  
 Foodstuff14 #  
 Foodstuff15 #  
 Foodstuff16 #  
 Foodstuff17 #  
 Foodstuff18 #  
 Foodstuff19 #  
 Foodstuff20 #

[All can be set to default to No]

[Alternatively, where most have consumed a particular foodstuff, it may be useful to know the amount of a particular foodstuff that was eaten, in order to look for a dose-response relationship.]

Would you say that you ate a small, medium or large {amount} of  
 foodstuff {1}? <A>  
 (S=small, M=medium, L=large)

or:

How many {portions} of foodstuff {1} did you eat? #

NB: portion sizes are notoriously subjective

- use more objective measures such as amount in tablespoons if feasible

Let me ask you about the different drinks that you had  
 while at .....

Drink1 #  
 Drink2 #  
 Drink3 #  
 Drink4 #  
 Drink5 #

Have you eaten food at any of the following establishments during  
 the period .....

Food establishment 1 #  
 Food establishment 2 #  
 Food establishment 3 #  
 Food establishment 4 #  
 Food establishment 5 #

Have you eaten food purchased at any of the following outlets  
 during the period .....

Food establishment 1 #

Food establishment 2 #  
Food establishment 3 #  
Food establishment 4 #  
Food establishment 5 #

Have you drunk water from any of the following sources during the period .....

Water source 1 #  
Water source 2 #  
Water source 3 #  
Water source 4 #  
Water source 5 #

Have you been swimming in any of the following places during the period .....

Swimming place 1 #  
Swimming place 2 #  
Swimming place 3 #  
Swimming place 4 #  
Swimming place 5 #

Have you visited any of the following places?

Place 1 #  
Place 1 #

Did you have contact with {animals} while at .....? #

Have you {travel}ed abroad since .....? #

{Destinat}ion? -----

Known {contact} with probable or confirmed case #

Further questions relevant to the outbreak can be included here  
e.g. did you reheat foodstuff 1?

\*\*\*\*\*

Additional information

\*\*\*\*\*

Laboratory {specimen} collected #  
{Date} of {spec}imen collection <dd/mm/yy>

{Results} of laboratory specimen <A >  
Results of {typing} <A >

Date of data {entry} <Today-dmy>

Notes:

Many thanks for helping us with our investigation.

*Health care associated infection questionnaire*

The following template and associated files can be modified for use in any suspected HCAI outbreak. Many of the questions will not be relevant to a particular outbreak and can be deleted.

To print this questionnaire, use File/Print Data Form in Epidata. Set Automatic Field Naming in Epidata options if not already done.

The following assumes data collection is from review of patient case notes and focuses on C.diff.

\*\*\*\*\*

{ID} number of investigating officer \_\_\_\_\_  
{Date} of {Entry} <Today-dmy>

## PATIENT INFORMATION

\*\*\*\*\*

Unique anonymising {ID} for patient <IDNUM>

Case {Status} #  
(0=control,1=probable case,2=Confirmed case)  
{Date} of {Interview} <dd/mm/yyyy>  
{Date} of {Birth} <dd/mm/yyyy>  
{Age} in years ###  
{Sex} #  
(1=M, 2=F, 9=Unknown)

{Date} of {Admission} <dd/mm/yyyy>  
{Source} of {Admission} #  
(1=usual place of residence, 2=other NHS hospital, 3=care home,4=other, 9=unknown)

{Inpatient} in the three months before this admission? #  
(0=No, 1=Yes, 9=unknown)

{Still} an inpatient? {inpatient} #  
(0=No, 1=Yes, 9=unknown)

{Date} of {discharge} <dd/mm/yyyy>  
{Date} of positive {sample} date <dd/mm/yyyy>

{Ward} at date of positive {sample} \_\_\_\_\_

{Wards} patient has occupied beds on during this inpatient stay \_\_\_\_\_

{Specialty} {code} at date of positive sample ###

{Other} {specialties} patient under during this inpatient stay) \_\_\_\_\_

(if under joint management by more than one specialty then please specify)

Potentially {expos}ed to Clostridium difficile? #  
(0=No, 1=Yes, 9=Unknown)

(Overnight stay on ward housing other patients with known Clostridium difficile)

{Outcome} of {pat}ient {Outcome}{pat} #  
(1=alive, 2=dead, 9=unknown)

{Prior} {diag}nosis of norovirus infection during this inpatient stay #  
(0=No, 1=Yes, 9=Unknown)

Has patient undergone {surgery} during this inpatient stay #  
(0=No, 1=Yes, 9=Unknown)

{Type} of {surg}ery -----

Has the patient undergone {tube}/enteral {feed}ing #  
(0=No, 1=Yes, 9=Unknown)

IV/oral {a}nti{b}iotic {therapy} during this inpatient stay #  
(0=No, 1=Yes, 9=Unknown)

Classes of prior antibiotic therapy

{Narr}ow {spec}trum penicillins #  
(0=No, 1=Yes, 9=Unknown)

(benzathine penicillin/benzylpenicillin (penicillin G)/  
phenoxymethylpenicillin penicillin V)/procaine penicillin/methicillin  
oxacillin/nafcillin/cloxacillin/dicloxacillin/flucloxacillin/temocillin)

{Mod}erate {spec}trum penicillins #  
(0=No, 1=Yes, 9=Unknown)  
(amoxicillin, ampicillin)

{Broad} {spec}trum penicillins #  
(0=No, 1=Yes, 9=Unknown)  
(coamoxiclav)

{Ext}ended {spec}trum penicillins #  
(0=No, 1=Yes, 9=Unknown)  
(azlocillin, carbenicillin, ticarcillin, mezlocillin, piperacillin)

{Aminogly}cosides #  
(0=No, 1=Yes, 9=Unknown)

{Macrol}ides #  
(0=No, 1=Yes, 9=Unknown)

{Cephalo}sporins ({1st} generation) eg cefalexin #

(0=No, 1=Yes, 9=Unknown)

{Cephalo}sporins ({2nd} generation) eg cefuroxime #  
(0=No, 1=Yes, 9=Unknown)

{Cephalo}sporins ({3rd} generation) eg ceftriaxone, ceftazidime, cefotaxime #  
(0=No, 1=Yes, 9=Unknown)

{Quino}lones ({2nd} generation) eg ciprofloxacin, norfloxacin, ofloxacin #  
(0=No, 1=Yes, 9=Unknown)

{Quino}lones ({3rd} generation) eg moxifloxacin #  
(0=No, 1=Yes, 9=Unknown)

{Sulpho}namides #  
(0=No, 1=Yes, 9=Unknown)

{Tetra}cyclines eg doxycycline #  
(0=No, 1=Yes, 9=Unknown)

{Carbap}enem eg imipenem #  
(0=No, 1=Yes, 9=Unknown)

{Nitroim}idazole eg metronidazole, tinidazole #  
(0=No, 1=Yes, 9=Unknown)

{Nitrofu}ran eg nitrofurantoin #  
(0=No, 1=Yes, 9=Unknown)

{Rifamy}cin eg rifampicin #  
(0=No, 1=Yes, 9=Unknown)

{DHFR} {inh}ibitor eg trimethoprim #  
(0=No, 1=Yes, 9=Unknown)

Use of shared {commode} during this inpatient stay {commode} #  
(0=No, 1=Yes, 9=Unknown)

Does the patient have any of the following conditions?:

{Myo}cardial {inf}arct #  
(0=No, 1=Yes, 9=Unknown)

{Cong}estive {heart} failure #  
(0=No, 1=Yes, 9=Unknown)

{Per}ipheral {vasc}ular disease #  
(0=No, 1=Yes, 9=Unknown)

{C}erebro{v}ascular {d}isease #  
(0=No, 1=Yes, 9=Unknown)

{Dem}entia #  
(0=No, 1=Yes, 9=Unknown)

{Chron}ic {pul}monary disease #  
(0=No, 1=Yes, 9=Unknown)

{Conn}ective {tiss}ue disease #  
(0=No, 1=Yes, 9=Unknown)

{Ulcer} disease #  
(0=No, 1=Yes, 9=Unknown)

{Mild} {liv}er disease #  
(0=No, 1=Yes, 9=Unknown)

{Diab}etes #  
(0=No, 1=Yes, 9=Unknown)

{Hemip}legia #  
(0=No, 1=Yes, 9=Unknown)

{Mod}erate or {sev}ere {ren}al disease #  
(0=No, 1=Yes, 9=Unknown)

{Diab}etes {with} end {o}rgan {d}amage #  
(0=No, 1=Yes, 9=Unknown)

Any {tumour} #  
(0=No, 1=Yes, 9=Unknown)

{Leuk}aemia #  
(0=No, 1=Yes, 9=Unknown)

{Lymph}oma #  
(0=No, 1=Yes, 9=Unknown)

{Mod}erate or {sev}ere {liv}er disease #  
(0=No, 1=Yes, 9=Unknown)

{Metast}atic solid {tum}our #  
(0=No, 1=Yes, 9=Unknown)

{AIDS} #  
(0=No, 1=Yes, 9=Unknown)

*Environmental questionnaire*

\*\*\*\*\*  
 Template questionnaire for use in the investigations related to  
 environmental exposures  
 \*\*\*\*\*

The following template and associated files can be modified for use  
 in an incident relating to possible environmental exposures,  
 whether data collection is by telephone interview or respondents  
 complete the questionnaire themselves. Many of the questions will  
 not be relevant to a particular incident and can be deleted.

To print this questionnaire, use File/Print Data Form in Epidata.  
 Before using this questionnaire in Epidata, set Automatic Field  
 Naming in Epidata options if not already done.

It may be helpful to have a calendar to hand when completing  
 this questionnaire.

\*\*\*\*\*  
 Preamble - suggested script  
 \*\*\*\*\*

Hello, this is ..... from the Health Protection Agency.  
 You may have heard that a number of people became unwell after  
 attending ...../with .....  
 We are conducting an investigation to try and find out why.  
 As part of that we need to compare what people who were unwell were  
 exposed to compared to those people who were not unwell.  
 Could I ask you a few questions about this?  
 Any information you provide will be completely confidential.

Unique sequential {ID} <IDNUM>  
 {Case} {stat}us #  
 (Confirmed case=2, probable case=1, control=0)  
 {Match} code (if matched study) ###  
 Interviewee #  
 (1=self, 2=parent, 3=spouse, 4=other)  
 Date of interview <dd/mm/yy>

PID should be recorded separately with the ID above to link the information  
 What is your surname?  
 What is your first name?  
 What is your DOB?

\*\*\*\*\*  
 Demographic data  
 \*\*\*\*\*

What is your {age}? ###  
Male or female {sex}? <A> (M/F)  
{Postcode} of residence <A >

\*\*\*\*\*

Exposures

\*\*\*\*\*

I would like to ask you a few questions about your experience of this event.

Were you {exposed} to this event as: #  
1=Resident 2=Passerby 3=Employee 4=Emergency services  
5=Local authority 6=Volunteer 7=Other

Were you {at} the event {site} when the event started? #

At the beginning of the event, {where} were you? #  
1=Inside building or structure 2=Inside a car/other vehicle  
3=Outside 4=At some other location

{0ther} {loc}ation (specify) -----

- Event specific question 1 #
- Event specific question 2 #
- Event specific question 3 #
- Event specific question 4 #
- Event specific question 5 #

\*\*\*\*\*

Health effects

\*\*\*\*\*

Before the event, did you have any of the following {conditions}?  
{Chronic} illness #  
{Phys}ical {disab}ility #  
{0th}er {disab}ility #

Please describe {your} {cond}itions -----

Do you {smoke}? #  
Are you {pregnant}? #

Were you {ill} as a result of this event? #

Did you have any of the following symptoms between -dates and times-?

Symptom 1 #  
Symptom 2 #  
Symptom 3 #  
Symptom 4 #  
Symptom 5 #

On what {date} did you first feel {unwell}? <dd/mm/yy>  
At what {time} of day did you first feel {unwell}? ##.##  
(24 hour clock)

Are you {still} {ill} now? #  
For how many {days} were you {unwell}? ##

Were you {admitted} to hospital with this illness? #

Case {died} #  
{Date} of {death} <dd/mm/yy>

\*\*\*\*\*  
Additional information  
\*\*\*\*\*

{Toxicology} sample collected #  
{Date} of {tox}icology sample collection <dd/mm/yy>  
{Results} of {tox}icology sample <A >

{Environmen}tal sample collected #  
{Date} of {envir}onmental sample collection <dd/mm/yy>  
{Results} of {envir}onmental sample <A >

Date of data {entry} <Today-dmy>

Notes:

Many thanks for helping us with our investigation.

*Analysis template*

```

* A simple example programme to analyse outbreak data

* Close any open data file
close

* Look up help for a command
help close

* Close any open log file
logclose

* Clear the screen
cls

* Change working directory
cd "C:\Documents and Settings\user.name\Desktop"

* Open log file
logopen outbreaklog

* Read in example data file included in field epi toolkit (outbreak.rec)
read

* List the variable names
var

* Visually check data for accuracy and missing data
browse *

* Tell Epidata Analysis which code (here 999) used to denote a missing variable
missingvalue age /999

* Look for data entry errors
* by summarising and plotting each quantitative variable
describe *
histogram age

* Correct outlier after checking paper form
select age > 100
list
if id=23 then age=38
select
histogram age

* Look for data entry errors by tabulating each categorical variable
tables * /f
tables sex /m

```

\* Correct data entry error after checking form

```
if sex="ff" then sex="f"
```

```
tables sex
```

\* Create any new variables required and add labels

```
define agegp #
```

```
agegp=999
```

```
missingvalue age /999
```

```
if age < 40 then agegp=0
```

```
if age >=40 then agegp=1
```

```
tables agegp
```

```
label agegp "Age group"
```

```
labelvalue agegp /0="Under 40"
```

```
labelvalue agegp /1="40 and over"
```

\* Describe outbreak in terms of time with an epidemic curve

```
epicurve status dateonset /edit
```

\* Describe outbreak in terms of place

\* (NB: no relevant data in this data set)

\* Describe outbreak in terms of person characteristics

\* (for case control or cohort study , often stratified by case/control status)

```
means age /by=status
```

```
tables status sex /c
```

\* (Alternatively look at "stattables" command)

```
help stattables
```

\* Univariate analysis

\* The following command produces a table for a cohort study

\* summarising attack rates and relative risks

\* with confidence intervals and p values

```
tables status beefcurry chicken salad /oa /ci /t /ex
```

\* The following command produces a table for a case control study

\* giving a 2 by 2 table with odds ratios

\* with confidence intervals and p values

```
tables status beefcurry chicken /ct /ci /t /ex
```

\* Further analysis can look at issues of confounding or interaction

\* Epidata can produce adjusted odds ratios

\* but does not do logistic regression

```
tables status beefcurry chicken /t /o
```

\* Epidata Analysis to ask user where to save data

```
savadata mydata /replace
```

\* Delete graphs  
erasepng /noconfirm

\* Close programme  
exit

## *Report template*

Responsibility to write: CCDC

Outbreak Report Template

Contents Page

Executive Summary

1. Introduction

2. Background

3. Investigation of the outbreak

3.1 Epidemiological

3.2 Environmental

3.3 Microbiological/Toxicological

4. Results

4.1 Epidemiological

4.2 Environmental

4.3 Microbiological

5. Control measures

5.1 Overall co-ordination and management of the outbreak

5.2 Care of cases

5.3 Prevention of further cases (primary and secondary spread)

5.4 Public information

5.5 Information to professionals/businesses, etc

5.6 Outline of food safety enforcement action

6. Communication and media

7. Discussion and conclusion

8. Lessons learned and recommendations

9. Appendices

Executive Summary

Introduction

A brief summary of the outbreak/ setting the scene.

Briefly describe:

When the outbreak occurred; How the outbreak was discovered; Where or what foods were implicated; Important facts to be drawn out; Total number; Summary of cases investigated

Background

Optional section depending on the outbreak and implicated organism(s).

If uncommon pathogen implicated/ organism with serious consequences (i.e. E. coli 0157), give brief description of clinical features, incubation period, infectious dose, source and modes of spread, diagnosis and treatment, etc.

Also give background prevalence of the disease locally, nationally and globally if relevant.

Investigation of the outbreak

Chronology of key dates and events.

### 3.1 Epidemiological

(i) Descriptive: e.g. description of initial cases/ case definition and hypothesis generation/ demographic characteristics/ geographical distribution of cases / enhanced surveillance

(ii) Analytical: case control and/or cohort studies.

### 3.2 Environmental

e.g. Inspection of premises/ source of food and its distribution / food, water or environmental sampling / risk assessment / process enquiry / staff interviews / possible sources of infection

### 3.3 Microbiological/Toxicological

Local labs, reference labs, etc, clinical, food/water and environmental samples

Results

### 4.1 Epidemiological

### 4.2 Environmental

### 4.3 Microbiological

Control measures

5.1 Overall co-ordination and management of the outbreak

5.2 Care of cases

5.3 Prevention of further cases (primary and secondary spread)

5.4 Public information

5.5 Information to professionals/businesses, etc

5.6 Communication and Media

Brief information/ description regarding communication throughout the investigation, both internal and external to all organisations involved.

Details of which organisation took the lead for communications with the media

Discussion and conclusion

Lessons learned and recommendations

Appendix

Contents may depend upon target audience

# *Audit standards*

## *Health Protection Agency Incident and Outbreak standards*

The Health Protection Agency Incident and Outbreak Standards aim to “...ensure the application of appropriate risk assessment and epidemiological investigation supported by microbiological and environmental investigation to determine and document the nature, extent and causation of incidents.” Among these are several standards which are relevant to field epidemiology, principally:

- Relevant key staff should be trained in and updated in their outbreak and incident plans and their roles and responsibilities and public health/epidemiology skills.
- Protocols should be drawn up to cover specific common outbreak/incident scenarios which specify trigger points for investigation, e.g. Legionnaires disease, TB, bacterial gastrointestinal illnesses, seasonal 'flu, or incidents in healthcare settings e.g *C. difficile*. These protocols should be reviewed at regular intervals.
- Data should be stored and transferred using an appropriate secure method that is compliant with Caldicott principles, the Data Protection Act and other HPA guidance on confidentiality and security of data and information.
- For Level 1 incidents, there should be a clear risk assessment process with a record of actions agreed based upon the assessment, along with good basic descriptive epidemiology.
- Level 2 or above incidents should also have good quality epidemiology carried out, risk assessments undertaken, and results documented. Investigations should include:
  - Consideration of any uncertainty and need for new knowledge
  - Initial hypothesis considered and recorded
  - Population at risk defined
  - Case definitions
  - An epidemic curve
  - Recording how case ascertainment was or will be carried out.
  - Involvement of relevant microbiologist and other partners early on
  - Line listings of confirmed, probable and possible cases

- For all outbreaks and incidents, analytic epidemiology should routinely be considered and decisions recorded on whether to undertake such studies or not.
- For Level 2 incidents, consideration should be given to an analytical study in consultation with a senior epidemiologist.
  - For outbreaks or incidents of national significance (i.e involving cases in several parts of the country or incidents of high public health scientific or political interest) this should always involve referral to the HPA Rapid Outbreak Response Panel (RORP).<sup>46</sup>
- There should be documented consideration of ethical and research governance issues.
- Investigating HPA staff should be competent either to undertake local analytical studies (simple cohort or case control studies) or should easily be able to access practical and active HPA epidemiological support to do so.
  - Local HPUs should be supported by training and assistance in the design, conduct and analysis of such studies.
  - Support, advice and practical help should be readily available from LaRS Specialist Epidemiology staff where necessary.
- A vehicle or source is identified for gastrointestinal outbreaks, wherever possible, and for every Level 2 and above food poisoning outbreak.<sup>47</sup>
- All Level 1 incidents should be well documented using a template<sup>48</sup> capturing standard information *e.g.* numbers at risk, numbers affected.
- For all Level 2 and above incidents there should be a report on the results of investigation and action points which is disseminated to partners in a timely way. It should include recommendations and lessons as well as a clear indication of who needs to take any action.
  - Nationally agreed templates for outbreak and incident reports should be produced.
  - Reports produced should be in compliance with them.
  - Within the HPA, Level 2 and above outbreak and incident reports should be held locally (HPU or region), copied to regional directors, and logged nationally (possibly through IRIS<sup>49</sup>) to allow searches for similar reports.
  - Lessons identified in the incident should be recorded and included in the final report.
  - Reports should be disseminated to relevant partner organisations.
- The presumed cause, source and mode of spread should be recorded, along with the total numbers at risk and affected.
- Incidents and outbreak investigations should be routinely audited against these standards.

<sup>46</sup> To be established<sup>47</sup> Aspirational standard<sup>48</sup> Yet to be agreed<sup>49</sup> See section on IRIS standards on page 47.

- Each Level 2 and above incident should have an audit carried out within the following year and implications for training and developing capacity and capability for epidemiological investigation explicitly reviewed.

A suggested audit tool based on LaRS outbreak incident and outbreak standards may be found in tables 7 to 11.

### *IRIS audit standards*

The HPA Incident and Reporting Information System (IRIS) is a centralised Web enabled database, managed by the Specialist Epidemiology Service at HPA North West on behalf of the Local and Regional Services (LaRS) Directorate, which allows incidents to be logged to communicate accessible and timely information to key senior HPA officers. The HPA defines 5 incident response levels, based on an ongoing risk assessment of incidents notified to the HPA or identified internally. IRIS has a number of auditable Key Performance Indicators relevant to outbreak and investigation investigation, which are summarised below.

- 90% of Level 1 incidents should be reported on IRIS within 24 hours.
- 90% of Level 2 incidents should be reported in IRIS within 12 hours.
- The log should be updated when the incident is closed.
- Incidents should be promptly and appropriately investigated, managed and recorded, with lessons identified.
- 100% of incident reports should be logged within 1 month of the end of the incident.
- Sources/vehicles of infection/pathways of transmission should be identified in 50% of Level 1 and 2 incidents within 3 weeks of recognition.

### *Possible additional audit standards*

The Field Epidemiology Toolkit development team have also produced a number of developmental/aspirational standards which could be of use to encourage performance of a higher standard than is set by the existing audit standards.

- The Field Epidemiology Toolkit should be reviewed and updated at intervals of no more than two years.
- Training for practitioners and public health specialists should include the field epidemiology competencies listed on page 7.
- Regional epidemiology units should lead a rolling programme of field epidemiology training and exercises to maintain the field epidemiology skills of practitioners and public health specialists.
- Systematic collection and collation of descriptive epidemiological data should commence within 48 hours of the recognition of an outbreak or incident.

- Systematic collection and collation of descriptive epidemiological data should commence within 24 hours of the recognition of an outbreak or incident of Level 2 or above.
- For Level 2 and above incidents and significant Level 1 incidents, timely interim and final descriptive epidemiological reports should be produced and circulated.
  - Summary points should be available within one month of the start of the investigation.
  - Final reports should be available within three months of the conclusion of the incident.
- Outbreak control teams should consider whether to initiate an analytical study at their first (and subsequent) meetings.
  - The decision should be recorded in the minutes or the incident log.
- When an analytical study is required, a draft study protocol should be agreed by the outbreak control team.
  - The rationale for the chosen study design should be chosen.
  - There should be clear inclusion and exclusion criteria.
- Data collection for an analytical study should begin within three days of the protocol being agreed by the outbreak control team.

| No.      | Criterion   | Data sources                     | Compliance with standard                |
|----------|---|----------------------------------|---|
| <b>1</b> | <b>Relevant plans, policies and best practice guidance</b>  |                                  |   |
| 1a       | Incident/outbreak management plan available   | Plan                             | Fully met<br>/Partially met<br>/Not met |
| 1a       | Plan and tested or used within the previous two years   | Record of test / evidence of use | Fully met<br>/Partially met<br>/Not met |
| 1b       | Specific local/national guidance available  | Guidance                         | Fully met<br>/Partially met<br>/Not met |
| <b>2</b> | <b>Incident Management Team (IMT) arrangements</b>  |                                  |   |
| 2a       | IMT convened when the incident triggers agreed levels   | Minutes of IMT meetings          | Fully met<br>/Partially met<br>/Not met |
| 2b       | Correct incident level declared   | Minutes of IMT meetings          | Fully met<br>/Partially met<br>/Not met |
| 2c       | Agreed terms of reference   | Minutes of IMT meetings          | Fully met<br>/Partially met<br>/Not met |
| 2d       | Membership appropriate to the incident (Level 1 outbreaks would typically include: Incident commander (CCDC/Senior HPN), PCT DPH (or appropriate deputy), EHO, communications & admin support. Optionally NHS microbiologist/or HPA lab rep, regional epidemiologist. Level 2 outbreaks: outbreak commander agreed by Regional director or nominee) | Minutes of IMT meetings          | Fully met<br>/Partially met<br>/Not met |
| 2e       | Roles and responsibilities agreed and allocated to IMT members  | Minutes of IMT meetings          | Fully met<br>/Partially met<br>/Not met |
| 2f       | Media spokesperson and lead communications officer agreed   | Minutes of IMT meetings          | Fully met<br>/Partially met<br>/Not met |
| <b>3</b> | <b>Adequacy of resources</b>  |                                  |   |
| 3a       | Key players trained and have participated in a training exercise/outbreak within the previous 2 years   | Training records                 | Fully met<br>/Partially met<br>/Not met |
| 3b       | Specific training on appropriate software used to record and analyse the outbreak provided to relevant staff in the previous 2 years <i>e.g.</i> Epidata or Access  | Training records                 | Fully met<br>/Partially met<br>/Not met |
| 3c       | Adequate staff resources including administrative and information officer support identified  | IMT feedback                     | Fully met<br>/Partially met<br>/Not met |
| 3d       | Adequate facilities/equipment, including incident room, communications, IT, catering  | IMT feedback                     | Fully met<br>/Partially met<br>/Not met |

Table 7: Suggested audit tool for incident management - structure

| No.      | Criterion   | Data sources                             | Compliance with standard                |
|----------|---|--|---|
| <b>4</b> | <b>Outbreak recognition and initial response</b>  |  |   |
| 4a       | Information leading to suspicion of an outbreak being received and leads to initial risk assessment without available delay                                 | Log/records                              | Fully met<br>/Partially met<br>/Not met |
| 4b       | Initial investigation to clarify nature and existence of outbreak undertaken within 24 hours (Level 2) or 48 hours (Level 1) of recognition of the outbreak | Log /records, initial report             | Fully met<br>/Partially met<br>/Not met |
| 4c       | Incident recorded on IRIS and reported according to HPA incident level  | IRIS entry/log                           | Fully met<br>/Partially met<br>/Not met |
| <b>5</b> | <b>Effectiveness of IMT</b>   |  |   |
| 5a       | Members aware of and followed the outbreak plan   | IMT feedback, log/records/ IMT minutes   | Fully met<br>/Partially met<br>/Not met |
| 5b       | Lead organisation with accountability for outbreak management agreed and recorded at first IMT meeting  | IMT minutes                              | Fully met<br>/Partially met<br>/Not met |
| 5c       | Members (including chair) fulfil allocated roles and responsibilities   | Outbreak plan, IMT minutes, IMT feedback | Fully met<br>/Partially met<br>/Not met |
| 5d       | Frequency of meetings in accordance with decisions required, and escalation criteria for additional action agreed at every meeting.                         |  |   |
| <b>6</b> | <b>Documentation</b>  |  |   |
| 6a       | Outbreak log maintained   | Log/records                              | Fully met<br>/Partially met<br>/Not met |
| 6b       | IMT meeting minutes produced and circulated within 24 hours   | IMT minutes                              | Fully met<br>/Partially met<br>/Not met |
| 6c       | Timely interim outbreak/epidemiological reports produced and circulated   | Reports                                  | Fully met<br>/Partially met<br>/Not met |
| 6d       | Timescale for production of final report, authorship, and distribution agreed   | IMT minutes                              | Fully met<br>/Partially met<br>/Not met |
| 6e       | Outbreak declared over  | IMT minutes                              | Fully met<br>/Partially met<br>/Not met |

Table 8: Suggested audit tool for incident management - processes and interventions

| No.      | Criterion   | Data sources         | Compliance with standard                |
|----------|---|----------------------|---|
| <b>7</b> | <b>Epidemiological investigations undertaken</b>  |                      |   |
| 7a       | Appropriate case definitions developed and reviewed at each IMT meeting   | Log/records, report  | Fully met<br>/Partially met<br>/Not met |
| 7b       | Appropriate case finding measures instituted  | Log /records, report | Fully met<br>/Partially met<br>/Not met |
| 7c       | Initial descriptive epidemiology undertaken and updated as appropriate; including line list outbreak curve, description of demographic and geographic features,             | Log/records, report  | Fully met<br>/Partially met<br>/Not met |
| 7d       | Hypothesis(es) generated on nature and origin of outbreak   | Log/records, report  | Fully met<br>/Partially met<br>/Not met |
| 7e       | Hypothesis(es) tested with analytic study if appropriate; using suitable study design; timeliness of design, implementation and analysis consistent with public health risk | Log/records          | Fully met<br>/Partially met<br>/Not met |
| 7f       | Appropriate microbiological investigations undertaken on patients and environment   | Log/records          | Fully met<br>/Partially met<br>/Not met |
| 7g       | Appropriate environmental investigation undertaken  | Log/records          | Fully met<br>/Partially met<br>/Not met |

Table 9: Suggested audit tool for incident management - processes and interventions

| No.      | Criterion  | Data sources   | Compliance with standard                |
|----------|--|--|---|
| <b>8</b> | <b>Control measures implemented</b>  |  |   |
| 8a       | All control measures are adequately recorded, including their rationale, responsibility for implementation and effect where known.   | Log/records, IMT minutes   | Fully met<br>/Partially met<br>/Not met |
| 8b       | All control measures have explicit criteria for change or withdrawal.  | Log/records, IMT minutes   | Fully met<br>/Partially met<br>/Not met |
| 8c       | Control measures instituted at appropriate time.   | IMT minutes  | Fully met<br>/Partially met<br>/Not met |
| <b>9</b> | <b>Effective communications</b>  |  |   |
| 9a       | Communications arrangements agreed   | IMT minutes  | Fully met<br>/Partially met<br>/Not met |
| 9b       | Communications implemented effectively between IMT members, with partner agencies, with health and other professionals with patients/cases and contacts, and with the media and public | Comms strategy, IMT minutes, letters, bulletins, briefings, media statements, IMT feedback | Fully met<br>/Partially met<br>/Not met |
| 9c       | Suitable balance achieved between protecting confidentiality and providing sufficient information to patients, the public and the media  | Media statements and coverage, IMT feedback, user feedback                                 | Fully met<br>/Partially met<br>/Not met |

Table 10: Suggested audit tool for incident management - processes and interventions

| No.       | Criterion  | Data sources              | Compliance with standard                |
|-----------|--|---------------------------|---|
| <b>10</b> | <b>Outbreak Control</b>  |                           |   |
| 10a       | Appropriate, effective and acceptable control measures implemented | Log/ records, IMT minutes | Fully met<br>/Partially met<br>/Not met |
| 10b       | Cause, source and mode of spread identified                        | Log/records, IMT minutes  | Fully met<br>/Partially met<br>/Not met |
| 10c       | Control of the outbreak achieved without avoidable delay.          | IMT minutes               | Fully met<br>/Partially met<br>/Not met |
| 10d       | Resource use appropriate   | Log/records               | Fully met<br>/Partially met<br>/Not met |
| 10e       | Effectiveness of communication to target groups                    | Log/records, IMT minutes  | Fully met<br>/Partially met<br>/Not met |

Table 11: Suggested audit tool for incident management - outcomes

## *References and further reading*

### Sources and reference materials:

- Disease outbreak manual. Porirua: Institute of Environmental Science & Research Limited; 2002. <http://www.surv.esr.cri.nz/episurv/Manuals/DiseaseOutbreakManual.pdf>
- Forward Thinking, Future Working. Framework specification for HPA Local and regional service provision 2008–2010. Health Protection Agency October 2008. HPA Local and Regional Services Business Plan 2009/2010.
- HPA Epidemiology Review
- International Ethical Guidelines for Epidemiological Studies. Council for International Organizations of Medical Sciences (CIOMS). Geneva 2009.
- Jewell NP. Statistics for epidemiology. Texts in Statistical Science 2004.
- Pajek. Free software for visualising social networks. <http://vlado.fmf.uni-lj.si/pub/networks/pajek/>
- Rodrigues L, Kirkwood BR. Case-control designs in the study of common diseases: updates on the demise of the rare disease assumption and the choice of sampling scheme for controls. *Int J Epidemiol.* 1990 Mar;19(1):205-13.
- STROBE statement. <http://www.strobe-statement.org/>
- Woodward CA, Chambers LW. Guide to questionnaire construction and question writing. The Canadian Public Health Association 1999.

### Further reading:

- CDC Epidemiology course.  
[http://www2a.cdc.gov/phtn/catalog/pdf-file/Epi\\_Course.pdf](http://www2a.cdc.gov/phtn/catalog/pdf-file/Epi_Course.pdf)
- Reference Guide on Epidemiology.  
<http://www.fjc.gov/public/pdf.nsf/lookup/sciman06.pdf/\protect\T1\textdollarfile/sciman06.pdf>
- An Overview of Outbreak Investigations.  
[http://nccphp.sph.unc.edu/focus/vol1/issue1/1-10verview\\_issue.pdf](http://nccphp.sph.unc.edu/focus/vol1/issue1/1-10verview_issue.pdf)
- Case Finding and Line Listing: A Guide for Investigators.  
[http://nccphp.sph.unc.edu/focus/vol1/issue4/1-4CaseFinding\\_issue.pdf](http://nccphp.sph.unc.edu/focus/vol1/issue4/1-4CaseFinding_issue.pdf)
- Epidemic Curves Ahead.  
[http://nccphp.sph.unc.edu/focus/vol1/issue5/1-5EpiCurves\\_issue.pdf](http://nccphp.sph.unc.edu/focus/vol1/issue5/1-5EpiCurves_issue.pdf)
- Mapping for Surveillance and Outbreak Investigation.  
[http://nccphp.sph.unc.edu/focus/vol5/issue2/5-2Mapping\\_issue.pdf](http://nccphp.sph.unc.edu/focus/vol5/issue2/5-2Mapping_issue.pdf)
- Hypothesis Generation During Outbreaks.  
[http://nccphp.sph.unc.edu/focus/vol1/issue6/1-6Hypothesis\\_issue.pdf](http://nccphp.sph.unc.edu/focus/vol1/issue6/1-6Hypothesis_issue.pdf)
- Hypothesis-Generating Interviews.  
[http://nccphp.sph.unc.edu/focus/vol2/issue1/2-1HypInterviews\\_issue.pdf](http://nccphp.sph.unc.edu/focus/vol2/issue1/2-1HypInterviews_issue.pdf)

- Selecting a Study Design.  
[http://nccphp.sph.unc.edu/focus/vol2/issue4/2-4StudyDesign\\_issue.pdf](http://nccphp.sph.unc.edu/focus/vol2/issue4/2-4StudyDesign_issue.pdf)
- Case-Control Studies for Outbreak Investigations.  
[http://nccphp.sph.unc.edu/focus/vol3/issue2/3-2Case-Control\\_issue.pdf](http://nccphp.sph.unc.edu/focus/vol3/issue2/3-2Case-Control_issue.pdf)
- Cohort Studies for Outbreak Investigations.  
[http://nccphp.sph.unc.edu/focus/vol3/issue1/3-1Cohort\\_issue.pdf](http://nccphp.sph.unc.edu/focus/vol3/issue1/3-1Cohort_issue.pdf)
- Database setup and EpiData.  
<http://www.rch.org.au/emplibrary/cebu/DatabaseSetupAndEpiData.pdf>
- EpiData Entry and Analysis software .  
<http://www.epidata.dk/>
- Data management for surveys and trials (EpiData).  
<http://www.brixtonhealth.com/DmEd.zip>
- Statistics at square one.  
<http://www.bmj.com/collections/statsbk/index.shtml>
- Data Analysis: Simple Statistical Tests .  
[http://nccphp.sph.unc.edu/focus/vol3/issue6/3-6DataTests\\_issue.pdf](http://nccphp.sph.unc.edu/focus/vol3/issue6/3-6DataTests_issue.pdf)
- Statistics review 4: Sample size calculations.  
<http://ccforum.com/content/6/4/335>
- OpenEpi sample size calculations online.  
<http://www.openepi.com/Menu/OpenEpiMenu.htm>
- Statistics review 1: Presenting and summarising data.  
<http://ccforum.com/content/6/1/66>
- Data Analysis Basics: Variables and Distribution.  
[http://nccphp.sph.unc.edu/focus/vol3/issue5/3-5DataBasics\\_issue.pdf](http://nccphp.sph.unc.edu/focus/vol3/issue5/3-5DataBasics_issue.pdf)
- Statistics review 3: Hypothesis testing and P values.  
<http://ccforum.com/content/6/3/222>
- Statistics review 8: Qualitative data - tests of association.  
<http://ccforum.com/content/8/1/46>
- 2-way Contingency Table Analysis.  
<http://statpages.org/ctab2x2.html>
- Confounding in Epidemiology.  
[http://www.collegeboard.com/prod\\_downloads/yes/4297\\_MODULE\\_10.pdf](http://www.collegeboard.com/prod_downloads/yes/4297_MODULE_10.pdf)
- Advanced Data Analysis: Methods to Control for Confounding (Matching and Logistic Regression).  
[http://nccphp.sph.unc.edu/focus/vol4/issue1/4-1AdvancedData\\_issue.pdf](http://nccphp.sph.unc.edu/focus/vol4/issue1/4-1AdvancedData_issue.pdf)
- Statistics review 14: Logistic regression.  
<http://ccforum.com/content/9/1/112>
- Analysis of epidemiological data using R and Epicalc.  
<http://apps.who.int/tdr/publications/training-guideline-publications/analysis-epidemiological-data/pdf/epicalc.pdf>

e-group for professionals using field epidemiology as part of health protection work:

<http://health.groups.yahoo.com/group/fieldepi/>

# *Index*

Analytical epidemiology, 10, 11  
Audit, 20

Bias, 19

Case cohort studies, 12  
Case control studies, 12  
Case definition, 8, 9, 13, 18  
Case finding, 9  
Cohort studies, 12  
Confidentiality, 15, 17  
Confounding, 19  
Controls, 12

Data analysis, 17  
Data cleaning, 17  
Data entry, 17

Descriptive epidemiology, 8

Environmental investigations, 22  
EpiData Entry and Analysis, 23  
Epidemic curves, 9, 10, 18

Health care associated infection, 21  
Hypothesis, 10, 18  
Hypothesis tests, 19

Inclusion and exclusion criteria, 13  
Interview methods, 15  
Interviewer training, 15

Key competencies, 7

Line listings, 8

Mapping, 10  
Matching, 13  
Multivariate analyses, 19

Questionnaire, 14

Report writing, 19  
Resource requirements, 11

Sample size calculation, 13  
Sources of advice, 11  
Study designs, 12  
Study protocol, 13

Univariate analyses, 19