



Institute of Environmental Science & Research Limited

Guidelines for the Investigation and Control of Disease Outbreaks



April 2012

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Suggested citation

Guidelines for the Investigation and Control of Disease Outbreaks. Porirua: Institute of Environmental Science & Research Limited; Updated 2011.

FW12020

Published in April 2002. Updated April 2012
by the Institute of Environmental Science & Research Limited

Kenepuru Science Centre
PO Box 50-348
Porirua, New Zealand

ISBN 978-1-877166-14-3 (Book)

ISBN 978-1-877166-15-0 (Web)

This document will be available on the ESR website www.esr.cri.nz

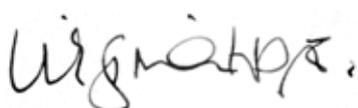
Foreword

This document is the latest revision of a series produced at different times over the past fifteen years. Over that time, there have been substantial changes to the environments in which outbreak investigators and responders operate.

The 2002 Disease Outbreak Manual was partly based on the *Guidelines for investigation of disease outbreaks in New Zealand* produced by the Institute of Environmental Science & Research Limited (ESR) in 1996 and revised in 1997. At that time, substantial changes were made to the overall approach to outbreak investigation, and new sections were included on environmental investigation, the contribution of laboratory techniques to outbreak investigation, communication during outbreak investigations and outbreak control activities. The section on case-control studies was revised to include more detailed guidance on designing and managing studies. It is now a decade since the 2002 Manual was produced. While the District Health Board and Public Health Unit landscapes have remained relatively unchanged over that period, there have been many significant and relevant changes elsewhere: changes to food and biosecurity legislation; changes in the structure, name and function of government departments (especially in relation to food safety); consequential changes in the organisational relationships between the different groups responding to aspects of an outbreak; a number of multi-DHB outbreaks which have been managed co-operatively under the oversight and direction of the appropriate government agencies; and a number of major international sporting events or domestic exercises which have focussed attention on how we can best respond to major infectious disease events.

The 2012 update has been re-named *Guidelines for the Investigation and Control of Disease Outbreaks (the Guidelines)* and, incorporated further changes - mainly in the areas of notifications systems, laboratory methods and incident response, including communications. It has also benefited from a previous review of best practice.

The title of the updated document has been changed to indicate its role as a guide to good practice in outbreak investigation. While its main focus is on food and waterborne infections, it should be emphasised that the content of several chapters is equally useful in other infectious disease outbreaks. We invite you to continue to let us know where improvements can be made as you use these Guidelines.



Virginia Hope

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Acknowledgements

The first edition of this manual was prepared by Craig Thornley and Michael Baker in 2002.

This update was edited by Don Bandaranayake.

Thanks are due to the following organisations:

Ministry of Health, Ministry for Primary Industries (formerly Ministry of Agriculture and Forestry) and the Public Health Units and specifically the following persons who contributed material for the updating of this document:

- Kerry Sexton, Shevaun Paine, Muriel Dufour, Ruth Pirie, Virginia Hope, Hilary Michie, Jenny Ralston, Jacqui Watson, Phil Shoemack, Greg Simmons, Craig Thornley, Darren Hunt, Trish Pearce, Helen Graham, Donald Campbell, Toby Regan, Christine Roseveare, Debbie Smith and Jackie Benschop.

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Executive summary

The ability to plan and implement effective disease outbreak management is a key responsibility of the public health services (PHS) in New Zealand and elsewhere. The *Guidelines for the Investigation and Control of Disease Outbreaks* provides a step-by-step approach to the basics of disease outbreak management for those who are new to the area, and a reference guide to specific aspects of the outbreak management process for those who already have a working knowledge in the area. These guidelines also provide copies of outbreak reporting forms and other outbreak resources.

Disease outbreaks are localised increases in cases of illness clearly in excess of that normally expected. The reasons for investigating and responding to outbreaks include the need to halt the outbreak and prevent further illness, to develop recommendations to prevent similar outbreaks occurring in the future, to address public concern, to improve understanding of new and emerging disease agents and transmission mechanisms, to satisfy local and international obligations and to use the opportunity to train staff.

Comprehensive disease outbreak management involves several separate components. The relative emphasis placed on each component varies depending on the circumstances of the outbreak. These guidelines recognise that the components need not always occur in a rigid, linear sequence to meet the overall objectives of disease outbreak management.

Agencies with responsibility for managing disease outbreaks need to prepare for outbreak contingencies. The keystone of preparation is development of an outbreak plan. The outbreak plan should identify the outbreak team, describe terms of reference for the team, provide outbreak investigation and response protocols, clarify the availability of materials and resources and define communication plans.

Occasionally disease outbreaks can seriously endanger health (or have the potential for doing so) due to their intensity or severity of outcome(s). These situations may occur at a local level, but are mostly multi-regional with agencies additional to those responsible for health being involved. In these emergency situations an outbreak management system utilising the Coordinated Incident Management System (CIMS) may be implemented. CIMS however can also be useful in local situations in managing emerging public health events. The key components of this system include incident control, operations, communication, inter-agency liaison, planning and intelligence & logistics. The New Zealand Coordinated Incident Management System (CIMS) blue book can be purchased from Fire & Rescue Services ITO - www.frsito.org.nz.

Optimal detection of disease outbreaks requires good disease information systems and regular and rigorous reviews of surveillance data. The information that is valuable for outbreak detection comprises reports of illness by the affected persons (self-reported illness) and surveillance of cases of notified disease reported by medical practitioners. Additional information is often required from these sources to enable outbreak detection.

Steps should be taken to verify detected disease outbreaks, unless the existence of the outbreak is self-evident. Verification involves confirmation of the accuracy of diagnosis and reporting, confirmation that the increase in cases is genuine and not due to changes in diagnostic and testing thresholds, and confirmation that the increase in cases is greater than expected. Once the outbreak has been confirmed, an assessment should be made about further steps to be taken, based on the relative priorities of the investigation and the response.

Outbreak description characterises the outbreak and involves the development of a case definition, further case finding, collection of standardised information about cases, descriptive analysis of case information, drawing an epidemic curve and calculating an incubation period. It is often useful to incorporate an environmental scan or situational analysis at this stage of the process. The descriptive

phase may be sufficient in itself to inform the outbreak response, or may show that a full investigation will not be worthwhile because a hypothesis cannot be defined.

Full outbreak investigation provides more robust information than the descriptive phase about the source and transmission route of the outbreak, but should be implemented only with due regard for the objectives of overall outbreak management. There are three major arms of full outbreak investigation: analytic epidemiological investigation, environmental investigation and laboratory investigation. Analytic epidemiological techniques primarily consist of retrospective cohort and case-control study designs. Environmental investigation progresses through several stages, including identification of the objectives and planning the investigation, accumulation of information, site visits and inspections and full environmental risk assessments. Laboratory investigation ranges from the provision of general microbiological and toxicological advice, assistance with outbreak identification, outbreak description and investigation.

Strategies to control the outbreak should be considered throughout outbreak management. Outbreak control measures are directed either at the outbreak source, at disease vectors or their reservoirs, or at protecting susceptible humans. These measures are often applied concurrently.

Communication should ideally be planned in advance, as part of overall outbreak preparation, with the development and implementation of a basic communication plan. The plan should address communication within the outbreak team, with the public and media, with government agencies such as the Ministry of Health, and with other agencies such as the Ministry for Primary Industries and, local authorities, industry groups and health service providers.

Outbreak documentation and reporting helps to ensure that maximum benefit can be accrued from lessons learnt from outbreak response activities. Early recording of interim outbreak details in the purpose-built database, EpiSurv,* (ideally as soon as the investigation begins) ensures that PHSs other than the one involved, ESR and the Ministry of Health can identify multi-region outbreaks. The three phases of outbreak documentation on EpiSurv are as follows: recording the early details of the outbreak, recording the immediate outcome of the outbreak response and the final report summary of the methods and results.

*EpiSurv is a secure web-based application based on the new Surveillance Information New Zealand (SurvINZ) architecture at ESR. Notifiable disease surveillance activities in New Zealand are carried out by both local and national authorities. ESR operates the national notifiable disease surveillance database, EpiSurv, on behalf of the Ministry of Health.

EpiSurv collates notifiable disease information on a real-time basis from the PHSs in New Zealand. Key data fields collected include case demographics, clinical features and risk factors. EpiSurv also incorporates an outbreak functionality that enables cases to be linked via a common cause. Information can be viewed via customisable local and national reports and maps. In 2007, ESR invested in an enhanced, robust and secure information management platform known as SurvINZ. ESR has integrated (and continues to integrate) its surveillance systems and activities onto SurvINZ to drive greater efficiency and deliver more integrated and timely information to its stakeholders and end users for the benefit of public health. EpiSurv7, a new web-based real-time version of the national notifiable disease surveillance system, was deployed in April 2007. National Guidelines 17 deployed a prototype contact-tracing module for use with EpiSurv7 for Exercise Cruickshank. EpiSurv7 is currently used by all public health units (PHUs) throughout New Zealand, and has 150 registered users. The system is extensible and scalable. Following the introduction of the direct laboratory notification system in May 2007, ESR is able to receive electronic laboratory notifications in HL7 format from external laboratories. ESR can process the messages to appear in EpiSurv so that local PHU staff can use EpiSurv to check whether the case already exists and then update or create a new case if required. The results can be appended to the appropriate case record and viewed as required.

Glossary

Agent (of disease)*	A factor, e.g., a microorganism, chemical substance or radiation, the presence or excessive presence of which is essential for the occurrence of disease.
Analytic epidemiological investigation*	Component of an investigation designed to examine associations, commonly putative or hypothesised causal relationships. Analytic epidemiological investigation is usually concerned with identifying or measuring the effects of risk factors, or is concerned with the health effects of specific exposure(s). Common types of analytic epidemiological investigation are case-control and cohort study designs.
Carrier**	A person or animal that harbours a specific infectious agent without discernible clinical disease and serves as a potential source of infection.
Case-case study	A study that compares the frequency of exposures among cases (ill people) with the frequency of exposures among other cases with a different strain of the same disease (ill people).
Case-control study	A study that compares the frequency of exposures among cases (ill people) with the frequency of exposures among controls (people without the illness).
Cohort study	A study that compares the rate of illness among people who have had a specific exposure with that among people who have not had that exposure.
Common event outbreak	An outbreak due to exposure of a group of persons to a noxious influence that is common to the individuals in the group, where the exposure is brief and essentially simultaneous and all resultant cases develop within one incubation period of the disease. Cases therefore have exposures that are grouped in place and time (synonym: point source outbreak).
Common site outbreak	An outbreak due to exposure of a group of persons to a noxious influence that is common to the individuals in the group, where exposures have occurred at the same place (or site) but over a longer time-period than those of common event outbreaks (i.e., grouped in place only). In the Outbreak Report Form, these outbreaks are called common source in a specific place.
Common source outbreak*	Outbreak due to exposure of a group of persons in a community to a noxious influence that is common to the individuals in the group. Under this definition, all outbreaks except community-wide outbreaks would be described as common source. This document therefore subcategorises these outbreaks into common event outbreaks (where exposures are grouped in time and place), dispersed common source outbreaks (grouped in time but not in place) and common site outbreaks (grouped in place but not in time).
Communicable disease**	An illness due to a specific infectious agent or its toxic products that arises through transmission of that agent or its products from an infected person, animal or inanimate source to a susceptible host, either directly or indirectly through an intermediate plant or animal host, vector or inanimate environment (synonym: infectious disease).
Community-wide outbreak	An outbreak affecting individuals in a community, where transmission predominantly occurs by direct exposure of susceptible people to infectious people (synonym: person-to-person outbreak).
Contact**	A person or animal that has been in an association with an infected person or animal or a contaminated environment in such a way that provides an opportunity to acquire the infection.
Contamination**	The presence of a disease agent on a body surface, in clothes, bedding, toys or other inanimate articles or substances, including water and food.

DFA test	Direct fluorescent antibody (DFA or dFA) (also known as "Direct immunofluorescence") It is called a DFA test because it directly tests the presence of antigen with a tagged antibody
Direct transmission**	Direct or essentially immediate transfer of infectious agents to a receptive portal of entry through which human infection may take place. Commonly by direct contact (e.g., by touching, kissing or sexual intercourse), by projection of droplet spray (e.g., by sneezing, coughing or talking), or by direct exposure to an agent in soil, compost or decaying vegetable matter.
Dispersed common source outbreak	Outbreak due to exposure of a group of persons in the community to a noxious influence that is common to the individuals in the group, where the exposures are not grouped in place (and may or may not be grouped in time). These outbreaks are often due to a distributed vehicle of infection transmission, such as a commercially prepared food item or a water supply. In this manual, the name for these outbreaks is abbreviated to dispersed.
Environment*	All that which is external to the individual human host.
Environmental investigation (of outbreaks)	An examination of the surroundings external to human hosts of illness, with the aim of identifying actual or potential vehicles of transmission and how processes in place failed to prevent human exposure to disease.
Epidemic*	The occurrence in a community or region of cases of an illness, specific health-related behaviour, or other health-related events clearly in excess of normal expectancy.
Exposure*	Proximity and/or contact with a potential source of a disease agent in such a manner that effective transmission of the agent, and harmful or protective effects of the agent may occur.
Household outbreak	Outbreak confined to members of a single household.
Incubation period**	The time interval between initial contact with an infectious agent and the first appearance of symptoms associated with the infection. In practice, symptoms used for calculation of the incubation period should reflect the case definition.
Index case*	The first case in a family or other defined group to come to the attention of the investigator.
Indirect transmission**	Transmission of infection that is either vehicle-borne or vector-borne.
Infectious agent**	An organism (virus, rickettsia, bacteria, fungus, protozoan or helminth) that is capable of producing infection or infectious disease.
Institutional outbreak	Outbreak confined to the population of a specific residential or other institutional setting, such as a hospital, rest home, prison or boarding school.
Laboratory investigation (of outbreaks)	Comparison of infectious disease agents in samples taken from different human hosts or vehicles of infection, with the aim of identifying vehicles for infection and delineating groups of individuals exposed to a common outbreak source.
MLVA	Multiple-locus variable-number tandem repeat (VNTR) analysis (MLVA) is a method employed for the genetic analysis of particular microorganisms, such as pathogenic bacteria, that takes advantage of the polymorphism of tandemly repeated DNA sequences.
Nosocomial infection**	An infection occurring in a patient in a hospital or other health care facility in whom it was not present or incubating at the time of admission.
Outbreak*	An epidemic limited to a localised increase in the incidence of a disease, such as in a village, town or closed institution.
Outbreak description	Component of outbreak investigation designed to describe the features of existing cases only (contrast with analytic epidemiologic study).

Outbreak investigation	Activities undertaken to establish the existence of an outbreak, describe the outbreak, and to identify the source, transmission mechanism and contributory factors, as a basis for outbreak response.
Outbreak management	All activities undertaken to investigate and respond to outbreaks (includes outbreak identification and preparation for investigation and response).
Outbreak response	Activities undertaken to prevent further transmission of disease, communicate effectively and to document the outbreak.
Pathogenicity**	The property of an infectious agent that determines the extent to which overt disease is produced in an infected population, or the power of the organism to produce disease.
PCR	The polymerase chain reaction (PCR) amplifies a single or a few copies of a piece of deoxyribonucleic acid (DNA) across several orders of magnitude, generating thousands to millions of copies of a particular DNA sequence.
Population*	All the inhabitants of a given country or area considered together.
Primary case*	The individual who introduces the disease into the group under study.
PFGE	Pulsed-field gel electrophoresis (PFGE) is a technique used to separate large DNA molecules by applying an electric field that periodically changes direction to a gel matrix.
Reservoir of infection**	Any person, animal, arthropod, plant, soil or substance (or combination of these) in which an infectious agent normally lives and multiplies, on which it depends primarily for survival, and where it reproduces itself in such a manner that it can be transmitted to a susceptible host.
Secondary case*	Case of disease occurring among contacts within the incubation period, following exposure to the primary case.
Source of illness**	The person, animal, objects or substance from which a disease agent passes to a host.
Susceptible**	A person or animal not possessing sufficient resistance against a particular pathogenic agent to prevent contracting infection or disease when exposed to the agent.
Suspect**	Illness in a person whose history and symptoms suggest that he or she may have or be developing a communicable disease.
Transmission of illness**	Any mechanism by which a disease agent is spread through the environment or to another person. Mechanisms are defined as either direct or indirect.
Vector**	An insect or living carrier that transports an infectious agent from an infected individual or its wastes to a susceptible individual, or its food or immediate surroundings.
Vehicle of infection*	The mode of transmission of an infectious agent from its reservoir to a susceptible host. This can include food, water or a vector.
VTEC	Verotoxin-producing <i>Escherichia coli</i> (VTEC) comprise strains of the bacterium <i>Escherichia coli</i> that, when infecting humans, have been linked with the severe complication of haemolytic-uraemic syndrome.
Zoonosis**	An infection or infectious disease transmissible under natural conditions from vertebrate animals to humans.

Notes: * Definition adapted from *Dictionary of Epidemiology*¹

** Definition adapted from *Control of Communicable Diseases Manual*²

Table of Contents

Foreword	iii
Disclaimer	iv
Acknowledgements	iv
Executive summary.....	v
Glossary	vii
Table of Contents.....	x
1. Introduction	1
1.1. Purpose of this manual	1
1.2. Changes in this edition	2
1.3. What is an outbreak?	2
1.4. Reasons for investigating outbreaks	3
1.5. Types of outbreaks	5
1.6. Ethical issues in outbreak investigation	7
1.7. Privacy of information	8
1.8. Data disclosure policies	9
1.9. Cultural competency in outbreak management	9
1.10. The Treaty of Waitangi in outbreak management	9
1.11. Where to go for help	10
1.12. Overview of the outbreak management process.....	11
1.13. How to use this manual.....	12
2. Preparation	14
2.1. Outbreak plans.....	14
3. Surveillance to detect outbreaks.....	19
3.1. Disease notifications and other formal surveillance	19
3.2. Self-reported cases of illness.....	21
3.3. Informally-reported suspected outbreaks	22
4. Outbreak confirmation and assessment.....	23
4.1. Step 1: Confirm the diagnosis is correct.....	23
4.2. Step 2: Confirm the increase in cases is real	24
4.3. Step 3: Confirm that the increase represents an outbreak.....	24
4.4. Step 4: Decide what type of outbreak is occurring	25
4.5. Step 5: Review the information: Make a decision on further investigation and control	25
5. Outbreak description	28
5.1. Step 1: Compile information collected.....	28
5.2. Step 2: Develop a case definition	28
5.3. Step 3: Find other potential cases.....	30
5.4. Step 4: Collect information about cases	31
5.5. Step 5: Perform descriptive analysis of cases	31

5.6.	Step 6: Draw an epidemic curve.....	32
5.7.	Step 7: Calculate an incubation period	33
5.8.	Step 8: Review the information: make a decision on further investigation and control	34
6.	Retrospective cohort studies.....	37
6.1.	Criteria for using the retrospective cohort study design	37
6.2.	Designing a retrospective cohort study	38
6.3.	Analysis of retrospective cohort studies	39
6.4.	Retrospective cohort investigation example	40
7.	Case-control studies.....	42
7.1.	Summary of case-control study design	42
7.2.	Criteria for using a case-control design.....	42
7.3.	Designing a case-control study	43
7.4.	Control recruitment	46
7.5.	Case-control ratio: study power.....	47
7.6.	Matching between cases and controls.....	48
7.7.	Analysis of case-control study data.....	49
7.8.	Case-control investigation example	50
7.9.	Case-case studies	51
8.	Further interpretation of analytic study results	52
8.1.	Possible explanations for results.....	52
8.2.	Could the observed association be due to chance?	52
8.3.	Could the observed association be due to bias?.....	59
8.4.	Could the association be causative?	61
8.5.	Statistical power and sample size	62
8.6.	Risk of disease attributable to exposure.....	63
9.	Environmental investigation	65
9.1.	Environmental investigation of common event outbreaks.....	66
9.2.	Environmental investigation of dispersed outbreaks	71
9.3.	Environmental investigation of common site outbreaks	71
9.4.	Environmental investigation of institutional outbreaks.....	71
9.5.	Environmental investigation of person-to-person outbreaks.....	72
9.6.	Environmental investigation of specific outbreak types: summary	72
10.	Laboratory investigation	74
10.1.	Laboratory involvement: overview of potential roles and services	75
10.2.	Organism typing techniques	78
11.	Outbreak control measures.....	86
11.1.	General considerations	86
11.2.	Examples of control measures aimed at the outbreak source.....	87
11.3.	Examples of control measures aimed at contaminated vehicles and vectors	88
11.4.	Examples of control measures aimed at susceptible humans	88

12. Communication during outbreak investigation	89
12.1. Communication expertise	89
12.2. Communication plans	89
12.3. Communication within the outbreak team.....	90
12.4. Communication with the public and media	90
12.5. Communication with the Ministry of Health and ESR.....	94
12.6. Communication with other agencies	95
12.7. Debrief following outbreak investigation and response	95
12.8. Hot Debriefs	96
12.9. Cold Debriefs	96
12.10. Multi-Agency Debriefs.....	96
12.11. Pre-Debrief Planning	97
12.12. Debrief Ground Rules.....	97
12.13. Debrief Agenda	97
12.14. Recommendations and Action Points	98
12.15. Further Information	98
13. Documentation	99
13.1. Documentation of outbreaks and investigations.....	99
13.2. Routine outbreak documentation.....	99
14. Conclusion	101
15. References	102
16. Appendix 1: Agency roles and responsibilities for outbreak management	106
16.1. Introduction	106
16.2. Glossary of terms used in this appendix	106
16.3. General roles and responsibilities	106
16.4. Roles and responsibilities in specific scenarios	115
16.5. References for Appendix 1	122
17. Appendix 2: Questionnaire design and interview techniques.....	123
17.1. Questionnaire Design.....	123
17.2. Standardised interview introduction	127
17.3. Principles of Interviewing.....	128
17.4. Quality control during data collection and entry	131
17.5. References for Appendix 2	131
18. Appendix 3: Outbreak questionnaire template	133
18.1. Disease outbreak questionnaire template	134
19. Appendix 4: Investigation protocol	140
19.1. Protocol for a directly-matched case-control study to investigate an enteric disease outbreak	140
20. Appendix 5: Interviewer log sheet (for controls)	143
21. Appendix 6: Characteristics of common bacterial foodborne pathogens	144
22. Appendix 7: Legislative responsibilities of medical officers of health (or designated officers) relevant to outbreak control.....	147

22.1. Disclaimer	147
22.2. Provisions in legislation and regulations relevant to outbreak control	147
23. Appendix 8: Outbreak report form.....	151
23.1. Outbreak definition for reporting	151
23.2. General points to note when using this form	151
23.3. Appendix	157
24. Appendix 9: Guidelines for the structure of an outbreak investigation report	169
24.1. Abstract	169
24.2. Introduction	169
24.3. Methods used	169
24.4. Results	170
24.5. Discussion and implications	170
24.6. Recommendations (as appropriate)	171
24.7. Examples of possible tables/graphs to accompany the report	171

1. Introduction

1.1. Purpose of this manual

The ability to manage disease outbreaks effectively is a key responsibility of public health services (PHSs) in New Zealand and elsewhere. Outbreaks call on public health staff to combine, at short notice, the application of rigorous scientific methods with the implementation of sound public health policy, sometimes under the spotlight of intense public concern. For those who undertake this important public health activity, outbreak response can offer a mixture of exhilaration, high stress, professional satisfaction and long hours of work.

PHSs manage most disease outbreaks independently, although for larger events the response can involve other agencies such as the Ministry of Health, ESR and other PHSs. While this distribution of responsibilities is entirely appropriate for local outbreaks and conveys clear advantages through the incorporation of local knowledge and the development of local capacity, there are benefits in sharing nationally some guidance on basic approaches to outbreak management.

This manual was therefore developed by ESR to give PHSs an external standard 'best practice' approach to outbreak management. The aims of this manual are to provide:

- a step-by-step guide to the basics of disease outbreak management for those who are new to the topic
- a reference guide to specific aspects of outbreak management for those who already have some working knowledge
- copies of outbreak reporting forms and outbreak materials.

ESR first published guidance on outbreak management in 1992 in the Manual for the investigation of food and waterborne disease³. This manual was expanded to provide a generic approach to outbreak investigation in the Guidelines for disease outbreak investigation in New Zealand⁴, released in 1996 and further revised in 1997 and 2002.

In 2002, the Guidelines were thoroughly revised and several new topics were introduced, including sections on:

- communication with authorities, public and media
- roles and responsibilities of agencies involved in outbreak investigation.
- the role of environmental investigation and laboratory methods in outbreak investigation
- outbreak control methods

In 2002 the title of the document was changed to *Outbreak Control Manual*.

1.2. Changes in this edition

The 2012 edition is not a complete revision; rather it updates the existing manual, with changes made mainly in the following areas:

- notifications system
- epidemiological studies
- laboratory methods
- incident response, including communications.

The title of the document has been changed to *Guidelines for the Investigation and Control of Disease Outbreaks* in order to reflect more precisely its intent as a guide to good practice in outbreak investigation. It should be emphasised that the contents of several chapters can be equally useful in non-notifiable disease outbreaks as they are in notifiable disease outbreaks. The epidemiological methods, communications during and following outbreaks, and the organisational structure used to deal with outbreaks (e.g., the Coordinated Incident Management System (CIMS)) are as applicable to non-communicable disease incidents and emergencies as they are to notifiable disease outbreaks.

This update builds upon previous sets of guidelines for managing disease outbreaks in New Zealand, published by ESR. The sections developed specifically for this manual are based on a review of published journal articles and other published and unpublished (in-house) documents, material used in previous outbreak courses and on a survey of outbreak coordinators in public health services. Journal articles were sourced from a Medline search using the MeSH subject headings Disease outbreaks/[classification, *prevention and control, epidemiology], public health/[methods], communicable diseases/[*prevention and control].

Published and unpublished documents not contained within journals were identified by:

- searching the internet using the search engine Google (<http://www.google.com>)
- searching outbreak-related information on the following websites: Centers for Disease Control and Prevention (<http://www.cdc.gov>), the World Health Organization (<http://www.who.int/en/>), the UK Health Protection Agency (<http://www.hpa.org.uk/>), the Australian Department of Health & Ageing (<http://www.health.gov.au>) and the European Centre for Disease Control (<http://ecdc.eu.int/>)
- holding discussions with key stakeholders within New Zealand
- searching outbreak-related material collected during the development of other ESR reports.
- searching material held in the Ministry of Health and ESR libraries.

1.3. What is an outbreak?

The term 'outbreak' has been defined as "an epidemic limited to a localised increase in the incidence of a disease, e.g., in a village, town, or closed institution"¹. The term 'epidemic' is defined as "the occurrence in a community or region of cases of an illness, specific health-related behaviour, or other health-related events clearly in excess of normal expectancy."¹

The term "outbreak" can actually be used interchangeably with epidemic and is often preferable merely because it is a less frightening term in many situations. The application of each of these terms is often clear cut; however there are events where the distinction is ambiguous. There are also more prescriptive definitions of an outbreak used for some diseases such as invasive meningococcal

disease and influenza. In general there is a lot of overlap between these terms and “outbreak” is used in this document as an overarching / generic term that covers “epidemic” as well.

The term ‘pandemic’ needs to be mentioned here even though this document will not address the topic. It is comprehensively covered in the recently revised New Zealand Pandemic Action Plan (NZPAP) [[http:// www.health.govt.nz/.../new-zealand-influenza-pandemic-plan-frame](http://www.health.govt.nz/.../new-zealand-influenza-pandemic-plan-frame)]. A pandemic is defined as a worldwide epidemic that, according to the World Health Organization (WHO), has to meet three conditions:

- the microbe infects and causes serious illness in humans.
- humans do not have immunity against the virus and
- the virus spreads easily from person-to-person and survives within humans. The terms ‘virulence’ and ‘mortality’ are not mentioned in the current WHO definition, although these factors have previously been included.

There is considerable overlap between the term ‘outbreak’, as defined here, and the term ‘cluster’. Both terms can describe an aggregation of diseases or events grouped in space, time or both. The main distinction is that clusters generally refer to groupings of diseases or events that are relatively uncommon, whereas this is not a condition for the definition of an outbreak. The distinction has more than semantic importance, as the approach to the investigation of apparent disease clusters (particularly those of non-communicable diseases) differs from that of disease outbreak investigation. Guidelines for the investigation of clusters can be found in the Ministry of Health’s publication *Investigating Clusters of Non-Communicable Disease*.⁵ ([http://www.moh.govt.nz/moh.nsf/Files/cluster/\\$file/cluster.pdf](http://www.moh.govt.nz/moh.nsf/Files/cluster/$file/cluster.pdf)). In addition the National Health Emergency Plan (2011) has a section on infectious diseases and can be located on <http://www.health.govt.nz/publication/national-health-emergency-plan-infectious-diseases>

For reporting purposes (see Chapter 13) the **outbreak case definition** is:

- two or more cases linked to a common source, in particular, where the common source is exposure at a common event, or to food or water dispersed in a community, an environmental source or a source in an institutional setting; OR
- a community-wide or person-to-person outbreak; OR
- any other situation where outbreak investigation or control measures are being used or considered. This situation would include a single detected case of an illness that is exotic to New Zealand or has been eradicated (e.g., dengue fever, poliomyelitis).

1.4. Reasons for investigating outbreaks

While outbreak control is of paramount importance, the benefits of effective outbreak management range beyond the immediate need to stop the outbreak progressing. Key benefits are listed next.

1.4.1. To halt the outbreak and prevent further illness

The most compelling reason to investigate an outbreak is that exposure to the outbreak source may be continuing, and by restricting transmission from the source of illness, further cases can be prevented.⁶ The importance of rapid outbreak investigation and the implementation of control measures is clearly stated in a South Australian coroner’s report on the death of a child during an outbreak of haemolytic-uraemic syndrome associated with *Escherichia coli* O111-contamination of a meat product in 1995. The coroner strongly criticised the PHS for a two-day delay to the investigation and a three-day delay to the analysis of the findings⁷.

1.4.2. To prevent further outbreaks from the immediate source

Even if an outbreak is essentially over by the time the investigation begins, investigation is necessary to find out why the outbreak occurred, and to prevent it happening again.

1.4.3. To prevent further outbreaks from other similar sources

Outbreak investigation may disclose a systematic error, leading to the exposure of people to disease agents. Knowledge gained from outbreak management may help to improve standard process guidelines.

1.4.4. To address public concerns

Disease outbreaks often attract considerable publicity. Public concern or even outrage is likely to increase if the public health agency responsible is seen to be ignoring concerns about a perceived disease outbreak. One of the most important steps towards addressing public concern is to acknowledge and investigate issues that are perceived to pose a risk to the public. Risk communication is an important tool in this regard.

1.4.5. To involve the public in disease control

Risk and outbreak communication is also about providing information regarding the situation, advising on what actions people can take and listening to the community. Well-communicated judicious communication can help with disease control.

1.4.6. To reduce direct and indirect costs

Prompt and timely outbreak responses can be economically beneficial by reducing health service expenditure, work absenteeism, child care costs and costs associated with the inability to meet unpaid responsibilities.

1.4.7. To identify new mechanisms of transmission of known illnesses

Information gained from outbreak investigation has provided early warnings about new transmission mechanisms by which people can become exposed to disease agents, and has provided a springboard for their comprehensive study. Examples include identification of the hazards involved with new food products⁸.

1.4.8. To identify new or emerging disease agents

Several new disease agents are first identified through the investigation of outbreaks of unexplained illness. Notable examples include the human immunodeficiency virus (HIV) that causes acquired immunodeficiency syndrome (AIDS) and *Legionella* spp. that cause Legionnaires' disease.

1.4.9. To satisfy legal and international obligations

The investigation and control of cases of notifiable diseases are the obligations of the PHSs (medical officers of health) under the Health Act 1956. Increasingly, outbreaks cross national borders⁹, and appropriate management supports New Zealand's contribution to international communicable disease surveillance and control, especially if the disease is appropriate for eradication. New Zealand has obligations under the revised International Health Regulations¹⁰ to report certain disease outbreaks and public health events.

1.4.10. To help train public health staff

Staff training is an on-going responsibility. Outbreak management skills are best learnt while involved in actual outbreak situations, under appropriate supervision. Management of 'routine' small-scale outbreaks can provide staff with the experience and confidence necessary to effectively manage large-scale, high-profile outbreaks.

1.5. Types of outbreaks

There are several types of outbreaks, reflecting differences in the way case exposures are grouped. The definitions of outbreak types given next are consistent with those used for outbreak reporting under the notifiable disease surveillance system – EpiSurv. In practice, however, outbreak types may not be mutually exclusive. Several outbreak types may comprise a single outbreak, although one type usually predominates.¹¹

1.5.1. Common event

An outbreak due to exposure of a group of persons to a noxious influence that is common to the individuals in the group, where the exposure is brief and essentially simultaneous and all resultant cases develop within one incubation period of the disease. Cases have exposures that occur at virtually the same place and time. Common examples include weddings, sports events, conferences, hui, catered functions or any other event that occurs within a specified time period. Examples of this type of outbreak have been reported in New Zealand^{12, 13}

1.5.2. Dispersed common source

Hereafter described as dispersed outbreaks, these outbreaks are due to exposure of a group of persons in a community to a noxious influence that is common to the individuals in the group, where exposures have not all occurred around the same place or necessarily around the same time. These outbreaks are often due to the consumption of a widely distributed vehicle of infection transmission, such as a contaminated food product or reticulated drinking-water. The 2009 outbreak of *Salmonella* Typhimurium phage type 1 associated with watermelon in Gisborne is an example of a dispersed outbreak.¹⁴

1.5.3. Common source in a specific place (or site)

Hereafter described as common site outbreaks, these outbreaks are due to the exposure of a group of persons in a community to a noxious influence that is common to the individuals in the group, and where all the exposures have occurred at the same place, but not at the same time. Typical examples

include those where exposures have occurred within the setting of a single swimming pool, restaurant, cruise ship, workplace or farm. The July 2006 outbreak of gastroenteritis caused by waterborne norovirus at a New Zealand ski resort is an example of this type of outbreak.¹⁵

1.5.4. Community-wide

An outbreak affecting individuals in a community, where transmission predominantly occurs by direct exposure of susceptible people to infectious people. New Zealand examples include an outbreak of hepatitis A within an Auckland immigrant community¹⁶, an outbreak of tuberculosis in the North Island¹⁷, and the 2009 outbreak of measles in Canterbury¹⁸

1.5.5. Institutional

An outbreak confined to the population of a specific residential or other institutional setting, such as a hospital, rest home, prison or boarding school.

An outbreak of acute viral gastroenteritis in an Auckland elderly care facility in 2000 is an example of an institutional outbreak.¹⁹

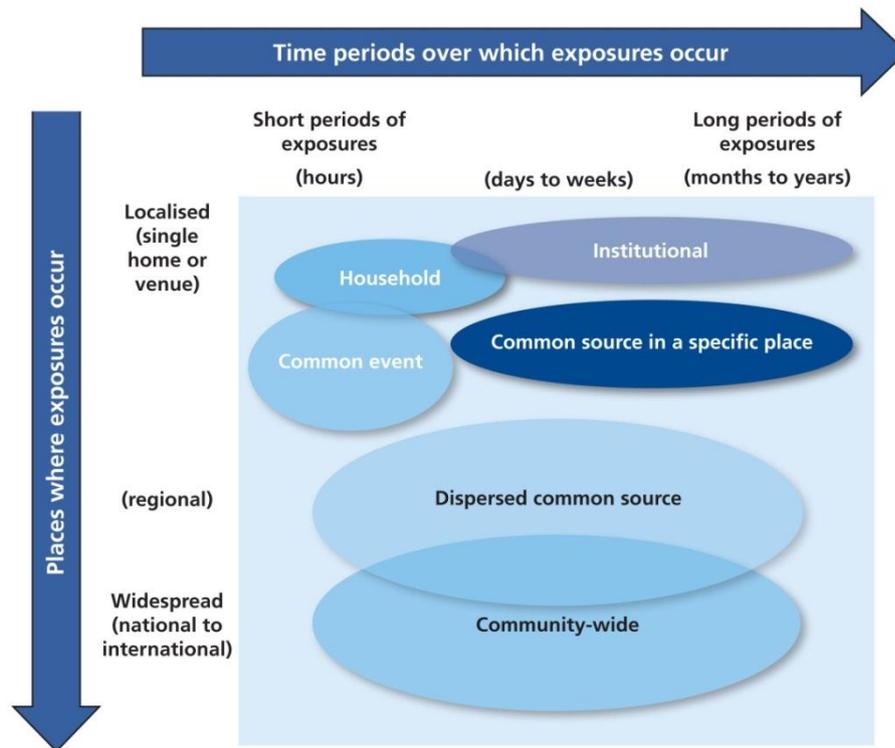
Many institutional outbreaks are reported in New Zealand each year, but most are not published or available in the public domain. In 2010, 606 outbreaks were notified, 277 of which were in institutions. Enteric viruses were the infectious agent in almost one-third of all outbreaks, and the majority (85.3%) of these were caused by norovirus²⁰.

1.5.6. Household

An outbreak confined to members of a single household. Household outbreaks probably occur frequently, but are likely to be under-reported. In 2010, 229 household outbreaks involving 1,034 cases were reported, that is, 37.8% of all outbreak settings were 'household', making them more commonly reported than those outbreaks set in restaurants (13.4%) and rest homes (11.4%).^{21, 22}

The distinctions between these main types of outbreaks are mainly drawn from the distribution of exposures over time and place. In general, common event and household outbreaks are associated with brief and highly localised exposures. Institutional and environmental outbreaks are also localised, but exposures may occur over a prolonged period. By definition, dispersed and community-wide outbreaks have widespread exposures, and may occur over a brief or prolonged time period. This is illustrated in Figure 1.

Figure 1: Types of disease outbreaks, differentiated by the degree to which exposures are grouped in space and time



Multi-district/regional outbreaks (sometimes incorrectly referred to as multi-jurisdictional) are of special importance as they pose threats of national significance and usually require collaboration between ministries and agencies for meaningful action. Such outbreaks are characterised by clusters of cases showing a wide geographic distribution usually over a short time period. A contaminated product e.g. food that is widely distributed could be implicated. Appendix 1 lists agencies and functions.

Throughout this document, the processes involved in outbreak management are illustrated with examples drawn from each main type of outbreak to demonstrate how the general approach needs to be modified to match the circumstances.

1.6. Ethical issues in outbreak investigation

Ethics and ethical principles extend to all spheres of human activity. They apply to our interactions with each other, with animals and with the environment. A guiding value for researchers is integrity, which includes a commitment to the search for knowledge, the honest and ethical conduct of research and the dissemination and communication of results.

Particular attention needs to be paid to ethics whenever human subjects are involved. More rigorous scrutiny is needed when an investigation is extended to include people who have not been ill, for example, as part of an epidemiological investigation that involves data collection from a participant in the control group or a population not expressing the disease characteristics. Four basic principles are particularly relevant to the ethics of research involving human subjects, as follows:

- autonomy: respect the rights of individuals to self-determination, and protect those with diminished autonomy
- beneficence: maximise possible benefits

- non-maleficence: minimise possible harm
- to estimate the disease burden of all seasonal influenza infections from asymptomatic, mild and severe infections to deaths. distribute benefits and burdens fairly.

In the context of outbreak management, these principles translate into such requirements as informed consent, careful assessment of the risks and benefits of the investigation for participants and fair selection of subjects.

Outbreak investigation will not usually require prior approval from a research ethics committee, provided that the investigation is being undertaken as an acute measure to address an immediate and serious threat to public health. If there is uncertainty about the need for ethics committee approval, it may be appropriate to discuss the study protocol with the chairperson(s) of the appropriate ethics committee(s).

If cases of disease have been occurring in a community over a long period of time, there is generally less urgency and the investigation may be more appropriately viewed as research. In such cases, the usual ethical approval process for research proposals should be observed.

Further information on guidelines for ethical behaviour can be found on the Health Research Council of New Zealand's website, <http://www.hrc.govt.nz/>

The conduct of an outbreak investigation, as a 'health related service', should also comply with the Code of Health and Disability Services Consumers' Rights (www.hdc.org.nz).

1.7. Privacy of information

Rules on the collection and management of health information by health agencies (including PHSs) are described in the Health Information Privacy Code 1994 (the Code). This code applies to all personal health information collected as part of outbreak management. The following rules in the Code have particular relevance for agencies responding to disease outbreaks.

- Rule 10 of the Code ("Limits on Use of Health Information") states that "a health agency that holds health information obtained in connection with one purpose must not use the information for any other purpose unless the health agency believes on reasonable grounds that the use of the information for that other purpose is necessary to prevent or lessen a serious or imminent threat to public health or public safety or the life or health of the individual concerned or another individual." [Rule 10 (1)(d)(i)-(ii)]
- Rule 11 of the Code ("Limits on Disclosure of Health Information") permits disclosure of health information if the information disclosure is "necessary to prevent or lessen a serious and imminent threat to public health or public safety or the life and health of the individual concerned or another individual." [Rule 11 (2)(d)(i)-(ii)]
- Rules 10 and 11 also give similar exceptions for the use and disclosure of health information for research, which would be equally applicable to outbreak investigation. The exception is granted "for research purposes (for which approval by an ethics committee, if required, has been given) and will not be in a form which could reasonably be expected to identify the individual concerned". [Rule 10 (1)(e)(iii) and Rule 11 (2)(c)(iii)]

All agencies that undertake outbreak management should be familiar with the Code and should comply with it. Copies of the Code are available from the offices of the Privacy Commissioner:

PO Box 466
Auckland 1140

PO Box 10-094
The Terrace
Wellington 6143

The Code is also available online at <http://www.knowledge-basket.co.nz/privacy/comply/hinfopc.html>

1.8. Data disclosure policies

All agencies involved in outbreak investigations should have in place policies for the disclosure of health data and, in particular, data identifying or potentially identifying individuals. These policies need to address what data may be exchanged between organisations taking into account the requirements of the Health Act 1956, the Privacy Act 1993, the Official Information Act 1982, and the Health Information Privacy Code 1994. The data request approval process should also be documented.

1.9. Cultural competency in outbreak management

The urgency of an outbreak investigation and response can encourage a strong focus on the source of the illness and actions to eliminate it. In such situations however it is essential to avoid marginalising the concerns and values of the people primarily affected by the outbreak. The authors of several New Zealand outbreak reports have emphasised the importance of considering the cultural context of outbreaks²³ and the advantages of cultural competency within the outbreak management team²⁴. Principles of cultural competency in outbreak management are:

1.9.1. Cultural competency as part of outbreak preparation

- Build cultural competency within the outbreak management organisation.
- Strengthen links between the outbreak management organisation and local communities.

1.9.2. Cultural competency during the outbreak investigation and response

- Ensure that the outbreak investigation and response does not disempower communities.
- Do not engage in victim blaming during the outbreak investigation and response.
- From an early stage in the outbreak investigation and response, ensure meaningful participation of culturally competent representatives, if capacity within the organisation is insufficient.
- Ensure that information collection instruments (e.g., questionnaires) use culturally appropriate wording or languages, such as culturally-specific names for exposures.

1.9.3. Cultural competency while implementing recommendations

- Develop culturally appropriate recommendations from the outbreak response.
- Encourage meaningful participation from the community in developing recommendations, so that they are appropriate, acceptable and are more likely to be adhered to.

1.10. The Treaty of Waitangi in outbreak management

The Treaty of Waitangi provides a framework for Māori and non-Māori to exercise control over their health and wellbeing, and therefore underpins all health protection work in New Zealand, including outbreak management.

Treaty of Waitangi principles derived from the provisions are argued to reflect the spirit and original aims of the Treaty of Waitangi, and to enable contemporary applications. The Waitangi Tribunal,

Court of Appeal, Royal Commission on Social Policy and the Crown itself have defined principles arising from the Treaty of Waitangi. The three principles derived from these sources are partnership, participation and active protection.

A considerable amount of work has been undertaken to develop a Treaty of Waitangi-based framework for health promotion (TUHANZ)²⁵, which should be consulted for further guidance. The TUHANZ framework places each of the Treaty of Waitangi provisions within a health promotion context. This framework may be equally relevant for outbreak management activities. The provisions are:

- **kawānatanga/ governance** – emphasises Māori involvement in all aspects of society within Aotearoa (New Zealand). Outbreak management organisations should encourage meaningful involvement of Māori in outbreak planning, prioritisation, investigation and response
- **tino rangatiratanga/ Māori control and self-determination** – refers to on-going relationships between the Crown and Māori with the goal of actively supporting advancement of Māori health aspirations as determined by Māori. This would include the development of Māori capacity for responding to outbreaks directly affecting Māori. Capacity within Māori health provider organisations, in partnership with mainstream PHSs, may be an example of this principle applied to outbreak management.
- **ōritetanga/ equality** – recognises that the Crown (and Crown agencies, such as PHSs) need to actively protect Māori interests, especially in regard to the health disparities that exist between Māori and non-Māori. Disease outbreak management that improves Māori health outcomes should be prioritised.

1.11. Where to go for help

ESR is funded by the Ministry of Health to assist with the epidemiological investigation of outbreaks. Under this arrangement ESR may provide advice on some or all of the following areas:

- clarification of the aims of the investigation
- relevant literature and related research
- developing the study design, including reviewing draft questionnaires
- conduct of the investigation
- statistical analysis of results
- preparation of the outbreak report.

A framework defining roles and responsibilities in outbreak management in complex situations is described in Appendix 1.

The National Centre for Biosecurity and Infectious Disease (NCBID) was established as a separate site in Upper Hutt in 2008. It is collaboration among four agencies:

- [ESR](#)
- [Biosecurity New Zealand](#)
- [AgResearch](#)
- [AsureQuality](#)

NCBID provides centralised coordination and emergency responses for disease outbreaks, biosecurity investigations, and chemical and biological threats and events.

NCBID also carries out joint training and research projects on infectious diseases; this includes everything from basic studies to methods for the collection and analysis of surveillance data and the development of procedures for the control or eradication of infectious diseases.

1.12. Overview of the outbreak management process

The overriding goal of outbreak management is to minimise the public health impact of disease outbreaks. There are eight principal components of outbreak management (Table 1). Although listed sequentially in the table, these outbreak management components are often not addressed in this order in practice. Some components, for example, investigation, are dependent (i.e., without outbreak identification there will be no outbreaks to investigate), but other components may occur simultaneously. Control and communication activities are not necessarily preceded by components such as outbreak description and full investigation, and it is often advisable to immediately implement simple practical control measures, where reasonable, following outbreak confirmation.

Table 1: Components of outbreak management

Components	Aims	
Minimising the public health impact of disease outbreaks	Preparation	Optimal level of preparedness
	Surveillance	Consistent and comprehensive collection and review of information on diseases with outbreak potential
	Confirmation and assessment	Sensitive, specific and timely detection of potential outbreaks with public health impact
	Outbreak description, including situational analysis and descriptive epidemiology	Characterisation of outbreak to identify the immediate need for control or hypotheses for further investigation
	Full investigation Analytic epidemiological investigation Environmental investigation Laboratory investigation	Identification of outbreak source, transmission mechanisms, contributing factors and control points
	Outbreak control	Prevent further disease transmission
	Outbreak communication	Public and relevant agencies appropriately informed and involved in outbreak management
	Outbreak documentation	Optimal dissemination of recommendations

Figure 2, at the end of this chapter, presents a framework showing the interrelationships among these elements. This approach to outbreak management is analogous to the risk assessment

framework²⁶. The processes involved in outbreak identification; description and investigation are examples of risk assessment activities, while control, communication and documentation activities represent risk management. The relationship between these two basic groups of activities is fluid, and differs according to the type and setting of each outbreak.

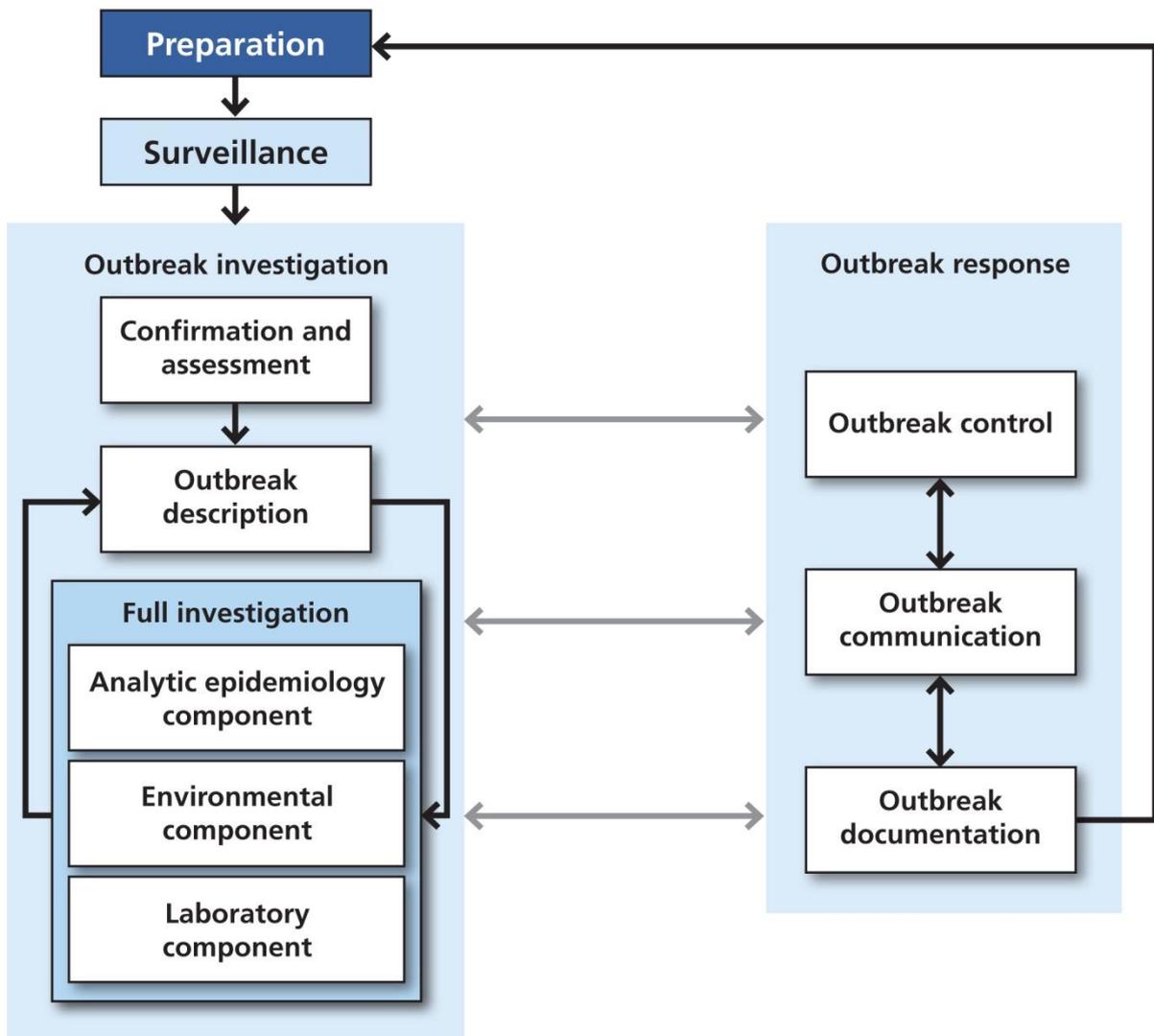
This framework tries to reflect the reality of outbreak management activities. The elements of the framework are expanded throughout the remainder of this manual. The following points may be useful in helping understand the framework at this stage:

- **outbreak preparation** (Chapter 2) includes the development of an organisational outbreak plan and maintaining general capacity to implement an outbreak investigation and response
- **surveillance** (Chapter 3) includes all flows of information that act as raw material to detect outbreaks. These information flows include self-reported outbreaks, notification data and sporadic self-reported illness
- **confirmation and assessment** (Chapter 4) includes the processes of verifying that a suspected outbreak is genuine, and assessing the relative needs for investigation and control, as well as overall prioritisation
- **outbreak description** (Chapter 5) plays a key role in outbreak investigation. This largely epidemiological function addresses the characterisation of the outbreak, including situational analysis and descriptive epidemiology, identifying its scale, identifying hypotheses and planning further investigation
- **full investigation** comprises three major components: *analytic epidemiological* (Chapters 6, 7 and 8), *environmental* (Chapter 9) and *laboratory* (Chapter 10) investigations. These components are not hierarchical in overall importance, nor do they occur in a particular sequence. The relative contribution that each could make to an investigation depends on the type of outbreak, but all should be given consideration
- **outbreak control** (Chapter 11) is self-explanatory. Note that outbreak control needs to be considered at all stages of the overall investigation, and may precede or obviate the need for further investigation
- **outbreak communication** (Chapter 12) includes communication within the organisation, with the public and media, and with other organisations. Communication is an on-going responsibility
- **outbreak documentation** (Chapter 13) refers to the early reporting of detected outbreaks and collation of final information in a permanent form. This information then feeds back into the preparatory stage to continuously improve outbreak management and to prevent further outbreaks.

1.13. How to use this manual

Chapters in the manual have been developed to correspond with the components of outbreak management presented in Table 1. Additional material is attached as appendices. The manual has been developed as a series of independent modules that can be read in the sequence dictated by the circumstances of the outbreak.

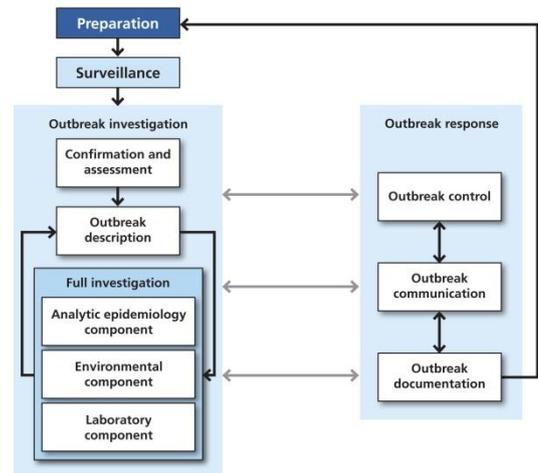
Figure 2: Outbreak management framework: major elements



2. Preparation

Outbreaks seem to invariably arise late on Friday afternoons, during holidays, or when key personnel are already overburdened with other projects. Valuable time is often lost organising the people and materials necessary to investigate and respond to the outbreak while the trail is still warm. Unfortunately, the likelihood of identifying the source of an outbreak and interrupting further disease transmission decreases steadily with every day of delay.

Organisations responsible for outbreak management should ensure that they have planned how they will deal with an outbreak when it occurs. This chapter examines general aspects of outbreak planning. An additional part of outbreak planning is to develop and maintain surveillance systems that provide early warnings of an outbreak, and this is discussed in the next chapter.



2.1. Outbreak plans

Each organisation responsible for outbreak management (usually the PHSs) should develop an outbreak plan. The objective of the plan is to define roles, resources and responsibilities for outbreak management. Outbreak management steps that should be documented are presented in Table 2. Specific aspects of outbreak preparation are described next. It is to be noted that while leadership roles for several components may be delegated, it is the Medical Officer of Health that has overall responsibility.

2.1.1. Outbreak protocols

The outbreak plan should clearly document or identify locally appropriate protocols for outbreak management. Note that these protocols differ from outbreak investigation protocols, which describe standardised processes to follow when collecting and recording information. By contrast, outbreak protocols should encompass the entire outbreak management process. Outbreak protocols should suggest thresholds for each stage of the outbreak investigation and response, including whether investigation should commence at all.

This manual suggests an approach to outbreak investigation and response, and this may be appropriate for use as a template for developing district protocols. It is important, however, that districts develop and individualise their own protocols so that they are relevant to local circumstances. Reaching local agreement on suitable threshold levels for action, and incorporating them in plans, helps avoid doubt about the course to take when an outbreak does occur. It is best to avoid the need for policy discussions of this sort during an outbreak.

Table 2: District planning for outbreak management

Outbreak management step	Outbreak management component	Individual or group responsible
Preparation	<ul style="list-style-type: none"> • Development of outbreak protocols • Designation of outbreak coordinator • Identification of outbreak management team that can cover all important outbreak scenarios • Assembling materials necessary for outbreak investigation and response • Identification of and addressing training needs 	e.g., PHS manager, outbreak coordinator
Routine surveillance	<ul style="list-style-type: none"> • Operation of a comprehensive infectious disease surveillance system at the district level • Collection of notifications from clinicians and laboratories • Collection of data on self-reported cases and other 'informal' reporting sources • Integration of local surveillance data from multiple sources • Collection of descriptive information on individual cases of disease with outbreak potential • Development of links with hospital infection control personnel 	e.g., EpiSurv coordinator or support officer
Identification	<ul style="list-style-type: none"> • Regular examination of surveillance data to detect increases in disease incidence and common risk factors • Maintenance of good systems to receive and evaluate reports of outbreaks from local health professionals and other agencies 	e.g., Health protection officer or disease investigator
Description	<ul style="list-style-type: none"> • Collection of information on cases involved with outbreaks • Development of outbreak case definition • Characterisation of outbreak by person, place and time • Development of hypotheses • Identification of need for further investigation 	e.g., Outbreak management team
Investigation	<ul style="list-style-type: none"> • Capacity for epidemiological investigation • Capacity for environmental investigation 	e.g., Outbreak management team
Control	<ul style="list-style-type: none"> • Implementation of control measures, including those requiring medical officer of health responsibility 	e.g., Health protection officer, Food Act Officer, disease investigator or medical officer of health

Outbreak management step	Outbreak management component	Individual or group responsible
Communication	<ul style="list-style-type: none"> • Immediate reporting of outbreaks of national importance to ESR and the Ministry of Health • Communication with media about district outbreaks 	e.g., Outbreak coordinator
Documentation and reporting	<ul style="list-style-type: none"> • Documentation of outbreak • Timely and accurate reporting of all outbreaks via outbreak surveillance system. Initial reports within one week of recognition, updated weekly, final record within one week of completion 	e.g., Outbreak coordinator

2.1.2. The public health service outbreak coordinator

The PHS outbreak coordinator has a key role in outbreak management. The PHS outbreak coordinator is a point of liaison between the PHSs, the Ministry of Health and ESR, ensuring the rapid dissemination of information about emerging outbreaks. The PHS outbreak coordinator also has primary responsibility for activating outbreak protocols and calling together the outbreak management team. During an outbreak itself, the PHS outbreak coordinator is a central point of contact for the different arms of outbreak management.

2.1.3. The outbreak team

Each PHS should designate experienced staff who can respond immediately when an outbreak is recognised. Such staff should be trained in outbreak management methods. They should have permission to suspend their regular duties when the need arises, and promptly undertake the tasks of initiating outbreak investigation and response.

The district outbreak plan should document the roles of individuals included in the outbreak team, and contain contingency plans in case particular team members are unavailable when an outbreak occurs. Not all team members need to be 'on site' within the PHS, although it may be appropriate to ensure that core team members share the same workplace.

2.1.3.1. Who needs to be on the outbreak team?

Outbreak teams usually have two layers. The core team is responsible for planning, co-ordinating and carrying out the outbreak investigation. In most circumstances, members of the core team will need to be able to make the outbreak their highest priority, at least in the initial phase. Outside the core team are individuals who can be called upon to act as advisors about specific aspects, but normally not to do the legwork required. However, the boundary between the core and outer teams is fluid, and during larger outbreaks outer team members may be required to have considerably more hands-on involvement than during small-scale outbreaks.

The composition of the outbreak team cannot be defined rigidly – requirements will vary depending on the size of the outbreak, the type of outbreak (described later) and the distribution of skills within the PHS. The outbreak plan should, however, describe who within the PHS has the requisite skills to be part of the core outbreak team, and should also identify a range of individuals who can be contacted to provide further advice if necessary. In this manual, the focus is on the appropriate mix

of skills, not on particular types of workers. A multidisciplinary composition of an outbreak team is, however, a distinct advantage²⁷.

The core outbreak team will usually require the following skills:

- outbreak management coordination skills (akin to project management) and relationship management skills
- administrative and secretarial skills
- environmental investigation skills
- statistical analysis skills
- questionnaire development skills
- data entry skills
- interviewer selection and training skills
- media and public communication skills
- knowledge of relevant legislation and regulations
- statutory authority to implement legislation and regulations.

The following advisory skills may be required, and it is important to consider in the outbreak plan where these skills can be obtained from, if necessary. During the outbreak itself, some of these skills may need to be brought into the core outbreak team.

- public health nursing
- cultural competency, in particular for responding to outbreaks among communities of Māori and Pacific peoples
- skills in non-English languages (i.e., translation services specific to health information)
- clinical medicine
- microbiology
- laboratory science
- food chemistry
- environmental science (soil, water, air)
- public health engineering
- advanced epidemiology
- veterinary epidemiology
- virology
- additional media and public communication expertise
- workplace health and safety / infection control and prevention
- industry specialists

2.1.3.2. Terms of reference for the outbreak team

The terms of reference of the outbreak team should be agreed upon in advance, as much as possible, and be included in outbreak plans. An example might be to:

1. review the evidence and confirm the existence or not of an outbreak
2. develop a strategy to investigate and control the outbreak and allocate responsibilities for taking action
3. arrange for the necessary interviews and other investigations to identify the illness and contributing risk factors
4. prevent further cases by taking all necessary and possible steps to ensure that the source of the outbreak is controlled or the cause is removed
5. prevent cases elsewhere by communicating findings to other agencies and the public
6. prevent secondary spread of infections by controlling or isolating cases, and by identifying and managing contacts appropriately
7. provide an accurate and responsible source of information for other professionals, the media and the public
8. develop systems and procedures to prevent the future occurrence of similar episodes
9. document the investigation and control measures.

2.1.4. Assembling materials required for an investigation

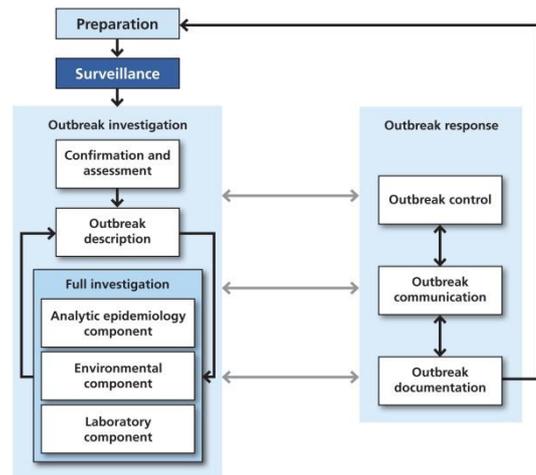
Outbreak plan development provides an opportunity to list the materials that may be required at short notice during an actual outbreak, and to identify where these materials are kept. Materials may include:

- basic stationery
- a hand-held calculator
- a sampling kit containing documentation and materials for collecting and transporting laboratory specimens
- a camera
- reference books or databases on communicable diseases and toxic substances
- a computer installed with a basic statistical package (probably EpiInfo and EpiData), packages for word processing and graph preparation, and (preferably) e-mail capability
- sample questionnaires from previous outbreak investigations or studies
- a list of telephone numbers of potentially useful agencies and individuals
- a cell phone
- personal identification documents, particularly those providing evidence of statutory designations that may be required during the investigation or management of an outbreak.

3. Surveillance to detect outbreaks

Most outbreaks come to the attention of PHSs in one of three ways:

- by detection of an increased number of cases or an unusual pattern among cases collected through formal surveillance systems, such as EpiSurv, the national notifiable diseases database, or through tools that identify aberrations in EpiSurv data or Salmonella typing data, such as the Early Aberration Reporting System* (EARS). These outbreaks are usually first recognised in the PHS, but may also be detected by ESR through the use of EARS or from laboratory surveillance, particularly if disease cases are distributed across several PHS areas. Unusual patterns among cases may include groups of cases with similar demographic characteristics, or with links to common risk factors, or cases with common laboratory subtypes.
- by detection of an increased number of cases of illness collected through informal surveillance systems, such as self-reported cases of enteric illness. These outbreaks are detected by the PHSs
- through a phone call from a health care provider or member of the public who knows of several cases of disease that appear to have had a common source. This informal reporting of suspected outbreaks is the most typical method for identifying common event outbreaks, and accounts for the largest proportion of outbreaks reported in New Zealand.



3.1. Disease notifications and other formal surveillance

Most cases of illness reported to PHSs occur as apparently isolated or 'sporadic' cases of illness without obvious connections to each other. A source of infection is rarely conclusively identified by an investigation of a single sporadic case of disease. Every sporadic case of illness should, however, be seen as part of an unrecognised outbreak potentially, and details should be documented with this in mind. Standardised interviews of a number of sporadic cases may be useful in generating hypotheses about possible common sources of illness among cases that did not previously appear to be associated.

There are 20 PHU offices around the country. PHU staff are responsible for delivering core public health services, including the management and containment of outbreaks of communicable diseases. For each notified case, the relevant EpiSurv Case Report Form should be completed. A review of this information may reveal commonalities among cases and provide clues to a common source of infection. It is important, however, not to over-interpret these findings as commonalities may only indicate a high prevalence of the exposure or activity in the community.

In addition to identifying outbreaks, the interview and follow up of sporadic cases meets other important public health objectives, these include:

* The Early Aberration Reporting System (EARS) was developed by the U.S. Centers for Disease Control and Prevention (CDC). ESR publishes the output from the EARS analysis of EpiSurv and *Salmonella* typing data weekly at www.surv.esr.cri.nz/EARS/. The username and password is available through survqueries@esr.cri.nz.

- identification of other cases among household and other contacts of the index case for the purposes of providing preventive treatment (i.e., prophylaxis or immunisation), and if appropriate, informing them of their exposure and helping them to avoid spreading the disease unknowingly
- education to prevent future occurrences of disease
- collection of further information to improve the understanding of the disease in the community.

Other than the EpiSurv disease notification system and EARS, formal surveillance systems that may identify sporadic disease cases that are part of an outbreak include laboratory-based reporting and surveillance, sentinel surveillance, notably for influenza, and the sexually-transmitted infections (STI) surveillance system. It is also important to appreciate the importance of and maintain links with the veterinary surveillance systems in this context.

3.1.1. Laboratory-based reporting and surveillance

Accurate and timely data are essential if we are to promptly identify and respond to important public health events such as pandemic influenza, or a similar emergent infectious agent with epidemic or pandemic potential. The Health Amendment Act 2006 was aimed at improving the Government's ability to respond to an outbreak of pandemic flu or a similar highly infectious disease. It also introduced the requirement for laboratories to directly notify to medical officers of health test results indicating the possibility of a notifiable disease. The old legislation (prior to 18 December 2007) saw considerable variations in reporting rates and some under-reporting. The new legislative requirements aimed to improve the old system, and provided for direct laboratory notification of notifiable diseases. This is expected to support reporting by clinicians and result in more comprehensive and faster overall reporting of communicable diseases. Advantages of this system are that medical officers of health may receive notifications in a more comprehensive and timely manner than was the case under the previous system that relied solely on medical practitioner-based reporting. Disadvantages of this system are that many notified laboratory results may be false-positives (i.e., may not actually indicate a case of notifiable disease), and that public health staff may be in the position of starting the investigation before the patient's clinician has communicated the diagnosis to the patient. A further possibility that needs to be avoided is that clinicians may not notify believing that laboratory notification has already been done. Laboratory notification currently occurs either by manual or electronic methods but progress to a national electronic system is now a reality.

[Note: Section 8 of the Health Amendment Act 2006 inserted the following section 74AA into the Health Act 1956 as from 18 December 2007.

Medical laboratories to give notice of cases of notifiable disease

1. The person in charge of a medical laboratory must take all reasonably practicable steps to ensure that there are in place in it efficient systems for reporting to him or her (or to any other person for the time being in charge of it) the results of a test or other procedure undertaken in it that indicate that a person or thing is, has been, or may be or have been, infected with a notifiable disease.
2. The person for the time being in charge of a medical laboratory to whom results are reported under subsection (1) (or who himself or herself becomes aware of results of a kind to which that subsection applies) must immediately tell the health practitioner for whom the test or other procedure concerned was undertaken, and the medical officer of health, of the infectious nature of the disease concerned.

3. A person who fails to comply with subsection (2) –
 - a) commits an offence against this Act; and
 - b) is liable to a fine not exceeding \$10,000 and, if the offence is a continuing one, to a further fine not exceeding \$500 for every day on which it has continued.

3.1.2. Sentinel surveillance, notably for influenza

There are approximately 90 volunteer sentinel primary care practices distributed throughout the country. The sentinel system defines a case of influenza-like illness (ILI) as *an acute respiratory tract infection characterised by an abrupt onset of at least two of the following: fever, chills, headache and myalgia*. Each primary care practice records the daily number of consultations for ILI and also collects three respiratory virology samples from the first patient seen with ILI on three days of the week. Reports of numbers and samples are sent to the World Health Organization (WHO) National Influenza Centre at ESR in Wellington and other hospital laboratories. Sentinel ILI rates are expressed as per 100,000 population and not per total number of consultations.

Alongside the above sentinel system, HealthStat is a computer-based routine surveillance system of a nationally representative random sample of approximately 100 general practices that code for ILI. This surveillance system monitors the number of people who have general practitioner (GP) consultations. HealthStat is based on the automated downloads from GP practice management computer systems. This service is provided to Health and Disability Intelligence by CBG Health Research Ltd. Surveillance data analysis is frequency based with alarms raised by identifying statistical deviations (aberrations) from previous counts.

In addition to influenza viruses identified from sentinel surveillance, year-round laboratory surveillance of influenza (and other viruses) is carried out by the four regional virus diagnostic laboratories at Auckland, Waikato, Wellington and Christchurch Hospitals.

3.1.3. Sexually-transmitted infections surveillance system

Since STIs (other than AIDS) are not notifiable, surveillance depends on voluntary information provided by laboratories and clinics. STI surveillance has historically relied on Sexual Health Clinics, Family Planning Clinics and Student & Youth Health Clinics to provide case numbers and demographic information for chlamydia, gonorrhoea, syphilis and six other STIs. Laboratory surveillance of chlamydia and gonorrhoea testing has become increasingly important as the number of participating laboratories nationwide expands.

All sources mentioned understandably provide anonymised data with all personal identifiers removed.

3.2. Self-reported cases of illness

Cases of illness that are directly reported by a member of the public to the PHS make an important contribution to outbreak detection because there may be substance to the complainants claim that “something (or somebody) caused the illness”, and complainants tend to report promptly, so the trail may be warm. The complainant may be aware of other cases of illness and therefore be signalling the outbreak itself.

Many PHSs have protocols for recording information about self-reported illness. Most cases will be enteric disease, and can be recorded in EpiSurv on the Enteric Disease Case Report Form. The basics are that, in recording a complaint of illness reported to a PHS, it is important to collect contact details

(such as name, address and phone/fax numbers) and then to systematically collect the following information (taken from Stehr-Green²⁸):

- what is the person's problem (e.g., clinical description of the illness, whether a health professional was consulted, whether any tests were performed or treatments provided)
- who else became ill, what are their characteristics (e.g., age, sex, occupation) and what is the nature of their illness (e.g., symptoms, whether any persons were hospitalised or died)
- when did the affected person(s) become unwell
- how can the affected persons be contacted (including names and telephone numbers)
- how do they think that they became ill (e.g., risk factors, suspected exposures, suspected modes of transmission, hints from others who did or did not become ill)?

Collect as much information as possible from the person reporting an illness the first time contact is made, as it may be difficult to make contact again. If the complainant cannot provide critical pieces of information, try to find out who may be a more appropriate information source and contact that person. Collect information on pertinent negative as well as positive information (e.g., absence as well as presence of particular symptoms).

All cases of self-reported communicable disease require advice to prevent transmission of illness to others (e.g., hygiene instructions). Further control measures may be required in special circumstances, such as the presence of enteric disease in a food handler, communicable disease in a child attending an early childhood centre or indications of adulterated food presenting an imminent danger.

3.3. Informally-reported suspected outbreaks

As mentioned previously, informal reports of suspected outbreaks are a very common method of outbreak identification. Suspected outbreaks can be reported by:

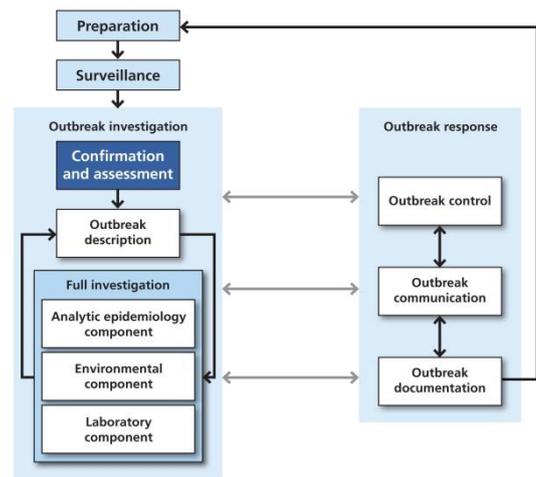
- members of the public
- health care workers
- service providers, such as operators of food premises or camps
- institutions, such as schools, prisons, rest homes
- infection control staff.

Collect detailed information from individuals reporting a suspected outbreak. Use a similar framework to that discussed previously for self-reported illness, paying particular attention to collecting information on the:

- type of illness
- number of people thought to be unwell
- name and contact details of the individual reporting the outbreak
- name and contact details of an individual (if any) responsible for organising the event (if associated with an event)
- suspected source of illness.

4. Outbreak confirmation and assessment

The first stage of outbreak investigation is to confirm whether a suspicious group of cases, a single case, or an emerging trend actually represents an outbreak. Confirmation has three steps: confirmation that the diagnosis is correct, confirmation that the increase in cases represents a real increase and confirmation that the increase represents an outbreak. These steps do not necessarily occur in this order, and may occur simultaneously. In many outbreaks (particularly common event outbreaks) these steps may be self-evident and quickly dispensed with, but should be given on-going consideration. Working through these steps methodically is of most value when investigating unusual or unexpectedly increased numbers of cases of illness not normally associated with outbreaks.



4.1. Step 1: Confirm the diagnosis is correct

Confirmation that the disease is occurring is closely linked to confirmation of the existence of an outbreak itself. Goals in confirming the diagnosis are to (a) to ensure that the problem has been accurately diagnosed, (b) to rule out laboratory error or changes in laboratory practice as the basis for the increase in diagnosed cases, and (c) to rule out changes in clinical practice.

In unusual outbreaks, clinical findings in reported cases should be reviewed closely, either directly by examining the patients, or indirectly by detailed review of the medical records and discussion with the attending health care provider(s), especially when a new disease appears to be emerging. Clinical findings should also be examined closely when some or all of the observed cases appear to have inconsistent features⁶. When known case data appear inconsistent, other potential explanations should be considered. These would include laboratory error, contamination of cultures or errors in data entry.²⁹

Pseudo-outbreaks are characterised by the isolation of the same microorganisms from a group of patients that do not have clinical signs and symptoms consistent with the typical features associated with the apparently infecting organism³⁰. These outbreaks are generally observed in clinical settings and are due to specimen contamination during sample collection (e.g., contaminated bronchoscope) or in the laboratory.^{31, 32}

If sufficient doubt exists about testing processes, it may be necessary to send a representative sample of specimens reported as positive to an outside reference laboratory for verification.

It is important to note that the diagnosis may take the form of a defined syndrome, rather than a specific aetiological diagnosis. This is commonly the case with gastroenteritis outbreaks. Such outbreaks can sometimes be described, investigated and controlled without ever confirming the identity of the agent involved, so the lack of a specific aetiological diagnosis should not stop the investigation process.

4.2. Step 2: Confirm the increase in cases is real

Changes in diagnostic, laboratory and reporting procedures should be considered as these can artificially increase the number of reported cases. For example, a sudden increase in verocytotoxic E. coli (VTEC) isolation may reflect the introduction of a more sensitive laboratory test to identify this pathogen, or changes in laboratory policy regarding which samples are tested for VTEC. Similarly, an increase in the number of salmonellosis reports may result from the appointment of a new physician at the local hospital and notification of hospitalised cases for the first time.

The potential causes of an artificial increase in case numbers are:

- an increase in testing by the laboratory
- the initiation of new testing by the laboratory
- implementation of changes in reporting procedures or more rigorous reporting.

If an inexplicable increase in case numbers is reported from a laboratory, the following steps may help clarify whether the increase is artificial or genuine³⁰.

- determine if a change in the total number of specimens submitted for testing might have artificially increased the number of cases
- determine whether there has been a change in the proportion of specimens that test positive. An increase in the percentage of specimens testing positive (number of specimens positive divided by number of specimens sent for testing) is a more reliable index of a true increase in the occurrence of cases than the total number of positive tests
- determine whether there has been a change in the method(s) used for laboratory testing, or a change in laboratory policy or personnel that may have caused a greater number of tests to be done or to be read as positive
- determine whether other nearby laboratories have seen similar increases
- determine whether the laboratory reporting most of the cases recently began providing services to a new client that might explain a sudden increase in the number of specimens testing positive.

An artificial increase in case numbers may disclose a disease burden that has previously been hidden, and is important. However, an outbreak investigation is usually not the best way to characterise this disease burden.

4.3. Step 3: Confirm that the increase represents an outbreak

A confirmed true increase in the actual number of cases of disease may not represent an outbreak. Other potential explanations of true increases in disease occurrence include the following:

- an increase in population size
- changes in population characteristics representing an influx of people at higher risk of illness
- an increase in the rate of illness due to random variation (fluctuation) in incidence
- an increase in the rate of illness due to an increase in risk behaviours (e.g., seasonal increase in use of barbeques for cooking).

Outbreaks due to common events will often be self-evident, but common site and dispersed outbreaks will probably require careful verification. To determine the existence of an outbreak in these circumstances, compare the observed with the **expected** levels of disease. Estimate the expected level from the number of cases of disease during the previous few weeks or months, or

from a comparable period during the previous few years, if the disease is seasonally distributed. The following datasets can be used to obtain case numbers for comparison with observed data:

- for notifiable disease, use surveillance records, such as case report data stored on EpiSurv
- for other diseases and conditions, use existing data collected locally, including hospital discharge records, mortality statistics, cancer or birth defect registries
- if local data are not available, apply rates from neighbouring districts, national data, or even published rates from other countries. Rates from other populations should be used as a guide only, bear in mind that differences in age, sex or other characteristics may negate the validity of these comparisons.

Establishing the background rate of a disease is generally more straightforward if confirmatory laboratory tests are available than if tests are unavailable or infrequently used. When a disease is infrequently laboratory-confirmed, establishing the background rate of disease in a community suspected of having an outbreak generally requires alternative case-finding strategies and is invariably more labour intensive. If unsure how to proceed, seek advice from experienced staff at ESR, the Ministry of Health or other PHSs. At ESR the Early Aberration Reporting System (EARS) may already have flagged the “outbreak”.

4.4. Step 4: Decide what type of outbreak is occurring

Understanding what type of outbreak is occurring has important implications for subsequent management. Common event and institutional outbreaks are usually self-evident, but it may be more difficult to distinguish between dispersed, common site and community-wide outbreaks. Use knowledge of the biological characteristics, reservoirs, epidemiology and usual transmission mechanisms of the disease agent, as well as insights gained from previous outbreaks.

4.5. Step 5: Review the information: Make a decision on further investigation and control

The balance between outbreak investigation and response activities depends on how much is known about the disease agent, source of illness and transmission mechanisms. Figure 3 illustrates the relative emphasis as influenced by knowledge about these factors. Identification and verification of the outbreak may be all that is required to implement control measures, particularly if the causative agent, source and transmission mechanism are known. Conversely, it may not be possible to implement measures to control the outbreak if the source and transmission mechanisms of the disease agent are unknown. Note that, in this context, ‘control measures’ do not include treatment and management of individual cases, which continue regardless.

Figure 3: Relative emphasis of investigation and response during outbreak management, as influenced by levels of certainty about disease agent, source and transmission mechanism

		Outbreak source and transmission mechanism	
		Known	Unknown
Disease agent	Known	Investigation + Control +++ (e.g., management of diphtheria case ³³ pertussis)	Investigation +++ Control + (e.g., marijuana as route of salmonellosis transmission ³⁴)
	Unknown	Investigation +++ Control +++ (e.g., parathion poisoning ³⁵)	Investigation +++ Control + (e.g., the outbreak investigation that led to the identification of Legionnaires' disease ³⁶)

Source: Adapted from Goodman³⁷

Notes: +++ high emphasis should be placed on this stage of outbreak management

+ low (or less) emphasis should be placed on this stage of outbreak management

Every confirmed outbreak should ideally be investigated to determine its source and to prevent further illness. However, as resources are not always available to fully investigate every outbreak, a rational prioritisation approach is needed to determine the appropriate level of investigation required. The factors listed next may be useful in assisting with making this decision; the existence of any of these factors increases the priority that should be placed on the investigation and the degree of urgency with which to initiate the investigation.

- A new or unusual disease agent or transmission mechanism is suspected. An investigation may help understand the disease in sporadic as well as outbreak circumstances.
- Descriptive characteristics of the outbreak (person, place, time) suggest that a common source is highly likely. Subtyping of common organisms (see Chapter 10) may play an important role in this. These characteristics increase the likelihood that the investigation will be successful.
- Descriptive characteristics of the outbreak (person, place, time) suggest that it is widespread (multi-regional) even with small numbers of cases.
- The source and transmission mechanism is unknown, such that measures to control the outbreak cannot be put into place, as shown in Figure 3.
- The outbreak is continuing (i.e., there is evidence of on-going transmission).
- Similar outbreaks have occurred before, or are expected in the future, and more information is needed to develop preventive measures.
- The outbreak is having, or likely to have, a very high impact on public health because:
 - a large number of people are affected
 - the illness is severe and associated with a high case fatality or hospitalisation rates
 - the characteristics of the population affected by the outbreak suggest particular vulnerability to serious illness (e.g., illness among children, the elderly or immunocompromised).

- The outbreak has high importance relative to other competing public health issues and activities.
- Suitable personnel and financial resources are available.
- The illness has been identified and reported in a timely manner. (Investigation weeks after the event is less likely to obtain reliable information.)
- The outbreak has attracted public, media or political interest.

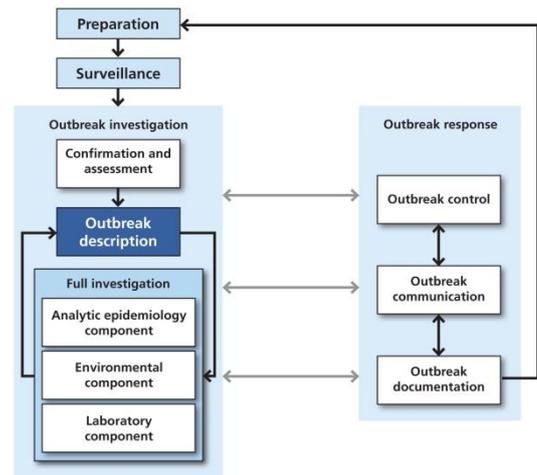
As soon as an outbreak is identified, preliminary data should be recorded on the outbreak surveillance system on EpiSurv (see Chapter 13 and Appendix 7), irrespective of whether further investigation is to proceed. The decision to investigate any outbreak should be made only after collection and review of the preliminary information on the outbreak and discussion of the situation by appropriate local public health personnel (e.g., the medical officer of health, public health medicine specialists, health protection officers, environmental health officers). In some instances, it may be desirable to consult with people outside the PHS, such as with the Ministry of Health, the Ministry for Primary Industries or ESR. Appendix 1 contains guidance on scenarios that require that these other agencies be involved in the decision-making process.

5. Outbreak description

The descriptive stage of the investigation characterises the outbreak once it has been confirmed. This is done by collecting and examining information from cases. The goal of the descriptive stage of the investigation is to provide sufficient information to make preliminary control recommendations and to develop hypotheses for further analytical investigation, if required.

Despite the sense of urgency that surrounds identification of an outbreak, the investigation should proceed in a planned strategic manner. Existence of a previously developed district outbreak plan will greatly ease this process.

This chapter describes the steps that should be taken in planning the outbreak investigation and describing the outbreak. Outbreak description may also involve preliminary components of environmental investigation and laboratory investigation, processes which are discussed in Chapter 9 and Chapter 10, respectively.



5.1. Step 1: Compile information collected

Before convening the first outbreak team meeting, compile all the routinely-collected information on the cases that have been initially reported, including incomplete information on suspected cases. It is essential to keep EpiSurv as up-to-date as possible for local and national monitoring of outbreaks by a number of agencies.

Briefly review this information so that the basis of the outbreak is clear. Identify the common features about the cases that suggest that they are involved in the outbreak. This information will be used to produce a case definition.

Review routinely-collected information about any potential environmental source of the outbreak. This information may be in the form of environmental health reports from particular food premises. Such information could lead to early intervention and control of the outbreak.

5.2. Step 2: Develop a case definition

A case definition is a standardised description of the disease associated with an outbreak which, for the purposes of the investigation, will be used to distinguish between cases and non-cases. The case definition should not be used as a basis for clinical diagnosis, treatment or other management of individuals.

The primary objective in developing a case definition is to include as many individuals as possible who are likely to be part of the outbreak (sensitivity), while excluding as many as possible who are not likely to be part of the outbreak (specificity). This balancing act always involves trade-offs.

The case definition should be developed by reviewing details of cases reported to date. This initial case definition need not be fixed, and may be revised later in the investigation. A complete case definition has the following requirements⁶.

- a definition of the health events to be counted. This definition usually consists of clinical and laboratory features. Clinical features include characteristic signs and symptoms of illness and

should be defined precisely. Ideally, all cases require laboratory test results confirming the presence of a pathogen or toxin causing illness. In practice, many investigations include a mix of clinical and confirmed cases

- a further description of the characteristics of the cases using:
- time (time period during which the diagnosis occurred)
- place (geographical area)
- and, sometimes, persons (population group of interest).

The case definition must not include characteristics that relate to the possible outbreak source. If details of the suspected exposure causing the cases of illness (e.g., consumption of a particular food or water from a particular source) are included in the case definition, it will be impossible to measure and statistically test the relationship between the exposure and illness.

For an unequivocally identified disease, a standard case definition such as that found in the Manual for Public Health Surveillance in New Zealand³⁸ or some modification of this definition, may be used or adapted. Examples of case definitions used in reported outbreak investigations are listed below.

5.2.1. Common event

Case defined as any individual who attended an event, for example, a party, and within 48 hours of attending the event developed either diarrhoea (defined as at least three loose motions in a 24-hour period) or at least two of the following: stomach pains, fever, vomiting or nausea.^{2, 13}

5.2.2. Dispersed

Case defined as a patient with the outbreak-associated strain of *Salmonella* Montevideo isolated from a stool sample collected in July.¹⁴

5.2.3. Common site

Case defined as any person domiciled in the health district and notified to the PHS before 31 May with laboratory-confirmed cryptosporidiosis, and onset of symptoms during the period from 1 January to 30 April 1998.¹²

5.2.4. Community-wide, person to person

Case defined as an individual of the particular immigrant ethnicity who had either a positive hepatitis A IgM antibody or a raised serum alanine aminotransferase and a consistent clinical illness (jaundice, nausea, anorexia or fever).¹⁶

5.2.5. Institutional

A case was defined as any resident of the nursing home with either an alteration in bowel habit (resulting in at least one loose stool) or vomiting between 4 and 7 June, inclusive.

5.3. Step 3: Find other potential cases

Identify additional cases by searching for people who might meet the case definition. This step is undertaken to:

- ensure recognition of the true scale of the outbreak
- minimise the bias that could result from an investigation focusing only on cases identified early in the outbreak
- provide more statistical power to identify risk factors.

Without this step, inappropriate control measures may be implemented. Do not, however, excessively slow the investigation while trying to find every last case.

5.3.1. Case-finding strategies for common event outbreaks

Case finding strategies for common event outbreaks can be tightly focused on the event itself. Try to locate a list of individuals who attended the event associated with the outbreak. If available, the list will normally be held by the event organiser. If a list is unavailable, contact the individual responsible for organising the event, and try to obtain a verbal list of names with contact details. If neither approach is fruitful, interview cases identified for names of other individuals attending the event.

Retain names and contact details of all individuals linked to common event outbreaks, whether cases or not, for the duration of the investigation.

5.3.2. Case-finding strategies for common site, dispersed and community-wide outbreaks

Case finding strategies that are more appropriate for outbreaks in other community contexts include:

- interviewing family contacts of cases
- reviewing notifiable disease reports
- requesting hospitals and general practitioners to report (retrospectively or prospectively) patients who meet the case definition
- requesting laboratories to report (retrospectively or prospectively) patients from whom the aetiological agent has been isolated
- reviewing accident and emergency department records
- reviewing data from other PHSs.

5.3.3. Case finding in institutional outbreaks

Identify other cases in institutional outbreaks by interviewing staff members responsible for other subsections of the institution (i.e., hospital wards, rest home wings, boarding school dormitory blocks).

5.3.4. Other case-finding strategies

On occasion, it may be appropriate to advertise for cases through the media (e.g., through newspaper health articles or public announcements on the radio). This method, however, should be used very carefully because it is likely to identify a large number of people with illnesses that are unrelated to the outbreak, details included in the newspaper article or radio announcement may bias reports of illness, and it may create unnecessary alarm.

5.4. Step 4: Collect information about cases

Detailed information on all cases involved in an outbreak should be collected using a **structured interview** based on a standardised questionnaire. The questionnaire should cover disease manifestations, patient characteristics and exposures that may be sources of infection. Appendix 2 contains detailed information about developing questionnaires and appropriate interview techniques, but the emphasis at this stage of the investigation should be on rapidly developing and administering a simple questionnaire designed to elicit information to identify possible hypotheses. Interviewers should probe where necessary to explore details of exposures.

Many PHSs have pre-prepared questionnaires for interviewing cases with common forms of sporadic illness, and these are entirely appropriate at the descriptive stage of the investigation. ESR has developed templates for some types of questionnaires, which are available on request. Templates include the Common Event Foodborne Outbreak Questionnaire and the General Food and Waterborne Disease Outbreak Questionnaire for dispersed outbreaks of food or waterborne disease. There is also a more recently developed questionnaire for use in food-associated outbreaks predominantly involving young children. Each of these questionnaires may be adapted to the circumstances surrounding the outbreak.

Information gathered from interviews should be combined with other sources of information, such as medical records and laboratory reports, if appropriate. If the outbreak has occurred in a hospital or continuing-care institution, it may be more appropriate to go directly to the medical records than to interview patients. Information collected from a review of medical records should also be collected and recorded in a standardised manner.

Before starting case interviews, consider whether the investigation is likely to require a full analytic investigation stage. If so, it may be appropriate to proceed directly to the analytic investigation as this will avoid having to interview the cases twice. Proceeding directly to the analytic investigation is usually only feasible if the outbreak is a clearly defined common event outbreak, or if sufficient information has already been collected from routine interviews and a hypothesis, or a limited range of potential hypotheses, about the source and transmission mechanism has been identified from the outbreak description.

5.5. Step 5: Perform descriptive analysis of cases

Descriptive analysis is extremely valuable in helping to identify hypotheses about the source of the outbreak that will be useful to guide a full analytic investigation. This information may also be sufficient in itself to help identify ways to control the outbreak, but beware, characteristics common among cases may be found just as commonly among people who are not cases. Obtaining background levels for such characteristics is of vital importance in avoiding unnecessary investigations. An analytic epidemiological study may still be needed to confirm the initial findings.

Enter data from questionnaires, case report forms or laboratory test results onto a computer database. Analysis of the descriptive data aims to characterise the cases in terms of time, place and person.

- **Time associations** refer to the onset of illness among cases within a certain time span (e.g., a few hours or days, depending on the usual rate of occurrence of the disease and the incubation period of the aetiological agent). Often onset dates are not available from the case report forms. In these situations a proxy date, for example, the date of specimen collection or notification may have to be used. Time associations are usually best examined by drawing an epidemic curve (see Step 6) that depicts the distribution of cases by onset of symptoms.
- **Place associations** refer to the presence at a common place although not necessarily at the same time (e.g., living in the same town, residing in the same building or neighbourhood, going to the same school or attending the same social function). Person and place associations can be assessed most easily by examining variables within a line listing of cases.
- **Person associations** refer to groups of people having similar personal characteristics (e.g., the same age group, sex, ethnic group or occupation).

As well as examining the data for these associations, describe the clinical characteristics of the cases. If a disease agent has not been identified by laboratory testing, predominant signs and symptoms among cases may be useful in identifying the agent and directing further laboratory testing. The incubation period (interval between exposure and disease onset) will also be useful (see page 33).

5.6. Step 6: Draw an epidemic curve

An epidemic curve depicts the time course of the onset of symptoms among cases in an outbreak. The epidemic curve is a two-dimensional bar graph or histogram with an x- and a y-axis that helps to illustrate the dynamics of the outbreak, including the number of people affected the time course of the outbreak and whether the outbreak is continuing. It may also indicate the mode of transmission and help to relate the timing of key events (such as possible exposures and control measures) to the onset of symptoms.

The epidemic curve has the following format:

- the x-axis depicts the time or date of onset of symptoms. Choose an x-axis scale based on the period covered by the outbreak and the incubation period of the disease (if known). For example, an outbreak of hepatitis A may have a scale of days-to-weeks, whereas an outbreak of staphylococcal food poisoning may have a scale of hours. Label the timing of key events
- the y-axis depicts the number of cases. The scale of the y-axis will depend on the number of cases involved in the outbreak. It may be helpful to denote cases occurring in different subgroups (e.g., different age groups) using different coloured bars or lines.

5.6.1. Interpreting the epidemic curve

The shape of the curve may indicate the mode of transmission.

- Characteristically, the epidemic curve of a common event outbreak has a sharp rise in cases to a peak, followed by a fall-off that is less abrupt than the rise (Figure 4). The length of the curve will be approximately equal to one incubation period of the infection.
- The rise in cases for a dispersed or common site outbreak may also be sharp, but will not fall off unless exposure to the source is discontinued or all susceptible individuals become infected.

- The epidemic curve of a community-wide outbreak, with person-to-person spread, is likely to be characterised by a relatively slow, progressive rise. The curve will continue over a period equivalent to the duration of several incubation periods of the disease (Figure 5).
- The epidemic curve of an institutional outbreak may resemble any of the above, depending on the mechanism of disease transmission.

Epidemic curves may not exactly fit any of these models. The outbreak may have mixed characteristics, and random variation may also affect the shape of the curve.

Figure 4: Epidemic curve of food poisoning following a dinner party (common event outbreak)

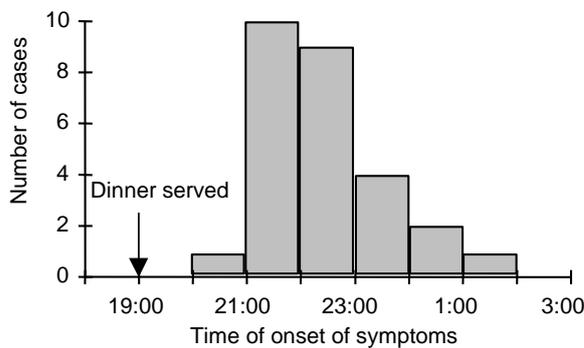
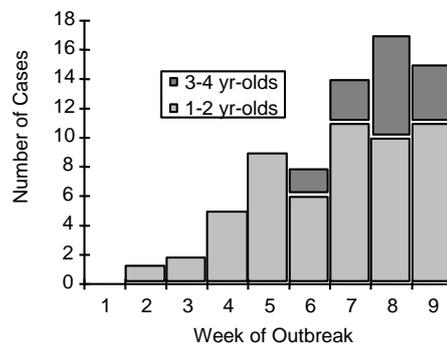


Figure 5: Epidemic curve for a cryptosporidiosis outbreak at a child care centre (person-to-person spread)



5.7. Step 7: Calculate an incubation period

The incubation period is the interval between exposure to the disease agent and appearance of initial symptoms of the illness. While each disease has a characteristic incubation period, the incubation period for the disease will vary among individuals, due to physiological variations, differences in the degree of exposure to the disease agent and biological factors that influence susceptibility.

The incubation period has two main uses when investigating disease outbreaks. If the exposure time is known, calculation of the incubation period can help to narrow the range of possible disease agents and will therefore direct subsequent laboratory tests and control measures. If the disease agent is known, but the time of exposure is not, the incubation period (as recorded in the published literature) can determine the approximate time of exposure, enabling the outbreak team to narrow the focus of the remainder of the investigation, including any analytic epidemiological, environmental and laboratory components.

The incubation period of gastrointestinal illness is particularly useful in categorising the potential disease agent as either an infection or intoxication. A very short incubation period (i.e., minutes to hours) suggests exposure to a toxin such as a bacterially-produced toxin, shellfish toxin or a chemical contaminant. Longer incubation periods tend to suggest an infection. Appendix 6 lists the incubation periods of common disease agents causing gastroenteritis.

Calculate the incubation period for each individual by subtracting the time of exposure from the time of onset of the first symptoms consistent with the case definition, that is, if cases are defined by the presence of diarrhoea or vomiting, do not use onset of nausea, headache or other symptoms to calculate the incubation period. Note the shortest and longest incubation periods (i.e., the range) in the group.

Calculate the incubation period for the group by using the median or mean. The **median** incubation period is calculated by sorting incubation periods from the shortest to the longest. The median incubation period is the incubation period of the individual at the mid-point on the list (or the average of the two middle values if the list has an even number of cases). The **mean** incubation period is the average or the sum of all incubation periods divided by the number of observations. In practice, the median incubation period is often preferred because, unlike the mean incubation period, it is not influenced by a small number of cases with extremely short or long incubation periods (called outliers).

Table 3 presents case data for 10 people who developed nausea and vomiting following a dinner party at a restaurant. The table shows times of exposure and onset of illness, and the calculated incubation period for each person who became ill. The mean incubation period was 9.7 hours and the median incubation period was 6.5 hours (range: 3–42 hours). This short incubation period and the clinical presentation are highly suggestive of the ingestion of a bacterial enterotoxin, such as that of *Staphylococcus aureus*, *Clostridium perfringens* or *Bacillus cereus*.

Table 3: Sample case data for calculation of incubation period

Patient	Time of Exposure	Onset of Illness	Incubation Period (h)
1	7:00 pm (13/4/91)	10:00 pm (13/4/91)	3.0
2	7:00 pm	11:30 pm	4.5
3	7:00 pm	12:00 am (14/4/91)	5.0
4	7:00 pm	12:00 midnight	5.0
5	7:00 pm	1:00 am	6.0
6	7:00 pm	2:00 am	7.0
7	7:00 pm	2:00 am	7.0
8	7:00 pm	3:30 am	8.5
9	7:00 pm	4:00 am	9.0
10	7:00 pm	1:00 pm (15/4/91)	42.0

Two points are notable from this example. First, the mean incubation period was somewhat longer than the median. In fact, the mean is longer than all but one of the incubation periods. This demonstrates how one particularly unusual value, that is 42 hours, can have a major impact on the mean. Secondly, it is highly likely that the case with the apparent 42-hour incubation period had an illness unrelated to the initial outbreak. This person may have had nausea and vomiting due to some other cause, or may have been exposed later than the other dinner guests, for example, through secondary infection or eating leftovers sometime later. Re-examine such outliers to determine whether the patient was really likely to have been associated with the outbreak. It may sometimes be necessary to exclude the outlier(s) when determining the incubation period.

5.8. Step 8: Review the information: make a decision on further investigation and control

Information gained from the descriptive phase, in combination with the environmental investigation and the results of laboratory testing, should be sufficient to characterise the outbreak and may also indicate the likely outbreak source and mode of transmission. The next stage of the investigation is the application of intensive analytic epidemiological methods, environmental investigation or laboratory investigation.

5.8.1. Decide whether to progress to further investigation

The criteria for progressing to the next stage of investigation are largely the same as those for progressing to the descriptive stage, as discussed on pages 28-29.

The primary reason for progressing to further investigation is if the descriptive stage of the investigation has not adequately informed the development and implementation of measures to control the outbreak or prevent further outbreaks occurring due to the same source. Other reasons for further investigation of the outbreak include the on-going nature of the outbreak, a high public health impact of the outbreak, a high public interest, a new or unusual disease agent or transmission mechanism, an unknown disease agent, a high likelihood of a common source, a high priority for the outbreak and availability of suitable human and financial resources.

Regardless of the decision to undertake further investigation, it is important to implement precautionary control measures to stop further spread of the disease (see Chapter 11). If a decision has been taken to proceed to further investigation, the nature of this investigation should be determined. There are three main types of outbreak investigation – analytic epidemiological, environmental and laboratory. An optimal mix of these methods should be applied to each outbreak being further investigated.

The following guide may be useful to help identify which outbreak investigation approaches to implement, given that one or more of the previously described criteria for outbreak investigation (pages 28–29) will have been satisfied.

Analytic epidemiological investigation may be appropriate when:

- it is necessary to identify the transmission mechanism and/or source so that control measures can be undertaken
- a hypothesis or limited range of potential hypotheses about the source and transmission mechanism has been identified from the outbreak description (i.e., characteristics of cases or their exposures suggest one or more unusual features that many cases have in common)
- sufficient numbers of cases have been identified or are likely to be identified to give the investigation sufficient statistical power to determine exposures with an acceptable level of statistical certainty. In practice, at least five cases are usually needed for such an analysis, though considerably more may be required, depending on circumstances. A study power calculation should be carried out (see page 67-68). Even if there are too few cases to be statistically significant, investigators may still undertake an analysis in order to practice their analytical techniques for when a significant outbreak occurs.
- a valid study is feasible (i.e., problems with bias or confounding are not insurmountable)
- the investigation is timely, that is, the delay from likely exposure to case interview is not so long that recall will be seriously impaired
- an epidemiological investigation undertaken in an outbreak situation is more appropriate than a study mounted more strategically
- an epidemiological investigation will help to focus the environmental or laboratory investigation.

Environmental investigation may be appropriate:

- to control the outbreak. Prevention of future outbreaks or policy development depends on the identification of faults in processes that cases cannot identify (e.g., food manufacturing process failure, water treatment failure, failures in maintenance of vaccine cold-chain)

- where the outbreak source is known in general terms, but further environmental information must be collected before control measures can be implemented (e.g., an outbreak of legionellosis in a workplace with a limited number of potential sites that could act as Legionella reservoirs)
- where it contributes sufficient information about exposures to enable the implementation of control measures without the need for analytic epidemiological or laboratory investigation (e.g., an outbreak of cryptosporidiosis associated with a petting zoo).

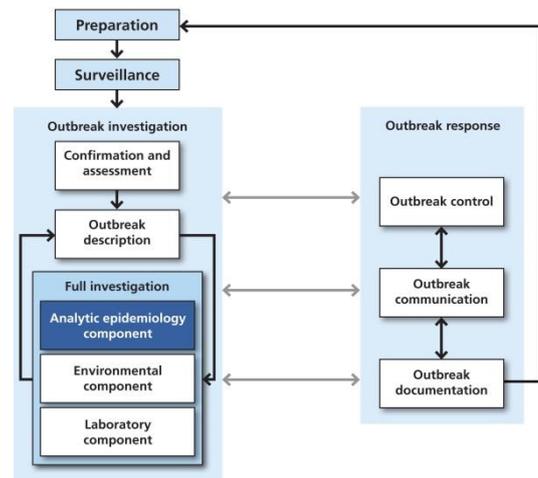
Laboratory investigation may be appropriate when the outbreak:

- is potentially associated with antimicrobial resistant organisms
- involves organisms for which molecular or subtyping methods are available and the use of these methods will assist the investigation, for example, to help to distinguish which cases are part of the outbreak or to help identify the source.

6. Retrospective cohort studies

Summary of retrospective cohort study design

- Retrospective cohort study designs are sometimes referred to as 'cross-sectional' studies when the time-frame is relatively short, such as in an acute disease outbreak.
- Cohort studies are typically used to investigate common event and institutional outbreaks, where the entire "at-risk" population can be defined easily.
- Retrospective cohort studies collect data on the entire "at-risk" population (e.g., all people attending a wedding reception, all people attending a particular school or all people on a cruise).
- Alternatively, if the population at risk is too large for the whole population to be examined, a random sample of the entire population may be selected.
- The cohort design compares disease risks in two groups defined according to exposure (i.e., the exposed group compared with the unexposed group).
- Outbreak investigation using the cohort design allows attack rates to be calculated during the analysis stage. This can contribute to the interpretation of the investigation findings.



6.1. Criteria for using the retrospective cohort study design

- For outbreaks confined to a group that is well-defined, easy to count and within which everyone may be identified, regardless of whether they became ill or not. Retrospective cohort studies are therefore most useful for the investigation of common event, institutional and household outbreaks. Examples include outbreaks involving children at a particular school, or attendees at a particular social event. A complete list of those in the group is desirable (e.g., the school roll or a guest list). This list defines the study cohort, and includes both cases and non-cases. Retrospective cohort study designs are generally not used for investigating dispersed, common site and community-wide outbreaks where the potentially exposed group cannot be enumerated.
- If investigation of the whole cohort is unfeasible, a cohort design can still be applied by taking a random sample of the cohort for study. The main disadvantage with this approach is that identified cases may not be included within the random sample. If this is an issue, it may be more appropriate to use a case-control design.

Table 4: Suitability of retrospective cohort studies in different outbreak situations

Outbreak type	Study suitability
Common event	Retrospective cohort study designs are well-suited to the epidemiological investigation of common event outbreaks, because the 'at risk' population can be easily defined
Common site	Retrospective cohort study designs are generally not applied to common site outbreaks, unless full lists of those exposed (e.g., complete lists of diners at a restaurant, hotel guests) are available
Dispersed	Retrospective cohort study designs are not well suited to the investigation of dispersed outbreaks
Community-wide	Retrospective cohort study designs are not well suited to the investigation of community-wide outbreaks
Institutional	Retrospective cohort study designs are well-suited to the investigation of institutional outbreaks. These are similar to common event outbreaks in that the site of transmission is known at the outset. Investigation should involve hazard identification and collection of environmental specimens

6.2. Designing a retrospective cohort study

Retrospective cohort studies should be well planned and documented in advance. However, planning for a cohort study tends to be much more straightforward than for a case-control study, because there is no need for an elaborate protocol for identifying and recruiting controls to remove selection bias: by definition, all the cohort members are eligible for recruitment into the study whether ill or not. The following points are likely to be important:

- obtain consent from a parent or guardian before interviewing children under the age of 16 years. Interview the parent or guardian (or an adult who observed the children's exposures) as a proxy if children are too young to provide useful information
- interview all participants as soon as possible to minimise information bias due to inadequate recall of exposures. Alternative methods of data collection are increasing in frequency – for example, electronic distribution of questionnaires for self-completion and web-based questionnaires. There is no 'one-size-fits-all' strategy. The advantages and disadvantages associated with all these approaches should be considered before a decision is made
- develop study materials before beginning the cohort study, these include:
 - a study protocol that briefly documents all aspects of the study design
 - an introductory sheet containing precise wording for the introductory statement in the questionnaire, as discussed on page 48. It may be worthwhile having separate introductory sheets, or statements, for the recruitment of adult and child controls.
 - a cohort log that lists all individuals known to be part of the cohort, whether they become part of the study or not, and records the results of attempts made to recruit cohort members to the study. As well as helping coordinate the study, information recorded in the cohort log enables calculation of the study response rate.
 - questionnaire development is discussed in Appendix 2.
 - a database (e.g. EpiData – www.epidata.dk) that allows entry and storage of data from the questionnaires in an electronic form. The database (converted directly from a questionnaire saved in a .rec file) can be used to analyse the data. EpiData is currently being revised.

- Other databases such as SurveyMonkey³⁹ and Surveygizmo⁴⁰ are also being used increasingly in the analysis of questionnaire data.

6.3. Analysis of retrospective cohort studies

Analysis of retrospective cohort study data involves comparing disease incidence rates (i.e., attack rates) in exposed and unexposed subgroups of the population at risk (e.g., those who ate a particular food compared with those who did not eat the same food).

The attack rate (i.e., frequency of disease in a subgroup) is calculated by dividing the number of cases of disease occurring in an exposure subgroup (e.g., all those who ate a particular food, or all those who did not eat that same food) by the total number of people in that subgroup. Attack rates in corresponding exposed and unexposed subgroups may then be compared by calculating a risk ratio. The risk ratio estimates the relative risk for the exposure in question. That is, the risk in the exposed group relative to the risk in the unexposed group. Relative risks (or risk ratios) can, in theory, range from zero to infinity.

If the attack rate in the exposed subgroup is similar to the attack rate in the unexposed group, the risk ratio will be close to 1.0. This provides evidence of no association between the exposure and the disease. However, a risk ratio of greater than 1.0 suggests an association between the exposure and the disease. The larger the risk ratio the stronger the apparent association. Despite this, it is important to remember that an identified association does not necessarily imply cause and effect (or exposure caused the disease of interest). It is possible that the apparent association is due to chance factors (random variation), bias in the selection of subjects or analysis of the data, or confounding by another factor. Such possibilities need to be considered by the investigators before firm conclusions are drawn. This is discussed in Chapter 8 in more detail.

Risk ratios below 1.0 imply a negative association between the exposure and the disease, that is, the exposure protects against the disease. Outbreak investigations are usually much more concerned with positive associations (i.e., risk ratio greater than 1). However, negative associations can occasionally provide useful clues to the actual source of disease. If, for example, an exposure which generates a negative association happens to be inversely correlated with another exposure, this suggests that the other exposure may have a positive association with the disease. An example of this would be when guests at a dinner have a choice of desserts, but can have one dessert only. If one of the desserts was the outbreak source, then the other desserts are likely to generate negative associations with disease, because choosing them protected against becoming ill.

6.3.1. Basic analysis of results from a retrospective cohort study

The calculation of attack rates and risk ratios is illustrated using the following two-by-two table that shows the relationship of the disease to a particular exposure.

Exposure	Disease present	
	Yes (case)	No (non-case)
Yes	a	b
No	c	d

$$\text{Attack rate} = \frac{\text{Number of people with disease in the subgroup}}{\text{Number of people in the subgroup}} \times 100$$

$$\text{Attack rate for exposed subgroup} = \frac{a}{a + b} \times 100$$

$$\text{Attack rate for unexposed subgroup} = \frac{c}{c + d} \times 100$$

$$\text{Risk ratio} = \frac{\text{Attack rate in exposed subgroup}}{\text{Attack rate in corresponding non – exposed subgroup}}$$

$$\text{Risk ratio} = \frac{a}{a + b} \div \frac{c}{c + d}$$

A different two-by-two table may be drawn for each exposure to represent the relationship with the disease.

Provided the size of the cohort is large enough, the confidence interval (CI) can be calculated to determine that the calculated risk ratio differs to the null value of 1.0 (i.e., no association between exposure and disease). This concept is addressed in some detail later in the document (page 59).

6.4. Retrospective cohort investigation example

The basic principles of designing and analysing a retrospective cohort study are illustrated in the following worked example. This example presents details of an actual retrospective cohort investigation of a common event outbreak⁴¹. The investigation and findings are reproduced here with the permission of the authors.

In July 1997, a local general practitioner notified the Auckland Regional Public Health Service of a case of gastroenteritis. The case had attended a hui 10 hours before becoming unwell and knew of three other attendees with similar symptoms. Following an initial assessment of the situation, it was decided that an epidemiological study would be conducted without delay while details of exposure were still available. A retrospective cohort design was chosen because a list of all attendees was available and the size of the cohort was suitable.

6.4.1. Case definition

Cases were defined as individuals who had attended the hui and experienced either diarrhoea (consisting of at least three loose motions in a 24-hour period), or at least two of the following: stomach pains, fever, vomiting or nausea, within 48 hours of attending the hui.

6.4.2. Case finding

Case finding was not necessary.

6.4.3. Questionnaire

A food questionnaire covering all meals (including food and drinks) served at the hui was compiled and administered to attendees.

6.4.4. Results

Table 5 shows a selection of the results produced from this study.

Table 5: Selected exposures reported from a retrospective cohort study of a gastroenteritis outbreak*

Food item	People eating item			People not eating item			Risk ratio
	Ill	Total	Attack rate (%)	Ill	Total	Attack rate (%)	
Raw mussels	30	42	71	33	71	47	1.5
Steamed pudding	7	12	58	56	101	55	1.1
Roast pork	60	87	69	3	26	12	6.0
Silverside	16	21	76	47	92	51	1.5
Potato salad	37	53	70	25	59	42	1.7
Roast pumpkin	38	59	64	24	52	46	1.4

Notes: *Adapted from Simmons et al, 1998⁴¹

Although the attack rates for most subgroups are fairly high, the difference in attack rates between those eating roast pork and those not eating roast pork is the most marked. This is reflected in the risk ratio column, which shows that people eating roast pork were six-times more likely to develop the illness than those not eating roast pork. This suggests that the roast pork may have been the source of the outbreak.

The possibility of a causal association with roast pork is not excluded by the fact that not everyone who reported eating roast pork became ill, and not everyone who did not eat it remained well. There are various explanations for why this might occur. The most likely one is that some attendees, by the time they were interviewed, may have forgotten exactly what they had eaten. Some who had not eaten roast pork may have incorrectly reported that they had eaten it, and, conversely, others who had actually not eaten it may have incorrectly reported having done so. Other possible explanations include prior immunity to the causative agent in some people, or the coincidental occurrence of other similar diseases at around the same time.

Before drawing conclusions about the role roast pork may have played in the outbreak, it is necessary to consider whether this result could have been due to random variation (chance), selection bias, information bias, or confounding. These issues are discussed further in Chapter 8.

Note: While it may have been difficult to obtain left-over food samples from this event, in other circumstances such samples could provide conclusive evidence of the causative vehicle following laboratory investigation. Such evidence would ideally require further investigation to determine how the organism established itself in the food item. Evidence for establishing the mode of contamination can be obtained by conducting an environmental investigation: such as food handling practices, training of staff, hand wash facilities etc. as appropriate.

For a recent comprehensive account of an outbreak investigation following a wedding reception using a retrospective cohort design⁴², see:

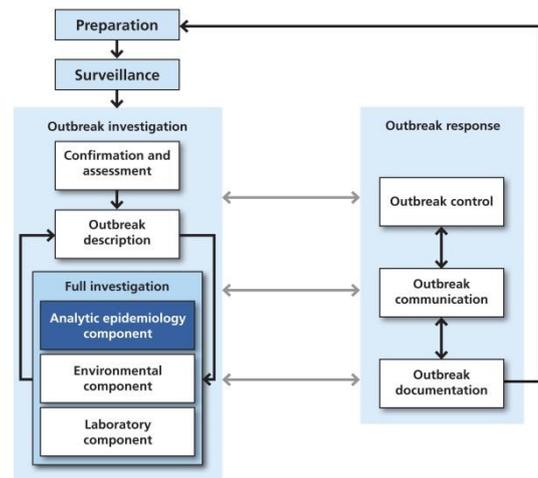
<http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20076>

7. Case-control studies

7.1. Summary of case-control study design

Case-control studies compare exposure frequencies in two groups defined according to *disease status* as opposed to cohort studies that compare disease frequencies in two groups defined by *exposure status*” The exposures of the group of ill individuals (cases) are compared with the exposures of a group of well individuals (controls). The control group must have had the same chance of being exposed to the hypothetical cause (outbreak source) of disease as the cases. The format and use of such studies are briefly described below.

- Exposures that occur more frequently among cases than controls are positively associated with the disease. Exposures which occur with approximately equal frequency in both case and control groups are unlikely to be associated with the disease. Exposures that occur more frequently in the control group than in the case group have a negative association with disease (they are protective).
- In case-control study designs, the association between exposure and disease is measured using the **odds ratio**. The odds ratio is, literally, the ratio between the odds (chance) of a particular exposure among cases and the odds of the same exposure among controls. Considerations of chance, bias and confounding apply to the interpretation of odds ratios as they do for risk ratios.



7.2. Criteria for using a case-control design

The case-control study design is appropriate for the analytic epidemiological component of an outbreak investigation as follows (Table 6):

- where cases have been identified, but the entire 'at risk' or potentially exposed group cannot be completely listed. They are therefore most useful for the investigation of dispersed, common site and community-wide outbreaks. Examples include outbreaks involving shoppers at a supermarket or people living in a particular area
- for the investigation of a common event outbreak where the size of the cohort is unfeasibly large or the number of cases represents a small proportion of the total 'at-risk' population
- for the investigation of risk factors for apparently sporadic disease.

Table 6: Suitability of case-control study design for different types of outbreaks

Outbreak type	Case-control study suitability
Common event	Case-control study designs are generally not used in the epidemiological investigation of common event outbreaks. The case-control study design may be applied to the investigation of common event outbreaks if special circumstances apply, e.g., when the size of the cohort is unfeasibly large
Common site	Case-control study designs are well suited to the investigation of common site outbreaks
Dispersed	Case-control study designs are well suited to the investigation of dispersed outbreaks
Community-wide	If an epidemiological investigation is required in such an outbreak, a case-control design would be appropriate.
Institutional	Case-control study designs are generally not applied to institutional outbreaks, but may be necessary if the group of individuals at risk cannot be easily enumerated

7.3. Designing a case-control study

The design of a case-control study requires close attention to detail to minimise bias (see p. 63). The study methodology should be carefully documented up-front and followed as much as possible during the investigation. To expedite rapid deployment of a case-control study, a standard methodological approach for likely outbreak scenarios should be developed in advance. The following sections describe key study design components that should be determined before information collection begins.

7.3.1. Case inclusion and exclusion criteria

Use the case definition (see p. 28) as the primary criterion for including cases. Exclusion criteria should be minimised. Valid exclusion criteria may include:

- potential cases who cannot be contacted (specify mechanisms for contacting e.g., telephone and mailed requests to return calls)
- travel overseas or outside the study area during the incubation period (if the hypothesis under investigation involves an exposure that could only have been acquired locally)
- inability to converse in English (this may be necessary if the urgency or resource restrictions on the investigation do not permit the involvement of interpreters)
- potential cases who cannot estimate the date of onset of illness.

7.3.2. Interviewing children

Consent from a parent or guardian must be obtained before interviewing children under the age of 16 years. Interview the parent or guardian as a proxy if children are too young to provide useful information.

7.3.3. Case exposure period

Cases are normally interviewed about their exposures during the incubation period of their illness. This incubation period should be documented.

7.3.4. Timeframe for interviews

Cases and controls should be interviewed as soon as possible after their identification to minimise information bias due to inadequate or inaccurate recall of exposures during the incubation period of the illness.

7.3.5. Protocol for control recruitment

In a case control study the guiding concept in the selection of controls is that they should come from the same population at risk for the disease as the cases. Issues associated with control recruitment are discussed below. Processes used should be standardised and documented. Requirements and issues concerning control recruitment are:

- delineation of an appropriate population from which controls will be recruited, either from the general population or a specific subpopulation e.g. defined community.
- identification of a recruitment method, either population-based or targeted.
- obtaining community controls for case-control studies is becoming very difficult and expensive due to the low participation rate from telephone recruitment methods (only 21.4% in a recent New Zealand study).⁴³
- control recruitment is often the most difficult and time-consuming part of an investigation. Controls have not had the disease and so may lack motivation to participate. Telephone landline-based control recruitment strategies may not be valid in an era where householders have many alternatives to fixed landlines for voice communication. Making use of controls that participated in an investigation into a similar situation in the recent past may have to be considered, as well as the possibility of using cases from non-identical strains of the suspected organism as controls, that is, a case-case study design described on page 56.
- establishing a process for managing non-response to recruitment. The control recruitment protocol should pay particular attention to non-response, that is, no answer to telephone calls or door-knocking. If non-responders are excluded purely on the basis they are unavailable on the first call, the control sample is likely to tend toward people who are regularly at home, introducing bias into the study. A standard process for managing non-responders is to make at least three attempts on different days to contact the potential control, with a minimum number of attempts in the evenings.

7.3.6. Introductory statement for control recruitment

Develop a standardised statement to read to potential controls. This statement should conform to the ethical guidelines for the preparation of information sheets, as described in the guidelines for completion of the national application form for ethical approval of research projects (available from the Health Research Council, and at the website <http://www.hrc.govt.nz/download/winword/ea06.exe>). Further information is contained in Appendix 2. The statement should:

- introduce the interviewer
- identify the organisation
- explain why the study is being undertaken
- explain how the potential control has been selected
- explain that participation is voluntary, and the participant has the right to withdraw from the interview at any time
- explain that information gained from the interview will be held in confidence, and that no material that could personally identify the participant will be used in reports on the investigation
- give an estimate the length of the interview
- describe incentives for participating, if any exist
- contain criteria for matching (see below)
- contain criteria for selecting a random member of the household (within matching criteria). The usual process for doing this is to ask to speak to the person in the household with the next birthday. If this person is unavailable, an arrangement should be made to call the identified individual at a more convenient time
- identify a process for calling at a time more convenient for the prospective control.

7.3.7. Matching criteria

Control recruitment may require matching by age, sex or geographic area of residence. Matching is discussed more fully on page 52. Matching requires careful attention and may itself introduce bias into a study.

7.3.8. Control exclusion criteria

As for cases, some controls may need to be excluded from recruitment. Exclusion criteria may include:

- the presence of symptoms confirmed or suspected to be related to the disease of interest (i.e., the control may be a case)
- recent travel
- inability to answer questions
- the presence of immunity to disease being studied (i.e., previous Hepatitis A).

7.3.9. Control exposure period

The control may be questioned about exposures during the exact dates of the case's incubation period. The advantage of this approach is that if the risk due to a particular exposure fluctuates over time (e.g., presence of an infected food handler on certain days of the week), the estimates of association will be more accurate. The main disadvantage is that control participants may be unable to recall exposures experienced several weeks previously. It may therefore be best to restrict the inclusion of cases and controls to a maximum period prior to the investigation, for example, two weeks.

If the risk due to the exposure of interest is unlikely to fluctuate over time, controls may be alternatively interviewed about recent exposures.

7.3.10. Ratio of controls to cases

The minimum ratio between controls and cases is usually 1:1, but other ratios (2:1, 3:1) may be necessary if case numbers are small. Issues associated with choosing a control to case ratio are discussed on page 51.

7.3.11. Development of study materials

Study materials to develop before beginning a case-control study include:

- a study protocol that should document all aspects of the study design
- an introductory sheet that contains precise wording for the introductory statement, as discussed on page 48. It may be worthwhile having separate introductory sheets, or statements, for recruitment of adult and child controls
- a control recruitment log that documents attempts to contact controls and the result of each attempt. This information is valuable for helping determine the control response rate for the eventual outbreak report. A sample control recruitment log is appended to this manual (Appendix 5)
- questionnaires – questionnaire development is discussed in Appendix 2. While it may be appropriate to develop separate questionnaires for cases and controls to ensure that the questions are worded appropriately, it is essential to keep things as similar as is practical with regard to questioning cases and controls.
- a database that allows entry of, and then stores, data from the questionnaires in an electronic form, for example, EpiData. EpiData files can be read and analysed directly using EpiInfo or exported in various other formats and analysed in packages such as Excel, Stata, SPSS or SAS. Both EpiData and EpiInfo are free and can be downloaded from the internet (www.cdc.gov/epiinfo).

7.4. Control recruitment

The most important aspect about control recruitment is that individuals included as controls must have had as much opportunity as the cases to be exposed to the outbreak source and to contract the disease. In other words, controls should be drawn from the same population that the cases have come from. If this does not occur, differences between the two populations are likely to lead to bias in the results, possibly falsely implicating sources of the outbreak and misdirecting control measures.

Choice of the most appropriate control group is frequently controversial because of possible selection bias. The easiest situation is when the control group is a random sample of people without disease symptoms who attended the same function as the cases, although this type of outbreak would normally be investigated using a retrospective cohort design, as described in the previous section. In other situations, three commonly-used types of control group are:

- random samples of the general population from which the cases came
- people seeking care at the same institution for conditions that are unlikely to be related to the same risk factors (hospital controls)

- people living in the same neighbourhoods as cases, selected in a systematic way.

Less commonly, immediate neighbours, friends, schoolmates or siblings may be used as controls. However, these have their potential problems in terms of selection bias. In particular, such controls may have exposures that are very similar to those of the corresponding cases. This similarity could prevent identification of the critical exposure in the investigation, by biasing its odds ratio estimate toward 1.0.

Where feasible, individuals who are unable to contract the disease of interest because they have acquired immunity due to past infection should be excluded from selection as controls.

Choice of control groups is generally dictated by:

- the source of the cases
- avoidance of selection bias
- the relative costs of obtaining the various types of controls
- the resources available to the investigator.

The choice of population from which to draw controls should be based on the hypothesis under investigation. If the opportunities for potential exposure are widespread, then controls should be drawn from the general population. If the hypothesis suggests that exposures are likely to have occurred only among a unique subgroup of the population (e.g., diners at a restaurant), controls should then be drawn from this group.

Sometimes, particularly when there is uncertainty about the most appropriate control group to use, more than one group of controls may be used. Each control group would be selected in a different manner.

7.5. Case-control ratio: study power

Although the number of cases in the study is usually fixed, there may be some degree of flexibility with the number of controls and therefore the ratio of controls to cases. The main advantage of using a control to case ratio that is greater than 1:1 (i.e., two, three or four controls to every case) is that the statistical power of the study will be enhanced. The trade-off is the additional time and resource costs that will be required to find and interview extra controls.

The statistical power of a study is a measure of its ability to detect a true association (i.e., odds ratio) of a given size, at a specified level of statistical confidence. The more subjects (cases and controls) there are in the study, the greater its power to detect an elevated risk if it truly exists. This is particularly important if other studies have suggested that the relative risk is likely to be close to 1.0, or in other words that the exposure does not greatly increase the likelihood of contracting the disease. The closer that the expected relative risk is to 1.0, then the larger the number of subjects required to demonstrate the risk as statistically significant. This is intuitive. A high relative risk is likely to be very obvious and it will not take many subjects to demonstrate it – the converse applies to low and therefore less obvious relative risks.

It is important to balance statistical power estimates against constraints of time or resources. In general, concerns about statistical power should not hinder starting or carrying out the epidemiological investigation when an outbreak is detected because:

- the magnitude of the relative risk estimates, even if not statistically significant, may be enough to guide environmental investigation and to implement control measures

- the relative risk estimates from investigations of outbreaks, particularly of infectious disease outbreaks, can be very high. In these situations, a relatively small number of cases and controls will have sufficient statistical power
- the size of the relative risk estimate cannot be known in advance. If the decision to proceed with the investigation was entirely based on considerations of statistical power, then many outbreak investigations would not proceed at all and many opportunities to identify the causes of outbreaks would be missed.

If there is scope to vary the number of controls, two rules of thumb may be useful for making decisions on the optimal case to control ratio for a particular outbreak investigation.

- The most efficient study design has a 1:1 control to case ratio. Therefore, when there are many cases and potential controls, and the cost of obtaining information from cases and controls is similar, a control to case ratio of 1:1 is the best choice.
- If the number of cases is small, or the cost of obtaining information from cases is appreciably greater than for controls, the control to case ratio can be increased to improve the study's power. The statistical power of the study increases significantly up to a control to case ratio of about 4:1. Beyond this, the small increase in statistical power achieved by a further increase in the ratio does not usually justify the cost or effort required.

7.6. Matching between cases and controls

Matching between cases and controls helps to adjust for confounding (explained further on page 65). In brief, confounding occurs when a particular factor is associated with both the exposure of interest and the outcome (disease) under investigation. For example, age would be a confounding factor in a case-control study investigating risk factors in a meningococcal disease outbreak. This is because age is closely related to the incidence of meningococcal disease (young children are more at risk than older people). If this confounding influence was not controlled, then other age-related factors (e.g., wearing nappies) would falsely appear to be associated with occurrence of meningococcal disease. An appropriate technique to adjust for this confounding influence would be to make sure that each case was matched with a control of approximately the same age.

Most case-control studies are matched to some extent in that they recruit controls with exposures that are matched by time period to cases. Matching on other criteria should be used sparingly and only for known, strong confounding factors for the disease under investigation. Be guided by the initial descriptive investigation and by background knowledge of the epidemiology of the illness. If the distribution of cases is strongly related to age, for instance, then matching on that basis may be appropriate. It would be rare that matching factors other than age, gender or neighbourhood would be justified in an outbreak investigation.

7.6.1. Disadvantages to matching

- It can be difficult and time-consuming, and thus expensive, to find a control (or several controls) with the appropriate matching characteristics for each case.
- It is not possible to explore the effect of the matching variable when matching for that factor has occurred.
- It is possible to “overmatch” cases and controls. This can occur if important disease risk factors are highly correlated with the matching variables. The result is that, because of the matching, the

case and control groups are also indirectly matched for the actual risk factor. The study will then be less able to detect the association between the risk factor and the disease.

Matching becomes progressively less necessary in large studies. With sufficient numbers of cases and controls, it is possible to avoid matching and to control for confounding during the data analysis through the use of various statistical methods, particularly stratification and multivariate analysis.

Note that the analysis of matched case-control studies differs from that of unmatched studies. If control participants have been selected on the basis of matching criteria, the analysis must account for this matching, or else the estimate of the odds ratio (see below) will be biased towards 1.0⁴⁴. Matched case-control studies should be analysed either through retention of the case-control pairing (matched analysis), or by ‘breaking the match’ and accounting for the matched design through use of stratified or multivariate statistical techniques. In general, the latter option is preferable if matching criteria have been limited to age and/or sex⁴⁵. Descriptions of these techniques are beyond the scope of this publication and a biostatistician/epidemiologist should be consulted for further guidance.

7.7. Analysis of case-control study data

The prevalence of characteristics or exposures among cases and controls is compared using an odds ratio, a measure of the association between exposure and illness. The odds ratio is calculated by dividing the odds of exposure among cases by the odds of exposure among controls. The odds of exposure for the case group are the number of cases with the exposure divided by the number of cases without the exposure. If the odds ratio is close to 1.0, the exposure is not associated with the illness; if the odds ratio is greater than 1.0 there is an apparent association between illness and the particular exposure; and if the odds ratio is less than 1.0, there is an apparent protective effect of the exposure.

Basic analysis of results from a case-control study

Calculation of the odds ratio for a particular exposure is illustrated using the two-by-two summary table below.

Exposure	Disease present	
	Yes (case)	No (control)
Yes	a	b
No	c	d

$$\text{Odds ratio} = \frac{\text{Odds of exposure among cases}}{\text{Odds of exposure among controls}} = \frac{a/c}{b/d} = \frac{ad}{bc}$$

A different two-by-two table may be drawn for each exposure to represent the relationship with the disease.

Interpretation of odds ratios must also be tempered by consideration of the possible effects of chance and bias (including confounding), which are discussed in detail in Chapter 8.

7.8. Case-control investigation example

This example presents details of an actual case-control investigation of a common-source outbreak in a specific place⁴⁶. The investigation and findings are reproduced here with the permission of the authors.

In March 1998, staff at Hutt Valley Health (HVH) public health unit detected an increase in notified cases of cryptosporidiosis. Descriptive investigation showed that almost half of the cases were aged less than 5 years, and many reported a history of swimming pool usage. A case-control design was chosen because it was not possible to clearly identify and list a group of 'at-risk' individuals.

7.8.1. Case definition

Cases were defined as any person notified to HVH before 31 May 1998 with:

- laboratory-confirmed cryptosporidiosis
- onset of symptoms during the period 1 January to 30 April 1998 and
- domiciled in the Hutt Health District.

7.8.2. Case finding

Laboratories servicing the district were actively encouraged to notify cases.

7.8.3. Control selection

Controls were recruited using telephone numbers selected from random start points in the telephone directory.

7.8.4. Case-control ratio

There were twice as many controls as cases (2:1 ratio).

7.8.5. Matching

Controls were frequency-matched for geographic area (using the first three digits of the phone number as a surrogate for the suburb) and age group.

7.8.6. Exclusion

Individuals with diarrhoea that occurred during a specified two-week period in March were excluded from selection as controls.

7.8.7. Questionnaire

Questions covered known risk factors for the two-week period before the onset of symptoms (for cases), or for a specified two-week period in March (for controls).

7.8.8. Results

The data obtained for the usage of pool A (the hypothesised source of the outbreak) and for the usage of any other pool are summarised in Table 7 (similar analyses of other exposures were also carried out).

Table 7: Selected exposures for 53 people with cryptosporidiosis*

Exposure		Cases (n = 53)	Controls (n = 106)	Odds ratio**
Used pool A	Yes	34	17	9.4
Did not use pool A	No	19	89	
Used other pool	Yes	13	20	1.4
Did not use other pool	No	40	86	

Notes: * Adapted from Baker et al 1998⁴⁶

** These odds ratios have been calculated without adjustment for confounding factors, and therefore differ from those reported in the original paper.

The size of the odds ratio strongly suggests that swimming in pool A was the cause of this outbreak, and that swimming in other Hutt pools was probably not the cause of this outbreak.

Despite the strong association with swimming in pool A shown by this analysis, consideration should still be given to the possible roles of chance, bias and confounding (Chapter 8).

7.9. Case-case studies

The main concerns regarding the use of case-control methods for the investigation of food- and water-borne infections are two-fold. First, they are time-consuming and demanding on usually limited health worker availability. Second, they are subject to recall bias because, on average, there could be a two-week delay (from the onset of symptoms in the first few cases) before interviews are conducted. The case-case method is less expensive and has minimal recall bias. It has been used to study enteric disease outbreaks, for example, salmonellosis⁴⁷. It usually involves selecting controls from people who have been infected during the same period with the same organism, but a different strain, and have been reported in the same surveillance system.

Some disadvantages of case-case studies need to be highlighted. Such disadvantages are not exclusive to case-case studies. They include selection bias among comparison cases, information/recall biases due to biased investigator data collection or respondent recall of exposures, confounding due to variables routinely collected in enteric disease surveillance data (e.g., age, gender, socioeconomic status, ethnicity etc.) and a lack of detail about exposures⁴⁸
<http://www.epi-perspectives.com/content/5/1/6>.

There are also important advantages of case-case studies. These are a lesser degree of recall bias compared with case-control studies, and the studies are potentially much less expensive. A further relative advantage of the case-case approach could be timeliness as the analyses can use case data that have already been collected.

8. Further interpretation of analytic study results

This section provides guidance on “causal inference” from the results of analytic outbreak investigation studies, and on estimating the excess risk of disease experienced by an individual as a result of being exposed.

8.1. Possible explanations for results

Whenever an epidemiological study results in an apparent positive association between an exposure factor and the disease under investigation (i.e., an elevated relative risk estimate), three possible explanations for the association should be considered:

- the association is due to chance
- the association is due to bias (including confounding)
- the association is real.

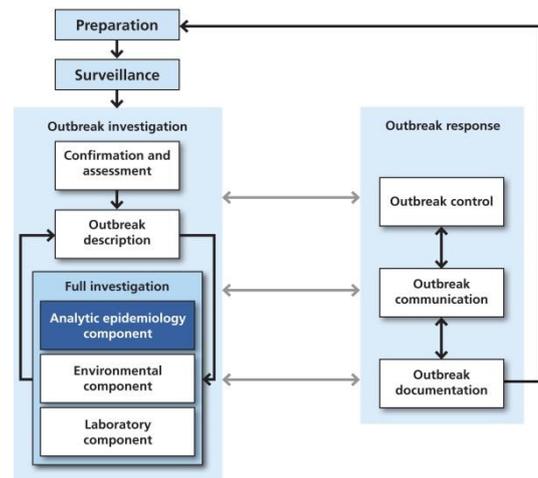
These explanations are considered in more detail below. A further possible explanation is that methodological or computational errors occurred while conducting or analysing the study. However, for this discussion it is assumed that the outbreak investigation has been competently conducted, and that such errors have not occurred.

8.2. Could the observed association be due to chance?

Every biological system, including any human population, contains a great many parameters that define that system. For epidemiological purposes, these parameters may be thought of as exposures. For people they include height, weight, gender, ethnicity, dietary composition, occupation, area of residence, water supply type, blood type and so on. For epidemiological methods to be successful, it is particularly important that there are inter-individual variations in the levels and types of exposures. If this were not the case, epidemiological methods would not work.

It is very rare to obtain a complete picture of the exposure and disease status of everyone in an entire population. Therefore, for practical reasons, we frequently take a **sample** of the population and examine the relationships between exposures and the disease status within that sample. Then we attempt to extrapolate the results from the sample to the entire population. The larger the sample (as a proportion of the total population) the more likely it is to represent the entire population. The smaller the sample, the greater the uncertainty that it represents the total population. It may be that by chance (random variation) the sample chosen completely misrepresents what is happening in the total population. Statistical methods were developed to account for these uncertainties.

Outbreak investigations are always constrained by available resources, to some extent. Therefore, frequently, a sample of the entire “at risk” population is chosen. An example of this is the choice of a number of controls from the community for a case-control study. It is always possible that had a different set of controls been chosen, the results of the statistical analysis would have been quite different. The implication of using a sample is that we can only estimate the actual underlying relative risk for the entire at-risk population.



Some outbreak investigations (particularly those that involve common event outbreaks) include the entire “at-risk” population in a cohort study. It might be argued that this involves the whole population and, therefore, no sampling has occurred. However, such cohorts are invariably of limited size and random variation plays a role similar to that for samples of a larger population. Therefore, it is best to treat outbreak investigations involving entire at-risk populations as if they were samples of some much larger population, and apply statistical methods to assess the importance of chance.

In evaluating the role that chance may have played in determining the results of an outbreak investigation, two related statistical criteria are used – the *p* (probability) value and the confidence interval.

8.2.1. *p*-values

Although they are increasingly being replaced by the more informative confidence intervals, *p*-values still have a useful role to play in the evaluation of epidemiological results.

P-values are commonly generated by most statistical tests of association. Different tests are used according to the nature of the data involved. However, when relative risk estimates generated by outbreak investigations are being considered, the most commonly used tests are the chi-square (χ^2) test and Fisher's exact test. The latter is used when the number of subjects in the investigation is relatively small. Both types of test are routinely carried out by statistical software, including EpiInfo, so the nature of the computations involved does not have to be considered. The important thing is to be able to understand the meaning of the results.

Statistical tests usually test the “null hypothesis”. That is to say they test the hypothesis that there has been no effect. When applied to relative risk estimates (odds ratios and risk ratios), this is equivalent to testing the hypothesis that the true value of the relative risk is actually 1.0, and any variation from that found in the study is likely to be due solely to random variation in the data associated with the study sample.

The *p*-value (which varies between 0 and 1) indicates the probability of obtaining by chance alone a result at least as extreme as that observed, if there is truly no association between the exposure and the outcome of interest (i.e., if the null hypothesis is true).

For example, a *p*-value of 0.21 for an odds ratio of 1.7 suggests that, given the sample size of the study, there would be a 21% chance that the observed value would be 1.7 or greater, even if the true odds ratio were 1.0. In other words, the observed odds ratio of 1.7 could quite easily have occurred purely by chance.

Commonly, 0.05 is used as α , or the point at which a *p*-value becomes “statistically significant” (i.e., $p \leq 0.05$). α is an arbitrary value based on a judgement that a false result that would not be expected to occur by chance on more than 1 in 20 occasions (or 1 in 20 similarly tested samples from the same population) is sufficiently unusual that it is tolerable. Put another way, a false positive rate of 1 in 20 is “acceptable”.

Sometimes more stringent criteria for statistical significance are set, such as $\alpha = 0.01$ or 0.001. This would be likely if the consequences of accepting a false positive result were serious.

Several problems are associated with over-reliance on *p*-values and statistical significance criteria, these are described next.

- A problem with putting too much weight on *p*-values is that the *p*-value achieved by a study result may be very dependent on sample size – this is an even greater problem when adopting arbitrary levels of statistical significance. As previously mentioned, sample size is often uncontrollable in outbreak investigation situations. This means that an elevated relative risk

estimate that has a p -value of greater than 0.05 could be dismissed as of no account because it is “not statistically significant”. Yet it may simply be that the study size was too small for statistical significance to be achieved at the relative risk estimate reported. The larger the relative risk estimate, the more likely it is to represent a truly elevated risk, and the smaller the study size needed to achieve statistical significance. However, a true relative risk of, say, 3 or 4, which represents a tripling and quadrupling of risk, may not achieve a level of statistical significance, because of small study size.

- The α level of 0.05 commonly used to delineate statistical significance is completely arbitrary. A p -value of 0.05 (statistically significant) is little different to a p -value of, say, 0.06 (not statistically significant).
- Although there may be prime candidates for risk factors (a priori hypotheses), outbreak investigations commonly involve testing many exposures for possible associations. The implication of this is that, with statistical significance set at a p -value of 0.05, 1 in 20 exposures that are not true risk factors are likely to present as false positive risk factors (i.e., $p \leq 0.05$). This is known as the problem of multiple comparisons, and illustrates the point that, just as not too much weight should be placed on the lack of statistical significance of an elevated relative risk estimate, a relative risk that achieves $p < 0.05$ should not necessarily be overemphasised, especially if it is only marginally significant or if many statistical tests have been carried out. In a study where multiple statistical tests have been carried out, the most weight should be placed on those results that are supported by other evidence.

These points illustrate the danger of the rigid application of an arbitrary level of statistical significance as a criterion for deciding on the importance of particular relative risk estimates in the results of an outbreak investigation.

8.2.2. Confidence intervals

The confidence interval is generally more informative than the p -value as an indicator of the degree of statistical confidence one can invest in results. The confidence interval provides virtually all of the information obtained from a p -value and has certain additional advantages:

- the width of the interval indicates whether a lack of statistical power (i.e., small sample size) affected the results
- it provides a plausible range for the relative risk estimate.

Most commonly, studies involve the calculation of 95% confidence intervals. The figure of 95% is a convention, and there is no reason why a 99%, or any other, confidence interval should not be calculated. However, the 95% confidence interval has the advantage that it provides information equivalent to the assessment of whether $p \leq 0.05$ and, as such, is useful in assessing whether the results achieve “statistical significance”.

The 95% confidence interval straddles the estimate of the relative risk and provides the range within which the true value of the relative risk is likely to lie. Implicit in this is the assumption that the study estimate of the relative risk has not been affected by bias (including confounding). This is a further consideration that is discussed later.

For relative risk estimates greater than 1.0, if the lower confidence limit is less than 1.0 (i.e., the interval includes the value 1.0) then this indicates that the association has not achieved statistical significance. When 1.0 is not included in the interval, then statistical significance has been achieved (i.e., $p < 0.05$).

The reverse situation applies when the relative risk estimate is less than 1.0. Then, if the upper confidence interval is less than 1.0 statistical significance has been achieved, indicating a protective effect. Again, inclusion of the value 1.0 within the interval indicates a lack of statistical significance. When either limit of the confidence interval is 1.0 then this is equivalent to $p = 0.05$.

The width of the confidence interval is inversely proportional to the study sample size. An adequate sample size leads to a narrow confidence interval (i.e., a precise result), which should be the aim of all epidemiological studies. Conversely, a wide interval indicates that the study sample was too small. This is particularly important if the study suggests that the relative risk is elevated appreciably above 1.0, but the confidence interval includes 1.0. This indicates the possibility that the reason for a low level of statistical confidence in the result may only be that the study size was too small. This can be contrasted with the situation where, for the same result, only a p-value, and no confidence interval, was calculated. In that situation the p-value would be greater than 0.05. In itself, that would give no indication of sample size limitations and could lead to a premature dismissal of the result as being of no importance.

In a situation with an elevated relative risk estimate and a confidence interval including 1.0, two interpretations are compatible with the data.

- The elevated relative risk estimate was a result of chance variation and a greater sample size would have shown it to be little different to 1.0.
- The elevated relative risk estimate was a good indicator of the true risk and lack of statistical significance was a result only of small sample size (low power). A larger sample size would have confirmed the relative risk as significantly different from 1.0.

These two possibilities are indistinguishable on the basis of the data from such a study. However, in an outbreak investigation it may still be justified to take some control action on the basis of an elevated relative risk estimate, even when there is the possibility that the result may be due to chance. The pros and cons of such action need to be carefully weighed by the investigators. If no additional cases of illness occur after such action has been taken, then this tends to corroborate and confirm as appropriate the action taken.

Despite the limitations of small sample investigations, they can be used to set an upper bound on the relative risk (i.e., the upper confidence limit), even though this bound would probably be smaller if the sample size were larger.

As with p-values, multiple testing is likely to lead to a number of confidence intervals that exclude 1.0. Similar caution should be applied to their interpretation.

8.2.3. Guidelines for considering the role of chance

The above discussion leads to several guidelines for the interpretation of the results of outbreak investigations.

- Most emphasis should be placed on the magnitudes of the relative risk estimates, and elevated risk estimates should not be dismissed simply because they are not statistically significant (i.e., because $p > 0.05$ or the confidence interval includes 1.0). Non-significant, but elevated relative risk estimates may point to actual risks and the upper limit of the confidence interval will provide a plausible upper bound for the true risk.
- It is better to display the actual p-value of a test result than to categorise results according to whether they achieve statistical significance or not (e.g., $p \leq 0.05$, $p \leq 0.01$, etc.).
- The possibility that statistically significant results (either $p \leq 0.05$ or confidence intervals excluding 1.0) may be due to multiple statistical comparisons should be considered. In such

situations, elevated relative risk estimates that confirm a priori hypotheses or are supported by other information are of most interest.

- More emphasis should be placed on confidence intervals than on p -values in the interpretation of the results of statistical testing. However, ideally, for each result both the p -value and the confidence interval should be presented for consideration.

The tables used to display the results of the examples of cohort and case-control analyses ([Table 5](#) and [Table 6](#)) follow, with the addition of p -values and confidence intervals.

Table 5: Selected exposures reported from a retrospective cohort study of a gastroenteritis outbreak, showing *p*-values and confidence intervals

Food item	People eating item			People not eating item			Risk ratio	<i>p</i> -value	95% confidence interval
	Ill	Total	Attack rate (%)	Ill	Total	Attack rate (%)			
Raw mussels	30	42	71	33	71	47	1.5	0.01	1.1–2.1
Steamed pudding	7	12	58	56	101	55	1.1	0.85	0.6–1.8
Roast pork	60	87	69	3	26	12	6.0	<0.001	2.0–17.5
Silverside	16	21	76	47	92	51	1.5	0.04	1.1–2.0
Potato salad	37	53	70	25	59	42	1.7	0.004	1.8–2.3
Roast pumpkin	38	59	64	24	52	46	1.4	0.05	1.0–2.0

Notes: * Adapted from Simmons et al, 1998⁴¹

The addition of *p*-values and confidence intervals reinforces the likelihood that the roast pork was the culprit associated with the gastroenteritis outbreak summarised in Table 5. The *p*-value for roast pork is highly statistically significant. It is noteworthy that other foods were also associated with significantly elevated risk. These could have been contaminated by the pork during storage, preparation or serving.

Table 6: Selection of exposures among cases of cryptosporidiosis, showing p-values and confidence intervals

Exposure		Cases (n = 53)	Controls (n = 106)	Odds ratio**	p-value	95% confidence interval**
Used pool A	Yes	34	17	9.4	<0.0001	4.1-21.8
	No	19	89			
Used other Hutt pool	Yes	13	20	1.4	0.4	0.6-3.3
	No	40	86			

Notes: * Adapted from Baker et al, 1998⁴⁶

** Odds ratios and confidence intervals have been calculated without adjustment, and therefore differ from those reported in the original paper.

Both the *p*-value and the confidence interval reinforce the impression that the observed relative risk estimate for swimming in pool A is most unlikely to have arisen by chance. However, the elevated relative risk estimate for swimming in any other Hutt pool is entirely compatible with a chance result.

8.3. Could the observed association be due to bias?

While interpreting the results of an analytic epidemiological investigation into an outbreak, always consider whether the results obtained could be due to bias. Bias may be defined as any systematic error in an epidemiological study that results in an incorrect estimation of the association between exposure and disease. Bias affects the size of the relative risk estimate, making it larger or smaller than the true (but unknown) value. It may also affect the generalizability of results.

The following discussion of bias is by no means comprehensive. Main features only are highlighted. For further information and more in-depth discussion, the interested reader may refer to any good textbook of general epidemiology⁴⁹.

Bias should always be considered. Bias can cause relative risks to appear high or it can hide true risks. The effect of the bias will depend on the nature of the particular bias. However, careful consideration can often determine in which direction the bias is likely to operate (i.e., raising or lowering relative risk estimates).

There are many possible biases that may occur in epidemiological studies. However, they can be grouped into three categories.

1. Selection bias: This occurs when there are systematic differences between those selected for a study and those who are not selected.
2. Information bias: This occurs when there is misclassification of the disease or exposure status.
3. Confounding: This occurs when an exposure of interest is correlated with another exposure that is an independent risk factor for the disease.

These biases are discussed in more detail next.

8.3.1. Selection bias

There are many varieties of selection bias. Their common feature is that the relationship between exposure and disease is different for those who participate in a study compared with those who are eligible to participate, but do not do so.

A particular example of this type of bias occurs in case-control studies when controls are selected from a different population to the cases. For example, if cases and controls tended to be selected from different neighbourhoods of different socio-economic statuses or ethnic mixes, then the magnitudes of the odds ratios may simply reflect the different prevalence of exposure factors in the two types of neighbourhood, rather than any true risk factors for disease. Where there is overlap between the neighbourhoods, then the degree of bias will be reduced to that which relates to the amount of overlap.

Even when there is perfect overlap between the areas from which cases and controls are obtained, there may still be selection bias. An example of this, which may be referred to as “overmatching”, would be when controls were selected as family members of cases. In such a situation, cases and controls will be similar for many possible exposures, and true risk factors, particularly those which are connected with family circumstances, could be obscured. The effect of such overmatching would be to bias the relative risk estimate toward 1.0.

Similar (but generally less severe) bias can occur when controls are selected as neighbours or friends of the cases. Neighbours and friends may share various exposures (including hobbies, socioeconomic factors and workplaces) leading to a degree of overmatching.

Selection bias should also be suspected when the participation rate in a study is low. It may be that those who participate are systematically different from those who do not participate. This would be of particular concern if participants in a study came forward on a self-selected basis and identified themselves as available for a study.

8.3.2. Information bias

Information bias affects the classification of subjects in a study as exposed or unexposed, or as ill or not ill. For example, subjects who were ill with a disease not related to the outbreak might be classified in the outbreak investigation as ill, or subjects actually exposed might be classified as unexposed, or vice versa. The impact of the misclassification will differ depending on whether it differs between study groups (differential misclassification) or is similar across study groups (non-differential misclassification).

Non-differential misclassification tends to bias relative risk estimates toward 1.0, whereas differential misclassification may bias relative risk estimates in either direction. The direction of the bias may often be determined by considering a two-by-two table and thinking about how subject numbers will change (i.e., increase or decrease) among the four cells if misclassification occurs.

Recall bias and interviewer bias are particular examples of information bias that may occur in outbreak investigations. Recall bias occurs if those who are ill and those who are not ill tend to report exposures differently. For example, people who are ill may have given much more thought to the exposures that they have experienced than people who are not ill. This will differentially affect the quality of information obtained from cases and non-cases. Cases may tend to report having consumed particular foods more frequently, whereas non-cases may not do so, if only because they have forgotten. The effect of this would be to make such foods appear as risk factors for disease, when in fact they may not be.

Interviewer bias may occur when interviewers are aware of who is or has been ill and when they report information differently because of this. For example, if an interviewer has developed their own view of what the most likely exposure is, then they may tend to selectively interpret and report cases as having had that exposure, and vice versa for non-cases.

8.3.3. Confounding

Confounding is regarded as a bias by some authors, and as different from a bias by other authors, because its effects can be eliminated in data analysis (provided information on the confounding factor is available). For these guidelines, we have classified confounding as a bias because, like selection bias and information bias, it can affect the size of relative risk estimates obtained in a study and adequate data for its effects to be eliminated in the data analysis are not always available.

Confounding occurs when the exposure of interest is correlated with another factor (the confounder) that is itself independently associated with the outcome (disease) under investigation. The exposure of interest may itself also be a risk factor for the disease or it may not really be associated with the disease at all. The confounding makes the exposure of interest appear to be associated with the disease (or more strongly associated if it is also a risk factor).

Age is a common risk factor for diseases and many exposures vary with age. Therefore, age is a common confounding factor for many diseases. This is not so likely to be a confounding factor for foodborne disease outbreaks. However, it may be important, for example, for Legionnaires' disease, which is predominantly a disease of older people. An example of how this might apply would be if cases of Legionnaires' disease were compared with a randomly selected group of other people living in the same city. The comparison group would generally be younger than the case group and may

include fewer retired people. Therefore, retirement and other factors associated with living at home might emerge from the data analysis as disease risk factors, whereas this might not truly be the case.

Confounding in foodborne disease outbreak investigations might occur if consumption of certain foods is linked. For example, although meat consumption might appear to be the risk factor of importance in a particular outbreak investigation, the real culprit might be the gravy, which is more commonly consumed by the people who ate the meat than those who did not. Provided data on gravy consumption are also collected then this possibility can be investigated.

The impact of confounding can be reduced or eliminated in four ways.

8.3.3.1. By restriction

This involves the application of prior selection criteria for the cases and non-cases. For example, if age is considered to be a strong risk factor for the disease, then it might be appropriate to include only adults in the study. Most outbreaks are also restricted by time and place.

8.3.3.2. By matching cases and controls on known risk factors, and conducting a matched analysis.

This should be done with caution and only for known strong risk factors that have reasonably well understood impacts. Generally, it is rarely justified to match on anything other than age group and sex.

8.3.3.3. By stratification

This involves separately examining risks at different levels of the confounder. For example; looking at relative risks in different age bands separately. Provided the separately calculated risks do not differ significantly (i.e., there is no evidence of heterogeneity) then they may be combined using methods that appropriately weight the various strata to give a combined estimate of the relative risk (e.g., the Mantel-Haenszel summary odds ratio).

8.3.3.4. By multivariate analysis (e.g., multiple logistic regression)

These methods work by simultaneously adjusting for the effects of different exposures such that the relative risk estimate obtained for each exposure is adjusted for confounding by all the others. A statistical software package to perform logistic regression is available as part of EpiInfo 2000, as well as packages such as SAS, SPSS and STATA.

8.4. Could the association be causative?

Once the possible effects of chance and bias have been considered and eliminated as likely reasons for an association detected in an outbreak investigation, it is appropriate to consider whether the finding is causative. In that regard, there are several other criteria that deserve consideration before conclusions are reached.

8.4.1.1. Strength of the association

This is related to the considerations of chance and bias in that, generally, the higher the relative risk estimate (i.e., the stronger the association) the more likely it is to represent a true association. Weak associations (i.e., less than 3) may readily be accounted for by various forms of bias.

8.4.1.2. Biological plausibility

If the suspected association is consistent with what is already known about the causal agent, this strengthens the likelihood that the association is real. For example, if legionellosis was associated with the consumption of a particular food item, then this association would lack biological plausibility because legionellosis has not been associated with food previously.

8.4.1.3. Time sequence

The exposure of interest must have preceded the outcome (disease) by a period of time consistent with the known or postulated biological agent. For example, the median incubation period for giardiasis is 7 to 10 days, with a range of 3 to 25 days. Therefore, exposures occurring, for example, within a day or so of illness onset are unlikely to be implicated.

8.4.1.4. Dose-response relationship

The evidence for causality is enhanced by the demonstration of a gradient of increasing risk associated with an increasing degree of exposure.

8.4.1.5. Effectiveness of intervention

The likelihood of a causal relationship is increased if, following intervention to eliminate the suspected exposure, there are no new cases of disease.

8.5. Statistical power and sample size

The purpose of undertaking an epidemiological study is to test hypotheses about the relationships between exposures and the disease outcome of interest. Studies proceed on the assumption that there is no association between the exposure and the disease unless the data “prove” it (rather like the assumption of “innocent until proven guilty” in law). The assumption of no association is known as the **null hypothesis**, and the alternative hypothesis is that there is an association between the exposure and the disease. The “standard of evidence” required to “prove” the **alternative hypothesis** is the level of **statistical significance** chosen by the investigator. This level is often set at 95% (or a p-value of 0.05). This means that if there is really no association between the exposure and the disease, there is only a 5% chance that the data could, by chance, give a false positive (known as a “Type 1 error”) where the null hypothesis is incorrectly rejected in favour of the alternative hypothesis. This is analogous to a 5% chance of a “wrongful conviction”. This chance of a type 1 error is set by the study investigators and is often represented by the Greek letter alpha (α). The confidence level of a study is represented by $1-\alpha$. Usually α is set at 0.05, and the confidence level would then be 95%.

The statistical power of a study is defined as the probability of rejecting the null hypothesis and concluding that there is a statistically significant association (relative risk) of a specified magnitude between the exposure and disease, if such an association truly exists (by analogy the likelihood of a conviction if the accused is really guilty). A study power of 80% (or greater) is commonly chosen – 80% power means there is a 20% chance that a mistake will be made, “allowing the guilty to go free”. This is a false negative (known as a “Type 2 error”), where the null hypothesis is accepted when it should have been rejected in favour of the alternative hypothesis. The chance of a Type 2 error is usually represented by the Greek letter beta (β). The power of a study is $1-\beta$.

The ability of a study to achieve a defined level of statistical power relates to four main factors.

1. The number of subjects in the study. The larger the sample size (cases and non-cases), the greater the power of the study (more evidence increases the chance of conviction).
2. The minimum size of any true relative risk (strength of the association) that the investigators wish to be confident of being able to detect at a statistically significant level. The larger the minimum size, the easier it is to detect with smaller numbers of subjects. For a given study size, statistical power increases with an increasing minimum relative risk of concern.
3. The value of α . Increasing α (i.e., permitting a higher false positive rate) increases the study power.
10. Either the proportion of controls who are exposed (in a case-control study), or the proportion of unexposed participants who are ill (in a cohort or cross-sectional study). This is usually unknown and has to be estimated or guessed.

The Statcalc function of EpiInfo can calculate necessary sample numbers for a study to achieve a defined level of power.

Before embarking on an analytical study of an outbreak, some consideration should be given to power and sample size, particularly if a case-control study is planned and the control to case ratio may be varied. However, as explained in Chapter 6, initiation of an outbreak investigation should not be held up by concerns about a lack of study power. The magnitudes of the relative risks may provide valuable information on the likely source of infection.

8.6. Risk of disease attributable to exposure

Measures of association, such as relative risk measures, represent the likelihood of disease in exposed individuals relative to those who are non-exposed. **Attributable risk** is a measure of association that provides information about the absolute effect of the exposure, or the excess risk of disease experienced by an individual as a result of being exposed. This information is useful, because it estimates the proportion of cases of disease that may have been avoided if the exposure had been eliminated (presuming that the exposure did, in fact, have a causal role in cases of disease). This is known as the proportional attributable risk (PAR)

The formula⁵⁰ for calculating the PAR is:

$$\frac{\text{Incidence among exposed} - \text{Incidence among non-exposed}}{\text{Incidence among exposed}} = \frac{\text{RR} - 1}{\text{RR}}$$

* relative risk

Using this formula, the proportional attributable risk for roast pork consumption in the retrospective cohort study presented in Table 5.

Table 5 is 0.83 (5.0/6.0). This means that roast pork consumption accounted for 83% of all cases of gastroenteritis among the individuals who consumed roast pork.

The overall impact of a risk factor on the population depends on the proportion of the population exposed to the risk factor. The prevalence of exposure can be included with the proportion attributable risk to calculate the **population proportional attributable risk** (PPAR), which measures the proportion of cases of disease in the population under study that is potentially preventable by removal of the risk factor. The PPAR is calculated using the following formula.⁵⁰

$$\frac{\text{Overall incidence} - \text{Incidence among non-exposed}}{\text{Overall incidence}} = \frac{\text{prevalence} \times \text{exposure} \times (\text{RR} - 1)}{1 + \text{prevalence} \times \text{exposure}}$$

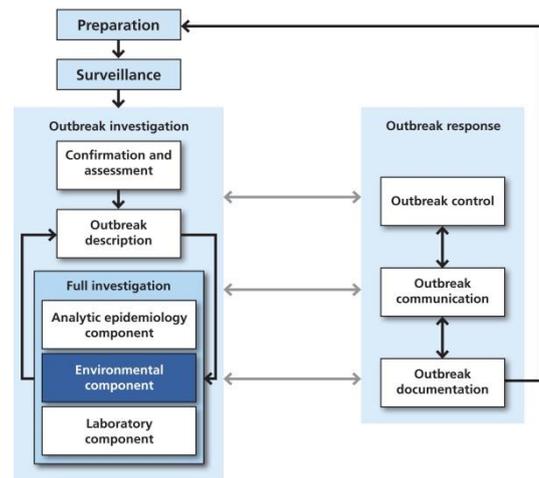
Using the retrospective cohort study data presented in Table 5, the prevalence of exposure to roast pork among the function attendees was 87 / (87 + 26), which equals 0.77. The population proportional attributable risk is therefore (0.77 x 5.0) / (1 + 0.77 x 5.0), which equals 0.79. This means that 79% of the cases of gastroenteritis among individuals attending the function were attributable to the consumption of the roast pork.

The following interactive link may be useful in practice:

http://epicentre.massey.ac.nz/Portals/0/EpiCentre/Graphics/2by2_table_measures_association7.swf

9. Environmental investigation

Note: There have been recent changes to the Food Regulations and a new Food Bill is has been tabled in parliament at the time of writing. Some administrative changes that have led to changes in the food regulation environment have already been implemented. For example some PHUs do food work under the authority of the MPI and others have little or nothing to do with the MPI. The following section should be considered alongside these changes.



Environmental investigation should be closely integrated with the epidemiological and laboratory investigations. Epidemiological information if available should be used to help focus the environmental investigation. In addition, consult with laboratory investigators about the likely transmission routes of the causative pathogen, if known.

The easiest way to conceptualise the environmental investigation is that it follows the principles of risk management. A risk management framework is a structured approach that can identify and manage risks in the environment to prevent the occurrence of disease. Risk management approaches have been adapted to specific settings such as health impact assessment²⁶, food safety programmes⁵¹ and occupational health (Health and Safety in Employment Reg 1995⁵² www.osh.govt.nz/law/hse.shtml).

An environmental investigation of a disease outbreak uses the systematic risk management approach to identify risks, but starts with the knowledge that disease has occurred and then works through the system to pinpoint where a systemic breakdown has occurred and risk management has failed. The major thrust of environmental investigation is risk assessment based on process, not on physical structure.

This guide presents a set of risk management-based generic guides that can be applied whenever an environmental investigation is required. An advantage of using the generic guides is that they provide a structured approach to the investigation of outbreaks that occur in new or unusual environmental settings. Checklists of potential hazards in familiar settings may be helpful, but should only be considered as guides to investigation and should not be adhered to dogmatically. Keep an open mind.

The remainder of this chapter presents a generic guide to environmental investigation of outbreaks, using the following sequence of steps.

- Step 1: Identify the objectives of the environmental investigation
- Step 2: Decide when the environmental investigation can begin
- Step 3: Gather background information
- Step 4: Site visit and inspection
- Step 5: Full environmental risk assessment

The environmental investigation of common event outbreaks is presented in detail. Thereafter, the environmental investigation of other types of outbreaks is presented only if they differ substantively from that of common event outbreaks.

A thorough and methodical environmental investigation is essential in most disease outbreak investigations. Table 7 indicates the role of environmental investigation in different types of food-

related outbreaks. Depending on the type of outbreak, the environmental investigation can help form hypotheses, direct the epidemiological investigation and identify issues that can be immediately addressed to control the outbreak.

Table 7: The role of environmental investigation in food-related outbreaks

Outbreak type	Role of environmental investigation
Common event	Environmental investigation is very important in the overall investigation of common event outbreaks. Components of environmental investigation of common event outbreaks include hazard identification and collection of environmental specimens. For enteric disease outbreaks, environmental investigation should include identification of infected food handlers, collection of leftover food for testing and hazard assessment of food preparation processes
Common site	Environmental investigation of common site outbreaks is necessarily preceded by identification of the site itself. Once the site has been identified, environmental investigation of common site outbreaks parallels that of common event outbreaks
Dispersed	Environmental investigation of dispersed outbreaks is necessarily preceded by identification of the site. It may involve product tracebacks to identify the sites and the processes involved in contamination
Community-wide	Environmental investigation of community-wide outbreaks is rare. In unusual circumstances, environmental investigation may involve traceback of vaccine supplies or investigation for breaches of the vaccine cold-chain
Institutional	Environmental investigation of institutional outbreaks is similar to common event outbreaks in that the site of transmission is known at the outset. Investigation should involve hazard identification and collection of environmental specimens

9.1. Environmental investigation of common event outbreaks

9.1.1. Step 1: Identify the objectives of the environmental investigation

Environmental investigation is required for all common event outbreaks. Objectives of common event outbreak environmental investigation include:

- identifying forthcoming events in which the circumstances of the common event under investigation may recur (e.g., events that will use the same premises, food handler, sanitation facilities)
- identifying obvious hazards that may require the immediate implementation of control measures, including premises closure, prohibition of forthcoming events or placement of restrictions on potential human sources (such as infected food handlers)
- obtaining environmental specimens of material potentially linked to the outbreak, such as leftover food or water
- identifying less obvious hazards that may require implementation of control measures or further investigation.

9.1.2. Step 2: Decide when an environmental investigation can begin

The circumstances associated with common event outbreaks are usually self-evident when the outbreak is initially reported. The preliminary stage of environmental investigation, that is, collection of background information, can therefore start at an early stage in the overall outbreak investigation.

The site visit and inspection stage should be undertaken early in the investigation, although these may need to be delayed if the site of the outbreak is in doubt. Full environmental risk assessment is a resource-intensive process, and may need to be delayed until provisional results of the epidemiological investigation are available.

9.1.3. Step 3: Gather background information

9.1.3.1. General information

Before making the first visit to the implicated environmental site, become familiar with the types of processes that are likely to be encountered, and the regulatory environment and standards for these processes. This may involve:

- determining which agency has the legislative authority to investigate. It may be appropriate to either hand this part of the investigation to them or to conduct a joint investigation e.g. food premises, occupational health and safety.
- consulting other experienced public health workers
- consulting experts in the types of processes to be investigated. Experts may be identified from trade associations or from comparable businesses
- reviewing guidelines for the sector, such as:
 - food – hazard analysis critical control point (HACCP) systems⁵³ and food safety programmes⁵¹ for that food industry; specific codes of practice
 - hospitals – infection control guidelines
 - pools – pool management guidelines
 - water – treatment plant operating guidelines⁵⁴ Guidelines for Drinking-water Quality Management for New Zealand <http://www.health.govt.nz/publication/guidelines-drinking-water-quality-management-new-zealand>
 - childcare – infection control guidelines.

9.1.3.2. Specific information

Information on many different types of environmental sites is collected routinely as part of licensing and normal regulatory arrangements. In general, this information has little to contribute to outbreak investigation. As an exception, water testing reports are often of value in the investigation of outbreaks involving water contamination. The best place to find this information is at the local authority, in the Water Information New Zealand (WINZ) database or in the water supplier's public health risk management plan. Liaising with territorial authority environmental health officers or other officials responsible for regulating the implicated site may be necessary. Wherever possible, the environmental investigation should be carried out jointly by the PHS and the local authority's environmental health officials.

9.1.3.3. Information from key individual(s) associated with the implicated event

Before visiting the implicated site or premises associated with the event, try to identify and make contact with key individual(s) involved with the event. This is a crucial part of the entire investigation. Establishing a good relationship with the person or people responsible for the event can expedite a fast and thorough investigation, and will encourage the adoption of control measures. During the initial discussion:

- present the basic details of the outbreak, frankly and openly. Clearly state that the source of the outbreak has not been identified at this stage (if this is the case), and explain that preliminary enquiries are necessary at an early stage to help guide the investigation
- do not present suspicions about the outbreak source, unless the epidemiological analysis is complete
- arrange a mutually acceptable time for the site visit
- identify whether there are any forthcoming events in which the circumstances of the common event under investigation may recur (i.e., events that will use the same premises, food handler, sanitation facilities, etc.)
- if the outbreak could be associated with a human source (i.e., an infected food handler), identify the number of potential sources and how they may best be contacted.

9.1.4. Step 4: Conduct a site visit and inspection

Site visits and inspections provide the interface between the investigation and control of an outbreak. Observations made during the site visit may reveal helpful clues about the outbreak source, address general hygiene and safety issues, and can directly lead to implementation of control measures regardless of the subsequent epidemiological findings. The site visit is likely to have maximum benefit if undertaken as soon as possible after identification of the suspect site. A prompt visit would try to identify, sample, cease or remove from sale any food that could be contaminated. Also this initial rapid visit may identify gross problems at the site which may be immediately controlled. A second visit may occur when more detailed information has been gathered and analysed

An additional function of visiting premises potentially linked to an outbreak is to meet those involved face to face. This emphasises the importance of the investigation, and when carried out in a polite and professional manner, tends to enhance communication and co-operation.

Key components of the site visit and investigation are inspection of the place, processes and people. Remember that while doing a site visit and investigation, **more is missed by not looking than not knowing**.

9.1.4.1. Place

Gain a general impression of the site and keep an open mind, as unforeseen factors relevant to the outbreak may become apparent. Identify any past events or situations that may have contributed to the outbreak. This 'floors, walls and ceilings' inspection is only useful insofar that it contributes to an assessment of risk, as contaminated food can emerge from a kitchen that appears hygienic.

While examining the site, consider whether specimens of leftover material associated with the common event are available and can be collected for testing. Aspects of specimen collection and

testing are addressed in Chapter 10. Collect specimens immediately, but if there is a lot of speculation on causative factors such as the specific source, mode of transmission or aetiological agent, it may be best to store the specimens after collection and decide what to test later. Ideally, the combined results of the epidemiological, environmental and laboratory investigation will help to guide decisions about what to test. Be cautious about widespread testing of the environmental specimens collected, because routine environmental culturing usually leads to results that cannot be interpreted⁵⁵. For example, many surfaces, areas or items will be contaminated by organisms that are not relevant to the outbreak or are part of the normal environment, and yet the return of a positive test may demand a response.

9.1.4.2. Processes

The initial site visit is an opportunity to broadly review all processes at the site. If multiple processes occur at the site, it may be too time-consuming to undertake a detailed risk assessment of them all at the initial stage.

- Closely observe processes and procedures, including those that are considered ‘normal’ or ‘not worth mentioning’. It is important to include aspects that tend to be overlooked, such as storage, distribution, instructions to consumers, product design and composition.
- Look for gross negligence, contamination or gaps in techniques.
- Check whether policies, protocols and manuals are available and used. Check these against current standards.
- Review monitoring and record-keeping systems. Obtain specific monitoring data relevant to the investigation.

The following ‘process sieve’ has been developed to help screen processes for further detailed review.

9.1.4.3. The process sieve

If the site is unusual or has not been previously encountered, systematically identify which processes may have a role in the sequence of events that led to the outbreak. This process sieve offers a simple framework for screening processes that will require closer examination using the points listed above. The following processes are likely to require close examination:

- processes developed to decontaminate raw materials (e.g., systems for cooking or preserving meat products, water treatment processes)
- processes for preventing humans from ingesting or absorbing material that cannot be entirely decontaminated (e.g., hand-washing facilities adjacent to a petting zoo, systems to avoid dispersal of lead-containing paint flakes)
- processes for avoiding recontamination of materials that have already been processed and decontaminated (e.g., cross-contamination of cooked food with uncooked products)
- processes developed to eliminate the potential for the contamination of products by human carriers (e.g., protocols for limiting food-handling by workers with diarrhoea or vomiting, for workers to cover cuts and sores or to wear gloves), either during the preparation or distribution of products
- processes developed to eliminate the potential for contamination of products from the environment (e.g., protocols for cleaning and maintaining appliances, processes to ensure that

raw materials or decontaminated product remain free of contamination by vermin, water backflow prevention mechanisms).

9.1.4.4. People

If the outbreak pathogen could have been transmitted from a person, then it is very important to interview and screen potential human sources using the following steps:

- identify a list of all individuals who may have come into contact with the suspected outbreak source(s)
- interview each individual with a standard questionnaire. The questionnaire should cover issues such as the presence or absence of symptoms of the outbreak illness, recent medical care or hospitalisation, presence of illness among close household contacts, level of contact with the suspected source(s) and involvement in other paid or unpaid work (e.g., care of elderly, assistance in an early childhood centre). The questionnaire may be similar to that used for the wider investigation. Further information on questionnaire design is contained in Appendix 2
- collect specimens if appropriate. If the pathogen can be transmitted by asymptomatic carriers, then all individuals who have had contact with the suspected source(s) should be screened. Details of specimen collection are given in Chapter 10.

9.1.4.5. Step 5: Full environmental risk assessment

Full environmental risk assessment requires a reasonable level of knowledge about the technical aspects of the processes potentially linked to the outbreak. It is beyond the scope of this manual to provide detailed descriptions of environmental risk assessment procedures and standards for the wide range of industries and processes with outbreak-causing potential. Discuss the characteristics of the outbreak with a technical advisor to obtain the most appropriate reference material. For the water industry, this material should be held in public health risk management plans.

This manual describes the general principles of full environmental risk assessment, based on the Hazard Analysis Critical Control Point (HACCP) assessment process developed for the food manufacturing industry. The acronym 'HACCP' derives from the procedure of performing a hazard analysis (a systematic analysis of the sensitive steps in a process that that could contribute to a hazard), to identify the critical control points (CCPs) in the process that, if not adequately controlled, could lead to an unacceptable safety risk⁵⁶.

The internationally-agreed framework for HACCP assessments, developed by the Codex Alimentarius Commission⁵⁶ uses seven steps.

1. Hazard analysis of the process
2. Determination of the CCPs
3. Specification of criteria (critical limits for each CCP)
4. Implementation of a monitoring system for the CCPs
5. Corrective action procedures when the CCPs are exceeded
6. Verification that the HACCP system is working
7. Documentation of the HACCP system

In an outbreak investigation, application of the HACCP assessment framework obviously starts from the point of view that an unacceptable safety risk has occurred. The objective of the assessment is to

identify which CCP has failed, and why. If no food safety programme or other hazard monitoring system is in place, there may be no documentation of CCPs. If this is the case, it may be important to take measurements, such as temperature readings, directly from the process itself.

Although developed for the food industry, the HACCP framework can be applied to other contexts that may be associated with disease outbreaks where the outbreak is likely to have been caused by a breakdown in complex processes as in poultry processing plants or water purification systems.

9.2. Environmental investigation of dispersed outbreaks

Some form of environmental investigation is likely to be required for dispersed outbreaks. Once the common source has been implicated from the epidemiological study, the objectives of the environmental investigation of dispersed outbreaks become the same as those for common event outbreaks (i.e., to identify future recurrence of circumstances that led to the first outbreak, to identify obvious hazards, to collect specimens and to identify less obvious hazards that require further investigation).

Prior to the implication of a common source, the environmental investigation of dispersed outbreaks has a role in collecting information about the origins of products, suspected to be the source(s) of the outbreak, in preparation for a potential recall or advisory warning when the results of the epidemiological investigation are available.

A full environmental investigation of a site or premises considered to be the potential common source of a dispersed outbreak cannot begin until the site has been identified, usually from the results of a descriptive review of cases or from a full epidemiological investigation. Collecting environmental information about the sources of products that appear to be linked to cases can start at an early stage.

Once a potential common source for a dispersed outbreak has been identified, background information should be collected as for the investigation of a common event outbreak. Information about food manufacturing processes, water treatment processes and distribution networks is likely to be important, depending on the outbreak source and aetiological agent. Further investigation continues as for common event outbreaks.

9.3. Environmental investigation of common site outbreaks

The characteristics and requirements of an environmental investigation into common site outbreaks that have been traced to a specific site are very similar to those of common event outbreaks. The objectives of environmental investigation are to identify obvious hazards that may require immediate implementation of control measures, to collect specimens of implicated material and to develop a plan for further management of other hazards. As with common event outbreaks, collecting information about the suspected common source of the outbreak and a site visit should be undertaken early.

9.4. Environmental investigation of institutional outbreaks

A thorough investigation of an outbreak in an institutional setting should include an environmental component, particularly if an inanimate object is epidemiologically implicated as a possible means of transmission. The 'site' visit and inspection must include an examination of equipment and interviews with care workers. Outbreaks of disease caused by airborne microorganisms merit a

thorough inspection of air-handling systems, isolation room airflow patterns and infection control techniques. Routine environmental culturing is not warranted.

9.5. Environmental investigation of person-to-person outbreaks

The need for an environmental investigation of person-to-person outbreaks may be less apparent than for other outbreak types. Environmental investigation techniques may be important as part of the overall management of outbreaks of vaccine-preventable disease among immunised individuals. An outbreak of vaccine-preventable disease may be linked to a batch of vaccine that has been rendered inactive by incorrect storage or handling. Environmental investigation should be undertaken to identify system failures in vaccine distribution. These may represent a failure of the 'cold-chain' to keep the vaccine within a defined temperature range.

9.6. Environmental investigation of specific outbreak types: summary

The following table summarises the typical components of environmental investigation of specific outbreak types.

Table 8: The components of environmental investigation in different food- and water-borne outbreaks

Outbreak type	Environmental investigation components
Common event outbreak, usually food- or water- borne	<ul style="list-style-type: none"> • Site visit and inspection • HACCP-based food safety assessment / public health risk management plan-based water assessment • Collection of food, water, environmental specimens • Collection of clinical specimens, e.g., faecal specimens from food handlers • Case finding
Dispersed outbreak, usually food- or water- borne	<ul style="list-style-type: none"> • As for common event when potential sources identified • Site visits (as required by circumstances) <ul style="list-style-type: none"> ○ Restaurants, cafes, takeaways, supermarkets, delicatessens, caterers, food processors/manufacturers/distributors ○ Hotels, hostels, camps, prisons ○ Rest homes, hospitals ○ Schools, early childcare facilities, meeting rooms ○ Workplaces, farms ○ Water treatment stations: review records, turbidity, chlorination (free available chlorine (FAC)), microbiological testing, catchment site visit, water samples

Outbreak type	Environmental investigation components
Institutional outbreak	<ul style="list-style-type: none"> • Site visits and inspections • Environmental risk assessment • HACCP-based food safety assessment, if appropriate • Collection of environmental specimens • Case finding
Common site outbreak	<p>Waterborne</p> <ul style="list-style-type: none"> • Visit implicated swimming pools: review records of use, faecal accidents, chlorination (FAC), staff illness, protocols <p>Legionellosis</p> <ul style="list-style-type: none"> • Visit potential sources and review operation and maintenance of potential reservoirs. See MoH publication on Prevention of Legionellosis in NZ 2011. http://www.health.govt.nz/publication/prevention-legionellosis-new-zealand-guidelines-control-legionella-bacteria <p>Zoonosis</p> <ul style="list-style-type: none"> • Visit potential sources and review level of human exposure and precautions in place
Community-wide, person-to-person outbreaks	<ul style="list-style-type: none"> • Environmental specimens not usually required
Outbreak caused by unknown, but potentially serious disease-causing agent	<ul style="list-style-type: none"> • Environmental specimens and investigation depend on disease and suspected source

10. Laboratory investigation

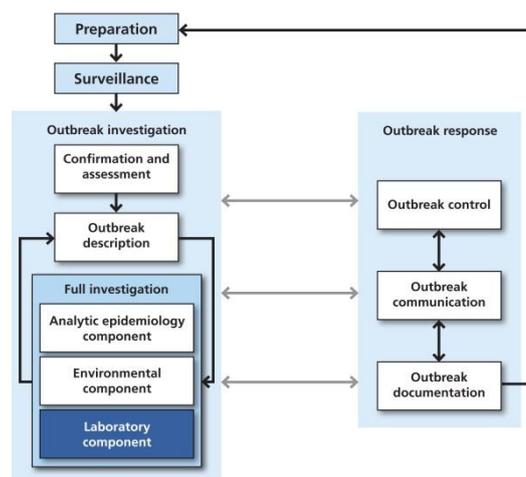
Laboratory techniques for identifying and quantifying organisms and toxins have always had an important role in disease outbreak investigation, mainly for identifying or confirming links between suspected contaminated substances and human illness. Laboratory data are often instrumental in identifying outbreaks. Recent developments in laboratory techniques mean that laboratory sciences can greatly improve the sensitivity of outbreak detection by identifying clusters of cases with a common source. Previously, these clusters would have appeared sporadic and unconnected. Such findings may help strengthen links between outbreaks and their sources.

As this manual is primarily directed towards personnel involved in responding to outbreaks in the field, this chapter does not attempt to describe laboratory testing processes in detail. Instead, the emphasis has been placed on the interface between laboratory investigation and field outbreak investigation personnel.

Table 9 indicates the precise role of laboratory investigation in different types of outbreaks. The earlier in the episode such investigations are done the more useful the results would be. Further characterisation of the organism by a reference laboratory is usually necessary for an epidemiological investigation.

Table 9: Role of laboratory investigation in different outbreak types

Outbreak type	Role of laboratory investigation
Common event	Laboratory investigation has an important role in the overall investigation of common event outbreaks. Laboratory investigation is important in confirming diagnoses, indicating possible sources and testing environmental specimens. This includes testing of clinical specimens from humans and animals as well as from food, water and the environment
Common site	Laboratory investigation of common site outbreaks contributes to the identification of links between cases, confirming diagnoses, indicating sources and testing specimens
Dispersed	Laboratory investigation of dispersed outbreaks has a particularly important role in identifying links between dispersed cases, as well as eventual testing of sources, once identified
Community-wide	Laboratory investigation of community-wide outbreaks is important in identifying links between cases
Institutional	Laboratory investigation has an important role in the overall investigation of institutional outbreaks. It is important in confirming diagnoses, identifying links between cases, indicating possible sources and testing specimens



10.1. Laboratory involvement: overview of potential roles and services

Laboratory scientists make a number of significant contributions to disease outbreak management. These contributions are described next.

10.1.1. Provision of general microbiological and toxicological advice

- Advising on the range of plausible organisms and toxins involved in an outbreak to help focus the epidemiological and environmental components of the investigation.
- Advising on appropriate specimens to collect, quantity of specimens and tests to perform.

10.1.2. Outbreak identification

- On-going surveillance of notifiable and non-notifiable organisms, thereby providing an early warning about emerging groups of cases potentially with a common source.
- Subtyping of selected organisms, thereby increasing the sensitivity of detection of dispersed outbreaks associated with a common source.

10.1.3. Outbreak description and investigation

- Identification or confirmation of the pathogen or toxin causing illness.
- Identification of organisms common to different cases, thereby increasing the specificity of the case definition and helping establish links between apparently unrelated cases and outbreaks.
- Detection of organisms of the same type in potential sources (e.g., in food, water and environmental specimens, and specimens from animals and humans).
- Identification, thereby facilitating exclusion, of non-susceptible individuals that would otherwise have been included as controls or non-cases in epidemiological investigations, such as people who are immune to infection from Hepatitis A.

10.1.4. Guide to effective laboratory involvement

10.1.4.1. Consult the laboratory early

Contact the laboratory as soon as the need for outbreak investigation is suspected. Identify a contact person and deputy for on-going consultation, so that continuity throughout the outbreak investigation and response is maintained. Initial discussions should include defining the laboratory's contribution, and should extend to inviting a laboratory representative to join the outbreak team. Early communication also enables the laboratory to schedule resources. At this time, investigators should request the laboratory to save any relevant specimens from diagnostic testing work (before they are thrown out) and/or to refer these for additional testing.

10.1.4.2. Establish appropriate laboratory testing

With the guidance of the laboratory, decide what pathogens or toxins should be tested for and by what method(s), and therefore what type(s) of specimens are required. When assessing quantity, it may be more feasible in some investigations to test a selected sample of cases rather than everyone. This would apply to retrospective cohort studies with large exposed populations.

It is a good idea to have an estimate of the turnaround time for testing and when results will become available. Timely follow-up of these results and their interpretation by the laboratory is important, and it may be necessary to discuss additional testing. Remember that tests requiring culture of microorganisms will take time.

10.1.4.3. Specimen collection, storage and transport

Make plans for specimen collection, storage, transport, receipt and testing as clearly and as early as possible. These plans should be detailed – what, how, who, where, when – and co-ordinated with all involved. The laboratory should always be consulted about specific requirements, including transport and temperature. Equipment such as special containers and processing reagents may need to be organised, especially if chemical toxin testing is planned.

10.1.4.4. Collection

Specimen collection kits should be already assembled in preparation for an outbreak, as part of the outbreak plan. They should be portable and have equipment for a range of situations and specimens. A suggested checklist follows.

10.1.4.4.1. General

- Sterile spoons, spatulas and gloves
- Method for surface sterilisation (e.g., chemical disinfectant)
- Laboratory test request forms
- 'Bio-bottles', chilly-bins, chiller-pads, labels

10.1.4.4.2. Food, water and environmental specimens

- Containers for food, water and environmental specimens
- Sterile plastic bags or unopened containers for food, fluids and environmental material (e.g., potting mix)
- Sterile bottles (250 mL) for water to test for indicator organisms and Legionella
- Sterile dry swabs (i.e., without media) for environmental swabs

10.1.4.4.3. Clinical specimens

- Sterile pottles for faeces, vomit specimens
- Additional items for collecting clinical specimens

- Phlebotomy supplies for blood/serum, including tubes with and without anticoagulant (EDTA)
- Specimen container for urine – may need preservative
- Specimen container for chemical toxins, may need to be pre-screened to eliminate background contamination
- Throat and nasopharyngeal swabs, plain and with viral transport media

10.1.4.4. Collection of clinical specimens

Where specimens are collected from people, informed consent in writing must be obtained. This includes adequate explanation of the reasons for testing, the process involved and clear instructions for any self-collection (e.g., faecal specimens). For serological testing, paired sera are commonly needed; therefore a second (convalescent) specimen may be required some four-to-six weeks after the first (acute) specimen. Identification details written on specimens and laboratory request forms must be legible and as comprehensive as possible. Providing additional information about the case and investigation on the request form is also important as it assists those performing the tests. For example, for diarrhoeal specimens the suspect food source, incubation period, symptoms and a history of recent overseas travel should be recorded.

Adequate precautions must be taken when collecting clinical specimens to protect the collector from the transmission of hazardous agents. These include standard precautions such as wearing gloves, gowns and masks where appropriate, and taking necessary care during collection of the specimens themselves. Specimens also need protection from contamination (e.g., chemical toxins must be protected from human contamination).

10.1.4.5. Storage and transport

After collection, the two key aims of storage and transport are to keep the specimens viable and to minimise contamination. Most specimens are stored at refrigerator temperature (2–4°C), not frozen. For transportation outside of the laboratory environment, an overnight courier or faster means should be employed, using chiller pads and insulated containers to keep the specimens cool. Infrequently, if *C. perfringens* is suspected, transport should be at room temperature

If cases are self-collecting specimens (e.g., faecal specimens), give detailed instructions about specimen storage while awaiting transport to the laboratory, so that exposure to other household members is minimised and the viability of the organisms is maintained. These instructions could include (for faecal specimens):

- collect the faecal sample in the pottle supplied
- wash hands
- place pottle in the supplied biohazard bag
- place bag in a cool area out of direct sunlight while awaiting collection. A good storage place would be in a chilly bin with a chiller pad.

10.2. Organism typing techniques

10.2.1. Background

Organism typing refers to a variety of processes that describe detailed characteristics of microorganisms of the same species, thereby allowing further subdivision into different organism types or subtypes. Organisms that are indistinguishable by typing are said to have epidemiological relatedness, and are therefore more likely to have come from a recent common ancestor and common source. This information can be used to link human cases to assist in the identification, description and investigation of outbreaks. In addition, human cases can be linked to environmental samples to determine potential sources of infection (e.g., by identifying the same *Legionella* type in a patient's sputum and in an environmental sample).

10.2.2. Advantages of organism typing

- Enhanced sensitivity for detecting dispersed outbreaks likely to have emerged from a common source. Subtyping has contributed directly to the identification of the sources of many salmonellosis outbreaks^{57, 58}.
- Enhanced ability to identify causal links between implicated environmental sources and human illness.
- Differentiation of outbreak-associated isolates from isolates not related to the outbreak, even among cases present in the same locality at the same time.

10.2.3. Limitations of organism typing

- Additional time delay pending typing results. Epidemiological investigation should not be delayed until typing results become available. However, in the analysis of samples from a large multicentre outbreak where the strain type is very common, results from molecular typing are required to narrow the case definition and exclude non-related cases.
- Discrimination. The inability of the system to sufficiently differentiate between organism types. For example, the genotyping system currently used for *Giardia lamblia* divides the organism into only two types, limiting its value for outbreak investigation.
- Reproducibility. Most laboratories only use tests that are highly reproducible. Be advised by the appropriate reference laboratory on the practicality and applicability of typing methods.

Examples of the typing methods used are given in Table 10; these are grouped into two main categories, phenotypic and genotypic.

Table 10: Categories of typing methods

Typing method	Type of organism	Example
Phenotypic (based on function and visible traits of the organism)		
Antimicrobial susceptibility	Bacteria	Methicillin-resistant <i>Staph. aureus</i>
Biotyping	Bacteria	<i>Shigella sonnei</i> , <i>Yersinia enterocolitica</i>
Serotyping	Some bacteria and viruses	<i>Salmonella</i> spp, <i>Neisseria meningitidis</i> , <i>E. coli</i> (VTEC)
Phage typing	Bacteria	<i>Salmonella</i> spp, e.g. <i>S. Typhimurium</i> , <i>S. Enteritidis</i> and <i>S. Typhi</i> <i>Staph. aureus</i>
Biochemical profile	Bacteria	<i>E. coli</i> , <i>Shigella</i> spp., <i>Vibrio cholerae</i>
Genotypic (analysis of nucleic acids within the organism)		
PCR (detection of specific virulence/toxin genes)	Bacteria	<i>E. coli</i> (VTEC), <i>V. cholerae</i>
Pulsed-field gel electrophoresis (PFGE)	Bacteria and fungi	<i>E. coli</i> (VTEC), <i>Listeria monocytogenes</i> , <i>Salmonella</i> spp., <i>Shigella</i> spp., <i>Campylobacter</i> , <i>V. cholerae</i> , <i>Yersinia pestis</i>
Restriction fragment length polymorphism (RFLP) and probing	Bacteria and viruses	<i>Mycobacterium tuberculosis</i>
MLVA, MLST often being included in investigations where PFGE analysis is not sufficiently discriminative	Bacteria	Within some phage types of <i>S. Typhimurium</i>
DNA sequencing	Bacteria and viruses	Noroviruses ⁵⁹
Plasmid profiling		<i>Salmonella</i> spp.

10.2.4. Interpretation of laboratory results

Laboratory test results are generally used to support a diagnosis or hypothesis, not to make it. Testing may not be 100% accurate because methods have to balance sensitivity and specificity. In other words, increasing the ability of a test to recognise specimens which are truly positive (making it more sensitive) also increases the chance of ascribing a positive result to negative samples which have similar characteristics to the agent of interest (making it less specific), and vice versa.

True positive results cannot determine causation to an absolute certainty (e.g., infection vs. asymptomatic carriage, persistence of antibodies from past seroconversion). Therefore, a positive result from a person or item without epidemiological association does not prove the person or item was a source or vehicle of infection. On the other hand, a positive result from an epidemiologically implicated person or item strongly suggests that person or item was most likely a source or vehicle of infection.

Conversely, negative results do not deny an association, but indicate only that the pathogen was not found in the specimen collected. Possible reasons, apart from the pathogen truly not existing in the specimen source, include:

- intermittent or non-uniform inoculation of the pathogen in the specimen, for example, due to intermittent faecal shedding of pathogens
- specimen size is too small
- competitive microorganisms outgrew pathogen (if culture)
- item / source not tested for pathogen
- diminished, injured or inactivated pathogen due to inappropriate processing, handling or storage
- for human faecal specimens, elimination of the pathogen may have already occurred
- inappropriate or inadequate laboratory methods
- agent is not a pathogen, for example, it could be a toxin
- agent is an emerging pathogen not detectable by currently available laboratory methods.

If an organism or type of organism different to the 'outbreak strain' is found, this may still provide evidence for a contamination or infective process and should be investigated further.

Tables 11 to 15 provide summary lists of specimens and tests available in a laboratory investigation under certain common outbreak scenarios.

10.2.5. Common event or dispersed outbreak of foodborne or waterborne illness

In a common event or dispersed outbreak of foodborne or waterborne illness, the role of laboratory investigation is to:

- confirm the diagnosis
- help identify the source
- establish links between cases using phenotypic or genotypic testing (particularly dispersed outbreaks).

Table 11: Human specimen collection for in food or waterborne outbreaks

Human specimens	
Specimen type	Testing
<p>Faeces</p> <p>Collect approximately 10 g (walnut sized) or 10 ml. If a wide range of tests is required, 10 g should be regarded as a minimum amount.</p> <p>For nappies, send entire nappy if liquid material fully absorbed</p>	<p>Bacteria:</p> <ul style="list-style-type: none"> • Campylobacter, Salmonella, Shigella, Aeromonas, Listeria, Yersinia, Vibrio, pathogenic E. coli (incl. VTEC), B. cereus, Staph. aureus, C. perfringens
	<p>Virus testing:</p> <ul style="list-style-type: none"> • Rotavirus • Norovirus
	<p>Toxin testing:</p> <ul style="list-style-type: none"> • Staph. aureus, B. cereus (diarrhoeal), C. perfringens
	<p>Parasites (immunoassay):</p> <ul style="list-style-type: none"> • Giardia, Cryptosporidium
<p>Vomit</p> <p>Collect approximately 10 g or 10 ml</p>	<p><i>Staph. aureus</i>, organism and toxin</p> <p>Bacillus cereus organism</p> <p>Norovirus</p>

Table 12: Food, water and environmental specimen collection

Food, water and environmental specimens	
Specimen type	Testing
Food 100–300 g of: Actual or suspected food Components or ingredients of suspected food Food prepared under similar conditions	Bacteria: <ul style="list-style-type: none"> • Campylobacter, Salmonella, Shigella, Aeromonas, Listeria, Yersinia, Vibrio, Pathogenic E. coli (incl. VTEC), B. cereus, Staph. aureus, C. perfringens
	Virus testing: <ul style="list-style-type: none"> • Norovirus
	Toxin testing: <ul style="list-style-type: none"> • Staph. aureus toxin
	Chemical: <ul style="list-style-type: none"> • Histamine
Water Required sample volume depends on range of pathogens for testing. Discuss with laboratory.	Bacteria: <ul style="list-style-type: none"> • Campylobacter, Salmonella, Shigella, Aeromonas, Listeria, Yersinia, Vibrio, pathogenic E. coli (incl. VTEC), B. cereus, Staph. aureus, C. perfringens
	Virus testing: <ul style="list-style-type: none"> • Norovirus
	Toxin testing: <ul style="list-style-type: none"> • Staph. aureus toxin
	Chemical: <ul style="list-style-type: none"> • Histamine
	Parasites: <ul style="list-style-type: none"> • Giardia lamblia, Cryptosporidium parvum
Water 250 ml	Indicator organisms

10.2.6. Institutional outbreak

In an institutional outbreak, the role of laboratory investigation is to:

- confirm the diagnosis
- help identify the source.

Table 13: Human specimen collection in institutional outbreaks

Human specimens	
Specimen type	Testing
Faeces, vomit	As for foodborne or waterborne outbreak
Blood, wound swab, pus, skin swab, etc.	MRSA
	Other bacteria (e.g., <i>Acinetobacter</i>)
Environmental specimens	
Specimen type	Testing
Potentially contaminated hospital equipment or supplies	Testing as appropriate

10.2.7. Environmental outbreak

In an environmental outbreak, the role of laboratory investigation is to:

- confirm the diagnosis
- establish environmental contamination and its source.

Table 14: Environmental specimen collection

Human specimens		
Organism	Specimens	Testing
Enteric bacteria	Faeces	Usually already tested by laboratory
Legionellosis, pontiac fever	Blood samples	Paired specimens for serology: acute and follow-up (at 3–9 weeks later). Extra samples for culture may be required
	Sputum / bronchial lavage	Culture, PCR and Direct Fluorescent Antibody (DFA)
Leptospirosis	Blood	Immediate specimen for serology and culture, follow-up specimen at 2 weeks for serology
	Urine	10 days into disease: culture
	CSF	5 days into disease: culture
Environmental specimens		
Organism	Specimens	Collection requirements
Cryptosporidium, Giardia	Water	Filter 380 L of water from environmental source or 1000 L drinking-water through approved wound-yarn cartridge filter, send to laboratory
Indicator bacteria	Water	250 ml water in sterile container. If chlorinated, use bottle containing sodium thiosulphate
Enteric bacteria	Water	1 L in a sterile container for each pathogen being investigated. If chlorinated, use bottle containing sodium thiosulphate
	Moore's swab	Discuss with laboratory
Viruses	Water	20 L sample, or consult laboratory regarding on-site filtration
Legionellosis	Water	250 ml sample: collect from cooling tower, hot water cylinder (bottom drain pipe), hot water taps, water filters, air conditioning if water present (especially if <i>Legionella pneumophila</i> is cause)
	Swabs	Taps, shower rosette, air conditioning system
	Soil	Sample potting mix, compost from bag (especially if <i>Legionella longbeachae</i> is the cause)
Zoonoses	Consult veterinarian, MPI, National Centre for Disease Investigation (Wallaceville)	

10.2.8. Community-wide, person-to-person outbreaks

In community-wide, person-to-person outbreaks, the role of laboratory investigation is to:

- confirm the diagnosis
- establish links among the cases.

Table 15: Human specimen collection in person-to-person outbreaks

Human specimens		
Organism	Specimens	Testing
General (varies depending on disease)	Sterile site specimens	Isolates
	Blood	Serology
Tuberculosis	Sputum, other	PFGE and probe
Shigella	Faeces	Serotyping, biotype
Norovirus	Faeces	DNA sequencing
Viruses (HCV, HIV)	Blood	DNA sequencing

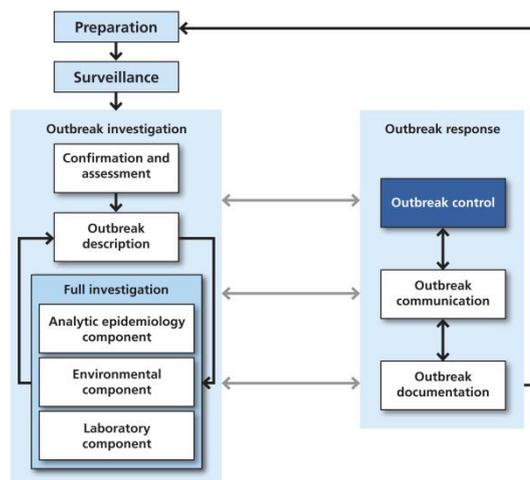
Table 16: Pathogens that can be further typed

Pathogen isolate	Typing available
Salmonella	Serotyping, phage typing, PFGE (in outbreak situation), MLVA (<i>S. Typhimurium</i> only if PFGE is not discriminatory enough), antimicrobial susceptibility testing
Shigella	Serotyping, biotyping, PFGE (in outbreak situation)
Campylobacter	Penner serotyping (<i>C. jejuni</i>), PFGE (in outbreak situation)
Yersinia	Biotype and MLVA (<i>Y. enterocolitica</i> in outbreak situation)
VTEC	Serotyping, Toxin and virulence genes detection using PCR, PFGE O157 VTEC isolates (routinely performed)
<i>L. monocytogenes</i>	Serotyping, PFGE (in outbreak situation)
Norovirus	DNA sequencing
MRSA	Phage typing, PFGE
Acinetobacter	PFGE

11. Outbreak control measures

These guidelines present a brief, somewhat generic, summary of outbreak control measures. It is beyond the scope of this document to provide detailed information about control measures for specific diseases and situations. This information can be found in the resources listed next.

- The American Public Health Association's *Control of Communicable Diseases Manual*² is an invaluable handbook of standard, internationally accepted measures for communicable disease control.
- The *Communicable Disease Control Manual*⁶⁰ provides New Zealand protocols for the management of notifiable infectious diseases.
- The *Food Administration Manual*⁶¹ provides prescriptive information on processes and the legislative framework surrounding the control of disease outbreaks associated with food.
- The *Guidelines for Tuberculosis Control in New Zealand 2010* has detailed information on tuberculosis management and care.⁶²
- The *Draft Guidelines for Drinking-water Quality Management for New Zealand 2005*⁵⁴ has information on managing risks associated with drinking-water supplies.
- Selected legal powers that are particularly relevant to outbreak control are listed in Appendix 7. These relate to the duties of Medical Officers of Health, Health Protection Officers and Food Act Officers. This list should not be considered as a substitute for the text of the actual statutes and regulations.



11.1. General considerations

Although definitive measures usually require knowledge of the source and reasons for the outbreak, control activities should be considered at all stages of the investigation. Initial control measures will be based on knowledge of the pathogen, and probable sources and modes of transmission.

The sources of an outbreak can usually be considered as a continuum from 'upstream' determinants to 'downstream' factors. For example, an outbreak of meningococcal disease in a community could be simultaneously due to social and economic conditions predisposing people to over-crowding and poor housing, a lack of availability of accessible primary health care services for early diagnosis, and to close physical contact with an individual carrying nasopharyngeal *Neisseria meningitidis*.

Points of potential outbreak control can also occur at several places on this continuum. In general, however, upstream determinants can only be addressed over a long time scale and with substantial political and community support. For this reason, most outbreak control measures focus on the immediate sources of the outbreak, but it is important to bear in mind that the causes of outbreaks occur in a much broader context. To use the example of an outbreak of meningococcal disease, immediate outbreak control measures will involve tracing and administering prophylaxis to close contacts of the index case, but it is important to remember that improved living conditions and improved access to affordable and appropriate health services (along with development of an effective vaccine) could have greater impact on meningococcal disease outbreaks in the long term.

The degree of urgency and priority placed on outbreak control depends on several factors, including the incidence and severity of disease (morbidity and mortality), whether or not the outbreak is continuing or likely to recur, the degree of public concern, and the effectiveness or practicality of the control measures themselves.

Control measures may be considered under three areas aimed at:

- the outbreak source
- contaminated vehicles of infection transmission
- susceptible humans.

The choice of control measure within these three areas is dictated by factors such as whether the outbreak source is known, whether a suspected vehicle has been identified and whether a vaccine or prophylactic treatment is available for susceptible humans.

11.2. Examples of control measures aimed at the outbreak source

11.2.1. Outbreaks associated with food, water or environmental sources

- Closure of premises or site of outbreak (e.g., food premises closure)
- Modification of procedures (e.g., swimming pool filtration)
- Cleaning or disinfecting contaminated equipment or fittings (e.g., cooling towers)

11.2.2. Outbreaks associated with animal contact

- Removal from contact, treatment, isolation, immunisation or destruction of animal reservoirs (e.g., immunisation of cattle to prevent human leptospirosis)

11.2.3. Outbreaks associated with human sources

- Treatment of cases and carriers (e.g., treatment of individuals with tuberculosis disease or infection)
- Exclusion or restriction of activities (e.g., temporary restrictions placed on food handlers or health care workers with gastroenteritis symptoms)
- Isolation (e.g., use of universal precautions to manage hospital inpatients infected with or carrying MRSA)
- Quarantine (e.g., people arriving in the country with viral haemorrhagic fever, close contacts of a confirmed case of measles)
- Education (e.g., advising individuals with STIs to use condoms during sexual contact)

11.3. Examples of control measures aimed at contaminated vehicles and vectors

11.3.1. Outbreaks associated with contaminated food or water

- Removal or recall of contaminated product (e.g., packaged food contaminated with *Listeria*)
- Treatment, pasteurisation or sterilisation of contaminated material (e.g., use of boiled or treated water)

11.3.2. Outbreaks associated with vectors

- Application of insecticides, setting traps, eliminating breeding habitats, improving management of solid waste (e.g., application of insecticide to breeding areas to control mosquito vectors)

11.4. Examples of control measures aimed at susceptible humans

11.4.1. Outbreaks associated with food, water or environmental sources

- Education to change behaviour associated with food preparation or hygiene (e.g., education to improve food safety, implementation of a food safety plan)
- Instructions to treat or sterilise contaminated material (e.g., issuing 'boil water' notices)
- Education to reduce contact with vectors (e.g., use of screens, bed nets, long-sleeved shirts and insect repellents to reduce risk of vector borne disease)

11.4.2. Outbreaks associated with human sources

- Administration of chemoprophylaxis (e.g., isoniazid for tuberculosis)
- Administration of active and passive vaccines (e.g., immune globulin and vaccine for hepatitis A)
- Advice on physical barriers (e.g., use of condoms to prevent STIs)
- General improvement in host resistance (e.g., correct malnutrition or vitamin deficiency to reduce the effects of measles)

already exist, then a basic plan can be developed relatively quickly. The communication plan should address four key areas:

1. communication within the outbreak team
2. communication with the Ministry of Health, the Ministry for Primary Industries, ESR, other PHS and key government agencies
3. communication with the public, either directly or through the media
4. communication with other agencies involved in the outbreak, such as local authorities, industry groups, local hospitals and local primary health care organisations.

12.3. Communication within the outbreak team

Processes for communicating within the team may also be covered by the overall outbreak plan. These processes may be straightforward if the team is small and shares the same workplace, but will need to be considered more explicitly if the outbreak investigation involves multiple health districts or involves multiple levels (e.g., local authority, PHS, Ministry of Health). Use the following principles:

- designate a single individual or agency as the outbreak co-ordinator. This individual/agency should organise and chair team meetings and should receive copies of all communications
- ensure that each 'subgroup' of the outbreak team (if large) has a key communication representative who can attend each meeting. Team subgroups may develop around different activities, such as interviewing or environmental investigation, around different agencies or around CIMS roles. If there are multiple 'subgroups' (e.g., in a large CIMS structure), ensure that one of these is communications / public information. There should also be someone tasked with interagency liaison
- schedule regular meetings of the outbreak team. Each meeting should include a summary of the outbreak as it initially presented, an update on overall progress, and then invite contributions from each arm of the investigation. Make sure that problems and barriers to the investigation are presented and discussed. At each meeting, nominate a person to take the minutes and note action points. Circulate the minutes and action points promptly after the meeting, including to those who were unable to attend
- consider how communication outside of meetings should occur, whether by email, phone or fax. Make sure that a list of contact numbers and email addresses for outbreak team members is compiled, accurate and distributed
- ensure the involvement of ESR, the Ministry of Health and the Ministry for Primary Industries (MPI) in specific scenarios, as discussed in Appendix 1.

12.4. Communication with the public and media

Public and media communication skills are often synonymous, so are considered together in this guide. The communication plan should identify a single individual, team, or agency responsible for responding to media enquiries and for managing public communication. All media enquiries should be directed to this individual or agency. It may be appropriate to have multiple key spokespeople, for example, a spokesperson for local issues and another spokesperson for national enquiries.

Media communication during an outbreak is made considerably easier if the organisation has built a positive and co-operative long-term relationship with the media, often with a specific contact person. This means that a solid framework is in place when outbreaks (and other events) occur, and

media communications become easier and more effective. The credibility of the organisation combined with trained personnel is the strongest combination for success in this area.

12.4.1. Positive and negative aspects of media/public communication

Communicating with the public and media may assist with the immediate outbreak investigation and control, and also with longer-term health goals. It gives the capacity for providing essential advice on initial control measures to large numbers of people quickly, while at the same time providing an opportunity to deliver important health promotion messages relevant to the outbreak (e.g., behavioural changes, food hygiene practices).

Another important function is that communicating with the public and media provides early, accurate and on-going information about the situation, even if uncertainty exists, and about the progress of the investigation. A vacuum of no information will invariably be filled by less accurate sources and can damage trust in, and the credibility of, the lead agency responsible for managing the outbreak.

The value of communicating well cannot be understated. If not done well, it can lead to mistrust, misrepresentation or distortion of the facts, undue sensationalisation of the outbreak or give the impression that a local problem is of national scale.

Understanding the principles of risk communication and risk perception has progressed considerably in recent years. Sandman⁶³ has developed eight general guidelines for public communication by epidemiologists that are also likely to be relevant for communicating about outbreaks and their investigation [the WHO principles for risk communication⁶⁴ are also extremely helpful].

<http://www.psandman.com/articles/who-srac.htm>

- Tell the people who are most affected what you have found, and tell them first.
- Make sure people understand what you are telling them and what you think the implications are.
- Develop a mechanism to bolster the credibility of your study and your findings.
- Acknowledge uncertainty promptly and thoroughly.
- Apply epidemiological expertise where it is called for and do not misapply it where it is unlikely to help.
- Show respect for public concerns, even when they are not scientific.
- Involve the affected people in the design, implementation and interpretation of the investigation.
- Decide that communication is part of your job and learn its basic principles.

12.4.2. General strategies to improve media communication

- Understand the needs of the media, notably deadlines and the specific requirements of print media, radio and television.
- Coordinate information among the agencies involved in the outbreak.
- Appoint a single spokesperson, if possible. For longer responses this will not be possible, as rotation of key staff becomes an important part of maintaining effective human resources.

- Identify the main communication message. This message is the ‘single overriding communication objective’ (SOCO). Make sure that the SOCO is clearly stated in simple language and in a brief well-defined sentence to make it easy for the journalist or editor to insert into news bulletins.
- Be proactive, for example, by announcing findings with a press release or calling a press conference.
- Manage a regular flow of information updates, for example, by having a regular briefing time.

12.4.3. Strategies to improve media interviews

12.4.3.1. Screening

When contacted by a reporter, first of all find out why they want an interview, what they wish to cover and their deadline. This will also assist in deciding if you are the most appropriate person to do the interview, and, if not, the matter should be referred on. If you will be speaking, obtain any necessary clearances prior to the interview.

12.4.3.2. Preparation

Arrange details for the interview (e.g., time, place) after you have had time to prepare, and negotiate limits so that questions are of appropriate breadth and depth – staying within your area and level of expertise.

Identify a SOCO ahead of time, and prepare and rehearse key message(s), phrases, and soundbites.

12.4.3.3. Location

Radio and television interviews can go better when they are done in a studio with the interviewer, but this is not always possible. In terms of live versus recorded interviews, there are pros and cons with each. For example, live interviews will be broadcast (the first time) unedited and this could be an advantage if the message is accurate, authoritative and acceptable.

12.4.3.4. Effective performance during interview

It is important to provide accurate information. With this in mind, tell the truth and do not exaggerate, if you make a mistake, correct it, and if you do not know, say so. You may be able to offer to find and provide more information later that day.

It is also important to communicate information effectively. Therefore, get your message in early, repeat it if necessary, and say it in an interesting way. Use simple language and avoid jargon.

12.4.3.5. Follow-up

Review the item once it has been published or broadcast, and assess your performance. Correct any errors or misrepresentations with the reporter.

12.4.4. Writing a press release

A press release does not need to read like a finely crafted journal article, but it should be written in a way that captures the journalist's interest and provides the facts necessary for an article to be developed subsequently. A press release should be brief (one to two double-spaced pages) and written simply; it should be written so that the general public can understand it, not include jargon or technical terminology, or assume that the reader has any prior knowledge of the subject that is being discussed. To grab the journalist's attention, the most important information should be at the beginning of the release, followed by the details (or an explanation of the most important points)⁶⁵.

General media principles to consider in all significant foodborne outbreak situations involving food outlets

The following section deals with a sensitive area that needs to be tackled with caution always bearing in mind that one is dealing with the livelihood of employees involved while trying to safeguard public health.

Infected food handlers can transmit infection to patrons and co-workers while attending to their usual duties. Bacterial (e.g., salmonellosis), viral (e.g., hepatitis A) and protozoal (e.g., giardiasis) infections can easily be spread due to poor hygiene. Different situations may require specific interactions with the media, but some general principles regarding media contact will apply in most situations. It is usually necessary to identify and inform users of a facility or patrons of a food outlet to warn and advise them about the situation and/or provide post-exposure prophylaxis. It may at times be necessary to contact patrons via the media. If such a decision is made, the institution or food outlet facility management should be informed about the requirement to go public to protect public health, and their cooperation sought at the outset. The medical officer of health (or representative) should initially:

- make every effort to obtain accurate information and make informed judgments about its veracity
- consider the past history of the institution's/food outlet's performance
- determine the current status of food hygiene training, supervision and performance evaluation
- ascertain the availability and application of an approved hazard control procedure
- enquire about protocols for handling high-risk foods, hand hygiene practice, wearing of gloves, masks and head covers, reporting illnesses of significance and unintentional contamination of foods
- undertake a careful risk assessment using above information.

(High-risk food is defined as food that is handled and not subsequently cooked before consumption, e.g., salad fixings, cake icing and sliced fruit.)

Decisions to be made by the medical officer of health include measures to be taken to warn the public (or at least potentially exposed persons) about the situation. This will also enable detection of more cases, thereby facilitating a more comprehensive investigation. However, such action could jeopardise business for the establishment involved (if named) or reduce consumption of the implicated food(s) in general. It may also introduce bias into any epidemiological study being conducted.

In such situations, all aspects should be carefully considered, with the need to protect the public being paramount. In almost all situations it will be necessary to contact the Ministry of Health as well as the Ministry for Primary Industries, as early as possible.

The following criteria should be followed for an informed evaluation of the situation and decision-making before deciding whether to contact the media. Of the scenarios shown below, only scenario 3 may be considered for media involvement.

1. The infected food-handler has not handled any foods, particularly high-risk foods. Contacting potentially exposed persons is rarely necessary (with the exception of co-workers of a person infected with hepatitis A).
2. High-risk foods have been handled by the infected worker, but staff (including management) has received food safety training and use an approved hazard control system. The potential for deviations from safe practice should be fully investigated. Public notification is usually not indicated if the following conditions are met:
 - a. there has been no transmission to fellow workers or patrons (this may not be known at the time for hepatitis A)
 - b. on routine inspection, standards have been met currently and in the past
 - c. audited protocols for hand-washing are in place and facilities for employees are adequate
 - d. the infected food handler followed good hand-washing practices (as verified by co-workers and management).
3. High-risk foods have been handled by the worker who is ill and staff (including management) has not received food safety training and do not have an approved hazard control system. Notification of potentially exposed persons via the media should be considered if:
 - a. other workers are already ill with a significant illness
 - b. hand-washing facilities are inadequate
 - c. toilet facilities are poor and unclean
 - d. hand-washing is not the norm among food handlers
 - e. past audit records are unsatisfactory
 - f. the infected worker has handled high-risk foods
 - g. food-handlers did not wear gloves.

Adapted from the draft Australian Hepatitis A Guidelines for Public Health Units⁶⁶

12.5. Communication with the Ministry of Health and ESR

It is good practice to inform the Ministry of Health (plus the Ministry for Primary Industries where relevant) and ESR during the early stages of any significant outbreak investigation. This may not need to be anything other than a courtesy call, but ensures that the national implications of the outbreak investigation have been considered. If necessary, a representative of the Ministry of Health and/or ESR may be included as part of the wider outbreak team. This will be important for communication at a national level, and to facilitate the incorporation of the statutory authority of the Director-General of Health, if necessary. Ministry of Health representatives may also be best placed to manage communication with other government agencies, such as the Ministry for Primary Industries, the Ministry of Foreign Affairs and Trade and the Ministry of Education. Involvement of the Ministry of Health and ESR is particularly important if the outbreak has national importance or crosses health district regions (as discussed in Appendix 1), or has international implications.

12.6. Communication with other agencies

12.6.1. Health workers

The communication plan should include contingencies for communicating with local general practitioners, hospitals and other health services. Do not work in isolation –involvement of PHS workers may assist case finding, will provide an opportunity to demonstrate the importance of disease surveillance activities and may provide further insight into the causes of the outbreak. Communicate with health workers either selectively, through predetermined contact points (i.e., emergency department chief or clinical manager for a primary care organisation), or by broadcast to individual workers by fax or email.

12.6.2. Industry groups

Communication with industry groups will depend on the nature of the outbreak and the stage of confirmation about the outbreak source. In general, make contact with industry groups only when there is a reasonable degree of certainty about the outbreak source, but try to make contact and provide a briefing before the general media become involved. As discussed in Chapter 9 on environmental investigation, state your suspicions and concerns precisely, without embellishment, and describe the plan for further investigation. If the industry group has national responsibility, it may be appropriate to involve the Ministry of Health, either to be party to discussions or to lead communications.

12.6.3. Local authorities

If local authorities (territorial authority or regional council) have jurisdiction over the type of setting for the outbreak, make sure that a representative has been contacted at an early stage. It may be appropriate to have a local authority representative as a member of the outbreak team.

12.7. Debrief following outbreak investigation and response

The completion of the outbreak investigation and response should be followed by a meeting to review the process. The focus of the meeting should be on critically examining aspects of the investigation that did and did not go well, with the aim of developing some constructive recommendations to improve future outbreak investigations.

This debriefing meeting should involve all of the core outbreak team, and sometimes members of the outer team, for example, representatives from laboratories. The issues addressed and recommendations emerging from the debriefing meeting should be documented in an outbreak report, as described in Chapter 13. In particular, consider whether there are matters of relevance for other agencies, such as other PHSs, the Ministry of Health or ESR. These matters could either be communicated directly, included in an outbreak report, or be published in a locally or internationally peer-reviewed journal.

The aim of organisational debriefing is for staff to communicate their work related experience of an outbreak to their own team and to any others who may subsequently be involved in outbreak investigation (and control). This is necessary so that the strengths and weaknesses of the response can be captured and incorporated into planning and training in the pursuance of best practice, to enhance the organisation's ability to respond optimally to future outbreaks.

The Incident Controller in consultation with the other CIMS Managers has responsibility for deciding the timing, location and framework of the debrief meeting. Three types of debrief are relevant, the 'hot' debrief, internal organisational 'cold' debrief, and multi-agency 'cold' debrief.

12.8. Hot Debriefs

The overall responsibility for ensuring the debrief takes place belongs to the Incident Controller for the outbreak. The key features include:

- Holding immediately after the outbreak response or shift (if a large outbreak) is completed
- Allows a rapid 'off-load' of issues and concerns
- Should address key health and safety issues
- Provides an opportunity to thank staff and provide positive feedback
- May be facilitated by a number of people in the organisation
- A number of hot debriefs may be held within the organisation simultaneously in each work area to identify key issues by area

12.9. Cold Debriefs

The cold debrief should be organised within two to four weeks of the end of the outbreak by the Incident Controller for the outbreak. However, if the outbreak continues to be managed over the medium to long-term it may be necessary to hold regular internal organisational debriefs at key milestones. The key features of the cold debrief should:

- Involve the same key players who were involved in the response and other people the recommendations may impact
- Address organisational issues not personal or psychological issues
- Look for both strengths and weaknesses as well as ideas for future learning
- Provide an opportunity to thank staff and provide positive feedback (may like to put on a morning tea)
- Be facilitated by a range of people within the organisation
- Appoint an administration person to take minutes to allow all participants to participate fully

12.10. Multi-Agency Debriefs

In the event of a multidistrict outbreak or where the outbreak response involved significant contribution from more than one organisation a multi-agency debrief will need to occur. The key features of the cold debrief should:

- Be held within six weeks of the outbreak. If the outbreak continues to be managed over the medium to long-term it may be necessary to hold regular multi-agency debriefs at key milestones
- Focus on the effectiveness of inter-agency coordination
- Address multi-agency organisational issues not personal or psychological issues
- Look for both strengths and weaknesses as well as ideas for future learning

- Provide an opportunity to thank staff and provide positive feedback
- Most likely be facilitated by ESR as the incident control point
- Form part of a tiered debriefing process, e.g. Public health units/agencies, followed by representatives contributing to a debrief of government agencies at a national level

12.11. Pre-Debrief Planning

The following actions should take place to prepare for debriefing:

- Send invitations to all those involved
- Confirm attendees and set the length of the debrief depending on the number attending
- Confirm venue and set-up (around a table (preferable if numbers permit), seats in rows (if large group))
- Create an agenda
- Create a feedback template
- Email debrief feedback template to all participants prior to the debrief meeting for completion and to formulate their thoughts and to handover for collation. It also allows those who are unable to attend to provide their input.
- Prepare an outbreak summary to set the scene which may include maps, graphs etc.

12.12. Debrief Ground Rules

It is important to set ground rules when undertaking a debriefing session to ensure the process and environment are safe for all participants and encourage active participation from all. Key features include:

Conducting the debriefing openly and honestly

Don't interrupt other people as each person is entitled to their own opinion

If the issue has already been identified there is no need to return to it

No one person should monopolise the debriefing

Be about organisational understanding and learning

Be consistent with professional responsibilities

Respect the rights of individuals

Value equally all those concerned

Be about learning not assigning blame.

12.13. Debrief Agenda

A successful debrief needs to be structured to make the most of the participants' time and experiences. It is best to start with the positives, move on to what might have been done better and conclude with positive take home messages.

The proposed agenda for debriefing should resemble the following:

- Introduction
 - Welcome participants
 - Overview of the debrief
 - Use of the debrief template
- Review of the outbreak by Incident Controller
- Work through sections on the debrief template with discussion
 - What were the most positive aspects of the response
 - What were the least successful aspects of the response
 - What was the most significant thing learnt during the event
 - What could be done better next time
 - General comments
- Summarise the action points developed from the discussion
- Thank participants for the input and assistance.

12.14. Recommendations and Action Points

Dealing with the output from a debrief should include the following:

- The minute taker should complete the minutes within 24-48 hours of the debrief and forward to the Incident Controller. Comments can be grouped into themes.
- The Incident Controller should review the minutes and action points and forward to all who attended the debrief and line management if appropriate.
- The Incident Controller should assume responsibility the action points/recommendations, or delegate to an appropriate staff member (Medical Officer of Health/Disease Investigators/Manager) to oversee their completion
- Recommendations should be incorporated into the conclusions and recommendations section of the outbreak report by the author(s)
- Action points need to be assigned to the relevant staff member(s) with a timeframe for completion
- The Incident Controller/Delegated Staff member needs to check to ensure that all action points are completed within one to two months of the debrief.

12.15. Further Information

Further information on Organisational Debriefing is contained in the Ministry of Civil Defence and Emergency Management 'Organisational Debriefing' document which can be accessed at the following link:

http://www.civildefence.govt.nz/memwebsite.nsf/Files/Information_Series/file/DeBriefingBook.pdf

13. Documentation

13.1. Documentation of outbreaks and investigations

High quality, comprehensive documentation of all recognised outbreaks is essential for any disease surveillance system because:

- national collection of outbreak data facilitates the recognition of relationships between events occurring in different areas of the country, such as the identification of widely dispersed outbreaks
- the reports can be used to convince health professionals and the public of the need for preventive measures
- documentation of outbreaks may be used to evaluate and improve prevention strategies
- it is rarely, if ever, possible to identify risk factors for disease from single, sporadic cases. Almost all risk factors are identified from investigations of outbreaks or groups of cases
- understanding of emerging diseases may be improved, especially modes of transmission and risk factors
- reports can be used as teaching aids for diseases and outbreak investigation, including identifying how future outbreak investigations may be improved
- outbreak investigations are generally improved through the discipline of systematic and comprehensive documentation
- local and national statistics on outbreak occurrence can more readily be compiled when a uniform approach to their recording is used
- it may be necessary for the fulfilment of international reporting requirements, especially if the disease is one where eradication is expected.

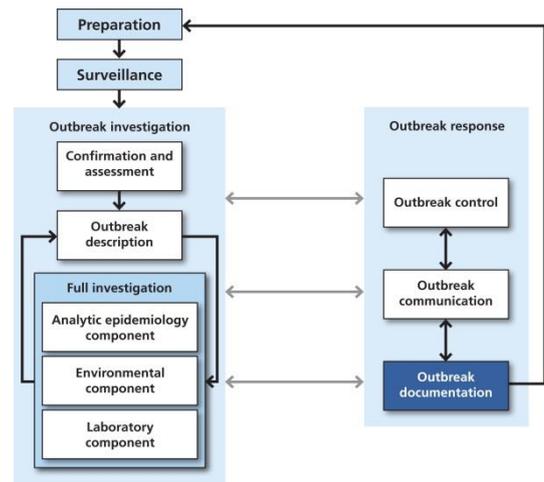
This document describes two levels of outbreak documentation. Whether both levels occur in a particular investigation will depend on the extent of the outbreak and its investigation.

13.2. Routine outbreak documentation

Document preliminary and final outbreak data onto the Outbreak Report Form included in EpiSurv, the national notifiable disease database. A copy of the form is provided in Appendix 8. Use the outbreak number assigned by EpiSurv for all food, water and other environmental samples submitted to the laboratory for analysis. The Outbreak Report Form in EpiSurv should be updated periodically as the investigation progresses.

13.2.1. Level one documentation: the Outbreak Report Form

Documentation and reporting using the Outbreak Report Form is the basis of the Outbreak Surveillance System, coordinated by ESR. Documentation on the Outbreak Report Form facilitates systematic recording of the early details of the outbreak, thereby providing information for a



decision on whether and how to proceed further. This information can also be used as a basis for discussions with the Ministry of Health and ESR, and contributes to the recognition of linked, multi-district outbreaks and early control measures.

Completed Outbreak Report Forms are also used in the production of local and national statistics on outbreak occurrence, including causal agents, modes of transmission and risk factors. Data are also commonly used in research projects.

13.2.2. Level two documentation: the Outbreak Investigation Report

A higher level of detail about the investigation can be documented in a formal Outbreak Investigation Report. These reports record the full details of the methods, results, discussion and recommendations from the outbreak investigation in a form suitable for wider distribution and possible publication. Preparation and dissemination of an Outbreak Investigation Report ensures that the investigation process is open for peer review, and that the findings can have an impact beyond the local circumstances.

Outbreak Investigation Reports can be circulated directly among other agencies, or disseminated using pre-existing communication networks such as FoodNet, OzFoodNet and the New Zealand equivalent, <http://www.foodsafety.govt.nz/>, the monthly ESR surveillance report and the New Zealand Public Health Surveillance Report (<http://www.esr.cri.nz>). Please attach a copy of all Outbreak Investigation Reports to the EpiSurv record so that details can be included in the monthly surveillance report and considered for inclusion in the New Zealand Public Health Surveillance Report. A suggested format for such reports is included in Appendix 9.

Documentation of procedures used in multi-district outbreaks is important. The Outbreak Control Team (OCT) in the New Zealand situation largely consists of representatives from the MoH, the relevant DHB's, ESR, and other concerned ministries (usually MPI). Their functions are detailed in Appendix 1. Formal procedures for establishing an OCT and dealing with the outbreak (including media contact) need to be established. Coordinated outbreak control plans with detailed check lists whilst ideal have not been considered as being essential in the local situation. Robert Weir in a draft (unpublished) report to ESR entitled Review on aberrant disease detection, referral, prioritisation, investigation, reporting, and management processes in New Zealand (January 2008)⁶⁷ includes examples of such documents from other countries such as Canada, USA and Scotland. These are not included in these guidelines but are available on request from ESR.

14. Conclusion

This guidelines document presents a unified framework for outbreak management in New Zealand. The document builds substantially on previous sets of guidelines by adding sections on environmental and laboratory aspects of outbreak investigation to the section on epidemiology, and by describing outbreak management (control, communication and documentation). As such, the document encompasses the entire range of outbreak response activities.

The title of the document has been changed to reflect more closely its particular focus on food- and water- borne outbreaks. However, it must be emphasised that the main sections on epidemiological methods, intra- and inter- agency communications and structural responses, including CIMS, could apply equally to other outbreak situations.

The guidelines document also shows that the interrelationships between the different components of outbreak management do not necessarily occur in a linear and progressive sequence. Outbreak management must be adapted to the circumstances of each outbreak as it emerges. It is important to adopt a flexible approach to outbreak management, and the document is therefore presented as a series of independent modules that do not necessarily have to be conducted in sequence during an outbreak investigation.

Nothing is ever perfect. Modification of this document is expected over time in response to comments by users. Aspects of the guidelines that require further clarification or expansion should be communicated to ESR. We expect the web-based version of this document to facilitate future revisions, updates and amendments in a timely and ordered manner. We hope that this updated document continues to contribute to improved outbreak management in New Zealand.

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16. Appendix 1: Agency roles and responsibilities for outbreak management

16.1. Introduction

This appendix provides a framework for the roles and responsibilities of agencies in managing disease outbreaks. The framework describes the:

- core roles and responsibilities of different agencies in managing disease outbreaks, both at a district and national level
- specific roles and responsibilities under outbreak scenarios that involve overlap between agencies.

Agencies referred to in this framework include PHSs (considered collectively), the Ministry of Health (MoH), the Ministry for Primary Industries and the Institute of Environmental Science and Research Limited (ESR). It is beyond the scope of this appendix to describe the roles and responsibilities of other agencies.

The need for such a framework has been prompted by the recognition that emerging forms of outbreaks and causative pathogens require an explicitly coordinated outbreak investigation and response beyond the level of individual PHSs. It aims to complement, but not replace existing outbreak management plans.

The framework assumes an environment where resources are available to undertake the roles and responsibilities, that the breadth and quality of national surveillance data steadily improve, and that legislative measures support optimal outbreak investigation. One important improvement has been the direct laboratory reporting of infectious diseases to improve the sensitivity of national surveillance, thereby enhancing outbreak detection and management.

16.2. Glossary of terms used in this appendix

Localised outbreak	Outbreak in which all transmission is occurring or has occurred in an area covered by a single PHS
Localised outbreak with distributed cases	As for localised outbreak, but one in which the cases have been identified in more than one PHS area
Multi-district outbreak	Outbreak in which transmission is, or is suspected to be, occurring in more than one PHS area
Outbreak of national importance	Localised outbreak that is highly likely to become a multi-district outbreak, or is of heightened national importance (see later criteria)

16.3. General roles and responsibilities

This section describes the overall outbreak management roles and responsibilities of PHSs, ESR, MoH and MPI. Roles and responsibilities at eight critical steps of outbreak management are described: preparation, routine surveillance, outbreak identification, outbreak description, outbreak investigation, control, communication and documentation and reporting.

16.3.1. Step 1: Preparation

PHS responsibility	ESR responsibility	MoH responsibility	MPI responsibility
<ul style="list-style-type: none">• Development of outbreak plans• Designation of PHS outbreak coordinator• Identification of outbreak management team that can cover all important outbreak scenarios• Maintaining appropriate levels of outbreak management skills• Assembling materials required for investigation, including questionnaires	<ul style="list-style-type: none">• Designation of ESR outbreak coordinator• Identification of outbreak management team that can cover all important outbreak scenarios• Development of standardised investigation resources, including guidelines, protocols and questionnaires• Maintenance of statistical software skills within ESR• Conducting outbreak training courses for district PHS officers, including outbreak simulations	<ul style="list-style-type: none">• National outbreak planning (including across Government plans)• Funding development of national investigation resources and training courses	<ul style="list-style-type: none">• Resourcing for the development of national investigation resources and training courses for Food Act Officers• Administering food safety and hygiene measures consistent with the risk management framework• Consumer protection via effective monitoring of legislation and regulation• Ensuring a “whole of government” approach to food-related policy advice• Managing the Australia New Zealand Joint Food Standards Treaty• Providing advice to local and central government as well as international agencies on all food safety issues

16.3.2. Step 2: Routine surveillance

PHS responsibility

- Operation of a comprehensive infectious disease surveillance system at the district level
- Collection of notifications and data on laboratory-identified cases
- Collection of data on self-reported cases and other 'informal' reporting sources
- Integration of local surveillance data from multiple sources
- Collection of descriptive information on individual cases of disease with outbreak potential

ESR responsibility

- Coordination and development of a comprehensive disease surveillance system at the national level
- Collation of EpiSurv data
- Collation of results of specialised laboratory tests
- Integration of laboratory and surveillance data
- Calculation of national and district disease incidence
- Dissemination of national surveillance information
- Maintaining links with international disease and laboratory surveillance systems

MoH responsibility

- Funding for infectious disease surveillance system
- Strategic planning for infectious disease surveillance
- International reporting obligations
- Providing an appropriate legislative framework

MPI responsibility

- Coordination and development of a comprehensive animal disease surveillance system at the national level
 - Integration of laboratory and surveillance data for animals and food
 - Dissemination of national surveillance information
 - Maintaining links with international zoonotic disease and laboratory surveillance systems
 - Providing an appropriate legislative framework, including the administration of food-related legislation
-

16.3.3. Step 3: Outbreak identification

PHS responsibility

- Regular examination of surveillance data to detect increases in disease incidence and common risk factors (see A.2 in next section)
- Maintenance of effective systems to receive and evaluate reports of outbreaks from local health professionals and other agencies

ESR responsibility

- Regular review of laboratory and notification data to detect dispersed outbreaks, particularly those where cases are being reported from multiple health districts (see C.2)

MoH responsibility

- Identification of national outbreaks

MPI responsibility

- Resourcing national outbreak identification systems for zoonotic diseases
-

16.3.4. Step 4: Outbreak description

PHS responsibility

- Collection of information on cases involved in outbreaks
- Development of outbreak case definition
- Characterisation of outbreak by person, place and time
- Development of hypotheses
- Identification of the need for further investigation (see A.3)

ESR responsibility

- Provision of assistance to PHSs in the interpretation of descriptive information
- Descriptive analysis of information collected by multiple PHSs
- Development of standard case definitions
- Identification of the need for the investigation of national outbreaks (see C.3)

MoH responsibility

- Resourcing / funding national capacity for outbreak description
- Development of standard case definitions

MPI responsibility

- Resourcing national capacity for outbreak description (Food Act Officers)
-

16.3.5. Step 5: Outbreak investigation

PHS responsibility	ESR responsibility	MoH responsibility	MPI responsibility
<ul style="list-style-type: none">• Undertaking epidemiological investigation, if appropriate (see A.4)• Undertaking environmental investigation, if appropriate (see A.4)	<ul style="list-style-type: none">• Providing assistance with PHS epidemiological investigation, on request• Coordinating or conducting national epidemiological investigations (see C.4)• Advising on sampling and testing• Testing environmental and biological specimens	<ul style="list-style-type: none">• Contributing to discussion about investigations• Providing clinical and regulatory assistance to PHSs, as required• Coordinating multiple PHS investigations, as required• Providing input and coordination with other sectors and agencies	<ul style="list-style-type: none">• Designation of a national outbreak coordinator once a food source is suspected• Contributing to discussion about investigations• Environmental investigation of food premises and farms/produce sources

16.3.6. Step 6: Outbreak control

PHS responsibility

- Implementation of measures, including those requiring medical officer of health authority to control and prevent outbreaks

ESR responsibility

- Advice on control measures

MoH responsibility

- Implementation of control measures with national or international significance
- Advise on implementation of control measures that involve special legislative or ministerial powers
- Coordinating control measures requiring collaboration with other agencies and sectors

MPI responsibility

- Leading the outbreak control activity when a commercially important food item has been identified as the probable cause
 - Collaborating with other agencies and industry
 - Taking food samples
 - Enforcement following investigation of food premises, including seizure, closure and prosecution
-

16.3.7. Step 7: Communication

PHS responsibility	ESR responsibility	MoH responsibility	MPI responsibility
<ul style="list-style-type: none">• Communication with the public, media and health sector on local-level issues, including District Health Board policy and local situation• Immediate reporting of 'outbreaks of national importance' to ESR, MPI and the MoH (see B.1)• Communication with the media about district outbreaks• Communication with local government and local industry groups• Communication with other PHSs	<ul style="list-style-type: none">• Coordination of communication during national outbreak management (see C.4)• Regular reporting to the public, media and health sector about the outbreak situation, in consultation with the MoH	<ul style="list-style-type: none">• Communication with the public, media and health sector about national-level issues, including Government policy and the national situation• Communication among central government agencies• International communication	<ul style="list-style-type: none">• Advice to consumers• Communication with industry groups• Note: Outbreaks associated with drinking-water supplies will involve suppliers and the Ministry for the Environment, in addition to the MoH as the regulator

16.3.8. Step 8: Documentation and reporting

PHS responsibility

- Assigning the outbreak number to the outbreak and the identification number to each case involved
- Documentation of the outbreak
- Timely and accurate reporting of all outbreaks via the outbreak surveillance system. Initial reports within one week of recognition, updated weekly, final record within one week of completion
- Report dissemination to local government and local industry groups

ESR responsibility

- For each national outbreak investigation being coordinated by ESR, assigning the outbreak number to the outbreak and the identification number to each case involved
- Operation of an active outbreak surveillance system
- Compilation of the annual outbreak surveillance summary
- Documentation and dissemination of outbreak reports through the MoH (coordinated by ESR)

MoH responsibility

- Resourcing for outbreak reporting by ESR
- Outbreak reporting at central Government level
- Report dissemination

MPI responsibility

- Recording all premises-related actions
 - Report dissemination to industry
-

16.4. Roles and responsibilities in specific scenarios

There are two important decision points with regard to outbreak management: the decision to begin a formal investigation of an outbreak that appears to be confined to a single health district; and the decision to begin a formal investigation of an outbreak that appears to be spread across multiple health districts. Both these scenarios reflect uncertainty about the criteria to 'upscale' the outbreak investigation and response. Of necessity, these criteria must be flexible: there will always be exceptions that will require a more or less intensive approach than that suggested here. These criteria should be used as guidelines only.

16.4.1. Outbreaks confined to a single PHS area

These are outbreaks where most disease transmission is occurring in a single PHS area, and all or most cases are being detected there. The general principles that apply are described next.

16.4.1.1. PHSs have overall responsibility for managing the outbreak investigation and response where the outbreak source is in their geographic area, unless the outbreak is of national importance.*

This responsibility includes:

- on-going routine surveillance for cases of disease with outbreak potential
- regular reviews of surveillance data to identify potential outbreaks
- routine assessment of identified outbreaks to determine which require further investigation and response (see A.3)
- implementation of outbreak investigation and response activities, including description, investigation, control and reporting for all identified outbreaks that have been prioritised.

16.4.1.2. The sensitivity of local surveillance systems for outbreak identification should reach nationally agreed performance standards.

Standards for outbreak identification use a scale based on the impact or potential impact of particular causal agents and the potential for effective public health preventive or control measures. This scale was developed for outbreak identification at the national level¹. Each pathogen with outbreak potential is placed into one of three performance levels of sensitivity expected for outbreak detection.

Performance level 1:	Rapid and complete identification critical for all outbreaks, regardless of size
Performance level 2:	Rapid and complete identification of outbreaks with approximately five or more cases
Performance level 3:	Rapid and complete identification of outbreaks with approximately 10 or more cases

* For definition of outbreaks of national importance, see **16.4.2**

Table A1 contains suggested performance levels for outbreak identification by PHSs, based on outbreak scenarios and causal agents. It should be emphasised that each situation must be judged on its own merits and decisions to act urgently should be made as appropriate, based on risk assessments.

Table A1: Dispersed food or waterborne pathogens

	Performance level
VTEC/STEC	1
L. monocytogenes	1
Salmonella	2
Hepatitis A	2
Shigella	2
Cryptosporidium	2
Giardia	2
Campylobacter	2
Norovirus	3
Rotavirus	3
Food-borne intoxicants	3

Pathogens transmitted person to person

	Performance level
Polio	1
Pandemic influenza A	1
Neisseria meningitidis	1
Measles	1
Tuberculosis	2
Pertussis	2
Mumps	2
Rubella	2
Hepatitis A	2
Enteroviridae	2
Adenoviridae	2
Influenza A	3
STIs (gonorrhoea, chlamydia, syphilis)	3

Environmental agents

	Performance level
Arbovirus acquired locally	1
Legionella	2
Chemical poisoning	2
Lead absorption	2
Leptospirosis	2

Pathogens acquired in institutional settings

	Performance level
MRSA	2
Other hospital pathogens	2

16.4.1.3. PHSs systematically assess all identified outbreaks to decide whether further investigation is needed.

Having identified and described an outbreak, and taken initial control measures, the key decision point is whether the outbreak investigation should be expanded.

The principal criterion for further outbreak investigation is that the PHS has insufficient information to take effective prevention and control measures. Such action usually requires knowledge of the mode of transmission and source, but not necessarily the agent involved.² This information will often not be known for dispersed food- and water- borne outbreaks, and some environmental outbreaks, so further investigation is usually required.

Other criteria that encourage further outbreak investigation include the following:

- the outbreak is continuing (i.e., there is evidence of on-going transmission)
- similar outbreaks have occurred before, or are expected in the future, and more information is needed to develop preventive measures
- the outbreak is having, or likely to have, a very high impact on public health because of its size and/or the severity of illness
- the outbreak has attracted public, media or political interest
- the outbreak transmission route is new or unusual
- the causative agent is unknown
- descriptive characteristics of the outbreak (time, place, person or organism subtype) suggest that a common source is highly likely.

16.4.1.4. PHSs investigate outbreaks using an optimal combination of methods.

PHSs should be familiar with key outbreak investigation approaches, and be able to appropriately design an investigation, using one or more approaches, to match the circumstances of the outbreak. Key outbreak investigation approaches are described in the main body of this manual – analytic epidemiological investigation, environmental investigation and laboratory investigation. Not all these approaches will be appropriate for all outbreaks, but the role of each should be considered. The manual also contains suggested criteria for determining the mix of outbreak investigation approaches.

16.4.1.5. For all identified outbreaks, PHSs should assess whether they have sufficient local capacity to undertake the outbreak investigation and response, and arrange for additional assistance, if required.

Effective outbreak management activities can require substantial resources and expertise. In some situations, these requirements may exceed the available capacity of individual PHSs. Once an outbreak has been identified, it is important that PHSs objectively assess their ability to undertake a thorough outbreak investigation and response. If insufficient capacity or expertise is available, support must be sought from other sources. Options for additional support include collaborating with:

- *another PHS*: In many cases, adjacent PHSs (especially if larger services) may be able to allocate capacity to assist the outbreak investigation and response. It is important to reach an agreement in advance about the overall leadership and accountability for the joint outbreak investigation and response
- *ESR*: ESR has expertise in outbreak investigation, and may be able to actively assist PHSs, over and above basic outbreak advice (discussed in Chapter 1 of the guidelines). This assistance may include participation in study design and assistance with conducting the investigation and data analysis.

16.4.2. B. Localised outbreaks of national importance

Outbreaks that appear to be confined to a single PHS area are defined as having national importance if there is a high potential for dispersal and transmission beyond the PHS area, or if the characteristics of the pathogen suggest that the outbreak has high national importance. This section presents criteria for defining an outbreak as being of national importance and proposes a framework for information flows should any such outbreak be detected.

The criteria that define an outbreak as being of national importance are described next. They are based partly on similar criteria developed in Australia.³

- *The outbreak is linked to a nationally distributed product*: Outbreaks linked by local investigation to a product that has a national distribution, such as a manufactured food item, have the potential to affect individuals in many health districts simultaneously. In these situations MPI must be informed as early as possible.
- *Case(s) of exotic disease acquired locally*: All cases of illness due to communicable diseases that are not endemic in New Zealand should be investigated rapidly to confirm whether the illness has been acquired locally or from overseas. Locally-acquired exotic disease (e.g., dengue fever, Ross River fever) are of national importance. In most of these situations the WHO should be informed through the MoH.

- *Diseases with high pathogenicity:* Outbreaks of highly virulent organisms (e.g., VTEC/STEC, L. monocytogenes) are likely to cause heightened public concern, and may require technical expertise and collaboration at a national level. In these situations MPI must be informed as early as possible.
- *Outbreaks in tourist facilities or at national/international events:* Outbreaks involving tourist facilities or national/international events are likely to rapidly spread as guests return to their health districts (or countries) of origin. In these situations there are likely to be specific lines of communication to other agencies. It is essential to keep the MoH (and if necessary MPI and any other relevant ministries or organisations) informed
- *Outbreaks associated with health service failure:* Outbreaks linked to breakdowns in standards of health care delivery, such as infection control failure, blood product contamination or systematic immunisation failure, will require a strategic national approach.
- *Outbreaks associated with travel:* Outbreaks associated with travel (e.g., cruise ships, airplanes and coaches) pose specific problems. Norovirus outbreaks, for example, on cruise ships have resulted in targeted public health measures being put in place for their control in recent times. Air travel poses specific problems linked to contact tracing involving other countries where rapid communication is essential. Outbreaks occurring in tourist coaches moving through different District Health Boards over short periods of time, also pose challenges. (Gastroenteritis and Coach Travel – A Guide for Tour Operators. Wellington - Ministry of Health, March 2010. Communicable disease publications). A number of diseases trigger international reporting obligations, especially if the source(s) or contacts are overseas, and should be reported to the MoH.

The following principle will apply in response to outbreaks of national importance:

16.4.2.1. PHSs are required to consult with ESR and the MoH if the outbreak has national importance

1. The PHSs retain responsibility for managing these outbreaks according to the principles described in A (Outbreaks confined to a single PHS area), but with the following addition:
 - a. upon identification of an outbreak that meets national importance criteria, the outbreak coordinator in the involved PHS
 - b. will immediately inform the outbreak liaison person in MoH and ESR by telephone and email. If a widely distributed food product is suspected, MPI must be informed.
2. The MoH outbreak liaison person will:
 - a. prepare any national plans, including media and international communication plans, if appropriate
 - b. initiate national communications across PHSs, the health sector and public, as appropriate.
 - c. liaise with ESR, as required, regarding national surveillance implications and, if required, ensure national monitoring and reporting are in place.
3. The ESR outbreak liaison person will:
 - a. implement a plan to intensify surveillance for the disease, if required
 - b. liaise with the PHS outbreak coordinator in providing appropriate tools and expertise to investigate and manage the outbreak
 - c. analyse and report on the distribution of disease nationally in consultation with the MoH

- d. if the causal agent is known, ESR may encourage local PHSs to collect additional relevant descriptive information on these cases
- e. if the causal agent is not identified, then ESR may introduce a system for informal reporting of the disease syndrome.

16.4.3. C. Outbreaks crossing multiple PHS areas

Two types of outbreaks involve multiple PHSs.

- *Localised outbreaks with distributed cases* – outbreaks where transmission occurs in a single PHS area, but cases are detected in other areas. This situation might apply to common event or environmental outbreaks when people then disperse to different parts of New Zealand, where they subsequently become ill.
- *Multi-PHS outbreaks* – outbreaks where transmission occurs in multiple PHS areas. This situation is most likely to occur with dispersed food- and water- borne outbreaks where the contaminated food or water is consumed in multiple places.

The important distinction here is where transmission is likely to have occurred. If all cases associated with an outbreak have acquired their illness through exposure in a single PHS area, the outbreak is regarded as localised regardless of where the cases are eventually identified. If transmission of infection appears to have occurred in more than one PHS area, the outbreak is regarded as a multi-PHS outbreak.

Multi-PHS outbreaks are often first identified as localised phenomena by single PHSs. Identification that the outbreak is widespread may, however, not occur until communication among PHSs reveals the presence of cases in multiple districts, or an ESR review of EpiSurv or laboratory surveillance data detects an increase of sporadic disease cases above expected levels, or groups of cases with rare pathogen subtypes.

The following general principles are proposed:

16.4.3.1. PHSs are responsible for assessing whether cases in their area are likely to have acquired their illness in another PHS area, and for informing that PHS.

This approach is suggested as a means to assist health districts in responding to localised outbreaks with distributed cases. It is likely that this principle is followed currently.

16.4.3.2. ESR is responsible for the identification of multi-district outbreaks according to agreed performance standards, but limited to a defined range of organisms.

ESR has ultimate responsibility for identifying multi-PHS outbreaks. ESR will use the same performance standards as local PHSs, but the performance standards will only be applied to outbreaks involving pathogens for which organism typing methods are available, or for which ESR coordinates national laboratory surveillance.

Organism typing is available for:

- VTEC/STEC
- *L. monocytogenes*

- Salmonella (including S. Paratyphi and S. Typhi)
- Shigella
- Norovirus
- N. meningitidis
- M. tuberculosis
- Legionella
- Leptospira
- Yersinia.

ESR coordinates national laboratory-based surveillance for the following pathogens: (Note: Measles virus is coordinated in the Christchurch Hospital laboratory and Cryptosporidium and Giardia are coordinated at Massey University.)

- local arboviral disease
- polio
- pandemic influenza A
- enteroviridae
- adenoviridae.

16.4.3.3. ESR rigorously assesses all identified multi-PHS outbreaks to decide whether further investigation is needed.

Again, this process would use similar criteria to those used locally. The process would include consultation with the local PHSs and the MoH, and would result in a recommendation as to whether a national investigation was indicated.

Further investigation would not proceed without MoH agreement, except in the following agreed emergency multi-district outbreak situations:

- suspected dispersed food- or water- borne outbreak of a very serious pathogen, for example, VTEC/STEC or L. monocytogenes
- serious exotic human disease, for example, local transmission of arboviral disease, polio or pandemic influenza A

In these situations, ESR would attempt to contact the MoH outbreak coordinator and obtain MoH agreement before proceeding with the investigation, as outlined in C.4 below. However, ESR would not delay the commencement of the investigation pending the MoH response.

16.4.3.4. If a multi-district outbreak investigation is required, then the MoH will lead or coordinate this process. The MoH may delegate management of the outbreak to another agency, such as ESR or a PHS. In specific situations (see below), MPI would become the lead agency.

Once a decision had been made that a true multi-district outbreak is occurring, then the MoH may convene a national outbreak management team. The MoH may also determine if another agency

should do so. MPI is almost always involved and may take over the lead agency role if a food source of national or international importance is suspected.

The lead agency will manage the national investigation and the response, including chairing teleconferences, monitoring the situation at the national level, and developing and implementing any national response plans, including any nationally consistent communication messages that may be required.

16.5. References for Appendix 1

1. Turnbull F, Baker M. Improving the identification of disease outbreaks in New Zealand [unpublished report]. Porirua: Institute of Environmental Science & Research Limited; 2001.
2. Goodman RA, Buehler JW, Koplan JP. The epidemiologic field investigation: science and judgement in public health practice. *Am J Epidemiol* 1990; 132: 9-16.
3. National Centre for Epidemiology and Public Health. National communicable disease outbreak control procedures [unpublished report]. Canberra: National Centre for Epidemiology and Public Health; 1996.

17. Appendix 2: Questionnaire design and interview techniques

Do not underestimate how long it takes to develop a good, thorough process for collecting information from subjects (cases or non-cases/controls) interviewed as part of the outbreak investigation. This is a painstaking process, but must be done. It is important to build the technological skill-base within the outbreak investigating agency so that the process runs smoothly.

Appendix 2 gives a general overview of the principles of questionnaire design, and then presents a step-by-step process for developing tools and undertaking data collection. An outbreak questionnaire template is given in Appendix 3.

17.1. Questionnaire Design

‘Questionnaire’ in the context of outbreak investigation refers to any survey instrument used to collect information directly from participants, regardless of the information collection technique. It should be noted, however, that questionnaires administered by an interviewer are more correctly termed interview schedules.¹

Questionnaires can be used at different stages of an investigation. At the outset when an outbreak is suspected, a hypothesis-generating questionnaire such as the “shotgun questionnaire” may be useful while to test a hypothesis an instrument modified from the template in Appendix 3 could be used. ESR maintains a questionnaire bank that can be accessed electronically if necessary.

Good questionnaire design is essential. While it is usually possible to repeat statistical analysis if it is performed incorrectly, there is seldom a second chance to question all the subjects in an investigation.

Whenever possible, investigators should save time and effort and make use of the experience of others by “borrowing”, wholly or in part, questionnaires that have been useful in previous investigations.

Only structured questionnaires, where all subjects are asked exactly the same questions, are likely to be of use in outbreak investigations. Unstructured questionnaires are useful for generating hypotheses from interviews conducted at the early stages of an investigation, but the information obtained from them is generally difficult to quantify for the descriptive or analytic stages of the investigation.

If it is necessary to construct a questionnaire from scratch or modify the questions in an existing document, use the following questionnaire design framework and principles.

17.1.1. Standard components

- Time and date of interview, interviewer name.
- Questionnaire number.
- Case identification and contact details (details of proxy if used).
- Demographic details – age and date of birth, sex, ethnicity, occupation, address.
- Space to record anything the participant would like to add, such as their suspected source of illness.

17.1.2. Variable components

- Potential exclusion criteria (these would normally be applied before the interview starts or early in the interview). See Chapter 6 for examples.
- Details of illness:
 - clinical features that are part of the case definition, onset date and time, duration of illness
 - outcome information, for example, whether seen by a general practitioner or other health care provider, name of health care provider, laboratory tests done, whether hospitalised, name of hospital, duration of hospitalisation.
- Past medical history if relevant, including on-going medical conditions, immunosuppression, regular pharmaceutical use, antibiotic use.
- Details of exposures of interest:
 - generally restricted to the hypotheses you are testing
 - refer to previous questionnaires, consult with experts and use literature reviews to identify potential exposures of interest
 - decide whether questions will be asked about exposures during a specific time period, or usual preferences
 - define the exposure period:
 - for cases, refer to the usual range of incubation periods for the illness, and use the longest period in the usual range
 - for control cases, use the reference date of matched cases
 - decide if degrees of exposure are important (i.e., dose and duration)
 - decide if timing of exposure is important (i.e., discrete, multiple, continuous).
 - Other risk and protective factors, if important.
 - Other potential confounders, e.g., smoking status.

17.1.3. Principles of questionnaire development

- Use questions from other outbreak questionnaires. This saves time, increases comparability and reduces the need for pre-testing.
- Involve the person(s) who will be doing the data analysis in the design of the questionnaire.
- Keep the questionnaire short by:
 - only using enough questions for the hypotheses under investigation
 - avoiding adding other research questions.
- Ensure the questions do not direct or bias responses by avoiding leading, loaded and unbalanced questions.
- Take care with sensitive questions by:
 - considering whether an attribute or a behaviour is socially desirable or undesirable
 - using wording to adjust impact.

- Ensure each question asks only one thing by avoiding double or triple questions where the different parts to the question are not necessarily linked.
- Ensure questions are reasonable and not burdensome by avoiding:
 - reference to other information sources
 - unreasonably long recall periods
 - the need for subjects to perform calculations
 - questions that require excessively precise recall.
- Ensure questions are explicit and precise by:
 - avoiding cryptic or obscure questions
 - avoiding ambiguous questions
 - avoiding vague words, e.g., usually, normally, regularly
 - specifying time periods to which questions apply, including the reference date and duration.
- Use simple language that subjects will understand by:
 - avoiding long questions
 - avoiding technical words, jargon and abbreviations
 - specifying the meaning of certain words, such as ‘diarrhoea’ or ‘contact’
 - avoiding double negatives
 - avoiding inconsistent use of terms.
- Use carefully constructed response categories by:
 - using options that fit the question
 - using options that are mutually exclusive
 - using options that are exhaustive
 - permitting “don’t know” options
 - using a consistent style of options, especially for quantifying exposures.
- Use closed questions whenever possible. Closed questions specify all possible answers. In comparison, open questions allow any response, and it may be difficult to understand the participant’s exact meaning at a later date. For example, an open-ended question enquiring about a drinking-water source could be: From where do you obtain water for drinking?

A closed question would be: Which of the following are you (or others in your household) currently using for drinking-water?

Bottled drinking-water	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Usual town supply	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Tanker truck water	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Private bore water	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Other water	Yes <input type="checkbox"/>	No <input type="checkbox"/>

If other, please specify _____

With the open-ended question, a response of “tap” would not allow the investigator to distinguish whether this really means town supply, private bore water or other water.

Allow ‘other’ options. Add an ‘other’ option to the list of answers, unless you are very confident that there are no other possible answers. ‘Other’ should usually be followed by:

“Please specify _____”.

- Order questions to aid the interview process by:
 - arranging questions in a logical sequence
 - grouping questions by topic
 - beginning with easy, non-threatening questions to put the participant at ease
 - putting sensitive questions at the end
 - moving from general to more specific questions
 - using skip statements when appropriate
 - not splitting questions and answers between pages.
- Keep interviewer instructions clear, brief and precise by minimising the use of instructions, such as “If No, go to Question 13”. When these instructions are necessary, they must be clear and easy to see, and the point at which questions resume must be obvious.
- Use fonts to aid clarity, for example:
 - questions in **bold**
 - answer options in a different font
 - instructions (for the interviewer or participant) in *italics*
 - avoid BLOCK CAPITALS and underlining.
- Number questions.
- Precode all closed questions by:
 - using tick boxes or codes that can be circled
 - avoiding large gaps between questions and tick boxes
 - avoiding tick boxes placed half way between alternative answers.
- Provide spaces for boxes for coding open-ended questions.

17.1.4. Questionnaire formatting

Questionnaire formatting is an essential step in order to avoid ambiguity and obtain accurate information. It also helps in navigating the questionnaire especially if it is long.

Q. Over the one-week period before you became ill, did you eat minced beef?

Yes	Y
No	N

If no, go to question 3

Q. How many times did you eat minced beef during that one-week period?

Write the number of times a week, or 99 for "don't know"

_____ times

If unexpected problems arise with any questions or any aspect of the questionnaire, these should be documented fully in the outbreak report so that they can be avoided in future investigations.

17.1.5. Questionnaire pre-testing

Questionnaire pre-testing should be balanced against the need to rapidly develop an interview tool to begin the investigation. Optimally, pre-testing should include at least a detailed desk review and a limited number of practice interviews.

- Desk review of questionnaire
 - Arrange for at least one experienced outbreak investigator or an external peer reviewer to examine the questionnaire for consistency with investigation aims, logical sequence of questions and clarity of instructions.
- Practice interviews
 - Run through the questionnaire in a mock interview situation, using individuals who are easily accessible, but not involved or familiar with the outbreak investigation or principles of surveying and questionnaire design. Optimally, set up mock interviews with people who are similar (e.g., in age) to the actual interview participants. The practice interviews should examine the questionnaire for clarity of wording and identification of ambiguities and misunderstandings.
- Pilot questionnaire on cases and controls
 - If time and case numbers allow, pilot the questionnaire on actual cases and controls. The pilot allows the questionnaire content, wording and instructions to be tested in a realistic setting using typical interviewers. It also allows for testing of case and control selection processes.

17.2. Standardised interview introduction

The preamble to the interview should be pre-scripted as much as possible to standardise information collection. It will be important to pre-test the interview introduction to ensure that it reads in a professional but relaxed style and builds a rapport with the participant. It is important that the introduction provides complete information about the aims and methods of the study and establishes the credibility and responsibility of the investigator.

The following points are key parts of the interview introduction. This material has been adapted from the guidelines for the preparation of information sheets, contained in the guidelines for completion of the national application form for ethical approval of a research project², developed by the Health Research Council.

- Identity of interviewer and interviewing organisation
 - Upon making contact with the participant, the interviewer should identify him/herself, including their affiliation with the PHS, and explain the purpose of the visit or call. This may duplicate the introductory statement read as part of the protocol for control recruitment (see page 48).
- Emphasise the importance of participation
 - The interviewer should state that the investigation is important (and why), and should emphasise the positive contribution that it will make to the control and prevention of disease. This may be part of a pre-scripted introductory statement.
- Assurance of confidentiality
 - Much of the information collected will contain personal identifiers. State that the information collected will only be used for the purposes of the investigation and will be kept confidential. Include a statement with wording such as: “No material which could personally identify you will be used in any reports on this study.”
- Interview duration
 - Provide an estimate of the length of the interview.
- Voluntary participation
 - Emphasise that participation is voluntary, and that participants have the right to withdraw participation at any time. Appropriate wording may be: “Your participation is entirely voluntary (your choice). You do not have to take part in this study”, and, “You do not have to answer all the questions, and you may stop the interview at any time.”
- Compensation for participation
 - State whether participants are to be offered compensation for their time, for example, in the form of gift vouchers or a copy of the final study report.
- Informed consent
 - After reading the interview introduction, explicitly ask for the participant’s consent to be interviewed. Document that consent has been obtained.
- Encourage aide memoire
 - Provide calendars to refresh participants’ memories of dates if the interview is face-to-face, or suggest that participants have a calendar or diary to refer to as they answer the questions, if a telephone interview.

17.3. Principles of Interviewing

Outbreak investigation questionnaires are usually administered to the subject by an interviewer, either face-to-face or by telephone. However self-administered questionnaires (e.g. postal, email or web based questionnaires) are also used in some situations. The relative advantages and disadvantages are explored in the table below.

Interview style	Advantages	Disadvantages
Face to face interviews	<ul style="list-style-type: none"> • Higher response rate • Longer list of questions • More accurate recording of responses • Appropriate for hard to reach populations (e.g. English as second language) • More timely 	<ul style="list-style-type: none"> • Costly and time consuming • Potential for interviewer error • Less anonymous than self-administered
Telephone interviews	<ul style="list-style-type: none"> • Less costly than face-to-face • Higher response rates than mailed • Even more timely • Can collect more sensitive information 	<ul style="list-style-type: none"> • Lower response rates than face-to-face • Shorter questionnaires used • Unable to capture important visual information (e.g. non-verbal responses, living or working conditions) • Potential for interviewer error • Under-coverage (e.g., population without phones) • May require after hours calls
Mail questionnaires	<ul style="list-style-type: none"> • More anonymous • May collect more honest responses • No interviewer error • Less expensive • Respondent has more time to think about question • 	<ul style="list-style-type: none"> • Questionnaire must be simple • Higher question non-response • Lower overall response rate • Data collection takes more time • Sample population must be literate in English
Web-based questionnaires	<ul style="list-style-type: none"> • Among some populations, most people may have access to the Web / email • Inexpensive and fast • No data entry required • Improves data quality • Many vendors send data in a variety of formats 	<ul style="list-style-type: none"> • Among some populations, most people may have access to the Web / email • Inexpensive and fast • No data entry required • Improves data quality • Many vendors send data in a variety of formats

Outbreak investigation questionnaires are usually administered to the subject by an interviewer, either face-to-face or by telephone. The advantages of this approach over postal or self-administered questionnaires are that the interviewer can ensure the completeness and quality of the recorded responses. Other advantages over postal or self-administered questionnaires include a superior participation rate and the opportunity for the education of subjects following completion of data collection.

The style of interview required for analytic epidemiological studies is somewhat different to the more relaxed style that may be used when interviewing apparently sporadic cases. The analytic

study interview is primarily for gathering high quality and consistent data. In the analytic study, all interviews are carried out in an identical, highly structured manner, using a standard questionnaire. It is, however, unethical to ignore requests for advice or to disregard proffered information about other people who may be at risk.

17.3.1. Important features of interviewing etiquette

- Respect the participant's privacy
 - If the interview is being conducted face-to-face, it should take place in a private, quiet setting.
- Use the participant's first language
 - The interview should be done in the participant's first language, or, if necessary, through an interpreter or a family member or friend who agrees to act as an interpreter. However, interpreters can be very expensive and time-consuming to organise in an urgent outbreak investigation situation. These issues should be taken into account in deciding whether to include non-English speakers in the investigation.
- Interview parents/guardians as proxies
 - Use a parent or guardian to answer questions as a proxy for a child under the age of 13 years (as a rule of thumb). If aged 13 years or older, it may be preferable to interview the child directly. Consent from a parent or guardian must be obtained prior to interviewing any children under age 16 years.
- Use a professional but friendly approach.
- Allow adequate time
 - Adequate time should be allowed at the end of the interview for the interviewee to ask questions and express concerns about anything that he/she regards as important, but which has not been covered in the interview.
- Appoint suitable interviewers
 - Interviewers must be able to understand the content of the questionnaire, to communicate clearly and to work methodically.
- Provide written instructions for interviewers. The written instructions should direct interviewers to:
 - read the questions as written, in the same order, with the same emphasis
 - unless instructed, not to prompt the participant or provide additional interpretation
 - thank the participant for their co-operation at the end of interview
 - specify basic advice for the prevention of transmission of the disease under investigation. Advice should be given at the completion of the interview
 - specify who the participant should contact for detailed clinical enquiries (usually the participant's own doctor or nurse).
- Train the interviewers to:
 - encourage familiarity with approaching subjects
 - encourage familiarity with the content of the questionnaire
 - role play the interview to build confidence and consistency.

- Supervise interviewers by:
 - sitting in on some interviews
 - reviewing interviewer logs and response rates
 - contacting a proportion of the interview subjects to check on responses
 - ‘randomising’ interviewers so that they interview both cases and controls.
- Fine-tune the interview process by checking the first batch of completed questionnaires for potential interpretation problems and taking corrective action.

17.4. Quality control during data collection and entry

Do not underestimate the potential for errors during data collection or data entry. No matter how urgent the investigation, it is important that outbreak control recommendations are based on information that is as error-free as possible.

17.4.1. Principles of data quality control

- Check all completed questionnaires
 - Somebody other than the interviewer should read through each completed questionnaire, as soon as possible after interview completion. Check for illogical sequences in responses, missing data or coding errors. Obtain missing information from the participants.
- Establish an effective data entry system by:
 - developing a data coding scheme that uses meaningful codes and uses specific codes for missing and unknown values
 - checking for logic, for example, by using the EpiInfo CHECK file.
- If resources permit double enter data using a different data entry person and cross-check in order to minimise data-entry errors. If using EpiInfo, the ENTER programme allows comparison of duplicate databases.
- Visual and logic check of entered data
 - Perform some basic frequency analyses on the database to check for obvious data errors such as misspellings and missing values, for example, by using the FREQ command in ANALYSIS on EpiInfo.

Perform basic logic checks of related data elements by cross-tabulating them, for example, by using the TABLES command in ANALYSIS on EpiInfo, to ensure that the answers are consistent. An example of this is questions relating to overseas travel. If a response to a question regarding recent overseas travel is ‘no’, but one or more countries are listed in subsequent fields, this is inconsistent and will need to be corrected.

17.5. References for Appendix 2

1. Last J. A dictionary of epidemiology. New York: Oxford University Press, 2001
2. National application form for ethical approval of a research project: Guidelines for completion of application form EA 06/99 [online] 1999 [cited 2002 Mar 20]. Available from:

http://www.ethicscommittees.health.govt.nz/moh.nsf/indexcm/ethics-forms-nationalapplication?Open&m_id=5.1

18. Appendix 3: Outbreak questionnaire template

This questionnaire template has been developed as an example of questionnaire layout and format only. *Questions on exposures should be designed to match the circumstances of the outbreak under investigation.* ESR maintains a set of questionnaires to match different outbreak types: food- and water- borne disease, legionellosis, bloodborne disease and nosocomial infection. These are available on request. Questions in these questionnaires will need to be modified, as described below:

1. questionnaire format will change depending on how the questionnaire is to be used:
 - a. some questions (e.g., laboratory results) will need to be completed by the investigator, not the case/patient or interviewer
 - b. the wording of questions will change depending on how the questionnaire will be administered. While most questionnaires will be administered over the telephone or in person (preferred methods), the wording of questionnaires may change if questionnaires are to be self-administered (e.g., mail-in questionnaires), or if someone else is answering on behalf of the case/patient.
2. the time frames used in the questions (e.g., one week before onset of illness) should be modified to match the incubation period of the disease under investigation, if the aetiological agent is known.

18.1. Disease outbreak questionnaire template

QUESTIONNAIRE NUMBER:

A INTERVIEW DETAILS	
1. Date questionnaire completed:
2. Time questionnaire completed:
3. Disease reported (if known):
4. Name of interviewer:
B CASE DETAILS	
5. Surname:
6. First name:
7. Home address:
8. Home city or town:
9. Work address:
10. Work city or town:
11. Phone number: Work:
12. Phone number: Home:
13. Phone number: Other:
14. Sex:	<input type="checkbox"/> Male <input type="checkbox"/> Female
15. Date of birth:
16. Age:	____ years OR ____ months (if less than 2 years old)
17. Ethnicity:	NZ European E
	Māori M
	Pacific P
	Other O Specify:
	Unknown U
18. Occupation (if applicable):
19. Place of Employment (if applicable):
20. Preschool/school/childcare centre (if applicable):

C SYMPTOMS

Have you experienced any of the following symptoms (tick all that apply):

[Examples given for food- and water- borne outbreak. Use symptoms consistent with disease under investigation]

21. Vomiting Yes No Unknown

22. Nausea Yes No Unknown

23. Stomach cramps Yes No Unknown

24. Diarrhoea (three or more loose bowel motions in a 24-hour period) Yes No Unknown

25. Bloody stools Yes No Unknown

26. Watery stools Yes No Unknown

27. Other Yes No Unknown

If yes, Please specify:

28. When did your symptoms first begin? Date: _____

Time: (24hr clock) _____

29. How long did your symptoms last? Days: _____ or Hours: _____ or On-going

30. Did you seek medical attention for these symptoms? Yes No Unknown

30a. If yes, Who was the doctor? Name: _____

Medical Centre: _____

31. Did you give a [specimen] for laboratory testing? Yes No Unknown

32. Were you admitted to hospital for these symptoms? Yes No Unknown

32a. If yes, specify: Name of hospital: _____

Ward: _____

Date admitted: _____

Duration in hospital: _____ days

33. Were you prescribed any medication for these symptoms? Yes No Unknown

33a. If yes, Give details: _____

34. Prior to becoming ill with these symptoms, did you have any other medical conditions during the past year? Yes No Unknown

34a. If yes, Give details: _____

35. Do you take any medication on a regular or frequent basis? Yes No Unknown

35a. If yes, Give details: _____

36. Have you taken any antibiotics during the last month? Yes No Unknown

36a. If yes, Give details: _____

D TRAVEL

37. Have you been overseas in the last [time period]? Yes No Unknown

37a. If yes, When did you return to New Zealand? Date: _____

38. What countries did you visit, and how long did you stay in each:

Sequence	Country/Region	Duration
Last		
Second last		
Third last		

39. Have you travelled within New Zealand in the last [time period]? Yes No Unknown

39a. If yes, Where have you been? [May need to define travel within NZ, e.g., travel out of town]

E RECREATION

In the _____ [insert time period] before you became ill, did you participate in any of the following activities: [List activities that may have presented risk of exposure to infection, e.g., swimming, camping, etc.]

40. [Activity 1] Yes No Unknown

40a. If yes, Where? _____

41. [Activity 2] Yes No Unknown

41a. If yes, Where? _____

[etc.]

F HUMAN CONTACT

[Ask questions about the types of human contact that may have presented a risk for infection. Examples include:]

In the _____ [insert time period] before you became ill, did you / your child:

42. Have contact with any children in nappies? Yes No Unknown

42a. If yes, Did you change a nappy or attend a faecal accident? Yes No Unknown

43. Attend a play group, preschool or childcare centre? Yes No Unknown

43a. If yes, give:

Name

Address

44. Attend any social or church functions? Yes No Unknown

44a. If yes, Give details

45. Attend any sports events? Yes No Unknown

45a. If yes, Give details

46. Have contact with anyone who had similar symptoms? Yes No Unknown

46a. If yes, Please give details of any ill people with whom you have had contact:

Name

Address

Phone No

G ANIMAL CONTACT

[If zoonotic transmission is a possible source of infection, ask questions about types of animals and nature of contact, for example:]

47. In the [insert time period] before you became ill, did you have any contact with animals? Yes No Unknown

If yes, What type of animals did you have contact with? (read out)

Household pets Yes No Unknown

If yes, Details:

Farm animals Yes No Unknown

If yes, Details:

Other animals Yes No Unknown

If yes, Details:

Were any of the animals ill (e.g., with diarrhoea)? Yes No Unknown

48. In the [insert time period] before you became ill, did you have any contact with animal manure (e.g., while gardening)? Yes No Unknown

H FOOD

[Ask specific questions about types of foods consumed during incubation period, if foodborne illness suspected]

49. Where do you normally buy your groceries?

During the [time period] before you became ill, did you eat the following foods?

FOOD TYPE:	Consumed in past [insert time period]?			Brand name (if known)	Where purchased (if known)
	Yes	No	Unknown		
50. [Food type #1]	Yes	No	Unknown		
51. [Food type #2]	Yes	No	Unknown		
[etc.]	Yes	No	Unknown		

I EATING ESTABLISHMENTS / SOCIAL FUNCTIONS

[If foodborne illness suspected, ask about venues where food consumed]

In the [insert time period] before you became ill, did you eat food from any of the following places:

	Consumption			Where	When
	Yes	No	Unknown		
52. Friend's home?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	a	
				b	
53. Restaurant?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	a	
				b	
54. Café/ lunch bar?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	a	
				b	
55. Takeaway?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	a	
				b	
56. Pub / bar?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	a	
				b	
57. Function? (e.g., wedding, hangi, BBQ, etc.)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	a	
				b	
58. Institution? (e.g., workplace, school, hospital cafeteria, etc.)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	a	
				b	
59. Other?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	a	
				b	

[If an event or establishment is later implicated, then add questions regarding specific foods consumed at or from that venue].

J WATER AND SEWAGE

[If waterborne disease suspected, ask about sources of drinking-water and sewage systems. Examples listed below]

In the [time period] before you became ill, did you drink water from any of the following sources:

60. Mains (council) water supply	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	If yes, Where?
61. Rooftop collection	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	If yes, Where?
62. Well or bore	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	If yes, Where?
63. Water race or drain	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	If yes, Where?
64. River, creek or stream	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	If yes, Where?
65. Lake or pond	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	If yes, Where?
66. Spring	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	If yes, Where?
67. Other	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	If yes, Where?
68. Was any of the water untreated (not chlorinated, filtered or boiled)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	
68a. If yes, Give details				
69. What type of sewage system do you have?	Council: C			
	Septic Tank S			
	Long drop L			
	Other O			
69a. If other, specify:				
70. In the [time period] before you became ill, did you have any problems with your sewer or septic tank, or did your toilet overflow?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	
70a. If yes: Give details				
71. In the [time period] before you became ill, did you have any contact with human wastes or sewage at work or at home?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	
71a. If yes: Give details				

K COMMENTS

72. Do you have any ideas about what may have made you ill in terms of what you ate, drank or came into contact with?

19. Appendix 4: Investigation protocol

19.1. Protocol for a directly-matched case-control study to investigate an enteric disease outbreak

19.1.1. General

- Conduct all interviews using a standardised questionnaire.
- To the greatest extent possible, the same person should interview all members of the matched set (case and matched controls).
- Conduct all interviews by telephone. When placing a call, if no one answers, allow the telephone to ring 10 times before hanging up.
- Treat calls answered by answering machines as non-responses and repeat call at next session.
- Record and categorise all unsuccessful phone calls.

19.1.2. Protocol for case interviewing

- Inclusion criteria: All patients with:
[Use case definition, for example:
 - Laboratory-confirmed [disease];
 - Onset of illness from [onset date] onward.
- Exclusion criteria: Exclude the following potential cases from the case-control study:
[Use case exclusion criteria, for example:
 - Those who are not contactable by telephone or have not responded to mailed requests to return calls.
 - Cases who were travelling outside New Zealand during the [incubation period] prior to onset of diarrhoea and vomiting.
 - Cases who do not have a landline telephone number available for their primary residence.
 - Cases who are not English-speaking.
 - Patients who are unable to give an estimated date of onset of their diarrhoea or vomiting, despite strong prompting.]
- For cases <13 years of age, interview a parent or guardian, preferably the parent or guardian most familiar with the eating habits of the case. Seek to obtain direct interviews with children aged between 13 and 16 years of age, but ensure that parental consent is obtained first.
- Questionnaire: Interview cases (or their parent/guardian) [by telephone or in person] with the standardised questionnaire containing health, exposure, and demographic information.
- Time frame: Interview cases as quickly as possible, no later than [x] days after the specimen collection date for the sample which yielded [pathogen].
- Exposure period: Cases will be interviewed about potential exposures in the [incubation period] days before their estimated date of onset of diarrhoea or vomiting.

19.1.3. Protocol for control selection and interviewing

- Interview [x] controls for each case
- Matching criteria. Match controls to cases on the basis of:
[Define matching criteria. Examples are:
 - Age strata. The strata are:
 - [stratum one]
 - [stratum two]
 - [stratum three]
 - [stratum four]
 - Geographic area of residence (e.g., suburb, town). Match on geographic area by rigorously following the control selection sequence below.
 - Period of exposure. Interview controls about exposures during the [incubation period] immediately prior to the date of onset of illness in the matched-case.]
- Control selection: Search for controls using the following sequence: [suggested control identification strategy]
 - Obtain the residential telephone book for the region the case lives in.
 - Generate a list of random numbers based on the number of pages in the relevant section of the phone book.
 - Turn to the page number corresponding to the first random number.
 - Work down columns alphabetically on the page until you find a number with the same suburb as the identified case. Exclude businesses.
 - If call is answered, explain study as per introduction sheet. Ask whether anybody within the case's age group lives at that address. Then:
 - if nobody within the case's age group lives at the address, discontinue the call, record the outcome on the log, and restart sequence from (4) above
 - if there is more than one person in the case's age group, ask who of that group will next have a birthday
 - if that person is older than 16 years, ask to speak to that person and go to (6) below
 - if that person is aged between 13 and 16 years, ask to speak to a parent or guardian to obtain consent for the interview, then ask to speak to the child. Go to (6) below
 - if that person is younger than 13 years, ask to speak to a parent or guardian: preferably the one most familiar with the child's eating habits. Go to (6) below.
- If the required person is there and agrees to be interviewed, then interview them and record the outcome on the log. Start next control selection: go to page number indicated by next random number in list, then go to (4) above.
- If the required person (either child or parent/guardian) is unavailable, make arrangements to interview them later. DO NOT interview people who are available instead. Go to (6) above at arranged time.
- If the call is not answered, or is answered by an answering machine only, record the details on the log and call again at the next session. Make at least three attempts in total (including at least [x] attempts between 6:00 pm and 8:30 pm on different days) to call if:

- the call is not answered
- the call is answered by an answering machine only
- the call is answered and the residence contains a person within the case's age-band (or parent/guardian of child within case's age band), but that person is unavailable at the time.
- Discontinue the call, enter the outcome on the log and restart sequence from (4) above if:
 - the call has not been answered (or is answered by an answering machine only) after at least three attempts (with at least three attempts between 6:00 pm and 8:30 pm on different days)
 - no English-speaking people are available at the residence called
 - the person answering the phone refuses to participate
 - nobody at the residence is capable of answering questions
 - the phone number is for a non-residential address, that is, the address is not a household (e.g., a commercial establishment)
 - the call is answered but no person within the case's age-band (or parent/guardian of child within case's age band) lives at the residence contacted
 - the call is answered by a facsimile machine
 - the telephone line is unserviceable.
- Exclusion criteria. The following persons will not be eligible to be controls in the study: [Control exclusion criteria. Examples are persons who:
 - were not present in New Zealand during the [incubation period] prior to the date of onset of vomiting or diarrhoea in their respective matched-case
 - are not English-speaking
 - are unable to answer questions (e.g., due to dementia)
 - report diarrhoea or vomiting at any stage in the 28 days before the onset date of diarrhoea or vomiting in the matched-case
 - report that somebody else in their household has had a culture-confirmed Salmonella infection within the last 28 days.]

21. Appendix 6: Characteristics of common bacterial foodborne pathogens

Organism	Vehicle/source	Incubation	Selected Symptoms	Duration	Growth/transmission	Control/Precaution
<i>Bacillus cereus</i>	Present in most raw, dried and processed foods, especially spices and cereals. Spores survive cooking and grow well in foods such as cooked rice dishes.	Emetic 1–6 hr	V common F rare D not prominent	<24hr	Growth of the bacteria occurs best at room temperatures, toxin that survives further cooking is produced. There are two toxin types - one causes diarrhoea, the other vomiting.	Cool pre-cooked foods quickly in shallow dishes (<10cm) and store below 5°C. Alternatively hold food above 60°C.
“	“	Diarrhoeal 6–24 hr	V rare F rare D profuse watery	<24hr	“	“
<i>Campylobacter</i>	Commonly found in animals (esp. cattle and poultry), food products of animal origin and water. May be carried by pets.	3–5 days (1–10 days)	V common F common D often with blood, mucous and pus	<10 days usually 3 to 5 days	Survival of bacteria due to insufficient cooking and cross contamination of cooked foods.	Ensure meats (especially poultry and offal) are adequately cooked. Prevent cross contamination via surfaces and utensils. Take care with personal hygiene.
<i>Clostridium botulinum</i>	Spore forming bacterium found almost everywhere, especially in soil and agricultural products.	12–36 hr	V common F absent D common	Fatal if untreated. Slow recovery (months to years) if treated.	Spores survive and grow in inadequately cooked canned and preserved foods such as meats and vegetables. Usually fatal unless quickly treated. Recovery may take years.	Approved thermal processes for canning and preserving food. Acidification of preserved food.

Organism	Vehicle/source	Incubation	Selected Symptoms	Duration	Growth/transmission	Control/Precaution
<i>Clostridium perfringens</i>	Spore forming organisms common in soil, on raw foods, vegetables and meat.	10–12 hr (6–24 hr)	V rare F rare D profuse, watery	<24 hr	Spores survive cooking and germinate in soups, stews and pies that are inadequately cooled or reheated. Food prepared in advance is most at risk.	Cool pre-cooked foods quickly in shallow dishes (<10cm) and store below 5°C. Alternatively hold food above 60°C. NEVER store stews etc. in deep pots. Reheat thoroughly. Reheat pies in an oven, not in warmer.
<i>Escherichia coli</i> Enterotoxigenic Enteropathogenic Enteroinvasive Enterohaemorrhagic	Enteric. Infection can be zoonotic, environmental, foodborne or person-to-person. Sources include cattle, beef, unpasteurised milk, and unwashed produce.	24–72 hr 9–12 hr 10–18 hr 12–60 hr (1–14 days)	V occasional F common in pathogenic & invasive types - rare in haemorrhagic type D profuse, watery, maybe with blood, mucous, pus	3– 5 days 1–3 weeks 1–2 weeks 7–10 days	Transmitted through poor personal hygiene and inappropriate handling of foods. Cross contamination and inadequate cooking.	Scrupulous cleanliness, especially after using toilet. Thorough cooking needed and control of cross contamination.
<i>Listeria monocytogenes</i>	Widespread in the environment. Sources include unpasteurised milk or milk products including cheese, pate, ready to eat chilled foods, salads and cold meats. Transmission is often foodborne or person-to-person.	3–70 days	V absent F common D absent	1–90 days	Grows at normal refrigeration temperatures. May be fatal to new-born or the elderly.	Control of handling and prevention of cross contamination of cooked meat and dairy products with raw ingredients and fresh produce. Store below 2.5°C.
<i>Salmonella</i> (non Typhi)	Wide range of animals and foods of animal origin - esp. poultry and meats, also infected person/carriers/food handlers.	16–36 hr (6–72 hr)	V occasional F common D loose, watery, sometimes bloody	3–5 days	As for <i>Campylobacter</i> and <i>E.coli</i> . Fatal in rare circumstances.	Thorough cooking and control of hygiene and cross contamination. Washing raw produce thoroughly before consumption. Exclude carriers from food preparation.

Organism	Vehicle/source	Incubation	Selected Symptoms	Duration	Growth/transmission	Control/Precaution
<i>Salmonella</i> Typhi and Paratyphi	Humans (enteric fever)	1–3 weeks (S. Typhi) 1–10 days (S. Paratyphi)	V rare F prominent feature D occasional	7–28 days	As for <i>Campylobacter</i> and <i>E.coli</i> . May be fatal.	Thorough cooking and control of hygiene and cross contamination. Exclude carriers from food preparation.
<i>Shigella</i>	Humans (enteric)	1–3 days (1–7 days)	V occasional F common D may contain blood, mucous, pus	4–7 days	Transmitted through poor personal hygiene and inappropriate handling of foods.	Scrupulous cleanliness, especially after using the toilet. Thorough cooking needed. Exclude carriers from food preparation.
<i>Staphylococcus aureus</i>	Humans: from skin, hair, open sores, nose & throat. Infected food handlers. Outbreaks have been associated with dairy products, ham, and chicken salad.	2–4 hr (30 min to 7 hr)	V common F rare D not prominent	1–3 days	Growth in food produces a toxin which is not destroyed on reheating.	Personal hygiene, thorough cooking and cooling.
<i>Yersinia enterocolitica</i>	Animals, especially pigs, and occasionally humans.	3–7 days (<10 days)	V occasional F occasional low grade D watery, may be very severe	1–11 days	May grow under refrigeration in vacuum packed meats and similar products.	Scrupulous hygiene, especially in the preparation of raw meats. Cook pork thoroughly.
Viral gastroenteritis (e.g., norovirus)	Humans, foodborne.	15–50 hr depends on viral agent and dose	V common F occasional to common D common, usually loose, watery	24–60 hours	Transmission can be via the faecal-oral route, airborne or contact with contaminated fomites.	Scrupulous hygiene, cooking and storage. Cook shellfish thoroughly.

22. Appendix 7: Legislative responsibilities of medical officers of health (or designated officers) relevant to outbreak control

These provisions in statutes and regulations have been excerpted in Table 1.1 (with amendments) from the *Guide to legislative responsibilities of medical officers of health*.¹ Please note that this table will need to be updated once the Food Bill has been passed. This Bill will replace the Food Act and Food Hygiene Regulations 1974.

22.1. Disclaimer

Neither this list nor the Guide itself should be considered as substitutes for the text of the actual statutes and regulations (these can be found at www.legislation.govt.nz). The Ministry of Health has decided to discontinue revising the above guide (and also the *Guide to legislative responsibilities of health protection officers*) due to difficulties of keeping it authoritatively up to date with the frequent amendments to the regulations and the considerable and on-going cost.

Note 1: A Medical Officer of Health may exercise powers to enter premises under the Health Act (see table 1.1). In PHUs without a food contract however there is usually a memorandum-of-understanding which further outlines procedures such as entering a food premise. This is expected to be followed, but ultimately if a medical officer of health wishes to enter a food premises in which they suspect there is a person with an infectious disease he/she is entitled do so.

Note 2: An amendment to the Food Act 1981 in 2002 changed many of references in that Act to 'Medical Officer of Health', to Designated Officer. All Medical Officers of Health are not necessarily also Designated Officers. Under section 17 of the Food Act, the power to require information still remains with Medical Officers of Health.

22.2. Provisions in legislation and regulations relevant to outbreak control

Brief description of power	Clause in legislation or regulation	Full description of power
Entry and inspection of food premises	Food Act 1981 s12 (2)(a)	Officer may enter and inspect any premises (other than a dwelling house) or vehicle the officer reasonably believes that any of the following is for the purposes of sale, prepared, processed, manufactured, packaged, carried, stored, delivered or sold: <ul style="list-style-type: none"> • (a) food • (b) appliances, • (c) advertising and labelling material, and • (d) packages for food and appliances.
Open and examine food-related appliance, receptacle or package	Food Act 1981 s12 (2)(c)	May open and examine any appliance, receptacle, or package that the Officer reasonably believes contains any food; appliance; advertising material or labelling material; and any package containing or intended to contain any food or appliance.

Brief description of power	Clause in legislation or regulation	Full description of power
Take samples of food	Food Act 1981 s12 (2)(e)	May purchase or take samples of any food the Officer reasonably believes to be intended for sale or to have been sold, or any appliance believed to be intended for sale or to have been sold for use with food preparation, processing, manufacture, packaging, storage, carriage, delivery of sale. This is subject to sections 20 and 21.
Impound packaging or advertising / labelling material	Food Act 1981 s12 (2)(f)	Officer may purchase or take any package in which the Officer reasonably believes food is intended to be packed for sale; or any advertising material or labelling material that the Officer reasonably believes is intended for the use in connection with the sale of any food or appliance, or to have been used for such purposes.
Examine records and obtain information from them	Food Act 1981 s12 (2)(g)	Officer may examine any records considered to contain information relevant to enforcement of the Act or any regulations or food standards and may take extracts or make copies of them.
Prevent use of food-related equipment	Food Act 1981 s12 (2)(h)	Officer may mark, fasten, seal or otherwise secure any equipment (the equipment must be used or intended to be used on those premises for the preparation or packing of food) that the Officer reasonably believes may have the potential to taint the food or make it injurious to health, and may direct the owner to refrain from using it, and detain it until analysis results are available or until remedial action can be taken, but for no longer than 14 days. The Officer may also mark, fasten, seal, or otherwise secure on any premises, food; any appliance; advertising material or labelling material; or package containing or intending to contain any food or appliance (section 12(2)(h)(ii) refers).
Take photographs	Food Act 1981 s12 (2)(k)	Officer may photograph any premises, vehicle, or article in relation to which the Officer reasonably believes an offence against the Act or any regulations made under the Act have been committed.
Collect information on food	Food Act 1981 s17 (1)	<p>Medical Officer of Health or Director may require any person reasonably suspected to be in possession of any</p> <ul style="list-style-type: none"> • (a) food(for purposes of sale) • (b) substances for the preparation or manufacture of sale of food • (c) advertising or labelling material <p>in breach of this Act, or any regulations made under the Act or food standards, to produce for inspection any relevant documentation.</p>
Divide food samples into three parts	Food Act 1981 s21 (1)	Officer shall divide a sample taken under s.20 into three marked and sealed parts, leaving one part with the owner of the food from which the sample was taken.

Brief description of power	Clause in legislation or regulation	Full description of power
Enable food premises closure and cleaning	Food Hygiene Regulations 1974 R82	Designated officer may require, by notice in writing, the occupier of any food premises to either clean, reconstruct or repair the premises within a given period, where the premises are in such a state that food may be exposed to contamination or taint, or deteriorate or become dirty. The designated officer can decide whether the premises remain open or closed during the period. The designated officer can also require that the premises not be used as food premises anymore. He/she may revoke the notice and notify the occupier.
Persons in contact with infected person	Food (Safety) Regulations 2002 R11	<ul style="list-style-type: none"> • (1) A Medical Officer of Health or designated officer may, by serving notice in writing on any person who has been in recent contact with a person to whom regulation 10 applies, prohibit the person from engaging in, or being employed in, the manufacture, preparation, storage, packing, carriage, or delivery, for sale, of a food. • (2) If, in the opinion of the Medical Officer of Health or the designated officer, there is no longer any risk of any food becoming infected by a person on whom the notice has been served, the Medical Officer of Health or designated officer must— <ul style="list-style-type: none"> ○ (a) revoke the notice; and ○ (b) notify the person in writing of the revocation. • (3) No person may be engaged, or be employed, in a business in contravention of a notice served under subclause (1).
Prohibit sale of food	Food (Safety) Regulations 2002 R12	Where Medical Officer of Health or designated officer suspects on reasonable grounds that any food is infected with an organism capable of causing food poisoning or a communicable disease, he/she may, by notice in writing, describe the source from which he/she believes food to have been supplied and prohibit the person from selling any food he/she knows or believes to be from that source. Such an order may last for up to one month and be extended for a further month. The notice must be revoked if the Medical Officer of Health / designated officer believes that food to which the notice applies is no longer infected.
Entry and examination	Health Act 1956 s77	Medical Officer of Health or medical practitioner authorised by the same/local authority of the district may enter premises at any reasonable time, where he/she has reason to believe that there is or recently has been a person suffering from a notifiable infectious disease or recently exposed to such a disease and may medically examine such a person on the premises to assess whether this is the case.

Brief description of power	Clause in legislation or regulation	Full description of power
Isolation of infectious disease carrier	Health Act 1956 s79 (1),(3)	Medical Officer of Health or any health protection officer may order the removal to hospital, or other suitable place of isolation, any person who he/she has reason to believe is likely to cause the spread of any infectious disease.
Cleansing and disinfection	Health Act 1956 s82 (1)	Medical Officer of Health may require a local authority by order in writing to cleanse or disinfect premises or articles within a specified time, if he/she believes it to be necessary otherwise for preventing danger to health, or for rendering any premises fit for occupation.
Compulsory assessment	Health (Infectious and Notifiable Disease) Regulations 1966 R10 (1)-(2)	Medical Officer of Health may require contacts or carriers to be medically examined and to produce specimens when and where the Officer directs.
Compulsory treatment	Health (Infectious and Notifiable Disease) Regulations 1966 R10 (3)	May require every contact or carrier to carry out treatment for the length of time as directed by the Officer.
Work restriction	Health (Infectious and Notifiable Disease) Regulations 1966 R13 (2)	Medical Officer of Health may prevent a carrier of cholera, diphtheria, dysentery, enteric fever, a salmonella infection, or streptococcal sore throat from being employed in any capacity where the Officer thinks he/she may cause or spread any such disease.
Authorisation of others	Health (Infectious and Notifiable Disease) Regulations 1966 R15	Medical Officer of Health may, in case of an outbreak of infectious disease, constitute local committees to operate within defined areas and assist the Officer and local authorities in checking the epidemic and conserving the public health.
Treatment of tuberculosis	Tuberculosis Act 1948 s7 (2)	Medical Officer of Health shall do all things he/she thinks necessary to ensure as far as possible that the person receives medical treatment, care and supervision; the source of infection is traced; the person's contacts are traced and if necessary given a medical examination and treatment; and contacts are immunised if they wish.
Isolation and detention of tuberculosis patients	Tuberculosis Act 1948 s16 (1)	May apply to a District Court to have a person suffering from tuberculosis who is in an infectious condition to be removed to a suitable place where proper treatment can occur for a period not exceeding three months, if satisfied that the person is in an infectious condition; it is in the patient's best interests; proper precautions cannot or are not being taken; and a substantial risk of infection is caused to others.

¹Ministry of Health. Guide to the legislative responsibilities of medical officers of health [unpublished report]. Wellington: Ministry of Health; 1998.

23. Appendix 8: Outbreak report form

23.1. Outbreak definition for reporting

The following types of outbreaks should be reported

- Two or more cases linked to a common source, in particular where the common source is exposure at a common event, food or water dispersed in the community, an environmental source, or a source in an institutional setting; OR
- An increase (usually sudden) in disease incidence, compared to average, or background, levels; OR
- A community-wide or person-to-person outbreak (except when this source has become well established as a national epidemic and reporting it as a discrete event no longer serves a useful purpose); OR
- Any other situation where outbreak investigation or control measures are being used or considered.

23.1.1. Outbreak reporting is encouraged for:

- A secondary case in an institution

23.1.2. Outbreak reporting is not usually required for:

- Most secondary cases. These should be distinguished on the individual case report forms as secondary cases.
- Single cases where a specific contaminated source is identified (eg food poisoning case linked to specific food premises). These should be recorded as a single case on the appropriate individual case report form.

23.1.3. Household outbreaks

- Any household outbreaks that are investigated should be reported regardless of mode of transmission. This is in contrast to the previous policy whereby reporting of household outbreaks likely to have resulted from secondary transmission was discouraged

23.2. General points to note when using this form

Judgement is required in filling out this form. The form does not record every aspect of the outbreak e.g. every possible setting, vehicle, and mode of transmission where numerous activities may be involved. Instead, it aims to record the most likely source, mode of transmission etc.

This form records the evidence used for the key outbreak conclusions, notably evidence for (i) recognising the outbreak, (ii) mode of transmission and vehicle/source, and (iii) implicating a contributing factor.

See appendix for

- List of common contaminants and their corresponding conditions
- Definitions of ‘Levels of evidence’ used throughout this form
- Food categories available for vehicle/source of outbreak
- General notes on date fields, drop-down lists, etc.
- Additional notes for specific fields

Outbreak Summary	
Outbreak Number	The Outbreak Number is a unique identifier generated by EpiSurv automatically when an outbreak is created and saved, and is in the following format: “OB”, followed by the current year (2-digit code), the next available national unique number (6-digit code), then the PHS office code (2-letter code). This code should also be used to identify all the individual cases involved in the outbreak on the relevant disease case report forms.
Reporting Authority	
Name of public health officer responsible for investigation	Name of the person responsible for investigating the outbreak.
Date outbreak reported	Date when the outbreak was first reported to the PHS or date when the PHS first recognised that there was an outbreak.
Interim or final report	Indicate whether this is an interim report or the final report. Information will be constantly updated during an outbreak so this lets ESR know whether the investigation is complete or not.
Not an outbreak	Select the Not an outbreak option if applicable. This will remove the outbreak from all standard reporting in EpiSurv
Name of outbreak	Optional field allowing an outbreak name to be included.
Condition and Implicated Contaminant	
Implicated contaminant (pathogen)	Provide the name and subtype (if applicable) of the implicated causative agent (pathogen/toxin/chemical) if known. If name is provided, the Condition (disease) field must be completed. The same applies if the Other known condition/implicated pathogen option is selected – the Condition (disease) must be specified. Note that where implicated contaminant might be unknown, it may still be possible to complete the Condition (disease) field. List of common contaminants and their suggested corresponding conditions is available in the appendix.
Case Definitions	<p>Specify case definitions used for confirmed and probable cases. Most of these definitions will include a reference to time and place requirements as well as laboratory and/or clinical features.</p> <p>Laboratory confirmed - Specify the case definition for a laboratory-confirmed case. This will usually be based on isolating a microorganism from a case or other specific laboratory evidence of infection or exposure.</p> <p>Clinically confirmed - Specify the case definition for a confirmed case where clinical criteria alone have been used to define a confirmed case or a clinically compatible illness and contact with a confirmed case.</p> <p>Probable case - Specify the case definition for a probable case. This will usually be based on a set of clinical features which were considered to be insufficiently specific to justify the case being considered confirmed.</p>

Outbreak Demographics	
Number of people exposed	<p>Specify the number of people exposed (include both cases and non-cases). Select the Actual option if number is definite, and select the Approx option if the number is not known exactly.</p> <p>This figure provides a denominator that may later be used to calculate an attack rate (the numerator being the number of cases, as recorded below). If unknown, select the Unknown checkbox.</p>
Number of cases	<p>Specify the number of laboratory confirmed, clinically confirmed, probable and total cases, based on the case definitions provided above (note: the total no. of cases should equal the no. lab confirmed + clinically confirmed + probable cases). Specify the number of cases that were hospitalised or died, if any.</p>
Outbreak dates	<p>Specify the date of onset of illness in the first case and the last case of the outbreak. If the outbreak has not finished, select the Outbreak ongoing checkbox, and update at the conclusion of the investigation.</p>
Age of cases	<p>Indicate the number of cases for which age information was available.</p> <p>Specify the median value (middle) and range of values (minimum and maximum) for these cases' ages in years. Note this should be for total cases (lab-confirmed, clinically confirmed and probable). If not known or unavailable then leave the appropriate space(s) blank.</p>
Sex of cases	<p>Specify the number of male and female cases. If not known or unavailable then leave the appropriate space(s) blank.</p>
Incubation period	<p>This is the time interval between initial contact with an infectious or toxic agent and the appearance of the first sign or symptom of the disease. Specify the median value (middle) and range of values (minimum and maximum) for incubation period, if it can be estimated, and select either the days or hours option to indicate the time unit. If not known or unavailable then leave the appropriate space(s) blank.</p>
Duration of illness	<p>Specify the median value (middle) and range of values (minimum and maximum) for the duration of illness, if it can be estimated, and select either the days or hours option to indicate the time unit. If not known or unavailable then leave the appropriate space(s) blank.</p>
Circumstances of Exposure/Transmission	
How was the outbreak first recognised?	<p>Select the option that best describes how the outbreak was first recognised. If none of the options apply, select the Other option and specify.</p> <p>Definitions of options are given below.</p> <ul style="list-style-type: none"> • Increase in disease incidence – recognised by an increase in disease incidence relative to expected background rate. • Cases attended common event - includes outbreaks from consumption of contaminated food/beverage or person-to-person transmission at a restaurant/café, takeaway, catered function, tangi / hui or community gathering or other defined event within a specified time period. • Cases linked to common source – includes outbreaks from consumption of a widely distributed food/beverage, such as food or drink purchased from a supermarket/delicatessen/butcher or other retail outlet or reticulated drinking water. This includes outbreaks from contact with a specific contaminated environment such as a swimming pool, farm, institution or workplace. • Person to person contact – includes outbreaks from contact with infected people in a wide range of settings. • Common organism type/strain – cases share pathogen.

<p>Were these cases part of a well-defined exposed group?</p>	<p>Indicate whether the cases were part of a well-defined exposed group. This will often be the case for common event and person-to-person outbreaks. It may also apply to some outbreaks linked to specific places such as a workplace.</p> <p>Provide the date of exposure and the date of the last exposure if the exposure occurred over several days. Provide a brief description of the exposure event.</p>
<p>Setting where exposure occurred</p>	<p>This section allows up to two entries for the exposure setting. If there is only one exposure setting, complete the first setting where exposure occurred and leave the second setting blank.</p> <p>To complete an exposure setting, first select the appropriate headline option:</p> <ul style="list-style-type: none"> • Food premises • Institution • Workplace/Community/Other <p>Once the headline option has been selected, indicate the setting where the exposure occurred. Only select the Other option if none of the preceding options are appropriate.</p> <p>Complete the Setting name field by selecting the appropriate option from the drop-down list, or add a new setting if applicable.</p> <p>The following lists are available in EpiSurv: <i>Food Premises, Long term care facility, Hospital, Prison, School, Childcare Centre, and Workplace.</i></p> <p>If the setting is not known, select the Setting unknown checkbox.</p>
<p>Setting where contaminated food/beverage was prepared</p>	<p>This section allows up to two entries for the preparation setting. If there is only one preparation setting, complete the first setting where food/beverage was prepared and leave the second setting blank.</p> <p>To complete a preparation setting, first select the appropriate headline option:</p> <ul style="list-style-type: none"> • <i>Overseas manufacturer</i> • <i>Food premises</i> • <i>Institution</i> • <i>Workplace/Community/Other</i> <p>Once the headline option has been selected, indicate the setting where the exposure occurred. Only select the Other option if none of the preceding options are appropriate. If Overseas manufacturer, specify the product and manufacturer.</p> <p>Complete the Setting name by selecting the appropriate option from the drop-down list, or add a new setting if applicable.</p> <p>The following lists are available in EpiSurv: <i>Food Premises, Long term care facility, Hospital, Prison, School, and Childcare Centre.</i></p> <p>If the setting is not known, select the Setting unknown checkbox.</p>
<p>Geographic location where exposure/transmission occurred</p>	<p>Specify the geographic location where the exposure occurred. Select either <i>New Zealand</i> or <i>Overseas</i>.</p> <p>If exposure occurred in New Zealand, complete the <i>Primary TA</i> and <i>DHB(s)</i> fields. If exposure occurred in several DHBs list all the DHBs involved. List all Health Districts as well if you would like the information recorded.</p> <p>If exposure occurred overseas, specify the country.</p> <p>If it is not known where transmission occurred, select the <i>Unknown</i> option.</p>

Mode of transmission	<p>Select all modes of transmission that are likely to apply in this outbreak. If the causative agent (organism/toxin/chemical) is known then the mode(s) of transmission will often be obvious. If the mode of transmission is not listed, select Other mode of transmission and provide details. If the mode of transmission is not known, select the Mode of transmission unknown option</p> <p>For each mode of transmission selected, indicate whether it was a primary or secondary mode, and select the option that best describes the level of evidence available. Primary mode relates to the mode responsible for the initiation of the outbreak and secondary modes are other modes that develop during the course of the outbreak. For most outbreaks, there should only be one primary mode of transmission. Definitions of the level of evidence codes are listed in the appendix.</p>
Vehicle/source of common source outbreak	<p>Users may enter up to three identified sources, or vehicles.</p> <p>Indicate whether a specific contaminated food/water or environmental source (e.g. sewage, greywater, etc.) was identified. If unknown, select the Unknown option. If yes, specify up to three sources identified. For each source entered, select the option that best describes the level of evidence available. Definitions of level of evidence codes are available in the appendix.</p> <p>If you have specified a food source, select from the drop-down list of Food Category that best describes the identified source. This field may be updated later by ESR, in which case the checkbox ESR Updated will be selected and the Date field completed. The list of food categories is available in the appendix.</p>
Factors Contributing to Outbreak	
<p>For each mode of transmission selected, select all corresponding contributing factors that apply in the relevant category. For each contributing factor selected, indicate whether the contributing factor is Confirmed, or Suspected by selecting the appropriate option.</p>	
Foodborne outbreak	<p>If the outbreak is foodborne, indicate all the risk factors that are likely to have contributed to the outbreak. If a risk factor is not listed, select the Other factor checkbox and provide details.</p>
Waterborne outbreak	<p>If the outbreak is waterborne, indicate all the risk factors that are likely to have contributed to the outbreak.</p>
Person to person outbreak	<p>If the outbreak is person to person, indicate all the risk factors that are likely to have contributed to the outbreak.</p>
Environmental outbreak	<p>If the outbreak is environmental, indicate all the risk factors that are likely to have contributed to the outbreak.</p>
Other outbreaks	<p>If none of the above is appropriate, select the Other Risk Factor, and specify as precisely as possible.</p>
Management of the Outbreak	
How was the outbreak controlled?	<p>Indicate whether there was any specific action taken to control the outbreak. If yes, indicate which control measures were undertaken and provide details. If the control measure(s) is not listed specify details in the Other control measures text field.</p>
Was insufficient information supplied to complete the form?	<p>Indicate whether insufficient information to complete the form was provided.</p>
Other comments on the outbreak	<p>Note any other comments about the outbreak that may be relevant, and ensure that comments do not provide key personal identifiable information such as names, phone numbers, addresses, or NHI numbers.</p>

23.3. Appendix

23.3.1. Condition and implicated contaminant

Some common contaminants (pathogen/toxin/chemical) and their suggested corresponding conditions (diseases) are listed below.

Note that the following conditions are also available in the conditions (diseases) drop-down list where pathogen might be unknown/ unavailable: conjunctivitis, dengue fever, gastroenteritis - unknown cause, influenza-like illness, respiratory illness, toxic shellfish poisoning, etc

Please contact EpiSurv Support to add to the list(s).

Pathogen/Toxin/Chemical - subtype(s)	Condition (disease)
Aeromonas - hydrophila	Gastroenteritis/foodborne intoxication
Bacillus - cereus	Gastroenteritis/foodborne intoxication
Bordetella - pertussis	Pertussis
Brucella - all subtypes	Brucellosis
Campylobacter - all subtypes	Campylobacteriosis
Chlorine	Chemical poisoning from the environment
Ciguatera fish poisoning	Gastroenteritis/foodborne intoxication
Clostridium - perfringens	Gastroenteritis/foodborne intoxication
Cryptosporidium - parvum	Cryptosporidiosis
Escherichia - coli	Gastroenteritis/foodborne intoxication
Escherichia - coli 0157:H7	VTEC/STEC infection
Giardia - all subtypes	Giardiasis
Haemophilus - influenzae type b	Haemophilus influenzae type b
Haemophilus - influenzae type NOS	Haemophilus influenzae type NOS
Hepatitis virus - A	Hepatitis A
Hepatitis virus - B	Hepatitis B
Hepatitis virus - C	Hepatitis C
Hepatitis virus - NOS	Hepatitis NOS
Histamine (scombroid) fish poisoning	Gastroenteritis/foodborne intoxication
Influenza virus - A (H1N1) 09	Non seasonal influenza A (H1N1)
Influenza virus - A, A (H1N1), A (H3N2), etc	Influenza A
Influenza virus - B	Influenza B
Influenza virus - NOS	Influenza NOS
Lead	Lead absorption
Legionella - all subtypes	Legionellosis
Leptospira - all subtypes	Leptospirosis

Pathogen/Toxin/Chemical - subtype(s)	Condition (disease)
Listeria - monocytogenes	Listeriosis
Measles virus	Measles
Mumps virus	Mumps
Mycobacterium - all species	Tuberculosis disease
Mycoplasma - pneumoniae	Respiratory infection
Neisseria - meningitidis, meningitidis B, etc	Meningococcal disease
Norovirus - all genotypes	Gastroenteritis/foodborne intoxication
Plasmodium - all subtypes	Malaria
Rotavirus	Gastroenteritis/foodborne intoxication
Rubella virus	Rubella
Salmonella - all phage types (non-typhoidal)	Salmonellosis
Salmonella - Typhi, Typhi A, etc	Typhoid fever
Salmonella - Paratyphi A, Paratyphi B, etc	Paratyphoid fever
Shigella - all subtypes	Shigellosis
Staphylococcus - aureus	Gastroenteritis/foodborne intoxication
Tutin	Gastroenteritis/foodborne intoxication
Vibrio - cholerae 01, cholerae 0139	Cholera
Vibrio - other subtypes	Gastroenteritis/foodborne intoxication
Yersinia - enterocolitica, pseudotuberculosis	Yersiniosis

23.3.2. Level of evidence codes

1	Elevated risk ratio or odds ratio with 95% confidence intervals not including 1 AND laboratory evidence (same organism and sub type detected in both cases and vehicle to the highest level of identification)
2a	Elevated relative risk or odds ratio with 95% confidence intervals not including 1
2b	Laboratory evidence, same organism and sub type detected in both cases and vehicle (to the highest level of identification)
3a	Compelling evidence, symptomatology attributable to specific organism e.g. scombrotoxin, ciguatoxin etc
3b	Other association i.e. organism detected at source but not linked directly to the vehicle or indistinguishable DNA or PFGE profiles
3c	Raised but not statistically significant relative risk or odds ratio
4	No evidence found but logical deduction given circumstances

23.3.3. Food Categories

- Fish
- Shellfish - crustaceans
- Shellfish – molluscs
- Rice
- Dairy
- Eggs
- Meat – poultry
- Meat – beef
- Meat – game
- Meat – pork
- Grains/beans
- Oils/sugars
- Fruits/nuts
- Vegetables – fungi
- Vegetables – leafy
- Vegetables – root
- Vegetables – sprout
- Vegetables – vine/stalk

General Instructions	
Date fields	<p>Most date fields have a 'date picker' attached to simplify entry of dates. Click on the ellipsis '⊙', and choose appropriate date.</p> <p>Double-clicking into the date field will also return today's date.</p>
Drop-down lists	<p>A number of fields restrict entry to options in a drop-down list. A list that matches your entry will appear as soon as you type in at least three characters into the field. Some lists will show all options available if you press the down (↓) button on the keyboard, for example <i>Food Category, Pathogen, Subtype</i>, etc.</p> <p>Please use the Clear button available to the right of the field, to clear any entries instead of using the Backspace or Delete keys on your keyboard to ensure your entry is properly cleared.</p> <p>Some drop-down lists allow users to add a new entry. This is possible when a New button appears to the right of the relevant field. Once the field(s) is completed, click the Save button (or Cancel to clear the entry) to save the entry. This entry will now appear in the list in future searches.</p> <p>Note that your outbreak report form cannot be saved in EpiSurv if have not saved (or cancelled) your new entry.</p> <p>For some drop-down lists, users are not permitted to add/edit entries – e.g. for pathogens/conditions, hospitals, prisons, schools, etc. Please contact EpiSurv Support if you would like any changes made to these lists.</p> <p>The option to search nationally is indicated by a <i>National</i> checkbox. By selecting this checkbox, the list will expand to include all relevant national options.</p>
Free-text fields	<p>Most free-text fields in EpiSurv are not marked as confidential (includes the Comments field), so remember to avoid entering identifying information into this field. You can use initials, relationships e.g. Mother of case, the EpiSurvNumbers etc. to refer to an individual. Please do not enter names, phone numbers, addresses or NHI numbers these fields.</p>
Un-selecting option buttons	<p>Pressing CTRL-Delete on your keyboard will remove the last selected option button (⊙).</p>
Clicking the Save button	<p>Clicking the Save button regularly will help you avoid losing any information or EpiSurv timing out while you are editing an outbreak report form. Note that EpiSurv times out after an hour of inactivity.</p>
Attaching documents to outbreak form	<p>If a written report has been prepared, please attach a PDF or Word copy to the Outbreak Report Form in EpiSurv</p>
Additional Instructions for Specific Fields	
Name of public health officer responsible for investigation	<p>The names will be available from a drop-down list. This is a memory list of any entry used/added in the last six months in EpiSurv. To add a new entry, just type ahead and save the outbreak.</p>

<p>Implicated contaminant (pathogen) and subtype</p>	<p>Select the name of the implicated contaminant (causative agent) from the drop-down list. This may be a pathogen, toxin or chemical. Select a subtype for a pathogen if applicable.</p> <p>Next, select the corresponding condition (disease). A list showing the condition to select for a given implicated contaminant in the appendix. Note that where it is not possible to specify an implicated contaminant, it may still be possible to select a condition, e.g. gastroenteritis – unknown cause, toxic shellfish poisoning, influenza-like illness, etc.</p> <p>Click in the Pathogen, Subtype, or Condition fields and press the arrow down key to see the values currently available.</p> <p>If there is a second implicated contaminant or condition, select the Yes option button for the <i>Other known condition/implicated pathogen</i> and complete the second Pathogen, Subtype, or Condition fields as above.</p> <p>Contact EpiSurv Support to add/edit the list(s).</p>
<p>Setting where exposure occurred</p>	<p>Once the header option, and the detail option have been selected, users can choose the <i>Setting name</i> from a drop-down list. Selecting a <i>Setting name</i> from the list will automatically populate all the relevant address fields.</p> <p>To add a new setting to the drop-down list, all address details should be completed, and the entry Saved. If the precise address is unknown, leave the address fields null, but geocode to the nearest TA by clicking on the <i>GeoCode</i> checkbox and selecting the appropriate TA from the list.</p>
<p>Setting where contaminated food/beverage was prepared</p>	<p>Once the header option and the detail option have been selected, users can choose the <i>Setting name</i> from a drop-down list. Selecting a <i>Setting name</i> from the list will automatically populate all the relevant address fields.</p> <p>To add a new setting to the drop-down list, all address details should be completed, and the entry Saved. If the precise address is unknown, leave the address fields null, but geocode to the nearest TA by clicking on the <i>GeoCode</i> checkbox and selecting the appropriate TA from the list.</p>
<p>Overseas exposure</p>	<p>Overseas outbreaks are those where two or more people have been infected from a common event or other defined source, not where a single case is imported into New Zealand and the disease subsequently transmitted.</p>

Outbreak Summary	Outbreak No. <input style="width: 90%;" type="text"/>
Circumstances of Exposure/Transmission	
How was the outbreak first recognised?	
<input type="radio"/> Increase in disease incidence <input type="radio"/> Cases had person to person contact with other cases(s)	
<input type="radio"/> Cases attended common event <input type="radio"/> Common organism type/strain characteristics between cases	
<input type="radio"/> Cases linked to common source (eg food, water, environmental site)	
<input type="radio"/> Other means (specify) <input style="width: 80%;" type="text"/>	
Were these cases part of a well-defined exposed group (eg Common event, institutional, environmental, household)	
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	
If yes, date of exposure <input style="width: 150px;" type="text"/>	
If exposure >1 day, date exposure ended <input style="width: 150px;" type="text"/>	
Description of exposure event <input style="width: 80%;" type="text"/>	
First setting where exposure occurred	
Setting unknown <input type="checkbox"/>	
<input type="radio"/> Food premises <input type="radio"/> Institution <input type="radio"/> Workplace/Community/Other	
<input type="radio"/> Restaurant/café/bakery <input type="radio"/> Hostel/boarding house <input type="radio"/> Workplace	
<input type="radio"/> Takeaway <input type="radio"/> Hotel/motel <input type="radio"/> Farm	
<input type="radio"/> Supermarket/delicatessen <input type="radio"/> Long term care facility <input type="radio"/> Petting zoo	
<input type="radio"/> Temporary or mobile service <input type="radio"/> Hospital (acute care) <input type="radio"/> Home	
<input type="radio"/> Fast food restaurant <input type="radio"/> Prison <input type="radio"/> Community, church, sports gathering	
<input type="radio"/> Caterers <input type="radio"/> Camp <input type="radio"/> Cruise ship, airline, tour bus, train	
<input type="radio"/> Other food outlet <input type="radio"/> School <input type="radio"/> Childcare centre <input type="radio"/> Other setting	
<input type="radio"/> Marae <input type="radio"/> Other institution	
Setting name <input style="width: 300px;" type="text"/>	
Setting Address	
Number <input style="width: 50px;" type="text"/>	Street <input style="width: 200px;" type="text"/>
Suburb <input style="width: 150px;" type="text"/>	
Town/City <input style="width: 250px;" type="text"/>	Post Code <input style="width: 60px;" type="text"/>
<input type="checkbox"/> GeoCode <input style="width: 40px;" type="text"/>	
Second setting where exposure occurred	
Setting unknown <input type="checkbox"/>	
<input type="radio"/> Food premises <input type="radio"/> Institution <input type="radio"/> Workplace/Community/Other	
<input type="radio"/> Restaurant/café/bakery <input type="radio"/> Hostel/boarding house <input type="radio"/> Workplace	
<input type="radio"/> Takeaway <input type="radio"/> Hotel/motel <input type="radio"/> Farm	
<input type="radio"/> Supermarket/delicatessen <input type="radio"/> Long term care facility <input type="radio"/> Petting zoo	
<input type="radio"/> Temporary or Mobile Service <input type="radio"/> Hospital (acute care) <input type="radio"/> Home	
<input type="radio"/> Fast food restaurant <input type="radio"/> Prison <input type="radio"/> Community, church, sports gathering	
<input type="radio"/> Caterers <input type="radio"/> Camp <input type="radio"/> Cruise ship, airline, tour bus, train	
<input type="radio"/> Other food outlet <input type="radio"/> School <input type="radio"/> Childcare centre <input type="radio"/> Other setting	
<input type="radio"/> Marae <input type="radio"/> Other institution	
Setting name <input style="width: 300px;" type="text"/>	
Setting Address	
Number <input style="width: 50px;" type="text"/>	Street <input style="width: 200px;" type="text"/>
Suburb <input style="width: 150px;" type="text"/>	
Town/City <input style="width: 250px;" type="text"/>	Post Code <input style="width: 60px;" type="text"/>
<input type="checkbox"/> GeoCode <input style="width: 40px;" type="text"/>	

Circumstances of Exposure/Transmission contd		
First setting where contaminated food/beverage was prepared		Setting unknown <input type="checkbox"/>
<input type="radio"/> Food premises	<input type="radio"/> Institution	<input type="radio"/> Workplace/Community/Other
<input type="radio"/> Overseas manufacturer, specify <input type="text"/>		
<input type="radio"/> Restaurant/café/bakery	<input type="radio"/> Hostel/boarding house	<input type="radio"/> Workplace
<input type="radio"/> Takeaway	<input type="radio"/> Hotel/motel	<input type="radio"/> Farm
<input type="radio"/> Supermarket/delicatessen	<input type="radio"/> Long term care facility	<input type="radio"/> Petting zoo
<input type="radio"/> Temporary or Mobile Service	<input type="radio"/> Hospital (acute care)	<input type="radio"/> Home
<input type="radio"/> Fast food restaurant	<input type="radio"/> Prison	<input type="radio"/> Community, church, sports gathering
<input type="radio"/> Caterers	<input type="radio"/> Camp	<input type="radio"/> Cruise ship, airline, tour bus, train
<input type="radio"/> Other food outlet	<input type="radio"/> School <input type="radio"/> Childcare centre	<input type="radio"/> Commercial food manufacturer
	<input type="radio"/> Marae	<input type="radio"/> Other setting
	<input type="radio"/> Other institution	
Setting name	<input type="text"/>	
Setting Address	Number <input type="text"/>	Street <input type="text"/>
	Suburb <input type="text"/>	
	Town/City <input type="text"/>	Post Code <input type="text"/>
		<input type="checkbox"/> GeoCode <input type="text"/>
Second setting where contaminated food/beverage was prepared		Setting unknown <input type="checkbox"/>
<input type="radio"/> Food premises	<input type="radio"/> Institution	<input type="radio"/> Workplace/Community/Other
<input type="radio"/> Overseas manufacturer, specify <input type="text"/>		
<input type="radio"/> Restaurant/café/bakery	<input type="radio"/> Hostel/boarding house	<input type="radio"/> Workplace
<input type="radio"/> Takeaway	<input type="radio"/> Hotel/motel	<input type="radio"/> Farm
<input type="radio"/> Supermarket/delicatessen	<input type="radio"/> Long term care facility	<input type="radio"/> Petting zoo
<input type="radio"/> Temporary or Mobile Service	<input type="radio"/> Hospital (acute care)	<input type="radio"/> Home
<input type="radio"/> Fast food restaurant	<input type="radio"/> Prison	<input type="radio"/> Community, church, sports gathering
<input type="radio"/> Caterers	<input type="radio"/> Camp	<input type="radio"/> Cruise ship, airline, tour bus, train
<input type="radio"/> Other food outlet	<input type="radio"/> School <input type="radio"/> Childcare centre	<input type="radio"/> Commercial food manufacturer
	<input type="radio"/> Marae	<input type="radio"/> Other setting
	<input type="radio"/> Other institution	
Setting name	<input type="text"/>	
Setting Address	Number <input type="text"/>	Street <input type="text"/>
	Suburb <input type="text"/>	
	Town/City <input type="text"/>	Post Code <input type="text"/>
		<input type="checkbox"/> GeoCode <input type="text"/>
Geographic location where exposure occurred (tick one)		
<input type="radio"/> New Zealand	<input type="radio"/> Overseas, specify <input type="text"/>	<input type="radio"/> Unknown
If exposure occurred in New Zealand, specify		
Primary TA	<input type="text"/>	
DHB(s)	<input type="text"/>	<input type="text"/>
	<input type="text"/>	<input type="text"/>
Health District(s)	<input type="text"/>	<input type="text"/>
	<input type="text"/>	<input type="text"/>

Outbreak Summary	Outbreak No. <input style="width: 90%;" type="text"/>
Circumstances of Exposure/Transmission contd	
Mode of transmission (indicate the primary mode and all secondary modes)	
<input type="checkbox"/> Foodborne, from consumption of contaminated food or drink (excluding water)	
Mode <input type="radio"/> primary <input type="radio"/> secondary	Level of evidence <input type="radio"/> 1 <input type="radio"/> 2a <input type="radio"/> 2b <input type="radio"/> 3a <input type="radio"/> 3b <input type="radio"/> 3c <input type="radio"/> 4
<input type="checkbox"/> Waterborne, from consumption of contaminated drinking water	
Mode <input type="radio"/> primary <input type="radio"/> secondary	Level of evidence <input type="radio"/> 1 <input type="radio"/> 2a <input type="radio"/> 2b <input type="radio"/> 3a <input type="radio"/> 3b <input type="radio"/> 3c <input type="radio"/> 4
<input type="checkbox"/> Person to person spread, from (non-sexual) contact with an infected person (including droplets)	
Mode <input type="radio"/> primary <input type="radio"/> secondary	Level of evidence <input type="radio"/> 1 <input type="radio"/> 2a <input type="radio"/> 2b <input type="radio"/> 3a <input type="radio"/> 3b <input type="radio"/> 3c <input type="radio"/> 4
<input type="checkbox"/> Sexual, from sexual contact with an infected person	
Mode <input type="radio"/> primary <input type="radio"/> secondary	Level of evidence <input type="radio"/> 1 <input type="radio"/> 2a <input type="radio"/> 2b <input type="radio"/> 3a <input type="radio"/> 3b <input type="radio"/> 3c <input type="radio"/> 4
<input type="checkbox"/> Parenteral, from needle stick injury or reuse of contaminated injection equipment	
Mode <input type="radio"/> primary <input type="radio"/> secondary	Level of evidence <input type="radio"/> 1 <input type="radio"/> 2a <input type="radio"/> 2b <input type="radio"/> 3a <input type="radio"/> 3b <input type="radio"/> 3c <input type="radio"/> 4
<input type="checkbox"/> Environmental, from contact with an environmental source (eg swimming)	
Mode <input type="radio"/> primary <input type="radio"/> secondary	Level of evidence <input type="radio"/> 1 <input type="radio"/> 2a <input type="radio"/> 2b <input type="radio"/> 3a <input type="radio"/> 3b <input type="radio"/> 3c <input type="radio"/> 4
<input type="checkbox"/> Zoonotic, from contact with an infected animal	
Mode <input type="radio"/> primary <input type="radio"/> secondary	Level of evidence <input type="radio"/> 1 <input type="radio"/> 2a <input type="radio"/> 2b <input type="radio"/> 3a <input type="radio"/> 3b <input type="radio"/> 3c <input type="radio"/> 4
<input type="checkbox"/> Vectorborne, from contact with an insect vector	
Mode <input type="radio"/> primary <input type="radio"/> secondary	Level of evidence <input type="radio"/> 1 <input type="radio"/> 2a <input type="radio"/> 2b <input type="radio"/> 3a <input type="radio"/> 3b <input type="radio"/> 3c <input type="radio"/> 4
<input type="checkbox"/> Other mode of transmission (specify) <input style="width: 400px;" type="text"/>	
Mode <input type="radio"/> primary <input type="radio"/> secondary	Level of evidence <input type="radio"/> 1 <input type="radio"/> 2a <input type="radio"/> 2b <input type="radio"/> 3a <input type="radio"/> 3b <input type="radio"/> 3c <input type="radio"/> 4
Mode of transmission unknown <input type="checkbox"/>	
Vehicle/source of common source outbreak	
Was a specific contaminated food, water or environmental vehicle/source identified? <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	
If yes,	
Source 1	<input style="width: 580px;" type="text"/>
Level of evidence	<input type="radio"/> 1 <input type="radio"/> 2a <input type="radio"/> 2b <input type="radio"/> 3a <input type="radio"/> 3b <input type="radio"/> 3c <input type="radio"/> 4
Food category	<input style="width: 150px;" type="text"/> ESR Updated <input type="checkbox"/> Date <input style="width: 80px;" type="text"/>
Source 2	<input style="width: 580px;" type="text"/>
Level of evidence	<input type="radio"/> 1 <input type="radio"/> 2a <input type="radio"/> 2b <input type="radio"/> 3a <input type="radio"/> 3b <input type="radio"/> 3c <input type="radio"/> 4
Food category	<input style="width: 150px;" type="text"/> ESR Updated <input type="checkbox"/> Date <input style="width: 80px;" type="text"/>
Source 3	<input style="width: 580px;" type="text"/>
Level of evidence	<input type="radio"/> 1 <input type="radio"/> 2a <input type="radio"/> 2b <input type="radio"/> 3a <input type="radio"/> 3b <input type="radio"/> 3c <input type="radio"/> 4
Food category	<input style="width: 150px;" type="text"/> ESR Updated <input type="checkbox"/> Date <input style="width: 80px;" type="text"/>

Outbreak Summary	Outbreak No.
Factors Contributing to Outbreak	
Foodborne outbreak (tick all that apply)	
<input type="checkbox"/> Inadequate reheating of previously cooked food	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Improper storage prior to presentation	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Inadequate thawing	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Preparation too far in advance	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Undercooking	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Improper hot holding	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Inadequate or slow cooling or refrigeration	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Cross contamination due to improper handling or storage	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Cross contamination from an infected food handler	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Chemical contamination	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Use of ingredient from an unsafe source	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Use of untreated water in food preparation	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Consumption of unpasteurised milk	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Consumption of raw food	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Other factors, specify <input style="width: 150px;" type="text"/>	<input type="radio"/> Confirmed <input type="radio"/> Suspected
Waterborne outbreak (tick all that apply)	
<input type="checkbox"/> Surface water with no treatment	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Roof collected rainwater with no treatment	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Groundwater not assessed as secure and with no treatment	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Source water quality inferior to normal, If source water quality inferior to normal, specify <input style="width: 250px;" type="text"/>	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Treatment process failure	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Inadequately treated water supply	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Untreated water supply	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Post treatment contamination	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Recent or ongoing treatment process failure	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Contamination of post treatment water storage	<input type="radio"/> Confirmed <input type="radio"/> Suspected
Specify the WINZ supply code of the implicated water supply <input style="width: 200px;" type="text"/>	
Person to person outbreak (tick all that apply)	
<input type="checkbox"/> Inadequate vaccination cover	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Inadequate vaccination effectiveness	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Exposure to infected person	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Poor hygiene of cases	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Excessively crowded living conditions	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Unprotected sexual activity	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Compromised immune system	<input type="radio"/> Confirmed <input type="radio"/> Suspected

Outbreak Summary	Outbreak No. <input style="width: 90%;" type="text"/>
Factors Contributing to Outbreak	
Environmental outbreak (tick all that apply)	
<input type="checkbox"/> Exposure to contaminated land	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Exposure to contaminated air (including ventilation)	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Exposure to contaminated built environments (inc dwellings)	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Exposure to infected animals or animal products	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Exposure to contaminated swimming/spa pools	<input type="radio"/> Confirmed <input type="radio"/> Suspected
<input type="checkbox"/> Exposure to contaminated other recreational water	<input type="radio"/> Confirmed <input type="radio"/> Suspected
Other outbreaks	
<input type="checkbox"/> Other risk factor, specify <input style="width: 300px;" type="text"/>	<input type="radio"/> Confirmed <input type="radio"/> Suspected
Management of the Outbreak	
Was there any specific action taken to control the outbreak? <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	
If yes, list the control measures undertaken (tick all that apply)	
Source	Specify
<input type="checkbox"/> Closure	<input style="width: 100%;" type="text"/>
<input type="checkbox"/> Modification of procedures	<input style="width: 100%;" type="text"/>
<input type="checkbox"/> Cleaning, disinfection	<input style="width: 100%;" type="text"/>
<input type="checkbox"/> Removal	<input style="width: 100%;" type="text"/>
<input type="checkbox"/> Treatment	<input style="width: 100%;" type="text"/>
<input type="checkbox"/> Exclusion	<input style="width: 100%;" type="text"/>
<input type="checkbox"/> Isolation	<input style="width: 100%;" type="text"/>
<input type="checkbox"/> Health education and advice	<input style="width: 100%;" type="text"/>
<input type="checkbox"/> Health warning	<input style="width: 100%;" type="text"/>
Vehicles and vectors	
<input type="checkbox"/> Removal	<input style="width: 100%;" type="text"/>
<input type="checkbox"/> Treatment	<input style="width: 100%;" type="text"/>
Contacts and potential contacts	
<input type="checkbox"/> Chemoprophylaxis	<input style="width: 100%;" type="text"/>
<input type="checkbox"/> Vaccination	<input style="width: 100%;" type="text"/>
<input type="checkbox"/> Health education and advice	<input style="width: 100%;" type="text"/>
Other control measures (specify)	
<input style="width: 100%; height: 100%;" type="text"/>	

24. Appendix 9: Guidelines for the structure of an outbreak investigation report

The following are guidelines for the structure of an outbreak investigation report. The contents of the report will vary depending on the circumstances of the outbreak. Each of the items listed below should at least be considered for inclusion in the investigation report.

24.1. Abstract

Key points including number of cases, location and outbreak setting (e.g., type of event where cases were exposed), investigation method, main findings (organism, mode of transmission, risk factors), key control measures and lessons learned.

24.2. Introduction

- How you became aware of the outbreak.
- Outbreak setting (circumstances, general description of time, place and persons involved).
- Why you investigated, and the objectives of the investigation.

24.3. Methods used

24.3.1. Environmental investigation

- Inspection and interviews with staff during site visit.
- Specimen collection.

24.3.2. Laboratory investigation

- How specimens were collected and analysed (laboratory and method).

24.3.3. Case investigation

- Case definition used (provisional and final, if appropriate).
- How the subjects were identified.
- How the questionnaire was constructed (a blank copy should be attached to the report).
- How the questionnaire was delivered to subjects (e.g., telephone interview, face-to-face).

24.3.4. Control selection

If part of the investigation involved collection of information from control participants, you will need to specify how:

- the at-risk population was defined for the purposes of the investigation

- controls were selected
- controls were recruited.

24.3.5. Method of statistical analysis

- The methods used (appropriate to the study design)
- Software (and version) used

24.4. Results

24.4.1. Environmental investigation

- What was observed during the site visit?
- Findings from other components of the environmental investigation, e.g., HACCP.

24.4.2. Laboratory investigation

- What organisms were identified from laboratory tests, including subtyping if performed?

24.4.3. Investigation of subjects

- Number of responses and participation rate (in total, and by cases and non-cases/controls).
- Number of cases (i.e., met case-definition) and overall attack rate (for cohort study).
- Symptoms of illness (table of symptoms and frequency in cases and non-cases).
- Duration of illness (median, range).
- Laboratory findings in relation to cases.
- Characteristics of cases and non-cases/controls: age (median, range and by age group), sex, status (e.g., guests/staff), ethnicity (if relevant). These data may most informatively be expressed in tables, including attack rates (see below for examples).
- Outcomes of illnesses: hospitalisations, deaths, lasting effects.
- Incubation period (including median and range). It is usually useful to graph the 'epidemic curve'.
- Relationship of exposures to illnesses: Table showing attack rates, risk ratios, odds ratios (as appropriate to study design), confidence intervals, and p-values.
- Vaccination status, doses and timing, if appropriate.

24.5. Discussion and implications

- Likely causative agent.
- Likely mode of transmission.
- Risk factors.

- Discussion of possible impact of bias and confounding on results.
- What was done to control the outbreak and/or prevent future ones.
- What lessons were learnt?

24.6. Recommendations (as appropriate)

- What should be done to control this outbreak.
- What should be done to prevent future outbreaks.
- What should be done to improve investigation of outbreaks in future.

24.7. Examples of possible tables/graphs to accompany the report

The appropriate tables to accompany the report will vary according to whether the investigation has a retrospective cohort or case-control design. Examples of typical table structures for these two designs are illustrated next.

24.7.1. Tables for retrospective cohort studies

Table 1: Attack rates by demographic characteristics.

Characteristic	Number of cases	Number of non-cases	Total	Attack rate (%)
Age Group (yrs.)				
0–9				
10–19				
20–29				
etc.				
Total				
Gender				
Male				
Female				
Total				
Ethnicity				
Māori				
etc.				
Total				

Table 2: Symptoms/clinical features, by case-status

Symptom/ clinical feature	Cases		Non-cases	
	Number	%	Number	%
Vomiting				
Diarrhoea				
etc.				
Total				

Table 3: Risk ratios (relative risk estimates) associated with food exposures

Food	Persons who ate the food			Persons who did not eat the food			Risk ratio	95% CI	<i>p</i> -value
	Cases	Non-cases	Attack rate (%)	Cases	Non-cases	Attack rate (%)			
Potato salad									
Prawn cocktail									
etc.									

24.7.2. Tables for case-control studies

Table 4: Demographic characteristics of cases and controls

Characteristic	Cases		Controls	
	Number	%	Number	%
Age Group (yrs.)				
0–9				
10–19				
20–29				
etc.				
Gender				
Male				
Female				
Ethnicity				
Māori				
etc.				

Note: Differences between cases and controls should be examined with appropriate statistical tests (Chi-square or t-test).

Table 5: Frequency distribution of case symptoms and clinical features

Symptom/ clinical feature	Number	Per cent
Vomiting		
Diarrhoea		
etc.		

Note that when controls are sampled from the population of non-cases in a clearly defined exposed population, it may be appropriate to show similar data on them also (see Table 2).

Table 6: Odds ratios (relative risk estimates) for exposures of interest

Exposure	Cases		Controls		Odds ratio	95% CI	p-value
	Exposed	Not exposed	Exposed	Not exposed			
Potato salad							
Prawn cocktail							
etc.							

Note that the above example would be most appropriate in a situation where controls are a sample of the non-cases in a clearly defined, exposed population where the exposure is likely to be foodborne. However, in other circumstances the exposed/not exposed dichotomy will not be appropriate. For example, if the degree of exposure is of interest, then it will be necessary to allocate cases and controls to exposure categories. One category should then be set as the reference category (i.e., OR = 1.0), and the odds ratios for the other categories calculated relative to this. For example, if the volume of water consumed is of interest, then cases and controls would be divided into several categories depending on the amount of water they consumed, and one of these categories (probably the one with the lowest consumption) would be used as the reference. It is important that the cut-points that divide the categories be determined in an unbiased way. One way of doing this is to obtain a frequency distribution of exposures for all subjects, without regard to case or control status and then to take, say, quartiles or tertiles of the whole group (depending on the number of subjects overall).

In other situations the different exposure categories will already be apparent. For example, a situation where the type of water supply (e.g., town supply, roof collection, artesian well) was of interest as a possible risk factor. For the purposes of the analysis, one of these categories should arbitrarily be set as the reference category (often the one that is least suspect, but that is not critical), and the others measured against it.

24.7.3. The epidemic curve

This is a histogram or bar chart showing the time-course of the outbreak on the horizontal axis, with the number of cases on the vertical axis. Time may be expressed as either specific dates, or as time since exposure, if that is known (e.g., hours or days, depending on what is appropriate).

Fig A1. Epidemic curve of outbreak- and non-outbreak- associated *Salmonella* Typhimurium DT42 cases notified 13 October 2008 to 28 January 2009 by onset date, showing key events.

