

Applied Epidemiology in the Australian Capital Territory

November 2015

Field Placement

Communicable Disease Control Section, Health Protection Service
ACT Health, Australian Capital Territory

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A thesis submitted for the degree of Master of Philosophy in Applied Epidemiology of
The Australian National University

Declaration of work

The author certifies that this work contains no material which has been accepted for the award of any other degree or diploma, in any university or other tertiary institution and, to the best of my knowledge, contains no material previously published or written by another person, except where due reference has been made in the text.



.....

Lucas James Mills

20/11/2015

“Not everything that can be counted counts, and not everything that counts can be counted.”

Albert Einstein

ABSTRACT

In this thesis, I present a body of work that was completed during my Master of Philosophy in Applied Epidemiology (MAE) placement at the Communicable Disease Control Section at the ACT Health Protection Service from March 2014 to November 2015. I discuss my experiences as an MAE scholar and my role in the day-to-day activities of the section, including the surveillance of notifiable diseases and my participation in the response to several acute public health events.

I present the findings from an epidemiological study, describing the asbestos exposures of people diagnosed with mesothelioma in the Australian Capital Territory (ACT).

I describe and evaluate a surveillance system that I helped establish, which monitors passengers returning from an Ebola-affected country in response to the epidemic in West Africa. An evaluation found that the system was able to assess and monitor returned travellers in a timely manner.

I investigated a foodborne outbreak of gastroenteritis at a large function in the ACT. Enterotoxin producing *Clostridium perfringens* was isolated from a sample of butter chicken consumed at the function. This was consistent with the epidemiological investigation that showed eating the butter chicken was associated with illness. This resulted in the preparation of an article for publication.

I present findings from a study that describes trends in pathology testing and test positivity for sexually transmissible infections in the ACT, 2003–2012. There has been a dramatic increase in notification rates for STIs, such as chlamydia and gonorrhoea. Analysis of ACT data show that for the period studied, test positivity was relatively stable. The study demonstrates that it is feasible to utilise pathology testing data to better understand notification-based surveillance data. I presented the findings in an oral presentation at the Communicable Disease Conference 2015 in Brisbane.

To demonstrate competencies around peer-led teaching, I prepared a ‘Lesson From the Field’ on choosing the right statistical test and conducted a teaching session for

first year MAEs on the appropriate use and interpretation of p-values and confidence intervals.

In summary, this thesis describes my experiences in the MAE program, and presents the findings of several epidemiological studies. The work presented in this thesis supported the public health response to a number of high-profile health events and helped to improve our understanding of communicable disease surveillance in the ACT.

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**1 THE MASTER OF PHILOSOPHY IN APPLIED EPIDEMIOLOGY
PROGRAM**

1.1 Introduction

In this chapter, I provide a summary of work that was completed during my Master of Philosophy in Applied Epidemiology (MAE) placement at the Communicable Disease Control Section at the ACT Health Protection Service from March 2014 to November 2015. I discuss my role in the day-to-day activities of the section, including the surveillance of notifiable diseases and my participation in the response to several acute public health events.

The work presented in this chapter describes my experiences in the MAE program, and summarises several epidemiological studies that demonstrate a range of competencies around a theme of applied epidemiology in the ACT.

1.2 Summary of field placement

The Communicable Disease Control Section (CDC) sits within the Health Protection Service of the ACT Health Directorate. The ACT Health Protection Service is the principal agency responsible for managing major incidents that have significant public health implications for the ACT population.¹ HPS is responsible for both state government and local government functions in relation to communicable disease surveillance and public health regulations, as there is only one level of Government in the ACT.

The CDC section is made up of three teams, Surveillance, Infection Control and Immunisation and has approximately 20 staff and is responsible for the surveillance of communicable diseases, investigating and controlling disease outbreaks, providing licences and inspections for businesses that carry out skin penetration procedures and the coordination of immunisation programs (including vaccine delivery) in the ACT.

1.3 Reflections on the program

Alexander Langmuir, founder of the Epidemic Intelligence Service (upon which the Master of Applied Epidemiology program was based) is quoted as saying “... we’ll get them on an epidemic as fast as we can. Throw them overboard. See if they can swim and if they can’t throw them a life ring, pull them out and throw them in again”.² While I think I have done a little of both at times (sinking and swimming), the program has given me an opportunity to develop a range of personal and professional skills that are essential for working in public health.

Throughout my placement at the CDC section I was involved in daily surveillance activities, including entering reports of notifiable disease onto the surveillance database, contact tracing and follow-up for a range of notifiable diseases. Participating in the day to day operations of the public health unit helped me to learn about a wide variety of issues that relate to epidemiological concepts, such as the application of case definitions, used in disease notification data.

The course material on the ANU website describes the MAE program at the ‘disease detectives’ and I thought this would be the most challenging (but fun) part of the program. Field investigations are often complex and the application of epidemiological concepts in an acute public health response often involves a degree of problem solving and improvisation in order to apply the core epidemiological concepts in a real life setting. I was involved in foodborne disease investigations, this included conducting interviews in relation to routine notifications of food borne illness, as well as participating in several outbreak investigations. I was able to work with other sections within the Health Protection Service such as Environmental Health and the ACT Government Analytics Laboratory that tested food samples for common foodborne pathogens. These experiences helped to teach me about the collaborative and complex nature of outbreak investigation and the issues specific to foodborne illness.

I developed a greater appreciation of the principles of disease surveillance to be used as a tool to assess and describe the pattern of illness in the community and to implement control measures preventing further infection. The CDC section held semi-regular data surveillance meetings that reviewed trends in notification data,

often there was useful discussion that allowed the team to share knowledge and experience of colleagues who had worked in the section for a long period of time.

I was involved in the EVD Response Planning Team that developed a plan for the public health management of travellers returning from West Africa and was appointed the Ebola Coordinator. Through this role I learnt about the application of emergency management principles and structures in a public health setting, I also had the opportunity to attend a two-day training course in the Australasian Inter-Service Incident Management System (AIIMS) and participate in several emergency management exercises.

The small size of the ACT is a double edged sword, the Health Protection Service has a relatively flat structure allowing contact and collaboration with a number of people at all levels. For instance, I worked closely with the Deputy Chief Health Officer on the Ebola public health response plan and conducted some work on asbestos exposure that emerged as a high-profile health issue in the ACT due to the historical use of asbestos insulation in Canberra houses, commonly referred to as 'Mr Fluffy'. Some of this work is presented in this thesis. However, it also means that you get pulled in several directions, working on numerous projects at the same time, while also responding to the day to day work of a public health unit that can take priority depending on circumstances. It also offered an opportunity to work on a diverse range of tasks, for example, I have included a risk analysis on the deregulation of hairdressing that I conducted in 2014 (Appendix A).

There was also limited scope to specialise in one area, as often there are not enough notifications for a number of conditions to conduct meaningful analysis and this limits the types of projects that can be conducted. It also limits the way your finding can be presented, the ACT has particular sensitivities around reporting any combination of attributes which may disclose personal information, this means that it can be difficult to report tables with less than five cases in a cell. This made reporting on a rare condition, such as mesothelioma, particularly difficult. However, I have attempted to balance these concerns with the need to present meaningful information on the asbestos exposures of these patients.



MAE Cohort 2014, Canberra

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Exercise Melilla, Canberra 2015.



Ebola Response Planning Team receiving an ACT Chief Health Officer Award for their work in responding to emerging health threats.

While in the MAE program I have further developed high-level statistical skills using the software program STATA; as well as the ability to convey complex scientific and mathematical concepts clearly and succinctly to a wide range of stakeholders including policy makers, clinicians, colleagues and the public.

Throughout my placement, I have communicated effectively to a range of audiences, both internally and externally. The role has required me to draft and prepare briefs and minutes for executive clearance, as well as general reports and fact sheets for members of the public. I contributed two articles for the ACT Population Health Bulletin, including one on the management of foodborne disease outbreaks (Appendix B) and another on the Middle East Respiratory Syndrome Coronavirus (MERS-CoV) (Appendix C). I believe that as someone with an interest in public health that I am not only responsible for researching and conducting analysis, but in communicating these results to inform political discussions as well as the wider public.

On the whole, the knowledge and experiences gained from my work placement has provided a unique opportunity to develop a range of skills in relation to public health practice and the application of epidemiological concepts.

1.4 Summary of public health impact

The work presented in this thesis supported the public health response to a number of high-profile health events in the ACT.

The asbestos exposures of people diagnosed with mesothelioma in the ACT had not previously been documented and was not able to be obtained from other sources. While this study was unable to assess the health effects of living in an affected house, it provides useful information on potential asbestos exposures in mesothelioma cases diagnosed in the ACT.

The surveillance system that I helped to implement in response to the outbreak of Ebola in West Africa, was used to assess the risk of travellers returning from affected countries and monitor their health status. The EVD response planning team, of which I was the co-ordinator was acknowledged with an ACT Chief Health Officer's award in the category of 'detect and respond to emerging population health issues'. This work has bolstered the bio-preparedness of the ACT to cope with other emerging infectious diseases that may arise. For example, many of the procedures that had been developed regarding welfare of people under quarantine will be documented in an Annex to the Infectious Diseases Plan for the ACT and could be amended quickly if required for a range of communicable diseases.

I was involved in several gastroenteritis investigations, the most substantial was a *C. perfringens* outbreak linked to a large catered function at a tourist attraction in Canberra. In this case a public health risk assessment made after conducting an initial investigation concluded that there was no on-going risk as a consequence of the function. However, it was important to undertake an investigation to help us quantify the extent of illness among attendees to better understand and prevent similar problems in the future. We identified a cohort of staff working on the night of the function and contacted them with the aim of identifying how many people had been ill, and which food contributed to their illness.

I presented findings from a study that described trends in pathology testing and test positivity for sexually transmissible infections in the ACT over a ten-year period. While there has been a dramatic increase in notification rates for STIs, analysis of

ACT data show that test positivity had been relatively stable. This study demonstrated that it is feasible to utilise pathology testing data to better understand notification-based surveillance.

1.5 Summary of core MAE requirements

The MAE is a field based research degree that involves a coursework component conducted over three course blocks as well as four research projects that demonstrate competencies in field epidemiology that are presented in this thesis.

1.5.1 Design and conduct an epidemiological study

I designed and conducted an epidemiological study into the asbestos exposures of mesothelioma patients at the Canberra Hospital.

1.5.2 Establish and evaluate a surveillance system

I described and evaluated a surveillance system which monitors passengers returning from an Ebola-affected country in response to the epidemic in West Africa.

1.5.3 Investigation of an acute public health problem

I investigated a foodborne outbreak of *Clostridium perfringens* gastroenteritis linked to a function at a tourist attraction in Canberra. Enterotoxin producing *C. perfringens* was isolated from a sample of butter chicken consumed at the function, this was consistent with an epidemiological investigation that showed eating the butter chicken was significantly associated with illness. This resulted in the preparation of an article for publication (Appendix G) and a 'plain language' summary of the outbreak investigation (Appendix H), to demonstrate my ability to communicate research findings to a non-scientific audience.

1.5.4 Analysis of a public health dataset

I present findings from a study that describes trends in pathology testing and test positivity for sexually transmissible infections in the ACT over a ten-year period. The study found that despite a dramatic increase in the number of notifications that test positivity has remained relatively stable, and demonstrates that it is feasible to utilise pathology testing data to better understand notification-based surveillance data. I presented these findings in an oral presentation at the Communicable Disease Conference 2015 in Brisbane (Slides from this presentation are included in Appendix I).

1.5.5 Teaching requirements

I prepared a 'lessons from the field' session on choosing the right statistic.

Included at Appendix L.

1.5.6 Conference presentation

Authors: L Mills, R Hundy & E Fearnley

Title: Trends in testing for chlamydial infection in the ACT, 2003 to 2012

Presented 1 June 2015, Communicable Disease Control Conference, Brisbane

Included at Appendix I

1.5.7 Scientific manuscript for a peer-reviewed journal

Authors: Mills, L., Xu, C. Roberts-Witteveen, Ford, L. A. Hundy, R., Hudson, L., Stedman, A., Krsteski, R., and Kirk, M.

Title: An outbreak of *Clostridium perfringens* gastroenteritis linked to a function at a tourist attraction in Canberra, June 2015

Included at Appendix G.

1.5.8 Communicate research findings to a non-scientific audience

A plain language summary of the investigation was prepared for the venue.

Included at Appendix H

1.5.9 Other publications

Mills, L. Kelly, C. Stedman, A. Management of foodborne disease outbreaks ACT Population Health Bulletin 2014 3(2):14–15. Included at Appendix B.

Mills, L. Middle East Respiratory Syndrome coronavirus (MERS-CoV) ACT Population Health Bulletin 2015 4(2): 72. Included at Appendix C.

Table 1.1: Summary of MAE core requirements

	Data analysis	Response to an acute public health event	Establishment and evaluation of a surveillance system	Epidemiological project	Peer reviewed publication	Communicate research findings to a non-scientific audience	Oral conference presentation	Lessons from the Field
Chapter 2 Epidemiological study				✓				
Chapter 3 Surveillance system			✓					
Chapter 4 Outbreak investigation	✓	✓			✓	✓		
Chapter 5 Data analysis	✓						✓	
Chapter 6 Teaching experience								✓

1.6 References

1. ACT Health Protection Service. ACT Government, 2015. (Accessed 5/11/2015, 2015, at www.health.act.gov.au/public-information/public-health/health-protection-service.)
2. Pendergrast M. Inside the outbreaks: the elite medical detectives of the Epidemic Intelligence Service. Boston: Houghton Mifflin Harcourt; 2010.

Appendix A:

Hairdressing risk assessment

The operation of hairdressing salon or barbershop is a licensable 'public risk activity' under the *Public Health Act 1997*. Hair dressing businesses are required to be licensed by the ACT Health Protection Service. *The Public Health (Hairdressing) Code of Practice 2000* applies to all hairdressers and sets minimum requirements for cleanliness, hygiene and infection control within these premises.

The ACT Health Protections Service aims to protect and promote the health of the ACT community through innovative and timely action.

The objective of the current hairdressing legislation is to:

- Provide information to assist in minimising the risk of transmission of microorganisms between the hairdresser, the clients and equipment used;
- Provide information to enable the adoption of best practice hygiene procedures;
- Provide information to assist in ensuring that only equipment that has been appropriately cleaned is used on each client;
- Promote a safe working environment for staff.

Hairdressing businesses are required to apply for an annual hairdressing license in the ACT when establishing a new business, or purchasing an existing business and on a two yearly basis thereafter. An inspection is conducted to ensure that hairdressing practices and the layout of the premises meet hygiene requirements, including the presence of a separate hand washing basin. Site inspections also provide an opportunity for public health officers to ensure that operators are reminded of the ACT Health *Public Health (Hairdressing) Code of Practice* and that they are aware of infection risks and appropriate control practices. The *Code of Practice* also prescribes the method for cleaning and disinfecting equipment and minimum hygiene standards.

The purpose of this review was to conduct a risk assessment of activities conducted at hairdressing salons and barbershops as part of a wider review of the licensing requirements for hairdressing premises in the ACT. High-risk skin penetrating activities including body piercing and tattooing are likely to generate significant health risks to the community and are covered under separate legislation and are out of scope for this assessment.

Transmission of an infection can occur during hairdressing practices. Procedures using items such as razors, scissors and clippers may present an infection risk because these items can accidentally pierce or damage the skin. If hygiene practices are inadequate there is a potential for skin infections on the scalp, face and neck to be spread between clients and a potential for blood borne viruses such as hepatitis B (HBV) and hepatitis C (HCV) and human immunodeficiency virus (HIV) to be spread through blood and body fluid contact. A list of potential communicable diseases and infections arising from hairdressing activities are shown at Box 1.

Box 1: Communicable diseases and infections arising from activities performed in Hairdressing and Beauty Therapy

Infections that can be transmitted during hairdressing procedures include:

- Impetigo;
- head lice;
- tinea capitis;
- ringworm;
- hepatitis B virus;
- hepatitis C virus; and
- HIV.

Particular consideration was given to the risk of infection from the use of equipment contaminated with blood. Sharp equipment such as razor blades, scissors and clippers may become contaminated if they pierce the skin or scalp and should be immediately cleaned and disinfected or discarded to prevent potential infection with a blood borne disease.

Relevant legislation and regulation for hairdressing businesses in Australian State and Territories

Hairdressing businesses are generally still required to meet hygiene standards and remain subject to public health regulation by health authorities and local councils around Australia, a summary of this information is provided at Table 1 below.

New South Wales

In New South Wales the following legislation relates to the Hairdressing industry:

- *Public Health Act 2010*
- *Local Government Act 1993*
- *Local Government Regulations 2005*

Practices vary in different Councils areas, hairdressing businesses may require registration with their Local Council. Premises are inspected by Council Environmental Health Officers to ensure compliance with the standards required by the Local Government Act 1993. Fees may be collected at the time of registration or alternatively when conducting inspections.

Victoria

In Victoria the following legislation relates to the Hairdressing industry:

- *Public Health and Wellbeing Act 2008*
- *Public Health and Wellbeing Regulations 2008*

All hairdressing or beauty therapy businesses are required to be registered with the local council. Authorised officers from local councils and the Department of Health are responsible for enforcing provisions under the Act. These officers may conduct inspections, respond to complaints and follow up compliance issues.

Queensland

In Queensland the following legislation relates to the Hairdressing industry:

- *Public Health (Infection Control for Personal Appearance Services) Act 2003*

- *Public Health (Infection Control for Personal Appearances Services) Regulations 2003*

Businesses that provide high-risk personal appearance services need a license from a local council, however, non-high-risk services (such as hairdressing) do not require a license. Hairdressing and beauty salons are inspected by Council Environmental Health Officers

Western Australia

In Western Australia the following legislation relates to the Hairdressing industry:

- *Health Act 1911*
- *The Hairdressers Registration Act 1946* was repealed in 2010
- *Hairdressing Establishment Regulations 1972*

Western Australia was the last state or territory to require registration of individual hairdressing professionals, this requirement was repealed in 2010. All hairdressing or beauty therapy businesses are required to be registered with the local council.

South Australia

In South Australia the following legislation relates to the Hairdressing industry:

- *Public and Environmental Health Act 1987*
- *Hairdressers Regulations 2003*

Registration of Hairdressing Businesses is not required, however, Hairdressing businesses are inspected by Council Environmental Health Officers under the Public and Environmental Health Act 1987

Tasmania

In Tasmania the following legislation relates to the Hairdressing industry:

- *Public Health Act 1997*

Registration of Hairdressing Businesses is not required.

Northern Territory

In Northern Territory the following legislation relates to the Hairdressing industry:

- *Public and Environmental Health Act 2011*

Annual registration of Hairdressing Businesses is required. Hairdressing businesses are inspected by NT Environmental Health Officers

Summary

The above information shows that although there is wide variation of legislation in each jurisdiction, the hairdressing industry is generally regulated to some degree in most jurisdictions. While some jurisdictions have specific legislation, others manage the industry through Standards and Codes of Practice and some have both.

Table 1: Current hairdressing regulation in Australian States and Territories

State / Territory	Relevant legislation and regulations	Requirements for Hairdressing businesses	Responsibility for the inspection of premises
NSW	<i>Public Health Act 2010</i> <i>Local Government Act 1993</i>	Registration of Hairdressing Businesses with Local Council	Inspections conducted by council EHO
VIC	<i>Public Health and Wellbeing Act 2008</i>	Registration of Hairdressing business with Local Council	Inspections conducted by council EHO
QLD	<i>Public Health (Infection Control for Personal Appearances Services) Regulation 2003</i>	Registration of Hairdressing Businesses is not required	Inspections conducted by council EHO
WA	<i>Hairdressers Registration Act 1946</i> was repealed in 2010 <i>Hairdressing Establishment Regulations 1972</i>	Approval for a Hairdressing Businesses with Local Council is required	Inspections conducted by council EHO
SA	<i>Public and Environmental Health Act 1987</i>	Registration of Hairdressing Businesses is not required	Inspections conducted by council EHO
TAS	<i>Public Health Act 1997</i>	Registration of Hairdressing Businesses is not required	Inspections conducted by council EHO
NT	<i>Public and Environmental Health Act 2011</i> <i>Public Health (Barbers' Shops) Regulations</i>	Annual registration of Hairdressing Businesses with NT Department of Health and Families	Inspections conducted by NT EHO
ACT	<i>Public Health Act 1997</i>	Annual registration of Hairdressing Businesses with ACT Health Protection Service	Inspections conducted by Infection Control

Risk assessment

While there is a range of literature documenting occupational blood exposures in healthcare settings or exposures related to intentional skin penetrating activities (including body piercing and tattooing), there has been very little research on the risks associated with this topic. Infection with a blood borne disease is biologically plausible, due to an accidental percutaneous exposure to blood while shaving or cutting hair.

A number of articles described awareness and attitudes towards blood borne infections amongst barbers and the risk of infection from street barbers in developing countries. The findings of this research cannot be readily applied to the Australian context due to the lower prevalence of blood borne disease and better awareness of hygienic practices and within the hairdressing industry and the community.

A risk assessment is a process for gathering and assessing information to assign a level of risk and provides the basis for reducing and managing the negative consequences of risks to public health. The characterisation of risk often involves assessing the severity of a potential hazard and the likelihood of exposure to that hazard. This risk assessment was made with reference to the *Health Directorate Integrated Risk Management Policy and Guidelines*, using the descriptions used in this document to assess both the likelihood and the consequences of this event. The following risk assessment was conducted on the public health risk of infection with blood borne diseases as a result of an accidental blood exposure in the hairdressing industry. Although the transmission of other transient skin infections is more likely to occur, they have an insignificant consequence on people's health.

Table 2: Consequence of event occurring

Rating	Description
<i>Insignificant</i>	Injuries or ailments not requiring medical treatment
<i>Minor</i>	Minor injury or First Aid Treatment required
<i>Moderate</i>	Serious injury causing hospitalisation or multiple medical treatment cases.
<i>Major</i>	Life threatening injury or multiple serious injuries causing hospitalisation.
<i>Catastrophic</i>	Death or multiple life threatening injuries.

This risk assessment has considered the following factors to characterise the consequence or severity of the hazard. Infection with one of the following blood borne diseases would severely impact a person's health.

- Hepatitis B virus (HBV) is usually transmitted by contact with the blood, semen, vaginal secretions or saliva of an infected person. The virus must be introduced through broken skin or the placenta or come in contact with mucous membranes for infection to occur.

Exposure to HBV may result in transient or chronic infection, either of which may be asymptomatic (only 30-50% of adults and less than 10% of children have symptoms).

- Hepatitis C virus (HCV) is usually transmitted when the blood of an infected person enters the bloodstream of an uninfected person.

About three quarters of people infected with hepatitis C develop chronic (long-lasting) infection without treatment and some eventually develop liver failure or cancer of the liver. While a quarter of people infected with hepatitis C virus clear their infection without specific treatment.

- Human immunodeficiency virus (HIV) is usually transmitted by contact with blood, semen, vaginal secretions or breast milk of an infected person. The virus must be introduced through broken skin, via the placenta or come in contact with mucous membranes for infection to occur.

The consequence, for an individual member of the public, acquiring a blood borne disease from an accidental exposure to blood while shaving or cutting hair could be characterised of being a **moderate**. Viral Hepatitis and HIV are chronic infections which require long-term treatment, and in the case of HIV is not curable.

Table 2: Likelihood of event occurring

Likelihood	Probability of occurrence	Indicative Frequency (Expected to occur)
<i>Almost certain</i>	Occurs more frequently than 1 in 10 tasks	Is expected to occur in most circumstances.
<i>Likely</i>	1 in 10 – 100	Will probably occur.
<i>Possible</i>	1 in 100 – 1,000	Might occur at some time in the future.
<i>Unlikely</i>	1 in 1,000 – 10,000	Could occur but doubtful.
<i>Rare</i>	1 in 10,000 – 100,000	May occur but only in exceptional circumstances.

This risk assessment considered the following factors to characterise the likelihood of exposure to that hazard:

- *The hairdresser or client must be a carrier of the infectious agent:* the prevalence of chronic HBV and HCV infection in the Australian community is very low by world standards, are estimated to be around 1.0% and 1.4% respectively. There are an estimated 28,000 to 34,000 Australians living with a HIV infection, with a national prevalence of around 0.1% (Kirby Institute 2013).
Likelihood *Possible* (probability 1 in 100–1,000)
- *Accidental injury caused by shaving or cutting hair:* the review was not able to find information on the frequency or severity of injuries to clients or hairdressers from razors, scissors or other equipment used to shave or cut hair.
Likelihood *Possible* (probability 1 in 100–1,000)
- *Inadequate infection control practices in the hairdressing business:* the review found little published information that examined awareness of blood borne disease in the hairdressing industry. Hairdressing practices are assessed as part of the licensing process in the ACT, anecdotally, responses given by the majority of hairdressers would suggest that current infection control practices are inadequate.

Likelihood Almost certain (probability more than 1 in 10)

- *The virus must remain viable on an environmental surface:* under laboratory conditions, HBV, HCV and HIV have all been shown to survive outside of the body for a number of days and weeks (Thompson et al. 2003). Used razor blades have the potential transmit HBV, a study by Eroglu et al. detected HBV DNA on used razor blades and found that public shaving, a practice more common in other parts of the world, poses a potential route for the transmission of HBV, particularly in countries with high carrier rates. Studies in healthcare workers have found that the rate of seroconversion after a direct exposure to HIV infected blood through needlestick injuries is less than 0.5%, the risk of HBV infection after a similar exposure is around 25% (Heymann 2008: 4).

Likelihood Unlikely (probability 1 in 1,000–10,000)

The likelihood this combination of events occurring resulting in an infection with a blood borne virus is characterised as rare, the probability of occurrence is very low (less than 1 in 100,000) but may happen in exceptional circumstances.

The implementation of **control measures** can be used to mitigate the risk of infection, standard precautions should be used to reduce the likelihood of transmission. Blood and bodily fluids should always be treated as infectious and hairdressing staff should be aware of the risks and know the safest way to protect themselves and customers from blood borne infection.

The Hygiene Standards described in the Code of Practice places the following requirements on all staff:

- hands should be washed before and after attending a client or after exposure to a bodily fluid
- all persons engaged by the business knows how to manage a blood exposure, including the disposal of contaminated waste;
- hairdressers who have a condition that can be transmitted to someone else must take reasonable precautions (appropriate to the condition) not to transmit the condition;
- hairdressing equipment must be appropriately cleaned before being used on another client;
- equipment that has penetrated the skin or become contaminated with blood must be appropriately cleaned and then disinfected, before being used on another client;
- a new single use disposable razor blades be used on each client, blades must be disposed of into a designated 'sharps' container; and
- all employees at hairdressing businesses should be immunised against hepatitis B.

Despite the low likelihood of infection this risk assessment characterised hairdressing activities as being of **medium** risk given the consequences to an individual member of the public. Control measures would mitigate this risk, reducing the likelihood of transmission.

Figure 1: Risk assessment of exposure to a blood borne disease

			→ Consequence →				
			Insignificant	Minor	Moderate	Major	Catastrophic
			1	2	3	4	5
Likelihood ↑	5	Almost Certain	Medium	High	High	Extreme	Extreme
	4	Likely	Medium	Medium	High	High	Extreme
	3	Possible	Low	Medium	Medium	High	Extreme
	2	Unlikely	Low	Medium	Medium	High	High
	1	Rare	Low	Low	Medium X	Medium	High

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Articles

Management of foodborne disease outbreaks

Lucas Mills, Chris Kelly, and Andrew Stedman, Health Protection Service, Population Health Division

The Health Protection Service is responsible for the investigation and management of food safety issues within the ACT. This article gives a brief overview of the management of outbreaks related to food premises.

In the context of an investigation, a foodborne disease outbreak is defined as two or more cases of gastrointestinal illness associated with a common food source.

An outbreak investigation may begin after a number of cases of illness are linked to a common source. The investigation seeks to identify the cause of illness and to introduce public health measures to prevent further disease.

The management of foodborne outbreaks is an essential public health measure to prevent further cases of foodborne illness and has an important role in maintaining a healthy community. In the ACT, the public health response to an outbreak is conducted in accordance with the Public Health Act 1997 and the Food Act 2001. The Health Protection Service (HPS) is responsible for managing the response to public health events and for ensuring that food sold in the ACT is safe to eat.

The main components of an effective outbreak response include a series of inter-related laboratory, epidemiological and environmental health investigations. The investigation and response will generally involve the following steps:

- the clinical treatment and testing of outbreak cases;
- an epidemiological investigation to identify the source and scope of the outbreak;
- the inspection of the premises, including a review of food handling practices;
- the collection and laboratory testing of food and environmental samples;
- the implementation of control and prevention measures to limit the impact of the outbreak;
- effective risk communication with the community and media; and
- if the outbreak source is identified, consideration of whether a prosecution should be pursued.

Notification of an outbreak

An outbreak may be identified in a number of ways:

- the Communicable Disease Control (CDC) section may identify clusters of disease as part of routine surveillance and data assessment of notifiable diseases in the ACT;
- the HPS may be notified of a suspected outbreak by a general practitioner or emergency department doctor treating a number of patients with similar symptoms; or
- members of the public may make a complaint about a food business.

The infectious agent may be suspected or identified through clinical diagnosis and laboratory testing associated with the notification. Available information is reviewed to assess the public health implications of a potential foodborne outbreak.

Investigation and response

Once an outbreak has been identified, a multi-disciplinary Acute Response Team (ART) is established, drawing on personnel from across the HPS to investigate and identify the source of the outbreak and to implement public health control measures. Areas of HPS that may be involved in managing the outbreak response include:

- CDC;
- Environmental Health (EH);
- the ACT Government Analytical Laboratory (ACT-GAL); and
- the Preparedness and Response Section (PaRS).

The ACT OzFoodNet epidemiologist coordinates epidemiological investigations into foodborne disease outbreaks in the ACT and collaborates with OzFoodNet (the national foodborne disease surveillance network), particularly in outbreaks that cross ACT borders. See page 16 for more information on OzFoodNet.

The epidemiological investigation involves contacting cases and interviewing them to provide details about when they first experienced symptoms and a detailed history of any food consumed in the days prior to their illness. These interviews may implicate a food business or common food source that requires further investigation.

Food samples and environmental swabs of food preparation areas taken from the food business as part of the environmental investigation are tested by ACTGAL at the HPS facility in Holder. Results from the laboratory investigation may further support findings from the epidemiological investigation if there is evidence of environmental contamination with the same pathogen.



Photograph: Population Health Division file photograph

Articles

Management of foodborne disease outbreaks (*continued*)

Investigation and response (*continued*)

The sudden spike in outbreak related presentations at ACT hospital emergency departments associated with a large scale outbreak can place a significant strain on the health sector. If the size of the outbreak is likely to challenge the capacity of an ACT hospital, the Chief Health Officer can activate the Health Emergency Plan to manage the health sector response. Activation of the plan facilitates enhanced communication and a centralised reporting structure.

Communication with the public is an important aspect of the response; this can be facilitated through a media release or a public health alert being issued on the ACT Health website to describe the situation, identify those at risk and provide information to those affected.

Prevention measures

Public Health Officers (PHOs) from EH conduct routine food business inspections, routine food sampling and investigate complaints against food businesses. PHOs also audit food safety programs at certain higher risk food businesses (e.g. businesses that provide food to vulnerable populations such as the elderly or young children). In carrying out these duties, PHOs may identify potential sources of foodborne illness.



Photograph: by Witthaya Phonsawat - FreeDigitalPhotos.net

PHOs can undertake a range of enforcement measures available under the Food Act and the Public Health Act to address issues identified during an inspection. Actions that may be taken to prevent the further spread of disease include directing a food business to address identified issues or issuing a prohibition order under the Food Act, effectively closing the premises to the public. Where an offence is alleged to have occurred, the alleged perpetrator may be prosecuted.

The decision to prosecute

During an outbreak investigation, the primary focus of the HPS is protecting public health by ensuring the outbreak is contained and the source identified. The information gathered by PHOs while investigating an outbreak may, incidentally, later be used as evidence in a subsequent prosecution. As such, while public health is the foremost consideration of the investigation, consideration must also be given to the need to meet evidentiary standards.

Following the investigation of the outbreak source (and generally after the conclusion of an outbreak), a recommendation is made to the Director of the HPS as to whether grounds exist for prosecution. In deciding whether to pursue a prosecution, the Director may consider the available evidence, proposed charges, the specific circumstances of the alleged breach and any previous breaches.



Photograph: by Salvatore Vuono - FreeDigitalPhotos.net

Where a decision is made to pursue a prosecution, a brief is provided to the Director of Public Prosecutions (DPP). The DPP works with the HPS to determine the merits of the case based on the available evidence. The DPP makes the final decision on whether to prosecute and in doing so determines which, if any, charges will be pursued.

Conclusion of the response

Once control measures have been implemented, the HPS continues to monitor the situation and maintain disease surveillance. When no further cases can be linked to the source of the outbreak the acute phase of the investigation is finished. A number of post outbreak activities are routinely undertaken within the HPS to enhance evidence-based practice and ensure continual organisational improvement in the management of foodborne outbreaks.

Middle East respiratory syndrome coronavirus (MERS-CoV)

Lucas Mills, MAE Scholar, Communicable Disease Control Section, Population Health Division

Since emerging in 2012, the Middle East respiratory syndrome (MERS) has resulted in more than 1,000 laboratory confirmed cases and 400 deaths. The high mortality rate and epidemic potential of this disease has led to concerns by health authorities of a widespread epidemic, as seen with Severe Acute Respiratory Syndrome SARS in 2002. This article discusses the recent emergence of MERS and its public health importance.

Middle East respiratory syndrome (MERS) is an emerging viral respiratory illness caused by the MERS Coronavirus (MERS-CoV) which was first reported in Saudi Arabia in 2012.¹ MERS infection causes severe and acute respiratory illness and can result in death. Sporadic cases have been reported in several countries in the Middle East or in people with a recent travel history to the region. To date, the World Health Organization (WHO) has been notified of 1,075 laboratory-confirmed cases of infection with MERS-CoV, including 404 related deaths.²

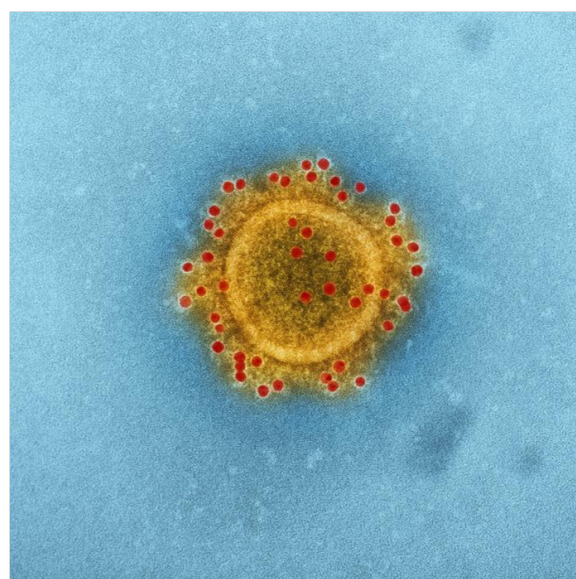
Emerging infectious diseases such as MERS pose a potential threat to global health due to their high mortality rate and epidemic potential. Of greatest concern for health authorities is the risk of transmission among the estimated two million pilgrims who travel to Saudi Arabia for the Hajj each year.³ The region is also host to a number of major travel hubs, including Dubai, one of busiest air transit cities in the world. The large number of passengers could rapidly disseminate the virus internationally. Public health authorities around the world continue to plan and implement disease control interventions designed to reduce the potential impact of any imported cases.

Coronaviruses are generally associated with mild seasonal respiratory illness similar to the 'common cold'. However, MERS-CoV is closely related to the coronavirus that caused the deadly SARS epidemic, emerging in the Guangdong province of China in 2002, resulting in over 8,000 cases and around 800 deaths.⁴

MERS is believed to originate in animals and while the natural animal reservoir for the virus is unknown, the virus has previously been isolated in bats⁵ and a number of studies have found evidence of MERS-CoV infection in camels in a number of Middle Eastern countries.^{6,7} While it is not clear how people initially become infected with the virus, person to person transmission is thought to primarily occur through respiratory droplets and direct contact. Clusters of person to person transmission have been documented among family members with close contact with a MERS case or in healthcare facilities.⁸

Active case finding has been critical in detecting new cases and increasing our knowledge about the course of disease and how it is spread. The implementation of public health measures in Saudi Arabia, including the screening of respiratory patients and contact tracing have been used to limit transmission of disease in the community.⁸ While infection control measures are critical to prevent the possible spread of MERS-CoV in a health care setting, certain groups of people appear to be at high risk of contracting MERS. These groups include people with underlying medical conditions such as diabetes, kidney failure, or chronic lung disease, and people who have weakened immune systems.¹⁰

Currently there is no evidence of widespread or sustained human to human transmission. A greater understanding of the source of infection and the primary mode of transmission in humans is needed to help develop strategies for the effective control of this emerging disease.



Photograph: Image of a Middle East Respiratory Syndrome Coronavirus (MERS-CoV) using an electron microscope. National Institute of Allergy and Infectious Diseases

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**2 ASBESTOS EXPOSURES IN PEOPLE DIAGNOSED WITH MALIGNANT
MESOTHELIOMA IN THE AUSTRALIAN CAPITAL TERRITORY,
2004–2014**

2.1 Abstract

Mesothelioma is a rare and aggressive form of cancer affecting the mesothelium, the tissue lining vital organs in the chest and abdominal cavities. Mesothelioma has one of the lowest survival rates of all cancers.

This study describes the asbestos exposures of 51 people that were diagnosed with or treated for mesothelioma at the Canberra Hospital over an eleven-year period. Information on previous asbestos exposures, including their residential and occupational histories, were sourced from medical notes. An asbestos exposure could be identified in 58.8% of all cases, with occupational exposures identified for the majority of men. From the records examined, there was evidence that potential exposures had been discussed with no specific exposure identified for a further 11.8% of cases, while the exposure remained unknown in 29.4% of cases.

2.2 Introduction

Mesothelioma is a rare and aggressive form of cancer affecting the mesothelium, the tissue lining vital organs in the chest and abdominal cavities.³ In 2011, the incidence of mesothelioma in Australia was 5.1 per 100,000 in males and 0.9 per 100,000 in females. The age-specific incidence rate increases with age and is highest in those aged 85 and over among both males and females (49.9 and 7.9 per 100,000 respectively).⁴ Mesothelioma has one of the lowest survival rates of all cancers, with a 5-year survival rate of 6% for a person diagnosed with the disease.⁵

Common symptoms of pleural mesothelioma are dyspnoea (shortness of breath) and chest pain, the person may also present with fever, cough and weight loss. Symptoms for peritoneal mesothelioma include abdominal distension, which may be associated with ascites (a build-up of fluid in the abdomen).⁶ The initial investigation for pleural mesothelioma may involve a chest X-ray or computerised tomography (CT) scan that finds a pleural effusion or other abnormality. Cytological examination of pleural fluid may be suggestive of malignant mesothelioma. A video assisted thorascopy (VAT) and biopsy may be required for a definitive diagnosis.⁷

A number of studies have demonstrated a strong association of mesothelioma with previous exposure to asbestos. The first suggestions that asbestos may result in tumours of the lung had been described by Doll in 1955,⁸ However, it was a case series by Wagner, Sleggs and Marchand that first linked mesothelioma (considered to be an extremely rare tumour at the time) with asbestos exposure at a crocidolite mine in South Africa.⁹ The evidence continued to mount throughout the second half of the twentieth century, the International Agency for Research on Cancer (IARC) classifies asbestos as being carcinogenic to humans.¹⁰ Asbestos exposure most often involves the inhalation of microscopic fibres that are deposited in the respiratory tract and retained in the lungs. Cancer develops following a long latency period, around 20–40 years after exposure.¹¹ Despite an interaction between the effect of asbestos exposure and smoking in the development of lung cancer, there does not appear to be an association between mesothelioma and smoking.¹²

Asbestos refers to a group of naturally occurring mineral fibres that can be divided into two groups, amphibole, a group that includes crocidolite and amosite, and serpentine which includes chrysotile.¹¹ Asbestos has a range of industrial

applications due to its versatility and physical properties. In the post-war period, Australia had the highest use of asbestos products per capita in the world, asbestos cement products were widely used in the construction industry over several decades and high levels of asbestos remain in the built environment,¹³ background levels of 100 asbestos fibres per cubic metre of air have been recorded in cities around Australia.¹⁴ The use of asbestos in Australia was reduced and phased out starting in the late 1970's, and regulations banning the use of all forms of asbestos were implemented in Australia in 2003.¹⁵ Asbestos products that are in good condition and are not disturbed pose minimal risk to health.¹⁶ Therefore, the identification of asbestos and the control measures to prevent the generation of airborne asbestos fibres are important components of managing the health risks.

Occupational exposure to raw asbestos during the mining or manufacturing of asbestos products remains the predominant cause of mesothelioma in Australia. Other common non-occupational exposures include having lived near an asbestos mine, or having a family member that worked with asbestos (due to the potential of bringing asbestos fibres home on clothing).¹⁷ Due to the large number of mesothelioma cases associated with the asbestos mine at Wittenoom in the north of Western Australia, the WA Mesothelioma Register began recording information on all of the known cases of the disease in the state. This information was initially gathered using a standardised questionnaire, but more recently exposure information has been gathered from clinical records close to the time of diagnosis.¹⁸ The number of mesothelioma cases without evidence of an occupational exposure has increased in recent years; in Western Australia most of this increase has been attributed to home renovations.¹⁹

2.2.1 Mesothelioma reporting in the ACT

In the ACT, information on incident cases of primary invasive cancer diagnosed are recorded on the ACT Cancer Register (ACTCR) under the Public Health Act 1997. Data are reported by a number of sources including pathology service providers, hospitals, oncology departments and death certificates (Figure 2.1). Pathology reports are the main source of notification of cancer diagnoses and are considered to be the 'gold standard'.²⁰ The ascertainment of cancer cases in Australia is believed to be near complete, although the process can take a number of years to finalise data.²¹

Newly diagnosed cases of mesothelioma are then notified by the cancer registry to the Australian Mesothelioma Registry (AMR) by state and territory cancer registries. Information on the patient's past asbestos exposures is collected by postal questionnaire and telephone interview if a doctor indicates that the patient is well enough to be contacted.²² However, there is a low response rate for asbestos exposure questionnaires, due to the short life expectancy following diagnosis.

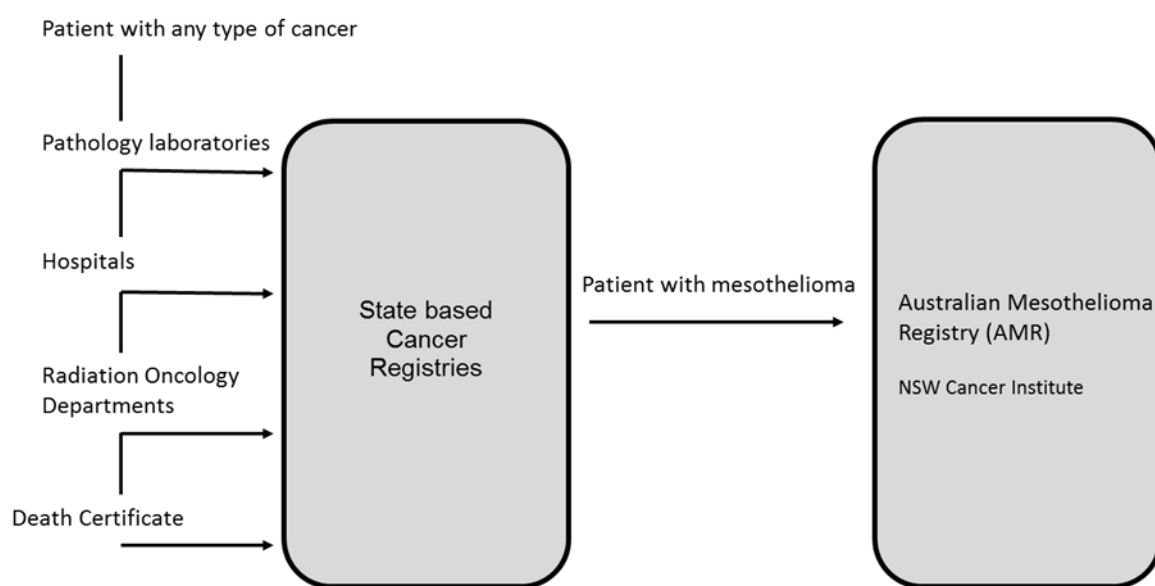


Figure 2.1: Cancer registration of mesothelioma in Australia

2.2.2 The legacy of asbestos insulation in the ACT

Between 1968 and 1979, a company trading under the name D. Jansen & Co. Pty Ltd (but sometimes referred to as ‘Mr Fluffy’) used loose amosite asbestos for thermal insulation in residential properties in Canberra and the surrounding region.²⁰ The Commonwealth and ACT Governments undertook a joint program to inspect and remove visible and accessible loose fill asbestos insulation (LFAI) from over 1,000 affected homes. The owners of houses involved in the Loose Asbestos Insulation Removal Program were informed of the potential of residual loose-fill asbestos and the need to take care when conducting building maintenance and renovation.²⁰

Community concern around the health effects of non-occupational asbestos exposure has been heightened in the Australian Capital Territory (ACT), after inspections conducted by asbestos assessors in 2013 found that some houses involved in this removal program may have residual asbestos fibres in the wall cavities and sub-floor

spaces.²³ Due to the high levels of asbestos found in some properties a number of families were directed to immediately vacate their homes.

The ACT Government response has resulted in the Loose Fill Asbestos Insulation Eradication Scheme that will see the purchase and demolition of up to 1,021 affected properties across many of Canberra's established suburbs.²⁴

The ACT Asbestos Health Study conducted by the Australian National University seeks to examine the health effects of living in a house with loose-fill asbestos insulation in the ACT. The group have already reported on mesothelioma incidence in the ACT, finding that although rates were lower in the ACT than the rest of Australia (excluding Western Australia), there is evidence to suggest that the rates may have increased faster in the ACT, at least in the years 2009-2011.²⁵ The ACT Asbestos Health Study will attempt to provide estimates of the risk of mesothelioma and other cancers associated with living in an affected residence.²⁶

The asbestos exposures of people diagnosed with mesothelioma in the ACT has not previously been documented. This information cannot be obtained from other sources, such as the AMR, which does not have information on a sufficient number of cases to provide a representative picture of asbestos exposures in ACT mesothelioma patients.¹⁷

Objectives of this study

The objectives of this study were to:

- document and describe the demographic and clinical characteristics of mesothelioma cases diagnosed in the ACT;
- identify and describe the key occupational and non-occupational asbestos exposures of people diagnosed with the disease; and
- identify any cases that had lived in Mr Fluffy houses.

2.3 Methods

2.3.1 Study design

A retrospective review of electronic patient records was conducted at Canberra Hospital, a major referral hospital with a catchment in the ACT and south east New South Wales. The primary investigator requested records for hospital admissions occurring between January 2004 and December 2014 that were coded as 'Mesothelioma (C45)' according to the International Classification of Diseases, 10th Revision, Australian Modification (ICD-10-AM).²⁷

Operational definitions for each variable were documented in a coding manual, as well as inclusion and exclusion criteria. The coding manual is attached at Appendix D. Medical records were examined independently by the primary investigator, ten cases (~10% sample of records) were abstracted by a second medically qualified coder as a quality assurance step. Results were cross examined for consistency, with discordant findings discussed.

The following information was recorded for each case patient: gender, date of birth, Indigenous status, date of death, smoking history, history of respiratory disease, presenting signs and symptoms, date of mesothelioma diagnosis, site of disease, and histology result.

A case was defined as a patient that had a hospital record coded with mesothelioma that was first diagnosed in the study period (2004–2014) and if the patient had ever resided in the ACT based on an address at any previous admission to the Canberra hospital.

A data collection tool was developed using Microsoft Excel 2007 to record information from the patient records.

2.3.2 Asbestos exposures

Clinicians would usually gather information on occupational history and other potential asbestos exposures when taking a patient history for a patient with respiratory problems that suggested mesothelioma.²⁸ Medical records were examined to identify the patient's occupational history and to assess non-occupational exposures, including their residential history to determine whether they had lived in a

LFAI affected house. Exposure information was gathered from sources such as clinical notes, discharge summaries and referral letters and has been summarised into the following categories: occupational, non-occupational, “no known” and “unknown” exposures.

Occupational exposures

The study identified occupational exposures of asbestos and, where possible, described the duration of exposure (based on the number of years in a particular occupation). Using this methodology, we were unable to retrospectively measure or quantify the levels of asbestos that individuals may have been exposed to in an occupational setting.

Non-occupational exposures

The study assessed non-occupational exposures, such as having lived near an asbestos mine, or having a family member that worked with asbestos as well as conducting (or being present during) extensive home renovations (due to the risk from asbestos dust from fibro sheeting and asbestos insulation and lagging). The quality of information on these types of exposures is unknown.

No known and unknown exposures

There were two additional categories for those patients for whom an asbestos exposure could not be identified. If a person had been questioned with no known source of exposure identified and this was noted in the medical record they were recorded as having ‘no known exposure’. If the person was not questioned or if sufficient details of the exposure could not be found on the record they were recorded separately as having an ‘unknown exposure’.

2.3.3 Address list of affected houses

The primary investigator compared patient addresses from all previous admissions against a list of remediated houses that had been insulated with loose fill asbestos insulation held by the ACT Asbestos Response Taskforce.²⁹

2.3.4 Linkage with Cancer Registry

Cancer Registries collect information on all cases of cancer within a well-defined population (patients that were resident in their jurisdiction at the time of diagnosis).

Data linkage was conducted to externally validate information collected from hospital records. The primary investigator provided a summary of patient information collected in the study to ACTCR. Patient details and diagnosis information were then compared against variables stored on the register, fields included: name; sex, date of birth; address at diagnosis; Indigenous status; approximate date of diagnosis (month and year); diagnosis (ICD 10 code); and histological morphology.

2.3.5 Ethics approval

The study received approval from both the ACT Health Human Research Ethics Committee and the Australian National University Human Research Ethics Committee.

2.4 Results

Records for 102 patients with a mesothelioma coded admissions were provided by the medical records department. Information from these records were extracted and entered onto data collection tool. Based on address information provided by the patient at the time of diagnosis or previous admission to Canberra Hospital, 58 of these cases had ever been resident in the ACT and were potentially in scope (Figure 2.2). The remaining 44 patients had an address in the south east region of NSW and there was no indication that these patients had even been an ACT resident.

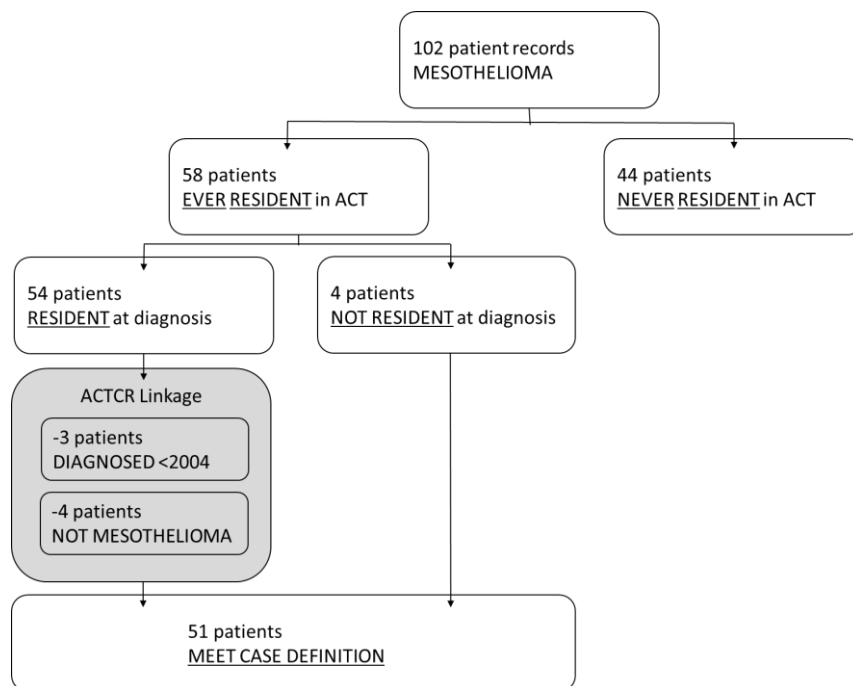


Figure 2.2: Mesothelioma cases included in the study

Linkage to the ACTCR excluded three cases based on an existing diagnosis before 2004, one case had been diagnosed with another type of cancer, and three patients who were not on the register with a diagnosis of mesothelioma or any other cancer. A further four patients that had been resident in the ACT in a previous admission but were resident in another state at the time of diagnosis and did not appear on the ACTCR. Following this process, a total of 51 patients met the inclusion criteria.

There was a high level of agreement between coders on key fields (whether the patient was in scope or had an asbestos exposure). Areas of discordance related to descriptive components of the study, such as whether a patient was noted as having a respiratory disease or details of their smoking history, in some instances one coder

may have noted that the patient had chronic obstructive pulmonary disease as an existing medical condition, while the other had not. As a result, details of the document in which a piece of information had been identified were noted in the data collection tool (i.e. “occupational asbestos exposure noted in discharge summary dated 1/7/2010”), so that details could be verified by the other investigator, if required.

2.4.1 Demographic details of case-patients

There were 51 case-patients included in the study, of which 78.4% (40/51) were male and 21.6% (11/51) were female (Table 2.1). Thirty-five percent (18/51) of cases were aged 60–69 years at the time of diagnosis and 31.4% (16/51) were aged 70–79, 17.6% (9/51) were aged less than 60, a further 15.7% of cases (8/51) were aged 80 and over. None of the cases in-scope for this study identified as being Aboriginal or Torres Strait Islander, with Indigenous status recorded in all cases.

Table 2.1: New cases of mesothelioma, by sex and age, Canberra Hospital, ACT, 2004–2014

	Number	Per cent
Sex		
Male	40	78.4
Female	11	21.6
Age group		
Less than 60	9	17.6
60–69	18	35.3
70–79	16	31.4
80 and over	8	15.7
Indigenous status		
Indigenous	0	0.0
Non-Indigenous	51	100.0
Total	51	100.0

2.4.2 Diagnosis details

Figure 2.3 shows the number of new cases of mesothelioma diagnosed at Canberra Hospital by year of diagnosis over the study period, there were between 2–5 cases in most years. With the highest number of cases diagnosed in 2012.

Diagnosis data showed that the tumour was located in the pleura for the majority of patients (84.3%, 43/51) with the peritoneum accounting for a further 15.7% (8/51) (Table 2.2). All cases that were resident in the ACT at time of diagnosis and appeared on the ACT CR had been histologically confirmed. Among these patients, epithelioid tumours were the most common histological subtype of (45.1%) of mesotheliomas notified in the ACT. Sarcomatoid tumours accounted for a further 13.7%. Biphasic mesothelioma, which has the microscopic appearance of both epithelioid and sarcomatoid cells accounted for 2.0%. Mesothelioma, not otherwise specified accounted for the remaining 31.4%.

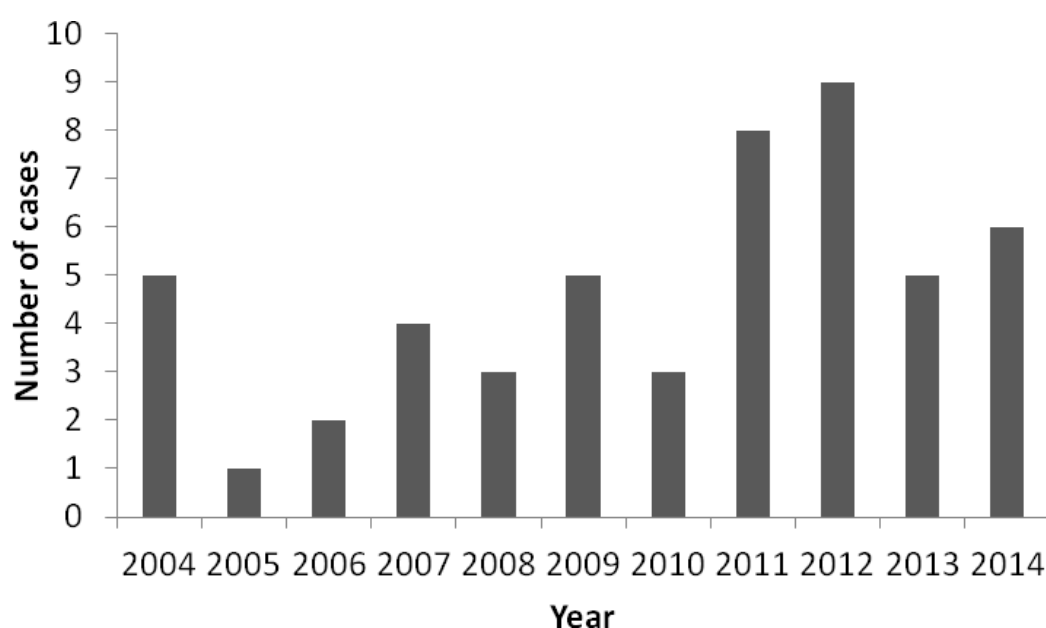


Figure 2.3: Number of new cases of mesothelioma by year of diagnosis, Canberra Hospital, ACT, 2004–2014

Table 2.2: Primary site of neoplasm in newly diagnosed cases of mesothelioma, Canberra Hospital, ACT, 2004–2014

	Number	Per cent
<i>Site of neoplasm</i>		
Pleura	43	84.3
Peritoneum	8	15.7
<i>Histology</i>		
Epithelioid	23	45.1
Sarcomatoid	7	13.7
Biphasic	1	2.0
Mesothelioma, Not otherwise specified	16	31.4
NSW resident (detail not available)	4	7.8
Total	51	100.0

2.4.3 Patient presentation and medical history

Information on signs and symptoms were collected from discharge summaries and ED continuation notes, as well as referral letters and other records and are summarised at Figure 2.4. In patients with pleural mesothelioma 65.1% presented with dyspnoea (shortness of breath), 23.3% reported chest pain, while 18.6% reported a cough. Patients also reported weight loss (11.6%) and fevers (9.3%). A pleural effusion (a build-up of fluid surrounding the lung) was diagnosed in 25.6% of patients. While none of the patients with peritoneal mesothelioma reported respiratory symptoms, a similar proportion reported weight loss (12.5%) and fever (12.5%). Half of this group of patients (50.0%) were diagnosed with ascites.

A history of respiratory disease could be identified in 13.7% of cases (7/51), conditions included chronic obstructive pulmonary disease, asthma. Three patients presented with asbestosis a further one with pleural plaques. A patient's smoking history was noted for the majority of patients, with under half (49.0%) having ever smoked, 19.6% having never smoked and 5.9% being current smokers. No smoking history was available for 25.5% of patients.

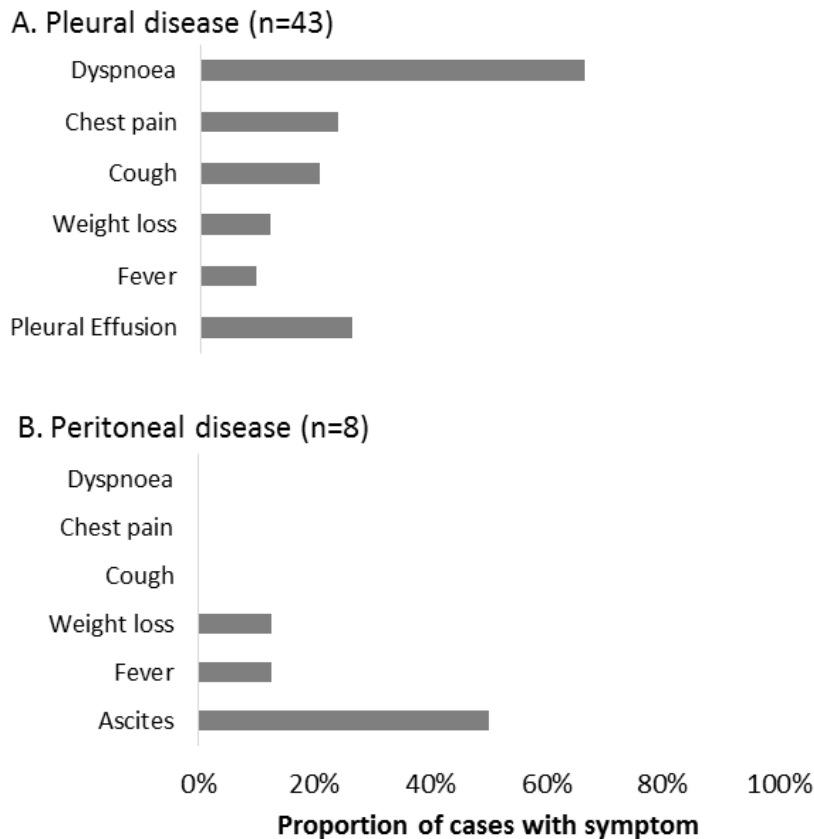


Figure 2.4: Proportion of mesothelioma patients with symptoms, Canberra Hospital, ACT, 2004–2014

2.4.4 Asbestos exposures

An asbestos exposure was identified in 58.8% (30/51) of the cases in-scope for this study, with evidence that potential exposures had been discussed with no specific exposure identified for a further 11.8% (6/51) of cases (shown in Table 2.3). From the records examined, the exposure was unknown in the remaining 29.4% (15/51) of cases.

An occupational exposure could be found in the majority of males (52.5%, 21/40), while there were no females with an identified occupational exposure. The occupations identified in the study included men who had worked in a trade (carpentry, plumbing or mechanic) or other work that involved handling asbestos during manufacturing processes. One case described installing asbestos insulation in the Canberra area.

A non-occupational exposure could be identified in 15.7% (8/51) of cases, 10.0% (4/40) of males and 36.4% (4/11) of females. Of these, the study identified 5.9%

(3/51) of cases that had lived or were living in a home that had been insulated with LFAI. The patient address could be matched to the list of affected houses in all three cases and an exposure from the house had been noted in the medical record in two cases. Among males, non-occupational exposures included living in an affected house and having visited an asbestos mine. Non-occupational asbestos exposures among females included being present during home renovations and washing the clothes of an asbestos worker.

Table 2.3: Summary of asbestos exposures in mesothelioma cases, by sex, Canberra Hospital, ACT, 2004–2014

Exposure identified	Male		Female	
	No.	%	No.	%
Known asbestos exposure	26	65.0	4	36.4
<i>Occupational asbestos exposure</i>	21	52.5	0	0.0
<i>Non occupational asbestos exposure</i>	4	10.0	4	36.4
<i>Asbestos exposure not specified</i>	2	5.0	0	0.0
No known asbestos exposure	3	7.5	3	27.3
Unknown Exposure	11	27.5	4	36.4
Total	40	100.0	11	100.0

Note: The number of exposures may not be equal the total number of people due to a person having multiple asbestos exposures.

2.5 Discussion

This study identifies asbestos exposures in patients diagnosed with mesothelioma admitted to the main tertiary hospital for the Canberra region over an 11-year period. Cases included in the study were all confirmed to have malignant mesothelioma based on histological evidence. In this study, an asbestos exposure could be identified in 58.8% of all cases, with occupational exposures identified for the majority of men. The predominance of mesothelioma diagnoses in men in Australia and other industrialised countries reflects the traditional gender divide of occupations associated with asbestos exposures. There were a large proportion of cases with unknown exposure. It is possible that relevant information on potential exposures were not adequately captured in the record management system.

Findings from this study are not directly comparable with asbestos exposures in the annual report released by the AMR,²² which present exposure information only for those that responded to the questionnaire and interview, in this report there were 30.0% of cases (192/641) reported nationally for whom exposure information was not available. Nonetheless, an occupational exposure could be identified in 73.5% of men and 4.4% of women, while a non-occupational exposure could be identified in 21.7% of men and 87.8% of women. The proportion of cases for whom no asbestos exposure could be identified was 4.7% of men and 7.8% of women. In this study, we identified a higher proportion of cases with no known exposure, however, this could be explained by differences in the manner in which these exposures were assessed and the small number of cases in the ACT.

While Western Australia is not directly comparable with the ACT due to the burden of disease caused by the Wittenoom mine. They have a well-established mesothelioma register which has been collecting data for over 50 years.^{18,19} An occupational exposure could be identified in 82.8% of men and 16.6% of women on the WA Mesothelioma Register, while a non-occupational exposure could be identified in 6.8% of men and 44.4% of women. The proportion of cases for whom no asbestos exposure could be identified was 2.8% of men and 15.7% of women, while the asbestos exposure was unknown in 7.5% of men and 23.3% of women. While the proportion of unknown exposure was higher in this study it was broadly comparable with WA which has a much more established system. Internationally, the

proportion of cases without any identified exposure to asbestos is usually 10–20% of males and 50–60% of females.³⁰

In the ACT, patients were admitted to hospital via two pathways. Patients either presented to the emergency department or were referred as an elective patient for further investigation, or a surgical procedure following diagnosis. A more detailed patient history was available for the majority of patients with multiple presentations or an admission through the emergency department. In our study, the case definition could have been tightened to only include cases that were newly-diagnosed at the Canberra hospital. However, the research team wanted to gather information on the maximum number of cases. This study was unable to assess the health effects of living in an affected house. However, it provides useful information on potential asbestos exposures in mesothelioma cases diagnosed in the ACT.

In this study, we identified three mesothelioma cases that were resident or who had previously resided in an affected house. The types of activities and level of asbestos exposure in these houses is unknown, so we were unable to quantify the specific risk from this source. It is interesting to note that an occupational exposure could be identified in only one of these people. The cases identified in this study did not include a case identified as part of the ACT Asbestos Health Study,²⁵ as they had attended another hospital and were out of scope. From this, we can conclude that there are at least four cases in the ACT. Four cases who had lived in an affected house identified to date is higher than the number of cases predicted using modelling on the levels of asbestos exposure in affected houses. The estimates prepared by Armstrong and Clements modelled low levels of asbestos exposure in the house, but did not account for exposures that occurred during the installation, maintenance and renovation of affected houses.³¹

A longitudinal data linkage study, proposed as part of the ACT Asbestos Health Study should be able to provide a more definitive estimate of the total number of people affected.²⁶

A strength of this study is the inclusion of patients diagnosed with mesothelioma at the Canberra Hospital, which is the main tertiary referral hospital in region and will have captured the majority of mesothelioma cases in ACT residents. Admission data was coded by hospital staff using standardised coding practices. However, a number

of patients were diagnosed and treated at other medical facilities and were not included in this study. Linkage to the Cancer Registry confirmed that cases were in-scope and provided additional details that may not have been recorded based on information contained in the patient record.

A clear limitation is the retrospective nature of this investigation, reviewing patient records that were filed over a decade prior. In particular, physicians were not contacted to clarify details that had been recorded, neither were patients or their families contacted to discuss their asbestos exposures. Record keeping practices were likely to have improved over this period, as the hospital moved to electronic filing system, although it is still possible that there were components of the patient record that had not been adequately captured.

Information was collected and recorded by clinicians in a non-systematic fashion, such inter-observer variation has the potential to introduce bias. In this study, it had the potential to result in a greater level of detail being recorded for some patients. In addition, the absence of details may have resulted in the misclassification of some exposure categories. It is also likely that clinicians would have been more likely to record a positive finding (i.e. that a patient had an identified asbestos exposure) when working up a patient history, and so the number of patients with no known exposures may be under reported. It should be noted that among the six cases with no known exposure, that this does not mean that they had not been previously exposed, only that their exposure had not been identified. The nature of incidental and non-occupational exposure and the long latency period for the disease are both factors that are likely to have impacted patient recall.

Address information was captured at the time of admission, we were unable to identify all previous addresses using this data source and it is possible that we have under-estimated the number that had lived in an affected house.

There have been few studies on the long-term health effects associated with asbestos exposure in residential buildings containing asbestos. The risk from asbestos exposure varies by cumulative exposure levels of the individual and such details are often missing or unable to be reported in studies of non-occupational exposure. Typical exposure concentrations in non-occupational settings are likely to be much lower than historical levels reported in some occupational settings.¹⁶

While there is no safe level of asbestos exposure, mesothelioma remains a relatively rare disease, even in those with very high asbestos exposures. The absolute risk of mesothelioma is low when compared to the risk of more common types of cancer (such as cancer of the breast or prostate). The main concern from a public health perspective, is those who may have been exposed to high levels of asbestos fibres including tradespeople or residents who had participated in or been present during extensive renovations, particularly if this work had been undertaken prior to remediation. The Loose Fill Asbestos Insulation Eradication Scheme provides an opportunity to finally resolve this issue and provide at least some assurance that there will be no on-going health risk for the residents of affected houses.

2.5.1 Recommendations

This study has demonstrated the feasibility of collecting asbestos exposure information of patients diagnosed in the ACT. It may be useful to adopt the model used in Western Australia where a committee periodically reviews mesothelioma cases as part of the cancer registration process and seeks additional information from clinicians to classify the source of asbestos exposure.¹⁷ This approach would provide timely exposure information and would be manageable due to the small number of mesothelioma cases diagnosed in the ACT each year.

2.5.2 Role of the scholar and public health impact

The scholar was the primary investigator for this study and prepared the study protocol and other study material including the coding guide. The scholar examined medical records, extracting and recording the relevant information and prepared a manuscript of the findings of this study.

The asbestos exposures of people diagnosed with mesothelioma in the ACT had not previously been documented and was not able to be obtained from other sources. While this study was unable to assess the health effects of living in an affected house, it provides useful information on potential asbestos exposures in cases of mesothelioma diagnosed in the ACT.

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Appendix D:

Coding manual for the clinical review of asbestos exposure in people diagnosed with malignant mesothelioma in the ACT, 2004–2013

General Instructions

Patient records are available for viewing using the Clinical Records Information System (CRIS). Use the 'Enquiry' drop down menu and select 'Researchers' for a list of patient records extracted by the Medical Records Department.

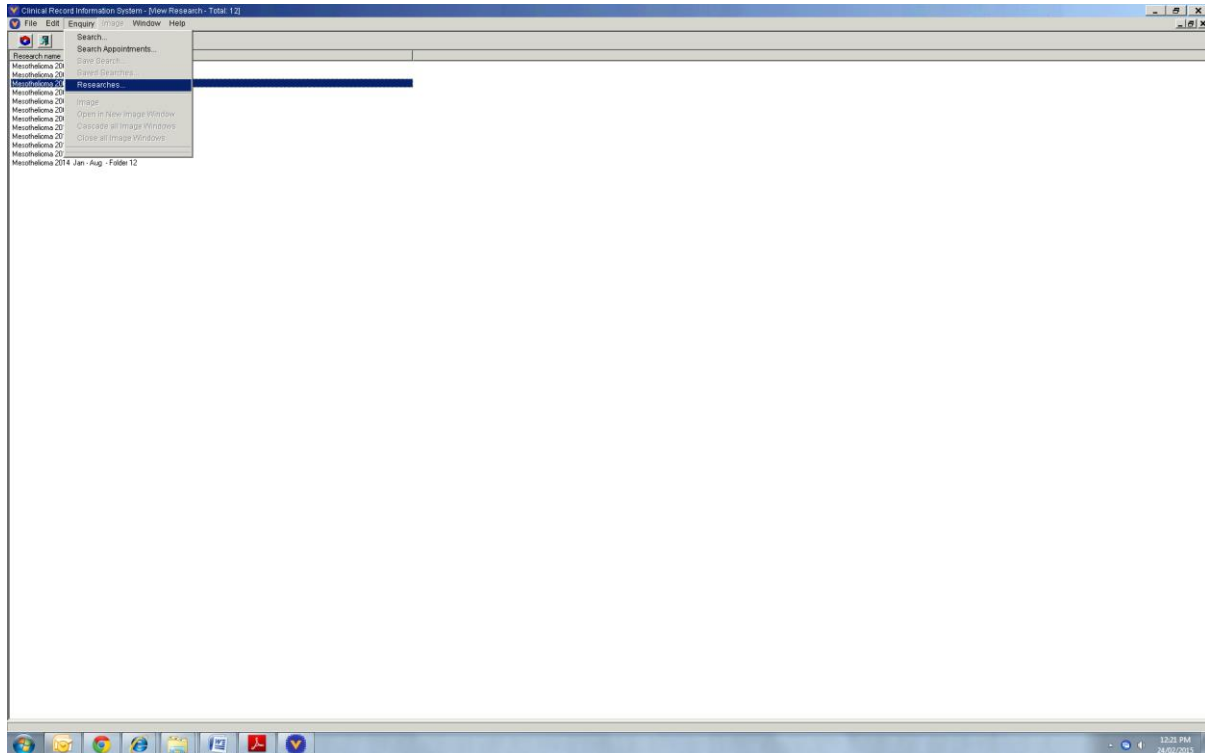


Figure 1: Screen shot from the CRIS

The MS Excel spreadsheet provided should be used to record information included in the medical record (e.g., pathology or radiology reports). Follow the instructions for each section to determine which data elements are relevant to that section and how they should be collected.

Instructions

- Search record by Document Type
- Primary source of information will include the Cancer Registration Notification and admissions under the Sleep and Respiratory or Oncology Departments.
- Search for the Cancer Registration form this will identify the month (and year) in which the mesothelioma was first diagnosed.
- The year of diagnosis should correspond with the folder number in which the medical record has been entered (i.e. folder 3 will include cases diagnosed in 2004).
- Information from referring physicians may be included if original reports are not included (e.g. the use of referral / specialist letters).
- It is important to distinguish whether the patient was questioned about possible asbestos exposures and was unable to identify an exposure 'no known exposure' or whether no investigation was noted in the medical record 'unknown exposure'.

Patient information

Administrative information

Data elements in this section

- Case Number: (Already assigned)
- Folder Number: (Already assigned)
- URN: (Already assigned)
- Surname: (Already assigned)
- In scope: (No=0, Yes=1)
- Comments: (free text)

Instructions:

- Administrative information has been pre-entered.
- A determination on whether the patient is in scope will be made by the coder based on whether the patient was diagnosed with an incident mesothelioma in the study period (1 January 2004 to 31 December 2013) AND that the patient had ever been resident in the ACT based on the residential address in any of the previous admissions (see *Residential Address* below).

Demographic information

Data elements in this section:

- Date of Birth: DD/MM/YYYY
- Sex: Male=0, Female=1, Other=3, Field missing / not completed=7
- Indigenous status: Non-ATSI=0, ATSI=1, Unsure / not known=9, Field missing / not completed=7

Instructions:

- Demographic information will be sourced from the Patient Identification Form completed during the admission in which the diagnosis was made.

Neoplasm information

Data elements in this section:

- Neoplasm diagnosed: (ICD-10)
- Location (Pleural / Peritoneal / Other): (free text)
- Histology (morphology code): NNNN/N
- Stage at diagnosis: (free text)
- Date of diagnosis: DD/MM/YYYY
- Age at diagnosis: NNN
- Died: No=0, Yes=1
- Date of Death: DD/MM/YYYY
- Cause of Death: (ICD-10)

Instructions:

- Enter information from the Cancer Registry Notification as the primary source of information, but refer to information recorded on the pathology or other reports / referral letters provided with the medical record if not noted elsewhere.
- Date of diagnosis refers to the date recorded on the pathology form in which the diagnosis is first made. If the specific date of diagnosis is not available give an approximate date.
- Stage at diagnosis, when noted, should be recorded using the TNM system, otherwise record mention of whether the tumour was localised or had spread.
- If the patient was not dead at the time of registration this information will not appear on the registry notification, details on the patient's death may be found on a Death Certificate attached to the medical record.

Medical history

Data elements in this section:

- Smoker: No=0, Yes=1
- Pack years: (free text)
- History of respiratory disease: No=0, Yes=1
- Comments: (free text)
- Previous investigations for a respiratory disease: No=0, Yes=1
- Symptoms: (free text)
- Signs: (free text)

Instructions

- A patient's smoking status will primarily be sourced from Referral / Specialist correspondence, if noted, record pack years or approximate duration of smoking.
- A patient's medical history will primarily be sourced from Referral / Specialist correspondence.
- Record signs and symptoms noted in the series of admissions leading to the diagnosis (see Table 1).
- If previous admissions to the Emergency Department / Respiratory and Sleep Department are noted, investigate diagnosis on discharge and record if there is evidence of a history of respiratory disease.

Table 1: Signs, symptoms and common investigations for mesothelioma

	Symptoms	Signs	Investigations
Pleural mesothelioma	• Fever / Night sweats • Dyspnea	• Pleural effusion	• CXR / CT Scan • Pleurocentesis[†] • VAT + Biopsy + Talc [‡] • Pleurodesis + Biopsy [‡]
Peritoneal mesothelioma	• Weightloss • Fatigue • Fever / Night sweats	• Abdominal distension • Ascites • Bowel obstruction	• Peritoneocentesis [†] • Laparotomy + Biopsy [‡]

Note: Chest X-ray (CXR), Computerised Tomography (CT), Video Assisted Thoractomy (VAT), [†]Cytology on aspirated fluid, [‡]Histology on biopsy

Radiology (Episode/sequalae leading to diagnosis)

Data elements in this section:

- Imaging investigation noted: No=0, Yes=1
- Type of examination CXR=1; CT=2; MRI=3; OTH=4
- Date of scan: DD/MM/YYYY
- Result: (free text)

Instructions:

- Use results recorded in radiology reports as the primary source of information, but referral letters included with the medical record may also be used if it is not noted elsewhere.
- Indicate whether the type of radiographic examination performed, using the abbreviations in parentheses below:
 - Chest X-ray (CXR)
 - Computerized tomography (CT)
 - Magnetic resonance imaging (MRI)
 - Include other radiographic or imaging exams (OTH)
- If the specific date of imaging examination is not available give an approximate date.
- Record results of radiographic and other imaging examinations noted in the medical record.
- If there is no information available (because results were not recorded in the medical record), enter 'Imaging not noted' and skip to next section

Pathology (Episode/sequalae leading to diagnosis)

Data elements in this section:

- Pathological investigation noted: No=0, Yes=1
- Specimen: Aspirated fluid=1, FNA=2, Biopsy=3 Result
- Date of specimen: DD/MM/YYYY
- Result: (free text)

Instructions:

- Use results recorded in pathology reports as the primary source of information, but referral letters included with the medical record may also be used if it is not noted elsewhere.
- If the specific date of sample collection is not available give an approximate date.
- Record results of pathologic investigations noted in the medical record.
- If there is no information available (because results were not recorded in the medical record), enter 'Pathology not noted' and skip to next section.

Radiology (Previous episodes of care)

Data elements in this section:

- Previous Imaging investigation noted: No=0, Yes=1
- Type of examination CXR=1; CT=2; MRI=3; OTH=4
- Date of last clear scan: DD/MM/YYYY
- Result: (free text)
- Date of last abnormal scan: DD/MM/YYYY
- Result: (free text)

Instructions:

- Record results of radiological or other imaging examinations from previous episodes of care noted in the medical record.
- Use results recorded in radiology reports as the primary source of information, but referral letters included with the medical record may also be used if it is not noted elsewhere.
- If the specific date of imaging examination is not available (for example, if the exam was done elsewhere and was noted in the medical record without a radiology report) give an approximate date.
- If previous admissions to the Emergency Department / Respiratory and Sleep Department are noted, and imaging was conducted.
- If there is no information available (because results were not recorded in the medical record), enter 'Imaging not noted' and skip to next section.
- Indicate the type of radiographic examination performed, using the abbreviations in parentheses below.
 - Chest X-ray (CXR)
 - Computerized tomography (CT)
 - Magnetic resonance imaging (MRI)
 - Include other radiographic or imaging exams (OTH)
- If the specific date of imaging examination is not available give an approximate date.
- If there is no information available (because results were not recorded in the medical record), enter 'Imaging not noted' and skip to next section

Pathology (Previous episodes of care)

Data elements in this section

- Pathological investigation noted: No=0, Yes=1
- Specimen: Aspirated fluid=1, FNA=2, Biopsy=3 Result
- Date of specimen: DD/MM/YYYY
- Result: (free text)

Instructions:

- Record results of pathologic investigations from previous episodes of care noted in the medical record.
- Use results recorded in pathology reports as the primary source of information, but referral letters included with the medical record may also be used if it is not noted elsewhere.
- If the specific date of sample collection is not available (for example, if this was done elsewhere and was noted in the medical record without the pathology report) give an approximate date.
- If previous admissions to the Emergency Department / Respiratory and Sleep Department are noted, and pathologic investigations were conducted.
- If there is no information available (because results were not recorded in the medical record), enter 'Pathology not noted' and skip to next section.

Asbestos exposures

Data elements in this section:

- Asbestos exposure identified: No=0, Yes=1

Instructions:

- A determination on whether asbestos exposure has been identified will be made by the coder based on whether information was noted in the medical record.

Asbestos exposures (Occupational History)

Data elements in this section

- Occupation at diagnosis: (free text)
- Occupation in previous admissions: (free text)
- Occupational asbestos exposure noted in correspondence: (free text)

Instructions:

- Occupation at diagnosis will be sourced from the Patient Identification Form completed during the admission in which the diagnosis was made.
- Occupation in previous admissions will be sourced from the Patient Identification Form completed for each overnight admission prior to diagnosis (excluding admissions for the routine management of an existing condition i.e. dialysis for renal failure).
- Occupational asbestos exposure noted in correspondence will be sourced from Referral Letters or Specialist correspondence.
- A list of occupations with possible asbestos exposures can be found at Table 2 below.
- It is important to distinguish whether the patient was questioned about occupations with a possible asbestos exposures and was unable to identify an exposure 'no known exposure' or whether no investigation was noted in the medical record 'unknown exposure'.

Table 2: Occupations with potential asbestos exposure

Occupation
Trade
Electrician
Construction (carpenter, bricklayer etc.)
Plumber
Boiler maker / welder
Other metal trades (fitter, turner, machinist)
Other trades (unspecified)
Land Transport
Driver
Mechanic
Water transport
Marine engineer
Ship building
Other sea going jobs
Asbestos mining / manufacturing

Asbestos exposures (Non-occupational)

Data elements in this section

- Home maintenance/renovation in a home built prior to 1988: (free text)
- Being present during home renovation (free text)
- Married to / doing washing for a worker with an occupational asbestos exposure (free text)

Instructions:

- Non-occupational asbestos exposure noted in correspondence will be sourced from Referral Letters or Specialist correspondence.
- It is important to distinguish whether the patient was questioned about possible asbestos exposures and was unable to identify an exposure 'no known exposure' or whether no investigation was noted in the medical record 'unknown exposure'.

Asbestos exposures (Residential History)

Data elements in this section

- Address at diagnosis: (free text)
- Address in previous admissions: (free text)
- Patient ever resident in ACT? No=0, Yes=1

Instructions:

- Address at diagnosis will be sourced from the Patient Identification Form completed during the admission in which the diagnosis was made.
- Address in previous admissions will be sourced from the Patient Identification Form completed for each overnight admission for prior to diagnosis (excluding admissions for the routine management of an existing condition i.e. dialysis for renal failure).
- A determination on whether the patient was ever resident in the ACT will be made by the coder based on whether an ACT address was noted in the medical record.

**3 ESTABLISHING AN EBOLA VIRUS DISEASE SURVEILLANCE SYSTEM
FOR TRAVELLERS RETURNING FROM WEST AFRICA,
AUSTRALIAN CAPITAL TERRITORY, 2014–2015**

3.1 Abstract

This chapter describes and evaluates a surveillance system which monitors passengers returning from an Ebola-affected country in response to the epidemic in West Africa. The system involved a combination of entry screening at international ports of entry to Australia and the assessment of risk and health surveillance of individuals returning to the ACT from travel in West Africa.

An evaluation was conducted using a CDC framework for evaluating surveillance systems, this evaluation found the system was able to assess and monitor returned travellers in a timely manner.

3.2 Introduction

This chapter describes and evaluates the establishment of a surveillance system for monitoring passengers returning from an Ebola-affected country in the ACT. Firstly, it will examine the epidemiology of Ebola virus disease (EVD), including the modes of transmission, the impact of the disease, and prevention strategies used to minimise illness in the ACT. The chapter then describes the public health surveillance system established to monitor individuals returning from Ebola affected countries and the evaluation process undertaken to ensure that the surveillance system was meeting the intended objectives. The chapter concludes with the findings from this evaluation.

3.2.1 EVD outbreak in West African

The outbreak of EVD in Guinea, Liberia and Sierra Leone was the largest recorded EVD outbreak in history. The index case occurred in Guéckédou, Guinea in December 2013, although a diagnosis of EVD was not confirmed until March 2014.³² The disease spread across porous country borders in West Africa and the number of cases rapidly overwhelmed the already fragile health systems in the affected countries. In August 2014, the World Health Organization (WHO) declared the EVD epidemic in West Africa a Public Health Emergency of International Concern (PHEIC). At 19 August 2015, there were around 28,000 reported cases of Ebola virus disease (EVD), with over 11,000 deaths.³³ In addition to the West African countries with widespread transmission in the community, a number of countries including the United States, Nigeria, Spain and England, reported one or more imported cases, and subsequent limited transmission in some cases.^{34,35}

The Australian Health Protection Principal Committee (AHPPC) coordinates Australia's approach to preventing and responding to public health emergencies, communicable disease threats; and environmental threats to public health.³⁶ Due to the potential for imported disease from returned passengers, the AHPPC agreed that all travellers from Ebola affected countries would undergo enhanced entry screening and monitoring for Ebola signs and symptoms until 21 days after their departure from an Ebola-affected country. The goal of the screening and monitoring was to detect a case at the earliest opportunity, initiate early treatment, and minimise the spread of disease in the community.

The ACT is a small jurisdiction with a population of around 400,000 people. The ACT Health Directorate is the government department responsible for both state government and local government functions in relation to communicable disease surveillance and public health regulations, as there is only one level of Government in the ACT.

3.2.2 Clinical features

EVD is a severe and acute viral illness with an incubation period of around 10 days (range 2–21). The initial phase is characterised by the sudden onset of fever, myalgia, fatigue and headache. The next phase of illness may include gastrointestinal symptoms (vomiting, abdominal pain and diarrhoea), headaches, a maculopapular rash and unexplained bruising or bleeding in some patients.^{37,38} There are four strains of Ebola virus that cause illness in humans: Zaire, Sudan, Bundibugyo and Tai Forest. The fifth, Reston virus has caused disease in non-human primates.³⁹ The case-fatality rate (CFR) of Zaire strain of Ebola virus, involved in the current outbreak, is estimated to be between 50% and 90%, although variability in reported case-fatality rates probably reflects host factors and access to, and standards of, clinical care.⁴⁰

The primary diagnostic method for EVD is detection of Ebola virus by Polymerase Chain Reaction (PCR) from an appropriate clinical sample, usually blood.⁴¹ Ebola virus can be detected in blood by PCR tests after up to three days following the onset of fever.

3.2.3 Transmission

While the natural reservoir for Ebola has yet to be confirmed, bats are considered the most likely candidate species.⁴² Ebola virus is transmitted through direct contact with blood or other bodily fluids of an infected person or animal. People are not thought to be infectious prior to the onset of symptoms. However, virus levels increase dramatically in the later stages of illness, increasing the risk of transmission.⁴³ Bausch *et al.* detected Ebola virus in a range of bodily fluids during the acute phase of illness.⁴⁴ Previous outbreaks have demonstrated that direct physical contact with an infected person was necessary, although not always sufficient, for secondary transmission. Sexual contact with a recovered patient is a potential source of

infection,⁴⁵ a number of studies have isolated Ebola virus in the semen of males up to three months after recovering from illness.⁴⁶

In the current outbreak, traditional funeral practices, in which mourners have direct contact with the deceased body were identified as a source of transmission. The estimated reproductive number for the current outbreak, was 1.76 in Liberia and 1.49 in Sierra Leone, after correcting for under-reporting.⁴⁷

3.2.4 Preventative measures

While a number of therapeutics (such as VSV-EBOV⁴⁸ vaccine currently in Phase III trials in Guinea and the experimental therapy ZMapp⁴⁹) are in development, there is currently no widely available vaccine to prevent disease and no proven safe and effective treatment. Clinical care is largely supportive, with the focus on managing fluid loss.⁵⁰

Prevention and control measures for EVD used in the West African outbreak include the early identification, isolation and testing of suspected cases to reduce human-to-human transmission and the safe and prompt burial of the dead, using trained burial teams with appropriate personal protective equipment (PPE). The risk of transmission in healthcare settings can be reduced through prompt recognition and management of cases and the use of appropriate infection control precautions and environmental cleaning.⁵¹

3.2.5 Public health importance

In Australia, viral haemorrhagic fevers (including Ebola, Marburg, Lassa and Crimean-Congo fevers) are nationally notifiable and quarantineable diseases, listed under the *National Health Security Act 2007*.⁵² Quarantine involves restricting the movement of people or animals to prevent the introduction or spread of diseases into Australia. The *Quarantine Act 1908*⁵³ provides officials with the authority to investigate suspected cases of illness and, if required, place people under quarantine.⁵⁴

EVD is currently a high-priority disease in Australia, and other countries around the world, due to the widespread transmission in the West Africa epidemic and the potential for an imported case to other countries. The management of returned

healthcare workers became highly politicised in Australia after a Queensland nurse who had returned from an Ebola hospital in Sierra Leone developed a fever during her monitoring period. This resulted in a large amount of political and media interest and emphasised the need for Australian jurisdictions to have a comprehensive plan for the management of healthcare workers returning from an Ebola-affected country. Even a single imported case of EVD in Australia would have serious consequences necessitating a large-scale public health, risk management and media response.

To mitigate the public health risk of EBV being introduced in the ACT, the ACT Health Directorate established a surveillance system. This system outlined specific procedures to systematically identify and monitor the health of people coming to the ACT from Ebola affected countries.

3.2.6 ACT Surveillance System for EVD

Objectives of the system

The objective of the surveillance system for EVD in the ACT was to rapidly identify and isolate a potential case of EVD early in the course of a person's infection to facilitate early treatment and minimise the risk of transmission within the community and health sector.

Identification of stakeholders

The following stakeholders were identified as having a responsibility in the monitoring or response components of the surveillance system:

- Office of the Chief Health Officer, ACT Health Directorate: The Chief Health Officer (CHO) is responsible for managing the implementation of the ACT Government's response to EVD.
- ACT Health Directorate is the principal agency responsible for managing major incidents that have significant public health implications for the ACT population.
- Canberra Hospital and Health Services (CHHS): has been designated as the Ebola treatment facility in the ACT
- ACT Ambulance Service (ACTAS): were responsible for patient transport in the event of a suspected case of EVD

- Commonwealth Department of Health: various surveillance networks for communicable diseases exist at a national level in Australia. The national EVD response plan was coordinated by the Commonwealth Department of Health and AHPPC, in line with guidelines produced by the Communicable Disease Network of Australia (CDNA), and the Public Health Laboratory Network (PHLN).

Legislation for surveillance

The surveillance system for infectious diseases in the ACT is supported by the following legislation:

- *Public Health Act 1997* (ACT)
- *Emergencies Act 2004* (ACT)
- *Quarantine Act 1908* (Commonwealth)
- *National Health Security Act 2007* (Commonwealth)

The *Public Health Act 1997* enables the Chief Health Officer to give a public health direction to a person with or exposed to a transmissible notifiable condition, including EVD, to prevent or alleviate a significant public health risk. The sharing of public health surveillance data by state and territory health authorities with the Commonwealth was enabled under provisions in the *National Health Security Act 2007*.

3.3 Methods

The ACT surveillance system needed to be consistent with other surveillance systems operating in Australia. The ACT Health Directorate developed procedures for monitoring individuals with a recent travel history to an Ebola affected country in accordance with national guidelines prepared by CDNA.⁵⁵ The ACT Health Directorate developed a process of identifying a potential case of Ebola virus disease and arranging patient transfer to the designated Ebola hospital in the ACT. These were documented in *Public Health Management of Ebola Virus Disease in the Australian Capital Territory*.

3.3.1 Description of the surveillance system

This section outlines how the ACT surveillance system was developed and provides a description of its components, including relevant definitions and procedures.

In response to the West African EVD outbreak, the surveillance approach adopted in Australia was to conduct a risk assessment (described in detail below) of potential Ebola exposures for every person arriving from an Ebola-affected country at international ports of entry (including airports and seaports). The Canberra airport does not routinely receive direct international flights and so ACT residents initially entered Australia through another jurisdiction. CDNA guidelines allowed for hand-over from the health authority in the state of arrival to the health authority in the state of residence of the returned traveller and the national surveillance system was a critical component of the ACT surveillance system.

The entire surveillance process is described below and summarised in Figure 3.1:

Step 1: Australian Border Protection Force staff identified potential passengers upon their entry to Australia using travel history declaration cards.

Step 2: Identified passengers were interviewed by Department of Agriculture staff, who have legislated responsibility for quarantine. These officers asked passengers additional screening questions and measured their temperature.

Step 3: Passengers with an elevated temperature (measured temperature $\geq 37.5^{\circ}\text{C}$) or reported direct exposure to an EVD case were referred for immediate assessment by a medical officer employed by the public health authority in the jurisdiction of arrival.

All screened passengers received a monitoring pack from border authorities at the port of entry, which included information about EVD, a digital thermometer and instructions on how to measure and record daily temperatures.

Step 4a: Passenger details of people returning from affected countries were emailed by border protection staff to jurisdictional health authorities via the National Incident Room (NIR) at the Commonwealth Department of Health on a daily a basis for follow-up.

Step 4b: If an assessment was made on a passenger with a final destination of Canberra in another jurisdiction, the assessing medical officer would contact ACT Health Directorate to discuss the details of this assessment.

Step 5: Assessment and ongoing monitoring of arrivals by jurisdictional health authorities for their 21-day monitoring period, using either passive or active surveillance as indicated by the assessment.

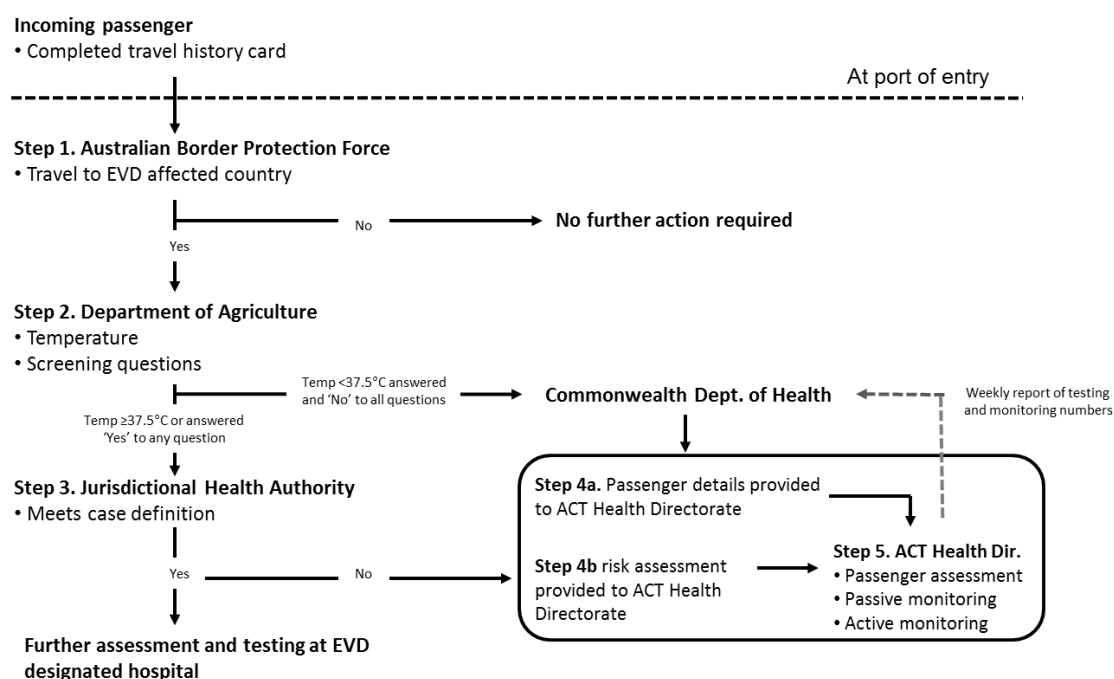


Figure 3.1: EVD surveillance system of returned travellers from West Africa, ACT, 2014–2015

3.3.2 ACT surveillance system

A working group was established within the ACT Health Directorate to coordinate the public health response to EVD in the ACT. This process resulted in the establishment of an EVD surveillance system in the ACT with the following procedures.

The ACT Health Directorate received information on passengers that would spend part of the monitoring period in the ACT through the processes described above. The first contact with returning passengers in the ACT was a telephone call from a Public Health Officer (PHO) to complete a contact investigation form (Appendix E) and assess their level of risk. The PHO also explained the public health measures that were required, including temperature monitoring and documentation.

The ACT procedures stipulated that individuals with a relevant travel history were advised by a PHO to monitor their temperature twice daily for 21 days after leaving an Ebola affected country (passive monitoring). Individuals with an identified exposure (physical contact with an EVD patient) were also advised to monitor their temperature twice daily and were contacted daily by a public health nurse or epidemiologist to report their daily health status (active monitoring).

Based on a public health risk assessment involving a PHO and the ACT CHO or his delegate that took clinical features and an exposure history of the passenger into account, a person with an identified exposure to EVD may have been advised to restrict their movements or refrain from certain activities (such as avoiding large public gatherings or working in a clinical setting) that may pose a risk to others in order to protect the health and safety of the community. Table 3.1 below provides an excerpt from the ACT procedures that describes the types of public health actions required for a humanitarian worker, depending on their activities in West Africa.

The PHO advised individuals in their monitoring period to contact the public health unit immediately if they had an elevated temperature (measured temperature $\geq 37.5^{\circ}\text{C}$) or any other symptoms consistent with EVD. This event acted as a trigger for a public health response, which involved a risk assessment to determine whether laboratory testing was required.

Table 3.1: Public health management of returning humanitarian workers from areas affected by Ebola Virus Disease, ACT, 2014–15

Contact definition	Public Health Management
Humanitarian workers not involved in direct patient care or contact tracing: <i>This includes all humanitarian workers who worked in country support in the EVD response but who were not directly involved in patient care, did not work in a laboratory or clinical setting and who did not conduct contact tracing in the community.</i>	• These individuals should be reassured that they have a very low likelihood of contracting EVD. • They must be provided with verbal advice on the signs and symptoms of EVD. • They should be advised to self-monitor their temperature twice daily for 21 days after leaving an EVD affected country. • These individuals should be advised to have easily accessible means of seeking medical assistance should symptoms develop. They must be advised to contact CDC immediately should they develop any symptoms of EVD. • They should be advised to discuss with CDC any intended travel within their monitoring period especially any long distance travel or travel greater than two hours duration within or outside of Australia. • There are no restrictions on attendance at work or education programs except for those who work in health care facilities. If they normally work in a clinical setting, they cannot work until their monitoring period is completed.
Humanitarian workers with low risk exposures: Humanitarian workers with low risk exposure includes those workers involved in routine clinical care of EVD patients and handling of laboratory samples whilst wearing appropriate PPE and who have no identified breach in PPE leading to an exposure. This includes health care workers who have had direct contact with an ill person with an unknown health status in an EVD affected area. It also includes those workers who have had brief direct contact (i.e. shaking hands), who have been within 1 metre of an EVD case or who have been in a patient care area for a prolonged period of time while not wearing appropriate PPE.	• These individuals should be informed that they have a low risk of contracting EVD. • They must be provided with verbal advice on the signs and symptoms of EVD and be given the Ebola Virus Disease factsheet • They should be advised to self-monitor their temperature twice daily for 21 days after leaving an EVD affected country. Temperature monitoring instructions and a record sheet to give to the individual. • They should be advised that a CDC Officer will contact them once daily to monitor their health and wellbeing. • These individuals should be advised to have immediately accessible means of seeking medical assistance should symptoms develop i.e. a mobile phone available and working regardless of location. They must be advised to contact CDC immediately should they develop any symptoms of EVD. • They should be advised to avoid intimate bodily contact (hugging, kissing, sex, bed sharing) until their period of self-monitoring is complete. • They should be advised, where possible, to restrict their activities to within the home, during their period of self-monitoring. • No international travel is permitted. Regional travel must be discussed and assessed on a case by case basis and must include a formal handover between the Chief Human Quarantine Officers of the relevant jurisdictions. • There may be no restrictions on attendance at work or education programs except for those who work in health care facilities. If they work in a clinical setting, they cannot work until their monitoring period is completed.

Source: ACT Health Directorate *Public Health Management of EVD in the ACT*

Demographic and contact details were recorded for all referred passengers, as well as the self-reported measured temperature of returned travellers for the duration of their monitoring period. A confidential line list with details of individuals under surveillance was maintained using a Microsoft Excel spreadsheet (Microsoft, Seattle). Using this spreadsheet, the EVD coordinator reported the number of people tested for EVD and the number of people being actively monitored to the NIR each week (an example of this reporting is presented at Figure 3.2 below). Probable and confirmed cases of EVD would be reported to the National Notifiable Diseases Surveillance System (NNDSS) using existing disease notification procedures.

	A	B	C	D	E	F	G	H	I	J	K	L
	STATE/TERRITORY DESTINATION (COMPLETED BY HEALTH)	ID	Date Screened	Airport	Flight number	Seat #	Referral Reason	Pax Name	Passport #	DOB	Gender	Australian Destination
1	ACT	271	14-Dec	Sydney	AA420	9F	PACE	Moore, Jonathan	L2021765	24/01/1977	Male	Canberra
2												
3												

Note: Not the name of a real passenger; any resemblance to real persons, living or dead, is purely coincidental.

Figure 3.2: Email containing contact details of a hypothetical passenger, ACT, 2014–2015

3.3.3 Case definitions

The case definitions and exposure categories used in the ACT are consistent with those in the *EVD CDNA National Guidelines for Public Health Units* (EVD SoNG)⁵⁵:

- A person with clinical symptoms and limited epidemiological evidence (recent travel to an Ebola-affected country) prior to assessment were classified as a person under investigation
- A person with clinical symptoms and epidemiological evidence (a potential exposure to EVD) were classified as a suspect case. If a risk assessment determines that a person under investigation required testing for Ebola, the person was managed as a suspected case from that point

- A person with clinical symptoms and epidemiological evidence and laboratory suggestive evidence of EVD was classified as a probable case. A definitive diagnosis required confirmation of EVD infection by Victorian Infectious Diseases Reference Laboratory (VIDRL) in Melbourne.

Exposure categories used in the ACT were:

- Casual contacts had no direct contact with a patient or bodily fluids but have been in the vicinity of an EVD patient
- Lower risk exposures included
 - household contact with an EVD case (this might be classified as higher risk depending on level of contact); or
 - close contact with an EVD case in a healthcare or community setting wearing appropriate PPE.
- Higher risk exposures included
 - direct contact with the patient or their bodily fluids, without appropriate PPE; or
 - laboratory processing of body fluids of suspected, probable, or confirmed EVD cases without appropriate PPE or standard biosafety precautions; or
 - direct contact with a dead body

Further risk categories of aid workers involved in the humanitarian response were described in the EVD SoNG⁵⁵:

- Humanitarian workers not involved in direct patient care – no known exposures: Included those who did not work in a laboratory or clinical setting caring for patients with EVD and who did not conduct contact tracing activities in the community.
- Humanitarian workers with lower risk exposures included healthcare workers involved in routine care of EVD patients and handling samples while wearing appropriate PPE
- Humanitarian workers with higher risk exposures: Included needlestick injury, unprotected exposure to blood or body fluids

3.3.4 Training

Once the EVD surveillance system was developed and approved by the CHO, the next step was to inform and train key stakeholders in the ongoing management of the system. In-service training for public health staff was conducted to outline the procedure for identifying and assessing a returned travellers and responding to a person under investigation. Many of those involved in the daily management of returned travellers had been involved in the development of the procedures, but it was necessary to circulate this information to others in the section. A copy of slides prepared for this session is shown at Appendix F.

In addition to training PHOs in the identification and assessment of passengers, clinical protocols for healthcare workers who may have contact with a suspect or probable case in a health service setting was essential. This process was led by clinicians at Canberra Hospital— the designated Ebola treatment hospital for the ACT. Guidelines on the clinical management of suspected Ebola patients in hospital were based on standard infectious disease protocols. The Infection Control team of Canberra Hospital conducted additional training in the donning and doffing of appropriate PPE by for all designated clinical staff who may have contact with a suspect or probable case.

3.3.5 Evaluation design

This section provides a summary of the evaluation of the ACT EVD surveillance system, including a discussion of the evaluation design and its results.

Public health surveillance is defined as “the ongoing systematic collection, analysis, and interpretation of health-related data essential to the planning, implementation and evaluation of public health practice, closely integrated with the dissemination of these data to those who need to know”.⁵⁶ Information from surveillance systems has an important role in informing public health action. However, it was necessary to assess whether this represents an efficient use of limited resources.

An evaluation was conducted using information gathered from an ACT Health Directorate staff debrief, and a number of semi-structured interviews with those involved in collecting data (the PHOs and Surveillance Manager). The evaluation used a CDC framework with a number of surveillance system attributes for

evaluating surveillance systems intended for the early detection of outbreaks.^{57,58} The evaluation includes an assessment of system performance as well as its acceptance and usability.

The following surveillance system attributes were used to assess the performance of the system:

- Timeliness: reflects the speed between steps in a surveillance system
- Sensitivity: refers to the proportion of cases detected by the surveillance system
- Positive predictive value: the PPV of a system is determined by the proportion of reported cases that actually have the health related event under surveillance.
- Validity: the validity of a surveillance system for outbreak detection varies according to the outbreak scenario
- Data quality: the completeness of a number of key data fields will be one measure of data quality.
- Representativeness: the ability of a public health surveillance system to accurately describe the occurrence of a health-related event

The following surveillance system attributes were used to assess the user experience of the system:

- Usefulness: a surveillance system is useful if it is able to detect outbreaks of public health significance early resulting to an effective intervention
- Flexibility: the surveillance system can adapt to changing information needs with little additional time or resources
- Acceptability: Feedback on the acceptability of the system was sought from stakeholders as part of the evaluation process.
- Stability: refers to the ability to collect, manage and provide data properly without failure
- Portability: describes how well the system could be duplicated in another setting
- Resources: staff, and other materiel required to maintain the system

3.4 Results

3.4.1 Descriptive analysis of persons under surveillance

An analysis of ACT surveillance data was conducted using data collected to 31 July 2015 (Figure 3.3). This describes the number of people that were assessed and monitored as well as a summary of their activities in West Africa and their demographic details. The surveillance system was operational prior to the first arrivals of returned travellers from an EVD affected country in November 2014.

From 1 November 2014 to 31 July 2015, 33 returned travellers were contacted and assessed following their arrival in the ACT from an Ebola-affected country. Five individuals were assessed as being returned travellers that were not involved in the humanitarian response, these people were categorised as no risk and were asked to monitor their temperature.

Twenty-eight individuals were assessed as having been involved in the humanitarian response, the rest of this section will focus on this group. The average (mean) age of subjects was 43 years (range 29–67); 53.6% (n=15) were female. Eighteen people had visited Sierra Leone within the past 21 days, with a further eight returning from Liberia and two from Guinea, this includes people that had travelled to multiple affected countries. Twenty-one of the returned humanitarian workers had no direct contact with EVD patients and were assessed as having no identified exposure and required only passive surveillance. This included two Australian Government diplomatic staff, 12 participants had been involved in project management and administration. Four had been logisticians working at Ebola treatment facilities, but had not entered the ‘red zone’. There were three epidemiologists who were conducting contact tracing and monitoring of household contacts of cases.

In this period, there were five healthcare workers who had direct contact with Ebola patients in West Africa, and despite having no identified exposure, they were assessed as having a low (but not zero) risk and required active monitoring. There was also an additional person in the humanitarian group who had brief physical contact with an Ebola patient in their convalescent phase without PPE who was categorised low risk.

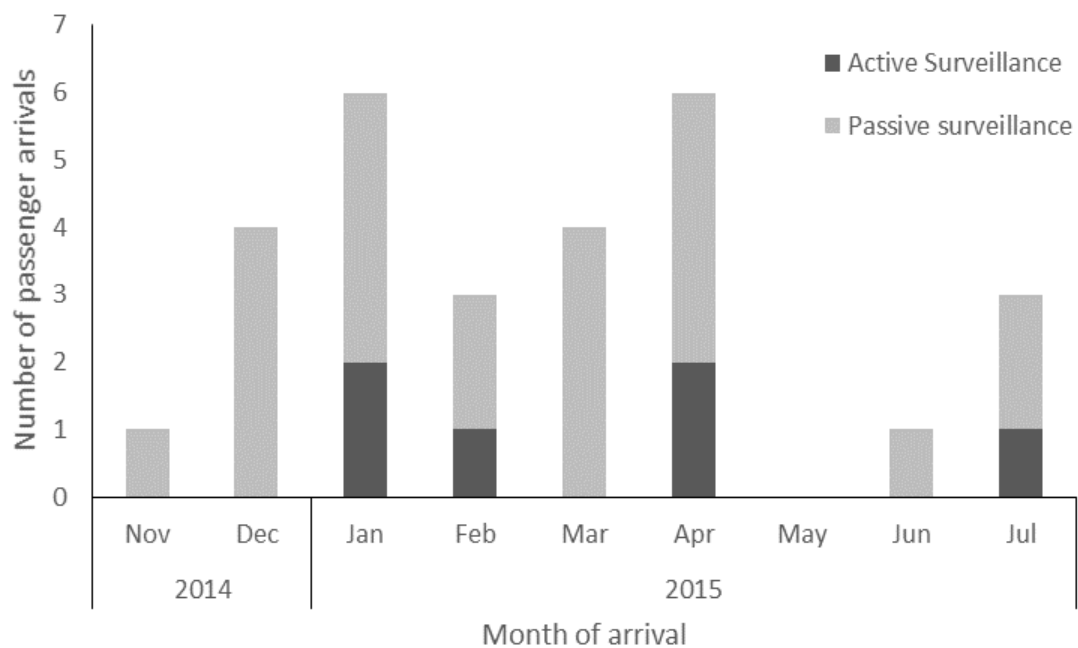


Figure 3.3: Monitoring of returned aid workers, by month of arrival, ACT, 2014–2015

3.4.2 Performance of the surveillance system

A single case of EVD in the ACT would be considered an outbreak and would require a significant public health response. The ability of the system to reliably and accurately detect an outbreak at the earliest possible stage was assessed using the following standardised surveillance system attributes.

Timeliness

Time was considered a critical component of the response and the surveillance system attempts to minimise delays between stages. The initial identification of passengers was dependent on notification from the Commonwealth Department of Health, this occurred daily, although these emails were occasionally delayed.

Occasionally, a passenger with a final destination of Canberra would spend some of their monitoring in another jurisdiction before completing the final leg of their journey, in which case an assessment was made by the relevant jurisdictional health authority (most often NSW Health). Details from this assessment were provided to the ACT, in addition to the notification from the Commonwealth. This was not seen

to hamper timeliness though, as the interviews were completed within 24 hours of arrival in Australia.

One healthcare worker that had been working in an Ebola triage centre in Liberia and was under surveillance in the ACT developed symptoms consistent with EVD during their monitoring period. They contacted the public health unit within one hour of the onset of symptoms. An assessment on the need for testing was made within two hours and the patient was transferred by ambulance to the designated Ebola hospital within four hours.

Sensitivity

Due to the serious consequences of disease, the system was highly sensitised to detect a change in health status. Clinical evidence in the case definition required fever or a combination of symptoms compatible with Ebola (headache, weakness, muscle pain, vomiting, diarrhoea, abdominal pain or haemorrhage). The alert threshold was set at a measured temperature of 37.5°C and the need for testing would be assessed at 38.0°C.

One individual under surveillance in the ACT was tested for EVD in this period. The individual contacted the public health unit and reported gastrointestinal symptoms with an elevated temperature (37.5°C). When the temperature was measured a second time it was over the threshold of 38.0°C. The individual had been a healthcare worker working with suspected EVD cases in Liberia in a period when there had been no reported Ebola transmission in the community. One additional passenger reported a fever on arrival to Australia and tested negative for EVD in Sydney before continuing his journey to Canberra for the remainder of his monitoring period. This person was reported as a suspected case in NSW under agreed cross-border notification protocols.

The sensitivity of this case definition cannot be calculated as there have been no documented cases of EVD in the ACT or Australia. Fever is a relatively sensitive symptom for the detection of EVD despite the fact that a small proportion of patients may not initially present with an elevated temperature.⁵⁹ However, given the monitoring of all returned travellers and active surveillance for people with likely EVD exposures, the sensitivity of the system is likely to be high. But it depends on

the accurate reports of the individual. The PHO provided a lot of education to people under surveillance to help improve compliance, so it is expected this is not a large risk to the system's sensitivity.

Positive predictive value

The positive predictive value could not be calculated as there have been no EVD cases documented in the ACT or Australia. Febrile illness in a person returning from the region could be caused by a number of diseases, as fever is a common symptom for several infectious or parasitic diseases endemic in West Africa.

Data quality

The completeness of a number of key data fields was used as a measure of data quality. The number of travellers contacted and the number of travellers completing their monitoring period. Based on information gathered on the Contact Investigation Form an assessment could be made for nearly all passengers.

There was one traveller who was not able to be contacted using the phone number provided but contact via email elucidated that the traveller was a US national travelling briefly through Australia. He reported no contact with Ebola patients while working in Sierra Leone, but did not reply to further correspondence.

Digital thermometers were supplied in a returned traveller pack by border authorities at the port of entry, along with a temperature logging sheet. PHOs recommended that people measure their temperature using the same technique around the same time each day. However, temperature monitoring surveillance cannot preclude temperature variation between people or differences in technique. However, when applied consistently, it would demonstrate a change in health status. In the ACT, the temperatures recorded were self-reported and the accuracy could not be independently verified. To overcome this weakness, some jurisdictions in the US required visual confirmation of measured temperatures using a web cam.⁶⁰

Representativeness

Passengers were required to complete a travel card and report their intended destination and declare if they had been in an Ebola-affected country in the 21 days prior to entering Australia. Assuming this information is entered accurately, the system is representative (i.e. the system covers people of all ages and geographic

locations and method of arrival) with near complete ascertainment. There is no known reason why any group would be systematically excluded from the system to make it unrepresentative. The system also was applied to travellers coming to Australia through means other than airplane.

3.4.3 Experience using the surveillance system

The experience of those working with the system was assessed using the following standardised surveillance system attributes.

Usefulness

This surveillance system was implemented to rapidly identify and isolate a potential case of EVD early in the course of infection to facilitate early treatment and minimise the risk of transmission within the community. The system provided a mechanism to identify when a person under surveillance developed symptoms consistent with EVD and assess the need for pathology testing. This information was used to help effectively manage a rapid public health response when a person under surveillance subsequently developed symptoms.

A number of staff found the national case definitions were difficult to understand and this led to some confusion. In particular, the progression from a person under investigation to a suspected case and the definitions of various exposure categories (casual, low and high risk).

The ACT public health unit was aware of all individuals who had been in an Ebola affected country that indicated that they would spend their monitoring period in the ACT and would be able to assess the level of risk for those with potential exposures. However, we are aware of one instance when an individual in their monitoring period visited ACT without notification from another jurisdiction. The person was giving a public presentation on their experience in West Africa at a university, they reported no direct contact with an EVD case and would not have required active monitoring. However, it does demonstrate the potential for someone to enter the ACT without notification to ACT Health.

Flexibility

A flexible surveillance system can adapt to changing information needs with little additional time or resources. The system has the capacity to adapt rapidly to new operational requirements, for instance, if new countries were added to the list of affected countries. Additional information or data fields could be incorporated into the system with minimal disruption, as data is entered manually. Changes to the case investigation form and database would also be feasible and relatively simple.

Acceptability

The steps in this surveillance system were designed to flow in a familiar progression: returned travellers (the population under investigation) were emailed to ACT Health by the Commonwealth Department of Health via email. A PHO would contact the individual by phone and conduct a risk assessment. This process is acceptable because it is similar to routine public health follow up or contact tracing for other communicable diseases. An Excel spreadsheet was used to record key fields, and identify those that required further follow-up and produce weekly reports. This software was familiar and acceptable for all users and did not require access to alternative software or additional training.

Staff members involved in conducting follow-up and assessment of returned travellers were provided an opportunity to provide feedback on the processes involved in the surveillance system. To improve acceptability, the order of questions and the layout of the questionnaire underwent some minor modifications based on early feedback from staff completing the Contact Investigation Form.

A small number of 'core' staff completed administrative components of the surveillance system, this included identifying passengers in daily emails and entering their details onto a line list after the interview and assessment had been completed. The CDC section email in-box was able to be monitored by a surveillance officer and details were able to easily be updated on the line list as required.

The ACT system uses few resources and surveillance could be maintained as long as the frequency of passenger arrivals remained at low levels. This process would be resource intensive and less acceptable if there were a large number of passengers.

Stability

After establishing all of the processes, the surveillance system required very little in the way of additional resources or support. Data were stored within a secure and stable IT environment. The stability of this surveillance system was largely reliant on the availability of staff in the Communicable Disease Control Section that were familiar with the processes involved. Procedures have been documented and circulated and there a number of adequately trained staff (including after hours on-call staff) at the time of the evaluation. However, any assessment on the ongoing requirements to maintain the system is dependent on the number of passenger arrivals destined for the ACT.

Resources

Digital thermometers were purchased by the ACT Health Directorate and could be distributed to individuals under surveillance if required. A large amount of resources were required in the initial stages of the outbreak to develop procedures and attend national teleconferences on the proposed management of returned passengers, this is estimated to have included more than 200 hours of work. Once established, the daily operation of the surveillance system required approximately 0.25 hours per day for a public health officer to read emails regarding incoming travellers and conduct weekly reporting requirements and an estimated 0.5 hours to complete each interview and discuss the management of the case, and enter their details on a Microsoft Excel database. Individuals under 'active' surveillance required an additional phone call each day, often at an agreed time. As passengers could arrive at any time on-call staff completed these tasks out of business hours, this ensured that passengers could still be assessed in a timely manner. However, the additional work incurred extra cost, but this had been budgeted as part of the response.

3.5 Discussion

This report describes a surveillance system used in the ACT to monitor returned travellers from Guinea, Sierra Leone and Liberia in response to the Ebola epidemic in West Africa. The system involved a combination of entry screening at international ports of entry in Australia and the assessment of risk and health surveillance of individuals returning to the ACT from travel in West Africa.

Travellers may be screened during large epidemics to detect passengers infected with a serious communicable disease in order to prevent transmission during the flight and in the country of destination. Exit screening for all outbound passengers was implemented in Guinea, Liberia and Sierra Leone.⁶¹ Entry screening and other surveillance measures were adopted in Australia and a number of other countries, despite limited evidence demonstrating the ability of temperature screening to detect cases of disease at the border. This screening targeted passengers travelling from EVD affected countries and allowed their level of risk to be assessed. This identified the population under surveillance and meant that passengers could be instructed on what to do if they become unwell during their monitoring period.

In accordance with recommendations in the CDNA EVD SoNG⁵⁵ that was agreed nationally by all Chief Health Officers and the Chief Medical officer of Australia via AHPPC, ACT Health Directorate developed a surveillance system for monitoring individuals with a recent travel history in an Ebola affected country and was able to assess the risk of exposure and monitor their health for 21 days. Many of the recommendations regarding temperature monitoring were consistent with advice provided by other agencies involved in the response.⁶²

Protocols were developed to facilitate patient transfer to the designated Ebola hospital for pathology testing in response to a surveillance signal or event. A public health response was initiated on one occasion, when a healthcare worker who had worked in an Ebola testing facility developed symptoms consistent with the case definition; results from pathology testing were negative for Ebola virus. However, this demonstrated that the surveillance system worked and the person was aware of what to do in that situation.

The system used minimal resources, yet it was able to adequately monitor the small number of people returning to the ACT from an EVD affected country. In November 2014, the Commonwealth Government awarded a Canberra company—Aspen Medical—a contract to manage an Ebola treatment facility in Liberia. This led to an increase in the number of individuals involved in the humanitarian response spending their monitoring period in Canberra, which had the potential to place a disproportionate burden on a small public health unit. A number of approaches were developed to reduce the resources required to conduct ‘follow-up’, including the use of SMS and web-based systems for people to self-report their daily temperature data,^{60,63} the application of a similar approach could help to reduce the workload in future epidemics.

The categories of risk often did not reflect the common usage of many people involved in the response, who would say after completing an interview, “this person didn’t have contact with patients, they’re low risk”. Low-risk being a specific category involving close contact with an EVD case in a healthcare or community setting. The distinction between a low risk traveller and low risk humanitarian worker (with no known exposures) was problematic for some of the staff involved at the periphery of the surveillance system. The use of a simple case definition and a single set of exposure categories would assist in future epidemics.

An evaluation of this system found that under current conditions, returned travellers could be assessed and monitored in a timely manner. However, this system would not have been sustainable with current resources if there had been large numbers of arrivals. Although it was difficult to assess the sensitivity of the case definition, it is likely to be highly sensitive, the surveillance system was consistent with current knowledge of the disease and the approach adopted internationally.

3.5.1 Recommendations

If a similar system were considered for similar public health events in the future the following approach is recommended:

- The development of a nationally consistent set of simple case definitions and risk exposure categories.

- The development of a standardised database should be considered at a national level prior to surveillance being implemented. Integration with existing systems has the potential to save on replication and development costs across several jurisdictions. Passengers were identified by Commonwealth agencies in the first instance and such a system could facilitate a more streamlined handover between jurisdictions. Concerns about privacy could be circumvented by controlling access to identifying details (for example, only health authorities in the relevant jurisdiction would be able to see name and contact details).
- Consideration of approaches to reduce resources required to conduct ‘follow-up’ this includes the use of SMS or web-based passive surveillance systems that would allow people in the low risk categories to enter their own temperature data.

3.5.2 Role of the scholar and public health impact

The scholar was designated as the Ebola co-ordinator, this role involved providing technical input on the development of the surveillance system, including information on components of other relevant systems operating in Australia and overseas, developing procedures for the public health response in the event of a suspected case of EVD.

The scholar was also responsible for maintaining a watching brief on developments of the outbreak response in West Africa and Australia, which involved attending regular teleconferences and reviewing situation reports from the World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC), as well as performing or assisting with many of the operational aspects of the surveillance system. These tasks included monitoring the daily emails from the NIR to identify ACT residents returning from affected countries, interviewing returned travellers to conduct the assessment and reporting to the NIR each week.

The surveillance system that the scholar helped to implement in response to the outbreak of Ebola in West Africa, was used to assess the risk of travellers returning from affected countries and monitor their health status. This work has bolstered the bio-preparedness of the ACT to cope with other emerging infectious diseases that

may arise. For example, many of the procedures that had been developed regarding welfare of people under quarantine will be documented in an Annex to the Infectious Diseases Plan for the ACT and could be amended quickly if required for a range of communicable diseases.

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Ebola Virus Disease Contact Investigation Form

Date of interview	/ /
Interviewer name	

1 CONTACT INFORMATION			
Case Name	First Name	Family Name	
Residential address and contact details	Street Address		
	Suburb	State/Territory	Postcode
	Tel (work)	Tel (mobile)	Fax
Will you be staying at this address for the next 21 days? ☐ Yes ☐ No	Email		
Sex ☐ Male ☐ Female ☐ Not stated	Date of birth / /	Country of birth	
Is the case of Aboriginal or Torres Strait Islander Origin ☐ Yes, Aboriginal ☐ Yes, Torres Strait Islander ☐ Yes, both Aboriginal and Torres Strait Islander ☐ No ☐ Unknown/Not stated		Interpreter required ☐ Yes → language ☐ No	
2 SCREENING QUESTIONS			
Have you been in an Ebola affected country in the past 21 days? ☐ Yes ☐ No		Travel history:	
Are you a humanitarian worker returning from a country with active transmission of EVD? (This involves people working in a non-clinical role) ☐ Yes ☐ No		Role:	
What activities were you involved in while in this country?		Specify:	

3 HOUSEHOLD DETAILS

Please describe your living arrangements

Will you be sharing a bedroom or bathroom?

☐ Yes ☐ No ☐ Unknown

Do you have any pets at this address?

☐ Yes ☐ No ☐ Unknown

Specify:

Other household members

Name

Relationship

Contact Details

4 WORK / STUDY DETAILS

Occupation

Details of employer

Employer

Street Address

Suburb

Tel (work)

Tel (mobile)

Email

Please describe the workplace / educational environment

Please describe any social groups or activities you typically participate in or plan to attend over the next three weeks

Do you have any planned travel in the next three weeks? (Please specify destination and duration)

NOTES

5 CLINICAL SYMPTOMS

Have you been tested for Ebola?

☐ Yes ☐ No ☐ Unknown

Test Result:

☐ Positive ☐ Negative ☐ Pending

If a person has been tested they may need to be treated as a suspected case until testing proves otherwise.

Are you currently experiencing any symptoms?

Does the person have a fever?
(measured temperature of 37.5°C)?

☐ Yes ☐ No ☐ Unknown

Does the person have abdominal pain?

☐ Yes ☐ No ☐ Unknown

Does the person have diarrhoea?

☐ Yes ☐ No ☐ Unknown

Does the person have vomiting?

☐ Yes ☐ No ☐ Unknown

Does the person have joint and muscle pain?

☐ Yes ☐ No ☐ Unknown

Does the person have severe headache?

☐ Yes ☐ No ☐ Unknown

Does the person have fatigue?

☐ Yes ☐ No ☐ Unknown

Does the person have unexplained bleeding or bruising?

☐ Yes ☐ No ☐ Unknown

Did the person have other symptoms or complications?
If yes, please specify:

☐ Yes ☐ No ☐ Unknown

Specify:

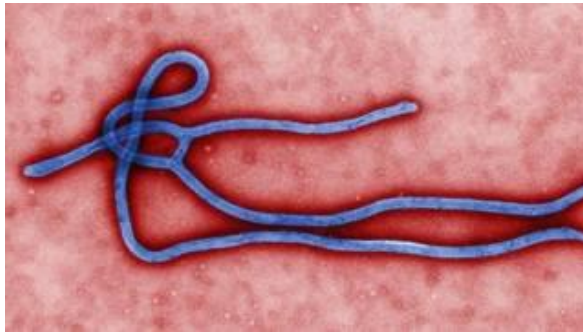
6.1 HIGH RISK EXPOSURES	
A person is "high risk" if any of the following are present: Did you receive a needle stick injury from a confirmed case? Did you have inadequate PPE and blood or fluid splash to mucous membrane from a confirmed case? Did you have inadequate PPE and your skin touched blood, vomit, diarrhoea, urine, saliva, semen from a confirmed case? Did you have inadequate PPE and process blood or body fluids in laboratory from a confirmed case? Did you have inadequate PPE and have direct contact with dead body or fluid from a dead body with confirmed EVD, or suspected to have EVD outcome not known or cause of death unknown in an EVD affected area?	If yes, date of exposure: / / ☐ Yes ☐ No ☐ Unknown ☐ Yes ☐ No ☐ Unknown ☐ Yes ☐ No ☐ Unknown ☐ Yes ☐ No ☐ Unknown ☐ Yes ☐ No ☐ Unknown
6.2 LOW RISK EXPOSURES	
A person is considered "low risk" if no high risks are present and they answer yes to any of the following: Are you a household member of a confirmed case? Did you have inadequate PPE and touch the skin or body of a living confirmed EVD case with no visible body fluid? Was there a potential droplet exposure to a confirmed EVD case? Meaning no PPE in the same room as a confirmed EVD case actively vomiting / diarrhoea / cough / AGP Did you have direct contact with an ill person or body fluids from a person of unknown health status in an EVD affected area? Did you have direct contact with wild animals in an EVD endemic region? Did you work in a mine / cave inhabited by bat colonies in an EVD endemic region?	If yes, date of exposure: / / ☐ Yes ☐ No ☐ Unknown ☐ Yes ☐ No ☐ Unknown ☐ Yes ☐ No ☐ Unknown ☐ Yes ☐ No ☐ Unknown ☐ Yes ☐ No ☐ Unknown ☐ Yes ☐ No ☐ Unknown
6.3 CASUAL RISK EXPOSURES	
A person is considered a "casual contact" if no high or low risks are present and they have any of the following: Have you been within 1 meter or within the room or care area of an EVD case for a prolonged period of time with inadequate PPE? Did you have inadequate PPE and have brief direct contact (e.g. shaking hands) with an EVD case? Did you have inadequate PPE and potentially touch a non-visibly stained surface in a room occupied by a confirmed case of EVD (e.g. was in waiting room with a case, was on a ward round of a case and did not touch case)? Did you work in a medical or nursing capacity in Australia and care directly for a confirmed EVD case using adequate PPE? Were you a cleaner on a ward with a confirmed case and wore adequate PPE when cleaning room?	If yes, date of exposure: / / ☐ Yes ☐ No ☐ Unknown ☐ Yes ☐ No ☐ Unknown ☐ Yes ☐ No ☐ Unknown ☐ Yes ☐ No ☐ Unknown ☐ Yes ☐ No ☐ Unknown
6.4 NOT AT RISK	
A person is considered to have no risk if there is an absence of high, low or casual risk exposures. However, returned humanitarian aid workers may be subjected to monitoring and may be asked to comply with a range of restrictions for 21 days after leaving an Ebola affected country.	

Name:

10. Temperature logging			
Date	Temperature (°C)	Record details of the contacts movements outside of the household and contact with other people	Signature of CDC Officer
Day 0	AM °C		
Date: / /	PM °C		
Day 1	AM °C		
Date: / /	PM °C		
Day 2	AM °C		
Date: / /	PM °C		
Day 3	AM °C		
Date: / /	PM °C		
Day 4	AM °C		
Date: / /	PM °C		
Day 5	AM °C		
Date: / /	PM °C		
Day 6	AM °C		
Date: / /	PM °C		
Day 7	AM °C		
Date: / /	PM °C		
Day 8	AM °C		
Date: / /	PM °C		
Day 9	AM °C		
Date: / /	PM °C		
Day 10	AM °C		
Date: / /	PM °C		
Day 11	AM °C		
Date: / /	PM °C		
Day 12	AM °C		
Date: / /	PM °C		
Day 13	AM °C		
Date: / /	PM °C		
Day 14	AM °C		
Date: / /	PM °C		
Day 15	AM °C		
Date: / /	PM °C		
Day 16	AM °C		
Date: / /	PM °C		
Day 17	AM °C		
Date: / /	PM °C		
Day 18	AM °C		
Date: / /	PM °C		
Day 19	AM °C		
Date: / /	PM °C		
Day 20	AM °C		
Date: / /	PM °C		
Day 21	AM °C		
Date: / /	PM °C		

Appendix F:

Ebola Virus Disease Manual Workshop

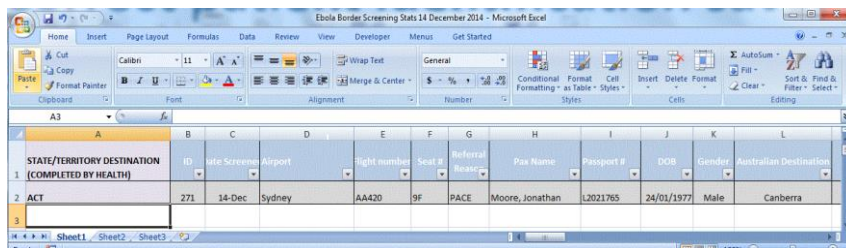


Scenario:

Sunday...

CDC On-call Officer notified of a returned traveller from Liberia

- 37 y/o Male
- Arrived at Sydney airport 14/12
(No fever / symptoms on arrival)



STATE/TERRITORY DESTINATION (COMPLETED BY HEALTH)	ID	Date	Airport	Flight number	Seat #	Referral	Pox Name	Passport #	DOB	Gender	Australian Destination
ACT	271	14-Dec	Sydney	AA420	9F	PACE	Moore, Jonathan	L2021765	24/01/1977	Male	Canberra

CDC On-call Officer must:

- Notify the On-Call CHO
- Contact the returned traveller
- Complete the Contact Investigation Form
- Contact the On-Call CHO to complete a Risk Assessment of exposure risk

Our returned humanitarian worker:

- Has been in Liberia for 4 weeks working as a logistician at an Ebola treatment facility with MSF
- He has been monitoring his temperature since leaving Liberia 3 days ago.
- Lives in a house in Kambah with his wife and two children (4 y/o Male, 7 Female) and a dog.
- Works in an office environment
- Has had direct contact with an ill person of unknown health status (8/12/2014)

The On-call CHO

- Advises that he will be categorised as an Aid worker with a low risk exposure;
- Advise of any movement restrictions or public health actions

The CDC On-call Officer

- Advise individual to self-monitor their temperature twice daily for 21 days
- Advise individual to contact CDC immediately should they develop symptoms
- Advise individual to restrict their activities to within the home during their self-monitoring period.
- Advise individual to avoid intimate bodily contact
- Provide an update via email to the CHO, On Call CHO, HPS Public Health Physician, Director CDC and member of the CDC team

Monday...

CDC Public Health Nurse

- Calls to check for the development of symptoms and record their temperature readings

Tuesday...

Receive a call on the CDC Infoline

37.9°C !!! No gastro intestinal symptoms. Wife is at work and children at Childcare / Primary School

The responding **CDC Officer** must notify

- CHO
- Public Health Physician at HPS
- On-Call ID Physician TCH
- Director CDC
- Members of CDC / PaRS

Based on the risk assessment it is decided to transfer the patient to TCH and test for Ebola virus.

The **CDC Officer** must arrange transfer to TCH. Call ACT Ambulance Service 000 and request transfer of the patient stating that they are a person under investigation for Ebola

The CHO or their delegate

- Activates an Acute Response Team

A nominated **CDC Officer** will contact the suspected case to complete the Case Investigation Form, identify contacts and potential hazards in the household.

Based on a risk assessment

- Family will remain in the household pending test result

Wednesday...

Overnight the testing has been completed

- **Ebola virus detected PCR**

Based on a risk assessment of the family members we now have a three household contacts with a low risk exposure.

Consider movement restrictions (work / school)

The nominated **CDC Officer**

- Advise individual to self-monitor their temperature twice daily for 21 days
- Advise individual to call CDC immediately should they develop symptoms
- Advise individual to restrict their activities to within the home during their self-monitoring period.

**4 AN OUTBREAK OF CLOSTRIDIUM PERFRINGENS
GASTROENTERITIS LINKED TO A FUNCTION AT A TOURIST
ATTRACTION IN CANBERRA, JUNE 2015**

4.1 Abstract

Clostridium perfringens is a spore forming bacterium, that has an incubation period of 6–24 hours, and causes self-limiting symptoms of diarrhoea, nausea and abdominal cramping, usually resolving within 24 hours.

In June 2015, an outbreak of gastrointestinal illness occurred following a dinner function at a large tourist attraction in Canberra. This report describes the epidemiological, environmental health and laboratory investigation of the outbreak. The objectives of the investigation were to identify the cause of illness and to implement appropriate public health measures to prevent further disease.

A case was defined as someone who attended the function and subsequently developed diarrhoea. We identified a total of 29 cases with a median duration of illness of 8 hours.

We conducted a retrospective cohort study of staff via telephone interviews, using a structured questionnaire developed from a list of food items served at the event. Epidemiological analysis on a cohort of staff members showed that eating the butter chicken was significantly associated with illness (adjusted OR = 5.19; 95% CI 1.08–24.92; $p=0.04$). Enterotoxin producing *Clostridium perfringens* was isolated from a sample of butter chicken prepared in the same batch that was eaten on the night.

The investigation found the most likely cause of the gastrointestinal outbreak was *C. perfringens* and reinforces the need to work with food businesses to ensure strict adherence to food safety programs and food handling requirements.

4.2 Introduction

4.2.1 Background

Clostridium perfringens is a spore forming environmental bacterium. *C. perfringens* has a reported incubation period of 6–24 hours, and causes self-limiting symptoms of diarrhoea, nausea and abdominal cramping, with illness usually resolving within 24 hours.^{64,65} Toxin-producing bacteria, such as *C. perfringens*, are suspected aetiological agents when outbreaks of diarrhoea are reported and the incubation period is short.

When food is prepared or stored with inadequate temperature control, bacteria capable of producing enterotoxins can multiply rapidly resulting in foodborne illness.⁶⁴ The enterotoxin of *C. perfringens* is formed after the organisms have been ingested, the bacteria release the enterotoxin as the organism multiplies in the intestine.⁶⁶ *C. perfringens* grow rapidly at temperatures between 15 and 50°C, with a generation time of 7–8 minutes under ideal conditions.⁶⁷

There are five strains of *C. perfringens*, each strain producing a different profile of toxins. Human illness is caused by the production of *C. perfringens* enterotoxin (CPE).⁶⁵ Only around 6% of isolates are capable of producing enterotoxin,⁶⁸ the gene appears predominantly on the plasmid (a small DNA molecule within the cell that is separate from the chromosome),⁶⁹ although it can also be expressed on the chromosome.⁷⁰ Previous studies have indicated that *C. perfringens* isolates that carry the CPE gene on their chromosome, have a higher heat tolerance than strains with CPE on the plasmid or CPE negative strains, which is thought to provide a selective advantage and may explain the association with foodborne outbreaks.^{71,72}

A review of U.S. CDC Foodborne Disease Outbreak Surveillance System found meat and poultry were implicated in 92% of outbreaks with an identified (single) food source.⁷³ Foods that may be cooked and subsequently reheated (such as stews, curries etc.) are most susceptible, as the initial cooking process kills off commensal bacteria while the spores activate during the cooling process and can multiply.⁶⁶ Foodborne illness caused by *C. perfringens* is preventable if the food is served shortly after preparation or if it has been cooked and chilled quickly to prevent bacterial growth.

In Australia, there were 107 confirmed toxin mediated foodborne outbreaks reported in the OzFoodNet outbreak register between 2001 and 2013, 76% (81/107) of which were caused by *C. perfringens*.⁷⁴ Fifty-one percent (55/107) of these were associated with outbreaks in aged care facilities, while a further 35% (37/107) were associated with food service providers including restaurants and commercial caterers.⁷⁴ Outbreaks due to bacterial enterotoxins are thought to be underreported due to the mild, short lasting nature of illness resulting in fewer people seeking care and the limited number of laboratories that are accredited to test for toxin producing bacteria means that there are few laboratory confirmed cases.⁷⁵

4.2.2 Outbreak description

On 14 June 2015, the Australian Capital Territory Health Protection Service (HPS) was alerted to an outbreak of gastrointestinal disease among guests and staff who had attended a dinner function at a large tourist attraction in Canberra. Staff at the venue had received separate complaints from two members of the public reporting diarrhoeal illness after attending the event and five staff had been absent from work with a similar illness. The ill staff members had all attended the function and eaten remaining food at the conclusion of the night, indicating a probable point source foodborne outbreak. The only known exposure that was common to both the staff members and the public complainants was an evening function at the venue hosted on 12 June, attended by an estimated 2000–3000 people. The following day, HPS convened an acute response team meeting and a multi-disciplinary investigation was initiated to identify the cause of illness and to implement appropriate public health measures to prevent further disease.

4.3 Methods

4.3.1 Epidemiological investigation

A probable case was defined as a person who attended the function on 12 June and had diarrhoea following the consumption of food. A laboratory confirmed case was defined as a person who attended the function on 12 June and had *C. perfringens* detected in their stool. We requested that people who were still symptomatic at the time of interview consult a general practitioner and submit a stool sample for testing.

A retrospective cohort of staff members working on the night of the function were interviewed via telephone using a standardised questionnaire including the respondents' demographic details, food items consumed at the function on the 12 June, as well as a description of symptoms and time of onset. Food items included in the questionnaire were based on a list of items served at the function that was supplied by the manager of the catering company. The objective of the staff cohort study was to identify the specific food vehicle that caused the outbreak.

To assess the risk to the public, non-staff attendees were interviewed from a partial list of family groups who had registered for the event to quantify the extent of illness in members of the public attending the function. A complete list of contact details for people attending the function was not available.

4.3.2 Data analysis

Interview data from both groups (the staff cohort and cross-sectional survey of attendees) were entered into a Microsoft Excel database for descriptive analysis, including median age, incubation period and duration of illness. The cohort dataset was transferred to STATA for the calculation of crude relative risks (RR), and associated 95% confidence intervals and *p*-values. Variables with a *p*-value <0.1 in the univariate analysis along with age and sex were included in a multivariate logistic regression model to estimate adjusted odds ratios (aOR). Non-significant variables were then removed one at a time using a backward stepwise approach.

4.3.3 Environmental investigation

Environmental Health Officers (EHO) from the HPS conducted a food safety inspection of the catering business and reviewed food preparation and storage

procedures related to the event. Food items served on the night were not part of the standard menu available at the café, however, leftover food was placed on sale the following day. Following reports of illness this food was withdrawn from sale and held at the food business. Samples of butter chicken, beef stroganoff, macaroni and rice prepared in the same batch served at the event were collected. Food samples were tested for *Salmonella*, *Escherichia coli*, coagulase positive *Staphylococcal aureus*, *C. perfringens* and *Bacillus cereus* at the ACT Government Analytical Laboratory. Analysis for the detection of these pathogens in foods was performed using modified Australian Standard Methods.⁷⁶

Confirmation of the causative agent was based on CDC criteria for confirming the aetiological cause of a foodborne outbreak. A confirmed outbreak of *C. perfringens* intoxication requires isolation of high numbers of the organism, or the detection of CPE in a stool sample, or the isolation of high numbers of the organism from a food sample.⁷⁷

C. perfringens isolates selected from culture plates were referred to Queensland Forensic and Scientific Services and genotyped using a multiplex PCR, used to detect the four major toxin genes as well as the enterotoxin gene CPE, as described in van Asten et al.⁷⁸ Then a second PCR assay was used to distinguish whether the CPE gene was located on the chromosome or two well characterised locations on the plasmids (*IS1151* and *IS1470-like*) of type A isolates, as outlined in Miyamoto et al.⁷²

4.4 Results

In total, 29 cases of gastroenteritis meeting the probable case definition were identified among attendees and staff who attended the function on the 12 June. No cases reported having consulted a physician and no stool samples were submitted for testing.

To rapidly assess the risk to the public, investigators attempted to contact 100 people that indicated that they would attend the event, with a response rate of 59%. Fifty-eight percent (34/59) indicated that they had attended the event, mostly in family groups of four or more, resulting in a completed questionnaire for 135 attendees. Eight percent (11/135) of respondents had an illness that met the case definition.

A toxin-mediated gastrointestinal illness was suspected based on the symptom profile, short incubation period and the preliminary microbiological analysis of food. There were no reported cases of severe illness, consistent with foodborne intoxication.

4.4.1 Descriptive epidemiology

This section presents descriptive information on all attendees and staff members that met the case definition. Commonly reported symptoms included diarrhoea 29/29 (100%), abdominal cramping 24/29 (83%) or nausea 8/29 (28%). The onset of symptoms ranged from 12 June 23:00 to 14 June 17:00 (see Figure 4.1). The median incubation period for the 29 cases was 13 hours (range 7–49 hours), with a median duration of 8 hours (range: <1–48 hours).

The epidemic curve demonstrates a point source infection followed with a long tail, which is plausible if these later cases had a longer than usual incubation period, rather than the expected 6–24 hours.

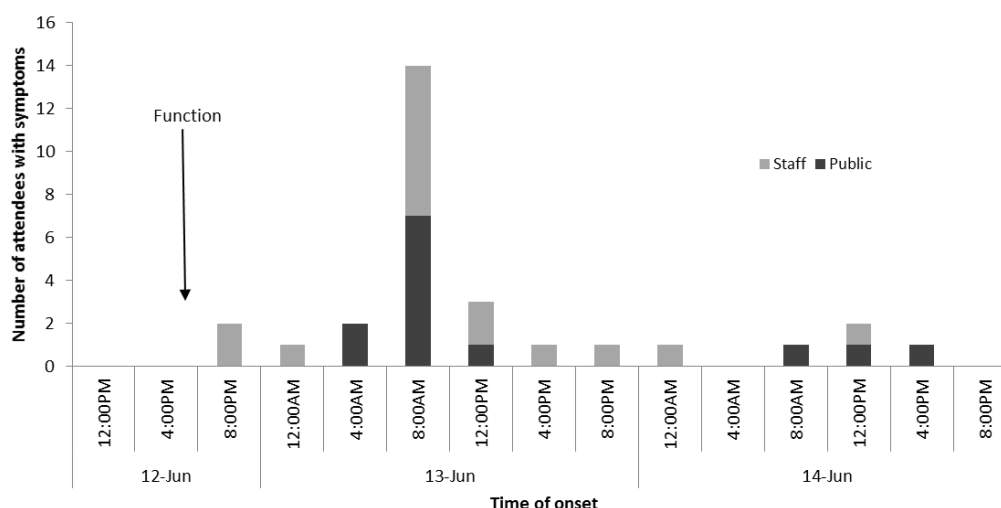


Figure 4.1: Epidemic curve of cases of gastrointestinal illness by time of symptom onset, Canberra, 12–15 June 2015

4.4.2 Analytical epidemiology

We interviewed 80% (72/90) of staff members via telephone that had been working on the night of the event. The forty-five staff members who reported eating at the event were included in the cohort for analysis. There were no significant differences between people who were ill and those who were not in respect of age and sex (Table 4.1).

Table 4.1: Demographic characteristics in a staff cohort, Canberra, June 2015

	Cases	Non-cases	p value
Median age (range)	24 (17–52)	28 (16–58)	0.97
Proportion male	56%	59%	0.88

Food was served throughout the evening, with 29% of the cohort eating before 9pm and 71% eating at the end of the function (9pm or later), all cases ate after 9pm, resulting in an attack rate of 50.0% (16/32) among that group. Food items remaining at the end of service included butter chicken, beef stroganoff and rice. The risk of disease was higher among those that ate butter chicken (RR 3.17), popcorn (2.93), beef stroganoff (RR 1.75) and rice (RR 1.74) (Table 4.2). Only butter chicken was statistically significant at $p < 0.05$ level. A risk ratio was unable to be estimated for a number of other foods due to the fact that no cases consumed them.

Variables which had a p value <0.1 were included in a multivariable model along with sex. The butter chicken (aOR 5.19, $p=0.04$) remained statistically significantly associated with illness (Table 4.3). We tested the interaction between chicken and the time it was eaten, but due to the fact that all cases ate the chicken after 9pm, an odds ratio could not be estimated.

Table 4.2: Results of univariate analysis of food exposures in a cohort of staff members, Canberra, June 2015

	Exposed			Unexposed			RR	95% CI	p value
	Cases	Non-cases	AR%	Cases	Non-cases	AR%			
Chicken Nuggets	0	6	0.0	16	23	41.0	-	-	-
Fish	0	4	0.0	16	25	39.0	-	-	-
Hot chips	0	5	0.0	16	24	40.0	-	-	-
Tomato sauce	0	1	0.0	16	28	36.4	-	-	-
Butter chicken	13	13	50.0	3	16	15.8	3.17	1.04-9.58	0.03
Beef stroganoff	14	22	38.9	2	7	22.2	1.75	0.48-6.35	0.46
Boiled vegetables	1	2	33.3	15	27	35.7	0.93	0.18-4.86	1.00
Rice	10	12	45.5	6	17	26.1	1.74	0.76-3.98	0.22
Macaroni & cheese	0	1	0.0	16	28	36.4	-	-	-
Fairy floss	0	0	-	16	29	35.6	-	-	-
Popcorn	1	0	100.0	15	29	34.1	2.93	1.95-4.42	0.36
Ice cream	1	7	12.5	15	22	40.5	0.31	0.05-2.00	0.23

AR: attack rate; CI: confidence interval; RR: risk ratio.

Table 4.3: Results of multivariate analysis of exposures in a cohort of staff members, Canberra, June 2015

	Adjusted Odds Ratio	95% Confidence Interval	p value
Butter chicken	5.19	1.08-24.92	0.04
Time food was eaten	10.08	1.03-98.81	0.05
Gender	1.01	0.23-4.48	0.98
Age	0.96	0.19-4.77	0.96

We conducted further analysis of cohort data excluding three cases with an onset of symptoms that was not consistent with *C. perfringens*, as two cases reported an incubation period of around 2 hours and one case an incubation period of more than 40 hours. Excluding these cases strengthened the association with butter chicken, but was not statistically significant (aOR=8.30, p=0.29).

4.4.3 Environmental investigation

The food safety inspection conducted by EHOs suggested that food handling practices and inadequate temperature control may have resulted in contamination of the food. The catering business was contracted to provide food for up to 3000 people, this was the largest catering event the business had attempted.

Preparation of food began three days prior to the event. Approximately 500 kilograms of chicken and beef were precooked on the second day prior to the event which involved both steaming and baking. The meat was cooked in a number of batches for approximately 45 minutes. Each batch was left to cool on the bench for around one hour before the liquid juice was drained from the meat and placed in the cool room. Temperature checks and time monitoring was not performed by the business when cooling on the bench or when being placed in the cool room. The temperature was also not monitored to ensure cooked potentially hazardous food was cooled from 60°C to 21°C within two hours and from 21°C to 5°C within a further four hours, as required by the Australian New Zealand Food Standards Code.⁷⁹

On the morning of the event the meat dishes were mixed with the sauce within the cool room and the steamed rice was prepared at midday. The rice was hot held in warmers that had been hired by the catering business for the event. No temperature checks were conducted on any of the dishes or trays that were reheated throughout the event. The first of the hot dishes were

placed in the Bain Maries by 4. 00pm. The temperature controls of the Bain Marie were set to 120⁰ C; however, no temperature checks were performed on any of the food. Three food service stations were set up and a constant flow of patrons was reported at each station, with a high turnover of food.

Food service ended at approximately 9pm and staff working during the event ate left over food from the Bain Maries at approximately 9.30pm. All remaining food from the Bain Marie was disposed of. Food items served on the night were not part of the standard menu available at the catering businesses café, however, two trays of butter chicken and beef stroganoff with rice that were not reheated during the event were placed on sale the following day.

The general food safety inspection did not identify any critical food safety risks and the premises were in a clean condition. Two food grade probe thermometers were available within the kitchen and in working order. The proprietor had completed the mandatory food safety supervisor training and most of the staff had completed basic food safety training. Following reports of illness and contact by the EHO, the leftover food from the event that had been placed on the café specials board was withdrawn from sale. This food was held at the food business and was available for sampling during the food safety inspection.

4.4.4 Laboratory investigation

EHOs submitted food samples to the laboratory for analysis. The five food samples were: butter chicken; rice; beef stroganoff; mashed potato; and macaroni. The analysis of food samples detected 8.6×10^5 colony-forming units of *C. perfringens* per gram (cfu/g) of food in the butter chicken. No other organisms were detected in any of the other food samples tested. Six *C. perfringens* isolates selected from culture plates from the butter chicken were referred to Queensland Forensic and Scientific Services and genotyped using a multiplex PCR. The multiplex PCR results showed the presence of CPE and one of these isolates expressed the CPE gene on the chromosome.

4.5 Discussion

This chapter presents the findings from an investigation of a gastrointestinal outbreak following a dinner function at a large tourist attraction in Canberra. We found that eating butter chicken was the likely cause of a point-source outbreak of *C. perfringens*. The food safety inspection revealed inadequate temperature control during the preparation and service of food at the function and microbiological analysis of food samples confirmed *C. perfringens* was the causative organism in this outbreak.

There were 81 toxin mediated foodborne outbreaks caused by *C. perfringens* reported in the OzFoodNet outbreak register between 2001 and 2013.⁷⁴ Outbreaks due to bacterial enterotoxins are difficult to identify due to the mild and short lasting nature of disease, as reported by cases in this outbreak and the fact that no one sought medical assistance. There are only a limited number of laboratories accredited to test for toxin producing bacteria.

Illness due to *C. perfringens* is not a notifiable condition, and would usually only be identified following an outbreak in an institutional setting or following a complaint about a food business, which are both reportable to health departments.

The epidemiological investigation was able to contact 80% of the staff members working on the night of the function and a sample of non-staff attendees to rapidly characterise the extent of illness and time of onset in cases. The apparent attack rate among the staff group (50.0%) was higher than among members of the public (8.1%) based on the sample surveyed. Symptoms experienced by cases were mild and the median incubation period was 13 hours. These findings are consistent with the commonly reported characteristics of *C. perfringens* infection. This investigation also found a significant association between the consumption of butter chicken and disease in a cohort analysis of staff.

Suboptimal food handling practices in the preparation of the butter chicken and beef stroganoff dishes were identified during the environmental health inspection, permitting the growth of *C. perfringens* and potential for enterotoxin accumulation. A sample of butter chicken prepared for the event tested positive for *C. perfringens* in high concentrations (8.6×10^5 cfu/g). Counts $>10^5$ cfu/g in food items are considered to be potentially harmful and provide the basis for confirmation of a causative agent based on established criteria.¹⁴ Further analysis of cultured isolates by a reference laboratory showed the presence of CPE with one isolate expressing the CPE gene on the chromosome.

One of the challenges in this investigation was the difficulty in obtaining stool samples from cases. The detection of *C. perfringens* in stool samples from one or more cases would have strengthened evidence for the causative agent. We used a sensitive case definition in order to maximise the number of cases, this may have led to a number of people with an unrelated illness being classified as a case. There were a group of cases with an onset on 14 June, their symptom profile was similar to the other cases although the incubation time and duration of illness would be much longer than the commonly reported incubation and duration for *C. perfringens*. This may have resulted from a lower infectious dose at the function, or be a result of the case definition used in the investigation. However, if these were not true cases associated with the outbreak it would have biased results towards the null.

Under ideal circumstances, simple randomisation would have been used in the selection of a sample of non-staff attendees. However, in an acute response setting it was necessary to compromise on some aspects of the epidemiological investigation. Despite repeated requests of the function organisers, we only had contact details for the first 100 members attending available by day 3 of the investigation. The members list was sorted alphabetically, which has the potential to introduce subtle biases based on the surname (i.e. certain ethnic backgrounds may be more likely to start with certain letters). It was decided to contact members from the available list, as it could be argued that all members had indicated that they would attend and we were not going to systematically bias our results by using this list (they all an equal opportunity for exposure) and their case status was dependent on self-reported symptoms. The result is statistically similar to random assignment, as we did not believe that the process in which the (members) list was generated could introduce bias, this is known as approximation to randomisation.⁸⁰

Despite a number of limitations, the epidemiological and microbiological evidence from food samples is sufficient to establish a strong association between consumption of butter chicken and subsequent illness. Together these findings suggest that among the staff cohort, butter chicken was the source of the outbreak.

Other outbreaks investigated in the ACT have demonstrated the potential hazards when small food businesses attempt to cater large functions with inadequate facilities and food handling procedures.⁸¹ Small catering businesses and cafés are less likely to be equipped with appropriate food processing equipment such as combine ovens and blast chillers and may not have sufficient storage facilities to maintain large quantities of food below 5°C. Toxin

mediated outbreaks are preventable with adequate education and training of food handlers on the appropriate temperatures for the preparation and storage of food.

Although the proprietor of the catering business had completed mandatory food safety supervisor training, and the majority of staff had completed basic food safety training, an understanding of the consequences of temperature abuse was clearly not sufficient. The business met its requirements to have a temperature measuring device, but the reason and importance of this requirement was clearly not understood. The large scale of the event and the quantity of food prepared was beyond the capacity of the premises and food safety knowledge of the business. The results from this investigation reinforce the need to work with food businesses to ensure food handlers understand the reason for these requirements.

Businesses expanding beyond the safety of their everyday business can lead to the preparation of unsafe food and result in illness. Regulation could be implemented, placing limits on the number of patrons that business can cater for based on their facilities, cooking and storage equipment. However, this would be an arbitrary number that could be exceeded with the appropriate processing equipment and food safety knowledge. Therefore, the need for ongoing education and information sharing on the implications of catering errors through case studies within the food service industry is required to ensure strict adherence to food safety programs and food handling requirements.

4.5.1 Role of the scholar and public health impact

The scholar was a part of the acute response team that investigated the foodborne outbreak of gastroenteritis. The scholar conducted interviews with cases and attendees at the function and participated in the situation response meetings and provided information from the initial epidemiological investigations, the scholar also prepared a report of the findings from this investigation.

A public health risk assessment made after conducting an initial investigation concluded that there was no on-going risk as a consequence of the function. While the epidemiological and microbiological evidence from food samples gathered from the investigation was sufficient to establish a strong association between consumption of butter chicken and subsequent illness.

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Appendix G:

An outbreak of *Clostridium perfringens* gastroenteritis linked to a function at a tourist attraction in Canberra, June 2015

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Introduction

Background

Clostridium perfringens is a spore forming environmental bacterium. *C. perfringens* has a reported incubation period of 6–24 hours, and causes self-limiting symptoms of diarrhoea, nausea and abdominal cramping, with illness usually resolving within 24 hours.^(1,2) *C. perfringens* is suspected when outbreaks of diarrhoea are reported and the incubation period is short.

When food is prepared or stored with inadequate temperature control, bacteria capable of producing enterotoxins can multiply, resulting in foodborne illness.⁽¹⁾ *C. perfringens* grow rapidly at temperatures between 15 and 50°C, with a generation time of 7–8 minutes under ideal conditions.⁽³⁾ Human illness is caused by the production of *C. perfringens* enterotoxin (CPE).⁽²⁾ Only around 6% of isolates are capable of producing enterotoxin,⁽⁴⁾ the gene appears predominantly on the plasmid, although it can also be expressed on the chromosome.⁽⁵⁾ Previous studies have indicated that *C. perfringens* isolates that carry the CPE gene on their chromosome, have a higher heat tolerance than strains with CPE on the plasmid or CPE negative strains, which is thought to provide a selective advantage and may explain the association with foodborne outbreaks.^(6,7)

Outbreak description

On 14 June 2015, the Australian Capital Territory Health Protection Service (HPS) was alerted to an outbreak of gastrointestinal disease among guests and staff who had attended a dinner function at a large tourist attraction in Canberra. Ill staff members had all attended the function and eaten remaining food at the conclusion of the night, indicating a probable point source foodborne outbreak. The only known common exposure between the staff members and public complainants was an evening function at the venue hosted on 12 June, attended by an estimated 2000-3000 people. The following day, a multi-disciplinary investigation was initiated to identify the cause of illness and to implement appropriate public health measures to prevent further disease.

Methods

Epidemiological investigation

A probable case was defined as a person who attended the function on 12 June and had diarrhoea following the consumption of food. A laboratory confirmed case was defined as a person who attended the function on 12 June and had *C. perfringens* detected in their stool. We requested that people who were still symptomatic at the time of interview consult a general practitioner and submit a stool sample for testing.

A retrospective cohort of staff members working on the night of the function were interviewed via telephone using a standardised questionnaire. Food items included in the questionnaire were based on a list of items served at the function that was supplied by the manager of the catering company.

To assess the risk to the public, non-staff attendees were interviewed from a partial list of family groups who had registered for the event to quantify the extent of illness in members of the public attending the function.

Data analysis

Interview data was entered into a Microsoft Excel database for descriptive analysis, including attack rates, median age, incubation period and duration of illness. STATA 13 was used for the calculation of crude relative risks (RR), adjusted odds ratios (OR) and associated 95% confidence intervals and *p*-values. Variables with a *p*-value <0.1 in the univariate analysis were included in a multivariate logistic regression model along with age and sex. Non-significant variables were then removed one at a time using a stepwise approach.

Environmental investigation

Environmental Health Officers (EHO) from the HPS conducted a food safety inspection of the catering business and reviewed food preparation and storage procedures related to the event. Food items served on the night were not part of the standard menu available at the café, however, leftover food was placed on sale the following day. This food was withdrawn from sale and held at the food business following reports of illness. Statutory samples of butter chicken, beef stroganoff, macaroni and rice prepared in the same batch served at the event were collected. Food samples were tested for *Salmonella*, *Escherichia coli*, coagulase positive *Staphylococcal aureus*, *C. perfringens* and *Bacillus cereus* at the ACT Government Analytical Laboratory. Analysis for the detection of these pathogens in foods was performed using modified Australian Standard Methods.⁽⁸⁾

Confirmation of the causative agent was based on CDC criteria for confirming the aetiological cause of a foodborne outbreak. Which requires isolation of high numbers of the organism, or the detection of CPE in a stool sample, or the isolation of high numbers of the organism from a food sample.⁽⁹⁾

C. perfringens isolates selected from culture plates were referred to Queensland Forensic and Scientific Services and genotyped using a multiplex PCR, used to detect the four major toxin genes as well as the enterotoxin gene CPE.⁽¹⁰⁾ Then a second PCR assay was used to distinguish whether the CPE gene was located on the chromosome or two well characterised locations on the plasmid (*IS1151* and *IS1470-like*) of type A isolates.⁽⁷⁾

Results

Twenty-nine cases of gastroenteritis meeting the probable case definition were identified among attendees and staff who attended the function on the 12 June. No cases reported having consulted a physician and no stool samples were submitted for testing.

Investigators attempted to contact 100 people that indicated that they would attend the event, with a response rate of 59%. Fifty-eight percent (34/59) indicated that they had attended the event, mostly in family groups of four or more, resulting in a completed questionnaire for 135 attendees. Eight percent (11/135) of respondents had an illness that met the case definition.

Descriptive epidemiology

The onset of symptoms ranged from 12 June 23:00 to 14 June 17:00 (see Figure 1). The median incubation period for the 29 cases was 13 hours (range 7–49 hours), with a median duration of 8 hours (range: <1–48 hours). Commonly reported symptoms included diarrhoea 100% (29/29), abdominal cramping 83% (24/29) or nausea 28% (8/29).

The epidemic curve demonstrates a point source infection followed with a long tail, which is plausible if these later cases were considered to have a longer than usual incubation period of up to 48 hours, rather than the expected 6–24 hours.

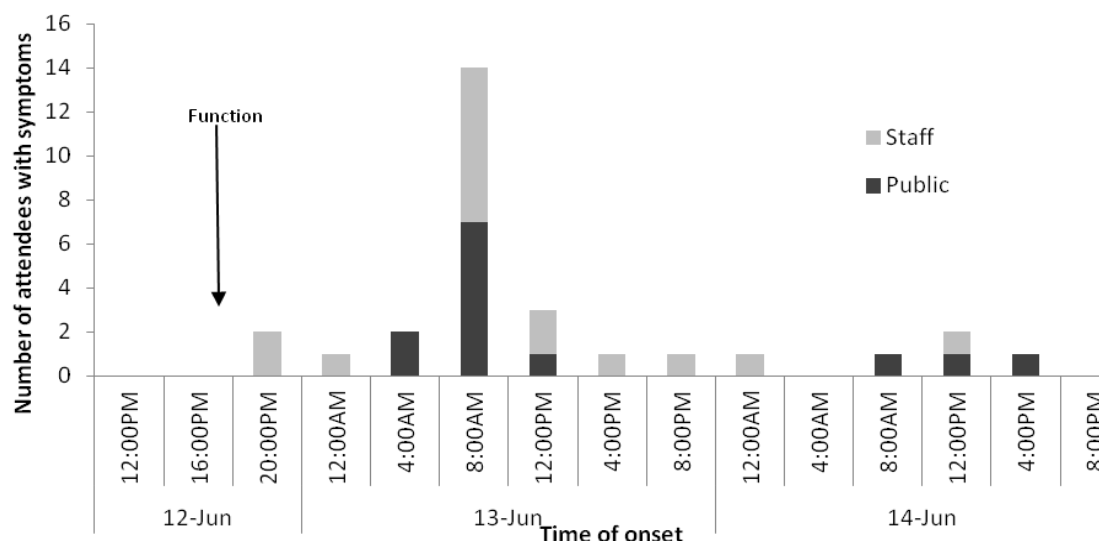


Figure 1: Epidemic curve of cases by date and time of symptom onset, Canberra, 12–15 June 2015

Analytical epidemiology

We interviewed 80% (72/90) of staff members that had been working on the night of the event. Forty-five staff members who reported eating at the event were included in the cohort for analysis. There was no significant difference between people who were ill and those who were not in respect of age and sex (p value 0.97 and 0.88 respectively). Food was served throughout the night, with 29% of the cohort eating before 9pm and 71% eating at the end of the function (9pm or later), all cases ate after 9pm resulting in an attack rate of 50.0% (16/32). Food items remaining at the end of service included butter chicken, beef stroganoff and rice. The risk of disease was higher among those that ate butter chicken (RR 3.17), popcorn (RR 2.93), beef stroganoff (RR 1.75) and rice (RR 1.74) (See Table 2). Only butter chicken was statistically significant at $p < 5\%$ level. A risk ratio was unable to be estimated for a number of other foods due to the fact that no cases consumed them.

Table 2: Results of univariate analysis of food exposures

	Exposed			Unexposed			RR	95% CI	p value
	Cases	Non-cases	AR%	Cases	Non-cases	AR%			
Food exposures									
Chicken Nuggets	0	6	0.0	16	23	41.0	-	-	-
Fish	0	4	0.0	16	25	39.0	-	-	-
Hot chips	0	5	0.0	16	24	40.0	-	-	-
Tomato sauce	0	1	0.0	16	28	36.4	-	-	-
Butter chicken	13	13	50.0	3	16	15.8	3.17	1.04-9.58	0.03
Beef stroganoff	14	22	38.9	2	7	22.2	1.75	0.48-6.35	0.46
Boiled vegetables	1	2	33.3	15	27	35.7	0.93	0.18-4.86	1.00
Rice	10	12	45.5	6	17	26.1	1.74	0.76-3.98	0.22
Macaroni & cheese	0	1	0.0	16	28	36.4	-	-	-
Fairy floss	0	0	-	16	29	35.6	-	-	-
Popcorn	1	0	100.0	15	29	34.1	2.93	1.95-4.42	0.36
Ice cream	1	7	12.5	15	22	40.5	0.31	0.05-2.00	0.23

AR: attack rate; CI: confidence interval; RR: risk ratio.

In the multivariate model, the butter chicken (odds ratio 5.19, $p=0.04$) remained statistically significantly associated with illness (Table 3).

Table 3: Results of multivariate analysis of exposures

	Adjusted OR	95% CI	p value
Butter chicken	5.19	1.08-24.92	0.04
Time food was eaten	10.08	1.03-98.81	0.05
Gender	1.01	0.23-4.48	0.98
Age	0.96	0.19-4.77	0.96

OR: Odds ratio; CI: confidence interval.

Environmental investigation

The food safety inspection conducted by EHOs suggested that food handling practices and inadequate temperature control may have resulted in contamination of the food. Preparation of food began three days prior to the event. Approximately 500kg of chicken and beef were prepared in several stages over 3 days, with multiple cooking and cooling processes. There was no evidence that temperature monitoring had been conducted during the preparation, cooling, reheating and serving of food items. The kitchen did not have appropriate cooking and cooling equipment and there were no clear and specific procedures for the preparation of food at this scale. The general food storage area, including the cool room was not of a sufficient size to safely store the large quantity of food during processing and before service. Food was served from 5–9 pm as a buffet. Hot dishes were reheated in batches and served in bain-maries at food stations located in the lobby and outside at the two entrances.

Laboratory investigation

EHOs submitted five food samples that were still available and served at the function to the laboratory for analysis. The five food samples were: butter chicken; rice; beef stroganoff; mashed potato; and macaroni. The analysis of food samples detected 8.6×10^5 colony-forming units of *C. perfringens* per gram (cfu/g) of food in the butter chicken. No other organisms were detected in any of the other food samples tested. Six *C. perfringens* isolates selected from culture plates from the butter chicken were referred to Queensland Forensic and Scientific Services and genotyped using a multiplex PCR. The multiplex PCR results showed the presence of CPE and one of these isolates expressed the CPE gene on the chromosome.

Discussion

The investigation of a gastrointestinal outbreak following a dinner function at a large tourist attraction in Canberra found that eating butter chicken was the likely cause of a point-source outbreak of *C. perfringens*. The food safety inspection revealed inadequate temperature control during the preparation and service of food at the function and microbiological analysis of food samples confirmed *C. perfringens* was the causative organism in this outbreak.

There were 81 toxin mediated foodborne outbreaks caused by *C. perfringens* reported in the OzFoodNet outbreak register between 2001 and 2013.⁽¹¹⁾ Outbreaks due to bacterial enterotoxins are difficult to identify due to the mild and short lasting nature of disease and the limited number of laboratories accredited to test for toxin producing bacteria.⁽¹²⁾ *C. perfringens* is not a notifiable condition and would usually only be reported following an outbreak in an institutional setting or following a complaint about a food business.

The epidemiological investigation was able to contact 80% of the staff members working on the night of the function and a small number of non-staff attendees to rapidly characterise the extent of illness and time of onset in cases. Symptoms experienced by cases were mild (diarrhoea, abdominal pain and nausea) and the median incubation period was 13 hours. These findings are consistent with the commonly reported characteristics of *C. perfringens* infection. Suboptimal food handling practices in the preparation of the butter chicken and beef stroganoff dishes were identified during the environmental health inspection, permitting the growth of *C. perfringens* and potential for enterotoxin accumulation. A sample of butter chicken prepared for the event tested positive for *C. perfringens* in high concentrations (8.6×10^5 cfu/g). Counts $>10^5$ cfu/g in food items are considered to be potentially harmful and provide the basis for confirmation of a causative agent based on established criteria.⁽⁹⁾ Further analysis of cultured isolates by a reference laboratory showed the presence of CPE with one isolate expressing the CPE gene on the chromosome.

One of the challenges in this investigation was the difficulty in obtaining stool samples from cases. The detection of *C. perfringens* in stool samples from one or more cases would have strengthened evidence for the causative agent. We used a sensitive case definition in order to maximise the number of cases, which may have led to a number of people with an unrelated illness being classified as a case. There were two cases with an onset of symptoms outside the standard incubation period. However, excluding these cases would have biased results towards the null.

Other recent outbreaks investigated in the ACT have demonstrated the potential hazards when small food businesses attempt to cater large functions with inadequate facilities and food handling procedures.⁽¹³⁾ Toxin mediated outbreaks are preventable with adequate education and training of food handlers on the appropriate temperatures for the preparation and storage of food. The results from this investigation reinforces the need to work with food businesses to ensure strict adherence to food safety programs and food handling requirements.

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Appendix H:

Summary of investigation of gastroenteritis in attendees at a dinner function in 2015

An outbreak of gastroenteritis was identified in June 2015 following notification to ACT Health Protection Service (HPS).

Epidemiological investigation

Cases of gastroenteritis were linked to a large dinner function (>2,000 people) held on 12 June 2015. A cohort study of 72 staff members working at the function identified 16 cases of gastroenteritis and found that eating the butter chicken carried an increased risk of illness.

Symptoms included diarrhoea, abdominal pain and nausea. No stool samples were available for testing. The average time from exposure to developing illness was 6-24 hours, with illness resolving within 24 hours in most cases.

HPS conducted a food safety inspection and reviewed food preparation processes related to the event with the caterer. Samples of food prepared in the same batch that was served at the event were collected and the butter chicken subsequently tested positive for *C. perfringens*.

Background information

C. perfringens is an environmental bacterium, which under certain conditions may multiply rapidly in food causing food-borne disease. It is controlled through appropriate temperature control during food preparation.

Investigation summary

- There were a total of 29 cases of gastroenteritis identified among members and staff that attended a dinner function on 12 June 2015
- The symptom profile was consistent with *C. perfringens* poisoning
- A sample of butter chicken prepared for the event tested positive for *C. perfringens*.
- The environmental health investigation identified insufficient temperature control during the preparation and storage of food served at the function.

**5 INCORPORATING PATHOLOGY TESTING DATA IN SEXUALLY
TRANSMISSIBLE INFECTION SURVEILLANCE IN THE AUSTRALIAN
CAPITAL TERRITORY, 2003–2012**

5.1 Abstract

Around Australia, notifications of sexually transmitted infections have increased rapidly over recent years. Notification data is susceptible to changes in testing in the community. This study sought to describe testing trends to assist the interpretation of disease notifications. Pathology testing data for chlamydial and gonococcal infection were received by two major pathology providers in the ACT for the period 2003 to 2012.

Analysis of ACT data suggest that there was no clear increase in test positivity and that at least some of the increase in notifications for chlamydial infection is associated with an increase in testing over this period. Testing and notifications for chlamydial infection were consistently higher among females, however, the proportion of tests among men had increased over this period.

The study found an apparent increase in notifications for gonococcal infection in 2011 that was not related to testing. We found that the majority of gonococcal infections in the ACT were diagnosed in males attending a sexual health clinic. However, there was a large increase in testing for gonococcal infection among females which occurred in a general practice setting, due to the use of dual testing for chlamydial and gonococcal infection, which warrants further investigation. This study has demonstrated that it is feasible to utilise pathology testing data to interpret trends in notification data.

5.2 Introduction

Sexually transmissible infections (STIs) encompass a range of bacterial or viral infections that are transmitted through sexual intercourse. Transmission of STIs can be prevented by adopting and maintaining protective behaviours, including condom use. Early detection is important to reduce the likelihood of complications and to limit further transmission of STIs in the community and can be achieved with targeted screening of some social groups. Broader public health strategies may also include improved sexual health education programs and allocating resources for contact tracing or partner notification as well as improved access to health services.

Chlamydial infection is the most commonly notified communicable disease in Australia, with 82,903 newly diagnosed cases reported in 2012. In the ACT, the notification rate has increased by 111.1%, from 162.1 per 100,000 population in 2003 to 342.2 in 2012 and this is consistent with the trend observed in jurisdictions around Australia.⁸²

Chlamydial infection is a sexually transmitted bacterial disease caused by the bacterium *Chlamydia trachomatis*, it affects both men and women and genital infection is transmitted through unprotected sexual contact.⁴³ Infection in pregnant women may result in congenital infection, presenting as conjunctivitis or pneumonia in neonates.⁸³ Genital infection is often asymptomatic, particularly in women.⁸⁴ While some genital infections resolve without treatment, infections may persist for several months.⁸³ Infection can have potential implications on sexual and reproductive health, particularly in women, leading to pelvic inflammatory disease and complications during pregnancy.⁸⁵ In those that experience symptoms infection manifests urethral itching and a burning sensation when urinating.⁸⁶ Reinfection is common, a cohort study of Australian women aged 16–25 years found a reinfection rate of 22.3 per 100 years of follow up.⁸⁷

In Australia, testing and treatment for chlamydia frequently occurs in general practice⁸⁸ with recommendations for opportunistic testing targeting young sexually-active people (aged 15–29) and other at-risk groups including Aboriginal and Torres Strait Islanders and men who has sex with men (MSM).⁸⁹ Annual screening of sexually active women has been shown to halve infection rates.⁹⁰ The use of nucleic acid amplification testing (NAAT), is recommended for routine screening. The use of a urine sample has largely replaced the use of urethral swabs,⁹¹ urine samples are non-invasive resulting in greater acceptance of routine

testing.⁹² The current approach to control chlamydial infections includes a combination of early testing and treatment with antibiotics as well as contact tracing.⁸⁹

The ACT notification rate of Gonococcal infection has increased by 166.3% from 9.2 per 100,000 population in 2003 to 24.5 in 2012,⁸² this trend has been observed in other jurisdictions around Australia, and has been described as a ‘dual-epidemic’ affecting Indigenous males and females in remote areas and MSM in metropolitan areas of the eastern states.⁹³

Gonococcal infection, also known as ‘the clap’, is a sexually transmitted bacterial disease caused by the bacterium *Neisseria gonorrhoeae*. It affects both men and women and is predominantly transmitted through unprotected sexual contact, causing infection in the genitals, rectum and throat. Infection follows an incubation period of 1–14 days, the course and severity of infection presents differently in males and females and by anatomical site. In males, symptoms of genital infection included discharge from the penis or stinging while urinating (dysuria).⁸³ In females, infection is often asymptomatic, although some women may present with vaginal discharge or bleeding after intercourse.⁴³

In the ACT, additional information on the patient’s sexual history are often collected as part of the public health follow up for a gonococcal infection and included as an enhanced dataset. Previous analysis has shown that oral and anal sex are additional risk factors among MSM.⁹³ Nucleic acid testing provides rapid, sensitive testing and has largely replaced culture as the preferred method of diagnosis. However, samples may be cultured in order to confirm the diagnosis and to provide additional typing information and drug sensitivity testing. Resistance to common antibiotics found in some gonococcal isolates is of growing concern.⁹¹

Recommendations for targeted testing of at-risk groups including Aboriginal and Torres Strait Islanders and MSM.⁸⁹ As with chlamydial infection, the use of NAAT is recommended for routine screening. The use of a urine sample has largely replaced the use of urethral swabs, although swabs may be used to test for infection in non-urethral sites.⁹¹

5.2.1 STI surveillance in the ACT

In the ACT, certain STIs, are notifiable to the ACT Health Directorate under the *Public Health Act 1997*. Pathology laboratories and doctors are required to notify cases of 136

communicable disease that are listed under this legislation. However, laboratories are not required to report negative pathology results for these notifiable conditions.

The reliance on passive surveillance means that the reasons for increased rates are not adequately explained using notification data alone. The increase may reflect a change in the underlying prevalence in the community or be an artefact of additional testing. Nucleic-acid based testing for Chlamydia has been used exclusively in the ACT since 1999, therefore test sensitivity would have been relatively stable over this period.⁹⁴ Further information on the number of tests conducted (a denominator), will allow for more accurate interpretation of ACT notification data. A previous study that reviewed pathology testing data for chlamydial infection in the ACT found the proportion of positive tests was 4.8% in females and 5.8% in males.⁹⁴

5.2.2 Objectives of the study

The hypothesis under investigation was that changes in pathology testing over the period from 2003 to 2012 contributed to an increase in the number of notifications for Chlamydial and Gonorrhoeal infection in the ACT.

The objectives of this project were to:

- describe trends in pathology testing and proportion of positive tests for Chlamydia and Gonorrhoea infection in the ACT, for the period from 2003 to 2012; and
- better understand notification-based surveillance data in the ACT.

5.3 Methods

5.3.1 Notification data

Notifications for chlamydial and gonorrhoeal infections with a diagnosis date between 1 January 2003 and 31 December 2012 were extracted from the ACT Notifiable Disease Management System. Mid-year estimated resident population data for the ACT were obtained from the Australian Bureau of Statistics for each year of surveillance.⁹⁵

5.3.2 Pathology testing data

Testing data for chlamydial and gonorrhoeal infections for the same period were provided electronically by two of the three major pathology service providers in the ACT. Fields requested included age, sex, date of test, clinical setting, specimen type and test result. Due to the small size of the jurisdiction, these two laboratories combined provide 77.3% of notifications for chlamydial infections and 78.2% of notifications for gonococcal infections. Datasets from the two pathology providers were checked for completeness and consistency before being merged for analysis. Patients with unknown sex were excluded from analysis. A unique identifier was included in the data from one of the pathology providers, for patients of the other provider a proxy identifier was created using the patients' sex, date of birth and postcode. Only a single result was counted if multiple tests were performed on the same day.

5.3.3 Statistical analysis

Notification rates per 100,000 persons were calculated using the number of disease notifications received each year divided by the estimated resident population. Analysis was conducted to identify the number of tests performed and the number of positive tests recorded by sex, age group and clinical setting for each year over the study period. Testing rates per 100,000 persons were calculated using the number of tests performed each year divided by the estimated resident population. The positivity rate was calculated by dividing the total number of positive chlamydia or gonorrhoea results by the total number of tests, expressed as a percent.

A X^2 test of trend was used to determine whether there was a significant trend in the proportion of positive tests over time. Statistical significance was set at $p < 0.05$ for all analyses. Data were extracted and prepared for analysis using Microsoft Office Excel 2007

(Microsoft, USA), with additional analysis and statistical tests conducted using Stata Version 13 software (StataCorp, USA).

5.3.4 Ethics approval

This study received ethics approval from the ACT Health Human Research Ethics Committee and the Australian National University Human Research Ethics Committee.

5.4 Results

5.4.1 Trends in the notification of chlamydial infection

Over the study period, there were 9,086 notifications of chlamydial infection, 5,203 notifications in females and 4,063 in males. The annual number of notifications in females increased by 110.6% from 312 in 2003 to 657 in 2012, while in males, notifications increased by 190.6% from 216 to 616 over the same period. The majority (83.3%) of notifications for chlamydial infection were reported among those aged 15–29 years while a further 16.1% were reported in those aged 30 and over.

The notification rate was higher in females than in males throughout the period. In 2012, the rate of chlamydial infection in females was 353.7 per 100,000 persons and 330.1 per 100,000 persons in males (Figure 5.1). Between 2003 and 2012, there was a statistically significant increase in chlamydial notification rates in both males ($p=0.02$) and females ($p=0.01$).

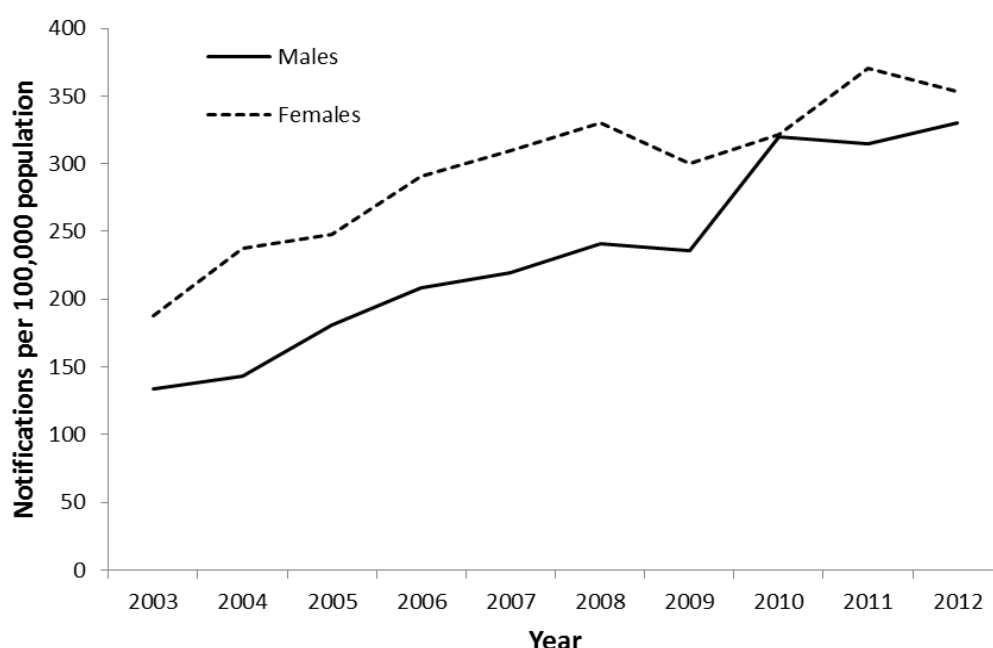


Figure 5.1: Notification rate for chlamydial infection, by sex, ACT, 2003–2012

5.4.2 Trends in testing for chlamydial infection

Between 2003 and 2012, the number of tests performed each year increased by 76% from 10,830 in 2003 to 19,099 in 2012. Sixty-seven per cent ($n=97,020$) of all tests were performed on women, although the proportion of tests performed on men has increased over

time, from 27.7% in 2003 to 38.1% in 2012. Around two-thirds (65.9%) of all tests for chlamydial infection were performed among those in the target age group (those aged 15–29 years), while a further 33.3% were reported in those aged 30 and over.

The number of tests in females each year increased by 57.0% from 7,917 in 2003 to 12,425 in 2012, while for males the annual number of tests increased by 129.1% from 2,913 to 6,674 (Figure 5.2). There was a statistically significant increase in testing among males and females ($p<0.001$).

The proportion of positive results was higher in males than females, with an overall positivity of 6.9% compared with 4.3%. Positivity rates for chlamydial infection in males fluctuated over the period under investigation, ranging between a low of 5.7% in 2007 and a high of 8.0% in 2010, with no statistically significant trend ($p=0.274$). While positivity in females was relatively stable over this period, ranging between 3.7% in 2003 and 4.6% in 2008, with no statistically significant trend ($p=0.966$).

Sixty-eight percent ($n=98,789$) of all testing for chlamydial infection was requested in general practice. Over this period there was an increase in number of test performed each year between 2003 and 2012 in both a GP and sexual health setting. The positivity rate in the sexual health clinic was 6.8% in males and 5.8% in females, while positivity rates in general practice was 7.0% and 3.8% respectively.

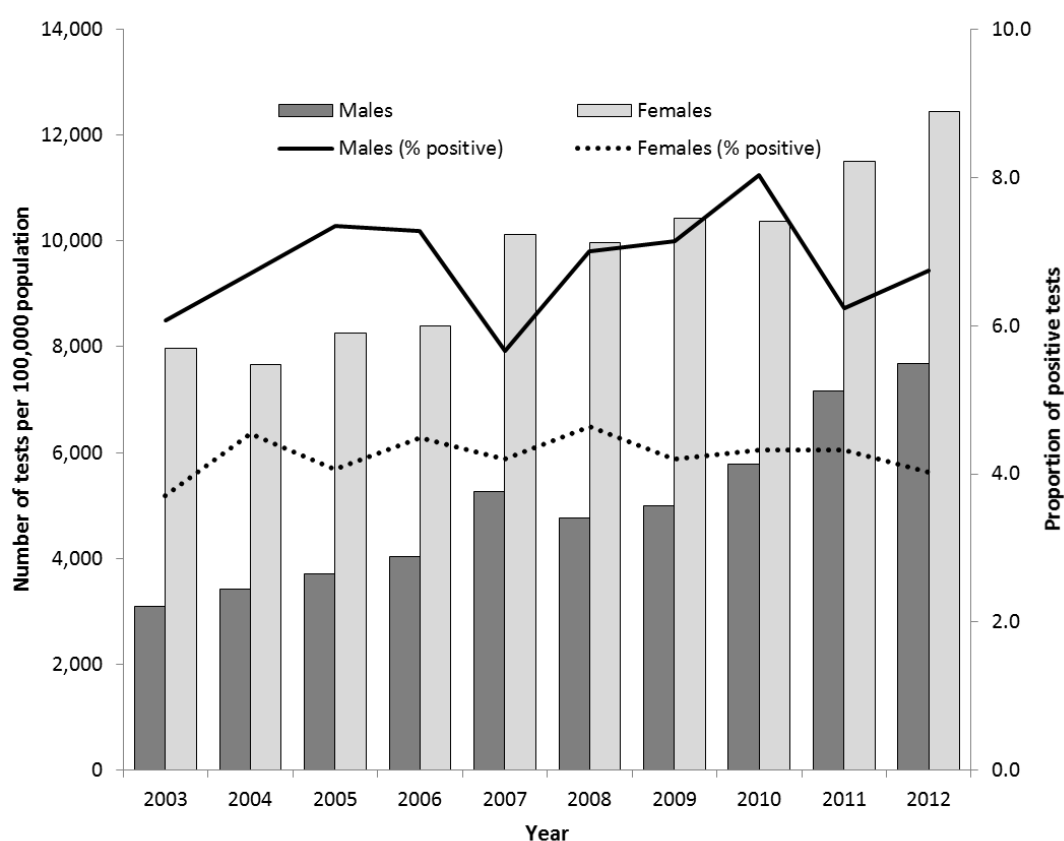


Figure 5.2: Trends in testing for Chlamydial infection, by sex, ACT, 2003–2012

5.4.3 Trends in the notification of gonococcal infection

In the period from 2003 to 2012, there were 530 notifications for gonococcal infection with 466 notifications among men and 64 among women. The majority of notifications for gonococcal infection (87.5%) were in males, with the number of notifications increasing from 25 in 2003 to 86 in 2012. While in females, notifications were relatively stable, except for an increase in the number of notifications in 2010 and 2011. A large proportion (58.5%) of notifications for gonococcal infection were reported among those aged 15–29 years, with a further 33.3% reported in those aged 30 and over.

The notification rate of gonococcal infection was highest in 2011 in males and females, with a rate of 59.0 and 10.8 per 100,000 respectively (Figure 5.3). Between 2003 and 2012, there was a statistically significant increase in gonococcal infection rates in males. The notification rate in females was highest in the 15–19 year age group (161.9), while in males it was highest in the 20–24 year age group (274.4).

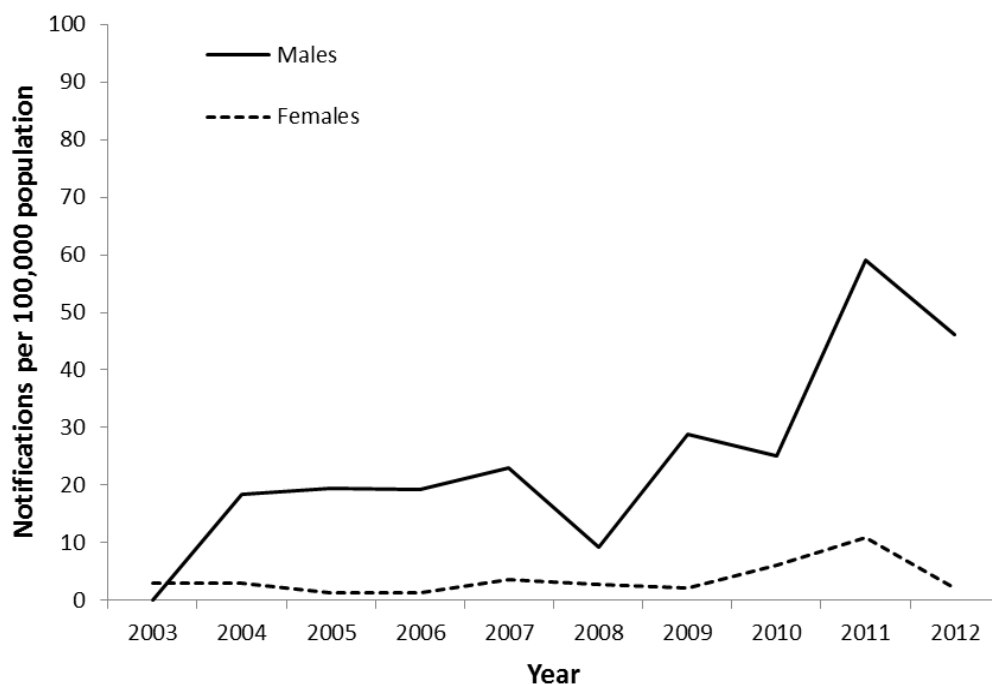


Figure 5.3: Trends in gonococcal infection notifications, by sex, 2003–2012

5.4.4 Trends in testing for gonococcal infection

Between 2003 and 2012, there were 72,617 tests performed for gonococcal infection. Females underwent more testing than males, accounting for 61.8% of tests performed over this period. The largest proportion of tests for gonococcal infection (64.1%) were performed among those aged 15–29, while a further 34.3% of tests were performed on those aged 30 and over.

The number of tests performed each year increased by 92.4% for females from 3,244 in 2003 to 6,248 in 2012, while for males the number of tests increased by 160.0% from 1,774 to 3,858 over this period (Figure 5.4). There was a statistically significant increase in testing among males and females ($p < 0.001$).

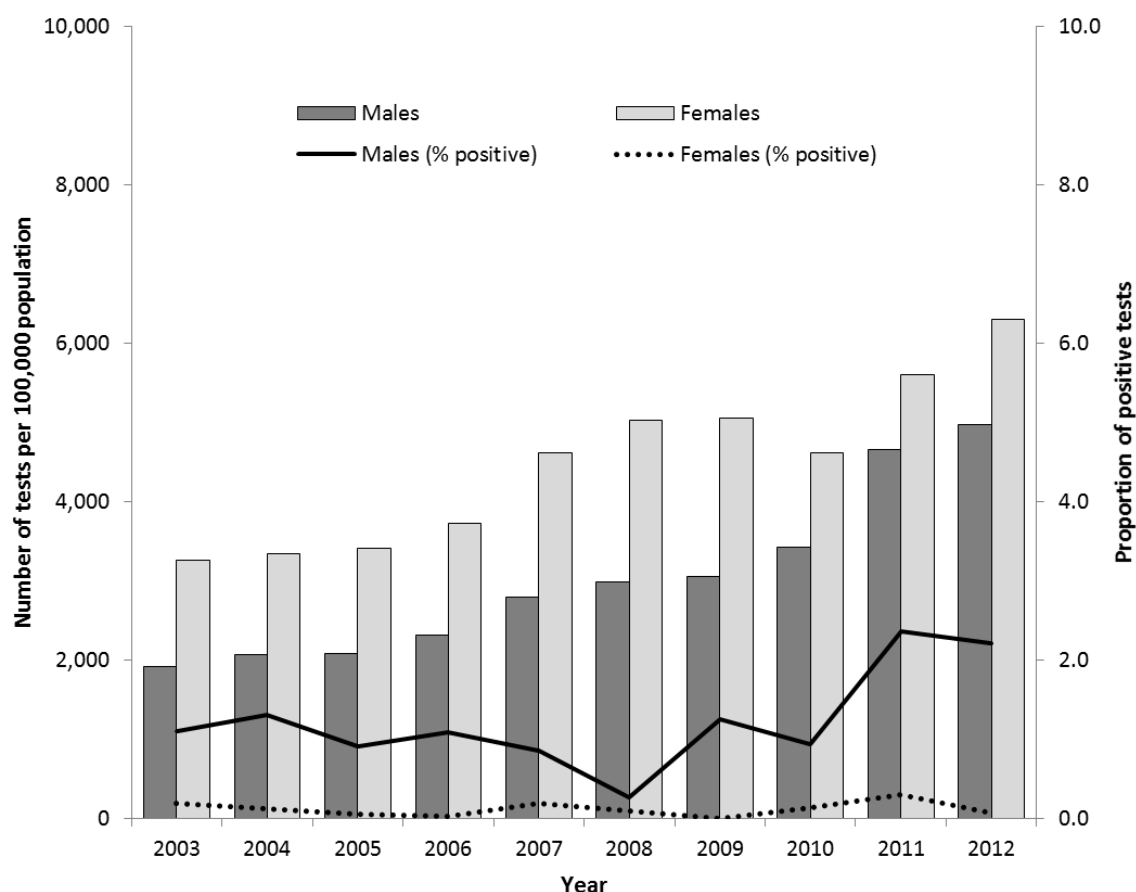


Figure 5.4: Trends in testing for gonococcal infections, by sex, 2003–2012

The proportion of positive results was again higher in males than females with an overall positivity rate of 1.4% and 0.1% respectively. The positivity rates for gonococcal infection in males fluctuated between 0.3% and 2.4% and this was a statistically significant increase ($p < 0.001$). The positivity rates in females ranged between 0.0% and 0.3%, with no statistically significant trend ($p = 0.799$).

During the study period there was an increase in testing by GPs, increasing from 3,180 in 2003 to 10,260 in 2012, there was also a modest increase in testing originating from the sexual health clinic. The proportion of tests requested in a GP setting increased from 53.2% to 77.5%, while the proportion in a sexual health setting decreased from 46.7% to 23.8%. The positivity rate of tests in CSHC was 2.2% for males and 0.3% for females, while positivity in general practice was 0.4% for males and 0.0% for females.

5.4.5 Trends in NAAT testing

Over the study period there has been an increase in the use of NAAT testing for chlamydial infection as well as a pronounced increase in the use of NAAT testing for chlamydial and gonococcal infection, with the total number of combined tests among females increasing by 307.6% from 1,233 in 2003 to 5,026 in 2012 and by 89.0% among males from 1,686 to 3,187 over the same period.

5.5 Discussion

The past decade has seen a dramatic increase in notification rates for STIs, such as chlamydia and gonorrhoea in Australia and most of this increase has occurred in the target age groups. In this study, we have demonstrated that in the general practice setting, where the majority of testing occurs, there was no clear increase in test positivity and that at least some of the increase in notifications for chlamydial infection is associated with an increase in testing over this period.

We found that the positivity rates for chlamydial infection in the ACT were higher in males than females (6.9% compared with 4.2%) with no statistically significant change in positivity over this period. This was comparable with findings from other Australian studies.^{96,97} Testing and notifications for chlamydial infection were consistently higher among females, however, the proportion of tests among men had increased over this period. The increase in testing performed in males over the period is particularly interesting in light of several initiatives that have sought to increase screening in a number of non-clinical settings. These have included testing being offered in a ‘community’ based setting around Canberra^{98,99} and trial programs that have used a small incentive payment.^{100,101} It is clear that understanding local testing patterns and targeted health-promotion campaigns is necessary to effectively interpret notification data. The study found that the majority of tests were performed in general practice and opportunistic screening in this setting will continue to be a central component of STI testing in the ACT.

The study found an apparent increase in notifications for gonococcal infection in 2011 that was not related to testing. We found that the majority of gonococcal infections in the ACT were diagnosed in males attending a sexual health clinic, this is consistent with the high numbers of infection among MSM in metropolitan areas of the eastern states of Australia.⁹³ There was a large increase in gonococcal testing among females which occurred in a general practice setting, this appears to be due to the use of dual testing for chlamydial and gonococcal infection, which is not recommended in the general population under the current guidelines.¹⁰² The prevalence of gonorrhoeal disease in females is believed to be extremely low, screening for a disease in groups with a low underlying prevalence could potentially result in a number of false-positive results as has been suggested by Chow et al.¹⁰³

This study involves data from two of the largest pathology providers in the ACT. Results from the remaining private pathology providers would present a more complete picture of

testing in the community but would be unlikely to change the findings dramatically. A limitation of this study was the absence of information on symptoms and sexual behaviours, as this is a major factor in testing and may provide more information in relation to the positivity by clinical setting. Patients attending sexual health clinics may have been more likely to seek care due to symptoms or the perceived risk of infection due to sexual behaviours or because they are sexual contacts of people with a diagnosed infection.

Testing data with a unique personal identifier from one of the pathology providers was requested, but was not available in time for inclusion in this study. This would have allowed us to better identify and de-duplicate patients with multiple tests and possibly assess whether patients with a positive result received a test of cure (recommended following gonococcal infection), or were retested at three months as recommended.¹⁰⁴ This would have also allowed us to identify patients that were tested in community screening programs that were conducted in the ACT over a number of years starting in 2007, in the current analysis these tests are included in testing data for the sexual health clinic.

The proportion of positive tests for chlamydial infection was highest in the target age groups, which supports the recommendations for annual screening for those aged 15–29 made in national guidelines. The low proportion of positive tests for gonococcal infection among females that were tested in a GP setting would indicate that testing for gonococcal infection should be reserved for at-risk groups with a higher prevalence of infection. The use of supplementary testing, using culture based methods, in low prevalence groups is recommended to ensure compliance with Public Health Laboratory Network guidelines.¹⁰² Further review of gonococcal infections by the ACT Communicable Disease Control Section may be may be required to ensure that this testing is conducted to confirm infection.

5.5.1 Recommendations

The following approach for STI surveillance is recommended:

- Testing data for the previous calendar year be requested from ACT Pathology, the public health laboratory in the ACT, on an annual basis, similar data is routinely collected in New South Wales and Western Australia;^{96,105}
- That ACT CDC ensure that gonococcal infections in low risk groups (such as women) have supplementary testing to confirm a diagnosis.

5.5.2 Conclusion

This study found that there was no clear increase in test positivity and that at least some of the increase in notifications for chlamydial infection is associated with an increase in testing over this period. Testing and notifications for chlamydial infection were consistently higher among females, however, the proportion of tests among men had increased over this period, which may reflect a number of community-based testing initiatives in the ACT.

The study found an apparent increase in notifications for gonococcal infection in 2011 that was not related to testing. We found that the majority of gonococcal infections in the ACT were diagnosed in males attending a sexual health clinic. However, there was a large increase in testing for gonococcal infection among females which occurred in a general practice setting, due to the use of dual testing for chlamydial and gonococcal infection, which warrants further investigation.

The study has also demonstrated that it is feasible to utilise pathology testing data to interpret trends in notification data. We would support attempts to obtain data on the number of tests performed in a more structured and continual basis in order to monitor ongoing trends and better understand notification-based surveillance data.

5.5.3 Role of the scholar and public health impact

The scholar extracted notification data for this period from the ACT Notifiable Disease Management System and cleaned and merged the datasets from the two pathology providers, before conducting statistical analysis using the software program STATA.

Findings from this study were presented at the Communicable Disease Conference 2015 in Brisbane (slides from the presentation are included at Appendix I).

This study demonstrated that it is feasible to utilise pathology testing data to better understand notification-based surveillance. While there has been a dramatic increase in notification rates for STIs, analysis of ACT data show that test positivity had been relatively stable.

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Trends in testing for chlamydial infection in the ACT, 2003 to 2012

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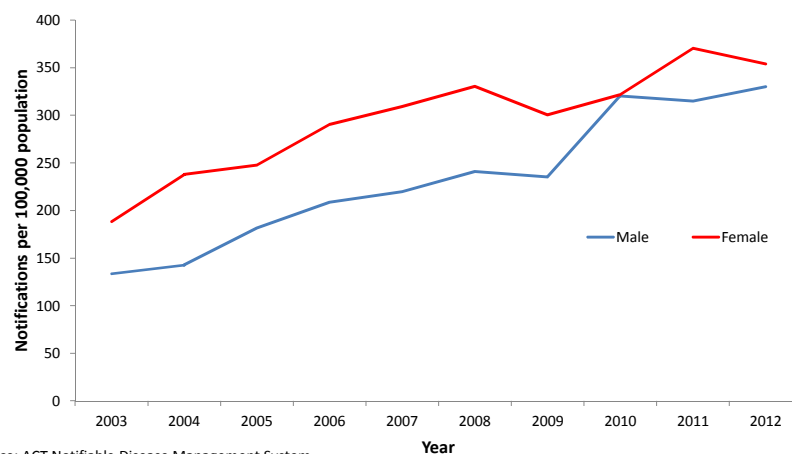
Chlamydia

- *Chlamydia trachomatis*
- Sexually transmitted bacterial infection
- Predominantly affects young, sexually active people
- Asymptomatic in 70% of females and 50% of males
- Frequent re-infection

Testing, prevention and control

- Increase use of condoms
 - Opportunistic testing recommended
 - Targeted groups (aged 15–29 years, Indigenous Australians and MSM)
 - Urine PCR - sensitive/specific
 - Contact tracing
 - Outreach events
 - Testing in non-clinical settings
-

Notification rate of Chlamydial infection, ACT, 2003–2012



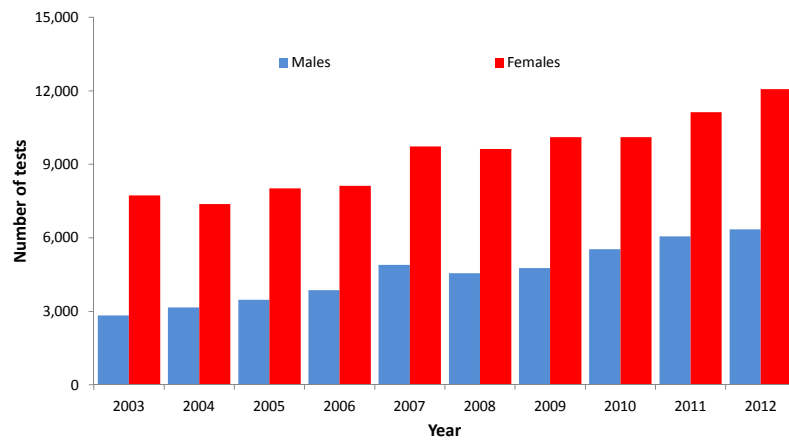
Objectives of the study

- To describe trends in pathology testing and test positivity for chlamydial infection in the ACT
 - To better understand notification-based surveillance data in the ACT
-

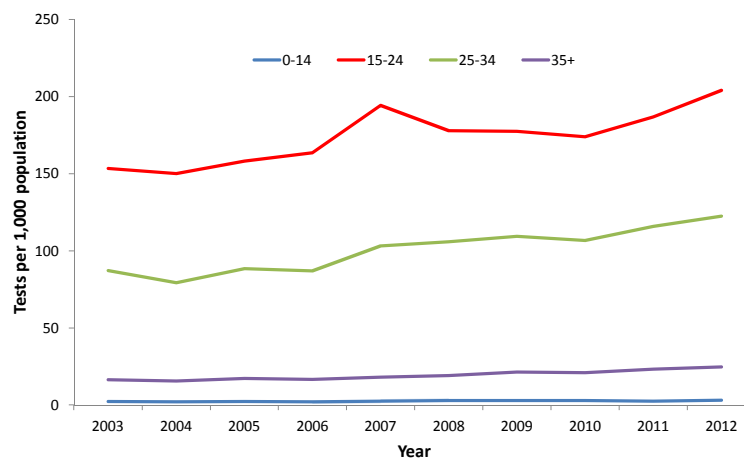
Summary of study

- Study period 1 January 2003 – 31 December 2012
 - ACT residents tested for chlamydial infection at participating laboratories (~77% of notifications)
 - De-identified data provided by pathology providers
 - Fields included: patient demographics, postcode, clinical setting, date of test, specimen type and test result
-

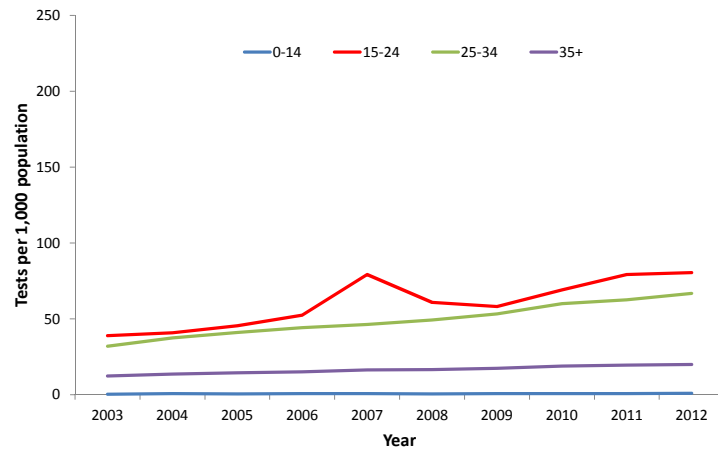
Number of tests for chlamydial infection, by sex, 2003–2012



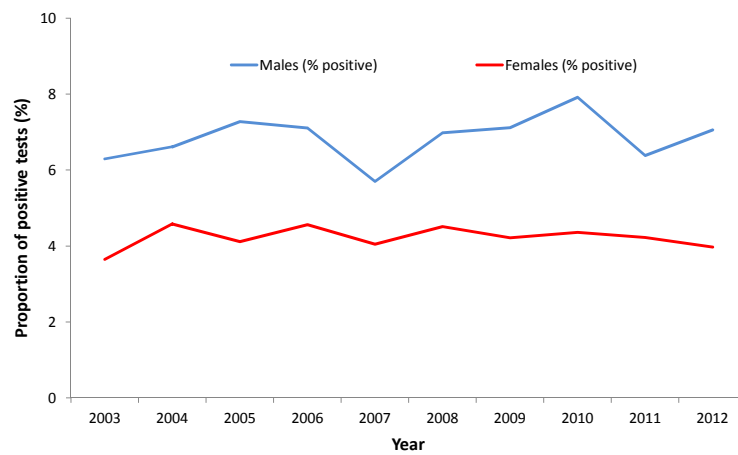
Estimated testing rate for chlamydial infection in females, by age group, 2003–2012



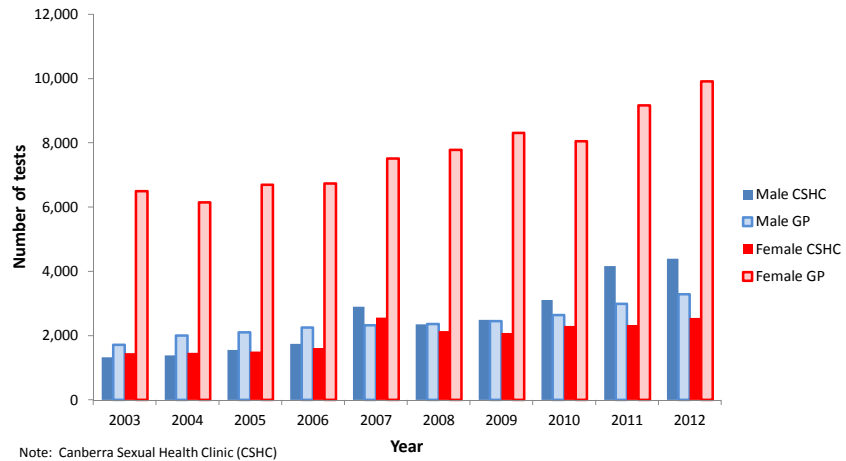
Estimated testing rate for chlamydial infection in males, by age group, 2003–2012



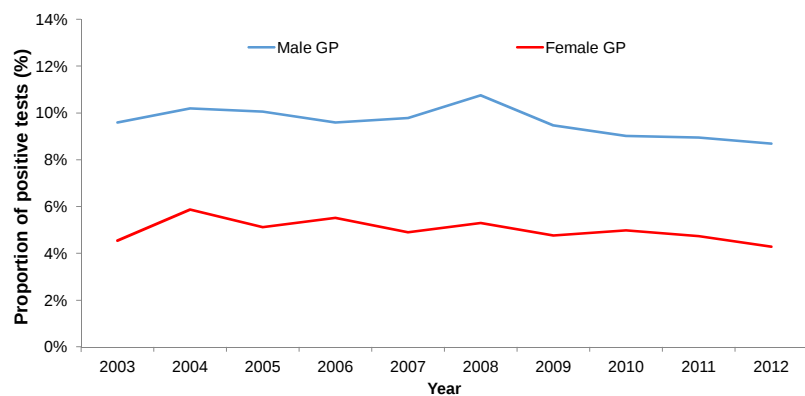
Test positivity for chlamydial infection, by sex, 2003–2012



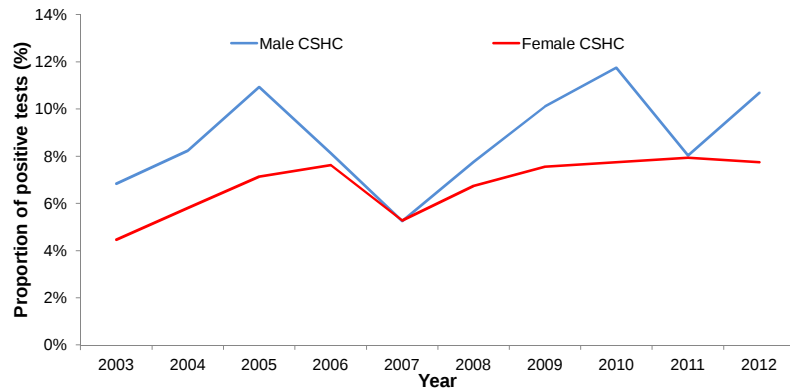
Number of tests, by sex and clinical setting, 2003–2012



Test positivity in target age group (15–29) in general practice setting, by sex, 2003–2012

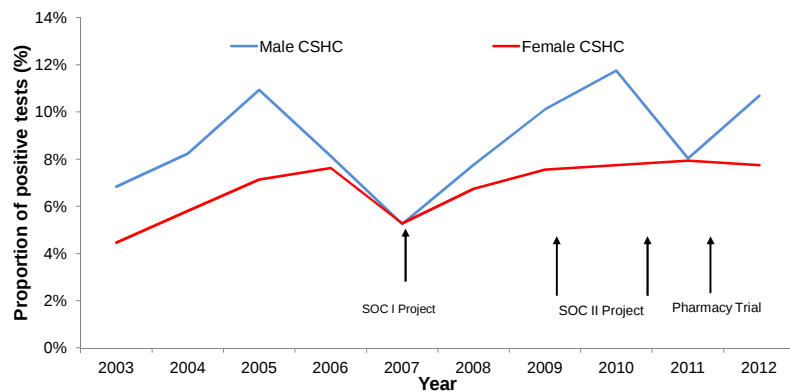


Test positivity in target age group (15–29) in sexual health setting, by sex, 2003–2012



Note: Canberra Sexual Health Clinic (CSHC)

Test positivity in target age group (15–29) in sexual health setting, by sex, 2003–2012



Note: Canberra Sexual Health Clinic (CSHC)

Summary of findings

- There has been a dramatic increase in the number of tests
 - Increased testing in the target age groups
 - Majority of testing occurs in General Practice
 - No clear increase in test positivity
 - Increase in notifications a testing artefact
-

Implications for surveillance data

- This study provides a descriptive analysis of laboratory testing for chlamydia
 - Increased understanding on the sources of notification data
 - Demonstrated the impact of targeted interventions: i.e. Screening / community testing
-

Acknowledgements

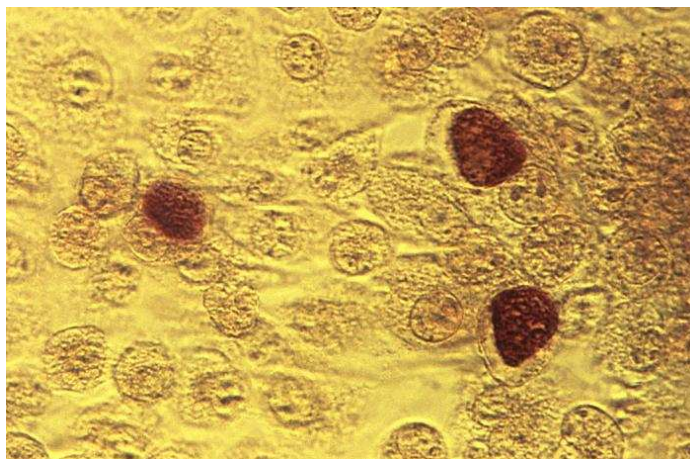
Supervisors:

Dr Emily Fearnley ANU

Rebecca Hundy ACT HPS

April Witteveen ACT HPS

Questions?



Source: US CDC Public Health Image Library (PHIL)

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- Department of Health. National Notifiable Diseases Surveillance System; 2015. <http://www9.health.gov.au/cda/source/cda-index.cfm> (Accessed May 2015)
- Davis B, Schmidt M, O'Keefe E, et al. Stamp Out Chlamydia Project - Brining Chlamydia Screening to Tertiary Students in the Australian Capital Territory. *Sexual Health* 2007;4(4):287.
- Currie M, Schmidt M, Davis B, et al. 'Show me the money' financial incentives increase chlamydia screening rates among tertiary students: a pilot study. *Sexual Health* 2010;7:60–5.
- Currie M, Deeks L, Cooper G, et al. Community pharmacy and cash reward: a winning combination for chlamydia screening? *Sex Trasm Infect* 2012:1–5.
- Bowden F, Currie M, Todkill M, et al. A pragmatic assessment of the relative efficiency of outreach chlamydia screening events conducted in non-clinical settings. *BMC Public Health* 2012;12:341–7.

**6 TEACHING SESSION OF FIRST YEAR STUDENTS / LESSONS FROM THE
FIELD**

6.1 Introduction

The Master of Applied Epidemiology program includes a coursework subject called Issues in Applied Epidemiology which includes teaching a cohort of first-year students and the inclusion of a peer-led teaching opportunity, called 'Lessons from the field', which draws on the experiences of scholars.

The following chapter demonstrates my ability to plan and develop a lesson plan and conduct teaching exercises of epidemiological concepts to my peers in a number of settings. The first section describes the teaching session prepared for a group for first year MAE students conducted in March 2015. The second section describes my Lesson from the field (LFF) on choosing the right statistical test which included a short tutorial using Stata conducted via teleconference in May 2015.

In a small group I assisted with the planning and implementation of a teaching session for first year MAE students, on the topic of the interpretation and application of p-values and 95% confidence intervals. I identified appropriate resources and prepared a section of a presentation delivered during course block. In order to be effective, teachers must develop a thorough knowledge of the subject matter and be prepared to explain a concept in a number of ways and answer a range of questions. It is also necessary to monitor students' progress (to ensure that everybody is at the same stage of the activity) and provide feedback throughout the session.

Later in the year, I developed an LFF on choosing the right statistical test, which included reviewing statistical text books and developing an exercise using the statistical software package Stata (StataCorp, Texas), to demonstrate the process for choosing an appropriate statistical test for continuous data. Preparing the exercise, using Stata, required a lot of work to identify the process and develop instructions in plain English. In running the session, I was mindful to ensure that everyone was progressing through the activity and had an equal opportunity to provide input while completing the exercise in the allotted time.

I have developed a greater appreciation of the amount of work involved in teaching. With both activities, a great deal of time was dedicated to developing appropriate learning objectives for the session; as it is vital to identify what we wanted the participants to get out of the session.

6.2 Teaching first-year MAE students

A competency of the MAE program includes a teaching session for first-year MAE students conducted during course block. We worked in a group of three and elected to prepare a session on the interpretation and application of p-values and 95% confidence intervals. This included formulating a lesson plan (described below), identifying a small group activity and preparing handouts. A summary of the content from this presentation is described below, slides from the session are attached at Appendix J, I presented slides 20–25 on confidence intervals.

6.2.1 Learning objectives for the session

Students should have the knowledge and skills necessary to:

- Recognise the impact of chance and bias;
- Identify the null hypothesis;
- Define and interpret p-values and confidence intervals; and
- Recognise the limitations of statistical significance.

6.2.2 Summary of lesson

A p-value is the probability that an observed difference has arisen by chance alone, by convention a p-value of $<5\%$ is considered statistically significant, this means that the difference would occur by chance alone only one in twenty times.

Confidence intervals are a range of values used to describe the uncertainty around an estimate. If you were to take repeated samples, the intervals would contain the true value 95% of the time. We tend to interpret this as meaning that the point estimate probably isn't exact, but we're confident that it is within this range.

In order to demonstrate what confidence intervals represent I used the average height of randomly selected people as an example using the whiteboard (see Figure 6.1 below):

- The normally distributed group had a mean height of 170 cm with SD 10 cm
- 68% of this population would range from 160–180cm (1 SD from the mean / ± 10 cm)
- 95% of this population would range from 150–190cm (1.96 SD from the mean / ± 20 cm)

I provided the following suggestions for ‘good practice’ in the interpretation of confidence intervals. It is often necessary to conduct a formal test of significance, if CI’s do not overlap then they will be statistically significant. However, depending on how they have been calculated, overlapping CI’s may be statistically significantly different.

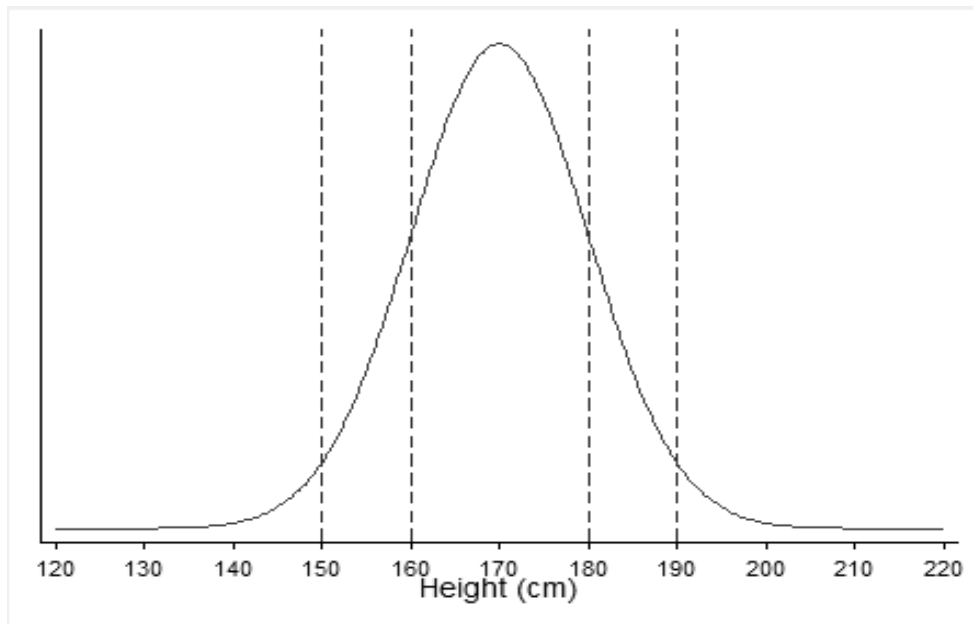


Figure 6.1: Normal curve showing mean height (cm)

6.3 Lessons from the field

‘Lessons from the field’ (LFF) draws on the experiences of scholars to provide a peer-to-peer teaching opportunity. Given my background in the application of statistical methods in public health surveillance and national statistical reporting, I was asked by the others in my cohort to develop and present a session on choosing an appropriate statistical test for a given dataset. I developed the session to address the learning objectives below. This included formulating a lesson plan, handouts and a training exercise using STATA statistical software.

6.3.1 Learning objectives for the session

After successfully completing the session, students will be able to:

- Test whether continuous variables are normally distributed
- Identify and select an appropriate statistical test
- Apply this knowledge using a statistical software package (Stata)
- Correctly interpret results

6.3.2 Summary of lesson

Selecting the correct test to use in each situation depends on the study design and the nature of the variables collected. I provided an article by Nayak and Hazra (2011)¹⁰⁶ that describes a ‘tool kit’ of a small number of tests that can be used to in the majority of studies. I also developed a decision matrix for choosing the right statistical test to help identify the most appropriate approach for a given dataset (Figure 6.2 below), this was provided in a handout that explained the matrix in more detail (attached at Appendix K).

Parametric tests make a number of assumptions about the distribution of the data and are appropriate when the outcome variable and exposure variable are independent of each other.¹⁰⁷ In some cases, when data are not normally distributed, the data can be transformed (usually using a logarithmic transformation) to make the distribution normal, allowing the use of a parametric test. Alternatively, non-parametric methods can be used when the dataset is non-normal or too small to determine the distribution, by assigning ranks to individuals the influence of outliers are reduced as information on the differences is lost.¹⁰⁷ This means that non-parametric tests require large differences in the data to show statistically significant differences between groups.

The LFF session was conducted via teleconference, I also prepared an exercise to introduce participants to the process of examining continuous variables and testing normality before applying a test statistic using the statistical software package Stata (the Participant Guide is attached at Appendix L).

Figure 6.2: Choosing the right statistical test matrix

			Exposure variable				Multiple exposure variables
			Categorical		Continuous		
			None	2 Groups	>2 Groups		
Outcome variable	Continuous	Independent	1-sample t-test	2-sample t-test ttest Mann Whitney U-test (Non-normal distribution) Ranksum	Analysis of variance (ANOVA) oneway Kruskal-Wallis test kwallis	Linear regression regress Correlation: Pearson's coefficient (r) corr Spearman's ρ (rho) spearman Kendall's τ (tau) ktau	Linear regression regress
		Related		Paired t-test ttest Wilcox signed rank test (Non-normal distribution) Signrank			
	Categorical	Independent		X^2 test chi2 Fisher's exact (Small cell <5) chi2, exact	X^2 test of trend chi2		Logistic regression logistic
		Related		Mc Nemar's test mcc			Conditional logistic regression clogit
	Count						Poisson regression poisson Negative binomial regression nbreg
	Time to event						Cox Proportional hazards regression stcox

6.4 Conclusions

This chapter demonstrates my ability to plan and develop a lesson plan and conduct teaching exercises of epidemiological concepts to my peers. In the course of preparing these sessions I developed a greater appreciation of the amount of work involved in preparing training sessions and the application of learning principles that goes into teaching. Preparing an exercise using Stata required a lot of work to identify the process and develop simple instructions for the exercise that could be completed in the allotted time.

6.5 References

106. Nayak BK, Hazra A. How to choose the right statistical test? Indian J Ophthalmol 2011; 59:85-6.
107. Kirkwood B, Sterne J. Essential Medical Statistics. Second ed. Melbourne: Blackwell Science; 2005.

Appendix J:

P-VALUES AND CONFIDENCE INTERVALS

Jocelyn Chan (NCIRS)

Jeff Stewart (SA)

Lucas Mills (ACT)

Learning Objectives

By the end of this session, students should have the knowledge and skills necessary to :

1. Recognise the impact of chance and bias;
2. Identify the null hypothesis;
3. Define and interpret p-values and confidence intervals; and
4. Recognise the limitations of statistical significance.

Lesson plan

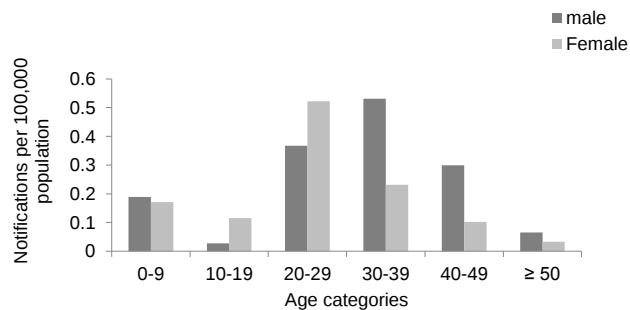
- * Three issues drawn from our field work around the application of p-values and confidence intervals
- * Discuss the theory around p-values, confidence intervals and their limitations
- * Practice applying these concepts in a group exercise

Rubella epidemiology in Australia

- * Background
 - * Mild illness in adults
 - * Illness in pregnant women - Congenital rubella syndrome
 - * Vaccine preventable – MMR
 - * 1971-1993 – schoolgirl vaccinations only
- * Aim
 - * To review rubella notifications in Australia 2008-2012

Rubella notification rates by age group and sex, Australia, 2008–2012

- * Is there a statistically significant difference between male and female notifications by age groups?



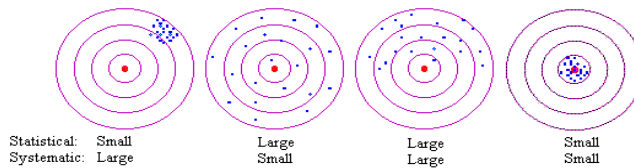
Tests of statistical significance



- * Inherent variation in most biological processes e.g. height, blood pressure, exposure to rubella virus
- * Study samples – used to make an inference about wider population
- * Results from any sample varies by chance (random error)
- * We use p-values and confidence intervals as a way of quantifying this uncertainty
- * Increase sample size → sample mean more likely to estimate population mean

Chance (random error) vs. bias (systematic error)

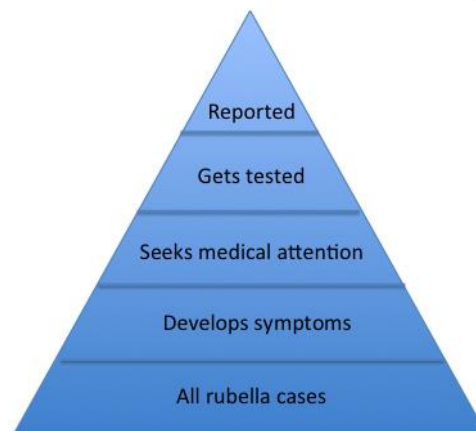
“An error in the conception and design of a study...leading to results or conclusions that are systematically different from truth”



Example: determining average height of Australians using group of parliamentarians

- Bias cannot be reduced by increasing sample size
- Valid inferences can only be drawn if the sample is representative of the population

Is it appropriate to apply statistical tests to notification data?



Rubella

- * Consideration before calculating statistical significance

Good practice...

- * **Always consider the effect of bias before applying a p-value or confidence interval**

First considerations:

- * Measurement /selection bias
- * Potential confounding
- * Study is adequately powered (sample size calculations)



p-values



Hypothesis testing

- * Null Hypothesis;

'that there is no difference between groups or no association between variables.'

Kirkwood, B and Sterne J, Essential Medical Statistics, 2nd Edition, 2013, Blackwell Publishing

- * A statistical test is used to decide whether there is sufficient evidence to reject the null hypothesis.

p-values

- * The probability of observing this result if the null hypothesis is true. The difference observed could have occurred by chance even if the groups were actually the same.
- * If the p-value is less than the pre-determined significance level (usually $p=0.05$) then we believe that the observed difference is not due to chance.
- * However, this means that there is a 1/20 possibility that the result is due to chance.

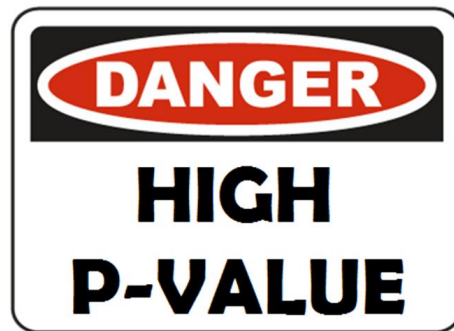
School Camp Outbreak

This cohort of school children consumed food over a five day period and we tested approximately 100 different foods or settings. How many of our significant results were due to chance?

Food	Exposed			Unexposed					
	Total	Ill	AR%	Total	Ill	AR%	RR	CI(95%)	p-value
Apple Juice Breakfast Day 2	11	8	73%	31	8	26%	2.8	1.4 – 5.7	0.01
Chicken Sandwich Lunch Day 2	11	7	64%	22	9	41%	2.2	1.1 – 4.6	0.05
Mashed Potato Dinner Day 2	20	11	55%	23	5	22%	2.5	1.1 – 6.0	0.03
Salad Lunch Day 3	4	4	100%	40	12	30%	3.3	2.1 – 5.4	0.01
Salad Dinner Day 3	11	7	64%	31	9	29%	2.2	1.1 – 4.5	0.05
Salad Lunch Day 4	3	3	100%	41	13	42%	3.2	2.0 – 4.9	0.04

How low should a p-value go?

- * The lower the p-value the stronger the evidence against the null hypothesis.



p-values

- * **Caution:** the larger the sample the more likely a difference will be considered significant.
- * Alternatively important differences observed in studies with a small sample should not always be ignored as non-significant based on a p-value >0.05 .
- * Need to consider the range of the confidence interval, plausibility, medical importance of the finding.
- * **Remember:** the p-value does not tell us anything about the size of our effect or its direction. It only tells us about evidence against the null hypothesis or whether our findings are due to chance.

Good practice...

- * **Always report the p-value**

Rather than just stating that a result is statistically significant.



P-values Quiz

Which of the following statements are true?

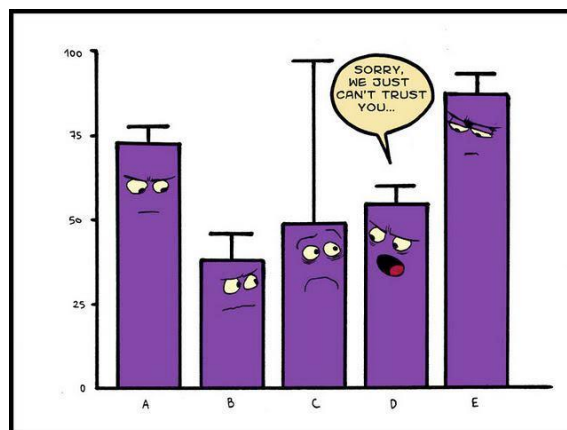
- a) The p-value provides a statement about the size of the difference between groups
- b) The p-value provides a statement about the direction of the difference between groups
- c) The p-value provides a test of significance of the statistical hypothesis

P-values Quiz

Which of the following statements are true?

- ~~a) The p-value provides a statement about the size of the difference between groups~~
- ~~b) The p-value provides a statement about the direction of the difference between groups~~
- c) The p-value provides a test of significance of the statistical hypothesis

95% Confidence Intervals



95% Confidence Intervals

- * Confidence intervals are a range of values used to describe the uncertainty around an estimate.
- * In reality the point estimate probably isn't right, but we're confident that it is in this range...
- * If the confidence interval bounds the value that indicates no difference we interpret it as not being significantly different

Birthday party outbreak

Cohort of attendees at a child's birthday party. We tested the significance of several food items as well as some other potential exposures.

Exposure	Exposed			Not exposed			RR	95% CI	p-value
	Ill	Not ill	AR (%)	Ill	Not ill	AR (%)			
Food consumed									
Water melon	11	2	84.6	5	5	50.0	1.69	0.87, 3.28	0.169
Grapes	6	1	85.7	10	6	62.5	1.37	0.84, 2.23	0.366
Chips	9	3	75.0	7	4	63.6	1.18	0.35, 2.05	0.667
Pretzels	5	1	83.3	11	6	64.7	1.29	0.78, 2.13	0.621
Lollies	5	1	83.3	11	6	64.7	1.29	0.78, 2.13	0.621
Wraps	9	5	64.3	7	2	77.8	0.83	0.49, 1.40	0.657
Dips	6	3	66.7	10	4	71.4	0.93	0.53, 1.65	1.000
Biscuits	1	1	50.0	15	6	71.4	0.70	0.17, 2.87	0.526
Carrot sticks	4	3	57.1	12	4	75.0	0.75	0.38, 1.54	0.626
Celery sticks	3	2	60.0	13	5	72.2	0.83	0.49, 1.40	0.621
Birthday cake	15	5	75.0	2	1	33.3	2.25	0.45, 11.37	0.209
Other exposure									
Contact with ill person	13	3	81.3	5	3	37.5	2.17	0.86, 5.46	0.065
Swam in pool	8	3	72.7	5	1	83.3	0.87	0.52, 1.45	1.000

Good practice...

- * Increase sample size to decrease the interval



95% Confidence Intervals

So what does the following statement mean?

“We are 95% certain that the true value is in this interval”

Remember:

- * Dependent on the sample you draw, you end up with one of a number of possible intervals.
- * If we were to take repeated samples, the different intervals would contain the parameter estimate 95% of the time.
- * The interval either covers the parameter estimate or does not, we can't be sure...

Confidence intervals Quiz

Which of the following statements are true?

- a) The 95% confidence interval represents the inaccuracy of the sample in estimating the population parameter
- b) If the sample size was increased the width of the 95% confidence interval would decrease
- c) A 99% confidence interval for the population would be narrower than the 95% confidence interval presented

Confidence intervals Quiz

Which of the following statements are true?

- a) The 95% confidence interval represents the inaccuracy of the sample in estimating the population parameter
- b) If the sample size was increased the width of the 95% confidence interval would decrease
- ~~c) A 99% confidence interval for the population would be narrower than the 95% confidence interval presented~~

Group work

- * Please read your groups paper and amongst the group consider the following questions to report back (15 min)
- * What is the research question? Use the PICO (population, intervention, comparison, outcome) format to describe the study.
- * What is the null hypothesis?
- * State and describe the statistical tests used in your study?
- * What factors would have influenced the statistical tests?

Take home messages

- * **Always consider the effect of bias before applying a p-value or confidence interval**
- * **Always report the p-value**
- * **Increase sample size to decrease the interval**
- * **P-values and confidence intervals require contextual explanation and should not be accepted on face value alone**



Appendix K:

Testing for normality

There are several ways of testing whether a continuous variable is normally distributed. Begin by plotting a histogram and comparing estimates of the centre of the data (mean and median).

Table 1: Summary of tests for normality

Examine histogram	Symmetrical and approximately bell shaped
Compare mean and median	Values approximately equal
Compute skewness (symmetry) and kurtosis (flat/peaked)	Values ± 1 indicate a bell shaped curve -1to-3 and +1to+3 indicate data are deviating from a bell shaped curve
Examine box plot	Symmetrical with no outliers

Methods for analysing normal data

Selecting the correct test to use in each situation depends on the study design and the nature of the variables collected.

One sample t-test is used to test the mean difference between the group and a known value. The t-value is the mean difference divided by the SE of the differences, the significance value can be obtained from a statistical table.

In health research, we often want to compare the mean value of a measurement between two groups in an observational study or between a control and intervention group in an experimental study. The **independent (2) sample t-test** is used to compare the mean values of two independent groups for which the outcome variable is normally distributed.

Assumptions for an independent samples t-test:

- two groups are independent
- the measures are independent
- the outcome variable is continuous and normally distributed
- sample size (>30)
- homogeneity of variance btw groups (similar SD in each group)

Paired t-test is used for paired observations of a continuous response variable and categorical explanatory variable. Suitable if the distribution of the differences is 'normal' and a sufficiently large sample size ($n > 30$).

Assumptions for a paired t-test:

- the outcome variable is continuous
- the difference between pairs are normally distributed
- sample size is large enough

Chi-square test (χ^2) is used to test the null hypothesis that two proportions are not different and is appropriate when both the explanatory and outcome variables are categorical.

Assumptions for a chi-square test:

- each observation must be independent
- each participant is represented in the table once only
- 80% of the expected cell counts should exceed a value of five
- all expected cell counts should exceed a value of one

*Pearson's used when sample is large or larger than 2×2 .
Fisher's exact test when a cell has < 5 expected cases.
Continuity correction for small samples ($< 1,000$).*

McNemar's test is used for paired categorical outcome variables and can be used to assess whether there is a significant change in proportions between two points.

Assumptions for a McNemar's test:

- used when observations are not independent
- the outcome variable is categorical

Correlation measures the strength of linear association between continuous variables. Gives a correlation coefficient (r) with a range of -1 to 1 (with 1 indicating a perfect correlation and 0 indicating no association, negative values indicate an inverse association).

Assumptions for Pearson's correlation:

- observations are independent
- both variables are normally distributed
- random sample from the general population
- relationship between the variables is linear

Pearson's coefficient (r) both variables are normally dist.

Spearman's ρ (ρ) one variable is normally dist. and the other is categorical or non-normal.

Kendall's (τ) Both variables are categorical or non-normal

Linear regression describes the relationship between two variables. Used to build a predictive model or to test whether there is a significant linear relationship between one or more variables and an outcome variable. . Interpret the result as the unit of change in the outcome variable with each unit change in the explanatory variable.

Assumptions for a linear regression:

- observations are independent
 - relationship between the variables is linear
 - relationship between variables is constant
 - residuals are normally distributed
- If the slope $\neq 0$ there is a linear association between variables.
Result not representative if sample was not from the general population or there was low response

The linear equation describes the intercept and the slope.

$$y = a + bx$$

outcome variable=intercept + slope explanatory variable

Predict the outcome for a given value using SPSS

outcome =constant+(exp variable $\times$ value)

R value (equivalent to Pearson's coefficient).

R Square indicates the variation in the outcome explained by the explanatory variable.

Methods for analysing non-normal data

In some cases when data are not normally distributed the data can be transformed (usually using a logarithmic transformation) to make the distribution normal, allowing the use of a parametric test.

Non-parametric methods can be used when the dataset is non-normal or too small to determine the distribution. By assigning ranks to individuals the influence of outliers are reduced as information on the differences is lost. This means that non-parametric test require large differences in the data to show statistical significance between groups.

Mann Whitney U-test is a non-parametric independent samples test that provides p-value that indicates the difference between groups. This test statistic could be provided alongside a non-parametric summary statistic of central tendency such a median length of stay.

Wilcoxon signed rank test is appropriate when the differences between paired measurements is non-normally distributed or the sample size is too small (<30). Absolute differences between the paired scores are ranked and the difference scores that are equal to zero (no difference) are excluded.

Regression analysis

Other methods were explained at the Data Analysis of Public Health course block

Figure 1: Choosing the right statistical test matrix

			Exposure variable				Multiple exposure variables
			Categorical			Continuous	
			None	2 Groups	>2 Groups		
Outcome variable	Continuous	Independent	1-sample t-test	2-sample t-test ttest Mann Whitney U-test (Non-normal distribution) Ranksum	Analysis of variance (ANOVA) oneway Kruskal-Wallis test kwallis	Linear regression regress Correlation: Pearson's coefficient (r) corr Spearman's ρ (rho) spearman Kendall's τ (tau) ktau	Linear regression regress
		Related		Paired t-test ttest Wilcox signed rank test (Non-normal distribution) Signrank			
	Categorical	Independent		χ^2 test chi2 Fisher's exact (Small cell <5) chi2 , exact	χ^2 test of trend chi2		Logistic regression logistic
		Related		Mc Nemar's test mcc			Conditional logistic regression clogit
	Count						Poisson regression poisson
							Negative binomial regression nbreg
	Time to event						Cox Proportional hazards regression stcox

Lessons from the field: Choosing the right statistical test

Participant guide

Learning objectives:

After successfully completing this session, students will be able to:

- Test whether continuous variables are normally distributed
- Identify and select an appropriate statistical test
- Apply this knowledge using a statistical software package (Stata)
- Correctly interpret results

1. Introduction

This exercise aims to introduce you to the process of examining continuous variables and testing normality before applying the right statistic using Stata. The layout of the Participant guide should be familiar as it is 'borrowed' from the sessions at the data analysis course block ;)

1.1. Basic terminology

- **Syntax:** The grammatical rules that you need to follow so that a computer program understands what you want it to do
- **Command:** You tell Stata to do something by using a command. A command is a combination of syntax elements, expressed following the rules of 'Stata language'

1.2. Conventions used in this document

The following conventions are used in this document:

1. Explanations and instructions are in Arial font
2. Stata syntax is in Courier New font (`this font is Courier New`).
3. Text within the Stata command that you will replace is in italics (*Italic*)
4. Screen shots in this guide are taken from Stata version 13

2. Getting started

2.1. The scenario

Students in an introductory statistics class participated in a simple experiment. The students took their own pulse. They were then asked to flip a coin. If the coin came up heads, they were to run in place for one minute. Otherwise they sat for one minute. Then everyone took their pulse again. The pulse rates and other physiological and lifestyle data are given in the data. Five class groups between 1993 and 1998 participated in the experiment.

Source: The dataset was prepared by Dr Richard Wilson at The University of Queensland.

<http://www.statsci.org/data/oz/ms212.html> (last accessed May 2015).

Table 1: Data Dictionary for wedding reception outbreak

Data item	Description	Format	Example
Height	Height (cm)	Number	XXX
Weight	Weight (kg)	Number	XX
Age	Age (years)	Number	XX
Gender	Sex	Number	1=Male, 0=Female
Smoker	Regular smoker	Number	1=Yes, 0=No
Alcohol	Regular drinker?	Number	1=Yes, 0=No
Exercise	Frequency of exercise	Number	1 = high, 2 = moderate, 3 = low
Ran	Whether the student ran or sat between the first and second pulse measurements	Number	1=ran, 0=sat
pulse1	First pulse measurement (rate per minute)	Number	XXX
pulse2	Second pulse measurement (rate per minute)	Number	XXX
Year	Year of class (93 - 98)	Number	XX

2.2. Set up a Do file

We are all diligent coders, so I shouldn't need to remind you to use a **.do file**.

It is a good idea to add comments to remind yourself why you used each command.

Type ***** (shift + 8, e.g. `*This is a comment`)

We are going to start our do file.

- Open a new do file using the icon in the command bar
- Type the following into your do file:
 - Write an introduction to your do file (e.g. `*This do file was created by (your name) on (date) for Lessons from the field - remember to put asterisk in front so that Stata does not read this as a command`)
 - `clear` (this clears any previous data and allows you to enter a new data set)
 - `set more off` (turns off page break)

2.3. Set up a directory

A useful way to keep all our work together is to keep it in one file (folder).

You can tell Stata which directory you want it to use (including saving your log and do files) by using the change directory command (`cd`) .

- Set your directory as follows: `cd "pathname"`
- An example of file path is: `C:\MAE\LFF4\`

If you wanted Stata to open data from this directory you'd have to type (into your do file):

- `use "C:\MAE\LFF4\LFFdata.dta"`

2.4. Open a log file

It is also good practice to start a log file when you begin working in Stata.

To set up a log file follow these steps:

- Type `log using LFF, replace.` (This will open a new log file and call it LFF, it will also replace any previous log files with the same name)

2.5. Open the data

Now we are going to open a file saved in the Stata format. If the dataset has been saved in the directory used above you can type the following command:

- `use LFF_Dataset`

Otherwise use the drop down menus to open the dataset.

2.6. Variable types and exploring the data

To help things run more smoothly I have saved you the hassle of formatting the data and applying labels, however, it is still useful to look at the data.

Activity 1: Type `summarize` into the command bar. How many variable are there? Can you tell which variables are categorical or continuous based on the output?

2.7. Testing normality

We can use a number of Stata commands to look at the distribution of continuous variables.

Activity 2: Type `histogram height, normal` into the command bar. What does this show?

Activity 3: Type `summarize height, detail` into the command bar. What does this show? What are common measures used to tell whether your data is normally distributed?

The Shapiro-Wilk test is a formal test of whether the variable is normally distributed, however these should be used with caution as small departures from normality can become statistically significant when using large datasets.

Variables like height or weight may vary by sex, we will add the `bysort` function to test the sexes separately.

Type `bysort gender: swilk height` into the do file and run.

Figure 1: Stata output for Shapiro-Wilk test for normal data

```
bysort gender: swilk height
-----
-> gender = Female  Shapiro-Wilk W test for normal data
Variable | Obs      W      V      z      Prob>z
-----+-----
height | 50    0.96447    1.671    1.095    0.13678
-----+-----
-> gender = Male    Shapiro-Wilk W test for normal data
Variable | Obs      W      V      z      Prob>z
-----+-----
height | 59    0.97112    1.549    0.942    0.17298
-----+-----
```

The output from the Shapiro-Wilks test provides a p-value of <0.05 if your data is not normally distributed.

Activity 4: Now you know a few approaches for testing normality, complete the table for following the continuous variables.

Variable	Is the data normally distributed
Height by sex	
Weight by sex	
Pulse1 by sex	
Pulse2 by sex and 'ran' status	

2.8. Data transformations

Some analyses require the dependent variable to have a normal distribution and may require a transformation. A logarithmic transformation is the most common, and you can generate a new variable by entering the following.

Type `generate lnweight=ln(weight)` into the do file and run.

Now is the data normally distributed?

3. Inferential statistics

Now that we are able to test whether continuous outcome variable is normally distributed we can consider applying a statistical test. The group of *t*-test commands in Stata allows you to compare the means of normally distributed continuous variables between two groups or to make a paired comparison of the same variable at two time points.

3.1. One sample t-test

We will start with a one sample t -test comparing the mean height of participants against a known population value or reference. We will use the measured height from the 1995 National Nutritional Survey conducted by the Australian Bureau of Statistics.

The mean height of males aged 18 and over was 174.9 cm and the mean height of females aged 18 and over was 161.4 cm.

Type the following into the do file and run:

```
ttest height==174.9 if gender==1
ttest height==161.4 if gender==0
```

Figure 2: Stata output for one sample t-test

```
ttest height==174.9 if gender==1
One-sample t test
```

Variable	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf. Interval]	
height	59	179.4068	.9742802	7.483588	177.4565	181.357

```
-----+-----
      mean = mean(height)                                t =      4.6258
Ho: mean = 174.9                                         degrees of freedom =      58
   Ha: mean < 174.9                Ha: mean != 174.9                Ha: mean > 174.9
Pr(T < t) = 1.0000                Pr(|T| > |t|) = 0.0000                Pr(T > t) = 0.0000
```

Activity 5: Assume we were interested in seeing whether our male study participants were significantly taller than the Australian population mean (174.9cm). Write down how you would express this as a null hypothesis. Which result from the t-test in Figure 2 above would be most appropriate?

3.2. Two sample t-test

In medical research, we may want to compare the mean value of a measurement between two groups in a study, the two sample t -test is used to compare the mean values (continuous data) of two independent groups for which the outcome variable is normally distributed.

With this dataset we will now see whether 1 minute of exercise was able to temporarily increase the heart rate of study subjects using only one set of measurements.

Type `ttest pulse2, by(ran)` into the do file and run

The output (Figure 3) shows that the difference in heart rate between those that ran was 52.7 bpm higher than in those that sat (95% CI: 45.8–59.6). The output is a little confusing as the difference has been calculated as the mean heart rate in those that sat - the mean heart rate in those that ran. So the middle p -value ($p < 0.0001$) is the result of a two-sided test (testing for a difference in either direction), the left p -value ($p < 0.0001$) is the result of one-sided test (testing whether the difference is less than zero), and this is the result we are interested in.

Figure 3: Stata output for two sample t-test

```
ttest pulse2, by(ran)
Two-sample t test with equal variances
```

Group	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf. Interval]	
Sat	62	74.12903	1.176512	9.263862	71.77645	76.48161
Ran	46	126.8478	3.707541	25.14577	119.3805	134.3152
combined	108	96.58333	3.044072	31.63493	90.54881	102.6179
diff		-52.71879	3.469186		-59.59679	-45.84079

```
diff = mean(Sat) - mean(Ran)
Ho: diff = 0
Ha: diff < 0
Pr(T < t) = 0.0000
t = -15.1963
degrees of freedom = 106
Ha: diff != 0
Pr(|T| > |t|) = 0.0000
Ha: diff > 0
Pr(T > t) = 1.0000
```

Underlying assumptions for the two sample *t*-test require that the outcome variable is normally distributed and that the variance between the two groups are normally distributed. We use the `sdtest` to test whether standard deviations can be considered equal.

Type `sdtest pulse2, by(ran)` into the do file and run

The output from the variance ratio test provides a *p*-value of <0.05 if the standard deviations are unequal. We are interested in the middle *p*-value that shows the two-sided test (*p*<0.001). This suggests that the standard deviations are not equal and we can't use an ordinary two-sample *t*-test. For a two-sample *t*-test with unequal variances we need to modify our command by adding `unequal` after the comma.

Type `ttest pulse2, unequal by(ran)` into the do file and run

In this instance the result is still statistically significant, although it has given wider confidence intervals.

Figure 4: Stata output for variation ratio test

```
ttest pulse2, by(ran)
Variance ratio test
```

Group	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf. Interval]	
Sat	62	74.12903	1.176512	9.263862	71.77645	76.48161
Ran	46	126.8478	3.707541	25.14577	119.3805	134.3152
combined	108	96.58333	3.044072	31.63493	90.54881	102.6179

```
ratio = sd(Sat) / sd(Ran)
Ho: ratio = 1
Ha: ratio < 1
Pr(F < f) = 0.0000
f = 0.1357
degrees of freedom = 61, 45
Ha: ratio != 1
2*Pr(F < f) = 0.0000
Ha: ratio > 1
Pr(F > f) = 1.0000
```

3.3. Paired t-test

We will now see whether 1 minute of exercise was able to temporarily increase the heart rate of study subjects using a paired set of measurements in the subjects that ran.

Type `ttest pulse2==pulse1 if ran==1` into the do file and run

Figure 4: Stata output for paired t-test

```
ttest pulse2==pulse1 if ran==1
```

Paired t test

Variable	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf. Interval]	
pulse2	46	126.8478	3.707541	25.14577	119.3805	134.3152
pulse1	46	75.45652	2.275623	15.43403	70.87318	80.03986
diff	46	51.3913	3.109511	21.08973	45.12843	57.65418

mean(diff) = mean(pulse2 - pulse1) t = 16.5271
Ho: mean(diff) = 0 degrees of freedom = 45

Ha: mean(diff) < 0 Ha: mean(diff) != 0 Ha: mean(diff) > 0
Pr(T < t) = 1.0000 Pr(|T| > |t|) = 0.0000 Pr(T > t) = 0.0000

The paired t-test estimated a mean difference of 51.4 bpm (95% CI: 45.1–57.7). This difference was statistically significant ($p < 0.001$). We could have phrased the question differently...

Type the following into the do file and run:

```
generate diff=pulse1-pulse2  
ttest diff==0 if ran==1
```

This calculates the mean difference in heart rate before and after the exercise activity. Note that the result is the same as the paired t-test.

3.4. Two-sample t-test

Using the paired t-test I was unable to measure the difference in the effect of exercise on the two groups. However, the following is a work around that provides an equivalent test, it allows us to measure the effect of the intervention on the mean difference between paired measurements (before and after).

Type `ttest diff, by(ran)` **into the do file and run**

Figure 4: Stata output for two-sample t-test

The two-sample t-test estimated a slightly higher mean difference of 52.4 bpm (95% CI: 47.0–57.8) than the paired t-test.

```
ttest diff, by(ran)
```

Two-sample t test with equal variances

Group	Obs	Mean	Std. Err.	Std. Dev.	[95% Conf. Interval]	
Sat	62	1.032258	.5011714	3.946228	.0301039	2.034412
Ran	46	-51.3913	3.109511	21.08973	-57.65418	-45.12843
combined	108	-21.2963	2.84506	29.56673	-26.9363	-15.6563
diff		52.42356	2.736721		46.99775	57.84938

diff = mean(Sat) - mean(Ran) t = 19.1556
Ho: diff = 0 degrees of freedom = 106

Ha: diff < 0 Ha: diff != 0 Ha: diff > 0
Pr(T < t) = 1.0000 Pr(|T| > |t|) = 0.0000 Pr(T > t) = 0.0000

Conclusion

In this brief session we have used Stata to test whether continuous variables are normally distributed, then we have selected an appropriate statistical test for the dataset and used the output to correctly interpret results.

Useful Stata resources

- Juul and Frydenberg *An introduction to Stata for Health Researchers 4th Edition* StataCorp: Texas; 2014.
- UCLA web site: www.ats.ucla.edu/stat/stata