APPLIED EPIDEMIOLOGY OF COMMUNICABLE DISEASES IN THE AUSTRALIAN CAPITAL TERRITORY

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

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Originality statement

I hereby declare that this submission is my own work and to the best of my knowledge, does not contain materials previously published or written by another person, or substantial proportions of material accepted for the award of any other course of study at the Australian National University or another educational institution, except where due acknowledgement is made. Any contribution to this research made by others is acknowledged in the thesis. The intellectual content of this thesis is the product of my own work, except where the assistance of others in the project's design, conception, style, presentation, or wording is acknowledged.

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I acknowledge and pay my respects to the Ngunnawal people, the Traditional Custodians of the lands of the Australian Capital Territory and acknowledge any other families or people with an ongoing connection to these lands. I recognise and respect their continuing culture and contribution to this region.

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Yes, we can get a puppy now!

Thesis abstract

This thesis was developed as a requirement for the Master of Philosophy in Applied Epidemiology (MAE). It presents four projects and additional public health experience undertaken during my placement within the Communicable Disease Control Section at the Australian Capital Territory (ACT) Health Directorate, between February 2022 and December 2023.

The first chapter describes my MAE experience and field placement and outlines the activities I undertook to meet the MAE competencies. The second chapter presents an analysis of notifications data for sexually transmissible infections and blood borne viruses in the ACT between 2013 and 2022 and considers the impact of the COVID-19 pandemic on notification rates. The third chapter details the investigation of an outbreak of salmonellosis associated with the consumption of food from a Canberra kebab shop and discusses the likely mechanism of the outbreak. The fourth chapter presents an evaluation of the ACT Adverse Events Following Immunisation Reporting System following changes to the system in 2021 to accommodate COVID-19 vaccination. The fifth chapter reports a study into the epidemiology of gonococcal infections and reinfections in the ACT between 2017 and 2022 and case-case analysis investigating the risk factors for gonococcal reinfections. The final chapter details my teaching experience in field epidemiology.

The projects and experiences detailed in this thesis demonstrate my completion of the competency requirements of the MAE program and contribute to the overall body of knowledge in field epidemiology.

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CHAPTER ONE: MAE EXPERIENCE

Chapter 1: MAE experience

Field placement background

I undertook my 22-month field placement in the Communicable Disease Control (CDC) Section of the Health Protection Service, Australian Capital Territory (ACT) Health Directorate (ACT Health). During my placement, the CDC was comprised of three units: Disease Surveillance, Immunisation, and Infection Control. The Disease Surveillance Unit, within which I was based, worked to reduce the occurrence of communicable diseases in the ACT through the implementation of disease control measures. This included through:

- managing the ACT notifiable disease management system
- collecting and recording disease notifications
- investigating and following up notifications to identify cases
- implementing control measures to prevent disease spread
- investigating and managing disease outbreaks
- developing disease prevention and control strategies.

The Disease Surveillance Unit was staffed by a director, a surveillance officer, epidemiologists (including a dedicated OzFoodNet epidemiologist), public health nurses, and MAE scholars. For most of my placement, the Disease Surveillance Unit was responsible for all notifiable conditions in the ACT, besides COVID-19.

MAE scholars were required to participate in the core work of the Disease Surveillance Unit. This included:

- undertaking follow-up of notifications for notifiable conditions
- undertaking follow-up and reporting for institutional outbreaks (e.g., gastroenteritis and acute respiratory illnesses)
- database entry of notifications data
- attending team meetings and participating in a rotating roster for minute-taking and chairing
- the development and review of documents such as fact sheets, standard operating procedures, and communication materials
- undertaking other work as required.

Summary of field placement experience

Between 2022 and 2023, I was involved in the core work of my field placement including:

- conducting interviews with clinicians, cases, and contacts relating to notifiable conditions such as salmonellosis, yersiniosis, typhoid, hepatitis A, shigellosis, gonococcal infection, cryptosporidiosis, and dengue
- drafting guidance on the ACT public health response to any future cases of invasive Group A Streptococcal disease, including a fact sheet for the general public
- drafting web content for childcare centres and residential aged care facilities on preventing and managing outbreaks of gastroenteritis and acute respiratory infection
- assisting with review of the CDC standard operating procedure for suspicious substances
- participating in acute response team (ART) meetings for acute public health incidents
- participating in Disease Surveillance team meetings
- participating in broader section, branch, and division meetings
- providing comment on external documents, such as for the Communicable Diseases Network Australia.

During my placement, I contributed to the public health investigation and response for a range of notifiable conditions. In February 2023, the first confirmed measles case was notified in the ACT since 2019, in a person who had recently travelled to Indonesia. Just weeks earlier, CDC staff had participated in a desktop simulation exercise, including role playing measles case and contact interviews, to strengthen capacity to respond to measles cases. Having participated in the exercise, I was well-prepared to assist with the investigation and response regarding the actual measles case. I attended ART meetings, assisted with contact tracing, and entered contact data into the relevant ACT Health databases.

Throughout my placement, I was provided with opportunities to participate in activities relating to foodborne disease surveillance and outbreak response through OzFoodNet. These included attending routine OzFoodNet videoconferences and multi-jurisdictional outbreak investigation meetings, entering data into the OzFoodNet outbreak register, and drafting the fortnightly OzFoodNet cluster report. During my first year, I assisted with two outbreaks of *Salmonella* associated with different food venues. During my second year, I participated in the ACT Health responses to multi-jurisdictional public health incidents involving contamination of baby spinach with *Datura stramonium* (Jimsonweed) and baby cucumbers with *Salmonella* Typhimurium. For these incidents, I conducted case interviews with ACT residents suspected of having been affected, developed and applied outbreak case definitions,

and participated in ART meetings. At the conclusion of each outbreak, I developed an epidemiological summary. For outbreaks involving *Salmonella*, I assisted with following up serotyping and whole genome sequencing results to determine whether case definitions were met.

I participated in both regular and ad hoc ACT Health education and professional development activities. These included a weekly journal club facilitated by CDC medical officers and desktop training exercises for Japanese encephalitis virus, Ebola, measles, and a range of other health conditions. I also regularly attend the Canberra Hospital and Health Services weekly Grand Rounds, monthly Upskill sessions (covering diverse topics relating to data management, analysis, and presentation), and the New South Wales Health Bug Breakfast presentations.

Laboratory visit

As a requirement of the MAE program, scholars visit a public health laboratory shortly after commencing their field placement. With a group of five MAE scholars, I visited the ACT Government Analytical Laboratory (ACTGAL) on 29 March 2022, and ACT Pathology laboratory on 1 April 2022. The ACTGAL is a multi-disciplinary scientific testing laboratory which provides analytical support for forensic and Coronial investigations, food and water microbiological analyses, and to support various regulatory activities. We visited the microbiology laboratory which conducts a range of tests, primarily relating to food and water quality including:

- recreational water quality testing
- food surveillance activities
- targeted surveys into food microbiology (e.g., sushi, salad, pulled meat, kebabs) guided by the findings of broader surveillance.

In contrast, ACT Pathology provides specialist pathology services for adult and paediatric patients in Canberra's hospitals and the community. Tests are performed either onsite at the Canberra Hospital or sent to partner laboratories in other jurisdictions. ACT Pathology also has dedicated facilities for microbiological analyses. At both laboratories, visiting MAE scholars learned about the tests undertaken and techniques used. These included general microbiological investigations (e.g., microscopy, culture, and susceptibility testing), molecular diagnostics (e.g., nucleic acid amplification), mass spectrometry (e.g., using a matrix-assisted laser desorption ionization-time of flight device), serology, and various techniques in food and water testing.

Summary of MAE course requirements

A summary indicating the chapters of this thesis which demonstrate completion of each MAE course requirement, is given below (Table 1).

Table 1: Summary of MAE course requirements

Course requirement		Chapter					
		1	2	3	4	5	6
Major competencies	Analysis of a public health dataset		✓			✓	
	Investigation of an acute public health problem or threat			✓			
	Establish or evaluate a surveillance system or other health information system				✓		
	Design and conduct an epidemiological study					✓	
Minor competencies	Teaching field epidemiology						✓
	Literature review					✓	
	Lay summary	✓					
	Conference presentation			✓	✓		
	Peer-reviewed publication			✓		✓	

Analysis of a public health dataset

My completion of the competency relating to the analysis of public health data is demonstrated in Chapter 2: Epidemiology of sexually transmissible infections (STI) and blood borne viruses (BBV) in the ACT, 2013-2022 and Chapter 5: Gonococcal infections in the ACT and risk factors for reinfection, 2017-2022. For Chapter 2, I descriptively analysed notifications data for STI and BBV in the ACT over a ten-year period, by demographic characteristics. The study found STI notification rates increased, particularly for gonococcal infections, and identified key groups which should be prioritised for future research and public health actions. Notification rates for BBV reduced steadily throughout the study period, indicating progress towards eliminating their transmission. The study detailed in Chapter 5, which focussed on gonococcal reinfections, demonstrates the use of more complex statistical methods, including hypothesis testing, to analyse public health data to answer a specific study question.

Investigation of an acute public health problem or threat

As detailed in Chapter 3: Investigation of an outbreak of *Salmonella* Agona at a kebab shop in Canberra, ACT, I investigated an outbreak of *Salmonella* associated with consumption of food from a doner kebab shop. In total, 12 outbreak cases were identified. At the conclusion of the outbreak, I performed descriptive analysis of case data and drafted an outbreak report. The findings of epidemiological, environmental and laboratory investigations suggested the likely outbreak mechanism was repeated contamination of rotisserie meat from inadequately cleaned meat shaving equipment. The findings of this outbreak investigation contributed to the development of a food sampling strategy in the ACT, specifically targeting kebab shops.

Establish or evaluate a surveillance system or other health information system

My completion of the competency relating to evaluating a surveillance system is demonstrated in Chapter 4: Evaluation of the ACT Adverse Events Following Immunisation (AEFI) Reporting System. AEFI represent an important public health problem as public confidence in vaccination programs relies on the appropriate surveillance and management of AEFI. I used the Centers for Disease Control *Updated Guidelines for Evaluating Public Health Surveillance Systems* to guide my evaluation. I obtained data by reviewing documents relating to the System, extracting data from the System, reviewing reports generated using data from the System, observing the operation of System components, and interviewing key stakeholders. The recommendations stemming from my evaluation sought to improve the way AEFI surveillance is conducted in the ACT.

Design and conduct an epidemiological study

Chapter 5: Gonococcal infections in the ACT and risk factors for reinfection, 2017-2022, presents an epidemiological study into a public health issue of importance in the ACT. The study quantified the contribution of gonococcal reinfections to overall gonococcal notifications. Through case-case analysis, the epidemiological characteristics of individuals with a single infection were compared with those with at least one reinfection. The study found reinfections accounted for approximately 20% of gonococcal infection notifications in the ACT across the study period, with the proportion of notifications represented by reinfections increasing over time. Multivariate analysis of case-case data found those with a reinfection had greater odds of having a same sex sexual exposure, being diagnosed at a sexual health/family planning clinic, and having used human immunodeficiency virus pre-exposure prophylaxis. Novel interventions aimed at reducing gonococcal reinfections should be targeted towards these groups.

Teaching field epidemiology

My experiences developing and delivering teaching sessions in field epidemiology are outlined in Chapter 6: Teaching experience. I prepared and presented a 'lessons from the field' (LFF) activity based on a hypothetical 'white powder incident'. I also performed the role of LFF Coordinator for my group and participated in LFF sessions delivered by the other group members. Alongside another scholar from my cohort, I updated and delivered a 15-minute presentation on descriptive analysis of surveillance data and one-hour practical Excel teaching session, to first year MAE scholars.

Literature review

As a component of the epidemiological study detailed in Chapter 5, I undertook a targeted literature search into recent evidence regarding the risk factors for gonococcal reinfections. I synthesised relevant information into a summary of findings, which informed the introduction and discussion sections of the chapter. The research question, search strategy and summary of findings are outlined in Chapter 5.

Lay summary

During the winter of 2022, I drafted content for the ACT Health website (Appendix A) to inform childcare centres about how to prevent infections (both gastroenteritis and acute respiratory infections) and remind them of the requirements for reporting gastroenteritis outbreaks. I also drafted similar content for residential aged care facilities. The content for both webpages was written in plain language, for a general public audience.

At the time this work was undertaken, the ACT Health website material relating to COVID-19 was being integrated with that for other respiratory pathogens, such as influenza and respiratory syncytial virus. The new website content sought to link existing advice for childcare centres and residential aged care facilities regarding COVID-19, with that for other respiratory illnesses. I sought input from the Infection Control Unit and ACT Health medical officers and used their input to inform the final versions.

After publication of the website content, I developed a letter addressed to childcare centre managers providing a winter update on the epidemiological situation regarding acute respiratory illnesses among children under five years old and included a link to the new website content. Drafting these summaries of public health advice aimed at non-technical readers, helped develop my skills in communicating public health issues to a layperson audience.

Conference presentation

At the Communicable Diseases and Immunisation Conference 2023, held in Perth from 19-21 June 2023, I delivered a virtual oral presentation of an abstract based on a component of my surveillance system evaluation detailed in Chapter 4. The abstract is included in Chapter 4.

At the first South Asia Field Epidemiology and Technology Network, Inc. Scientific Conference, held in Canberra from 12-15 September 2023, I delivered a long oral presentation based on my outbreak investigation detailed in Chapter 3. The abstract is included in Chapter 3.

Peer-reviewed publication

A short report based on the outbreak investigation detailed in Chapter 3 titled, *Kebabs with a side of Salmonella: Two outbreaks of Salmonella linked to kebab shops in Canberra, ACT,* was published in the December 2022 issue of *Communicable Diseases Intelligence.* The article is available at: https://www1.health.gov.au/internet/main/publishing.nsf/Content/2A15CD097063EF40CA2587CE008354F1/$File/kebabs_with_a_side_of_salmonella_two_outbreaks_of_salmonella_linked_to_kebab_shops_in_canberra_act.pdf

An original article based on the epidemiological study detailed in Chapter 5 titled, *Gonococcal infections in the ACT and risk factors for reinfection, 2017-2022,* was submitted to a peer-reviewed journal in 2023 for consideration for publication.

Appendix A – Lay summary: Website content on gastroenteritis and acute respiratory infection for childcare centres

Childcare setting gastroenteritis and acute respiratory illness outbreaks

Gastroenteritis (or gastro) is a common infection of the stomach and bowel that causes vomiting and/or diarrhoea. It is usually a mild illness and can be caused by many different viruses, bacteria, and parasites.

Acute respiratory illness includes common infections which cause symptoms affecting the respiratory tract. There are many viruses which cause acute respiratory illness in young children. Some common respiratory viruses include rhinovirus, respiratory syncytial virus, influenza, and parainfluenza. COVID-19 also causes acute respiratory illness. The symptoms caused by these viruses can range from mild (runny nose, cough, fever) to more severe (inflammation of the small airways, called bronchiolitis, and pneumonia).

The spread of all respiratory viruses can be reduced using the same infection control practices.

Preventing spread of infections

Discourage people from attending the childcare centre if they are unwell with any symptoms of gastroenteritis or acute respiratory illness. Unwell siblings should not attend the centre during drop off and pick up.

Children who have been diagnosed with COVID-19 must isolate at home. See children and COVID-19 for more information.

Exclude children, educators, or other staff with gastroenteritis symptoms from the centre until 48 hours has passed since the last loose bowel motion or vomit. Exclude people with acute respiratory symptoms until they are well.

Use the Gastroenteritis Line List for Child Care Centres to record details of all unwell people, or you can use your own institutional illness register.

For more information about minimising the spread of disease, see Staying Healthy: Preventing infectious diseases in early childhood education and care services.

See the ACT Education Directorate website for more information about preventing and managing COVID-19 in early childhood education and care services and ACT public schools.

Reporting a gastroenteritis outbreak

Under the *Public Health Act 1997*, childcare facilities are required to notify Communicable Disease Control if they have two or more cases of gastroenteritis (diarrhoea and/or vomiting) among children and/or staff in a 24-hour period. For childcare settings, only outbreaks of gastroenteritis are notifiable to ACT Health. You are not required to notify ACT Health of any outbreaks of respiratory illness in your childcare service.

Report a gastroenteritis outbreak in a childcare facility. You can also call the Health Protection Service, Communicable Disease Control Information Line on 02 5124 9213 during business hours. A Public Health Officer will take your details and provide you with public health advice to help limit the spread of the outbreak.

Infection control

Limit the spread of infectious diseases by ensuring appropriate infection control practices are adhered to, year-round. Infection control is important to minimise transmission and control outbreaks of gastroenteritis in childcare centres. Use effective hand hygiene and exclude unwell children and staff. Other infection control measures include using personal protective equipment and effective environmental cleaning.

For advice about infection control, call the Communicable Disease Control Information Line on 02 5124 9213 and ask to speak to a member of the Infection Control team.

Resources to assist with infection control

- Viral gastroenteritis factsheet
- STOP - gastro outbreak sign for ACFs
- Staying Healthy: Preventing infectious diseases in early childhood education and care services
- COVID-19 in early childhood education and care services
- COVID smart public schools
- Gastroenteritis line list – Childcare centre
- Communicable disease information

CHAPTER TWO: ANALYSIS OF A PUBLIC HEALTH DATASET

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Chapter 2: Epidemiology of sexually transmissible infections and blood borne viruses in the ACT, 2013-2022

Prologue

This chapter details a descriptive analysis of ten years of notifications data for sexually transmissible infections (STI) and blood borne viruses (BBV) in the ACT between 2013 and 2022. It fulfills the major competency, *Analysis of a public health dataset.*

My role

Prior to commencing this project, I was required to develop a study proposal, draft the research protocol, and obtain ethics approval. With input from my supervisors, I determined the scope and design of the study, planned the analyses, and drafted a data analysis plan. As the study period crossed the transition point from the previous iteration of the ACT notifiable disease management system to a new system, I was required to extract data from both databases and link the datasets. I undertook data cleaning and assessed data quality, validity, and completeness, performed the analyses, and presented the results. Under the guidance of my supervisors, I led the drafting and refinement of the eventual chapter.

Public health impact

This study presents the first long term descriptive analysis of notifications data for all notifiable STI and BBV in the ACT. The findings of this study are intended to guide and prioritise more granular analyses into the factors underpinning notification trends among identified populations. These findings may also be used to inform the allocation of resources to support the development of interventions to improve STI and BBV surveillance and prevention in the ACT.

The selected study period captures data from before and after the implementation of public health and social measures (including gathering and movement restrictions) associated with the COVID-19 pandemic. Reductions in notifications for STI and BBV since the beginning of the COVID-19 pandemic both in Australia and overseas have been attributed, at least partially, to reduced testing and access to sexual health services. As such, this study provides a broad overview of the impact of the pandemic on notifications for STI and BBV among demographic groups in the ACT. These findings may inform future studies and local public health decision-making.

Lessons learned

Importantly, this project provided me with my first experience securing ethics approval to conduct human research. The end-to-end process of preparing, submitting, and finalising the application taught me to carefully consider the ethical aspects of a study relating to sensitive topics, such as STI and BBV.

As a descriptive study of a range of distinct diseases, this project presented an opportunity to learn more about the unique public health challenges associated with STI and BBV. These conditions are known to disproportionately affect certain sociodemographic groups. The public health approach to their control therefore requires nuanced consideration of sensitive factors which may not be applicable to other communicable diseases. Examples include a focus on eliminating the stigma and discrimination experienced by those diagnosed and consideration of the unique needs of distinct priority populations, such as people in custodial settings, people who inject drugs, gay men and other men who have sex with men, and sex workers.

Through undertaking this project, I gained an understanding of existing work being undertaken in Australia, including the surveillance and reporting undertaken by the Kirby Institute and the implementation of the national STI and BBV strategies. While there remains plenty for me to learn, undertaking this project provided me with a sound introduction to these issues.

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Abstract

Background

Understanding local epidemiological trends in notifications for sexually transmissible infections (STI) and blood borne viruses (BBV) can inform prioritisation of future studies and guide the development of public health activities to reduce their impact. A descriptive cross-sectional study was undertaken to describe the epidemiology of STI and BBV notifications in the Australian Capital Territory (ACT) between 2013 and 2022. The findings of this analysis may be used to support public health decision-making in the ACT to contribute to reductions in transmission of STI and progress towards eliminating BBV in Australia.

Methods

Case data for STI and BBV notifications for ACT residents diagnosed between 2013 and 2022 were exported from the ACT notifiable disease management system. For all diseases, data for the disease, diagnosis date, sex, age, residential postcode, and Aboriginal and/or Torres Strait Islander status, were exported. Data for confirmation status (probable or confirmed) and likely mode of acquisition were exported for selected diseases and data for subtype and multidrug-resistance status were exported for sexually acquired shigellosis cases.

Descriptive analyses were undertaken using Microsoft Excel 2017 and Stata (Version 17) for individual diseases by demographic characteristics. Where the number of notifications permitted, trends in notification rates per 100,000 population were described.

Results

The overall STI notification rate increased between 2013 and 2022, primarily due to an increase in gonococcal infection notifications. For gonococcal infections, females had a larger relative increase in notification rate than males, with a steep increase for females aged 15-34 years, including throughout the COVID-19 pandemic. Infectious syphilis notifications increased dramatically between 2016 and 2019, then decreased sharply from 2020. For chlamydial infections, the largest relative increases were for males 25 years and older while notification rates decreased for females and overall. Aboriginal and/or Torres Strait Islander people had greater absolute increases in both gonococcal and chlamydial infection notification rates than Non-Indigenous people. Sexually acquired shigellosis accounted for approximately 30% of confirmed shigellosis cases, with 77.8% of locally sexually acquired cases *Shigella sonnei* biotype G, most of which were multidrug-resistant.

Notifications for BBV reduced steadily between 2013 and 2022. Aboriginal and/or Torres Strait Islander people, particularly males, accounted for a high proportion of hepatitis C notifications. However, notification rates reduced across the study period. There was an increase in newly acquired hepatitis B cases in 2022. HIV notification rates decreased with no newly acquired HIV cases in 2021 and 2022.

Conclusion

Increasing STI notification rates in the ACT demonstrate the need for public health action targeted towards identified populations. Gonococcal infections among females, chlamydial infections among males 25 years and older, and both gonococcal and chlamydial infections among Aboriginal and/or Torres Strait Islander people, should be considered priority areas. Future studies using enhanced surveillance data on sexual exposures and risk factors are required to better understand the factors underpinning increasing STI notification rates among these groups. Targeted interventions to reduce STI transmission, are also required.

Notification rates for BBV reduced steadily throughout the study period, indicating progress has been made towards eliminating their transmission in the ACT. However, high hepatitis C notification rates among Aboriginal and/or Torres Strait Islander people, particularly males, suggest the need for further public health action to address this disparity.

Introduction

Sexually transmissible infections (STI), viral hepatitis, and human immunodeficiency virus (HIV) represent important global public health problems, collectively responsible for an estimated 2.3 million annual deaths (1). Although significant progress has been made over the past decade, insufficient advancement towards achieving global targets for the reduction of STI and elimination of blood borne viruses (BBV) resulted in most targets for 2020 being missed (1). International efforts to reduce the impacts of STI and BBV have been interrupted through disruptions to essential health services caused by the COVID-19 pandemic (1). In Australia, the national responses to STI and BBV are guided by the national strategies, which set out the goals, targets, and priority areas for addressing the public health threats associated with STI and BBV (2). Surveillance undertaken at the state or territory and national levels enables monitoring of Australia's progress towards achieving the targets set out in the strategies (3).

Nationally notifiable STI in Australia include chlamydia, gonorrhoea, syphilis, shigellosis, mpox, and donovanosis (4). For surveillance purposes, syphilis infections are classified as congenital, <2 years duration, and >2 years or unknown duration, as the infectious period is considered to be the first two years for untreated infections (5). For most STI, the risk the risk of more severe sequelae and onward transmission is greater for undiagnosed and untreated infections (6,7,8,9). Reduced or delayed testing during the COVID-19 pandemic may have resulted in increases in undiagnosed STI since 2020 (10,11,12,13). In Australia, notification rates for chlamydial infection, gonococcal infection, and syphilis increased between 2012 and 2019 before reducing between 2019 and 2021 (14). For all three diseases, Aboriginal and/or Torres Strait Islander people and those living in remote areas had higher notification rates over this period compared with other groups (15). No cases of donovanosis have been notified in Australia since 2014 (16).

Mpox became nationally notifiable in Australia in June 2022 following an increase in cases outside the countries in which it was known to be endemic (17,18,19). All cases of mpox notified in Australia in 2022 (n=144) were among males (16). The vast majority of infections in the current global outbreak are thought to have been acquired through sexual activity, predominantly among gay, bisexual and other men who have sex with men (GBMSM) (19). Similarly, shigellosis acquired through sexual contact has been widely reported, especially among GBMSM, with the emergence of multidrug-resistant resistant (MDR) strains a global public health concern (20,21,22,23).

The nationally notifiable BBV in Australia are hepatitis B, hepatitis C, hepatitis D, and HIV (4). For hepatitis B, hepatitis C, and HIV cases notified between 2004 and 2022, cases were classified as either newly acquired or unspecified (24). Through its national responses to BBV, Australia is working towards

becoming one of the first countries in the world to eliminate hepatitis B and C as public health threats and virtually eliminate transmission of HIV (25,26,27). Although national notification rates have decreased since 2012, reduced testing during the COVID-19 pandemic may have contributed to the reduction since 2019 (28,29,30). Identified groups including males, Aboriginal and/or Torres Strait Islander people, and people who inject drugs, are typically over-represented in notifications for BBV compared with other groups (28,29,30).

In the Australian Capital Territory (ACT), work is underway to strengthen local services and design a service system aimed at addressing the burden of STI and BBV, with a focus on priority populations (31). These activities will support achievement of the national goals for reducing or eliminating transmission of STI and BBV. Analysis of local STI and BBV notifications data can support this process by informing the direction of commissioning activities. This study aimed to describe the epidemiology of STI and BBV notifications in the ACT between 2013 and 2022.

Methods

In the ACT, diagnosed cases of STI and BBV meeting national surveillance case definitions are notifiable under the *Public Health Act 1997* (24,32). A descriptive cross-sectional study was undertaken to describe the epidemiology of notifications for STI and BBV in the ACT between 2013 and 2022. The study population included ACT residents who had an STI or BBV notified to the ACT Health Directorate (ACT Health) with a diagnosis date during the study period.

Case data for the disease, diagnosis date, sex, age, residential postcode, confirmation status (probable or confirmed), and Aboriginal and/or Torres Strait Islander status were exported from the ACT notifiable disease management system. Residential postcode was used to determine residence within the ACT. Notifications with a residential postcode outside the ACT were excluded and notifications for individuals with no fixed address were included where the test was requested by a health service within the ACT. Data for likely source of acquisition (locally acquired, interstate acquired or overseas acquired) were exported for hepatitis B (newly acquired), hepatitis D, shigellosis, and HIV (newly acquired and unspecified) as source of acquisition data are routinely collected for these conditions. For shigellosis cases, data for likely mode of acquisition (overseas, interstate, sexual, or non-sexual person-to-person) and subtype, were also exported. Only confirmed shigellosis cases likely acquired through sexual activity were included in the analyses as data for likely mode of acquisition were unavailable for most probable cases due to limited follow-up. For locally sexually acquired shigellosis cases, data were also exported for whether the isolate was identified as MDR, defined by resistance (according to widely-used susceptibility test criteria in Australia) to three or more of the following:

ampicillin/amoxicillin, ciprofloxacin/norfloxacin, cotrimoxazole, ceftriaxone/cefotaxime/ceftazidime, or azithromycin (33). Other infections known to be infrequently sexually acquired (e.g., cryptosporidiosis) were not examined due to unavailability of data for likely mode of acquisition. Confirmed cases of hepatitis D required the case to be co-infected with hepatitis B to meet the case definition (24).

Analyses were undertaken using Microsoft Excel 2017 and Stata (Version 17). Total notifications for STI and BBV across the study period were described using counts and proportions. Annual notification rates per 100,000 population were calculated using ACT annual mid-year estimated resident population to examine trends (34). For individual diseases, counts and proportions were used to describe data for the entire study period in terms of demographic characteristics, depending on the number of notifications. Data for Aboriginal and Torres Strait Islander people were combined for analyses by Aboriginal and/or Torres Strait Islander status due to low numbers. Age was described using median, range, and interquartile range (IQR).

For diseases with a sufficiently high number of notifications, total and sex- and age-specific annual notification rates for all ACT residents, and sex-specific rates for Aboriginal and/or Torres Strait Islander people and Non-Indigenous people, were calculated to examine trends among demographic groups. Annual mid-year estimated resident and projected populations for Aboriginal and/or Torres Strait Islander Australians were used to calculate rates by Aboriginal and/or Torres Strait Islander status (35).

Where the number of notifications for a disease or demographic group was low (n<5), the exact number was not reported to prevent potential re-identification. For syphilis <2 years, the exact number of notifications for females was not reported to conceal the number of cases for people of indeterminate/non-binary sex (n<5). Due to low numbers of notifications, individuals of indeterminate/non-binary sex were excluded from calculation of sex-specific rates and age-specific rates were not reported for individuals aged <15 years.

To investigate the effect of the COVID-19 pandemic on notification rates for gonococcal, chlamydial, and hepatitis C infections, relative percentage change in notification rates were calculated. To do this, pre-pandemic quarterly notification rate means were calculated for each quarter (Q1 to Q4) for the five years prior to the pandemic (Q2 2015 to Q1 2020) and subtracted from the corresponding quarterly notification rate during the pandemic (Q2 2020 to Q4 2022). The result was then divided by the pre-pandemic quarterly notification rate mean and multiplied by 100. The use of quarterly rates for the five years prior to the pandemic assumed that notification rates in the ACT would have remained the same during the period of Q2 2020 to Q4 2022, had the pandemic not occurred.

Ethics

The protocol for the study was approved by the ACT Health Human Research Ethics Committee (HREC) Low-Risk Sub-Committee and acknowledged by the Australian National University HREC.

Results

In total, 19,441 notifications were included in the analyses—16,955 for STI and 2,486 for BBV. Data were 100% complete for date of diagnosis (the earliest of onset date, specimen collection date, and notification date), confirmation status, sex, and age. Data for Aboriginal and/or Torres Strait Islander status were 73.8% complete for STI and 84.6% for BBV. Data for likely source of infection were 27.3% complete for hepatitis B (newly acquired), 14.3% complete for HIV (newly acquired), 42.0% for HIV (unspecified), and 73.7% complete for shigellosis. Data for *Shigella* subtype for sexually acquired cases were 89.5% complete and MDR status for locally sexually acquired cases of *Shigella sonnei* were 85.7% complete. There were 30 notifications for people with no fixed address for BBV (1.2%) and 34 for STI (0.2%).

Sexually transmissible infections

Of the total 16,955 STI notifications, 13,985 (82.5%) were for chlamydial infections, 2,465 (14.5%) gonococcal infections, 339 (2.0%) syphilis (<2 years duration), 144 (0.8%) syphilis >2 years or unspecified duration, 19 (0.1%) sexually acquired shigellosis, and three mpox (<0.1%). There were no notifications for donovanosis or congenital syphilis during the study period.

The total notification rate per 100,000 population for all STI increased from 364 in 2013 to 411 in 2022 (Figure 1). In 2019, the notification rate per 100,000 population peaked at 473 before reducing to 403 in 2020, further reducing to 380 in 2021 and then increasing again to 411 in 2022.

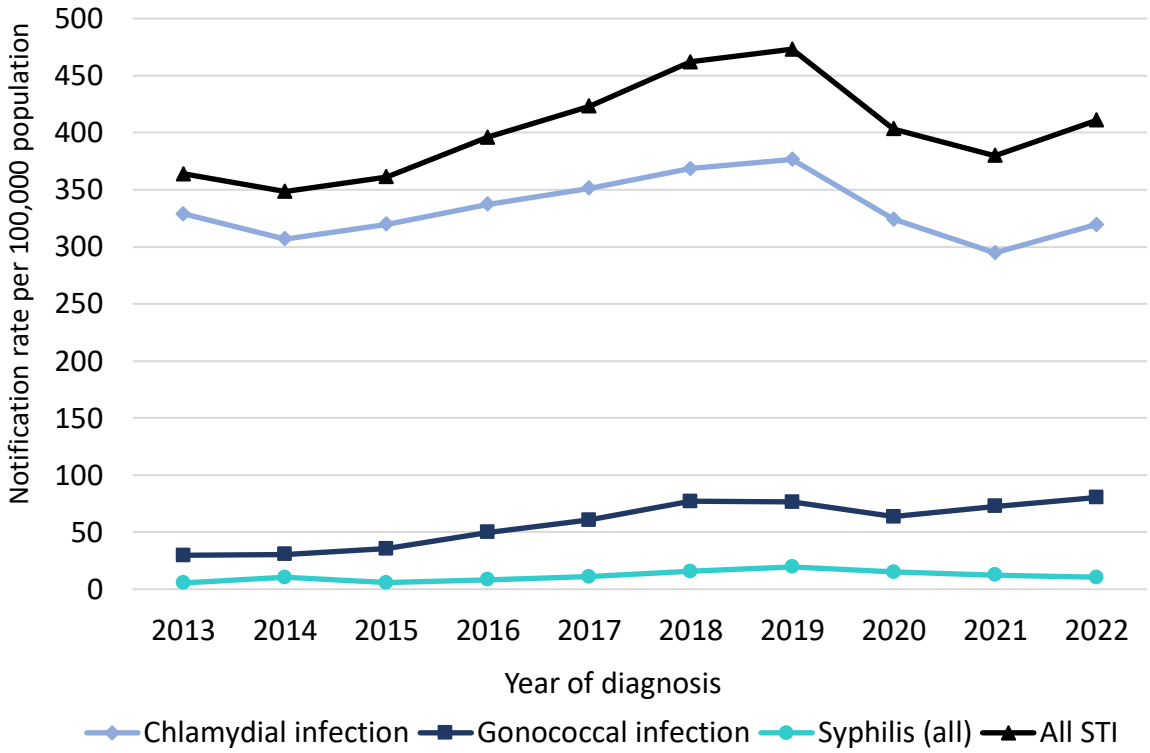

Figure 1: Notification rates per 100,000 population for all STI and selected diseases in the ACT, between 2013 and 2022

Gonococcal infections

Between 2013 and 2022, 80.9% of gonococcal infection notifications (n=1,993) were for males, 18.7% for females (n=460), and 0.5% (n=12) for indeterminate/non-binary people. There were 101 gonococcal infection notifications for Aboriginal and/or Torres Strait Islander people (4.1%) and 2,272 for Non-Indigenous people (92.2%). The remainder had unknown Aboriginal and/or Torres Strait Islander status. Among Aboriginal and/or Torres Strait Islander people, 43.6% of notifications (n=44) were for females and <5 (<5.0%) for indeterminate/non-binary people. The remainder (>51.4%) were for males.

The median age was 29 years (range <15-75, IQR 13) for all people, 30 years (range <15-75, IQR 13) for males, 26 years (range <15-65, IQR 11) for females, and 22 years (range 19-35, IQR 6.5) for indeterminate/non-binary people. For Aboriginal and/or Torres Strait Islander people, the median age was 26 years (range <15-60, IQR 7), compared with 30 years for Non-Indigenous people (range <15-75, IQR 13).

Among males, the notification rate per 100,000 population increased more than two-fold from 52 in 2013 to a peak of 132 in 2019 before reducing to 100 in 2020 and increasing again to 103 and 122 in 2021 and 2022, respectively. For females, the notification rate increased more than five-fold from 8 in 2013 to 43 in 2021, with a slight reduction to 38 in 2022 (Figure 2).

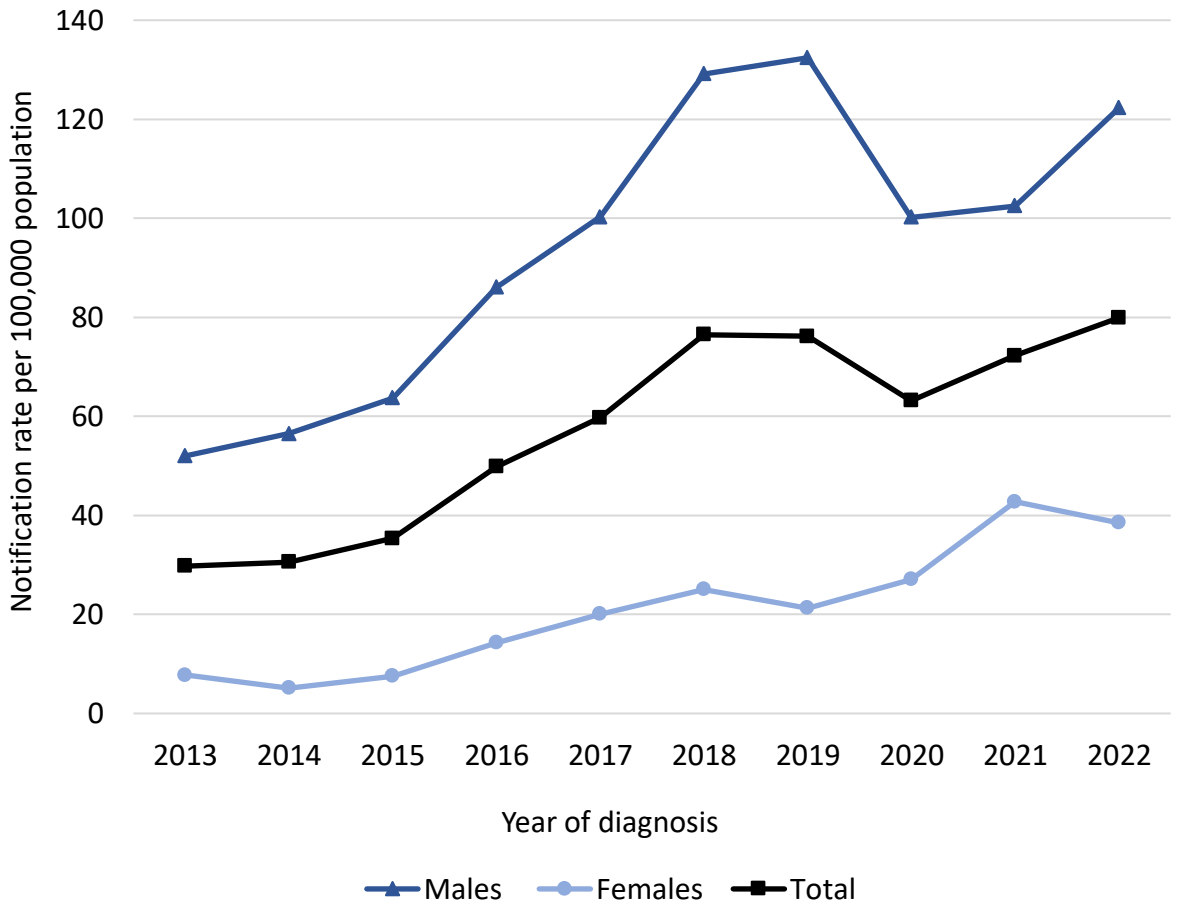

Figure 2: Total and sex-specific gonococcal infection notification rates per 100,000 population in the ACT, between 2013 and 2022

There was a greater increase in the gonococcal infection notification rate per 100,000 population for Aboriginal and/or Torres Strait Islander people between 2013 and 2022, from 28 to 282—approximately ten-fold, than the corresponding rate for Non-Indigenous people, from 30 to 69—more than two-fold (Figure 3). Among Aboriginal and/or Torres Strait Islander people, the notification rate of 282 in 2022 was more than four-fold the corresponding rate (69 per 100,000) for Non-Indigenous people. Although low numbers limited interpretation of trends in notification rates for Aboriginal and/or Torres Strait Islander people by sex, the notification rate per 100,000 population for Aboriginal and/or Torres Strait Islander males in 2022 was 256, more than two-fold that for Non-Indigenous males at 111. For Aboriginal and/or Torres Strait Islander females, it was 309—more than 10-fold the corresponding rate for Non-Indigenous females at 29.

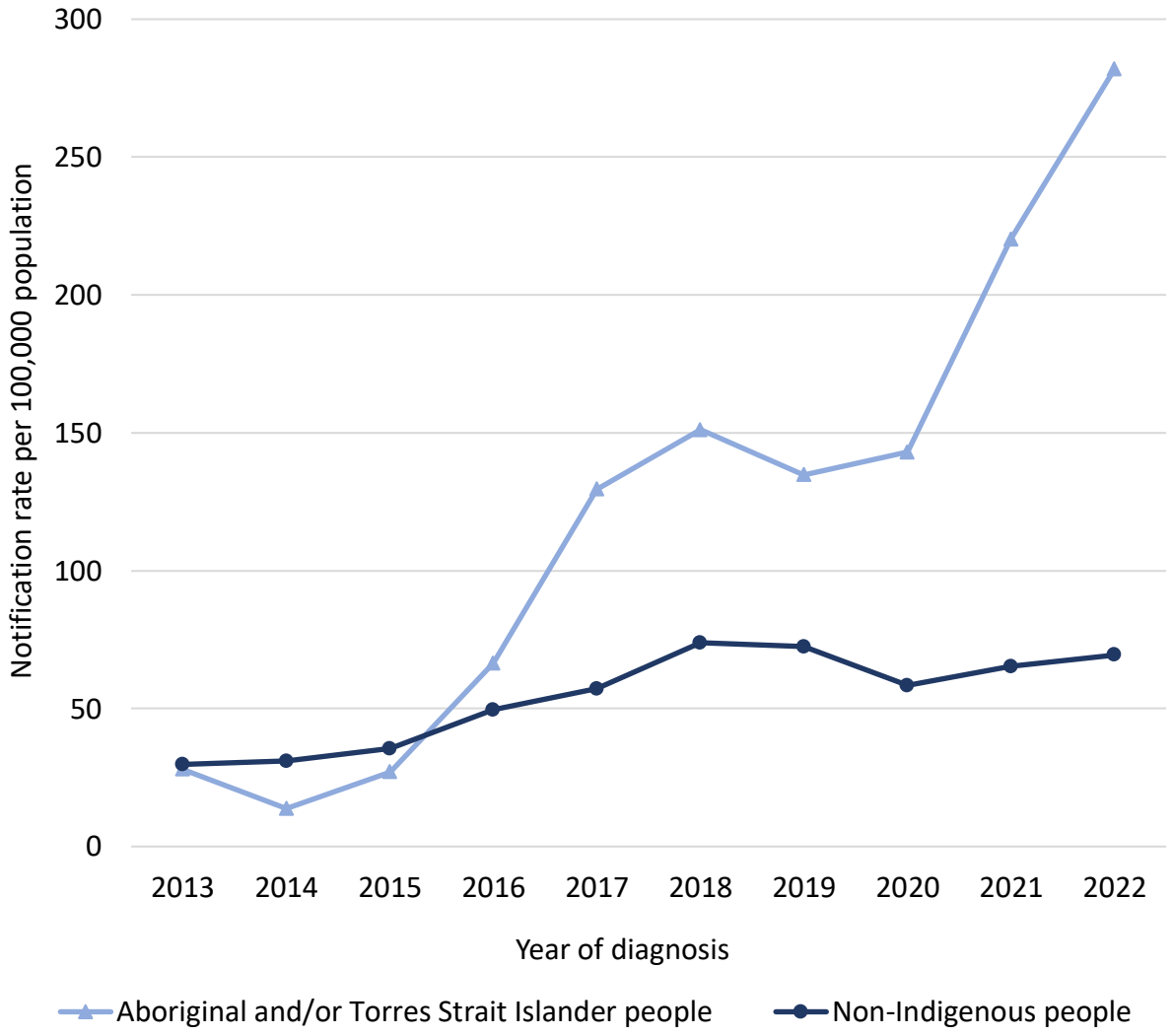

Figure 3: Aboriginal and/or Torres Strait Islander status-specific gonococcal infection notification rates per 100,000 population in the ACT, between 2013 and 2022[a]

For males, age-specific gonococcal infection notification rates increased between 2013 and 2022 for all age groups (Figure 4a). Compared with other age groups, the 15-24-years age group had only a modest absolute increase across the study period, from 129 per 100,000 population in 2013 to 152 in 2022. The largest relative increases were among the older age groups with an approximately four-fold increase in the rate for the 45-54-years age group, from 33 per 100,000 population in 2013 to 133 in 2022. Between 2015 and 2019, there was a greater than two-and-a-half-fold increase in the notification rate for males in the 25-34-years age group, from 133 to 347, followed by a sharp drop to 250 in 2020.

[a] Data completeness for Aboriginal and/or Torres Strait Islander status for gonococcal infection notifications between 2013 and 2022 was 96.3%.

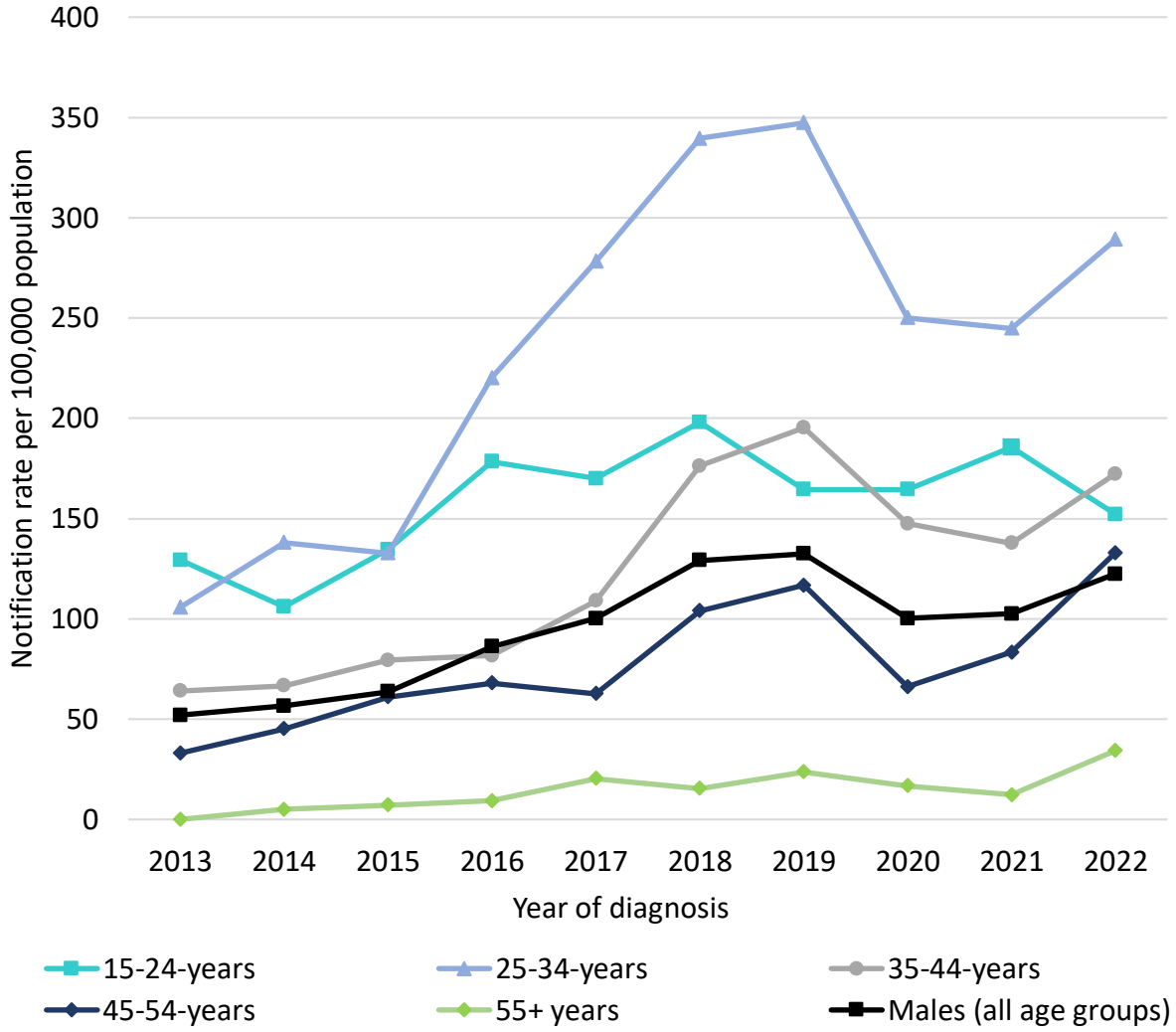

Figure 4a: Age- and sex-specific gonococcal infection notification rates per 100,000 population among males in the ACT, by age group, between 2013 and 2022

For females, notification rates across the study period increased for all age groups besides 55+ years (Figure 4b). The most substantial absolute increase was for the 25-34-years age group, which increased from 6 to 100 per 100,000 population—a greater than 16-fold increase—between 2013 and 2022. There was also a greater than two-fold increase for the 15-24-years age group, from 35 per 100,000 population in 2013 to 83 in 2022. For both males and females, the only age group for which notification rates reduced between 2020 and 2022, was the 15-24-years age group—from 164 to 152 per 100,000 population for males and from 108 to 83 for females (Figures 4a and 4b).

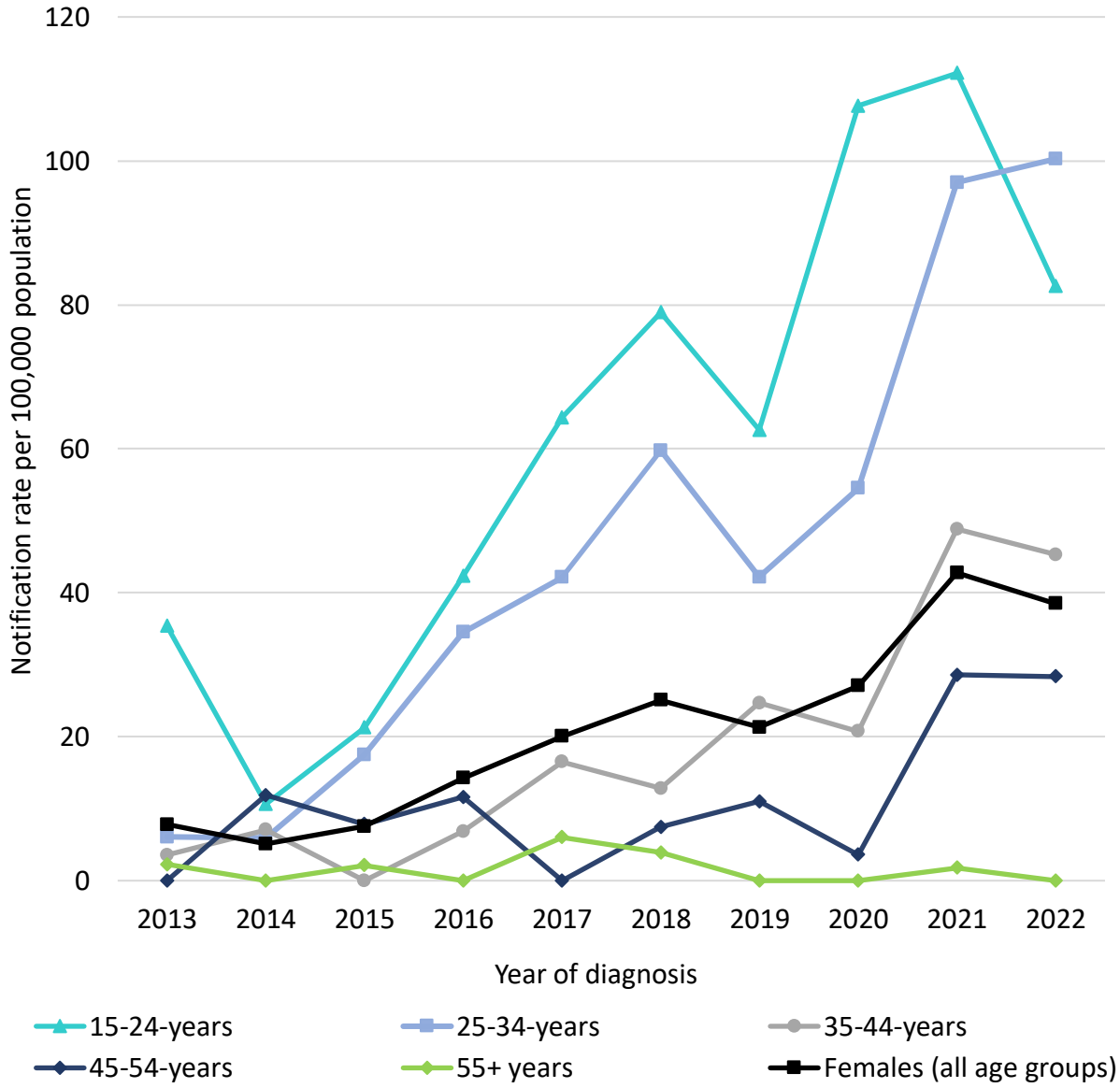

Figure 4b: Age- and sex-specific gonococcal infection notification rates per 100,000 population among females in the ACT, by age group, between 2013 and 2022

The gonococcal infection notification rate relative percentage change for females was positive for every quarter from Q2 2020 to Q4 2022 (Figure 5). For males, it was negative for all quarters until Q2 2021 and seven out of 11 quarters (63.6%) overall. For both males and females, the relative percentage change was positive for the last three quarters of 2022.

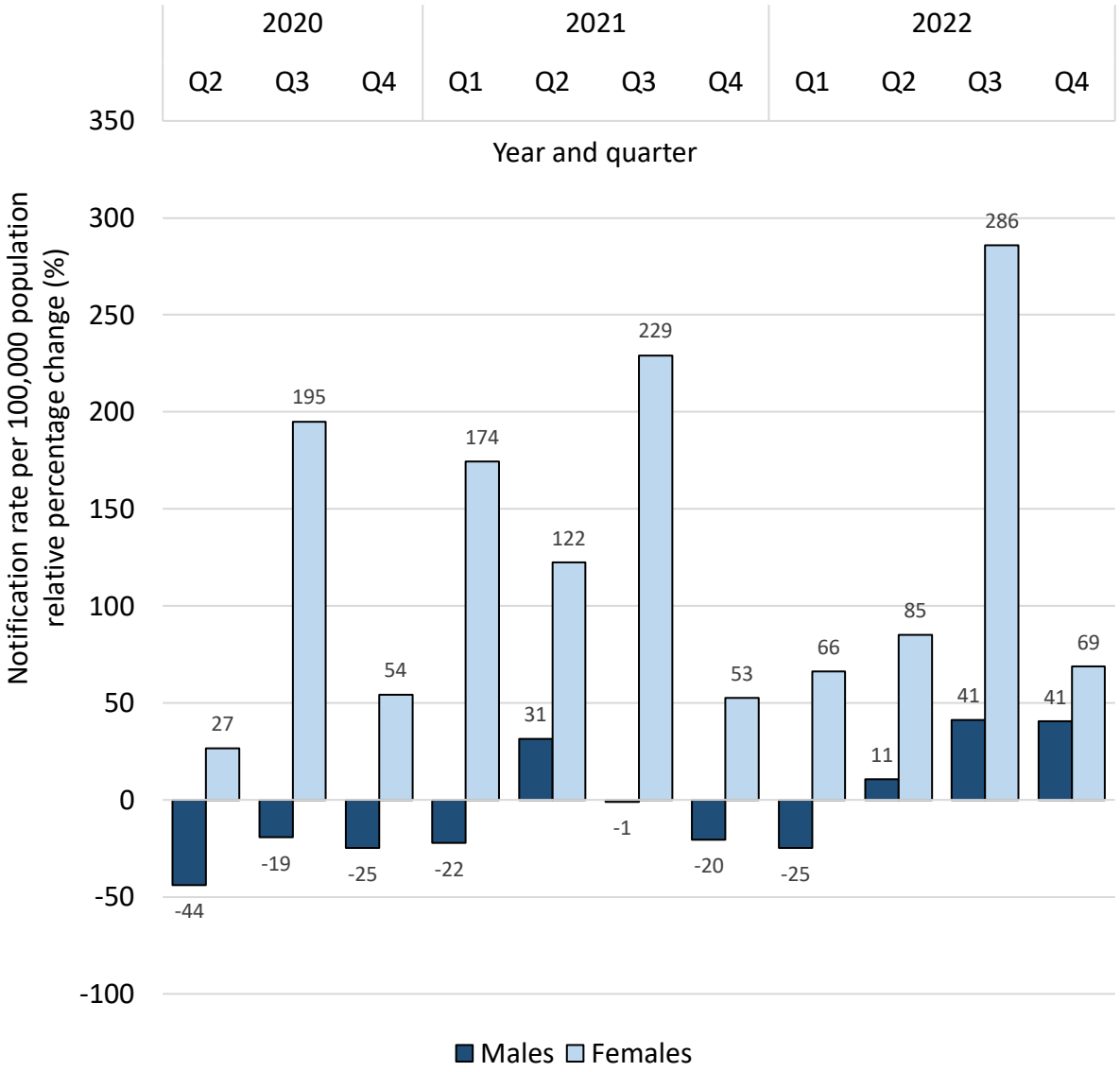

Figure 5: Sex-specific relative percentage change in quarterly gonococcal infection notification rate per 100,000 population in the ACT, between Q2 2020 and Q4 2022

Syphilis

For syphilis <2 years, 94.7% of notifications between 2013 and 2022 (n=321) were for males and <5.3% for females (n<18). The remainder were for indeterminate/non-binary people. There were 17 notifications for Aboriginal and/or Torres Strait Islander people (5.0%) and 318 for Non-Indigenous people (93.8%). The remainder had unknown Aboriginal and/or Torres Strait Islander status. The median age was 32 years (range 18-77, IQR 15) for all people, 33 years (range 18-77, IQR 15) for males and 26 years (range 19-40, IQR 14) for females. For Aboriginal and/or Torres Strait Islander people, the median age was 25 years (range 18-53, IQR 8), compared with 33 years (range 18-77, IQR 15) for Non-Indigenous people.

For syphilis >2 years or unspecified duration, 71.5% of notifications (n=103) were for males and 28.5% for females (n=41). There were seven notifications for Aboriginal and/or Torres Strait Islander people (4.9%) and 128 for Non-Indigenous people (88.9%). The remainder had unknown Aboriginal and/or Torres Strait Islander status. The median age was 43 years (range 17-87, IQR 27) for all people, 45 years (range 17-83, IQR 27) for males and 39 years (range 17-87, IQR 30) for females. For Aboriginal and/or Torres Strait Islander people, the median age was 47 years (range 36-51, IQR 11), compared with 42.5 years (range 17-87, IQR 28) for Non-Indigenous people.

The total notification rate per 100,000 population for syphilis <2 years duration increased five-fold between 2016 and 2019, from three to 15, before almost halving again to eight in 2022. For syphilis >2 years or unspecified duration, the notification rate fluctuated between two and six per 100,000 between 2013 and 2022 (Figure 6).

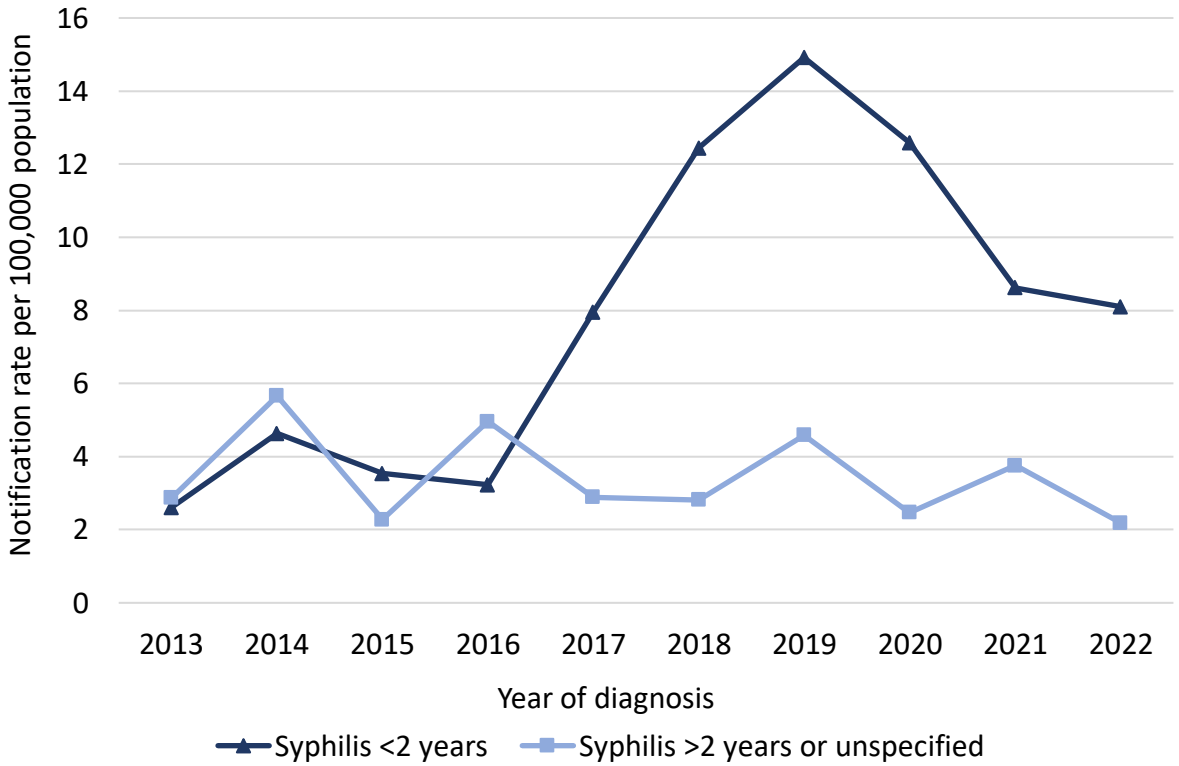

Figure 6: Syphilis notification rates per 100,000 population in the ACT, between 2013 and 2022

Among Aboriginal and/or Torres Strait Islander people, there were <5 notifications for syphilis <2 years for all years besides 2020, in which there were five notifications. This equated to a notification rate of 60 per 100,000 Aboriginal and/or Torres Strait Islander population in the ACT and represented 8.2% of notifications for syphilis <2 years in 2020. For syphilis >2 years or unspecified duration, there were <5 notifications per year for Aboriginal and/or Torres Strait Islander people. Low numbers limited interpretation of syphilis notification rate trends. However, there were no syphilis notifications for Aboriginal and/or Torres Strait Islander people in 2021 or 2022.

Chlamydial infections

Between 2013 and 2022, 51.3% of chlamydial infection notifications were for males (n=7,177), 48.6% for females (n=6,797) and <0.1% (n=11) for indeterminate/non-binary people. There were 437 notifications for Aboriginal and/or Torres Strait Islander people (3.1%) and 9,206 for Non-Indigenous people (65.8%). The remainder had unknown Aboriginal and/or Torres Strait Islander status. Among Aboriginal and/or Torres Strait Islander people, 38.4% of notifications (n=168) were for males and 61.6% (n=269) for females.

The median age was 24 years (range <15-82, IQR 9) for all people, 26 years (range <15-82, IQR 10) for males, 22 years (range <15-71, IQR 7) for females, and 23 years (range 19-35, IQR 11) for indeterminate/non-binary people. For Aboriginal and/or Torres Strait Islander people, the median age was 23 years (range <15-56, IQR 8), compared with 24 years for Non-Indigenous people (range <15-82, IQR 9.

Among males, the notification rate per 100,000 population increased from 308 in 2013 to a peak of 422 in 2019 before reducing to 323 in 2020 and 311 2021 and increasing again to 371 in 2022. In comparison, the notification rate for females reduced from 349 per 100,000 population in 2013 to 269 in 2022. Females had higher chlamydial infection notification rates than males for all years until 2016 when the notification rate for males (363 per 100,000 population), surpassed that for females at 312 (Figure 7).

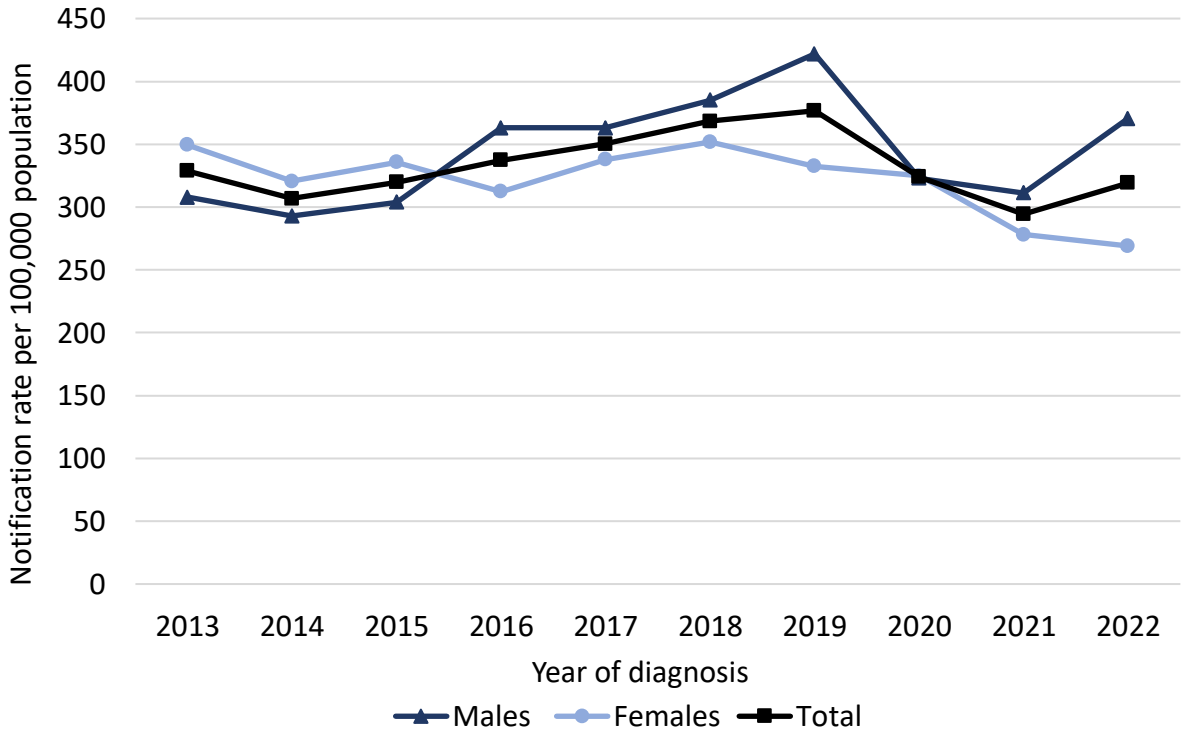

Figure 7: Total and sex-specific chlamydial infection notification rates per 100,000 population in the ACT, between 2013 and 2022

For both Aboriginal and/or Torres Strait Islander males and females, there were greater absolute increases in chlamydial infection notification rates between 2013 and 2018 than for Non-Indigenous people. However, rates for Aboriginal and/or Torres Strait Islander males and females both reduced between 2018 and 2022. Aboriginal and/or Torres Strait Islander females had a higher notification rate than males throughout the study period and a two-to-four-fold higher notification rate than Non-Indigenous females (Figure 8).

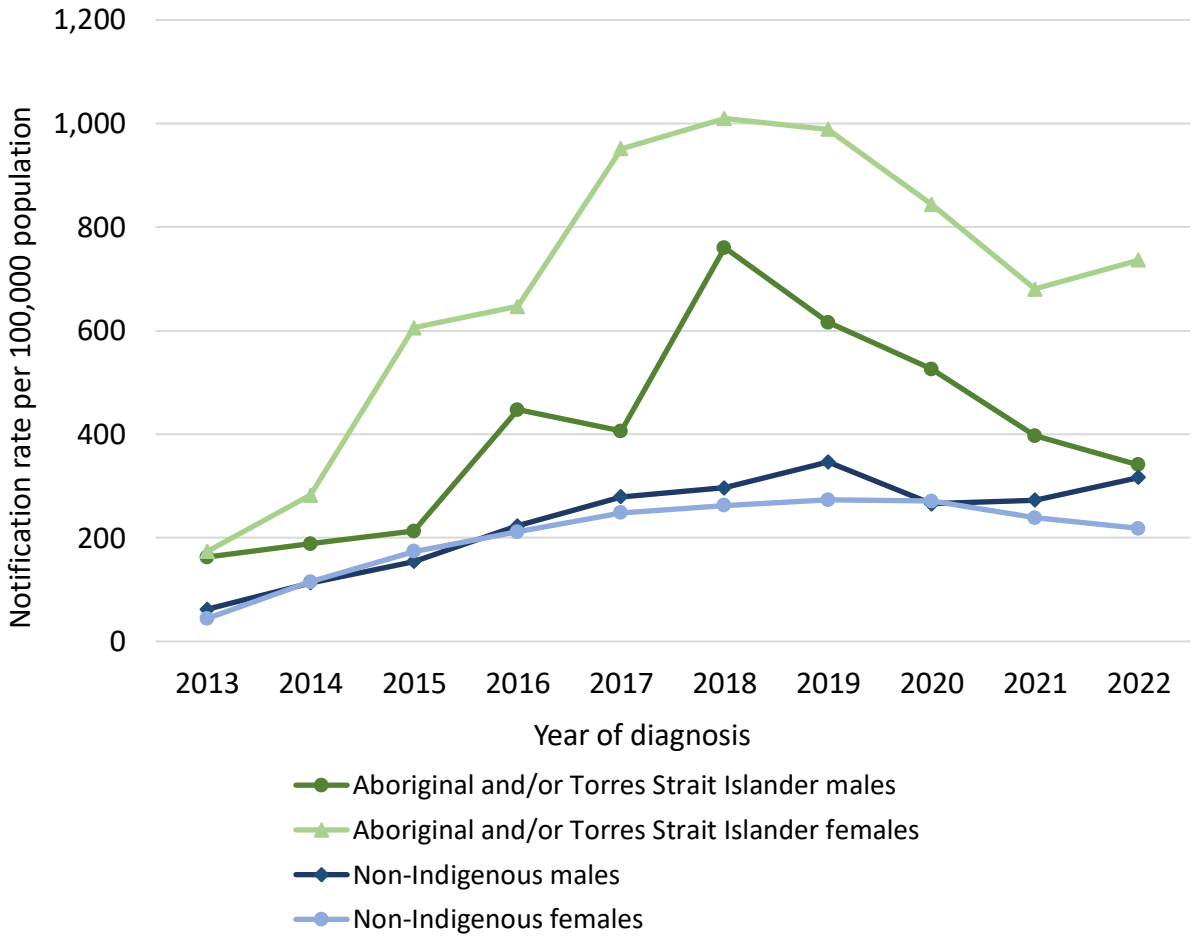

Figure 8: Sex- and Aboriginal and/or Torres Strait Islander status-specific chlamydial infection notification rates per 100,000 population in the ACT, between 2013 and 2022[b]

For both males and females, age-specific chlamydial infection notification rates were highest for the 15-24-years age group, followed by 25-34-years (Figures 9a and 9b). For males, the 25-34-years age group had the greatest absolute increase in notification rate per 100,000 population between 2013 and 2019—from 562 to 979—before dropping sharply to 750 in 2020 and 638 in 2021 and increasing again to 830 in 2022 (Figure 9a).

[b] Data completeness for Aboriginal and/or Torres Strait Islander status for chlamydial infection notifications between 2013 and 2022 was 69.0%, lower than for other STI as enhanced follow-up is not routinely undertaken for chlamydial infections notified in the ACT.

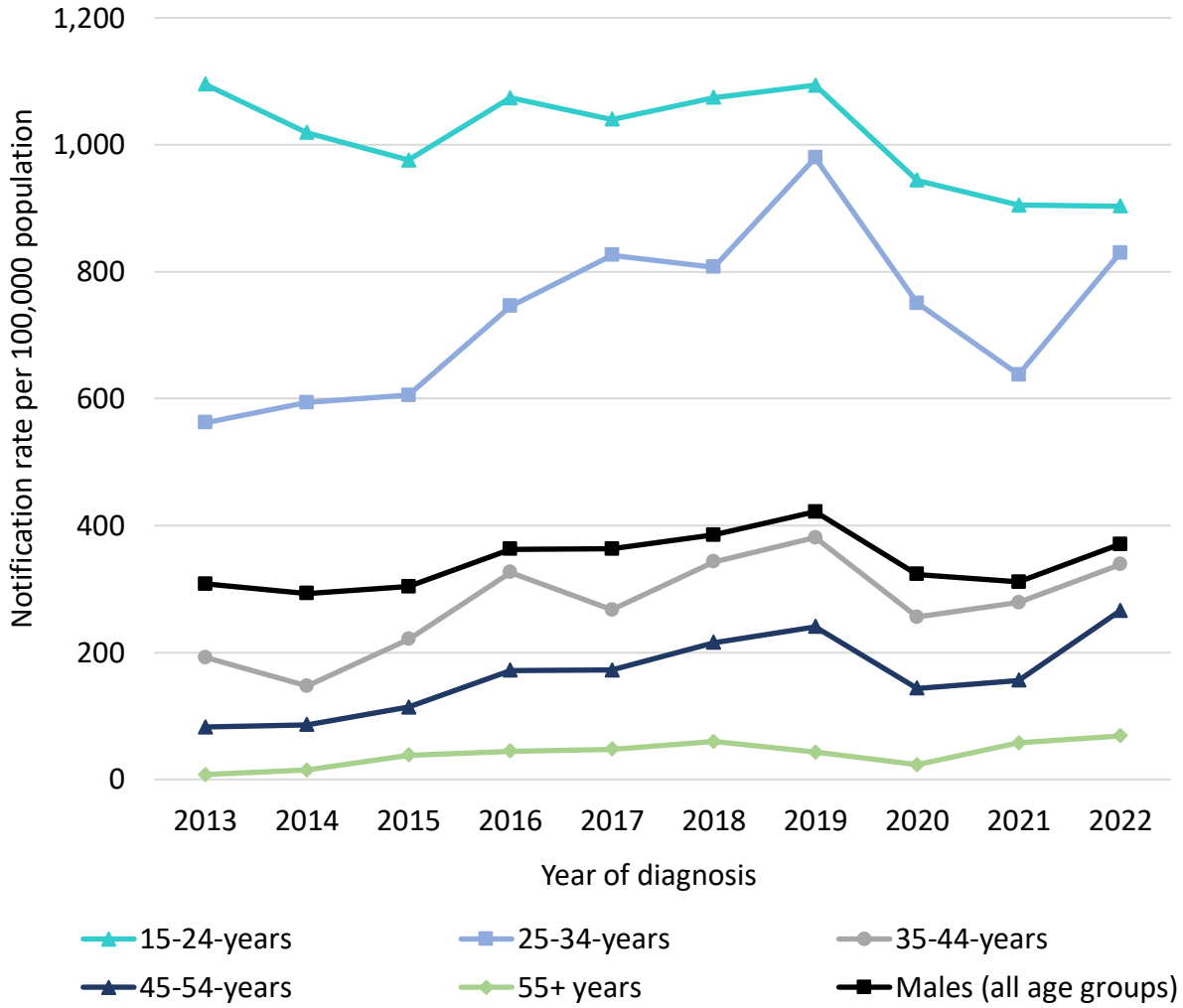

Figure 9a: Age- and sex-specific chlamydial infection notification rates per 100,000 population among males in the ACT, by age group, between 2013 and 2022

For females, the 15-24-years age group had the highest notification rate—approximately three-fold higher than the age group with the next highest notification rates (25-34-years)—across the study period (Figure 9b). Notification rates for females remained relatively stable for most age groups, apart from the 15-24-years age group which saw a substantial reduction from 1,773 in 2013 to 1,318 in 2022.

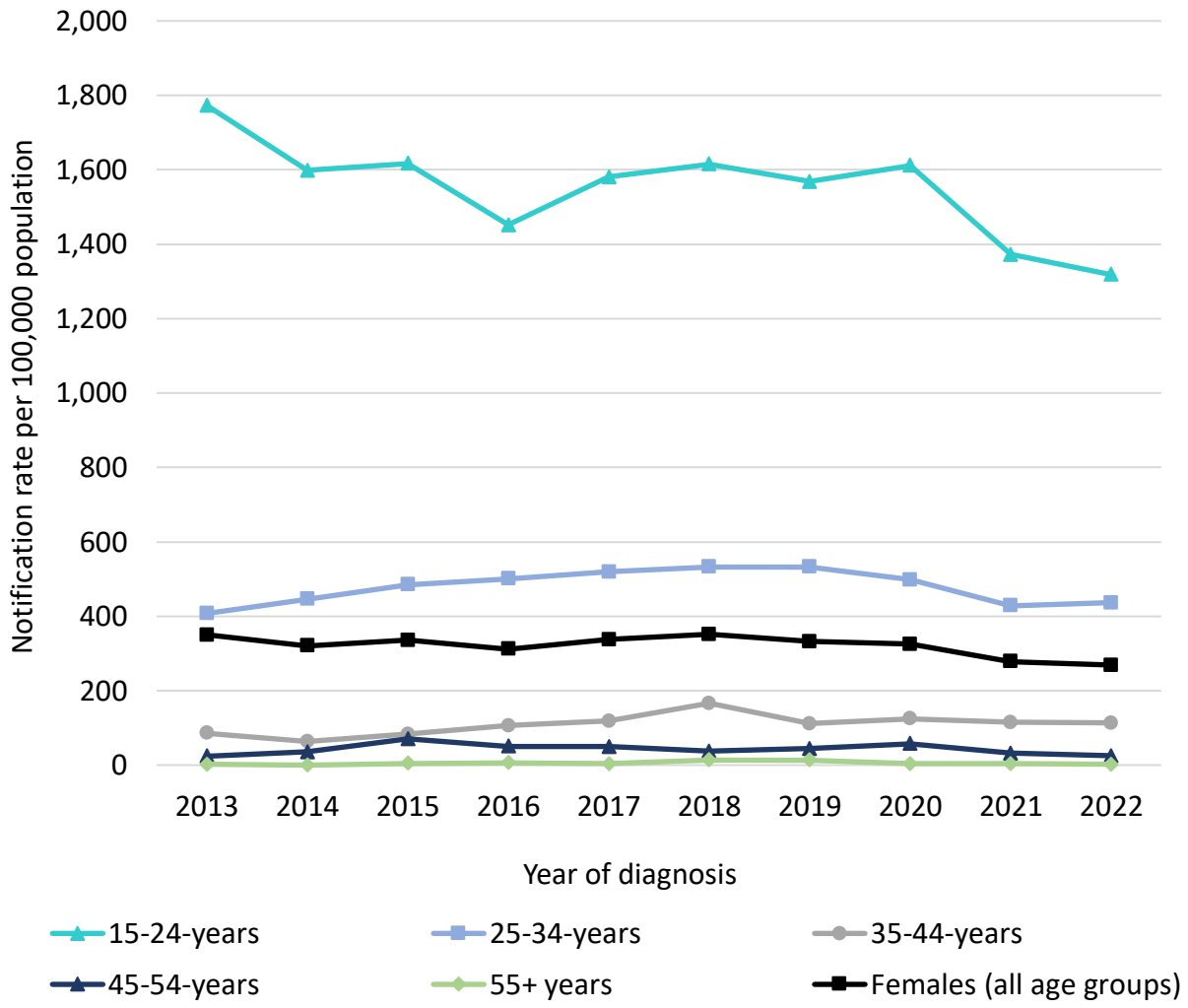

Figure 9b: Age- and sex-specific chlamydial infection notification rates per 100,000 population among females in the ACT, by age group, between 2013 and 2022

For both males and females, the notification rate relative percentage change during the COVID-19 pandemic was negative for most quarters between Q2 2020 and Q4 2022 (Figure 10). Overall, males had a greater negative relative percentage change during 2020 and 2021 than females, with values positive from Q2 2022 onwards.

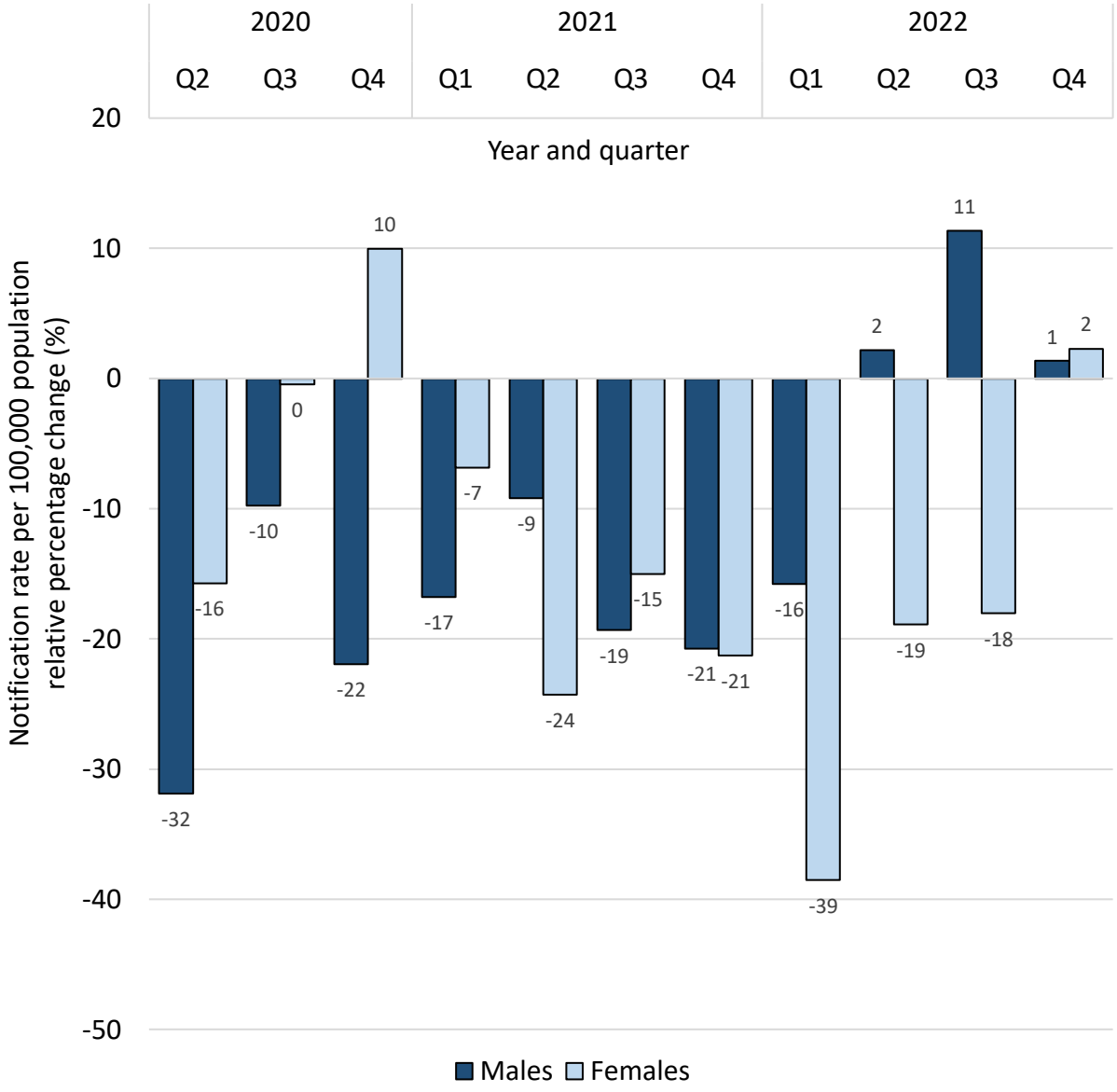

Figure 10: Sex-specific relative percentage change in quarterly chlamydial infection notification rate per 100,000 population in the ACT, between Q2 2020 and Q4 2022

Sexually acquired shigellosis and mpox

There were 19 confirmed cases of sexually acquired shigellosis, all between 2014 and 2020, representing 29.7% of all confirmed shigellosis cases between 2013 and 2022 (n=64). The annual notification rate ranged from 0 to 1 per 100,000 population with the highest number of cases (n=5) in 2018. The vast majority were for males with a median age of 31 years (range 20-64, IQR 19). The likely place of acquisition was in the ACT for 42.1%, interstate for 21.1%, overseas for 10.5%, and unknown for 26.3%. All were for Non-Indigenous people. The vast majority of infections were likely acquired through GBMSM same-sex sexual contact.

For notifications with subtyping data available (n=17), 82.4% (n=14) were *Shigella sonnei* (12 biotype G and two biotype F) and 17.6% (n=3) *Shigella flexneri* (two serotype 3a and one 3b). For infections likely acquired in the ACT (n=9) (all likely acquired through GBMSM same-sex sexual contact), 77.8% (n=7) were *Shigella sonnei* (all biotype G). Of these, isolates were identified as MDR for five cases (71.4%), one case (14.3%) did not meet the definition of MDR, and susceptibility was unknown for one case.

There were three mpox notifications, all between July and September 2022: two confirmed and one probable. All were for males, likely acquired through GBMSM same-sex sexual contact, and overseas acquired.

Blood borne viruses

Of the total 2,486 notifications for BBV between 2013 and 2022, 124 (5.0%) were for hepatitis C (newly acquired), 1,339 (53.9%) hepatitis C (unspecified), 11 (0.4%) hepatitis B (newly acquired), 831 (33.4%) hepatitis B (unspecified), eight (0.3%) hepatitis D, 42 (1.7%) HIV (newly acquired), and 131 (5.3%) HIV (unspecified). The total notification rate per 100,000 population for all BBV decreased from 81 in 2013 to 42 in 2022 (Figure 11).

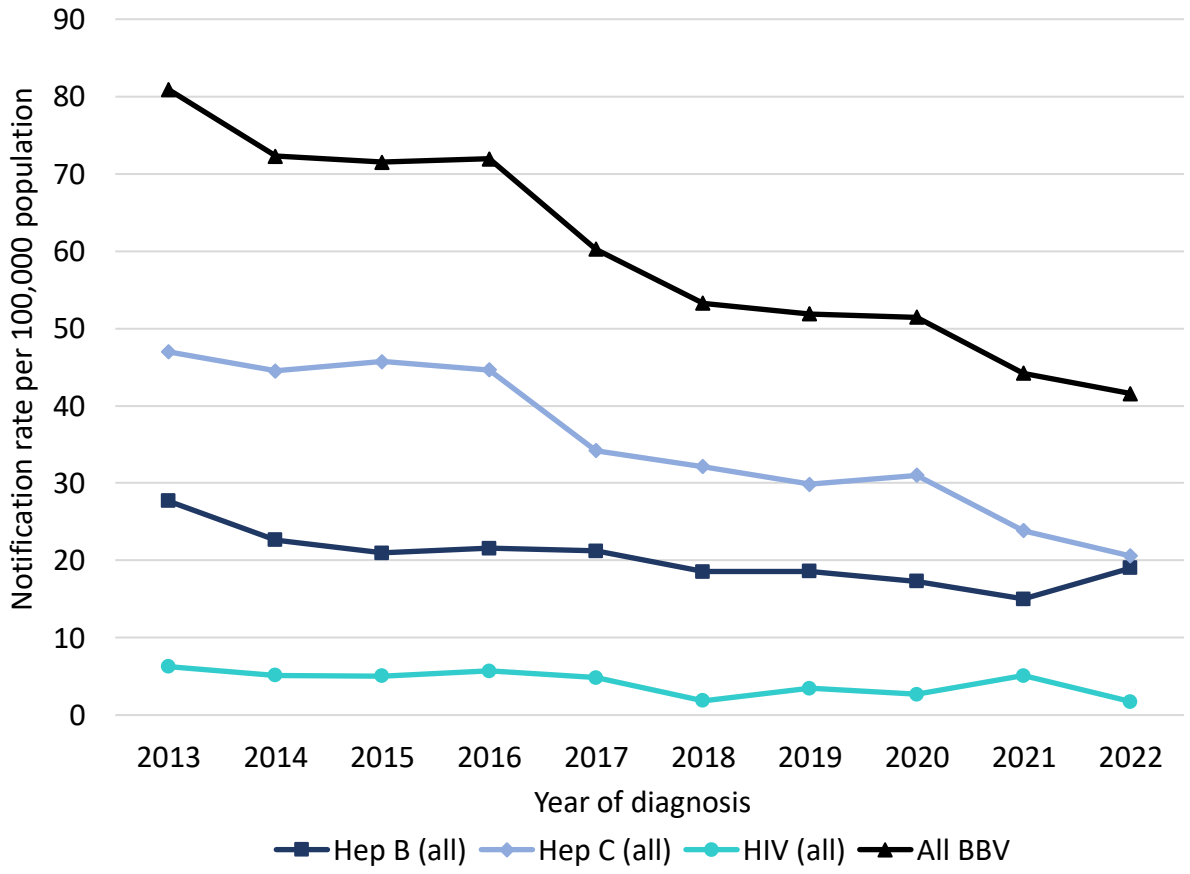

Figure 11: Notification rates per 100,000 population for all BBV and selected diseases in the ACT, between 2013 and 2022

Hepatitis C

For hepatitis C (newly acquired), 71.0% of notifications between 2013 and 2022 (n=88) were for males and 29.0% for females (n=36). There were 24 notifications for Aboriginal and/or Torres Strait Islander people (19.4%) and 92 for Non-Indigenous people (74.2%). The remainder had unknown Aboriginal and/or Torres Strait Islander status. The median age was 28 years (range <15-61, IQR 13.5) for all people, 28.5 years (range <15-61, IQR 10) for males, and 28 years (range <15-47, IQR 14) for females. For Aboriginal and/or Torres Strait Islander people, the median age was 25 years (range <15-44, IQR 11.5) and for Non-Indigenous people, 31 years (range <15-61, IQR 13).

The total notification rate per 100,000 population for hepatitis C (newly acquired) reduced by half between 2013 and 2022, from 4 to 2 (Figure 12). For males, the notification rate reduced overall with fluctuations in 2016 and 2020. For females, the notification rate reduced to 0 in 2022. For Aboriginal and/or Torres Strait Islander people, there were <5 notifications for hepatitis C (newly acquired) per year for all years except 2020, in which there were six cases notified. This equated to a rate of 71 per 100,000 population, compared with 2 per 100,000 for Non-Indigenous people the same year. However, low numbers limited interpretation of trends.

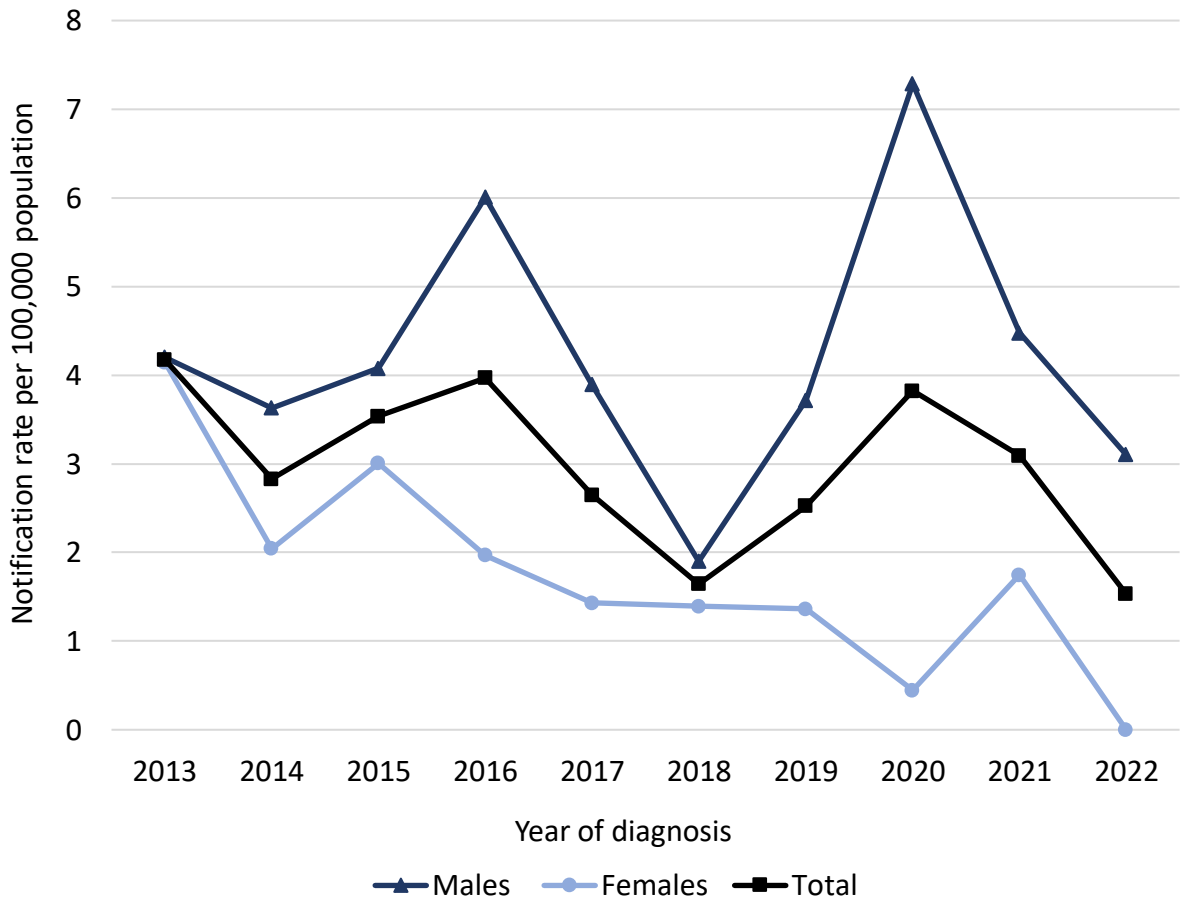

Figure 12: Total and sex-specific hepatitis C (newly acquired) notification rates per 100,000 population in the ACT, between 2013 and 2022

For hepatitis C (unspecified) 64.8% of notifications (n=868) were for males and 35.2% for females (n=471). There were 151 notifications for Aboriginal and/or Torres Strait Islander people (11.3%) and 886 for Non-Indigenous people (66.2%). The remainder had unknown Aboriginal and/or Torres Strait Islander status. The median age was 41 years (range <15-90, IQR 20) for all people, 42 years (range <15-90, IQR 17) for males, and 40 years (range <15-85, IQR 22) for females. For Aboriginal and/or Torres Strait Islander people, the median age was 37 years (range 17-66, IQR 17) and for Non-Indigenous people, 41 years (range <15-90, IQR 20).

The total notification rate for hepatitis C (unspecified) reduced between 2013 and 2022, from 43 to 19 per 100,000 population (Figure 13). There was a modest increase in the notification rate for males from 25 in 2021 to 30 in 2022.

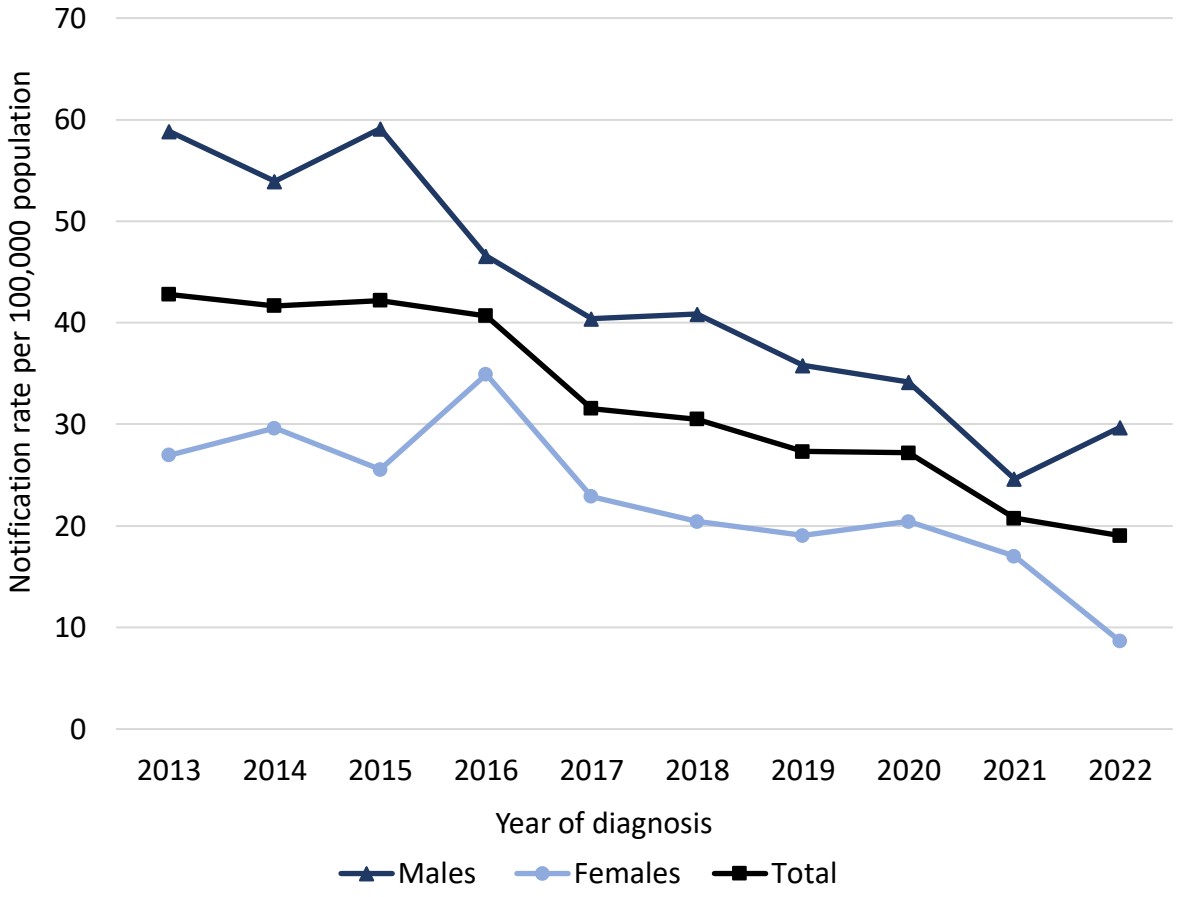

Figure 13: Total and sex-specific hepatitis C (unspecified) notification rates per 100,000 population in the ACT, between 2013 and 2022

The hepatitis C (unspecified) notification rate per 100,000 population for Aboriginal and/or Torres Strait Islander people increased from 140 in 2013 to 233 in 2019, followed by an almost two-thirds reduction to 79 in 2022 (Figure 14). Notification rates for Aboriginal and/or Torres Strait Islander males were higher than for females, with peaks in 2014 and 2017 where the rate exceeded 400 per 100,000 population.

The overall notification rate for Aboriginal and/or Torres Strait Islander people was higher than for Non-Indigenous people—by up to twelve-fold. However, this gap reduced over the study period (Figure 14).

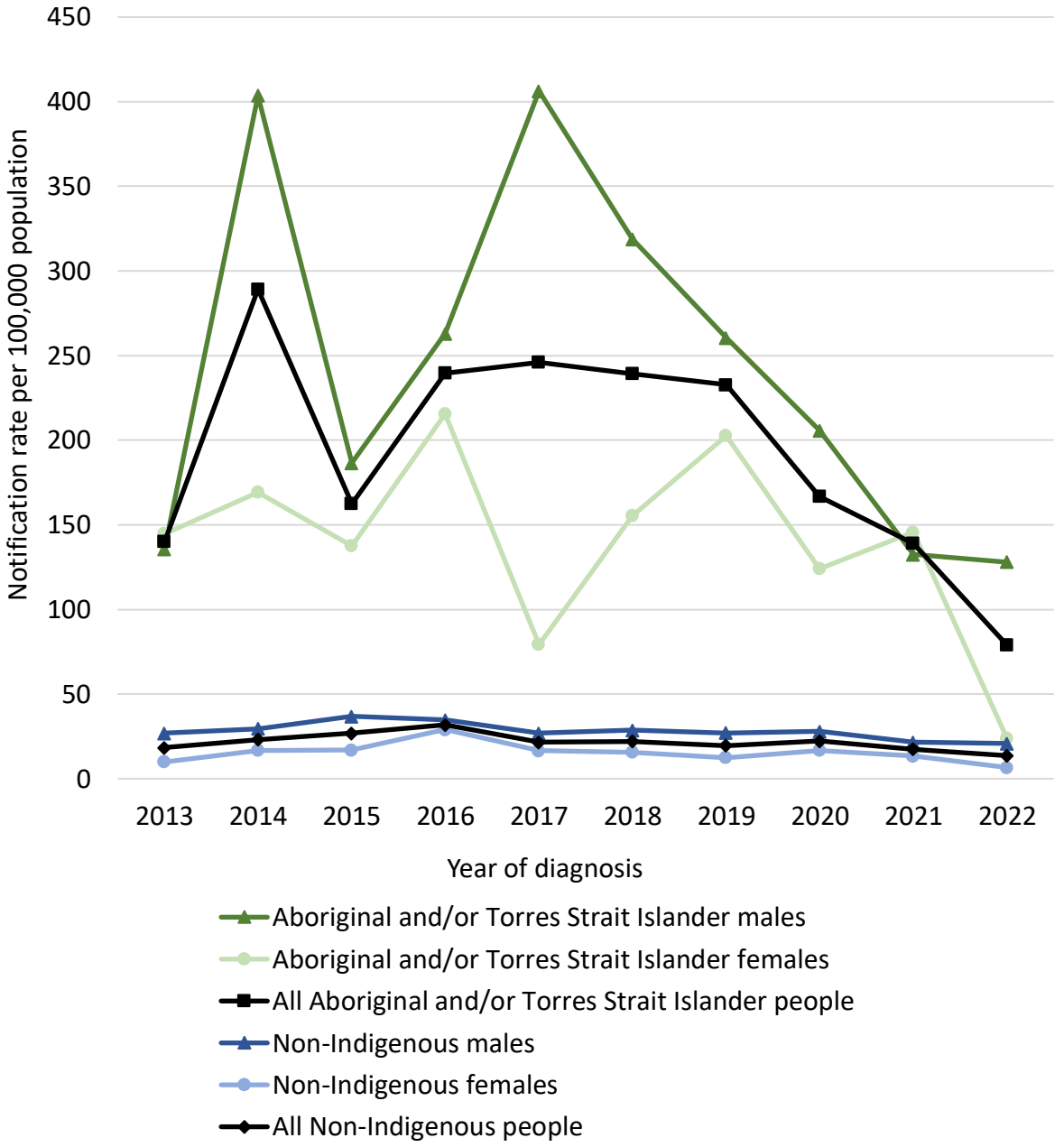

Figure 14: Sex- and Aboriginal and/or Torres Strait Islander status-specific hepatitis C (unspecified) notification rates per 100,000 population in the ACT, between 2013 and 2022

For hepatitis C (unspecified), the notification rate relative percentage change was negative for every quarter from Q2 2020 to Q4 2022 (Figure 15). For hepatitis C (newly acquired), the relative percentage change was positive for the second half of 2020 and all quarters of 2021 besides Q3, but lower for all quarters of 2022.

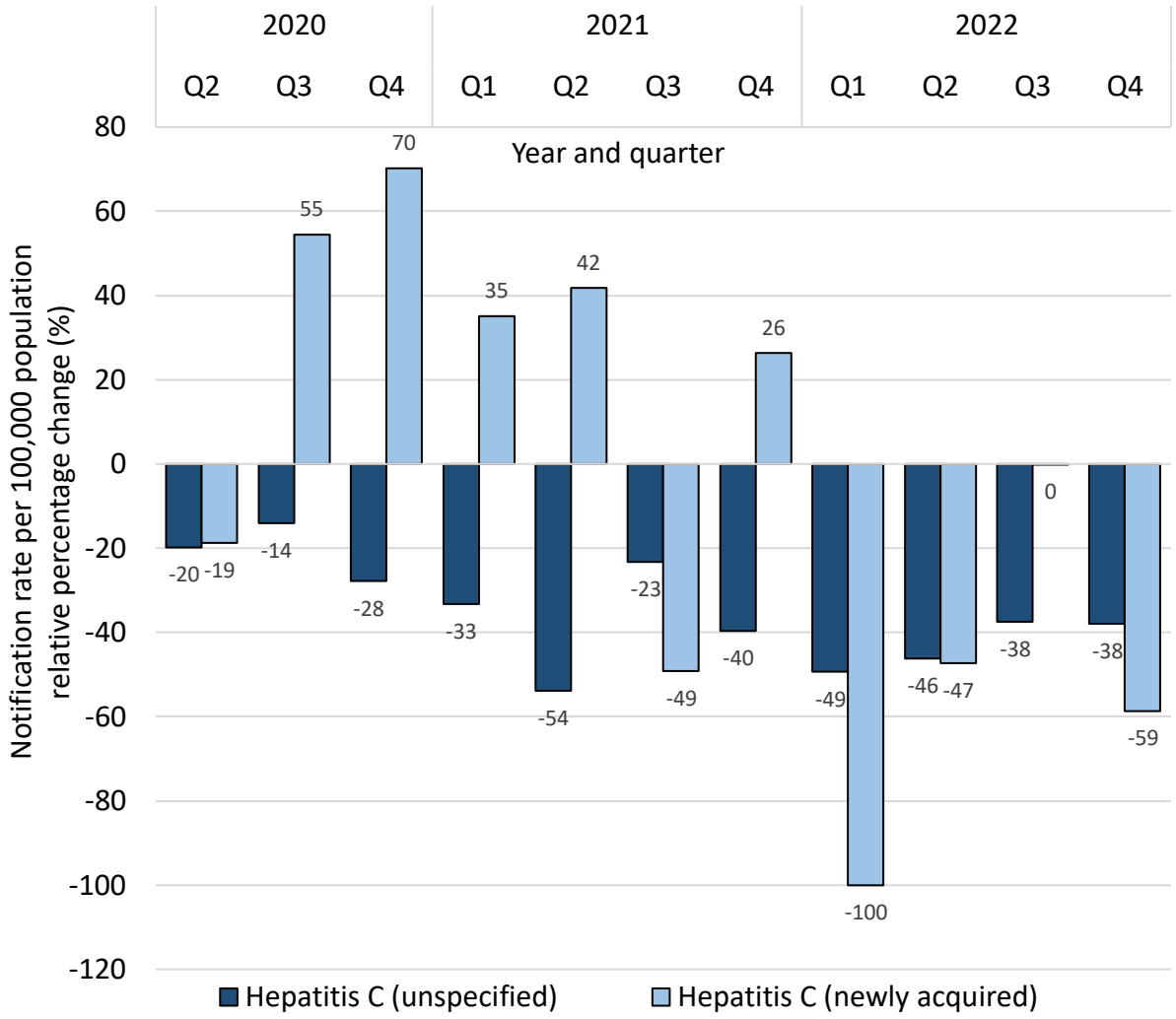

Figure 15: Relative percentage change in quarterly hepatitis C (newly acquired and unspecified) notification rates per 100,000 population in the ACT, between Q2 2020 and Q4 2022

Hepatitis B

For hepatitis B (newly acquired), the majority of notifications were for males with <5 notifications for females. All notifications were for Non-Indigenous people. The median age was 51 years (range 26-75, IQR 33) for all people, 52 years (range 26-75, IQR 28) for males and 44 years for females. Although low numbers limited interpretation of rates, the annual notification rate for hepatitis B (newly acquired) ranged from 0 to 1 per 100,000 population between 2013 and 2022.

For hepatitis B (unspecified), 54.4% of notifications (n=452) were for males and 45.6% for females (n=379). There were 12 notifications for Aboriginal and/or Torres Strait Islander people (1.4%) and 754 for Non-Indigenous people (90.7%). The median age was 36 years (range <15-94, IQR 19) for all people, 37 years (range <15-94, IQR 17) for males, and 35 years (range <15-88, IQR 20) for females. The median age for Aboriginal and/or Torres Strait Islander people was 40 (range 18-57, IQR 20) compared with 36 years (range <15-94, IQR 19) for Non-Indigenous people.

The total notification rate per 100,000 population for hepatitis B (unspecified) decreased from 27 in 2013 to 15 in 2021, before increasing again to 19 in 2022 (Figure 16). Between 2021 and 2022, the notification rate increased from 15 to 19 per 100,000 population, with similar increases for males and females.

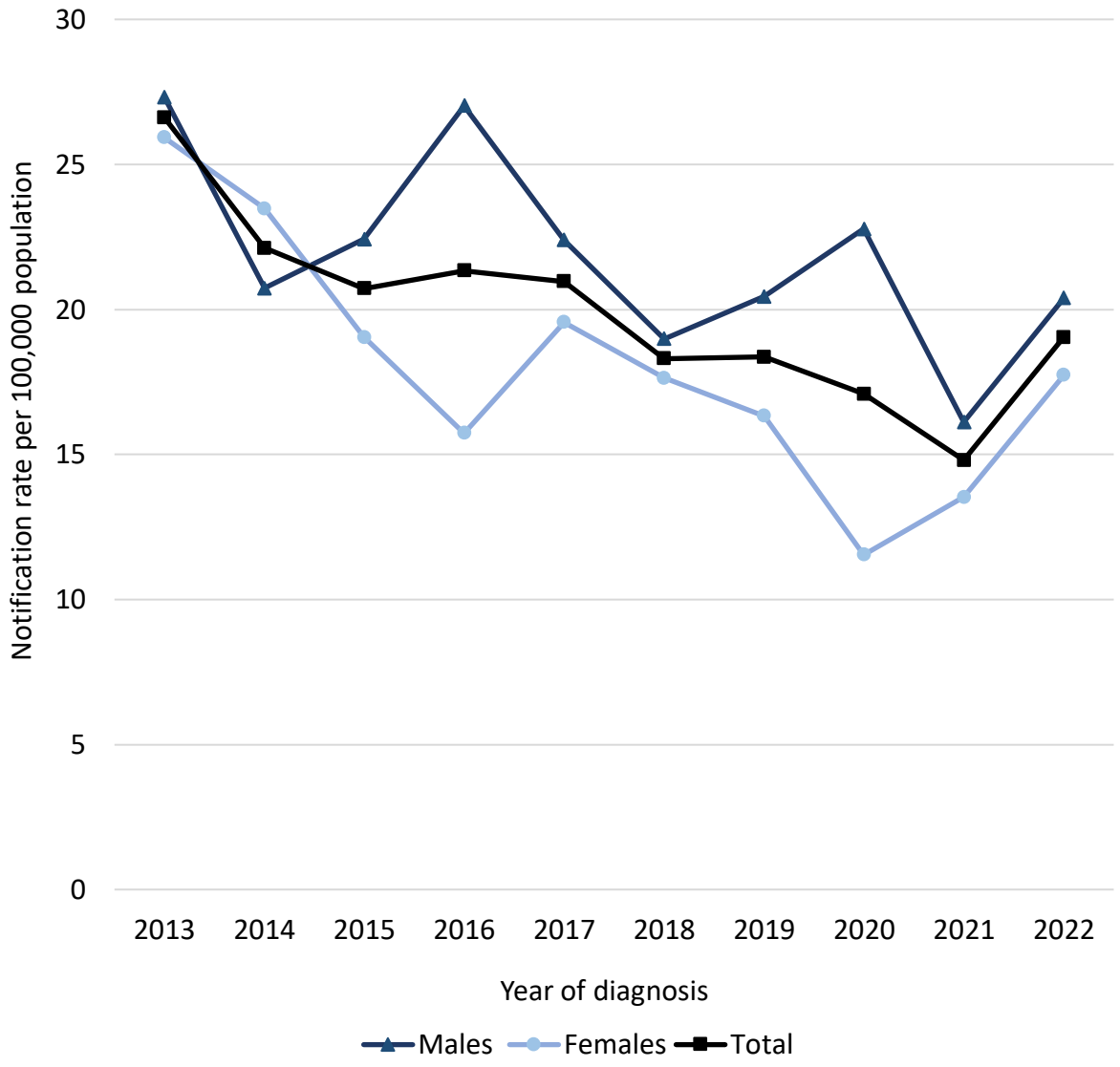

Figure 16: Total and sex-specific hepatitis B (unspecified) notification rates per 100,000 population in the ACT, between 2013 and 2022

For hepatitis B (unspecified), the highest age-specific notification rates were among the 25-34- and 35-44-years age groups (Figure 17). Although the notification rate for the 25-34-years age group fluctuated across the study period, there was an overall reduction from 71 in 2013 to 20 in 2021 before notifications increased by more than two-fold to 44 in 2022.

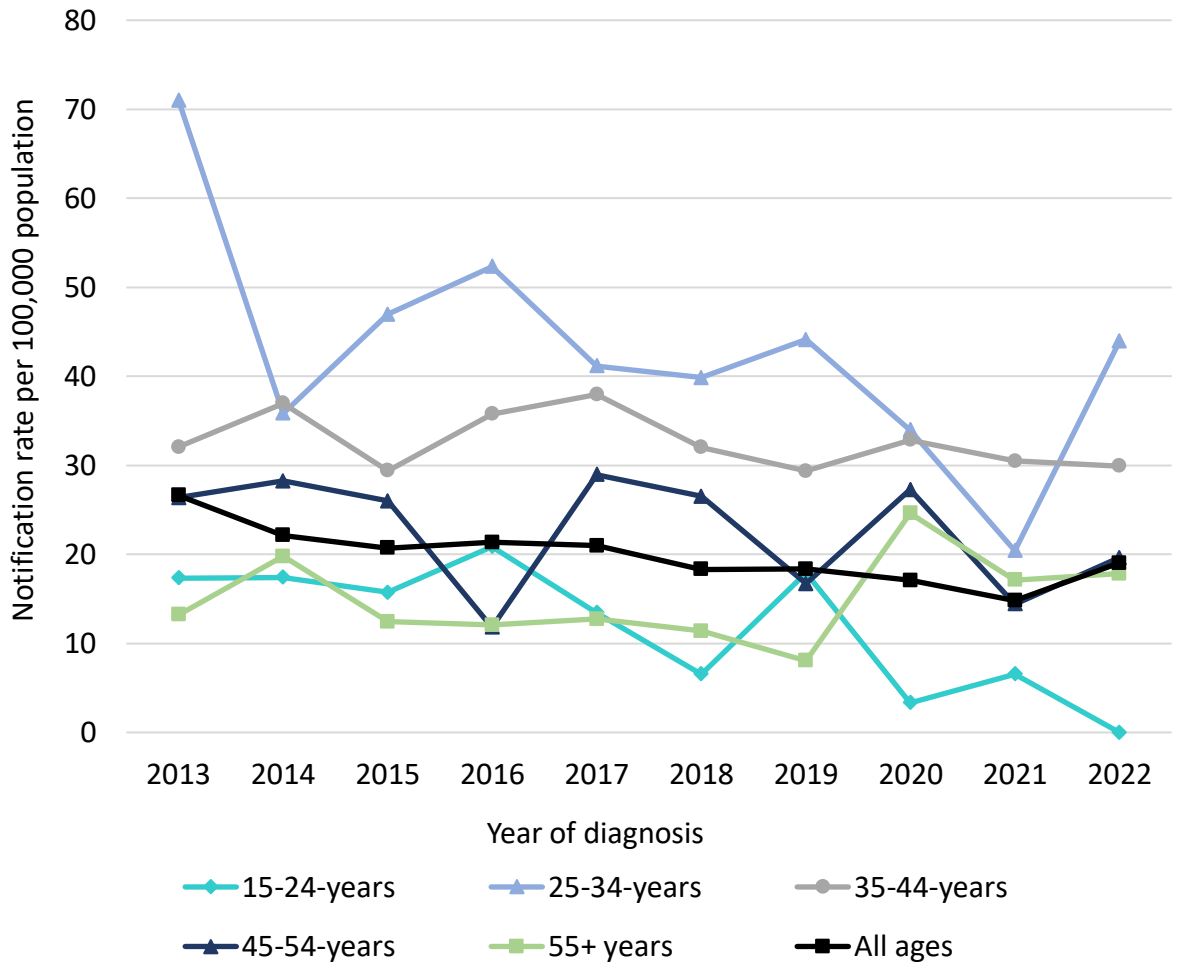

Figure 17: Age-specific hepatitis B (unspecified) notification rates per 100,000 population in the ACT, by age group, between 2013 and 2022

Hepatitis D

There were eight notifications for hepatitis D, all notified between 2018 and 2022. Notifications were predominantly for males and all were for Non-Indigenous people. The median age of cases was 37.5 years. A small number of cases (n<5) were overseas acquired. However, data for likely source of infection were only available for <5 cases. The number of notifications did not increase between 2018 and 2022. However, analysis of trends was limited by low numbers.

HIV

For HIV (newly acquired), the vast majority of notifications between 2013 and 2022 (n=42) were for males with <5 for females. There were no notifications for Aboriginal and/or Torres Strait Islander people, 40 for Non-Indigenous people (95.2%), and two for people of unknown Aboriginal and/or Torres Strait Islander status. The median age was 29 years (range 20-72, IQR 23) for all people, 29 years (range 20-72, IQR 22) for males, and 41 years for females. There were 27 confirmed cases (64.3%) and 15 probable cases (35.7%).

For HIV (unspecified), 74.8% of notifications (n=98) were for males and 25.2% for females (n=33). There were <5 notifications for Aboriginal and/or Torres Strait Islander people (<3.8%) and 125 for Non-Indigenous people (95.4%). The median age was 39 years (range 16-79, IQR 19) for all people, 39.5 years (range 21-79, IQR 18) for males, and 39 years (range 16-70, IQR 19) for females.

The total notification rate per 100,000 population for HIV (unspecified) decreased from 4 in 2013 to 2 in 2022, with fluctuations across this period (Figure 18). For HIV (newly acquired), the total notification rate reduced substantially, from 2 per 100,000 population in 2013 to 0 in 2021 and 2022.

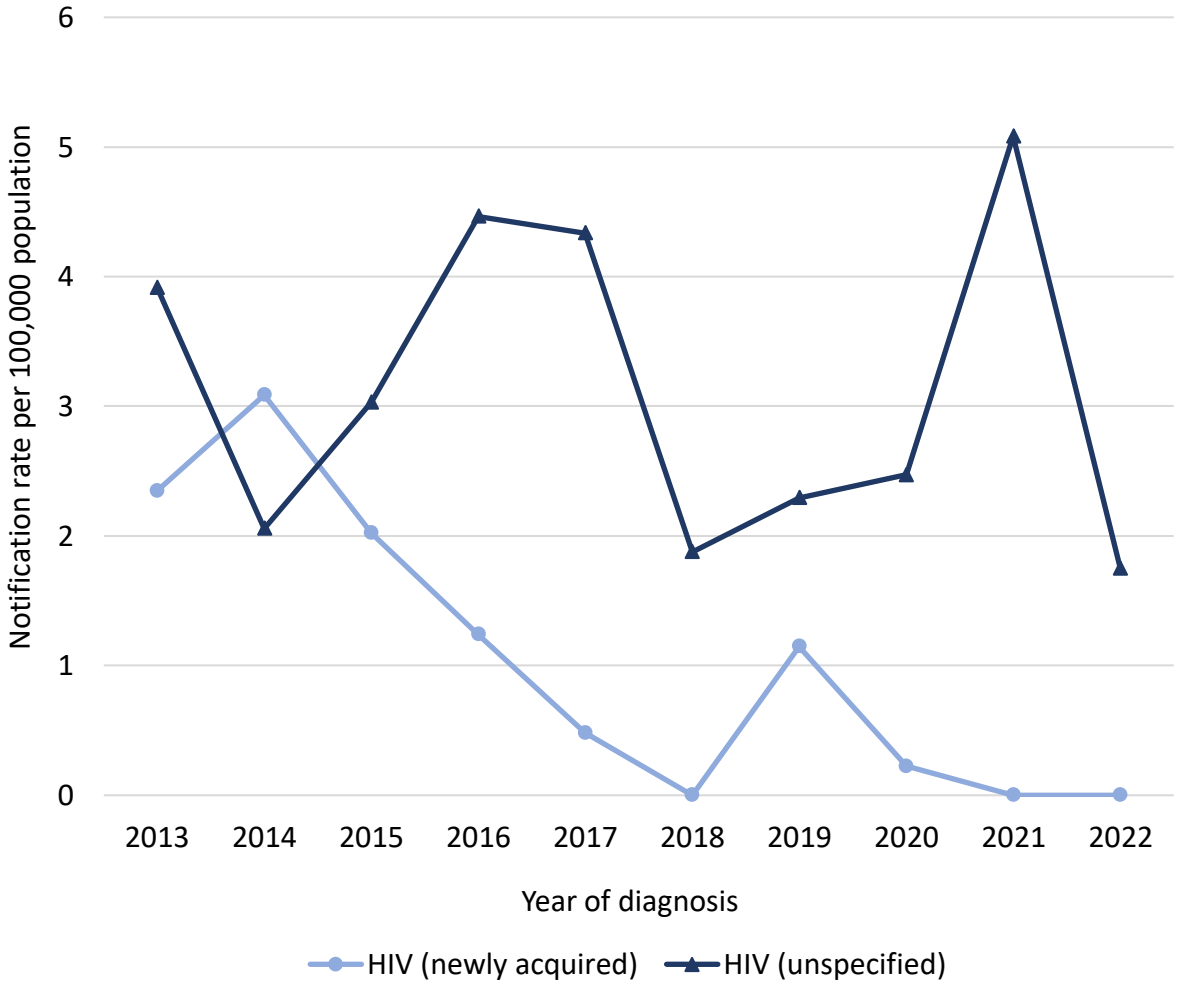

Figure 18: HIV (newly acquired and unspecified) notification rates per 100,000 population in the ACT, between 2013 and 2022

For HIV (unspecified), the sex-specific notification rate for males reduced from 6 in 2013 to 2 in 2022 but fluctuated across the study period (Figure 19). For females, notification rates were similar in 2013 and 2022 at <2 per 100,000 population.

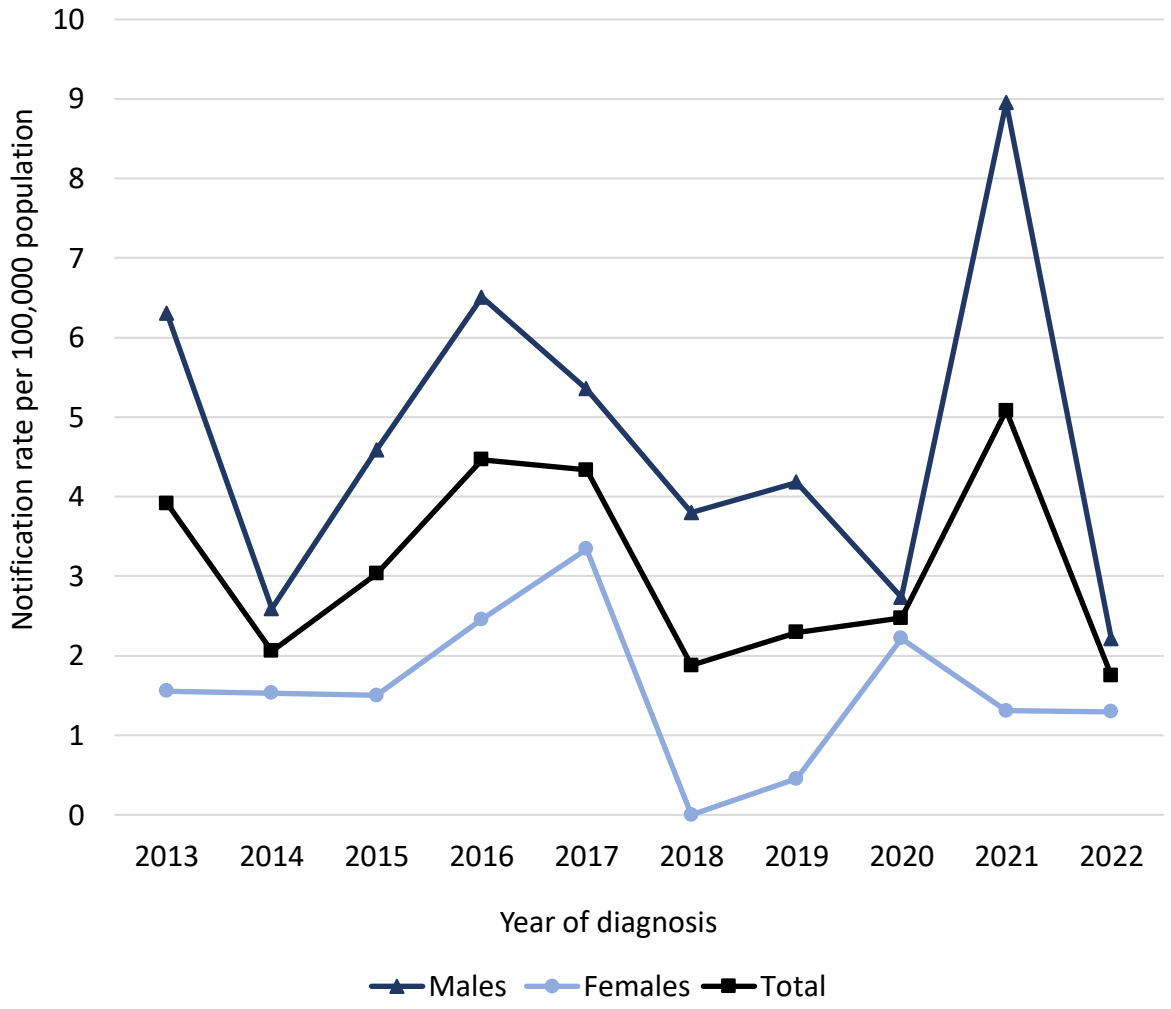

Figure 19: Total and sex-specific HIV (unspecified) notification rates per 100,000 population in the ACT, between 2013 and 2022

Discussion

Sexually transmissible infections

For all STI, the total notification rate per 100,000 population in the ACT increased from 364 in 2013, to 411 in 2022, primarily due to an increase in gonococcal infection notifications. These findings indicate additional work, with a focus on gonococcal infections, is required to address increasing STI notification rates in the ACT.

Between 2013 and 2022, there was a two-and-a-half-fold increase in the total gonococcal infection notification rate, with a modest dip in 2020. Although notifications were predominantly (80.9%) for males, notification rates for both males and females increased across the study period. While the absolute increase was greater for males, females had a larger relative increase—almost five-fold. The most substantial absolute increases for males were among the 25-34-years and older age groups, with

only a modest increase for males aged 15-24 years. In comparison, the notification rate for the 15-24-years age group for females increased by greater than two-fold. A shift in the epidemiology of gonococcal infection notifications away from largely GBMSM to a greater number of heterosexual young adults was reported in national data for the period between 2017 and 2021, and by a South Australian study between 2012 and 2017 (15,36). Changes in risk perceptions among young heterosexual adults in Australia, may have contributed to the increase in notifications among younger females, who are more likely to be infected through opposite sex sexual exposures (compared with same sex for males) (37). Limited understanding of the potential consequences of STI, normalisation of STI, and uptake of online methods of meeting sexual partners, have been identified as contributing factors (37). Increases in the notification rate among males in the older age groups may be related to the uptake of HIV pre-exposure prophylaxis (PrEP), which has increased gradually since 2018 (38). Asymptomatic STI screening is recommended three months after initiation of PrEP and every three months while PrEP is used, resulting in high ascertainment of asymptomatic STI cases among this group (39). Between 2019 and 2022, uptake of PrEP in Australia was highest among males in the 25-34-years age group (38).

Aboriginal and/or Torres Strait Islander people had higher gonococcal infection notification rates than Non-Indigenous people with a steeper upward trend, especially from 2020 onwards. The proportion of gonococcal infection notifications for females was higher for Aboriginal and/or Torres Strait Islander people—43.6% compared with 18.7% for the whole of the ACT—for all notifications between 2013 and 2022. Although low numbers limited examination of trends by sex, Aboriginal and/or Torres Strait Islander females had a notification rate more than 10-fold that for Non-Indigenous females in 2022. This is consistent with national data which showed that in 2021, compared with Non-Indigenous people (who had higher rates of transmission among GBMSM), there was greater heterosexual transmission and higher female-to-male ratio for gonococcal infections among Aboriginal and/or Torres Strait Islander people (40). Targeted future studies and the collection of high-quality enhanced surveillance data are needed to understand the factors contributing to increased gonococcal infection notifications among Aboriginal and/or Torres Strait Islander people, especially females, in the ACT. Co-designed public health interventions targeting Aboriginal and/or Torres Strait Islander people are also required to address escalating gonococcal infection notification rates.

Examination of the relative percentage change showed the gonococcal infection notification rate for females continued to rise throughout the COVID-19 pandemic, positive for every quarter between Q2 2020 and Q4 2022. In comparison, the notification rate for males appeared to be supressed by the pandemic, with a negative relative percentage change for most quarters until Q2 2022. A range of factors may have contributed to this pattern. Reduced availability of health services and associated

reductions in asymptomatic screening may have had a greater impact on notification rates for males, as three-monthly STI screening is recommended for all men who have had any type of sex with another man in the past three months (41). Compared with females, males may also be more likely to acquire infections through sex on premises venues or clubs, the closure of which during periods of 2020 and 2021 may explain some of the discrepancy in sex-specific relative percentage change (42). The routine collection of enhanced data on sexual exposures and risk behaviours, which commenced in the ACT in early 2022, and analyses using genomic data to explore transmission dynamics among sexual networks, may assist in better understanding these patterns. Additionally, public health interventions aimed at addressing increasing gonococcal infection notification rates in the ACT, especially among females, are needed.

The notification rate for infectious syphilis (<2 years) increased by around two-and-a-half-fold during the study period, with a sharp spike peaking in 2019. Notifications were predominantly for males. In comparison, there was no overall increase in notification rate for syphilis >2 years or unspecified duration. The notification rate for infectious syphilis among Aboriginal and/or Torres Strait Islander people was substantially higher than the overall ACT rate; however, there were no notifications for Aboriginal and/or Torres Strait Islander people in 2021 and 2022. These findings are in line with national syphilis surveillance data indicating Non-Indigenous men represented the highest proportion of syphilis notifications in major cities in 2022 (43). However, the increase in syphilis infections among females reported in some states and territories was not seen in the ACT, likely contributing to the absence of notifications for congenital syphilis over the study period (44,45).

Although total and female chlamydial infection notification rates decreased slightly between 2013 and 2022, rates among males increased for all age groups besides the 15-24-years age group. Across the study period, there was a shift from higher notification rates for females from 2013 to 2015, to higher rates for males from 2016 onwards, primarily due to an increase for males in the 25-34-years age group. As for gonococcal infections, use of HIV PrEP and its associated three-monthly STI screening may have contributed to the increase among males due to the detection of asymptomatic or mildly symptomatic infections (38). Females with STI are more likely than males to be asymptomatic (6,7). Although data for sexual exposure type and use of HIV PrEP were not examined in this study, future investigations using enhanced surveillance data are needed to determine the reasons underpinning the shifting epidemiology towards increasing gonococcal infection notifications and paradoxical reduction in chlamydial infection notifications, among younger females—particularly as these infections are frequently tested for simultaneously (41). Increasing rates of both gonococcal and chlamydial infections among older males (25-34-years age group and older) suggest the need for future targeted research to clarify the role of HIV PrEP in increasing STI notifications among this group. Such

studies may assist in determining what further public health actions may be most effective in reducing transmission.

Among Aboriginal and/or Torres Strait Islander people, chlamydial infection notification rates increased substantially over the study period, particularly for females, although remained lower than the national rates for Aboriginal and/or Torres Strait Islander people (14). Large increases in notification rates for both gonococcal and chlamydial infections among Aboriginal and/or Torres Strait Islander females in the ACT suggest the need for further investigation into the drivers underpinning these trends, to inform the design of interventions to address them. However, data for Aboriginal and/or Torres Strait Islander status were only 69% complete for chlamydial infection notifications, as case follow-up—including the collection of information on Aboriginal and/or Torres Strait Islander status—is not routinely undertaken for chlamydial infection notifications in the ACT. Initiatives to improve the completeness of Aboriginal and/or Torres Strait Islander status, such as the inclusion of an Aboriginal and/or Torres Strait Islander status field on pathology request forms and the development of an electronic clinician notification form, are recommended.

Sexually acquired shigellosis accounted for approximately 30% of confirmed shigellosis cases between 2013 and 2022, almost entirely among GBMSM. Of these, all infections locally acquired within the ACT were for GBMSM, with 77.8% *Shigella sonnei* biotype G, most of which were MDR. Previous studies have found *Shigella sonnei* to be the most common species in Australia, with biotype G predominating in sexually acquired shigellosis cases among GBMSM (46,47,48). The circulation of MDR *Shigella sonnei* among GBMSM in Australia presents a significant public health threat (21). Effective surveillance of sexually acquired shigellosis should be undertaken and advice routinely provided to GBMSM with shigellosis regarding preventative practices, such as avoiding sex during symptomatic infections until medically cleared, using barriers during all types of sex, and washing genitals, toys, hands and anus thoroughly before and after sex (49). Three overseas acquired cases of mpox were notified in the ACT in 2022. Although all were overseas acquired, there remains a need for ongoing consideration of the potential for local mpox transmission in the context of increasing rates of STI.

Blood borne viruses

For all BBV, the total notification rate per 100,000 population decreased steadily from 81 to 42 between 2013 and 2022, indicating the ACT contributed to Australia's progress towards eliminating BBV as a public health threat. High uptake of childhood hepatitis B vaccination, improvements in testing and treatment, education, more equitable access to health care, and other prevention activities, have led to an overall reduction in notifications for hepatitis B, hepatitis C, and HIV in Australia over the past decade (25,26,27).

Notification rates for both newly acquired and unspecified hepatitis C infections halved across the study period. Examination of the relative percentage change during the COVID-19 pandemic showed the notification rate was lower than the pre-pandemic five-year quarterly mean for all quarters of 2022 for hepatitis C (newly acquired) and all quarters of the pandemic for hepatitis C (unspecified). This suggests the ACT contributed to the national goal of making significant progress towards eliminating hepatitis C as a public health threat, including during the COVID-19 pandemic (26). However, reductions in testing may have resulted in reduced detection of infections from 2020 onwards (50,51). Notifications for Aboriginal and/or Torres Strait Islander people represented a high proportion of hepatitis C notifications—19.4% for newly acquired and 11.3% for unspecified infections—compared with approximately 2.0% of the ACT population who are Aboriginal and/or Torres Strait Islander people (35). Although interpretation of trends for hepatitis C (newly acquired) among Aboriginal and/or Torres Strait Islander people was limited by small numbers, notifications for hepatitis C (unspecified) declined by more than 40% between 2013 and 2022. While this indicates progress is being made through existing interventions, disproportionate hepatitis C notification rates for Aboriginal and/or Torres Strait Islander people—particularly males—suggests a public health disparity in the ACT. Ongoing public health action aimed at maximising engagement with testing and treatment services, in addition to prevention activities, is needed to ensure the continued reduction of hepatitis C rates among Aboriginal and/or Torres Strait Islander people in the ACT.

Hepatitis B notification rates decreased steadily over the study period with low rates of newly acquired infections. However, there was an uptick in the notification rate for hepatitis B (unspecified) in 2022 due to a more than two-fold increase for the 25-34-years age group. The resumption of international travel to Australia from late 2021 may have contributed to this increase (52). For all hepatitis B notifications, the highest age-specific rates were among the 25-34-years age group. Decreasing rates of hepatitis B among younger age groups in Australia is attributed to high uptake of childhood vaccination, recommended for infants, non-immune Aboriginal and/or Torres Strait Islander people, health care workers, people with medical risk factors, migrants from hepatitis B-endemic countries, and other groups (53). Notifications for Aboriginal and/or Torres Strait Islander people accounted for only 1.4% of notifications for hepatitis B (unspecified) over the study period and no notifications for hepatitis B (newly acquired) or hepatitis D. Therefore, existing interventions, such as vaccination, appear to have been effective in limiting hepatitis B infections among Aboriginal and/or Torres Strait Islander people in the ACT (54).

Between 2013 and 2022, notification rates for HIV (newly acquired) reduced steadily with no cases notified in the ACT in 2021 or 2022. Uptake of HIV PrEP—with the ACT recording the highest use per 100,000 population of any Australian state or territory—has likely contributed to reductions in newly

acquired HIV cases since its listing on the Pharmaceutical Benefits Scheme in April 2018 (38). Notification rates for HIV (unspecified) fluctuated but reduced by approximately half, broadly in line with national trends (30). Most notifications were for males and newly acquired infections were almost exclusively for males. Although data for sexual exposures were not examined in our study, GBMSM sexual contact remains the predominant mode of HIV transmission in Australia (30). Aboriginal and/or Torres Strait Islander people accounted for a very small number of notifications for HIV (unspecified) and no newly acquired cases between 2013 and 2022, suggesting the ACT contributed to the national target of reduced HIV transmissions among Aboriginal and/or Torres Strait Islander people (54).

Strengths and limitations

Among the strengths of this study was the inclusion of data for all notifiable STI and BBV in the ACT, providing a broad overview of notification patterns over the study period. The study used notifiable disease data collected by trained staff using robust government processes, with high data completeness for most variables.

A limitation of this study was that it relied on notifications data obtained through passive surveillance. Notifications only represent the proportion of infections in the population where health care was sought, testing was undertaken, a diagnosis was made, and the case was notified to the health department. Changes in notification rates do not reflect changes in disease prevalence or incidence alone but can be affected by modifications to testing policies, clinical practice guidelines, test types (and their sensitivity), health promotion campaigns, and screening programs. Changes in case definitions for some diseases during the study period, may also have affected our estimates. However, as these changes were predominantly minor, this impact is likely to have been minimal (24).

For some diseases, small numbers of annual notifications limited the analyses that could be undertaken and impeded interpretation of trends. Analysis of notification rates by demographic variables could not be undertaken for all diseases and demographic groups. Data for STI and BBV testing were not examined due to unavailability, preventing assessment of changes in notification rates relative to the total number of tests performed for each disease. Reduced testing during the COVID-19 pandemic for some diseases may have resulted in underestimates in the number of infections over this period. Data from enhanced surveillance regarding sexual exposures, risk factors, and clinical management, were also not examined due to unavailability for some diseases, limited time, and being outside the scope of the study, which limited investigation of the reasons underpinning the identified patterns.

Although demographic data were highly complete, data for likely source of infection had limited completeness, precluding examination of trends in travel-related and locally acquired infections. Data

for Aboriginal and/or Torres Strait Islander status were only moderately complete, particularly for STI, which presented a limitation for comparisons of notification rates based on Aboriginal and/or Torres Strait Islander status.

Conclusion

Between 2013 and 2022, STI notification rates increased in the ACT. The most substantial increase was for gonococcal infections, most notably for females in the 15-34-years age group. Although there was an overall drop in STI notifications from the beginning of the COVID-19 pandemic in 2020, the gonococcal infection notification rate for females continued to increase. Chlamydial infection notification rates reduced slightly over the study period but increased among older males (25-34-years age group and older). Aboriginal and/or Torres Strait Islander people had greater increases in both gonococcal and chlamydial infection notification rates than Non-Indigenous people. Notifications for infectious syphilis fluctuated with an overall increase across the study period; however, syphilis notifications for females and Aboriginal and/or Torres Strait Islander people did not increase. The majority of locally sexually acquired shigellosis cases were found to be *Shigella sonnei* biotype G, of which most were MDR.

Recommended future studies include those using enhanced surveillance data on sexual exposures and risk factors, including use of HIV PrEP, to better understand the drivers behind increased STI notification rates in the ACT, with gonococcal infections among females a priority. Public health action to address rising rates of gonococcal infections among females, chlamydial infections among males 25 years and older, and both gonococcal and chlamydial infections among Aboriginal and/or Torres Strait Islander people, are needed. Mechanisms to ensure the collection of highly complete data for Aboriginal and/or Torres Strait Islander status are also required.

Notifications rates for BBV reduced over the study period, with a low number of notifications for newly acquired hepatitis B and HIV infections, indicating the ACT is making progress towards eliminating the public health threat associated with BBV. Although reductions in hepatitis C notification rates suggest progress has been made through existing interventions, disparate rates of hepatitis C among Aboriginal and/or Torres Strait Islander people—particularly males—compared with Non-Indigenous people, suggest the need for public health actions to ensure continued progress towards elimination of hepatitis C as a public health threat.

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CHAPTER THREE: INVESTIGATION OF AN ACUTE PUBLIC HEALTH PROBLEM OR THREAT

Table of Contents

Chapter 3: Investigation of an outbreak of *Salmonella* Agona at a kebab shop in Canberra, ACT

Prologue

This chapter details an investigation into an outbreak of *Salmonella* Agona associated with the consumption of food from a Canberra kebab shop. It fulfills the major competency, *Investigation of an acute public health problem or threat* and the minor competencies, *Peer-reviewed publication* and *Conference presentation.*

Components of this chapter were published in the *Communicable Diseases Intelligence* journal as a short report: Padrotta J, Post J, Marmor A, Pingault N, Pourmarzi D. Kebabs with a side of *Salmonella:* Two outbreaks of *Salmonella* linked to kebab shops in Canberra, ACT. *Commun Dis Intell (2018).* 2022 Dec 15;46. doi: 10.33321/cdi.2022.46.84.

I delivered a long oral presentation of an abstract based on this chapter at the first South Asia Field Epidemiology and Technology Network, Inc. Scientific Conference, held in Canberra from 12-15 September 2023. The abstract is at Appendix A.

My role

This outbreak presented the first opportunity for me to apply and further develop my knowledge in communicable disease outbreak investigation and response. My tasks included:

- attending acute response team (ART) meetings
- developing and applying outbreak case definitions
- undertaking case interviews
- entering case data into the ACT notifiable disease management system and Research Electronic Data Capture databases
- undertaking descriptive analysis of case data
- communicating the findings of the investigation.

I also collated the findings of environmental and laboratory investigations and produced epidemiological summaries throughout the outbreak. At the conclusion of the outbreak, I participated in an after-action review, entered details of the outbreak into the national OzFoodNet Outbreak Register, and drafted an outbreak report. Throughout this process, I worked closely with the ACT OzFoodNet epidemiologist and observed her participation in inter-jurisdictional meetings and liaison with colleagues at New South Wales (NSW) Health regarding the outbreak.

Public health impact

Doner kebabs are known to pose a risk of salmonellosis, having been implicated in previous outbreaks, both in Australia and overseas. This investigation demonstrated the risk of *Salmonella* transmission posed by commercially prepared kebabs, the need for appropriate cleaning and sanitising of kebab shaving equipment, and the importance of a second kill step in the preparation of kebabs. In response to this outbreak investigation, food safety education and training was provided to staff at the business in question. The business subsequently improved its food safety processes and obtained new equipment and consumables. Follow-up swabs were negative for *Salmonella* and no further outbreak cases were identified. The results of this investigation have also contributed to the initiation of further public health activities in the ACT, including a food sampling strategy specifically targeted at kebab shops.

A few weeks after the outbreak had ended, a second (smaller) outbreak occurred, with two cases who had both eaten at a different kebab shop. Due to the recency of the first outbreak, the second was identified and responded to rapidly, likely preventing further cases. Similar food safety issues were identified at both kebab shops, reinforcing the need for targeted public health interventions for kebab businesses. To communicate this, both outbreak investigations were drafted into a report, published in *Communicable Diseases Intelligence*.

Lessons learned

As the first foodborne outbreak I had been involved in and having occurred early in my MAE, I had much to learn from this outbreak investigation. Although I had interviewed salmonellosis cases prior to this outbreak, witnessing how data collected through routine case interviews can be used to identify and investigate outbreaks cemented my understanding of the importance of collecting sufficient detail, especially around food exposures. As I gained experience interviewing cases, I gradually learned how to word questions to get the best information possible and support cases to recall their food exposures, without being overly suggestive. One case in this outbreak initially did not recall having eaten at the kebab shop in question. By checking their bank records, the case was able to confirm they had eaten a kebab from the business in the days before becoming unwell. Other cases I have interviewed have used their fitness tracker entries to remember what they ate on a particular day. Employing interview strategies such has these has improved my ability to generate detailed and accurate food exposure data from case interviews.

This outbreak provided me with my first exposure to serotyping in outbreak detection and allowed me to witness how outbreaks can be detected through the identification of unusual serotypes, without the need for additional genomic information. It also demonstrated the importance of culture to enable

further analysis of isolates. Participating in ART meetings was useful to understand the teams involved in the management of an outbreak. Observing different chairs lead the meetings also helped me understand the public health leadership strategies used to constructively support teamwork and communication during an acute public health incident.

Drafting a manuscript for publication, selecting a peer-reviewed journal, adhering to author guidelines, managing input from a group of authors, putting together the submission package, and addressing reviewer comments on the draft manuscript was a great experience. Going through this process early in my MAE gave me the skills and confidence to submit future manuscripts for peer-review.

Acknowledgements

I would like to acknowledge and thank my supervisors and co-authors for their guidance and support during this outbreak investigation and subsequent development and revision of this chapter, the published manuscript, and the conference abstract (Appendix A). Thank you to OzFoodNet epidemiologist, Jenny Post, for her work on the outbreak investigation and for patiently guiding me through the process of foodborne outbreak investigation and response.

I acknowledge all ACT Health Directorate staff who contributed to the collection of data used in this analysis. I also acknowledge the following ACT Health Directorate teams who contributed to the outbreak investigation and response: Surveillance Unit, Health Emergency Management Unit, Environmental Health Unit, and medical officers. I acknowledge the work undertaken by NSW Health relating to this outbreak and the contribution to the laboratory investigation provided by the following: ACT Government Analytical Laboratory, Microbiological Diagnostic Unit, the Institute of Clinical Pathology and Medical Research, and ACT Pathology. I acknowledge OzFoodNet and the Office of Health Protection, Department of Health and Aged Care, for providing Outbreak Register data.

Abstract

Background

In April 2022, routine surveillance activities detected an increase in the number of *Salmonella enterica* subspecies *enterica* serovar Agona (*S.* Agona) cases in the ACT. Typically, there are around one-to-two cases of *S.* Agona per year in the ACT. Between February and April 2022, 10 new cases of *S.* Agona were identified with two further cases detected through retrospective review of notification data. This report details a descriptive epidemiological investigation into the outbreak.

Methods

Cases were identified from *S.* Agona notifications made to the ACT Health Directorate through routine passive surveillance. Case interviews were undertaken using standard salmonellosis questionnaires. Outbreak case definitions were established and a case-series study conducted to generate hypotheses regarding potential sources of infection. A descriptive epidemiological investigation was undertaken to describe the outbreak and its associated public health investigation and response, including environmental and laboratory investigations.

Results

Twelve outbreak cases (six males and six females) were identified with onset dates between September 2021 and April 2022. Of the 11 cases interviewed, nine reported having eaten at the same kebab shop in Canberra, ACT in the seven days before becoming unwell. Rotisserie chicken was the only food eaten by all nine cases. These cases were classified as confirmed outbreak cases. The remaining three cases, whose food exposures could not be confirmed, were classified as probable outbreak cases.

Environmental investigations at the business identified several food safety concerns, including cooked meat being kept at insufficient temperatures and inadequate cleaning and sanitising of motorised meat shaving equipment. In addition, cut rotisserie meat was served to customers without the recommended further cooking.

Laboratory investigations identified *S.* Agona in multiple food and environmental samples, including swabs taken from the inner and outer aspects of two meat shaving blades. Phylogenetic analysis of whole genome sequencing showed all human samples were highly related to one another and to environmental samples.

Conclusions

The outbreak's protracted nature and the findings of epidemiological, environmental and laboratory investigations suggested repeated contamination of rotisserie meat from inadequately cleaned meat shaving equipment as the likely outbreak mechanism. This outbreak adds to the evidence regarding the risk of foodborne illness associated with doner kebabs in the context of inadequate food safety practices. The development of specific guidance on appropriate cleaning and sanitising of kebab shaving equipment and the implementation of a second kill step prior to serving rotisserie meat, may reduce the risk of salmonellosis from doner kebabs.

Introduction

Salmonella species are among the most significant foodborne pathogens worldwide, representing the third highest cause of death due to diarrhoeal illness (1). Globally, an estimated 93.8 million cases of gastroenteritis can be attributed to *Salmonella* species annually, resulting in around 155,000 deaths (2). In Australia, *Salmonella* infection is associated with significant morbidity and mortality. In 2015, *Salmonella* gastroenteritis was responsible for more than 90,000 cases, around 4,300 hospitalisations, and 19 deaths with an estimated total cost of AUD $124.4 million (3). Therefore, targeted interventions aimed at preventing *Salmonella* infections remain a public health priority. Consumption of contaminated food is responsible for at least 70% of salmonellosis cases in Australia with outbreaks most commonly associated with poultry meat, eggs, beef, pork, dairy, and fresh produce (4,5). The incubation period is 6 to 72 hours, most often 12-36 hours (6).

There are more than 2,600 distinct *Salmonella* serotypes defined by the World Health Organization (7). Less than 100 of these account for most infections in humans (7). In Australia, *S.* Typhimurium is the most frequently notified serotype, estimated to be responsible for more than 90% of foodborne *Salmonella* outbreaks; however, outbreaks of non-Typhimurium serovars present an increasing public health problem (5,8). *S.* Agona was first described in the early nineteen sixties (9). Outbreaks of *S.* Agona occur infrequently in Australia. In 2015, an outbreak of *S.* Agona in Western Sydney was associated with consumption of contaminated sushi (10).

Under certain conditions, doner kebabs are a potentially hazardous food, associated with an increased risk of transmission of foodborne pathogens, including *Salmonella* (11). Doner kebabs have been linked to previous *Salmonella* outbreaks in Australia and overseas (12,13,14). Between 2000 and 2021, there were 42 outbreaks of foodborne illness in Australia, reported to and investigated by OzFoodNet, that were suspected or confirmed to have been related to the consumption of kebabs, souvlakis, or gyros.[c] This highlights the risk of foodborne illness associated with kebabs, particularly in the context of inadequate food safety practices. The handling, cooking, and storage of large blocks of kebab meat can permit rapid growth of bacteria under certain conditions. These include meat being handled with poor hygiene practices, holding meat at temperatures that enable bacterial growth, inadequately thawing meat before cooking, and repeatedly cooking and chilling kebab blocks over multiple days (9).

Salmonellosis is a notifiable condition in the ACT under the *Public Health Act 1997*. Serotyping is derived *in silico* from whole genome sequencing (WGS), routinely performed for culture-positive

[c] Outbreak Register data (unpublished) provided by the Office of Health Protection, Department of Health and Aged Care, on October 6, 2022, on behalf of OzFoodNet.

specimens at either the Microbiological Diagnostic Unit (MDU) or Institute of Clinical Pathology and Medical Research (ICPMR). When multiple cases with the same serovar/subtype are identified in the ACT, analysis of exposure history may be undertaken to identify commonalities. Further phylogenetic analysis by multilocus sequence typing (MLST) (low level of discrimination) and core genome MLST (cgMLST) (high level of discrimination) can provide additional information to support epidemiological investigations based on WGS (15).

In the ACT, notifications for *S.* Agona typically represent fewer than 2% of salmonellosis cases per year (16). Between 2015 and 2020, there were 10 cases of *S.* Agona notified, with six of these overseas acquired (Figure 1). An increase in *S*. Agona cases in the ACT between February and April 2022 prompted a public health investigation into possible links and sources.

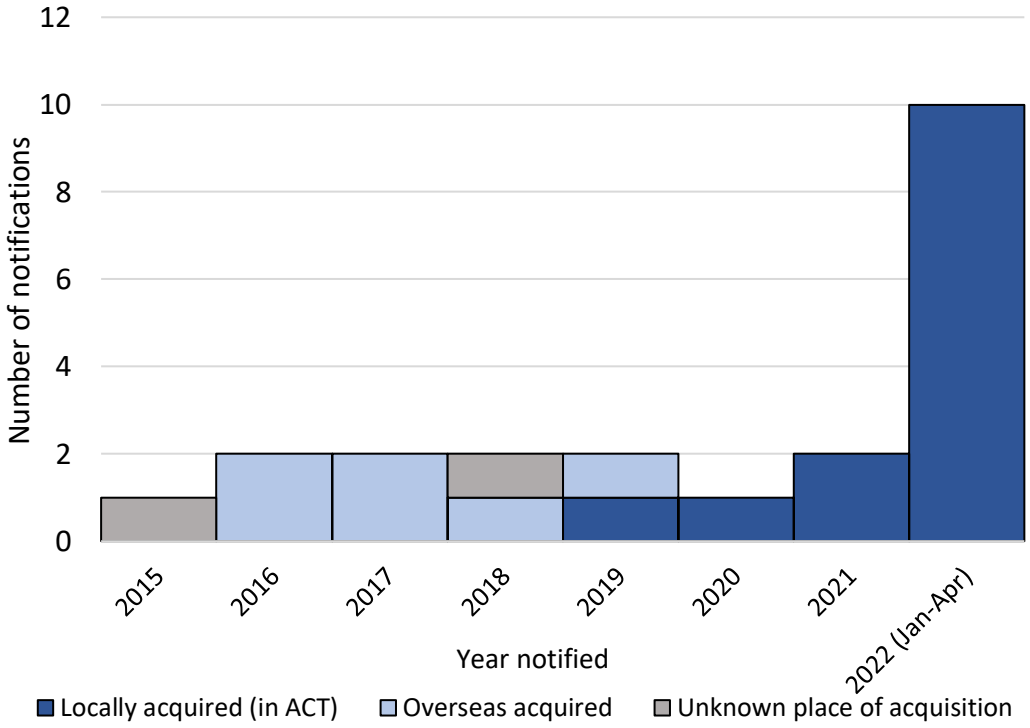

Figure 1: Number of *S.* Agona notifications in the ACT per year by suspected place of acquisition, January 2015 to April 2022

Methods

Human specimens were tested using reflex culture. *Salmonella* isolates were sent to the ICPMR in Sydney or MDU in Melbourne for WGS with *in silico* analysis of serotype. A confirmed outbreak case was defined as laboratory confirmed *S.* Agona reported to the ACT Health Directorate (ACT Health) between September 2021 and April 2022, where the case reported eating from the kebab shop in the seven days before symptom onset. A probable outbreak case was defined as laboratory confirmed *S.* Agona reported during this period, where the case's food exposures were unconfirmed.

The Surveillance Unit conducted interviews for ten cases with residential addresses in the ACT using the standard ACT *Salmonella* Questionnaire for enhanced data collection, which included a three-day food history. Case interview data were stored in a Research Electronic Data Capture database. New South Wales (NSW) Health interviewed one case who lived close to the NSW/ACT border using the OzFoodNet *Salmonella* Hypothesis Generating Questionnaire. No active case finding was undertaken.

A case-series study was conducted to generate hypotheses regarding potential sources of *S.* Agona infection among confirmed and probable outbreak cases. A descriptive epidemiological investigation was undertaken using de-identified case data to describe the outbreak and its associated public health investigation and response. The demographic and clinical characteristics of cases were analysed using Microsoft Excel 2017.

Inspections of the implicated business were carried out by the ACT Health Environmental Health Unit. Environmental swabs and food samples were also collected. Initial microbiological analyses were undertaken by the ACT Government Analytical Laboratory (ACTGAL) using polymerase chain reaction (PCR) and culture. Isolates were sent to MDU for WGS (NextSeq 500, Illumina, USA), MLST, and cgMLST using in-house methods. Phylogenetic analysis of isolates from human and environmental samples using cgMLST was undertaken using the maximum-likelihood method to generate phylogenetic trees. Alignment and single-linkage clustering were used to calculate pairwise single nucleotide polymorphism (SNP) distances. The degree of genomic relatedness was assessed based on only the SNP distance matrix through single-linkage analysis.

These investigations were conducted under the *ACT Public Health Act 1997*. This study was covered by ethics approval from the Australian National University Human Research Ethics Committee (Protocol 2017/909).

Results

Epidemiological investigation

Between 16 February and 4 April 2022, eight cases of *S.* Agona were notified to ACT Health, including one NSW resident from a town close to the ACT border. A further two cases were subsequently notified during the remainder of April 2022. A retrospective review of *S.* Agona notifications during the 12 months prior identified two further cases, notified in September and December 2021. This resulted in a total of 12 *S.* Agona cases notified to ACT Health between 27 September 2021 and 29 April 2022.

Case interviews, completed for 11 of the 12 cases (92%), revealed that other than the NSW resident who travelled daily into ACT, no cases reported travel outside the ACT in the week prior to becoming

unwell. Two cases (one confirmed and one probable) (18%) reported having been in contact with a family or household member (who did not undergo faecal specimen testing) with a similar illness during the seven days prior to their illness. No other common non-food, occupational, or environmental exposures were identified.

During initial case interviews, eight cases (73%) reported having eaten at the same kebab shop in Canberra during the week prior to symptom onset. These cases were classified as confirmed outbreak cases. The remaining three cases (27%) who were interviewed had limited recall of their activities and dietary intake during the week prior to their illness. These cases were initially classified as probable outbreak cases. Two were subsequently re-interviewed and asked to check their bank records to assist recall of foods purchased within the relevant period. One further case subsequently reported having eaten at the kebab shop during the seven days prior to symptom onset and was re-classified as a confirmed case. The individual who could not be interviewed was classified as a probable case.

Data from case interviews for the two cases notified in 2021 revealed both ate at the kebab shop during the seven days before symptom onset. These cases were classified as confirmed outbreak cases. In total, nine confirmed and three probable outbreak cases were identified (Figure 2).

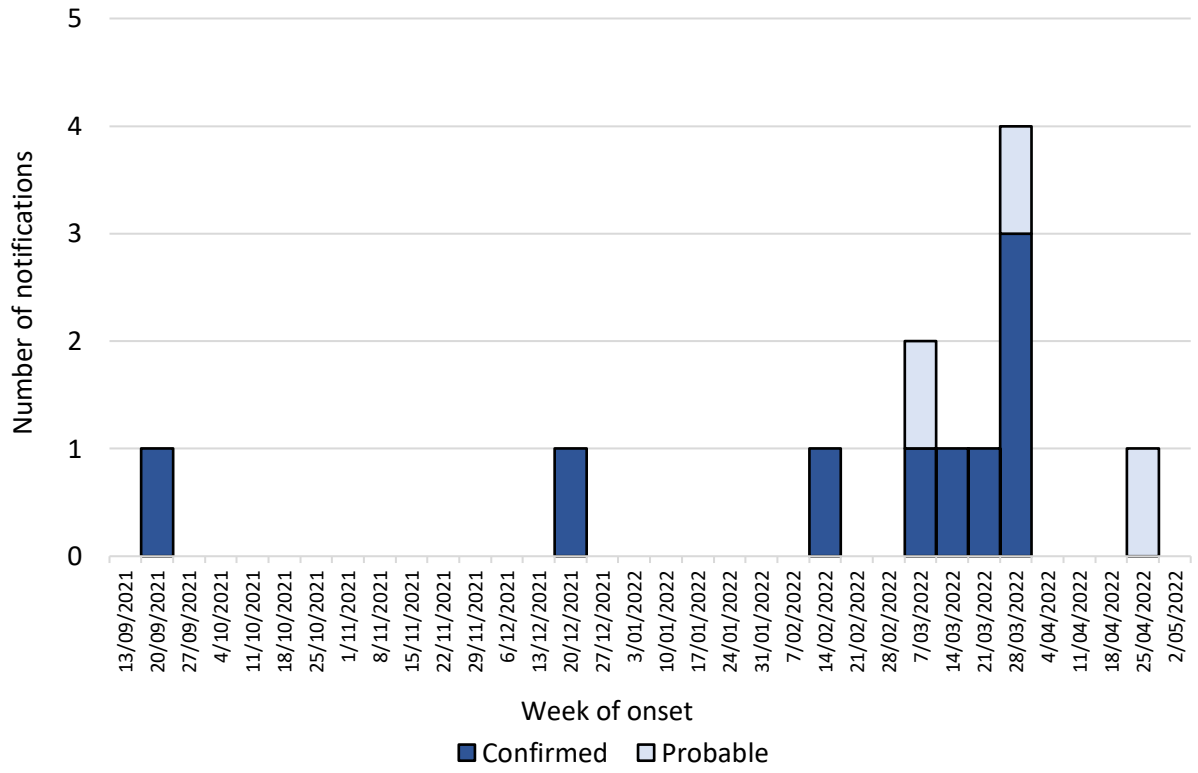

Figure 2: Number of confirmed and probable outbreak cases in the ACT by week of onset, September 2021 to April 2022

The age range of cases was 6-62 years with a median of 28 years. Most cases (75%) were aged between 19 and 41 years. Half of the cases were males and half were females.

Symptom onset dates for 11 of the 12 cases (92%) ranged from 22 September 2021 to 29 March 2022. One case (with a specimen collection date in late April 2022) could not be interviewed so illness onset date could not be confirmed. Specimen collection date was used in lieu of onset date for this case. Excluding this case, the median time between symptom onset and specimen collection was 1 day (range 0 to 7 days). Testing for *Salmonella* spp. was requested by a general practitioner for seven cases (58%) and by an emergency department (ED) doctor for five cases (42%). The median incubation period was 69.7 hours (range 30.5 to 112 hours). However, incubation period could only be calculated for six of the 12 cases (50%) due to limitations in recall regarding the time of food consumption and first symptom onset.

All 11 cases reported diarrhoea. Cases whose diarrhoea had resolved at the time of interview (n=7) reported a median duration of 5 days (range 3-6 days). Diarrhoea was ongoing at the time of interview for four cases. Three cases (27%) reported seeing blood in their stool. Other symptoms reported included abdominal pain (10 cases, 91%), nausea (nine cases, 82%), lethargy (nine cases, 82%), headaches (seven cases, 64%), joint/muscle pain (six cases, 55%), fever (four cases, 36%), and vomiting (three cases, 27%). Five cases (42%) presented to ED for their illness. Cases who reported blood in their stool (all confirmed outbreak cases) were more likely to present to ED than those who didn't (67% compared with 33%). One of these cases was admitted to hospital, treated with antibiotics and rehydration and was discharged on day 4 of their admission. This was the only case who was hospitalised for their illness. Antibiotics were administered to two cases (17%) and intravenous rehydration to four cases (33%). There were no deaths.

Of the nine cases who reported having eaten at the kebab shop, all cases (100%) reported eating a meal containing rotisserie chicken. Six (67%) reported having eaten a chicken kebab and three (33%) reported eating a mixed chicken and lamb 'snack pack'. Cases reported eating a variety of salads and sauces with their meal: five cases (56%) reported eating garlic sauce, two (22%) sour cream, two (22%) chilli sauce and two (22%) hummus.

Environmental investigation

On 11 April 2022, the business was inspected by the Environmental Health Unit. The business advised it had not received any direct complaints from customers and there had been no recent gastrointestinal illness among staff. Details for the business' chicken and egg suppliers were also collected.

Observation of the kebab preparation process found meat was either shaved from the rotisserie and immediately served to customers (particularly when the business was busy), or shaved meat was moved to the holding unit and further cooked on a hot plate prior to serving. Overnight, rotisserie meat was put back in the cool room for use the next day.

Additional food safety concerns identified included:

- inadequate hand hygiene practices
- inadequate temperature control of meat with shaved chicken kebab meat in the holding bay measured at 56-74°C
- inappropriate storage of sauces in a display cabinet with fluctuating temperatures
- sauce bottles not appropriately cleaned and sanitised between uses
- excess old foods, such as herbs, kept on site for long periods.

A further inspection was conducted the following day with 12 food and environmental samples collected for microbiological analysis. Samples included swabs from the kebab shaving blades (one used for chicken and one for lamb); swabs from the chicken scoop pan, chicken holding unit, and food preparation sink; one cleaning cloth; samples of rotisserie chicken, lamb meat from the holding unit, and garlic sauce; a garlic sauce bottle; a sample of crushed garlic; and a sample of dry mint (an ingredient in the yoghurt sauce).

Several subsequent inspections were undertaken in April 2022. During one inspection, it was noted staff could not unscrew the blade from the motorised kebab shaving equipment used to cut rotisserie meat, which limited proper cleaning and sanitising. A Seizure Notice was issued for two kebab shaving blades (one for chicken and one for lamb), which were collected for microbiological testing.

Laboratory investigation

Initial microbiological analyses using PCR were undertaken at the ACTGAL. PCR detected *Salmonella* spp. in five samples: the chicken blade (swab), the lamb blade (swab), the chicken scoop pan (swab), lamb meat from the holding unit (food sample), and rotisserie chicken (food sample). Samples from the food preparation sink (swab), chicken bain-marie (swab) and a cleaning cloth were PCR negative for *Salmonella* spp. Samples of crushed garlic, garlic sauce, the garlic sauce bottle and dried mint were also PCR negative for *Salmonella* spp.

Reflex culture was undertaken to confirm the results of PCR with the cleaning cloth culture positive for *Salmonella* spp. All other samples were culture negative for *Salmonella* spp. Swabs from the inner and outer aspects of each of the two kebab shaving blades (four swabs in total) after they had been seized, were all found to be PCR positive for *Salmonella* spp.

Environmental isolates were sent to MDU for WGS. This included four from swabs taken from the chicken and lamb shaving blades (two each, inside and outside), the chicken scoop pan, a cleaning cloth, and a sample of rotisserie chicken. All were identified as *S.* Agona, MLST 13, cgMLST 2045. WGS of all human samples matched the environmental results, identifying cgMLST 2045. Phylogenetic analysis showed clustering of isolates at the 10, 5 and 2 SNP single linkage clustering thresholds.

Public health response

Following the first inspection, an Improvement Notice was issued requiring the business to address identified food safety issues. Staff were provided with food safety education and training. Follow-up indicated the business had addressed the required food safety issues and had obtained new equipment and consumables, including appropriate sanitiser. Meat shavers were disassembled daily for cleaning and cut rotisserie meat was subjected to a second kill step before serving. Subsequent swabs of the cleaned and sanitised equipment were negative for *Salmonella* spp. No further outbreak cases were identified and no further *S.* Agona cases were detected in the ACT during May or June 2022.

Discussion

This outbreak investigation supports previously published findings regarding the risk of salmonellosis associated with kebab meat, particularly in the context of inadequate food safety practices. Large blocks of rotisserie meat can permit rapid growth of bacteria if appropriate food safety practises are not employed. Although chicken kebab meat was the common food consumed by all cases, environmental and laboratory investigations identified multiple detections of *Salmonella* at the business, suggesting the potential for cross-contamination between equipment, surfaces, and food. Notably, the protracted nature of the outbreak, with cases detected across a seven-month period, suggests food may have been intermittently contaminated by improperly cleaned equipment.

The kebab shaving equipment, found to have been inadequately cleaned due to staff having difficulty disassembling the blades from the mechanical components, presents a possible vehicle for *Salmonella* spread in this outbreak. Rotisserie meat shaved using the blades was sometimes placed in holding units before serving. *S.* Agona was detected from samples of rotisserie chicken and lamb meat from the holding unit and on all four swabs taken from the two shaving blades (one for chicken and one for lamb). These findings support repeated contamination of rotisserie meat from inadequately cleaned shavers as the possible outbreak mechanism. Previous studies have found inadequately cleaned cutting utensils can lead to cross-contamination of *Salmonella* to other foods and surfaces (17,18). One study found *S.* Typhimurium could survive on deli slicers for six days, with the physical complexity of mechanical slicers, intermittent nature of use, and large area of food contact surfaces contributing

factors (19). Another study confirmed the potential for bacteria to attach to the micro-ridges and grooves of mechanical deli slicer blades, allowing for sporadic transfer to previously uncontaminated products (20). Over time, continuous use and cleaning of blades can result in roughening of the blade surface, providing greater opportunity for attachment of bacteria (20). Effective cleaning and sanitisation of disassembled blades has been shown to reduce the risk of cross-contamination (18).

In Australia, food businesses are required to ensure equipment and utensils are clean and sanitary (21). However, specific guidance emphasising the importance of routine disassembly, cleaning, and sanitisation of rotisserie shaving blades is lacking. Future public health guidance should emphasise the risks associated with contaminated shaving equipment, particularly in the context of doner kebabs, and provide explicit advice for businesses to ensure appropriate steps are taken to minimise risk.

Inadequate temperature control of meat may have been a contributing factor in the outbreak. Australian food businesses are required to store heated chicken at a temperature of 60°C and above (21). In this outbreak, the temperature of shaved chicken kebab meat in the holding bay was measured at below 60°C. Meat was either shaved directly into flatbread and immediately served to customers or cooked further on a hot plate prior to serving. This provides a potential explanation for the gap between notifications for outbreak cases, as those who were served a kebab with meat which had undergone the second kill step may have avoided becoming ill. The temperature required for thermal inactivation of *Salmonella* spp. is dependent upon a range of factors including the serovar, the composition of the food, and the cooking method used (22,23). A study into the thermal characteristics of *S.* Typhimurium in rotisserie chicken found the risk of *Salmonella* is more likely to be due to inadequate cooking than high *Salmonella* thermal resistance (24). The study noted there is a risk of serving inadequately cooked chicken when slices are cut from the rotisserie before the meat surface has been adequately exposed to the heat source (24). The study concluded further cooking of sliced meat prior to serving (such as on a grill) to 75°C or above reduces the risk of salmonellosis (24). These findings support the use of a second kill step, employed consistently before serving meat to customers, to reduce the risk of salmonellosis.

This outbreak demonstrates the importance of routine and timely typing for *Salmonella*. Surveillance Unit staff identified the source of the outbreak through case interview data, reinforced by serotyping data which demonstrated an increase in *S.* Agona notifications. Serotyping, or other *Salmonella* subtyping, cannot be done locally in the ACT. Isolates are sent to either Melbourne or Sydney for subtyping and analysis with delays of up to several weeks before results are received by ACT Health. It is not feasible to wait for serotyping results before conducting case interviews as recall of food and environmental exposures diminishes over time. The timely identification of outbreaks in the ACT is

therefore heavily reliant on case interview data. This means interview must be attempted for every case requiring significant staff resources, despite the data collected at interview for most cases not resulting in any subsequent public health action. Local, real time *Salmonella* subtyping would allow case interviews to be targeted at cases more likely to be associated with outbreaks requiring public health action.

This outbreak emphasises the importance of reflex culture for all human specimens that are PCR positive for *Salmonella* spp. Where faecal multiplex PCR alone is requested, culture is generally not performed resulting in missed opportunities for collecting data for public health surveillance, including the identification of outbreaks and estimation of outbreak magnitude. Genomics is increasingly important for public health surveillance. However, without culture, genomic analyses cannot be performed, limiting the granularity of *Salmonella* surveillance data. In this outbreak, the results of phylogenetic analysis strongly indicated that all human and environmental samples were highly related to one another.

A limitation of this study is that case identification relied on passive surveillance of *Salmonella* notifications. Active case finding was not required as the outbreak was identified, responded to, and resolved through follow-up of cases identified through routine notifications. However, estimates of the true community incidence of salmonellosis in Australia suggest the true number of infections greatly exceeds identified cases (25). Only those who visited a doctor, collected a faecal specimen, received a positive test result, and had the result reported, were captured by this outbreak investigation and it is likely more people were affected by the outbreak than those identified through passive surveillance.

The low number of cases identified in this outbreak limited analysis of disease severity. Only one case was hospitalised, suggesting the illness was not particularly severe for most cases. However, the relatively young age of cases, with most aged between 19 and 41 years, may have been protective against severe illness.

Only descriptive analyses were undertaken as an analytical study was not needed. A case-control study was not undertaken as the results of environmental and laboratory investigations confirmed the presence of *Salmonella* contamination at the business. The limited menu offered negated the need to investigate the relative risk of illness associated with consumption of different foods. A cohort study was not conducted as it was not possible to contact all customers who ate food from the business during the relevant time period. Customer contact details were not collected due to the predominantly takeaway nature of the business and it was not possible to access customer details from third party delivery businesses, as the *ACT Food Act 2001* does not have provision for collecting this information.

In the context of increasing uptake of third-party food delivery, the absence of a formal mechanism by which customer data can be obtained limits the ability of public health agencies to undertake active case finding and analytical studies for foodborne outbreaks. The potential for accessing customer data from third-party delivery services should be further explored to enable active case finding for future outbreaks.

Conclusion

This investigation adds to the evidence regarding the potential risk of salmonellosis associated with doner kebabs and demonstrates the importance of implementing appropriate food safety practices to minimise the risk. The findings of this study may be used to inform future environmental investigations during foodborne outbreaks by considering motorised meat shaving equipment as a potential vehicle for ongoing contamination of rotisserie meat. The development of specific guidance for food businesses emphasising the importance of routine disassembly, cleaning, and sanitisation of meat shaving blades, should be considered.

This outbreak also demonstrates the need for adequate cooking and temperature control in the preparation of doner kebab meat. In this outbreak, routinely—rather than intermittently—cooking meat on a hotplate prior to serving, may have prevented or reduced *Salmonella* transmission. The requirement for a second kill step in the preparation of doner kebab meat should be considered to reduce the risk of foodborne disease associated with its consumption.

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Appendix A – Abstract presented at the South Asia Field Epidemiology and Technology Network, Inc. Scientific Conference 2023

Salmonella Agona Outbreak Linked to Consumption of Kebabs in Canberra, Australian Capital Territory, 2022

Jill Padrotta, Jenny Post, Alexandra Marmor, Nevada Pingault, Davoud Pourmarzi

Background: Salmonella infection is associated with significant morbidity and mortality in Australia, mostly through consumption of contaminated foods. In April 2022, routine surveillance detected an increase in Salmonella enterica serovar Agona (S. Agona) cases in the Australian Capital Territory (ACT) with 10 cases notified between February and April 2022. This study presents the public health investigation into the outbreak.

Methods: Cases were identified from S. Agona notifications made to ACT Health through passive surveillance. Interviews were undertaken using standard questionnaires. Outbreak case definitions were established, and a case-series study conducted to generate hypotheses regarding potential sources of infection. A descriptive epidemiological investigation was undertaken to describe the outbreak and associated public health investigation.

Results: Twelve outbreak cases were identified with onset dates between September 2021 and April 2022. Of the 11 cases interviewed, nine reported having eaten at the same kebab shop in the seven days before becoming unwell. Rotisserie chicken was the only food eaten by all cases. Environmental investigations identified food safety concerns including improper cleaning of kebab shaving equipment, meat being kept at inadequate temperatures, and cut rotisserie meat served to customers without further cooking, as recommended. Laboratory investigations identified S. Agona in multiple food and environmental samples, including those taken from the inside and outside of two kebab shaving blades. Phylogenetic analysis of whole genome sequencing showed all human samples to be highly related to one another, and to environmental samples taken from the business.

Conclusions: The outbreak's protracted nature and investigation findings suggest repeated contamination of rotisserie meat from inadequately cleaned kebab shaving equipment as the likely outbreak mechanism. Targeted education on cleaning and sanitising of kebab shaving equipment and review of the need for a second kill step prior to serving rotisserie meat, may reduce the risk of salmonellosis from kebab shops.

Key words: Salmonella, gastroenteritis, foodborne diseases, surveillance

CHAPTER FOUR: ESTABLISH OR EVALUATE A SURVEILLACE SYSTEM OR OTHER HEALTH INFORMATION SYSTEM

Table of Contents

Chapter 4: Evaluation of the ACT Adverse Events Following Immunisation Reporting System

Prologue

This chapter details an evaluation of the Australian Capital Territory (ACT) Adverse Events Following Immunisation Reporting System (the System). It fulfills the major competency, *Establish or evaluate a surveillance system or other health information system* and the minor competency, *Conference presentation*.

I presented a virtual oral presentation of an abstract based on components of this chapter at the Communicable Diseases and Immunisation Conference 2023. The abstract is at Appendix A.

Background

Effective surveillance of adverse events following immunisation (AEFI) is a critical component of vaccine safety monitoring, enabling the detection of vaccine safety signals to provide information about potential connections between vaccinations and health events. In the ACT, AEFI are notifiable under the *Public Health Act 1997* with data collected and managed by the System. In 2021, the System was revised to replace the previous, predominantly paper-based system, with a digital system to improve its ability to cope with the increasing number of AEFI associated with high uptake of COVID-19 vaccination in the ACT. This project sought to evaluate the revised System.

My role

With the assistance of my supervisors and relevant staff within the ACT Health Directorate (ACT Health), I oversaw the end-to-end development and execution of the evaluation process. I undertook a brief review of recent literature relating to AEFI, developed the project plan, liaised with relevant stakeholders, collected documents relating to the System's operation, extracted data from the System, observed the functioning of System components, observed AEFI clinical review meetings, developed interview questions, conducted stakeholder interviews, analysed the quantitative and qualitative data, drafted a written report, and disseminated the key findings. I also presented an abstract detailing components of the evaluation relating to the System's acceptability at the Communicable Diseases and Immunisation Conference 2023 (Appendix A).

Public health impact

As the first systematic evaluation of the System, this project offered the potential to improve AEFI surveillance in the ACT by informing potential changes to enhance the System's performance. At the time of writing, the recommendations stemming from this evaluation were under consideration. Recommendations aimed at improving the System's simplicity sought to optimise the use of finite public health resources by reducing the number of steps required to operate the System. Those aimed at improving the System's acceptability sought to increase the volume and timeliness of AEFI reporting, thereby enhancing the System's ability to collect highly representative data in a timely manner. Overall, the potential improvements to the System resulting from this evaluation aimed to support efficient and optimised public health responses to AEFI in the ACT and contribute to broader public health actions based on national AEFI surveillance data.

Lessons learned

This project represented my first experience evaluating a surveillance system, which enhanced both my understanding of the process and appreciation of its importance. I undertook this evaluation using the Centers for Disease Control *Updated Guidelines for Evaluating Public Health Surveillance Systems.* These guidelines were useful for ensuring I had considered all aspects of the evaluation and guided my planning and preparation. Using the guidelines, I examined the System based on defined attributes, weighing their relative importance and considering their trade-offs and interactions to generate recommendations.

This was my first experience undertaking mixed methods research. Interviewing stakeholders taught me valuable skills in qualitative data collection, such as building rapport and carefully crafting questions to generate high-quality data. The semi-structured nature of the interviews helped refine my skills in navigating the delicate balance between obtaining the required data and allowing the conversation to flow naturally without the impediment of excessive rigidity. On the advice of my academic supervisor, I used voice-to-text software to produce transcripts of stakeholder interviews, avoiding the need for manual notetaking which saved valuable time and freed me up to focus on the conversation. Speaking with consumers who had reported AEFI proved to be a humbling experience, giving me insight into the unique human experiences which underpin AEFI surveillance data.

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Abstract

Background

Adverse events following immunisation (AEFI) are untoward medical events following an immunisation. Although most AEFI are minor and resolve without treatment, the surveillance and management of AEFI underpin public confidence in vaccination. In Australia, AEFI surveillance is predominantly passive through reports made to state and territory health departments. Data are transmitted to the Therapeutic Goods Administration (TGA) to enable national monitoring and regulatory action, which may be taken in response to identified safety concerns.

In the Australian Capital Territory (ACT), AEFI must be notified under the *Public Health Act 1997*. Vaccination providers, the TGA, and consumers report AEFI to the ACT Health Directorate with AEFI notifications data captured by the ACT AEFI Reporting System (the System). In 2021, the System was revised and digitised to improve its ability to handle an increased number of AEFI notifications associated with high uptake of COVID-19 vaccination. This was the first systematic evaluation of the System.

Methods

The System was evaluated using the Centers for Disease Control *Updated Guidelines for Evaluating Public Health Surveillance Systems.* The System was described in terms of its objectives, components, operation, and required resources and assessed on the specific attributes of simplicity, flexibility, acceptability, data quality, stability, and timeliness. The System's usefulness was assessed and described.

Data were obtained between July and October 2022. Quantitative data were obtained through extraction of notifications data from the System and review of reports generated using data from the System. Qualitative data were collected through review of documents relating to the System, semi-structured interviews with key stakeholders, and direct observation of the System's operation. Quantitative data were analysed descriptively and qualitative data were analysed deductively to systematically assess the attributes based on available data.

Results

The System's simplicity was low with significant requirements for manual data entry using multiple databases, involving time-consuming, duplicative, and inefficient processes. It had reasonable flexibility with a demonstrated ability to accommodate changes in the demands on the System, but low ability to integrate with other systems. There was high acceptability among internal stakeholders

and clinical reporters but variable acceptability among consumers with the online notification form an area of limited acceptability. The System had high timeliness, data quality, and stability. Overall, the System had high usefulness, contributing to public health action and research undertaken in response to national AEFI surveillance. However, the System did not have clearly defined objectives by which to measure its performance.

Conclusions

Although the System was found to perform effectively for most attributes evaluated, simplicity and acceptability among consumers were identified as areas of relative weakness. Identified potential improvements included the development of clear objectives, consolidation of System databases, revisions to the online notification form and ACT Health AEFI webpage to improve their acceptability among consumers, and the development of a communication strategy aimed at increasing awareness of the importance of AEFI reporting among clinicians and consumers.

Introduction

Adverse events following immunisation

Adverse events following immunisation (AEFI) are any unfavourable medical event with a temporal association with a vaccine (1). The event may be an untoward or unintended sign or symptom, a disease, or an abnormal laboratory finding. An event does not necessarily have to have a causal relationship with the vaccine to be considered an AEFI and may have either been caused by the vaccine or by factors unrelated to the vaccine (Table 1) (1).

Table 1: Cause-specific categories of AEFI and their definitions

Related cause	Definition
Vaccine product	Caused or precipitated by a vaccine due to an inherent property of the vaccine
Vaccine quality	Caused or precipitated by a vaccine due to a defect in the quality of the vaccine product or the administration device provided by the manufacturer
Immunisation error	Caused by inappropriate administration, prescribing, or handling of a vaccine
Immunisation anxiety	Cased by anxiety about an immunisation
Coincidental event	Where there is a temporal association with a vaccination, but the event is caused by something other than the vaccine product, administration error or immunisation anxiety

Public health importance

Although vaccines administered in Australia are rigorously assessed for safety and effectiveness, all vaccines carry an inherent risk of AEFI. Most AEFI are minor and resolve without treatment. Serious AEFI (those requiring hospitalisation, or which result in serious illness, or death) are very rare, occurring in fewer than 0.01% of vaccinations (1).

The surveillance and management of AEFI underpin confidence in vaccination as a public health strategy. If they are not dealt with in an effective and timely manner, AEFI have the potential to negatively impact vaccination coverage, as media reports may lead to increased public concern about vaccination (1,2).

AEFI surveillance aims to detect changes in the rates of known, unexpected or unrecognised adverse events and errors in the delivery of vaccines such as incorrect administration (1). A key objective of vaccine safety surveillance is the early detection of AEFI and rapid response to minimise the negative impacts on the health of vaccinated individuals and the vaccination program (1).

AEFI surveillance in Australia

Immunisation providers can report any event suspected of being related to a vaccination (3). National AEFI monitoring and reporting is undertaken by the Therapeutic Goods Administration (TGA). All vaccines used in Australia must be approved by the TGA following clinical trials and vaccine safety evaluation. Once a vaccine is approved, the TGA continually monitors the safety of the vaccine through passive surveillance, where reports are made either directly to the TGA (by clinical staff or consumers) or indirectly via state and territory health departments. For most states and territories, AEFI surveillance data flow to the TGA via the national SAFEVAC database. After data are received by the TGA, AEFI are assessed for causality and entered in the Australian Adverse Event Management System (AEMS) database (4). The TGA releases de-identified AEFI data from the AEMS to the National Centre for Immunisation Research and Surveillance (NCIRS) for analysis and reporting (4). The TGA also maintains a searchable public facing database with de-identified listings of adverse events associated with vaccines, the Database of Adverse Event Notifications (DAEN). Monitoring of national AEFI data enables the TGA to take regulatory action in response to safety concerns regarding vaccines or make changes to the availability and recommended use of vaccines. This can include cancelling the registration of a vaccine, limiting the population in which it can be used, requiring changes to labelling (such as warnings) and post-marketing investigations into safety concerns (5). The TGA also has a vital role in the communication of advice about vaccine safety to health professionals and consumers, through health alerts and publications.

The Australian Technical Advisory Group on Immunisation (ATAGI) is an expert group which provides advice to the Minister for Health and Aged Care, research organisations, and industry sponsors on the administration of vaccines in Australia (6). ATAGI considers national AEFI data from the TGA and other evidence and publishes advice on the risks versus benefits and clinical recommendations for use for specific vaccines (7).

AusVaxSafety, led by NCIRS, undertakes a range of national AEFI surveillance activities (8). AusVaxSafety facilitates AEFI monitoring through active surveillance, hospital surveillance, safety investigation using linked data, and through the Adverse Events Following Immunisation Clinical Assessment Network (AEFI-CAN), which brings together clinical specialists who collaborate through regular teleconferences on the clinical management of severe AEFI cases (8). Active vaccine safety surveillance is undertaken through surveys sent to participants in the days following vaccination using surveillance tools such as Vaxtracker (8). Data obtained from AusVaxSafety surveillance activities are used to develop regular vaccine safety reports, which may be published in peer-reviewed journals (9).

Epidemiology of AEFI in Australia

Between 2000 and 2020, the annual AEFI reporting rate per 100,000 population increased, largely as a function of expanded vaccination in Australia over this period (Figure 1) (4). The vast majority of AEFI reported over this period were considered non-serious (4). The highest annual reporting rate (17.4 per 100,000 population) was seen in 2010 when a high number of AEFI were reported among children due to increased uptake of vaccinations for seasonal influenza and pandemic H1N1 influenza (4).

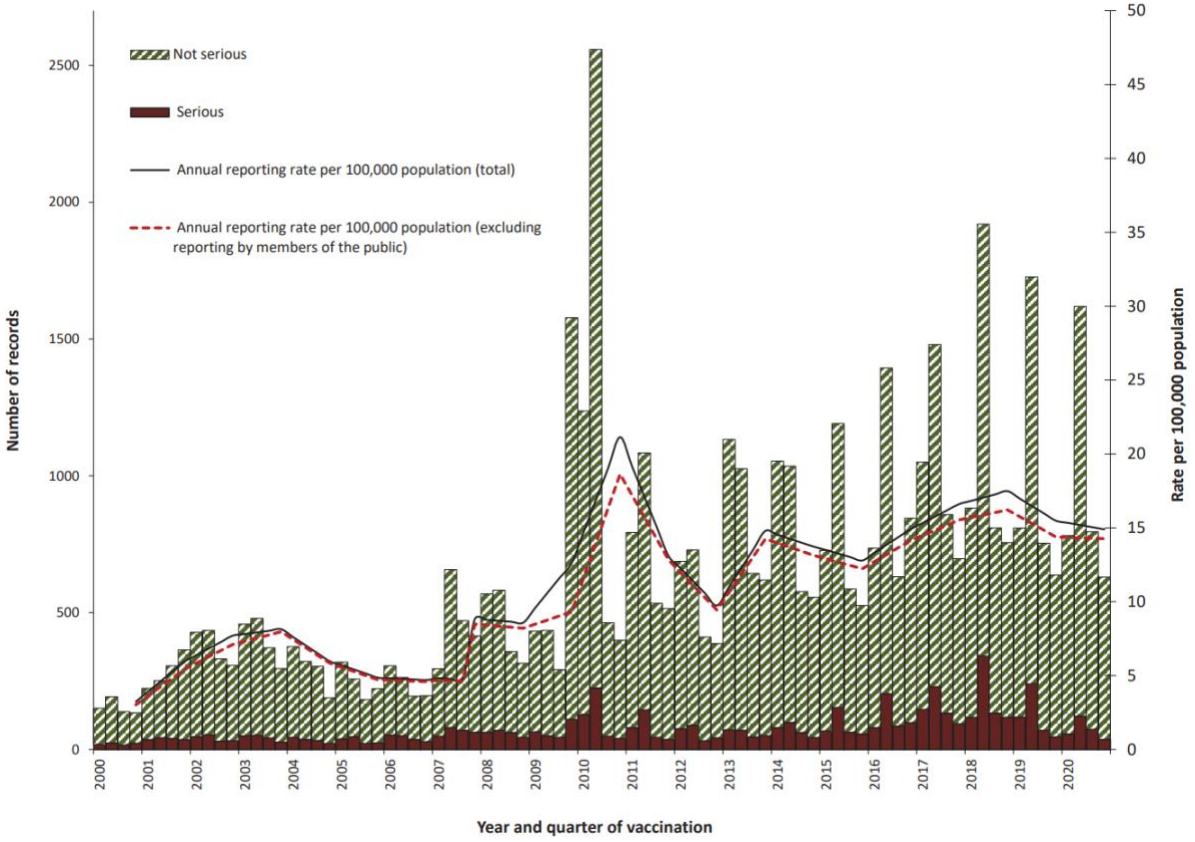


Figure 1: **Number of serious and non-serious AEFI reports in Australia and annual reporting rate per 100,000 population, by year and quarter of vaccination, between 2000 and 2020**[a,b]

In 2020, 3,827 AEFI were recorded in AEMS with the majority (92.4%) considered non-serious (4). Of these, 40.6% were for males and 57.8% were for females, with 2.1% for Aboriginal and/or Torres Strait Islander people (4). The overall rate of AEFI per 100,000 population (excluding reporting by members of the public) was 14.1 (Figure 1) (4). Of the AEFI records in AEMS with an onset date in 2020, 78.6% were sent to the TGA by state and territory health departments, 14.4% by health professionals, 4.3% by consumers, and 2.7% by pharmaceutical companies (4).

[a] Source: *Surveillance of adverse events following immunisation in Australia annual report, 2020*, Communicable Diseases Intelligence.

[b] For reports where the date of vaccination was not recorded, date of onset or date the event was reported to the TGA was used.

Adverse events of special interest

Adverse events of special interest (AESI) represent a sub-group of AEFI where a defined event or condition may be causally associated with a vaccine (10). AESI are closely monitored by the TGA due to their potentially high public health importance. AESI may be the target of AusVaxSafety research and ATAGI may provide advice or guidance regarding the relevant vaccine (11,12).

AEFI surveillance in the ACT

In the ACT, AEFI must be notified under the *Public Health Act 1997* (13). The ACT Health Directorate (ACT Health) receives AEFI notifications for ACT residents through the ACT AEFI Reporting System (the System). AEFI reports can be made by medical practitioners, nurses, pharmacists, hospitals, government health agencies, or by the vaccinated person themselves or their carer.

In July 2021, the System was revised to replace the previous, predominantly paper-based system, with a digital system using a Research Electronic Data Capture (REDCap) database. The updated System included a public facing REDCap form to enable online notification of AEFI by clinicians and consumers, reducing the manual work required by ACT Health staff to capture AEFI data.

Evaluation objectives

This evaluation aimed to systematically examine the System's performance and identify areas for potential improvement or requiring more focussed investigation. The objectives of this evaluation were to:

- describe the objectives, components, and operation of the System
- describe the resources required to operate the System
- evaluate the System's usefulness, including the extent to which its defined objectives were being met
- assess the System's performance with regards to specific attributes
- recommend areas for the System's potential improvement.

Methods

Evaluation framework

This evaluation was undertaken using the Centers for Disease Control *Updated Guidelines for Evaluating Public Health Surveillance Systems* (14). The System was assessed based on its usefulness and on the following specific attributes: simplicity, flexibility, acceptability, data quality, stability, and timeliness.

The System's sensitivity was not determined because, as AEFI surveillance in the ACT is predominantly passive, it was not possible to determine the true number of AEFI within the ACT population using available data. Similarly, positive predictive value (PPV) was not calculated as data for false positives were not available. To be considered an AEFI, there must be a temporal association between an event and the delivery of a vaccine, regardless of whether the vaccination caused the event (1). For AEFI reports captured by the System, details of the vaccination were routinely cross-checked against data in the Australian Immunisation Register (AIR). Where no vaccine was found to have been administered, the notification was not entered into the System. Therefore, all notifications entered in the System were considered true positives, prohibiting estimation of PPV. Representativeness was not assessed due to limitations in the available data in accurately describing the true occurrence and distribution of AEFI within the ACT.

System description

The System's objectives, components, operation, and required resources were described. Information on the System's components and operation was obtained through: observation of the day-to-day activities of the AEFI public health nurses (PHN), review of the AEFI Standard Operating Procedure (SOP), and informal discussions with ACT Health staff involved in the operation of the System. Information regarding the resources required to operate the System was obtained through interviews with ACT Health staff.

Assessment of attributes

Attributes were assessed systematically based on available data. The attributes assessed, the methods used to assess each attribute and the corresponding method of data collection are shown in Table 2.

Table 2: Assessment of System attributes and methods of data collection

Attribute	Method of assessment	Method of data collection
Simplicity	• Description of System components and the steps involved in its operation • Description of data storage and sharing, integration and relationships with other systems and organisations and staff training requirements	• Review of documents relating to the System • Direct observation of the System's operation • Stakeholder interviews

Flexibility	• Description of the System's demonstrated ability to cope with previous changes to demands or resourcing and ability to integrate with other systems • Description of anticipated changes to demands or resources and any mitigations employed	• Stakeholder interviews
Acceptability	• Review of the functionality and accessibility of the online notification form and AEFI webpage • Review of stakeholder feedback on the notification form and reporting process • Review of stakeholder feedback on the acceptability of data generated by the system	• Review of the online notification form and webpage • Stakeholder interviews
Timeliness	• Description of the intervals between steps in the operation of the System • Description of the median interval between AEFI and report for all AEFI and for different reporter types	• Exported REDCap data reports • Stakeholder interviews
Data quality	• Quantification of the number of duplicate records. • Calculation of the proportion of reports with complete data for selected variables • Description of identified potential for errors in data collection, entry, or collation	• Exported REDCap data reports • Stakeholder interviews
Stability	• Description of stakeholder feedback regarding the stability of the System • Consideration of the resources required to operate and maintain the System • Consideration of funding arrangements	• Stakeholder interviews

Assessment of usefulness

The System's usefulness was assessed through description and evaluation of:

- the System's overall performance relative to its objectives
- research undertaken and reports produced using data from the System
- specific public health actions undertaken in response to data from the System
- descriptive analysis of the trends, morbidity, and mortality of AEFI in the ACT.

Data used for assessment of usefulness were obtained through review of documents relating to the System, exported REDCap data reports, review of reports generated using System data, and stakeholder interviews.

Data collection

Data were collected between July and October 2022.

Quantitative data were collected through:

- extraction of AEFI data from the REDCap database for inspection, assessment of data completeness and descriptive analysis[c]
- collection and review of reports developed using data generated by the System
- review of literature relating to AEFI in Australia, including national AEFI surveillance reports (4).

Qualitative data were collected through:

- review of documents relating to the operation of the system, including the AEFI SOP, ACT Health AEFI website and online AEFI notification form
- semi-structured interviews with identified key ACT Health (internal) and non-ACT Health (external) stakeholders who interacted with the System
- direct observation of the operation of components of the System which occurred through real-time discussion, such as weekly AEFI clinical review meetings and phone calls to reporters and other stakeholders.

Stakeholder interviews

Relevant internal and external stakeholders were interviewed via videoconference, telephone, or face-to-face through one-on-one, semi-structured interviews during October 2022. Voice-to-text software was used to transcribe interviews into text. Interviewees were provided with a participant information sheet (Appendix B) via email, prior to interview, to provide them with information about the research, their involvement, ethics approval, and how their data would be handled. Contact details for interviewees were obtained from Immunisation Unit staff (for professional stakeholders) and REDCap records (for clinicians and consumers).

Internal stakeholders and those from professional organisations who had regular interactions with the System were selected for interview based on their professional role (Table 3). Clinician and consumer interviewees were selected from REDCap records based on the recency of their report; only those who

[c] Data exported for AEFI notified between 1 July and 10 October 2022.

had reported an AEFI within the past six months were contacted for interview to assist recall. For clinicians, interviews were only attempted for general practitioner (GP), nurse, or pharmacist reporters. Interviews with hospital-based clinical staff were not attempted due to potential challenges contacting the individual reporter. Consumers were only contacted for interview where the notifier was aged over 18 years, the AEFI was recorded as finalised, they had given explicit consent for ACT Health to contact them regarding the AEFI, and there was no evidence of the vaccinated person having died, being currently hospitalised, or being otherwise seriously unwell.

Data were collected from 23 interviews with stakeholders from nine different roles (Table 3). Initial questions probed for information on the interviewee's experiences with the System relating to identified attributes and their perceptions of the System's relative strengths and weaknesses (Appendix C). Follow-up questions explored the interviewees experiences, views, thoughts, and perceptions in greater depth, depending on their role, the nature of their interactions with the System, and responses to earlier questions.

Table 3: Stakeholders interviewed and their role relating to the System

Type	Broad category	Role	Involvement in System	Number of interviewees
Internal	Data utilisation	Immunisation Unit Director	• Oversees operational aspects • Uses data to inform vaccine policy • Manages resourcing and funding • Liaises with other (internal and external) stakeholders	1
		Immunisation Unit Coordinator	• Supervises operational aspects • Uses data to inform vaccine policy • Liaises with other stakeholders	1
		Immunisation Unit PHN	• Receives AEFI notifications, collects data and enters into databases • Uses data to inform vaccine policy • Liaises with other stakeholders • Presents clinical cases to medical officers	1
		On-call officer	• Receives AEFI notifications outside standard work hours	1

		Public Health Physician (PHP)	• Oversees review of clinical cases, provides advice • Uses data to inform policy • Communicates summary of AEFI review meetings to key ACT Health senior executive staff • Liaises with other stakeholders	2
		Public Health Registrar	• Reviews clinical cases and provides advice • Uses data to inform policy • Liaises with other stakeholders	1
External	Data contribution	Consumer	• Reports AEFI	6
		Clinical staff (GP, nurse, pharmacist)	• Reports AEFI	6
	Data collection, analysis, reporting	TGA representative	• Receives AEFI data and undertakes monitoring, reporting and regulatory activities	2
		SAFEVAC representative	• Receives AEFI data and facilitates transfer to the TGA	2

Data analysis

De-identified quantitative data for AEFI reported between 1 July 2021 (the implementation of the revised) and 10 October 2022, were exported from REDCap for assessment of data quality and descriptive analysis. Data quality was assessed by quantifying the number of duplicate records in the dataset and calculating data completeness (%) for selected variables. Data completeness could not be calculated for variables which used an 'opt in' checkbox, where the field only appeared when a specific response was selected for the preceding question (branching logic), and where an optional free text field was used.

Descriptive analysis was undertaken using Microsoft Excel 2017. Notification rates per 100,000 population were calculated using quarterly estimated resident population for the ACT (15). The trends, morbidity, and mortality of AEFI in the ACT were described. The median intervals (in days) between steps in the notification process were calculated and compared for each reporter type.

Qualitative data were analysed using a deductive approach. Data were categorised according to each attribute under assessment and System usefulness.

Ethics

This evaluation was covered by ethical approval from the Australian National University Human Ethics Committee (Protocol number 2017/909). All participants provided verbal consent for participation after being provided with a participant information sheet (Appendix B).

Results

Description of the ACT AEFI Reporting System

System overview

The System's surveillance population was residents of the ACT. There was no specific case definition used as any adverse health event succeeding a vaccination met the definition of AEFI. Under the *ACT Public Health Act 1997*, AEFI must be notified within five days of diagnosis. However, there was no defined time limit within which AEFI could be notified (13).

System objectives

The AEFI SOP[d], stated that the aims of the System were to:

- maximise vaccine safety in the ACT by monitoring and documenting AEFI and ensuring this information is passed onto the TGA in a timely fashion
- identify and assess potentially epidemiologically relevant vaccine side effects (e.g., clusters or batch number specific reactions)
- quickly identify unusually high rates of AEFI
- detect and correct immunisation program errors. (e.g., incorrect vaccine schedule, delivery, or storage)
- collate local data on AEFI
- maintain quality and confidence in the immunisation program by responding to consumer and community concerns
- provide immunisation information to consumers and immunisation providers.

The System did not have clearly documented specific objectives by which to measure its performance. However, all internal stakeholders interviewed reported a perception that the System performed its intended functions.

[d] Under review as at 10 October 2022.

Perceived System objectives reported by internal stakeholders included:

- facilitating notification of AEFI under the *ACT Public Health Act 1997*
- collection and documentation of AEFI and AESI data for reporting to the TGA
- contributing to national AEFI surveillance
- reporting AEFI data to various organisations, particularly for serious events
- monitoring clinical progress following AEFI
- showing those who experience AEFI that their report is being taken seriously.

Stakeholders

The ACT Health Immunisation Unit was overseen by a director, responsible for the staffing and resourcing of the System and broadly overseeing its operation (Figure 2). An Immunisation Coordinator oversaw the day-to-day operation of the System, providing supervision to the PHN. The PHN had a central role in the functional operation of the System, receiving AEFI reports, entering data, and conducting follow-up as required. Outside of standard business hours, telephone enquiries relating to AEFI reports were received by ACT Health on-call staff.

Medical officers, including PHPs and public health registrars, worked alongside the PHN to make recommendations for those affected by AEFI (Figure 2). Immunisation Unit staff and medical officers monitored the operation of the System and undertook surveillance activities, research, and communication activities, such as informing external stakeholders of changes to the System and promoting AEFI reporting among clinical staff. PHPs also engaged with external stakeholders, such as the TGA and AEFI-CAN.

External stakeholders included those who made AEFI reports and received the subsequent recommendations from ACT Health (primarily clinicians and consumers) and those who received AEFI data from the System (SAFEVAC and the TGA) (Figure 2). The primary role of SAFEVAC was to receive and store AEFI notifications data and facilitate its transmission to the TGA to fulfil national AEFI monitoring and reporting requirements. In addition to receiving data via SAFEVAC, the TGA also regularly reported AEFI to ACT Health after receiving reports directly from clinicians and consumers in the ACT.

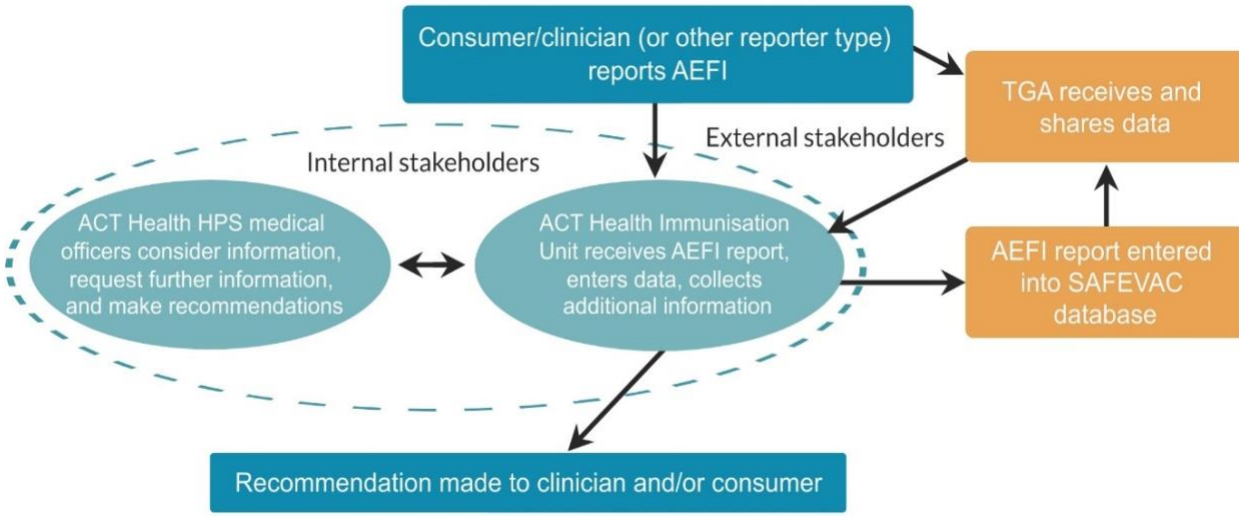


Figure 2: Internal and external stakeholder groups involved in the System

Structure and operation

Reports were received by telephone, email, paper form, fax, or directly into the ACT Health REDCap database through a public facing online form, accessed through the ACT Health AEFI website (Figure 3). The Immunisation Unit was alerted to reports made using the online form through an automatically generated email. For notifications received by telephone, paper form, email or fax, details of the report were manually entered into REDCap by the PHN. Associated files, such as imaging reports or test results were also uploaded to REDCap. Data for each report were manually entered into the SAFEVAC database by PHN, generating a unique SAFEVAC ID which was then entered into REDCap to enable linkage of the records.

Details of serious and/or urgent AEFI reported to ACT Health were sent directly to the TGA via email (immediately, or at least within one business day) (Figure 3). This generated a unique TGA ID number, which was also entered into REDCap. The TGA shared data for non-serious AEFI reports it had received directly from clinicians and consumers through a fortnightly email to ACT Health. Data for serious and/or urgent AEFI were shared immediately. Following receipt of a report from the TGA, the PHN searched REDCap for an existing record and created a new record if none could be located.

Individual cases were discussed at a fortnightly AEFI clinical review meeting attended by PHN and medical officers, to determine the recommendation to be made back to the case and/or clinician (Figure 3). The frequency of clinical review meetings increased or decreased to accommodate the volume of AEFI. Urgent and/or serious cases were discussed out of session, if needed. Before review meetings, PHN transcribed AEFI data from REDCap into a separate Excel spreadsheet, stored in the Immunisation Unit SharePoint site. During review meetings, PHN presented AEFI for discussion, guided by the spreadsheet and updated the spreadsheet with the agreed course of action for each

case. Following each meeting, the PHN also updated case REDCap records to reflect the outcome of the review, including any recommendations. The PHP emailed a summary of the meeting for the information of the Chief Health Officer and other senior executive ACT Health staff (Figure 3).

AEFI captured in Vaxtracker were regularly reviewed by PHN to ensure AEFI identified through AusVaxSafety's active surveillance activities were also captured by the System (Figure 3). PHN cross-checked records in Vaxtracker against notifications in REDCap and where an AEFI appeared in both systems, entered the Vaxtracker ID number into the case's REDCap record. For AEFI without a corresponding REDCap record, the PHN created a new notification in REDCap and undertook follow-up, as required.

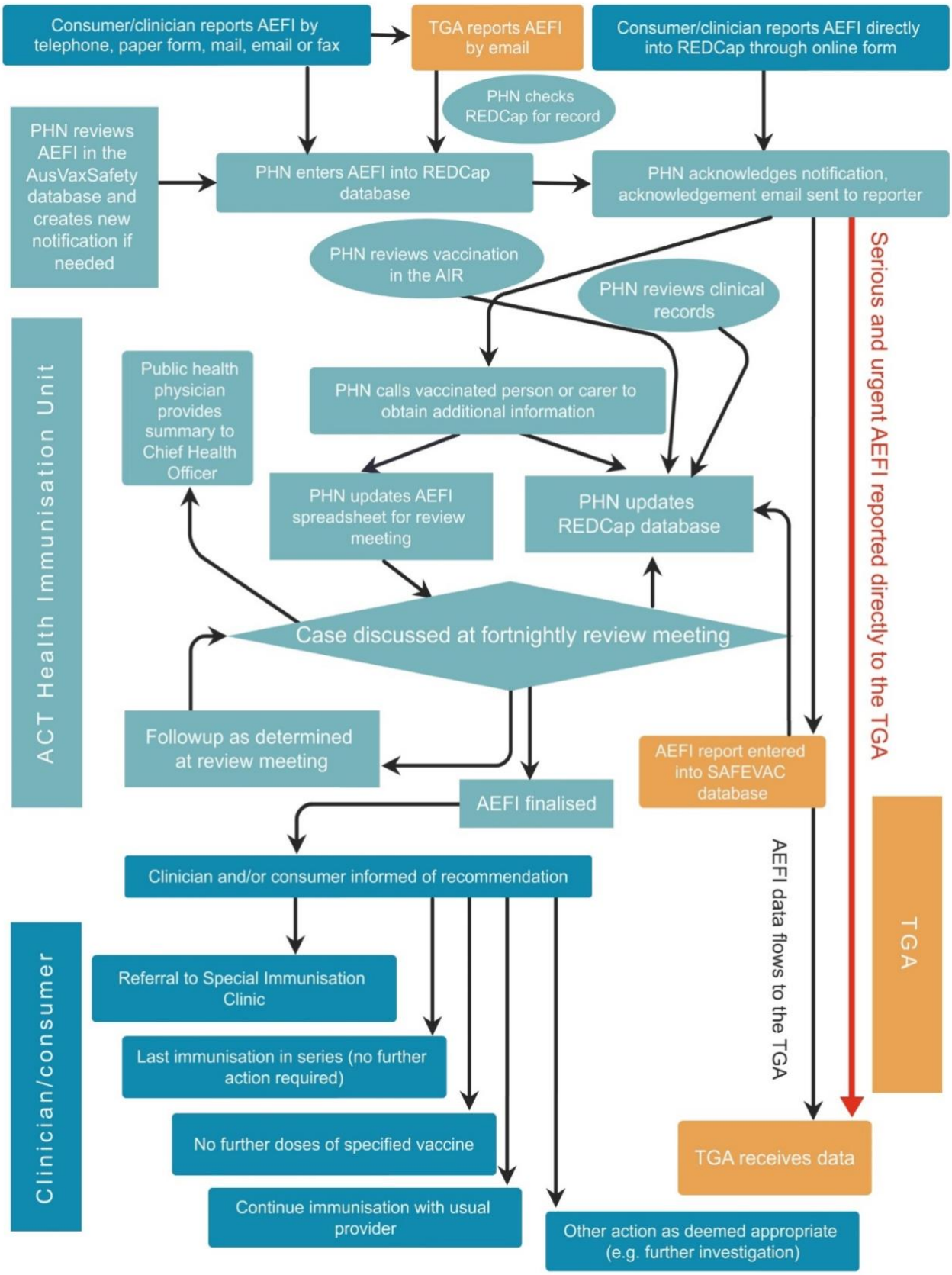


Figure 3: Overview of the AEFI reporting and response process in the ACT

Resources needed to operate the System

The System was funded by the ACT Government with ongoing operating costs predominantly related to personnel requirements. During the rollout of COVID-19 vaccination in 2021, 3.2 full time equivalent (FTE) PHN and 0.2 FTE PHP were required to manage the volume AEFI reports associated with high uptake of COVID-19 vaccination. Staffing levels were gradually stepped down as COVID-19 vaccination volumes tapered off. As of October 2022, the approximate personnel requirements for the System's operation were: 0.1 FTE PHP, 0.1 FTE Public Health Registrar, 0.1 Immunisation Coordinator, and 0.5 FTE PHN (registered nurses). Staff were not required to travel for their roles. Intermittent ad hoc support, particularly relating to communication activities, was provided by a Vaccine Delivery and Data Entry Officer and technical REDCap support by ACT Health epidemiologists.

The non-personnel costs required to operate the System were minimal. As the System was predominantly digital, the requirement for consumable supplies and other equipment were low. System administration and server access costs associated with the REDCap database were borne by the Digital Solutions Division of ACT Health. As AEFI represented only one of many REDCap projects used within ACT Health, these costs represented only a small proportion of the Digital Solutions Division budget.

The Immunisation Unit distributed a newsletter sent (both via regular mail and email) to immunisation providers and other stakeholders every second month. However, the content of the newsletter related to the broader work of the Immunisation Unit with irregular references to AEFI.

Assessment of System attributes

Simplicity

Assessment of a system's simplicity requires consideration of both its structure and ease with which it is operated (14). The overall simplicity of the System was low due to numerous steps involving duplicative processes, resulting in reduced efficiency and ease of operation.

The wide range of available reporting methods necessitated monitoring of multiple communication channels by PHN. Although all consumers who were interviewed reported using the online form to report their AEFI, the majority advised they chose this method because they telephoned the Immunisation Unit and were directed to use the online form. Lack of awareness of the online form among reporters contributed to reduced System simplicity as the additional step of a telephone call was often required before a report was made online.

PHN were required to enter data into both the internal ACT Health REDCap database and external SAFEVAC database – each with separate access requirements and login details. Transcription of data into the spreadsheet before AEFI review meetings and back into REDCap after the meeting, added additional duplicative steps. Details of serious and/or urgent AEFI were emailed to the TGA separately. The use of multiple databases resulted in time-consuming manual processes involving constant switching between System components. This also increased the complexity and duration of training for new staff.

PHN monitoring of Vaxtracker records added further complexity to the System and required the use of another database. The components of the System were poorly integrated with no mechanism by which data could automatically flow from one component to the next. The System's lack of simplicity led to a heavy reliance on the knowledge and experience of PHN, who skilfully triaged and prioritised potentially serious AEFI (including AESI), enabling important cases to be dealt with in a timely manner, despite the System's low simplicity.

Flexibility

A flexible system can accommodate changes to events under surveillance or available resources (14). The overall flexibility of the System was reasonable. The addition of new vaccines to the National Immunisation Program and new indications to existing vaccines, frequently resulted in intermittent fluctuations in demands on the System. However, stakeholders reported the System had previously demonstrated its ability to accommodate such changes, resulting in high confidence in its ability to accommodate future changes.

Despite its low simplicity, the System's multitude of intersecting processes provided a range of options which could be employed as needed to cope with changes in demands, a consequence of having to rapidly expand and contract in response to changing notification volumes associated with fluctuations in COVID-19 vaccination uptake. As the System used an internally hosted REDCap database, changes to form specifications could be made quickly and easily by ACT Health staff. For example, following the implementation of mpox vaccination, an option for intradermal route of administration was quickly and easily added to the REDCap form to accommodate the new vaccine. However, the System's low ability to integrate with other systems, such as SAFEVAC and Vaxtracker, resulted in reduced overall flexibility.

Acceptability

Acceptability relates to the willingness of individuals and organisations to participate in a system (14). Other attributes, including data quality and timeliness, are underpinned by participation (14). The

acceptability of the System was high among internal stakeholders, organisational external stakeholders, and clinicians; however, acceptability among consumers was variable.

Internal stakeholders viewed the System as highly effective, ensuring robust follow-up of AEFI cases. Interviewees from the TGA and SAFEVAC also reported high satisfaction with the System. However, they noted the limited scope of their interactions with the System. The TGA regarded the data generated by the System as acceptable, noting it infrequently had to request further information following notification of an urgent and/or serious AEFI.

Clinicians interviewed reported overall high acceptability of the reporting process with clinicians who used the online form to report AEFI noting it quick and easy to complete. Although clinicians appreciated the range of available reporting methods, some reported uncertainty regarding the best method and one reported using the paper form due to not having known about the online form. In contrast, consumers indicated high satisfaction regarding their telephone interactions with ACT Health staff but low acceptability of the online form. Some consumers reported having to be guided to the correct webpage over the telephone, which increased the time and effort required to make a report. For some consumers, lack of familiarity with the term 'AEFI' presented a barrier to locating the correct webpage to make an online report. Consumers who used the online form reported it:

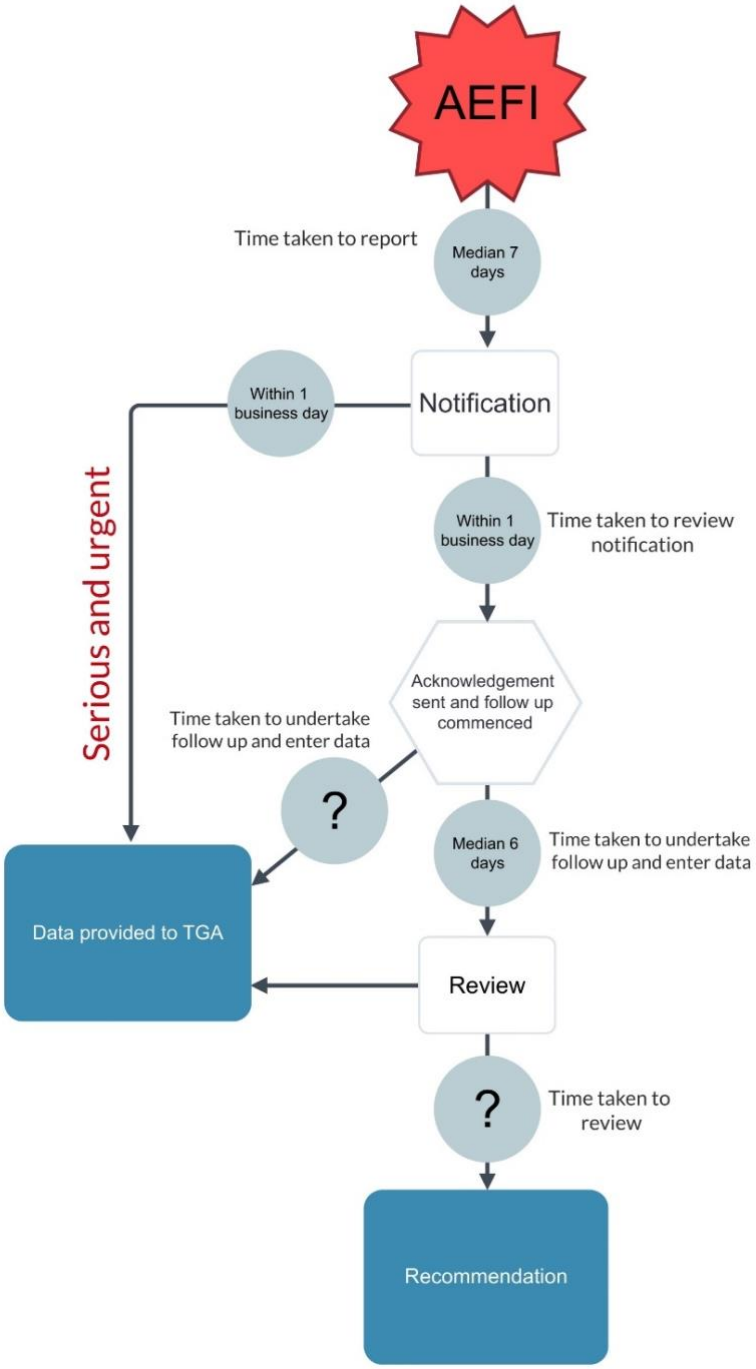
- was difficult to locate
- was detailed and requested information that consumers may not have available (e.g., vaccine brand)
- took too long to complete (20-30 minutes)
- required duplication of details (e.g., address and phone number) for both the notifier and vaccinated person where the parent may be notifying on behalf of their child
- was difficult to see the link to the notification form on the website as it was embedded in text.

Review of the ACT Health AEFI website found the text invited reporting of AEFI by phone, fax, email or online and included a link to download the paper form. The website text included long sentences, requiring a reasonably high reading level and did not mention the benefits of reporting.

Timeliness

Timeliness relates to the time taken between steps in the surveillance system (14). Overall, the System was viewed by internal stakeholders and the TGA as having high timeliness with serious and urgent AEFI always received by the TGA within one business day of the report being made. Interviews indicated recommendations from clinical review meetings were made in a timely manner. However,

cases would often be kept 'open' in REDCap after the recommendation had been made (e.g., while awaiting the results of clinical investigations). This prevented accurate calculation of time to finalisation of reports. Analysis of REDCap data[e] showed high timeliness between most steps in the System (Figure 4). However, there was frequently a delay between AEFI occurring and the report being made with a median interval of 7 days (Figure 4). Data for the interval between clinical review meetings and the clinician/consumer being notified of the recommendation was captured in free text fields and could not be easily calculated.



[e] For AEFI notifications made between 1 July 2021 and 10 October 2022 (n=841), excluding notifications identified through historical audits of medical records (n<5).

Figure 4: Median interval between steps in the System for AEFI reported in the ACT, between 1 July 2021 and 10 October 2022

For all reporter types, the median interval between an event and the report being made to ACT Health was seven days (range 0-434 days) with 11.1% of reports (n=93) made on the same day the AEFI occurred. Nurses had the lowest median interval at one day followed by pharmacists at two days (Figure 5). Non-GP medical specialists had the highest interval with a median of 56 days. In contrast, GP reporters had a median interval of 12 days, emergency department medical officers three days, and consumer reporters eight days.

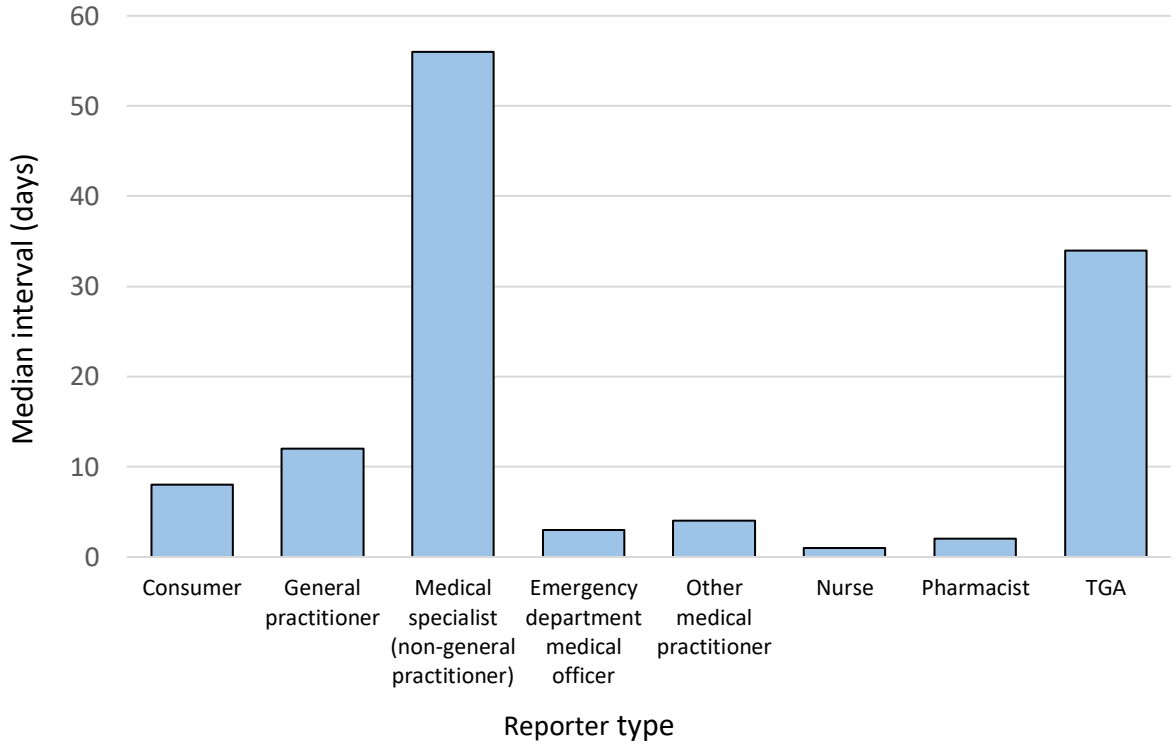


Figure 5: Median interval between AEFI (excluding those identified through historical audits) and a report being made to ACT Health, by reporter type, for notifications made between 1 July 2021 and 10 October 2022

Data quality

Data quality is an important determinant of representativeness and is dependent on the completeness and validity of data (14). Overall, the System's data quality was good with high completeness for most variables and no specific sources for potential errors in data collection or collation identified. However, multiple touch points created additional opportunities for manual data entry errors. Interviews with internal stakeholders indicated data validity was thought to be generally better for reports received electronically than when the use of a paper form necessitated interpretation of handwriting. No duplicate records were identified in data exported from the System. Where data completeness could be calculated, it was high (>85%) for most variables (Table 4). However, data did not allow accurate

assessment of the proportion of reporters who used each method to report, which prevented comparison of data completeness for data obtained through different reporting methods.

Table 4: Completeness of AEFI data in REDCap for key variables in the ACT, between 1 July 2021 and 10 October 2022

Variable name	Data completeness (%)
Notification date*	100.0
Reporter type*	99.4
Reporter phone number*	98.1
Reporter email address	53.3
Reporter address	44.9
Reporter last name*	99.5
Reporter first name*	99.4
Vaccinated person's last name (where not reporter)*	89.5
Vaccinated person's first name (where not reporter)*	89.5
Date of birth*	99.9
Sex*	99.9
Aboriginal and/or Torres Strait Islander status	90.7
Postcode	95.8
Aged care or disability care resident or worker	88.6
Vaccine brand or type*	100.0
Setting in which vaccination was administered	94.2
Date the reaction occurred	93.9
Time the reaction occurred	48.8
Management of event	98.8
Important medical conditions	92.3

*Required field for online notification form.

Comparison of data for reports made by clinical and consumer reporters found similar completeness for most variables (Figure 6). However, consumer reporters were nearly twice as likely to provide an email address and had higher data completeness for reporter address, Aboriginal and/or Torres Strait Islander status, and setting in which the vaccination was administered. Clinical reporters were slightly more likely to report the time the reaction occurred.

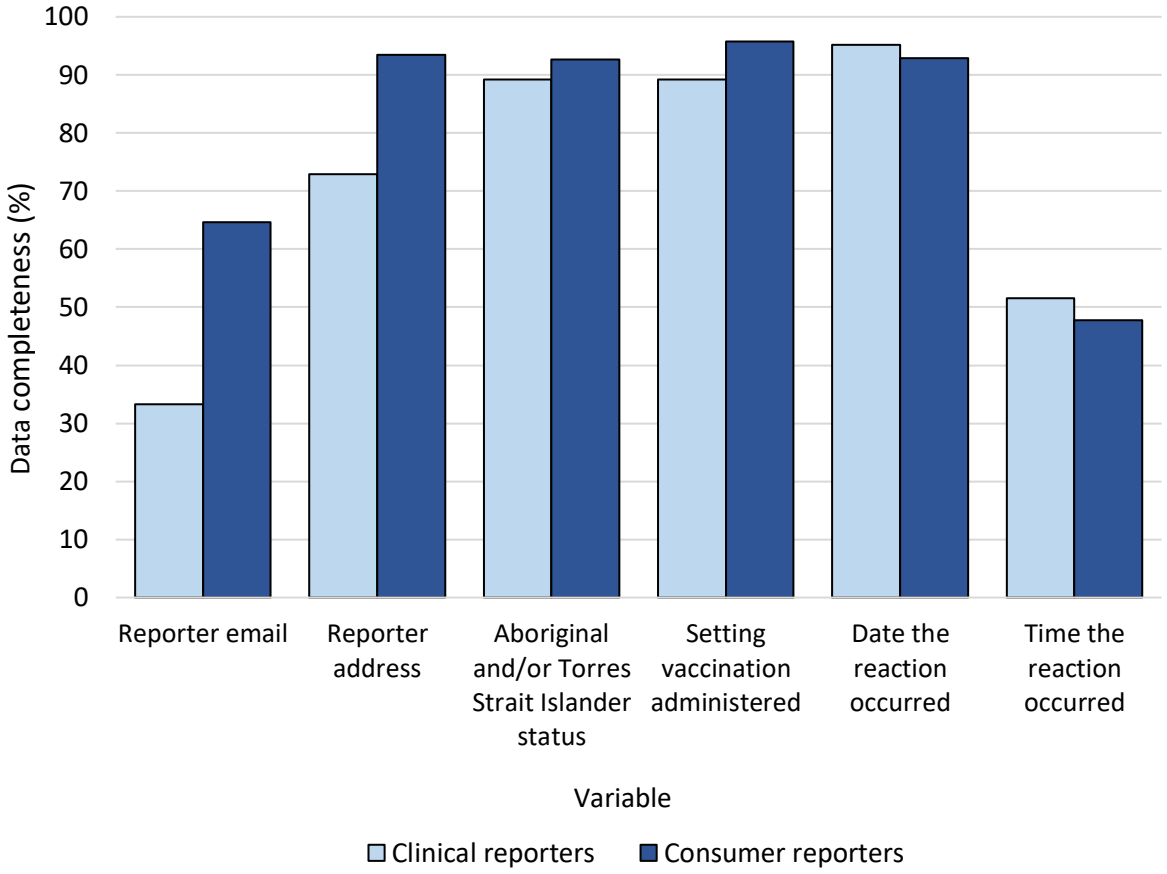


Figure 6: Data completeness for selected variables for AEFI reports made by clinical and consumer reporters in the ACT, between 1 July 2021 and 10 October 2022

Review of the online notification form showed up to 24 free text fields could be populated for one AEFI, depending on the number of vaccines administered and responses entered in other fields. Free text fields that appeared through branching logic artificially inflated data completeness for some variables. For example, completeness for reporter type appeared high at 99.4%. However, this included 53 records (5.4%) with a response of 'Other' for which data completeness for the subsequent free text field was only 60.4%. However, interview data showed consumer reporters appreciated having space to explain the details of their event in free text. The 'Sex' field in the form didn't allow for capturing data for gender diverse consumers. Only the options 'Female', 'Male', 'Other', and 'Unknown' were given, which limited the granularity of data obtained on sex and gender.

Stability

The stability of a system is defined by both its availability, and its ability to reliably collect, manage and provide data without failure (14). Overall, the System was highly stable with both high availability and reliability. The System operated continuously 365 days a year with online notifications able to be made at any time of day. Outside standard business hours, on-call staff were available to respond to telephone enquiries, 24 hours a day. Interview data showed the System was regarded by stakeholders as highly stable. No stakeholders interviewed reported concerns regarding the System's availability or reliability. Stakeholder confidence in the System's ability to remain highly stable during future periods of increased demand was also high.

A multitude of methods for reporting and data entry contributed to the System's stability as the failure of one method meant others could be employed. For example, telephone notifications could still be received during a website outage, and vice versa. However, a reliance on experienced operators presented a risk to the System's stability should staff leave and be replaced with less experienced operators. Funding arrangements for the System were also highly stable as in the ACT, AEFI are notifiable by law.

Usefulness

A useful public health surveillance system is one which contributes to the control and prevention of adverse public health events (14). This may include through detecting changes in the trends of health events, enabling assessment of the effectiveness of prevention and control activities, and stimulating research to inform prevention and control activities (14).

Overall, the System had high usefulness as it contributed to public health action undertaken in response to national AEFI surveillance. Although the System's objectives were not clearly defined, the System effectively facilitated the collection, entry, storage, and transfer of AEFI data for ACT residents. Data were consistently transmitted to the TGA in a timely manner, to contribute to the detection of vaccine safety signals and serious AEFI were followed up and managed appropriately.

Data from the System helped to inform a range of public health actions to improve vaccine safety, predominantly in the form of regulatory action by the TGA. Data in the AEMS were used for signal detection to direct further investigations. Depending on the signals, the TGA took action, such as working with pharmaceutical companies to modify the product information for the vaccine. For example, in response to the detection of myocarditis and pericarditis cases following administration of COVID-19 vaccines in Australia (including in the ACT), detailed guidance was produced by ATAGI

and the Cardiac Society of Australia and New Zealand to advise on the administration of COVID-19 vaccines and guide the assessment and management of these conditions following vaccination (16).

System data were also used by the TGA for a range of reports and communiques. These included the AEFI annual reports (produced by NCIRS), which summarised spontaneous AEFI surveillance data collected by Australian states and territories and examined trends and clinical outcomes (4). The TGA also produced fortnightly COVID-19 vaccine safety reports detailing regulatory actions undertaken in response to AEFI surveillance (17). Individual AEFI notifications were used by the TGA to populate the DAEN, for use by professionals and the general public for a variety of purposes. Indirectly (via the TGA), System data also helped to inform the development recommendations and statements developed by ATAGI, contributing to improved clinical and policy practices.

Internally, ACT Health staff used REDCap data to generate summaries, particularly for COVID-19 vaccinations, for the awareness of ACT Health senior executive staff, to enable early identification and communication of changes in the magnitude of AEFI. Interview data indicated case series analysis was undertaken irregularly to examine associations between adverse events and certain dose regimes to identify factors associated with the event.

Descriptive analysis of System data enabled examination of trends in AEFI notification rates by demographic characteristics (Figure 7). Between 1 July 2021 and 10 October 2022, the System recorded 841 AEFI notifications. The total notification rate per 100,000 population reduced from 22.8 in July 2021 to 1.7 in September 2022 (Figure 7). Over this period, there was a shift in the age distribution from a higher proportion of notifications for older age groups, to a higher proportion for younger age groups. There were 525 notifications for females (62.4%), 312 for males (37.1%), and four with a sex of 'Other' (0.5%). There were 189 cases (22.5%) admitted to hospital (including admissions to the emergency department), 130 (15.5%) classified as 'serious', and 95 (11.3%) considered AESI. For records where both admission and discharge date were available (n=147), the median length of stay in hospital was one day (range 0-128 days). Seven people who had an AEFI notified during this period (0.8%) died. However, causality assessment, outside the scope of this evaluation, was required to determine the cause of death.

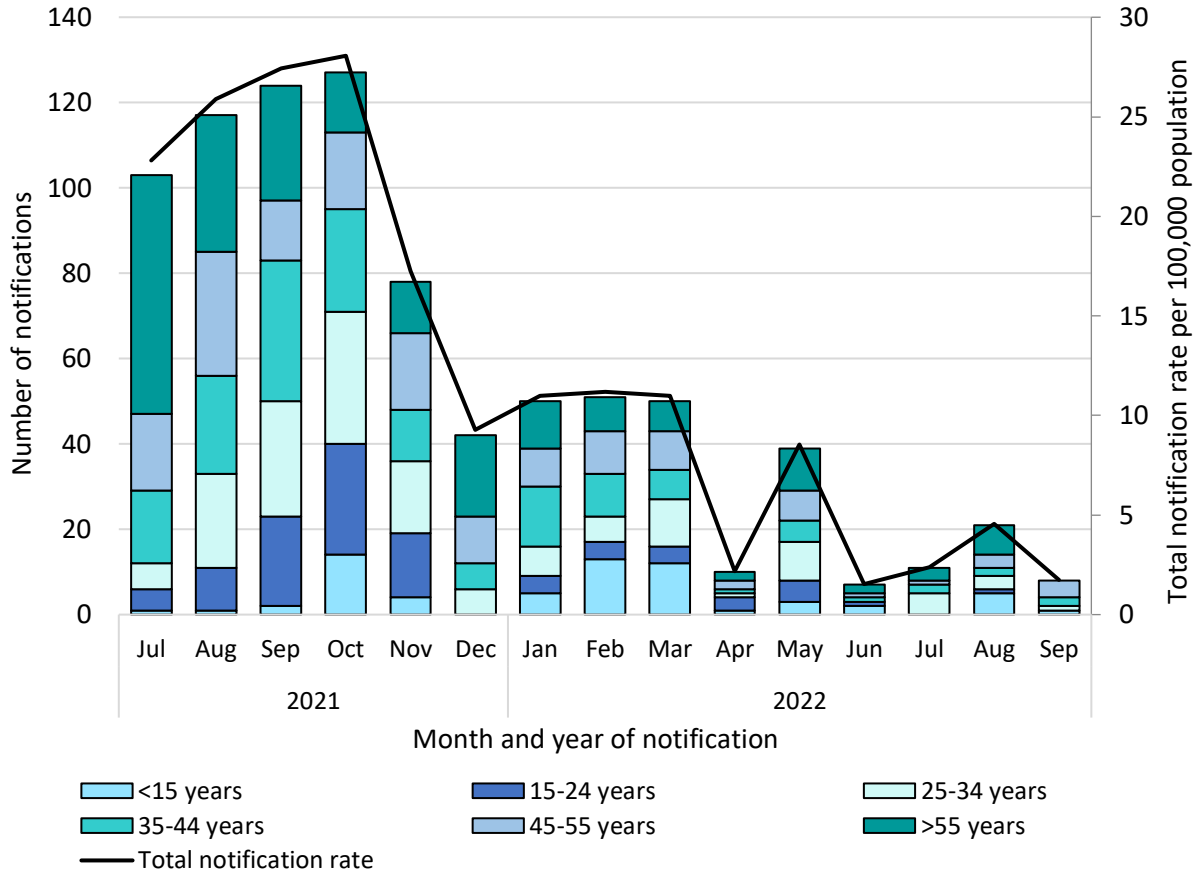


Figure 7: Trends in the number of AEFI notifications in the ACT by age group and total notification rate per 100,000 population, between July 2021 and September 2022

Discussion and recommendations

Summary of evaluation findings

Overall, the System was found to have high usefulness, stability, and data quality, with reasonable flexibility. However, its simplicity was low and acceptability among stakeholders was variable. The System's reliance on the experience of the PHN also presented a potential risk to its stability, particularly in the absence of clearly defined objectives.

As a smaller jurisdiction, the ACT is unlikely to be the first Australian state or territory to detect vaccine safety signals. However, data generated by the System contributed to the detection of vaccine safety signals at the national level, resulting in public health actions including changes to vaccination advice. Communications produced by the TGA incorporating data from the System had a significant role in maximising consumer confidence in vaccine safety, particularly during the COVID-19 pandemic, through the publication of objective information for the public about AEFI and their frequency. System data also contributed to estimates of the magnitude of morbidity and mortality relating to AEFI in

Australia. These contributions to national AEFI surveillance resulted in overall high usefulness. However, analyses of System data for internal purposes were undertaken irregularly and the expectations with regards to analysis and reporting of ACT AEFI data to inform local public health actions, were unclear. The development of clear objectives would enable objective assessment of the System's usefulness and guide ongoing future improvements to the System.

Among the attributes assessed, the System's most significant weakness was its low simplicity, primarily due to its numerous data collection methods and repositories. Receiving notifications through multiple channels and the persistence of paper-based reporting increased the burden on staff and added to both the training requirements for new staff and the likelihood of manual data entry errors. In the absence of granular data on reporting method, the uptake and quality of data produced through different reporting mechanisms could not be assessed. Although clinical reporters appreciated the range of reporting methods available—which contributed to the System's acceptability among this group—reducing the range of reporting channels would increase the System's simplicity.

The System's limited ability to integrate with other systems was a major contributor to its low simplicity. Data entry into multiple databases resulted in a labour-intensive process and reliance on the prioritisation skills of experienced staff to preserve timeliness. Although previous changes had already been made to digitise the System, further improvements to reduce the manual processes and consolidate data repositories would improve the System's simplicity. Although REDCap was used for the collection of data from the public facing online form and acted as the primary data repository for internal ACT Health use, transmission of data to the TGA occurred via SAFEVAC. The lack of integration between REDCap and SAFEVAC necessitated separate manual data entry into both databases. The adoption of a public facing SAFEVAC reporting form, as has been done in Victoria and Western Australia, would enable direct entry of data by reporters, automatically accessible by the TGA. Additionally, using REDCap to guide discussions at clinical review meetings (with real-time updates made to case data) and eliminating the use of a separate spreadsheet would reduce the need for transcribing data.

Although the System's acceptability was high among internal stakeholders and clinical reporters, consumer stakeholders identified areas for improvement in the reporting process, particularly the online form. Since the introduction of COVID-19 vaccination, consumer interest in AEFI has grown with vaccine hesitancy and concern about vaccine safety both increasing (18). Collection of AEFI data from consumers provides an interface between consumers and vaccine safety systems, offering the potential to enhance consumer confidence in the vaccine safety monitoring process. The addition of

text to the AEFI website promoting the benefits of reporting may encourage completion of the form by consumer reporters. Increased consumer reporting may also have flow-on benefits for data representativeness and timeliness. To address consumer feedback that the form was too technical and took too long to complete, it could be abbreviated for consumer reporters by hiding fields for clinical data unless reporter type is entered as a clinical/organisational reporter. As vaccine details are routinely cross-checked against AIR records, there may be little benefit in requesting vaccine details, such as batch numbers, from consumers who may be deterred from making a report if they don't have this information handy. Making the form easier to locate through search engine optimisation and improving the visibility of the link to the form by separating it from text, may also support consumer reporting. Additionally, to enable future evaluation of the form's acceptability, a mechanism for gathering feedback from reporters, such as the addition of a 'feedback' box, should also be considered.

Low awareness of the online form resulted in many reporters having to telephone before notifying online, reducing System simplicity through the addition of an unnecessary step. Furthermore, although the System demonstrated high overall timeliness, delays between the event and notification present a risk to timeliness. Although non-GP medical specialist reporters had a median interval of 56 days, the nature of care provided by non-GP specialists means there may be a delay before the patient is seen, which may explain the longer interval for this group. However, the median intervals for consumer and GP reporters, of eight and 12 days, respectively, suggest the need for improvements in the timeliness of reports. Improved reporter awareness of the form and making it easier to locate on the ACT Health website could be achieved through the development of a communication strategy to promote AEFI reporting to clinicians and consumers and raise awareness of the online form. The bimonthly Immunisation Unit newsletter presents an opportunity for communication with immunisation providers, who could cross-promote AEFI reporting among consumers. Increased reporting would also serve to reduce the number of records identified through Vaxtracker which haven't already been captured in the System.

The large number of free text fields in the online form allowed for collection of rich and detailed data and may be the best method for capturing data on symptoms (19). However, they added to the time required to complete the form and analyse the data collected. Reducing the number of free text fields, through expansion of categorical options to include responses commonly provided in free text, may enhance the System's usefulness by facilitating easier analysis. The quality and representativeness of data on sex and gender could be improved through expanded options, such as the inclusion of 'X (indeterminate/intersex/unspecified)'. The addition of a 'gender' field would provide an avenue for gender diverse individuals to report their gender, promoting inclusivity, and potentially enhancing engagement with the form (20).

Evaluation strengths and limitations

The strengths of this evaluation included the use of a validated evaluation framework to facilitate a systematic approach and the collection and analysis of both quantitative and qualitative data. Qualitative data were collected through detailed interviews with a range of stakeholders, including vaccination providers and consumers, in addition to highly experienced ACT Health staff and organisational stakeholders. The semi-structured format of interviews enabled free-flowing and flexible discussion of stakeholder viewpoints. However, the range of clinical reporters interviewed was limited by the small number of AEFI reported by each reporter type during the preceding six months and only included two GPs. Ideally, the views of a wider range of clinical reporters, including hospital-based clinicians, would be captured to inform the evaluation. Assessment of timeliness was limited by available data for date of recommendation and finalisation of the notification. Available data also limited assessment of representativeness.

Recommendations

Based on the findings of this evaluation, the System's overall performance in terms of the attributes assessed, may be improved through the adoption of the following recommendations.

Recommendation 1: Develop clear System objectives

System objectives—which are specific, measurable, achievable, realistic, and time-bound—should be developed. These objectives should clearly address the role of the System in generating data for local analysis and reporting and serve to enable ongoing regular systematic evaluation of the System's performance.

Recommendation 2: Consolidate the databases used in the System

The potential for replacing the public facing REDCap form with a SAFEVAC form should be considered to improve System simplicity and flexibility through improved integration with other systems. The spreadsheet used to guide clinical review meetings should be eliminated with real-time updates made to case REDCap records to further improve simplicity.

Recommendation 3: Revise the public facing and internal REDCap forms

The public facing online notification form should be revised to improve its acceptability among consumers. An abbreviated version of the form which uses plain language, can be completed quickly, and provides space for consumers to share their experience without requesting detailed technical information, should replace the current form. The number of free text fields should be reduced through the addition of drop-down menus or check boxes reflecting frequently given responses. A free text field inviting reporter feedback should be added to enable future evaluation of acceptability. To

improve data quality and acceptability, a 'gender' field should be added to capture data for gender diverse people and the 'sex' field expanded to include people of indeterminate/non-binary sex.

The internal REDCap form used for case follow-up should be amended to include a field for reporting method, to allow for future evaluation based on the method used to report. The addition of dates for when the recommendation was made, data were transmitted to the TGA, and the report was finalised, would enable more fulsome future assessment of System timeliness.

Recommendation 4: Revise the ACT Health AEFI webpage

Plain language advice and information regarding who can report AEFI and the benefits of reporting, should be added to the ACT Health AEFI webpage. The link to the online reporting form should be moved from a text link to a more visible 'button' and search engine optimisation employed to increase the ease with which reporters can locate the form. These changes would support participation in reporting, with downstream benefits for acceptability, data quality, and representativeness. The link to download the paper form should be removed to encourage digital reporting, improving simplicity.

Recommendation 5: Develop a communication strategy to increase reporting

A communication strategy should be developed, aimed at improving awareness of the need for timely reporting among consumers and clinicians and informing them of the existence of the online form. This would increase participation and support System simplicity through the reduced need for telephone enquiries. The Immunisation Unit Newsletter may be utilised as a potential avenue for communications aimed at clinicians.

Conclusion

Overall, the System's data contributed to public health action and important research undertaken in response to national AEFI surveillance, resulting in high usefulness. The System's simplicity was low involving a high degree of manual data entry and duplicative processes. It had reasonable flexibility with a demonstrated ability to accommodate changes but low ability to integrate with other systems. The System was highly acceptable among internal stakeholders and clinicians, but the online notification form had relatively low acceptability among consumers. The System had high data quality and stability and appeared to have high timeliness. However, lack of dates data for all steps in the System prevented evaluation of the time between notification and recommendation or the notification being finalised. Potential improvements include the development of clear objectives, consolidation of System databases, revisions to the online notification form and ACT Health AEFI webpage to improve their acceptability among consumers, and the development of a communication strategy to promote AEFI reporting and increase awareness of the online form.

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Appendix A – Abstract presented at the Communicable Diseases and Immunisation Conference 2023

Adapting reporting of adverse events following immunisation to enhance acceptability among consumers

Jill Padrotta, Nevada Pingault, Alexandra Marmor, Davoud Pourmarzi

Background: Surveillance of adverse events following immunisation (AEFIs) is a crucial component of vaccine safety monitoring, which underpins public confidence in vaccination. The comprehensiveness and accuracy of data collected by AEFI surveillance systems depends on adequate reporting.

In July 2021, the ACT AEFI Reporting System (the System) was revised in response to increased AEFI notifications associated with COVID-19 vaccination. The previous paper-based system was replaced with a digital system using a REDCap database. This study aimed to understand the acceptability of the new reporting process among clinicians and consumers.

Methods: We used a mixed methods study design. Qualitative data were collected through semi-structured interviews with clinicians (n=6) and consumers (n=6) who had reported at least one AEFI in the preceding six months. Deductive analysis was undertaken. Quantitative data were collected through extraction of data from the System and analysed descriptively.

Results: Between 2020 and 2021, the number of AEFIs reported in the ACT increased 13-fold (largely due to the high number of COVID-19 vaccinations administered) and the proportion of reports made by consumers increased from 25.3% to 40.4%.

The online notification process had limited acceptability among consumers who reported difficulty locating the form, difficulty completing the technical components, and dissatisfaction with the time required to complete the form. In contrast, clinicians noted high acceptability of the reporting process.

Conclusion: To improve acceptability among consumers, AEFI surveillance systems should ensure online reporting forms are easy to locate, include clear instructions, are written in plain English, do not request technical information, and are quick to complete. This may enhance the quality of AEFI surveillance data by encouraging consumer reporting. Increased consumer interaction with AEFI surveillance systems presents an opportunity to maximise consumer reporting. High consumer acceptability of the AEFI reporting process supports collection of robust AEFI data and promotes public confidence in vaccine safety.

Key words: COVID-19 vaccines, surveillance and data systems, vaccine programs and implementation, emerging immunisation practices

Appendix B – Participant information sheets

Professional Participant Information Sheet

Participant Information Sheet

Researchers:

- Dr Jill Padrotta: Master of Philosophy in Applied Epidemiology (MAE) Scholar, National Centre for Epidemiology and Population Health, College of Health and Medicine, Australian National University (ANU). Communicable Disease Control Section, Health Protection Service, ACT Health
- Ms Alexandra Marmor: Epidemiologist, Communicable Disease Control Section, Health Protection Service, ACT Health
- Dr Nevada Pingault: Senior Epidemiologist, Public Health Intelligence, COVID-19 Public Health Operations, Western Australia Department of Health
- Dr Davoud Pourmarzi: National Centre for Epidemiology and Population Health, College of Health and Medicine, ANU

Project Title: *Evaluation of the ACT Adverse Events Following Immunisation Reporting System*

General Outline of the Project:

This project is being undertaken to evaluate how adverse events following immunisation (AEFI) are monitored in the ACT, and how data on AEFI are collected, managed, and used. This project will form part of Dr Jill Padrotta's MAE thesis. The MAE is a higher degree by research undertaken through the ANU.

Stakeholders who are involved in the ACT AEFI Reporting System (the System) are being asked to participate in short, semi-structured interviews, either in person or via telephone, to enable the gathering of information regarding the System. Data obtained through interviews will be used to draft a report which will describe the System, detail the aspects of the evaluation undertaken, and make recommendations for how the System might be improved. This report will be included in the primary investigator's thesis and will be provided to ACT Health for consideration.

Participant Involvement:

You have been identified as a stakeholder of the System and have been asked to participate in an interview because your views and perspective are considered valuable for this evaluation.

Participation in interviews is voluntary and there will be no negative consequences if you choose not to participate. You may decline to answer particular questions if you wish and may cease the interview at any point. If you withdraw, your data will be removed from the evaluation and corresponding report.

Interviews are expected to take approximately 30 minutes and may be conducted in person or via telephone. Interviews will take place during October 2022. At the time of interview, you will be asked to provide verbal consent for an audio recording to be taken of the interview. Audio recordings will be used to generate detailed written notes after the interview and will then be permanently deleted. Only the primary investigator will have access to audio recordings, and these will not be shared with any third party. You may decline to have your interview audio recorded if you wish. Written notes (in electronic form) will also be taken to capture the information you provide. No physical records will be used.

The results from stakeholder interviews will help inform recommendations around how the System might be improved. Ultimately, the data obtained through interviews is intended to result in improvements in how AEFI surveillance is undertaken in the ACT, which may have benefits for individuals who experience AEFI and for vaccine safety monitoring more broadly.

Confidentiality:

Reasonable steps will be taken to ensure confidentiality as far as possible. The names of interviewees will not be recorded, and specific comments will not be attributed to any individual. In written interview notes, interviewees will be identified using a unique numbered code. The code will be provided to you at the time of your interview. You can keep the code in case you would like to request correction or removal of any comments you have made during the interview. You may request changes or removal of anything you tell us during the interview up to one week after the interview. After one week, it may not be possible to delete or change things you have told us during interview. In the resulting MAE thesis, only the general stakeholder role (e.g., clinical staff) will be documented.

Data Storage:

All data associated with this project (excluding audio recordings) will be stored on the secure, password protected ACT Health IT system. Data will be stored for a period of at least five years from publication of the research in the MAE thesis. After this period, data will be archived on the ACT Health IT system. Interview data collected during this project will not be used for any other projects or future research.

Privacy Notice:

Australian privacy law (or rules) require me to tell you how my organisation handles your private information, and you can ask me to give you more details of that or how you can find out what information we have about you and to fix it if it is wrong.

Queries and Concerns:

If you have any questions or concerns about this project, you are welcome to contact the primary investigator, Dr Jill Padrotta, at Jill.Padrotta@anu.edu.au or on 5124 6218.

Ethics Committee Clearance:

The ethical aspects of this research have been approved by the ANU Human Research Ethics Committee (Protocol 2017/695). If you have any concerns or complaints about how this research has been conducted, please contact:

Ethics Manager
The ANU Human Research Ethics Committee
The Australian National University
Telephone: +61 2 6125 3427
Email: Human.Ethics.Officer@anu.edu.au

Consumer Participant Information Sheet

Participant Information Sheet

Researchers:

- Dr Jill Padrotta: Master of Philosophy in Applied Epidemiology (MAE) Scholar, National Centre for Epidemiology and Population Health, College of Health and Medicine, Australian National University (ANU). Communicable Disease Control Section, Health Protection Service, ACT Health
- Ms Alexandra Marmor: Epidemiologist, Communicable Disease Control Section, Health Protection Service, ACT Healt
- Dr Nevada Pingault: Senior Epidemiologist, Public Health Intelligence, COVID-19 Public Health Operations, Western Australia Department of Health
- Dr Davoud Pourmarzi: National Centre for Epidemiology and Population Health, College of Health and Medicine, ANU

Project Title: *Evaluation of the ACT Adverse Events Following Immunisation Reporting System*

General Outline of the Project:

This project is looking at how adverse events following immunisation (AEFI) are monitored in the ACT, and how data on AEFI are collected, managed, and used. AEFI include any negative reactions that follow an immunisation. This project will form part of Dr Jill Padrotta's MAE thesis. The MAE is a research degree through the ANU.

People who are involved in the ACT AEFI Reporting System (the System) are being asked to participate in short interviews. These will be done either face-to-face or over the phone. The interviews are being used to collect information about the System. The information collected from interviews will be used to draft a report which will include recommendations for how the System might be improved. This report will be included in the primary investigator's thesis. It will also be provided to ACT Health.

Participant Involvement:

We would like to interview you because you have been identified as a person who has made a report to the System. We value your opinion and would like to hear about your experiences reporting an AEFI.

You can choose whether or not to participate in the interview. Nothing negative will happen if you decide not to participate. You can also choose which questions you want to answer. If you decide to be interviewed but then change your mind, you can withdraw at any time. If you withdraw, the information you have provided us will not be included in the project or the report.

Interviews will take no longer than 30 minutes and will be done in October 2022. When we interview you, we will ask you to give us permission to take an audio recording of the interview. We would like to record your interview so that we can take detailed notes without missing important information. After we have used the audio recording to take notes, we will permanently delete the audio recording. Only the primary investigator will have access to audio recordings and these will not be shared with anyone. You can say no to having your interview audio recorded if you like. Typed notes will also be taken to record the information you provide.

The information we collect through interviews will help us to make recommendations about how the System might be improved. The information we collect through interviews should help us make recommendations that improve how AEFI are monitored in the ACT. This should help people who experience AEFI and will help with vaccine safety monitoring more broadly.

Confidentiality:

We will take steps to make sure your information is kept confidential. We will not record your name and our report will not say which person has provided which comment. In written interview notes, we will use a unique numbered code to keep track of each participant. We will tell you the code when we interview you. You can write the code down and if you would like to ask us to change or remove any of your interview responses in the future, you can tell us the code so that we know which responses are yours. You can ask us to change or remove anything you tell us during the interview up to one week after the interview. After one week, it may not be possible to delete or change things you have told us during interview. In the MAE thesis which is written following this project, we will identify you as “a consumer”.

Data Storage:

All data for this project (apart from audio recordings) will be stored on the secure, password protected ACT Health IT system. Data will be stored for a period of at least five years from publication of the research in the MAE thesis. After five years, data will be archived on the ACT Health IT system. Interview data collected during this project will not be used for any other projects or future research.

Privacy Notice:

Australian privacy law (or rules) requires me to tell you how my organisation handles your private information, and you can ask me to give you more details of that or how you can find out what information we have about you and to fix it if it is wrong.

Queries and Concerns:

If you have any questions or concerns about this project, you are welcome to contact the primary investigator, Dr Jill Padrotta, at Jill.Padrotta@anu.edu.au or on 5124 6218.

Ethics Committee Clearance:

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The Australian National University
Telephone: +61 2 6125 3427
Email: Human.Ethics.Officer@anu.edu.au

Appendix C – Stakeholder interview questions

ACT Health Directorate stakeholders

Director and Immunisation Coordinator, Immunisation Unit, Health Protection Service, ACT Health Directorate (face-to-face interview)	Attribute
1. Do you think the current system meets its stated objectives?	Usefulness
2. Are you able to provide an example of public health action which has resulted from the data collected by the system?	Usefulness
3. What do you see as the strengths of the system?	All
4. Are there any aspects of the system you think should be improved?	All
5. What resources are required to operate the system?	Stability, simplicity
6. Who funds the system and how long is funding secured for?	Stability
7. What training is required for new staff who operate the system and how long does it take to train new staff?	Flexibility, simplicity
8. Has there been a significant change to the demands of the system, or available operational supports for running the system? If so, how has this been dealt with?	Flexibility
9. Are you aware of any positive feedback regarding the system which has received from those who report AEFI? If so, what was the nature of the feedback?	Acceptability
10. Are you aware of any negative feedback regarding the system which has received from those who report AEFI? If so, what was the nature of the feedback?	Acceptability
11. Is the system reliable and always available? Are there any times it has not been reliable and/or available?	Stability
12. What reports are generated using data obtained from the system?	Usefulness
13. Has there been a time the system needed to change to work in with another system or new technology?	Flexibility
14. What differences, if any, have you observed between the current AEFI reporting system and the previous system? Have you seen improvements since the implementation of the new system?	Usefulness, acceptability
Public health nurse Immunisation Unit, Health Protection Service, ACT Health Directorate (face-to-face interview)	**Attribute**
1. Do you think the current system meets its stated objectives?	Usefulness
2. Are you able to provide an example of public health action which has resulted from the data collected by the system?	Usefulness
3. What do you see as the strengths of the system?	All
4. Are there any aspects of the system you think should be improved?	All

5. What are the steps involved in receiving an AEFI, following up, and entering data? How much time is spent at each step? Are all of these steps necessary?	Simplicity, timeliness
6. How much does the time spent at each step change, depending on the AEFI?	Timeliness, flexibility
7. Approximately what proportion of online forms are received in a completed state?	Data quality
8. Has there been a significant change to the demands of the system, or available operational supports for running the system? If so, how has this been dealt with?	Flexibility
9. Are you aware of any positive feedback regarding the system which has received from those who report AEFI? If so, what was the nature of the feedback?	Acceptability
10. Are you aware of any negative feedback regarding the system which has received from those who report AEFI? If so, what was the nature of the feedback?	Acceptability
11. Is the system reliable and always available? Are there any times it has not been reliable and/or available?	Stability
12. What reports are generated using data obtained from the system?	Usefulness
13. Has there been a time the system needed to change to work in with another system or new technology?	Flexibility
14. What differences, if any, have you observed between the current AEFI reporting system and the previous system? Have you seen improvements since the implementation of the new system?	Usefulness, acceptability
Communicable Disease Control on-call staff, Health Protection Service, ACT Health Directorate (face-to-face interview)	**Attribute**
1. Can you tell me about your experience using the System to record a notification when you were working on-call?	Usefulness, acceptability
2. Did you ever receive an AEFI notification prior to the change to the system that occurred in 2021? If so, what differences have you observed between the current AEFI reporting system and the previous system?	Usefulness, acceptability
3. What do you see as the strengths of the system?	All
4. Are there any aspects of the system you think should be improved?	All
Public health physician/registrar, Health Protection Service, ACT Health Directorate (face-to-face interview)	**Attribute**
1. Do you think the current system meets its stated objectives?	Usefulness
2. Are you able to provide an example of public health action which has resulted from the data collected by the system?	Usefulness
3. What do you see as the strengths of the system?	All
4. Are there any aspects of the system you think should be improved?	All

5. What is the average interval between when a notification is made and when a recommendation is provided?	Timeliness, acceptability
6. How much variability is there in the time taken to make a recommendation and what are the impacts of delays?	Timeliness, acceptability
7. What factors impact the interval between notification to recommendation?	Timeliness, stability
8. What reports are generated using data obtained from the system?	Usefulness
9. Are you aware of any positive feedback regarding the system which has received from those who report AEFI? If so, what was the nature of the feedback?	Acceptability
10. Did Are you aware of any negative feedback regarding the system which has received from those who report AEFI? If so, what was the nature of the feedback?	Acceptability
11. Is the system reliable and always available? Are there any times it has not been reliable and/or available?	Stability
12. Has there been a time the system needed to change to work in with another system or new technology?	Flexibility
13. What differences, if any, have you observed between the current AEFI reporting system and the previous system? Have you seen improvements since the implementation of the new system?	Usefulness, acceptability

Stakeholders external to the ACT Health Directorate

General practitioner/nurse/pharmacist (phone interview)	Attribute
1. How often have you had to use the system to report an AEFI?	Acceptability
2. What method (phone/online) did you use to report the most recent AEFI you reported?	Acceptability
3. Did you report an AEFI prior to July 2021? If yes, what differences have you noticed between the old system and the current system?	Usefulness, acceptability
4. If you have used the online form, how easy is it to locate and use?	Acceptability
5. How much time does it take you to report an AEFI? Where is the greatest amount of time spent?	Acceptability, timeliness
6. Has there ever been a time where you could not report an AEFI or experienced difficulty using the system? If so, what was the difficulty?	Acceptability, stability
7. Have you previously provided any positive feedback regarding the system? If so, what was it?	Acceptability
8. Have you previously provided any negative feedback regarding the system? If so, what was it?	Acceptability
9. Do you receive/read reports which include data generated by the system (e.g., AEFI Annual Report)? If yes, has this impacted your clinical practice and/or increased your confidence in administering vaccines?	Usefulness
10. What do you see as the strengths of the system?	All
11. Are there any aspects of the system you think should be improved?	All
TGA representatives (phone interview)	**Attribute**
1. Can you please provide an overview of the role of the TGA in AEFI surveillance and describe your experience with the ACT AEFI Reporting System?	Acceptability
2. What steps are involved in AEFI data being reported to the TGA?	Simplicity
3. I understand there is some variability in how different jurisdictions provide AEFI data to the TGA. Can you comment on the differences and which way you think is best?	All
4. What do you see as the strengths of the current system of reporting of AEFI data to the TGA?	All
3. Are there any aspects of the system you think should be improved?	All
4. Are you aware of any positive feedback from any stakeholders involved in AEFI reporting regarding the system? If so, what was it?	Acceptability
5. Are you aware of any negative feedback from any stakeholders involved in AEFI reporting regarding the system? If so, what was it?	Acceptability

6. Can you comment on the timeliness of AEFI data being provided to the TGA? How long does it normally take for an AEFI notification to reach the TGA after it has been notified by the reporter?	Timeliness
7. What are the impacts of delays in AEFI data reaching the TGA?	Stability
8. Do you have any concerns about the reliability of the way AEFI data are reported to the TGA? Are there any times the system has not been reliable and/or available?	
9. Have you ever held any concerns about the quality of ACT AEFI data reported to the TGA?	Data quality
SAFEVAC representatives (phone interview)	**Attribute**
1. Can you please describe your experience with the ACT AEFI Reporting System?	Acceptability
2. What do you see as the strengths of the system?	All
3. Are there any aspects of the system you think should be improved?	All
4. Have you previously provided any positive feedback regarding the system? If so, what was it?	Acceptability
5. Have you previously provided any negative feedback regarding the system? If so, what was it?	Acceptability
6. Is the way data regarding ACT AEFI is provided to the TGA consistent from one notification to the next?	Data quality, stability
7. What steps are involved in AEFI data being reported to SAFEVAC?	Simplicity
8. How long does it take for AEFI data to be provided to SAFEVAC?	Timeliness
9. Is the system reliable and always available? Are there any times it has not been reliable and/or available?	Stability
10. Is there a way to 'batch upload' data to SAFEVAC via .csv or .xlsx file?	Flexibility
Consumer (phone interview)	**Attribute**
1. Can you please tell me about the AEFI you reported, when you reported it, and if you reported it over the phone or using online form?	Acceptability
2. Why did you choose this method to report this AEFI?	Acceptability
3. (If online) Was it easy to find the online form?	Acceptability
4. (If online) Did you have any difficulty completing the online form? If so, what was it?	Data quality, acceptability
5. How long did it take you to report the AEFI over the phone/ fill out the online form?	Timeliness
6. Were there any details about the AEFI you could not provide? If so, why not?	Data quality, acceptability

7. Have you received any public health advice from ACT Health following your AEFI? If so, what was it?	Usefulness
8. Do you have any positive feedback regarding your experience with reporting an AEFI?	Usefulness, acceptability
9. Do you have any negative feedback regarding your experience with reporting an AEFI?	Usefulness, acceptability

CHAPTER FIVE: DESIGN AND CONDUCT AN EPIDEMIOLOGICAL STUDY

Table of Contents

Chapter 5: Gonococcal infections in the ACT and risk factors for reinfection, 2017-2022

Prologue

This chapter details an epidemiological study into gonococcal infections and reinfections notified in the Australian Capital Territory (ACT) between 2017 and 2022. In addition to describing the epidemiology of gonococcal infections and reinfections in the ACT over this period, it seeks to answer the study question: *What factors are associated with an increased risk of gonococcal reinfections in the ACT?*

A final draft manuscript, under peer review at the time of submission, is at Appendix A. This chapter fulfills the major competency, *Design and conduct an epidemiological study* and the minor competencies, *Literature Review* and *Peer-reviewed publication.*

My role

Under the guidance of my supervisors and informed by informal discussions with relevant ACT Health Directorate (ACT Health) staff, I led the planning and design of this study. This included identifying the public health issue of interest, selecting the study design and population, choosing an appropriate methodology, determining what data to include, and developing a data analysis plan. Prior to commencing the study, I was also responsible for drafting the research proposal and securing ethics approval.

I extracted, collated, and cleaned the data and oversaw the linkage of data from the ACT notifiable diseases management system with data from enhanced surveillance from the ACT Research Electronic Data Capture database. To enable analysis of records by person (as well as by notification), I merged the observations for individuals with more than one notification in the dataset to produce a new dataset with only one entry per person. I planned and conducted the statistical analyses and hypothesis testing and interpreted the results. I led the drafting of the eventual manuscript (Appendix A), which included managing the study team, coordinating input from authors, selecting a peer-reviewed journal, and ensuring the manuscript adhered to the journal's requirements.

To better understand the recent evidence regarding the risk factors for gonococcal reinfection, I undertook a targeted review of the published literature. The literature review methods I used are detailed in Appendix B. I synthesised the results of my analyses with those obtained through the literature review to inform the discussion of this chapter.

Public health impact

The emergence of antimicrobial resistant lineages of *Neisseria gonorrhoeae* (*N. gonorrhoeae*) has propelled gonococcal infections to the forefront of public health challenges relating to sexually transmissible infections. The reproductive, neonatal, and broader health implications associated with multi-drug resistant *N. gonorrhoeae* are significant, making the effective prevention and control of gonococcal infections an important public health priority. In this chapter, the terms 'gonorrhoea' and 'gonococcal infection' are used interchangeably to describe laboratory confirmed infections caused by *N. gonorrhoeae*.

Studies looking specifically at the risk factors for gonococcal reinfection are limited, demonstrated by the results of my targeted literature review (Appendix B), which only returned a small number of published articles. Therefore, this study seeks to address an apparent knowledge gap. Anecdotally, recurrent infections have been observed to contribute to the increasing volume of gonococcal infection notifications seen in the ACT in recent years. However, this study represents the first investigation aimed at quantifying the magnitude of gonococcal reinfections and identifying the risk factors for reinfection, in the ACT. Significant public health resources are dedicated to the follow-up and management of gonococcal infections. This study will provide insight into the scale of the problem, to inform the allocation of public health resources dedicated to interventions and allow ongoing monitoring of our progress towards reducing gonococcal reinfection rates. Understanding the risk factors for reinfection will enable interventions to be appropriately targeted at the relevant groups.

Lessons learned

This study represented my first experience designing an epidemiological study from scratch and my first effort at linking data from multiple databases. What initially appeared to be a straightforward process, quickly proved to be a complex undertaking. Having to define 'reinfection' in the absence of a universally agreed timeframe after treatment for a gonococcal infection for a subsequent infection to be considered 'new', presented one challenge. Examining multiple variables, some of which necessitated analysis 'by person' and others 'by infection', presented another. Linking data from multiple databases, which had been collected over different time periods, was extremely nuanced. Finally, the multitude of potential biases which arose during the analysis of data for multiple infections for the same individuals, required careful planning and consideration. Negotiating each of these obstacles provided many valuable learning opportunities relating to designing and executing an epidemiological study.

Acknowledgements

I acknowledge the contribution of my supervisors and co-authors to the planning of this study and drafting and revision of the manuscript. Thank you for your supervisory support and assistance navigating the challenging aspects of this study. Thank you to the public health nurses: Rachael Crane, Lauren Baden, and Felicity Greenville, who provided valuable advice during the planning and preparation of this study. Thank you to Timothy Sloan-Gardner for providing comment on the draft manuscript. I acknowledge and thank Jacob Kael and Dharshi Thangarajah for assisting with data linkage. I also acknowledge all ACT Health staff who contributed to the collection of data used in this analysis and the work of the Canberra Sexual Health Centre which contributed to this research.

Appendix A – Final draft manuscript under peer review: Gonococcal infections in the ACT and risk factors for reinfection, 2017-2022

Jill Padrotta, Alexandra Marmor, Nevada Pingault, Davoud Pourmarzi

Abstract

Objectives

To describe the epidemiology of gonococcal infections and reinfections between 2017-2022 in the Australian Capital Territory (ACT), Australia, and examine the risk factors for reinfection.

Methods

Retrospective analysis of ACT gonococcal infection notifications data for 2017-2022 was undertaken. The epidemiological characteristics of individuals with a single infection and reinfection were compared through case-case analysis.

Results

There were 1,886 gonococcal infection notifications, including 385 reinfections (20.4%). Of 1,501 individuals, 1,254 (83.5%) had a single infection and 247 (16.5%) had a reinfection. Between 2017 and 2022, the gonococcal infection notification rate per 100,000 population increased from 59.98 to 80.14 and the proportion of reinfections from 4.0% to 26.8%. Multivariate analysis showed compared with a single infection, those with a reinfection had greater odds of a same sex sexual exposure (adjusted odds ratio [aOR] 2.75, 95% confidence interval [CI] 1.36-5.55), diagnosis at a sexual health/family planning clinic (aOR 2.07, 95% CI 1.27-3.38), and having used HIV pre-exposure prophylaxis (PrEP) (aOR 1.97, 95% CI 1.30-2.98).

Conclusions

Gonococcal reinfections contribute significantly to overall gonococcal infection notifications in the ACT, with certain groups at increased risk.

Implications for public health

Targeted novel interventions are needed to prevent reinfections, particularly among individuals who engage in same sex sexual activities, use PrEP, or attend sexual health/family planning clinics.

Introduction

Worldwide, there were an estimated 82.3 million new gonococcal infections diagnosed among people aged 15-49 years during 2020, making it the second most commonly diagnosed sexually transmissible infection (STI).[1] Reducing transmission remains a global public health priority owing to the emergence of antimicrobial resistant lineages limiting effective treatment options.[1,2] Untreated, gonococcal infections can lead to adverse reproductive and perinatal outcomes and enhanced transmission of human immunodeficiency virus (HIV). [1,3,4,5,6]

In Australia, laboratory confirmed gonococcal infections are nationally notifiable.[7,8] Notification rates have risen over the past decade, peaking at 141.4 per 100,000 population in 2019 before declining to 109.4 in 2021, during the COVID-19 pandemic.[9] In the Australian Capital Territory (ACT), notification rates have followed a similar pattern to other Australian states and territories, increasing from 22.0 to 66.9 per 100,000 population from 2012-2021.[10] People aged 15-29 years, Aboriginal and/or Torres Strait Islander people, gay, bisexual, and other men who have sex with men (GBMSM), and sex workers are among priority populations who may be disproportionately affected.[11]

Testing is recommended for symptomatic and exposed body sites.[12] Three-monthly asymptomatic testing is recommended at all three sites (oropharyngeal, anorectal, and first pass urine) for men who have engaged in any type of sex with another man in the past three months.[12] Clinicians should also screen for STIs, including gonococcal infection, at commencement of HIV pre-exposure prophylaxis (PrEP) and every 90 days while PrEP is used.[12,13] After diagnosis, clinicians should provide education about preventing future infections and initiate discussion about contact tracing for all partners for at least the past two months.[12] Testing for reinfection is recommended at three months.[12]

Although evidence on the contribution of reinfections to overall gonococcal infections is limited, reinfections have been shown to represent approximately 18% of total gonococcal infection notifications in defined study populations.[14,15] Definitions of 'reinfection' after treatment for a prior infection reported in the literature range from two weeks to two months.[14,16,17,18,19]

Relatively few studies have investigated the risk factors for gonococcal reinfections. International evidence suggests male sex, age <20 years, GBMSM, previous history of STI, and co-infection with another STI at diagnosis of initial infection, may increase the risk of gonococcal reinfection.[14,16,18,20] Lower socioeconomic status (SES), sex work, inconsistent condom use, having had more than one sexual partner in the past six months, or having a partner who had another partner in the recent past, have also been shown to increase risk.[14,15,16,18,20] Recent Australian studies are lacking; however, a

2020 study in Adelaide, South Australia, identified GBMSM, people living in low SES areas, and older age groups (among five age groups aged 20-69 years compared with 10-19 years) as having a higher risk of reinfection.[15]

This study aimed to describe the epidemiology of gonococcal infections and reinfections in the ACT between 2017 and 2022 and examine the risk factors for reinfection during this period.

Methods

Study design and population

In the ACT, laboratory confirmed gonococcal infections are notified to the ACT Health Directorate (ACT Health). Public health officers (PHO) conduct routine case follow-up through interview with clinical staff and/or the case, to collect enhanced surveillance data, which is entered into the ACT notifiable diseases databases. Further enhanced data on sexual behaviours are collected through an online questionnaire sent to cases via text message. Where a positive result is received within 28 days of a previous gonococcal infection notification for the same individual, PHO investigate (in consultation with the clinician) whether the notification represents a persistent or new infection. Infections deemed new (e.g., where there was a negative test in the intervening period) are classified as confirmed.

A retrospective cross-sectional study was undertaken to describe the epidemiology of gonococcal infection notifications in the ACT. The study population included ACT residents with a gonococcal infection notification with specimen collection between 2017 and 2022. Sex at diagnosis was used for analyses as data for gender were not available for the entire study period. A reinfection was defined as a subsequent notification for an individual who had a prior gonococcal infection notification during 2017-2022.

A case-case study design was used to investigate the risk factors for reinfection. Cases of interest were defined as individuals with more than one notification during the study period (Reinfection group). Cases with a single notification during the study period served as comparison cases (Single Infection group). To reduce misclassification bias, individuals with additional gonococcal infection notification(s) during 2014-2016 were excluded from the Single Infection group. Prior to 2014, the number of gonococcal infection notifications in the ACT was low so notifications for this period were not explored.[10]

Data sources

Demographic and clinical data were exported from ACT notifiable diseases databases. Enhanced data fields included self-reported sexual exposure type for this infection (opposite sex, same sex, both sexes, or unknown) and sex worker status during the past 12 months. Data for number of sexual partners, use of dating apps, and condom use were available for notifications from February 2022 when collection of these data commenced in the ACT. Data for use of PrEP at diagnosis were available for notifications from October 2018. For the Reinfection group, epidemiological data from the first infection during the study period (or first infection at which data were available), were used for comparisons with the Single Infection group. Duplicate entries, notifications with a postcode outside the ACT, and notifications for individuals aged less than 14 years, were excluded.

Statistical analyses

Analyses were undertaken with Microsoft Excel and Stata (Version 17). Counts and proportions were used to describe epidemiological characteristics. Where numbers for a variable were low (n<5), categories were combined to prevent potential re-identification. Trends in the number and rate (per 100,000 population) of gonococcal infection and reinfection notifications during the study period, were described. Annual population rates were calculated using Australian Bureau of Statistics mid-year ACT estimated resident population data.[21]

For reinfections, the interval (days) between infections and the proportion of individuals with intervals <182, 182-365, and >365 days, were calculated. To identify risk factors for reinfection, epidemiological data for the Reinfection and Single Infection groups were compared univariately with P values <0.05 considered statistically significant. Pearson's Chi-squared test was used for categorical variables and Mann-Whitney U test for median age. Records with indeterminate/non-binary sex, anatomical site of infection of 'other', and unknown or not reported Aboriginal and/or Torres Strait Islander status, sexual exposure type, PrEP use, and sex worker status, were excluded from comparisons based on these variables. Variables with a statistically significant difference on univariate analysis were included in the multivariate logistic regression analysis to generate adjusted odds ratio (aOR). The Hosmer-Lemeshow test was performed to assess goodness of fit.

Ethics

The protocol for the study was approved by the ACT Health Human Research Ethics Committee (HREC) Low-Risk Sub-Committee and acknowledged by the Australian National University HREC.

Results

Descriptive analysis

After exclusions (n=13), a total of 1,886 gonococcal infection notifications were included in the study for 1,501 unique individuals. For all notifications, data completeness (with 'unknown' responses considered missing) was 100% for age, sex, diagnosing clinical facility, and anatomical site of infection and >95.0% for Aboriginal and/or Torres Strait Islander status, sexual exposure type, sex worker status, and use of PrEP (for 1,385 notifications from October 2018 onwards). Enhanced questionnaire data were available for 103 individuals. Data completeness was 82.5% for both number of partners in the past two months and condom use and 98.2% for the dating app used.

There were 1,485 notifications (78.7%) for males, 391 (20.7%) for females and 10 (0.5%) for individuals with indeterminate/non-binary sex. The median age was 30 years (range 14-75, interquartile range [IQR] 13). For notifications for Aboriginal and/or Torres Strait Islander people, the median age was 26 years (range 14-60, IQR 7.5). Table 1 shows the number and percentage of notifications within each variable category, by sex.

Table 1: Number and percentage of notifications by variable category

Variable	Variable category	Number (%)[a]	
		Males	Females
Age at onset (years)	14-24	319 (67.3)	155 (32.7)
	25-34	649 (81.0)	152 (19.0)
	35-44	306 (84.5)	56 (15.5)
	45-54	136 (86.1)	22 (13.9)
	55 and over	75 (92.6)	6 (7.4)
Aboriginal and/or Torres Strait Islander status	Neither Aboriginal nor Torres Strait Islander	1375 (81.0)	323 (19.0)
	Aboriginal and/or Torres Strait Islander	46 (52.9)	41 (47.1)
	Unknown/not reported/inadequately described	64 (70.3)	27 (29.7)
Sexual exposure type	Same sex	1072 (>99.0)	≤10 (<1.0)
	Opposite sex	325 (47.2)	363 (52.8)
	Both sexes	58 (78.4)	16 (21.6)
	Unknown/not reported	30 (≥75)	≤10 (≤25)

HIV PrEP at diagnosis[b]	No	555 (65.0)	299 (35.0)
	Yes	475 (>99)	≤10 (<1.0)
	Unknown	39 (≥79.6)	≤10 (≤20.4)
Sex worker	No	1426 (80.9)	337 (19.1)
	Yes	8 (19.0)	34 (81.0)
	Unknown/not reported	51 (71.8)	20 (28.2)
Diagnosing clinical facility	Sexual health clinic	1036 (89.8)	118 (10.2)
	General practice	373 (67.3)	181 (32.7)
	Hospital	25 (36.8)	43 (63.2)
	Family planning clinic	10 (43.5)	13 (56.5)
	Other	41 (53.2)	36 (46.8)
Anatomical site of infection[c]	Urogenital only	473 (63.1)	277 (36.9)
	Throat only	385 (91.2)	37 (8.8)
	Rectum only	294 (98.0)	6 (2.0)
	Rectum and throat	181 (>99.0)	<5 (<1.0)
	Urogenital and throat	48 (59.3)	33 (40.7)
	Urogenital and rectum	59 (80.8)	14 (19.2)
	Urogenital, rectum and throat	43 (68.3)	20 (31.7)

[a] Excludes sex of indeterminate/non-binary (n=10).

[b] For 1,385 notifications from October 2018 to December 2022.

[c] Excludes 'other' (n<5).

Males with a same sex or both sexes sexual exposure represented 59.9% of all notifications and >99.0% of notifications where PrEP was used at diagnosis. The majority (80.2%) of those diagnosed at a sexual health clinic were also males with a same sex or both sexes sexual exposure. For site of infection, approximately half of notifications included a urogenital infection, 40.0% included throat, and 33.0% included rectum (Table 1).

Sexual behaviours

Of 85 individuals with data available for the number of sexual partners in the past two months, 19 (22.4%) reported one, 28 (32.9%) reported two to five, 23 (27.1%) reported six to 15, and 14 (16.5%) reported 16 or more. For 85 individuals with data available, condom use was reported as 'Always' by 10 (11.8%), 'Sometimes' by 47 (55.3%), 'Only for some types of sex' by six (7.1%), and 'Never' by 22 (25.9%).

Of 103 individuals with data available, 56 (54.4%) reported having used a dating app to meet their partner/s for this exposure. The most common was Grindr (n=43, 76.8%), followed by Tinder (n=15, 26.8%). Twelve (21.4%) reported using Scruff, Squirt and/or Bumble. Two or more apps were used by 13 individuals (23.2%). Of those who used a dating app for whom data on the number of partners were available (n=55), more than 90.9% reported having had at least two to five partners in the past two months compared with 50.0% for those who did not report using an app.

Reinfections

There were 385 notifications classified as reinfections—20.4% of total notifications. Of 1,501 unique individuals, one gonococcal infection was notified for 1,254 individuals (83.5%) and more than one for 247 individuals (16.5%). Of those with one infection notified during the study period, 37 were excluded as they had at least one notification reported during 2014-2016 resulting in 1,217 individuals in the Single Infection group. Of the 247 individuals in the Reinfection group, 169 (68.4%) had two infections, 42 (17.0%) had three infections, 21 (8.5%) had four infections, 10 (4.0%) had five infections, and five (2.0%) had six or more infections.

Trends

Between 2017 and 2019, the proportion of reinfections increased from 4.0% to 28.9% before reducing in 2020 and 2021 and increasing again to 26.8% in 2022 (Figure 1). The overall rate of gonococcal infection notifications per 100,000 population increased from 59.98 in 2017 to 80.14 in 2022, with a dip in 2020 before increasing again in 2021 and 2022. The rate of reinfections per 100,000 population, which increased from 2.40 in 2017 to 21.46 in 2022, also saw a dip in 2020-21.

Prior to 2020, the rate of first infections was declining while both the rate and proportion of reinfections increased between 2018 and 2019 (Figure 1). Although the rate of both first infections and reinfections decreased in 2020, there was a greater increase in the rate of reinfections than first infections between 2021 and 2022.

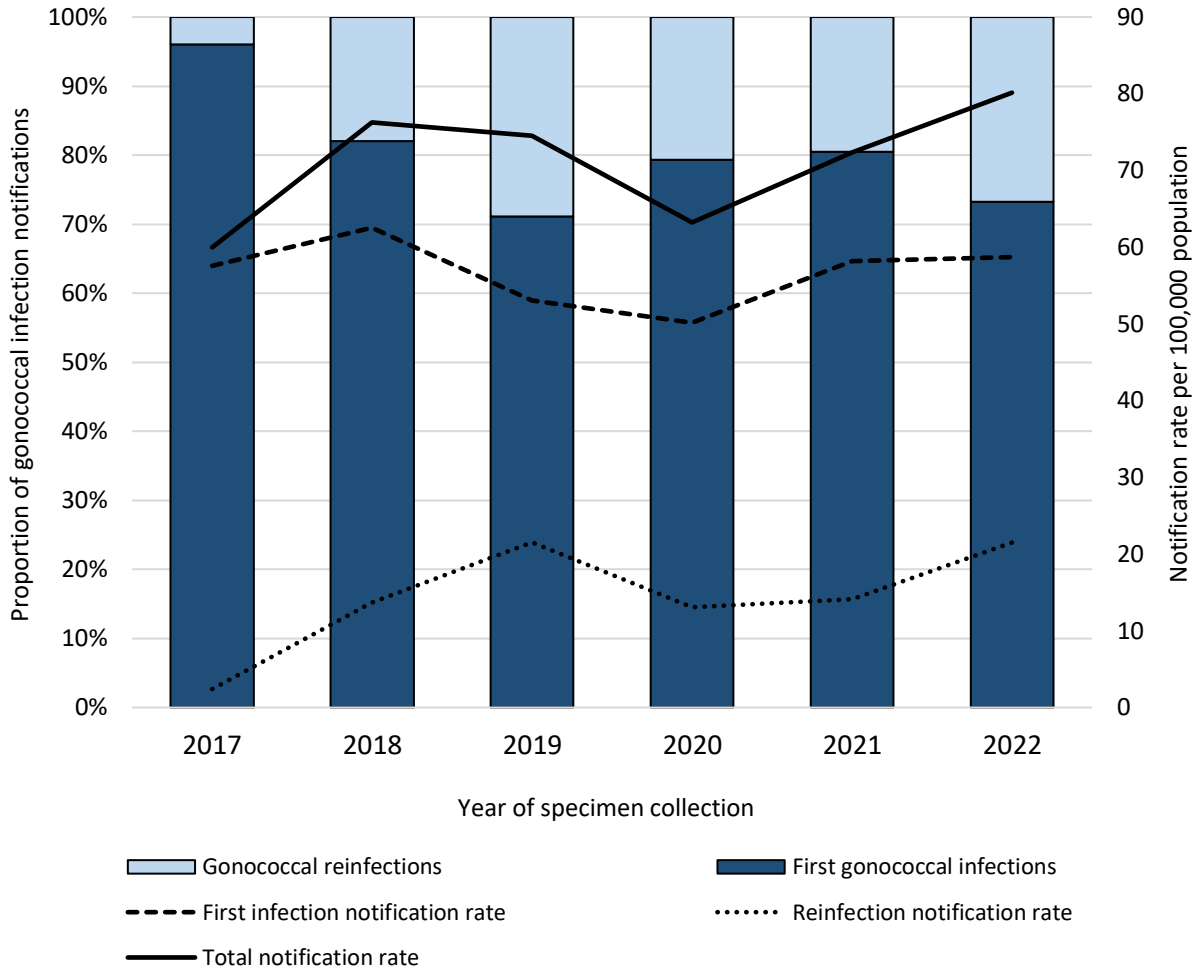

Figure 1. Proportions of gonococcal reinfections and first infections, by year of specimen collection and ACT notification rates per 100,000 population for first gonococcal infections, gonococcal reinfections, and total gonococcal infections, 2017-2022

Interval between infections

For the Reinfection group, 42.1% (n=104) had an interval of <182 days (approximately six months), 19.0% (n=47) 182-365 days (six months to one year), and 38.9% (n=96) >365 days with a median interval of 308.0 days (range 17-2068, IQR 499.0). The median interval between first and second infections (n=247) was 338.5 days (range 23-2068, IQR 523.8), second and third (n=78) 262.0 days (range 17-1453, IQR 366.8), and third and fourth (n=36) 238.0 days (range 53-1540, IQR 430.0). Of 78 individuals with more than two infections, 42 (53.8%) had a shorter interval between their second and third infections than between their first and second, with a median reduction in interval of 192.5 days (range 1-980, IQR 148.0 days).

Case-case analysis

The median age at first infection for the Reinfection and Single Infection groups were 30 years (range 16-61, IQR 13) and 28 years (range 14-75, IQR 53), respectively (p=0.050). Univariate analysis showed that compared with the Single Infection group, the Reinfection group had significantly greater odds of being male, having a same sex (compared with opposite sex) sexual exposure, having used PrEP at diagnosis, and having been diagnosed at a sexual health/family planning clinic rather than a general practice. Based on age at first infection, the Reinfection group had significantly greater odds of being in the 25-34-, 35-44-, and 45-54-years age groups than being in the 14-24-years age group (Table 2). The odds of anatomical site of first infection being only the rectum, only the throat, or at more than one site, compared with urogenital only, were significantly greater for the Reinfection group. No statistically significant differences were found between the two groups for Aboriginal and/or Torres Strait Islander status or sex worker status (Table 2).

A total of 880 observations were included in the multivariate logistic regression analysis. Only same sex sexual exposure, use of PrEP, and having been diagnosed at a sexual health and/or family planning clinic, were associated with reinfection (Table 2). The Hosmer-Lemeshow test indicated a well-fitted model (p>0.05).

Table 2: Number and proportion of individuals in the Reinfection and Single Infection groups, by epidemiological characteristics, with univariate and multivariate analyses of association

Variable	Variable category	Reinfection (%)	Single Infection (%)	Unadjusted OR (95% CI)	p-value (Chi-squared)	Adjusted OR (95% CI)	p-value
Age (years)	14-24	51 (12.0)	373 (88.0)	Ref.	-	Ref.	-
	25-34	115 (19.1)	487 (80.9)	1.73 (1.21-2.47)	0.003	1.18 (0.75-1.84)	0.473
	35-44	49 (19.0)	209 (81.0)	1.71 (1.12-2.63)	0.013	1.25 (0.73-2.14)	0.408
	45-54	23 (19.3)	96 (80.7)	1.75 (1.02-3.02)	0.041	1.00 (0.50-1.99)	0.993
	55 and over	9 (14.8)	52 (85.2)	1.27 (0.59-2.73)	0.546	-	-
Sex[d]	Female	23 (6.3)	341 (93.7)	Ref.	-	Ref.	-
	Male	223 (20.4)	868 (79.6)	3.81 (2.42-5.99)	<0.001	1.91 (0.84-4.33)	0.121
Aboriginal and/or Torres Strait Islander status[e]	Neither Aboriginal nor Torres Strait Islander	231 (17.6)	1080 (82.4)	Ref.	-	Ref.	-
	Aboriginal and/or Torres Strait Islander	11 (15.3)	61 (84.7)	0.84 (0.44-1.63)	0.611	-	-
Sexual exposure type[f]	Opposite sex	43 (6.8)	590 (93.2)	Ref.	-	Ref.	-
	Same sex	194 (26.6)	535 (73.4)	4.98 (3.46-7.15)	<0.001	2.75 (1.36-5.55)	0.005
	Both sexes	7 (10.4)	60 (89.6)	1.60 (0.69-3.72)	0.270	-	-
HIV PrEP at diagnosis[g]	No	94 (12.1)	685 (87.9)	Ref.	-	Ref.	-
	Yes	122 (38.9)	192 (61.1)	4.6 (3.33-6.43)	<0.001	1.97 (1.30-2.98)	0.001
Sex worker[h]	No	235 (17.2)	1134 (82.8)	Ref.	-	Ref.	-
	Yes	5 (13.5)	32 (86.5)	0.75 (0.29-1.96)	0.560	-	-

Diagnosing clinical facility[i]	General practice	40 (8.0)	463 (92.0)	Ref.	-	Ref.	-
	Sexual health and/or family planning clinic	193 (23.3)	635 (76.7)	3.52 (2.43-5.08)	<0.001	2.07 (1.27-3.38)	0.004
	Hospital	8 (13.1)	53 (86.9)	1.75 (0.78-3.94)	0.173	-	-
Anatomical site of infection[j]	Urogenital only	66 (10.0)	597 (90.0)	Ref.	-	Ref.	-
	Rectum only	47 (22.8)	159 (77.2)	2.67 (1.76-4.06)	<0.001	0.96 (0.51-1.83)	0.905
	Throat only	67 (21.3)	248 (78.7)	2.44 (1.68-3.56)	<0.001	0.67 (0.36-1.23)	0.194
	Two or more sites	67 (24.3)	208 (75.7)	2.91 (1.99-4.23)	<0.001	1.03 (0.57-1.85)	0.932

[d] Excludes indeterminate/non-binary (n<10) due to low numbers.

[e] Excludes unknown, not stated, or inadequately described (n=81). Records with Aboriginal and/or Torres Strait Islander status of Aboriginal, Torres Strait Islander, and both Aboriginal and Torres Strait Islander have been combined to prevent re-identification.

[f] Excludes unknown/not reported (n=35).

[g] For Reinfection group, reflects the first infection with data available for use of PrEP at diagnosis. Excludes unknown (n=44).

[h] Excludes unknown/not reported (n=58).

[i] Excludes 'other' (n=72).

[j] Excludes 'other' (n<5).

Discussion

Reinfections contribute substantially to gonococcal infection notifications in the ACT. More than one-fifth of the notifications in our study were for reinfections. The rates of both reinfections and gonococcal infection notifications overall, appear to be increasing in the ACT, emphasising the need for the timely development of interventions aimed at identified at-risk groups.

More than three-quarters of gonococcal infection notifications over the study period were for males. The highest proportion of females (32.7%) was among the 14-25-years age group, decreasing for every subsequent ten-year age group. The median age for all notifications was 30 years. However, notifications for Aboriginal and/or Torres Strait Islander people had a lower median age, at 26 years, and higher proportion of females. This is consistent with another study which found a higher female

to male ratio and higher notification rates in females in the younger (15-19-years) age groups among Aboriginal and/or Torres Strait Islander people.[22]

Although just over one-half of notifications were for urogenital infections, around 40% involved the throat and around one-third, the rectum. This finding supports the need for testing of these sites, where recommended by clinical guidelines.[12]

Based on our findings, more than a quarter of individuals with data available indicated they never used condoms, more than three-quarters had more than one sexual partner during the past two months and more than half reported using dating apps. Among those who used dating apps, more than 90% reported having had more than one partner in the past two months. Previous studies have shown inconsistent condom use and greater number of partners increase the risk of gonococcal reinfection.[16,23] Use of dating apps has been associated with higher risk sexual behaviours, such as condomless sex with multiple and/or casual partners, and is associated with an increased risk of gonococcal infections compared with in-person methods of meeting partners.[24,25,26] An Australian qualitative study identified inconsistent condom use, normalisation of STIs, low perception of risk, having several casual partners, and limited communication with partners about sexual history, as potential contributors to increased gonococcal infections among heterosexual young adults.[27] To prevent reinfection, novel prevention strategies are needed to reduce participation in risky sexual behaviours among those with a previous gonococcal infection. These may include health promotion strategies, such as embedded STI warnings in dating apps, and counselling or educational techniques which aim to change risk perception around STIs.

In our study, over 20% of notifications were reinfections, slightly higher than the proportions reported in other studies, which may reflect both testing practices and behaviours in the ACT.[14,15] The ACT has the highest rate of PrEP use per 100,000 population of any Australian state or territory, potentially contributing to the higher proportion of gonococcal reinfections.[28] More than two-thirds of those in the Reinfection group had only two infections, with the number of individuals with each subsequent number of infections approximately halving from three infections onwards. This is consistent with a previous study which found reinfections were concentrated among a small subset of individuals.[29]

Examination of trends suggests an increase in both the proportion and rate of gonococcal reinfections contributed to the increase in overall gonococcal infection notifications seen in the ACT since the relaxation of COVID-19-related restrictions in 2021. In 2022, the ACT recorded its highest ever gonococcal infection notification rate, with a greater increase in reinfections than first infections between 2021 and 2022.

Measurement of the intervals between infections showed a wide range from 17 days to more than five years with a median of 308 days. The median interval reduced with each subsequent infection and more than half of the 78 individuals who had three or more infections became infected again more quickly after their second infection than after their first. This may reflect earlier diagnosis due to regular asymptomatic testing for individuals in identified priority groups. However, it further supports that, for a subset of individuals, the STI prevention education provided at previous diagnoses may not be effective in preventing—or even delaying—future infections.

The use of PrEP at diagnosis and same sex sexual exposure were significantly associated with reinfection, consistent with previous studies identifying PrEP users and GBMSM as groups at increased risk.[15,18,29,30,31] In another study, which found commencing PrEP was associated with an increase in gonococcal infection incidence, the overwhelming majority of those using PrEP were GBMSM.[29] Although data for whether the case was symptomatic or asymptomatic were outside the scope of this study, regular asymptomatic STI screening is recommended for GBMSM, at commencement of PrEP, and every 90 days while PrEP is used, increasing the likelihood of diagnosis.[13] Individuals taking PrEP may be both at inherently greater risk of gonococcal reinfections, and more likely to have their infections identified through regular testing.[12] In addition to the need for tailored health promotion and educational initiatives to reduce gonococcal infections and reinfections, these groups should also be prioritised for future pharmacological interventions to prevent transmission.

Diagnosis at a sexual health/family planning clinic was associated with around a two-fold increase in odds of reinfection and more than 80% of those diagnosed in sexual health/family planning clinics were males with a same sex or both sexes sexual exposure. This confirms the critical role of sexual health/family planning clinics in managing gonococcal reinfections. These settings provide an important potential avenue for the delivery of interventions to prevent subsequent infections in their clients and sufficient resources must be allocated to clinics to enable their development.

Strengths and limitations

The strengths of this study include the use of a case-case study design, with those with a notification prior to the study period excluded from the Single Infection group to reduce misclassification bias, and the use of multivariate analysis. Data were collected by experienced PHO using established processes and completeness was high with only a small number of notifications excluded.

As this study used data from notifications, asymptomatic or otherwise undiagnosed infections may not have been captured. However, regular testing among priority groups, as recommended by clinical

guidelines, may have reduced the effect of this limitation. Movement of people in and out of the ACT within the study period also presents a limitation to identifying all repeat infections.

Due to the retrospective study design, it was not possible to track changes in epidemiological variables for individuals in the Reinfection group. Data for the first infection were used for comparisons with the Single Infection group. However, for some individuals, the status of some variables may have changed for subsequent infections, potentially affecting our estimates. Data for sexual behaviours were collected through an opt-in questionnaire using self-reported responses and may have been subject to recall bias or underreporting due to concerns around stigma and privacy.

In this study, multivariate analysis sought to examine the relationships between each variable and risk of reinfection, rather than predict a specific outcome. However, the complex inter-relationships between some variables presented limitations to examining their individual effects on risk of reinfection. As the vast majority of individuals using PrEP at diagnosis were males with a same sex sexual exposure, these variables were highly correlated. Additionally, the small number of females with a same sex sexual exposure prevented examination of males and females separately. Therefore, the finding of same sex sexual exposure as a risk factor for reinfection likely reflects male same sex sexual exposure. Available data for sexual exposure type related to the specific infection being notified, rather than the individual's broader sexual history. This prevented comparison of GBMSM with males who were not GBMSM, as those who reported an opposite sex sexual exposure for a given infection could not be reliably excluded from the GBMSM group.

Conclusion

The findings of this study show the contribution of reinfections to overall gonococcal infection notifications in the ACT is substantial and increasing. People who use PrEP, have a same sex sexual exposure, and use sexual health/family planning clinics, are at increased risk of gonococcal reinfections. The development of appropriately targeted new interventions to reduce gonococcal infections and reinfections among these groups, is required. This may include specific health promotion activities, novel methods in education and counselling (including those delivered through dating apps), and prioritisation of these groups for future pharmacological interventions. Further studies are needed to understand risk perceptions around STIs and why current prevention initiatives may be ineffective for some individuals, to support the development of effective future interventions.

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Appendix B – Targeted literature review methods

Aim and research question

The literature review was aimed at identifying peer-reviewed, published reports to answer the research question: *What are the risk factors for gonococcal reinfections?*

Methods

I searched the PubMed database on 4 April 2023 and included all studies published during the 10 years prior. Search terms were developed iteratively, starting with key words separated by OR and narrowed to identify articles addressing the research question. The reference lists of included articles were screened to identify relevant articles not identified during the original search.

The following search terms were used: *((("Neisseria gonorrhoeae") OR ("gonococcal infection") OR (gonorrh*)) AND ((reinfection) OR (re-infection) OR ("recurrent infection") OR ("multiple infections") OR (repeat*)) AND ("risk factor*"))*

The findings of the search were collated with duplicate papers removed. For the remaining articles, the inclusion and exclusion criteria detailed in Table A1 were applied.

Error! Reference source not found. **Targeted literature review inclusion and exclusion criteria**

	Inclusion	**Exclusion**
Condition	Studies into gonococcal reinfections	Studies into single gonococcal infections, studies of more than one sexually transmissible infection where data for gonococcal reinfections were not presented separately, studies into testing for reinfection where risk factors for reinfection were not investigated
Language	English	Languages other than English
Year of publication	2013 – 2023	Prior to 2013
Population	Humans	Animal studies
Publication type	Peer-reviewed articles	Pre-print publications, opinion articles, commentaries
Methodology	Observational study designs, randomised controlled trials, scoping reviews, systematic reviews	Narrative reviews, modelling, case reports, qualitative studies
Access type	Open access or full text accessible via institutional access for the Australian National University	Full text not accessible via institutional access for the Australian National University

Search results

The initial search returned 72 results. Titles and abstracts were reviewed with 43 papers excluded. After review of full text articles, a further 24 papers were excluded. Review of the reference lists of papers meeting the inclusion criteria identified two papers which were subsequently included. A total of seven studies were ultimately included in the literature review, summarised in Table A2.

Table A2: Details of papers included in targeted literature review

Reference	Study period	Study design	Study population	Sample size	Definition of reinfection	Risk factors for reinfection explored[a]	Risk factors for reinfection[a,b,c,d,e,f,g]
Bautista et al. (2)	2006-2012	Population-based case series	Male or female service members in the U.S. Army who had at least one gonorrhoea infection reported in the Defense Medical Surveillance System during the study period	17,602	A repeat gonorrhoea infection where the diagnosis occurred at least 30 days from the previous diagnosis	Age, ethnicity (white, African-American, Hispanic, other), education (no high school, high school, some college or higher), marital status (single, married, other), Army rank, years of military service until first gonorrhoea infection	Women: Age (Ref. ≥25) 17-17 years (HR 1.51; 95% CI ; 1.22-1.86), 20-24 (HR 1.4; 95% CI 1.17-1.69), ethnicity (Ref. white) African-American (HR 1.26; 95% CI 1.06-1.50); education (Ref. college or higher) high school only (HR 1.8; 95% CI 1.25-2.58), military rank (Ref. officers) junior (HR 2.64; 95% CI 1.21-5.74), years of military service (Ref. ≥4) 1 or fewer (HR 1.23; 95% CI 1.05-1.45) Men: Age (Ref. ≥25) 17-19 years (HR 1.71; 95% CI 1.48-1.97), 20-24 (HR 1.40; 95% CI 1.28-1.54), ethnicity (Ref. white) African-American (HR 2.17; 95% CI 1.92-2.46), Hispanic (HR 1.44; 95% CI 1.18-1.77), military rank (Ref. officers) junior (HR 1.37; 95% CI 1.02-1.84), years of military service (Ref. ≥4) 1 or fewer (HR 1.37; 95% CI 1.23-1.52), 2-3 (HR 1.21; 95% CI 1.09-1.34)
Ellis et al. (6)	2012-2017	Retrospective cross-sectional	Residents of Greater Adelaide who had a gonorrhoea notification recorded on the South Australian Health Department's surveillance system during the study period	3,680	A new gonorrhoea notification in the same individual within the study period	Age group, sexual orientation, SES (high/low)	Age (Ref. 10-19 years) 20-29 (RR 2.22; 95% CI 1.44-3.42), 30-39 (RR 2.93; 95% CI 1.90-4.54), 40-49 (RR 3.20; 95% CI 2.05-5.15), 50-59 (RR 3.23; 95% CI 2.02-5.15), 60-69 (RR 3.69; 95% CI 2.18-6.21), sexual orientation (Ref. heterosexual male) MSM (RR 3.21; 95% CI 2.65-3.89), SES (Ref. high) low (RR 1.33; 95% CI 1.13-1.56)

Hughes et al. (3)	2004-2008	Cross-sectional	Patients attending the STI clinic in Sheffield (Royal Hallamshire Hospital) in the UK who had a gonorrhoea episode recorded during the study period	1,650	A second attendance for gonorrhoea at least 42 days after the first episode	Age, gender, sexual orientation, ethic group, year of initial gonococcal infection, index of deprivation, history of STIs, number of sexual partners in past 3 months, sex abroad in past 3 months, having a high-risk sex partner in the previous year, sex work, history of injecting drugs	Gender and sexual orientation/age (Ref. heterosexual men, age ≤19 years) MSM aged 19 or younger (HR 1.98; 95% CI 1.72-5.44), ethnicity (Ref. white) mixed/other (HR 1.67; 95% CI 1.10-2.54), reported history of gonorrhoea (Ref. no) yes (HR 3.98; 95% CI 1.64-9.68), number of partners past 3 months (Ref. 0-1) 2-5 (HR 2.63; 95% CI 1.10-6.26), 6+ (HR 4.52; 95% CI 1.52-13.5)
Kenyon et al. (7)	1999-2003	Secondary analysis of longitudinal cohort study	Non-pregnant women aged 15-44 years presenting for a routine health care visit at one of 12 health department clinics in Birmingham, Alabama during the study period	3,620	Gonococcal infection present at current visit in a person who had a gonococcal infection present at a previous visit	Partner concurrency (partner having had another partner in the recent past), cumulative number of STIs	Previous gonococcal infection at last visit (OR 4.5; 95% CI 1.7-11.6), partner concurrency (Ref. no partner concurrency reported in preceding period) (OR 4.3; 95% CI 1.7-10.9)
Meesaeng et al. (1)	2010-2020	Retrospective cohort	Male patients of Royal Thai Army Hospitals	2,465	The first episode of gonococcal urethritis diagnosed at least 14 days after a previously recorded infection during the study period	Age, occupation, region, number of lifetime sexual partners, marital status, history of consistent condom use	Age <30 years (AHR 1.7; 95% CI 1.0-2.8), number of lifetime sexual partners equal to 2 (AHR 3.4; 95% CI 2.3-7.5), residing in the north (AHR 4.1; 95% CI 2.3-7.5) and northeast regions (AHR 2.1; 95% CI 1.1-3.9)

Trecker et al. (5)	2003-2012	Cross-sectional	Laboratory confirmed gonorrhoea from the notifiable disease files of the Regina Qu'Appelle Health Region, 2003-2012	1,027	Individuals who appeared more than once in the 10-year database with verification of appropriate therapy for the prior infection and interval between infections was ≤2 months	Age, sex, co-infection with chlamydia, whether received correct treatment, number of sex partners in last 6 months, previous STI, sex trade involvement, alcohol or drug abuse, same sex relationship reported, place of residence (urban/rural), initial visit (sexual health clinic/other)	Age 19 or younger (OR 2.71; 95% CI 1.54-4.75), coinfection with chlamydia (OR 2.05; 95% CI 1.33-3.19), 2 or more sexual partners in last 6 months (OR 1.63; 95% CI 1.63-2.52), sex trade involvement (OR 3.60; 95% CI 1.64-7.91), alcohol or drug abuse (OR 1.96; 95% CI 1.14-3.38)
Trecker et al. (4)	2003-2012	Cross-sectional	Laboratory confirmed gonorrhoea from the notifiable disease files of the Regina Qu'Appelle Health Region, 2003-2012	1,027	Individuals who appeared more than once in the 10-year database with verification of appropriate therapy for the prior infection and interval between infections was ≤2 months	Coinfection with chlamydia, urban location, sex trade involvement, component size (number of nodes in network maps generated of gonorrhoea cases and their reported contacts)	Coinfection with chlamydia (OR 2.57; 95% CI 1.31-5.05), reporting sex trade involvement (OR 5.35; 95% CI 1.56-18.3), high component size (OR 1.33; 95% CI 1.08-1.61)

[a] SES: socioeconomic status
[b] CI: confidence interval
[c] HR: hazard ratio
[d] MSM: men who have sex with men
[e] RR: relative risk/risk ratio
[f] AHR: adjusted hazard ratio
[g] OR: odds ratio

Summary of findings

Definitions of 'reinfection' reported in the literature varied. Timeframes for consideration as a 'new' infection ranged from two weeks to two months after treatment for the prior infection (1,2,3,4,5). Younger age (30 years and under) and male sex were reported as risk factors for gonococcal reinfection (1,3,5). Being aged under 20 years at initial diagnosis has been found to be associated with an increased risk of reinfection compared with older age groups (2,5). However, a study of gonococcal infection notifications between 2012 and 2017 in Adelaide, South Australia found the risk ratio (RR) for gonococcal reinfections increased with older age (6). Studies have identified gay, bisexual and other men who have sex with men (GBMSM) as an at-risk group for gonococcal reinfection (3,6). The South Australian study found that among 675 gonococcal reinfections, GBMSM had increased odds of reinfection compared with other groups (RR 3.21; 95% CI 2.65-3.89) (6).

Greater number of recent sexual partners has been shown to be associated with an increased risk of gonococcal reinfection (1,5,7). A study in the United Kingdom (UK) found two or more partners in the past three months was associated with higher risk compared with one partner (3). The association was stronger for six or more partners (hazard ratio [HR] 4.52; 95% CI 1.52-13.5) than for two to five partners (HR 2.88; 95% CI 1.30-6.42) (3). A Canadian study found two or more partners in the past six months was associated with increased risk of reinfection (OR 1.63; 95% CI 1.06-2.52) compared with one partner (5). Having more than one lifetime sexual partner has also been shown to increase the risk of reinfection (1). Even for individuals with only one recent sexual partner, partner concurrency (having a partner who had another partner in the recent past) has been demonstrated to increase the risk of gonococcal reinfection compared with those without (odds ratio [OR] 4.3; 95% CI 1.7-10.9) (7). Similarly, a Canadian study found larger component size (a subgroup within a sexual network where each individual is connected by at least one tie) was significantly associated with gonococcal reinfections (OR 1.33; 95% CI 1.08-1.61) (4).

Greater socioeconomic deprivation may be a risk factor for gonococcal reinfection. A UK study found living in areas of greatest socioeconomic deprivation was associated with higher risk of gonococcal reinfection (HR 1.85; 95% CI 1.27-2.73) (3). The South Australian study also found low socioeconomic status was associated with greater risk of gonococcal reinfection (RR 1.33; 95% CI 1.13-1.56) (6). Having a history of STIs or co-infection with another STI at initial gonococcal infection have been shown to be associated with increased risk of subsequent gonococcal infections (3,5,7). Sex trade involvement, substance abuse, and inconsistent condom have also been shown to be associated with increased risk of gonococcal reinfection (1,5).

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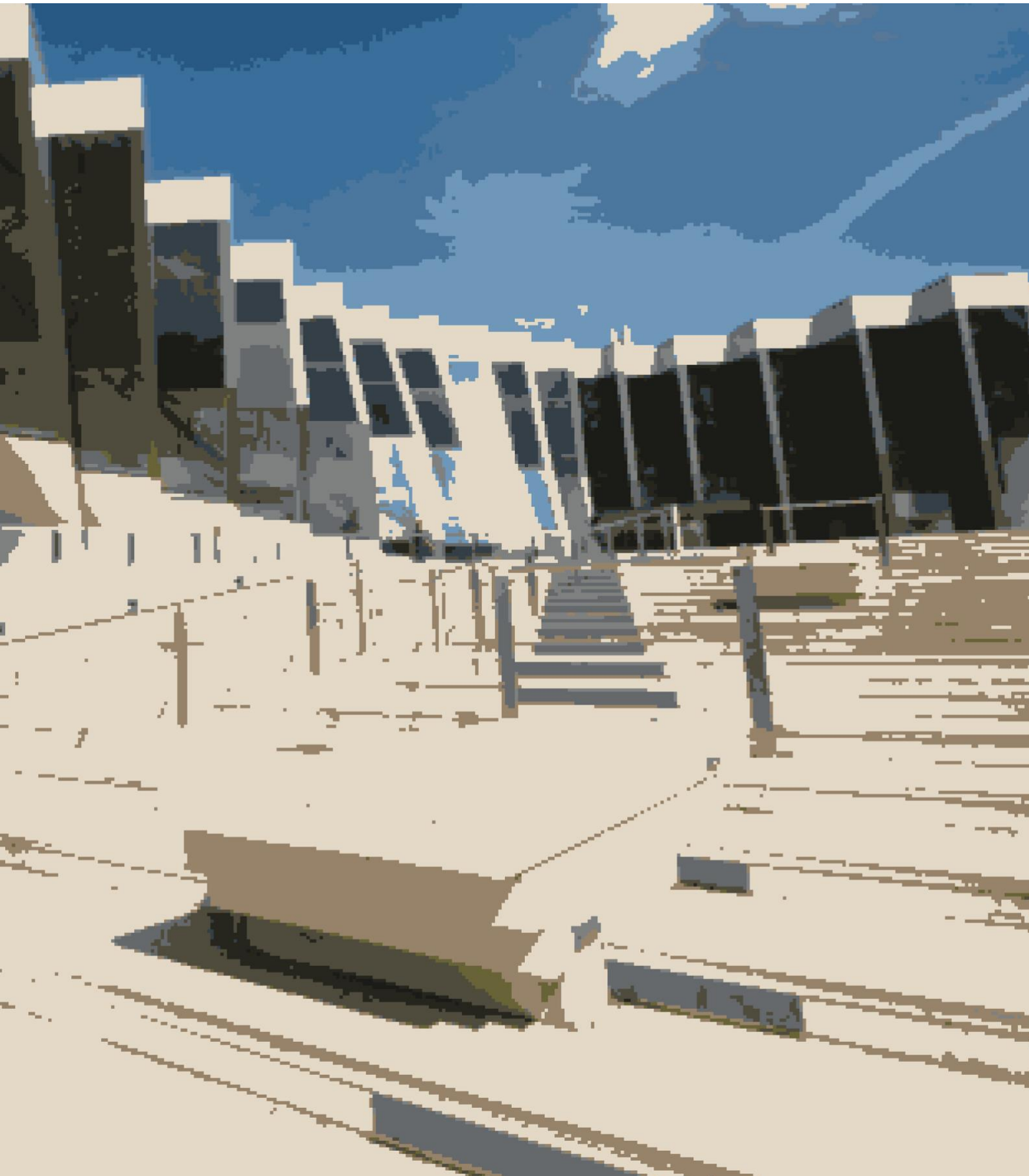
CHAPTER SIX: TEACHING EXPERIENCE



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Chapter 6: Teaching experience

This chapter details my experiences developing and delivering teaching sessions in public health, to fulfil the MAE teaching competency. It includes my lessons from the field (LFF) and teaching to the first year MAE cohort activities.

Lessons from the field

Overview

The LFF presents an opportunity for scholars to undertake peer-to-peer teaching and learning, through sharing lessons learnt during their placements. My LFF group consisted of seven scholars from my cohort. I undertook the role of LFF Coordinator. In consultation with my peers, I developed a roster for when each scholar would present and communicated with the group regarding timeframes and the expectations for presentations.

Lesson: The public health management of a 'white power incident'

For my 'lesson', I chose to present a case study for a 'white powder incident', informed by several incidents (none of which eventuated in a true biological threat) which occurred during my placement in Communicable Disease Control (CDC) at the ACT Health Directorate. I prepared a brief handout with a fictional 'white powder incident' scenario and problem-solving exercise for my cohort to complete ahead of the videoconference (Appendix A).

Learning objectives

The learning objectives for the activity were that by the end of the session, participants would be able to:

1. Outline the public health response to a 'white powder incident'
2. Describe the public health significance of *Bacillus anthracis* (anthrax)
3. Explain the different clinical presentations of anthrax
4. Discuss some of the key jurisdictional and Australian government actions following the identification of a case of anthrax
5. Apply anthrax case definitions.

Exercise

The LFF exercise required the six participants to review selected reading materials and complete an activity to demonstrate their understanding of the background, testing, clinical characteristics, and public health response to an incident involving a potential anthrax exposure (Appendix A).

The completed exercise was returned by four of the six participants. The subsequent videoconference walked participants through the scenario, encouraging discussion of key issues through the inclusion of open-ended questions and provided an overview of the public health investigation, management, and follow-up of individuals exposed to anthrax.

Feedback

Following the videoconference, participants were asked to complete a short survey with four questions probing for feedback on the lesson. Participants were asked to provide a star rating from one (*'Very unsatisfied'*) to five (*'Very satisfied'*). At the end of the survey, participants were invited to provide any feedback or comments in free text. All six participants completed the survey. The results are given below (Figure 1). Overall, the feedback was extremely positive with an average rating above four stars (*'Satisfied'*) for all questions. In the free text responses, one participant commented: *'I really liked that the session was a mix of specific subject matter about the disease and more general info about public health responses and interviews, which is more relevant to other diseases/issues as well.'*

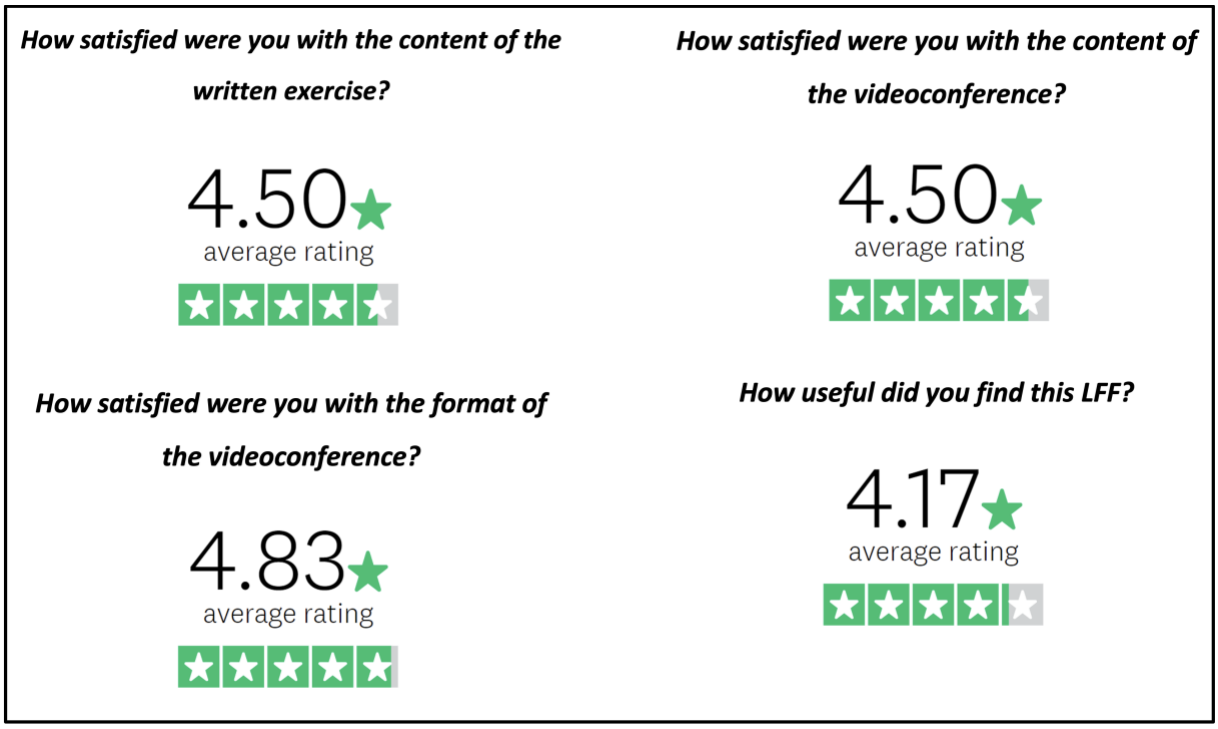


Figure 1: Results of the feedback survey administered to participants following delivery of the LFF

Lessons learned

Preparing and delivering this learning activity taught me the importance of considering the unique perspective of scholars in the group, when determining what lesson to present. Although a 'white powder incident' seemed like a useful lesson to share (due to its potential seriousness as a public health threat), participants noted this lesson may not be as useful for scholars based overseas, as anthrax exposures may be dealt with quite differently in some countries. Even for Australian-based scholars, incidents involving white powder may not occur as frequently in other states and territories as they do in the Australian Capital Territory (ACT), as the ACT is Australia's political capital. To ensure participants were engaged in the activity, the learning objectives aimed for the zone of proximal development by building on knowledge participants already had (e.g., applying case definitions) in the context of a unique public health scenario. I gained the audience's attention through an exciting, semi-fictional story, complemented by pictures. I emphasised the importance of scholars being familiar with the topic by including information on the high proportion of negative outcomes associated with some types of anthrax. Overall, participants were highly engaged in the discussion and appreciated the interesting nature of the topic.

Teaching the first year MAE cohort

Overview

In February 2023, I presented a teaching session on descriptive analysis of surveillance data to first year scholars, alongside another scholar from my cohort. We were the only group of two presenters, with other scholars presenting in threes. This gave us each a greater opportunity to speak and made it easy to coordinate meetings. As we were both based in Canberra, we had the benefit of being able to meet and practice in person. At our initial meeting, we divided our allocated topics and learning objectives between us and agreed on which components we would each present. We drafted a schedule of meetings and arranged a time to practice in person at the Australian National University.

The session consisted of a 15-minute presentation and one-hour practical Excel session, plus 15 minutes for questions and evaluation. Teaching materials, including a slide presentation and written Excel activity, were provided to us by the MAE team ahead of our teaching session. We were required to revise the slides and amend the existing Excel activity to ensure they were up to date and addressed our learning objectives. We drew on some of the principles we had learned during Course Block 2 relating to giving good presentations, such as using slides with minimal text, providing clear learning objectives, and allowing sufficient opportunities for questions. An MAE staff member supported and guided us through the process, meeting with us to practice and assisting during the teaching session.

Teaching session

Learning objectives

The learning objectives were that by the end of the session, scholars would be able to:

- define counts, ratios, proportions and rates
- describe the steps in descriptive analysis of surveillance data
- perform basic functions for analysis of surveillance data using Microsoft Excel.

Teaching session

The teaching session provided us with valuable perspective and experience dealing with a range of challenges faced by teaching staff, such as technological difficulties, responding to questions, and managing our own nerves. Throughout our presentation, we endeavoured to keep participants engaged by frequently swapping who was presenting, embedding questions for the group in our presentation, and ensuring our slides were varied and interesting with minimal text.

There were 20 participants in the session, including two students who participated online via videoconference. To enable the effective participation of those attending online, we had to ensure we projected our voices, remained aware of our proximity to the microphone, and checked in with them regularly to confirm they were following. Those participating remotely were able to complete the activity without issue and reported they could hear the discussions in the room clearly.

The practical part of our session involved demonstrating a range of functions in Excel using the written guide, which had been provided to participants ahead of the session. While one of us presented, the other executed the functions with Excel projected onto the screens in the tutorial room. The laptops and versions of Excel used by participants varied so some participants encountered technical problems which we did not foresee and were not easily solved by our pre-prepared troubleshooting strategies. To address these problems, we effectively utilised the MAE teaching staff in the room who provided an additional set of hands to assist individual participants.

Although accommodating a broad spectrum of Excel skills, from limited to advanced, was always going to present a challenge, we managed this through acknowledging this issue to the group upfront and administering a single-question survey before the session asking participants to self-rate their Excel skills on a scale from zero to 100. The results of this survey provided us with a broad idea of the diversity of Excel skill in the room. This allowed us to better target the session at the appropriate level by covering basic concepts quickly and asking those who rated their skills more highly to assist those around them, if needed.

We effectively managed our time and ensured each component of our presentation stayed approximately within our pre-determined timeframes. Overall, the session was very successful with many scholars commending us on its quality.

Feedback

Following the teaching session, participants were asked to provide feedback through a short, four question survey, accessed via QR code. Participants were asked to provide a star rating from one (*'Very unsatisfied'*) to five ('*Very satisfied'*). Participants were also asked to provide any additional feedback or comments in free text. All 20 participants completed the survey. The results are given below (Figure 2). Overall, the feedback was extremely positive with an average rating above four stars (*'Satisfied'*) for all questions.

In the 'comments' section, 13 participants provided a written response. Most responses were complimentary towards the session. However, four responses indicated the session covered the material too quickly. One participant commented: *'Need more time at each step for troubleshooting and following steps.'* Another three responses indicated the session was too basic. One participant commented: '*A little basic and slow at times but understand the diversity of the cohort.'*

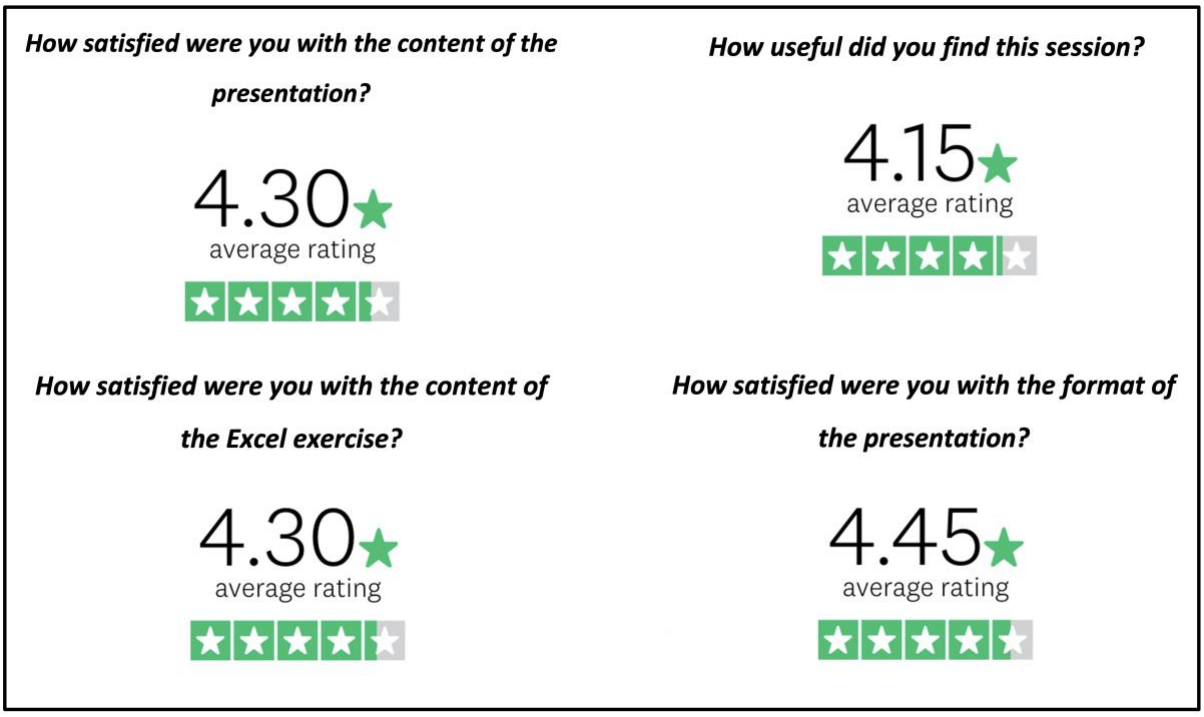


Figure 2: Results of the feedback survey administered to MAE teaching session participants following the session

Lessons learned

Preparing and presenting this teaching exercise was a highly educational experience. Although I am generally quite confident speaking in front of an audience, I was nervous in the lead up to this session. This is primarily due to the length of the presentation (1.5 hours) which far surpasses any amount of time I have previously spent speaking in front of a group. However, we were exceptionally well-prepared having practiced the session many times in the preceding weeks. This included one complete run-through in the presence of an MAE staff member who provided helpful feedback and advice which we incorporated into the final presentation. As a team of two, we demonstrated excellent teamwork. We provided one another with honest and constructive feedback throughout our preparations and assisted one another as much as possible during the actual presentation.

Although we anticipated diversity in Excel skills among the cohort and had prepared strategies to address this, the feedback we received from participants following the session indicated that even with our mitigations, some participants felt the session covered the material too quickly while others felt it was too slow. Embedding more flexibility into the pace of the exercise (such as through the inclusion of extension activities for those with more advanced skills), may have assisted in overcoming this challenge. In any case, the feedback we received on both the presentation and the exercise was overwhelmingly positive.

Appendix A – LFF handout

Lessons from the field: Public health response to a white powder incident

Background

Anthrax is a zoonotic infection caused by *Bacillus anthracis (B. anthracis)*. In Australia, anthrax occurs in grazing animals. Human cases are rare with only three recorded in Australia since 2001.[a] People become infected with *B. anthracis* bacterial spores through inhalation, ingestion, or contact with skin. Symptoms depend on the route of infection, but anthrax can be fatal, particularly when acquired through the inhalation route or ingested.

While there is no vaccine available for civilian use in Australia, vaccination may be provided to defined groups at highest risk (such as laboratory staff working with *B. anthracis* cultures) under the Therapeutic Good Administration's Special Access Scheme. The treatment of anthrax includes antibiotics, such as penicillin, ciprofloxacin, and doxycycline.

Anthrax has high potential as a biological weapon as it is easily cultured and has a high case fatality rate if inhaled or ingested. Bioterrorist attacks using anthrax overseas have resulted in significant morbidity and mortality. Deliberate release of *B. anthracis* in Australia would be a matter of national security involving Commonwealth and state and territory governments, the Australian Federal Police (AFP), and animal health authorities.

This LFF uses a hypothetical case scenario to work through the initial components of the public health response to an incident involving possible anthrax. The subsequent video conference will ask participants to work through an anthrax case investigation to determine whether exposed individuals meet the case definition.

Learning objectives

At the end of this session, participants will be able to:

1. Outline the public health response to a 'white powder incident'.
2. Describe the public health significance of *Bacillus anthracis* ('anthrax').
3. Explain the different clinical presentations and case definitions of anthrax.

[a] https://www.health.gov.au/diseases/anthrax

4. Discuss some of the key jurisdictional and Australian government actions following a case of anthrax.
5. Apply anthrax case definitions.

Scenario

Please note: the following scenario is loosely based on a real-life situation but all details, including people, places, and outcomes, have been modified and embellished for the purposes of this teaching session.

It is a sunny Tuesday morning in the nation's capital, and you have just arrived at your workplace at the ACT Health Protection Service where you work as an epidemiologist. On this particular Tuesday, you are feeling excited and a little apprehensive as your epidemiologist colleagues have all taken the day off to celebrate the Solar Eclipse in Scorpio, leaving you to represent as the only epidemiologist in the building.

You sit down at your desk and have just started scrolling through your emails when the Surveillance Officer, who has been on-call overnight, races over to your desk out of breath. She tells you, with a hint of panic, that an unidentified white powder with an accompanying threatening letter have been found at the Australian National University.

What additional information would you like?

The Surveillance Officer advises that the incident occurred at around 7:55am that morning in the John Curtin School of Medical Research (JCSMR). A JCSMR staff member opened a mail item which contained a threatening letter and around the equivalent of one teaspoon of white powder. The white powder did not come in contact with the staff member's skin but spilled out of the packaging and onto the floor. The staff member immediately called the AFP who assessed the risk as a credible threat with potential risk to health. A HAZMAT team was called in from the ACT Fire & Rescue service.

There were four other people in the room at the time of the incident and approximately 40 people in the building, all of whom were evacuated and quarantined. Assessment and decontamination are underway, and a sample of the powder has been collected and transported to ACT Pathology at The Canberra Hospital for urgent testing.

Read the information about the BioFire FilmArray BioThreat Panel, available here, and name four targets the Panel can be used to test for.

The Surveillance Officer has advised the Senior Director and public health physician (PHP) who has updated the Chief Health Officer (CHO). An urgent meeting has been called and is due to start in 15 minutes. You quickly rack your brain to think of intelligent things to say in the meeting. You vaguely recall, from your MAE days, that the Australian Government Department of Health has published an anthrax public health response plan for Australia. You frantically start Googling and quickly locate the document, available here.

Review the document "*Anthrax: Public health response plan for Australia*" and answer the following questions.

What is *Bacillus anthracis* (*B. anthracis*) and what is its relevance to the public health of Australians?

Complete the table below regarding the different clinical presentations of anthrax.

	Potential mode of transmission	Typical symptoms	Incubation period	Case fatality rate
Cutaneous anthrax				
Inhalational anthrax				
Gastrointestinal anthrax				

What is the national case definition for anthrax?

If the white powder is found to be anthrax, which national response code is likely to be most appropriate?

Provide a brief overview of the appropriate jurisdictional and Australian government actions.

Jurisdictional actions	
Australian government actions	

You feel quite accomplished after your brief cramming session and confidently dial into the videoconference. The PHP advises she has just been contacted by ACT Pathology to notify the Health Protection Service of a positive BioFire *B. anthracis* result from the sample and spores seen on microscopy. These results are highly suggestive of anthrax. Culture is underway but results will not be confirmed for another 48 hours.

An acute response team (ART) is established with a meeting scheduled for later that morning. Environmental Health and the Health Emergency Management Unit have been informed and invited to the ART meeting. The PHP has notified the AFP of the positive result and the CHO advises she will notify the Commonwealth Chief Medical Officer to advise the Australian Health Protection Principal Committee (AHPPC).

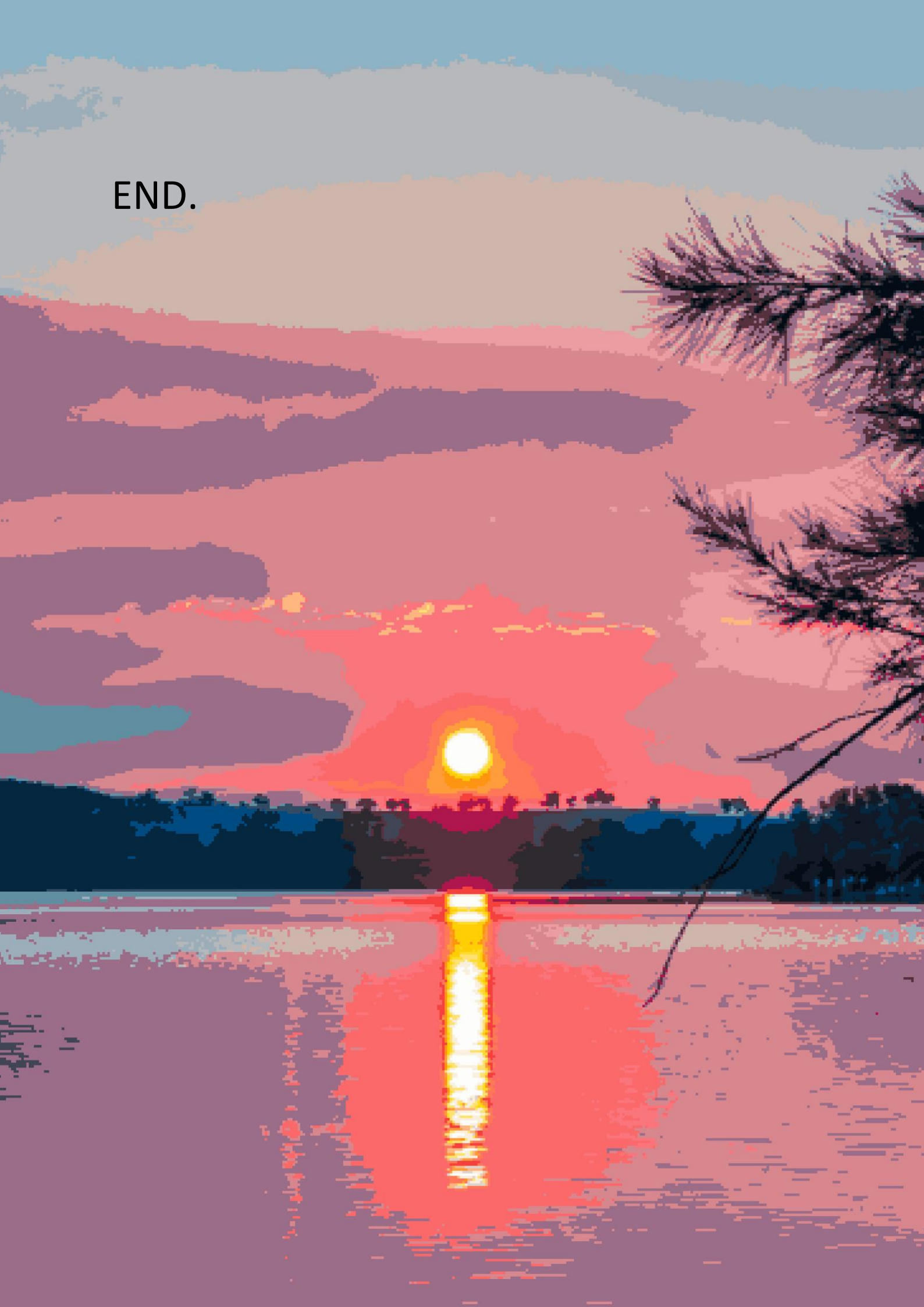
The PHP is coordinating the public health response. After decontamination, all potentially exposed individuals will be interviewed by ACT Health. The PHP asks you to construct a line list to manage information relating to potentially exposed individuals.

Populate the top row in the table below indicating what information you would like to collect from potentially exposed individuals for the line list? Note: This does not need to be exhaustive.

No.									
1									
2									

You are preparing to interview those who have potentially been exposed. Before our LFF videoconference, please give some thought to the following:

- What information might need to be collected in an anthrax exposure interview?
- What are some key considerations in interviewing this group of people?
- What additional resources or information might you be able to provide them with?
- What follow-up would be appropriate after the initial interview (assuming they remain well)?
- What information might need to be prepared for the media?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