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A foodborne norovirus outbreak associated with six events and a single caterer, Canberra, November 2022

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Abstract

Introduction

An outbreak of gastrointestinal illness was investigated, affecting six events where attendees consumed food catered by a single catering business, in the Australian Capital Territory (ACT).

Methods

Event attendees and the catering business were surveyed using tailored food questionnaires developed in REDCap and administered on-line. Descriptive analyses were conducted for all event attendees and employees of the business, and non-fatal productivity loss estimates calculated. Retrospective cohort studies were conducted for events that occurred on two specific days. A food safety inspection was undertaken of the catering business, and food and environmental samples were collected for microbiological analysis. Faecal specimens were collected from symptomatic event attendees.

Results

A total of 82.2% of event attendees (129/157) completed a survey, of whom 49.6% (64/129) reported gastrointestinal illness resulting in an estimated non-fatal productivity loss of AUD $23,700. Univariate analysis of data collected from events on 16 November identified that illness was significantly associated with consumption of vegetarian rice paper rolls (risk ratio [RR]: 1.6; 95% confidence interval [95% CI]: 1.0–3.0; *p* = 0.04). Multiple foods were significantly associated with illness from events that occurred on 17 November 2022. On multivariable analysis, vegetarian rice paper rolls were associated with illness on 16 November 2022 (RR: 1.7; 95% CI: 1.01–2.8;, *p* = 0.046); however no individual food categories were significantly associated with illness on 17 November 2022.

Seven faecal specimens were positive for norovirus. While no food handlers reported illness prior to the outbreak, one food handler reported that their child had had gastroenteritis in the preceding week. Environmental Health inspection of the catering business identified inadequate handwashing facilities. Microbiological testing of seven food samples produced two marginal results: coagulase positive *Staphylococcus* in a sandwich egg mix and a high standard plate count in the roast beef.

Discussion

This gastroenteritis outbreak was determined to be due to norovirus. The infection source was suspected to be an asymptomatic food handler and inadequate food handling controls allowing contamination of certain foods. This study demonstrates the importance of effective hand hygiene and food handling practices at all times, given that asymptomatic individuals can excrete and transmit norovirus and these outbreaks can be large and costly.

Keywords: foodborne diseases; gastroenteritis; norovirus; diarrhoea; caterer; outbreak

# Introduction

Foodborne norovirus is a significant public health problem and the most common cause of foodborne gastrointestinal illness in Australia, with an estimated 328,000 cases (90% uncertainty interval [UI]: 89,600–671,000), including 1,530 hospitalisations (90% UI: 823–2,400) yearly circa 2019, resulting in an estimated total cost of AUD $128 million, predominantly due to lost productivity.1 It is highly contagious requiring a small infectious dose. Food can be contaminated by human faeces or vomitus, and can occur through symptomatic or asymptomatic food handlers excreting virus.2,3,4 Where the source of contamination has been reported in foodborne norovirus outbreaks, 70% were caused by infected food handlers.5,6

On 21 November 2022, the Health Protection Service (HPS), Australian Capital Territory Health Directorate (ACT Health) received complaints of gastrointestinal illness from two events with food provided by the same business. An acute response team was formed to conduct an outbreak investigation with the objectives of identifying the cause of the outbreak and preventing further cases.

# Methods

## Epidemiological investigation

A probable case was defined as a person who attended an event between 16 and 18 November 2022 that had food supplied by the catering business, and experienced vomiting and/or diarrhoea and/or abdominal pain, with one or more of nausea, fever, myalgias and lethargy, within 72 hours of food consumption. A confirmed case met the probable case definition and had norovirus detected by nucleic acid amplification testing.

Event attendees were emailed an online REDCap[[1]](#footnote-2) questionnaire adapted from an existing foodborne-outbreak questionnaire, which included specific food items for each event. Cases of person-to-person transmission, and cases who ate left-over food from the events but were not in attendance, were not included. Active case finding from catered events that did not make a complaint was not performed.

A separate online REDCap questionnaire was sent to catering business employees who worked between 14 and 18 November, including questions about days worked, food preparation involvement, whether they ate food made onsite, and whether they had been unwell or had contacts who were recently unwell.

Descriptive analyses were conducted on data collected from all events and from the business. Retrospective cohort studies were conducted combining events on each of 16 and 17 of November, the days with the highest numbers of event attendees, to identify risk factors for illness on the basis that on each day food was prepared centrally and then distributed to the respective events.

Descriptive and analytical analysis was undertaken in R version 4.1.0. The risk ratio (RR) was calculated for food items served on each day, using data from all individuals who attended functions at which the food item was served. The statistical significance of the RR was determined using Fisher’s exact and chi squared tests with their associated *p* values. Poisson regression models as described by Mcnutt et al7 and Naimi et al8 were constructed for each cohort on each day to assess independent association with illness. Risk factors with a *p* value < 0.1 on univariate analysis were included in the multivariable regression analysis. Cost estimates of non-fatal productivity losses for the outbreak were calculated using the Food Standards Australia New Zealand (FSANZ) foodborne disease costing model and the human capital method.9

Ethics approval was provided by the Australian National University Human Research Ethics Committee umbrella protocol for use of data in research for Masters of Applied Epidemiology scholars for outbreak investigations (Protocol:2017/909). The investigation was also part of a public health response under the ACT *Public Health Act 1997*.10

## Environmental Health investigation

Environmental Health Officers from the HPS conducted a food safety inspection at the catering premises on 22 November. The inspection included food preparation and cooking areas, food storage facilities, bathrooms and handwashing facilities and food handling practices. Statutory food samples and environmental swabs were collected under the ACT *Food Act 2001*.11 During the inspection, Environmental Health Officers interviewed the proprietor and food handlers regarding food handing processes, cleaning and sanitising within the premises, and staff illness.

## Laboratory investigation

### Clinical samples

Faecal specimens collected from symptomatic attendees were tested for viral and bacterial gastrointestinal pathogens by nucleic acid amplification testing (NAAT) and culture. Genotyping was performed at the Serology, Virology and OTDS Laboratories (SAViD) New South Wales (NSW) Health Pathology Randwick.

### Food and environmental samples

Food samples and environmental swabs were processed at the ACT Government Analytical Laboratory (ACTGAL). Food samples were tested for *Salmonella* spp. and *Listeria monocytogenes* with a preliminary screening using polymerase chain reaction (PCR) and for the enumeration by culture of *Escherichia coli*, *Clostridium perfringens*, *Bacillus cereus*, coagulase positive *Staphylococcus* spp. and standard plate count (SPC). Results were compared to the FSANZ Compendium of Microbiological Criteria for Food.2

Environmental samples were tested for *L. monocytogenes* and *Salmonella* spp. Preliminary screening for *L. monocytogenes* and *Salmonella* spp. was undertaken using PCR with all samples also undergoing culture. Testing for norovirus in food and environmental samples could not be performed by ACTGAL and was not conducted.

# Results

## Epidemiological investigation

### Descriptive analysis

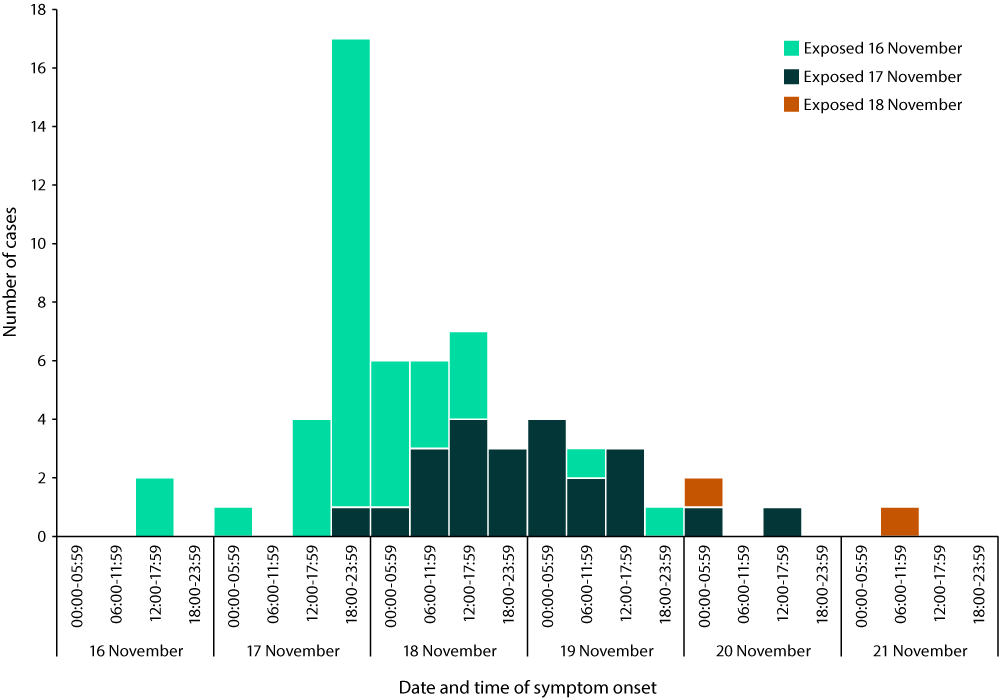
A total of 157 persons attended six events with food prepared by the caterer or consumed catered food while working at the business. Of these, 129 (82.8%) completed a questionnaire and there were 64 outbreak cases identified (7 confirmed cases and 57 probable cases). Cost estimates of non-fatal productivity losses for a norovirus outbreak of this size were found to be $23,700.

The median age of cases was 47 years (range: 15–69 years); 64% of cases (41/64) were female. The median incubation period was 33 hours (range: 3.8–97.0 hours); the median duration of illness was 68.2 hours (range: 7.3–230.3 hours).

Symptoms reported most commonly were nausea (51/64; 80%), followed by vomiting (47/64; 73%), diarrhoea (45/64; 70%), and abdominal pain (45/64; 70%). No cases reported blood in the stool. Six cases (9.3%) sought medical attention, including four who presented to the emergency department. There were no hospital admissions or deaths.

Figure 1 displays an epidemic curve of cases of outbreak cases.

Figure 1: Epidemic curve of gastroenteritis outbreak cases, Canberra, November 2022



### Employee survey

Fourteen employees reported working at the catering premises during the week commencing Monday 14 November 2022. Five employees were involved in food preparation and handling. One food handler, working on Wednesday 16 November and Thursday 17 November, reported having a pre-school child who had vomiting and diarrhoea in the week before the outbreak. This food handler was involved in the preparation of sushi, vegetarian rice paper rolls and sausage rolls on Wednesday; and wraps, sushi, vegetarian rice paper rolls and sausage rolls on Thursday. They reported no symptoms of gastrointestinal illness.

Three employees from the business, one food handler and two drivers, developed gastrointestinal illness during the week of 14 November 2022. Illness onset was from 12 am Friday 18 November to 1 pm Sunday 20 November. None reported sick contacts and all three had consumed food made on the premises.

### Analytical studies

Retrospective cohort studies were conducted across five events for Wednesday 16 November 2022 and Thursday 17 November 2022 to identify risk factors for illness. Of the 134 attendees across the five events, 110 (82%) completed the food questionnaire; 57/71 attendees (80%) on Wednesday and 83/100 (83%) on Thursday. Two individuals were excluded as they did not provide sufficient information and were unable to be contacted for interview. Just over half of the respondents (55/108; 51%) met the outbreak case definition.

The median age of study participants was 45 years (range: 15–67 years) and 69% of participants were female. There was no statistically significant difference in age (*p* = 0.59), sex (*p* = 0.21) or event attended (*p*= 0.66) between those who developed illness and those who did not. Those who attended an event on Wednesday 16 November were more likely to develop illness than those who attended on Thursday 17 November (RR: 1.7; 95% CI: 1.2–2.5; *p* = 0.005).

Results of the univariate and multivariable analyses are shown in Tables 1 and 2. On univariate analysis, gastrointestinal illness was significantly associated with the consumption of vegetarian rice paper rolls (RR: 1.6; 95% CI: 1.0–2.6; *p* = 0.04) on Wednesday 16 November. On Thursday 17 November, any sushi (RR: 1.8: 95% CI: 1.2–2.8; *p* = 0.02), but particularly teriyaki beef sushi (RR: 2.3; 95% CI: 1.7–3.0; *p* = 0.01) and tuna sushi (RR: 1.9; 95% CI: 1.1–2.9; *p* = 0.05), as well as roast beef wraps (RR: 1.7; 95% CI: 1.1–2.7; *p*= 0.03) were significantly associated with illness. On multivariable analysis, vegetarian rice paper rolls were independently associated with illness on 16 November 2022 (adjusted RR: 1.7; 95% CI: 1.01–2.8; *p*= 0.046); however, no foods were independently associated with illness on 17 November 2022.

Table 1: Univariate and multivariable analyses of risk factors for illness at events supplied by a single caterer, Canberra, Wednesday 16 November 2022

| Exposurea | Exposed | | | Not exposed | | | Univariate analysis | | | Multivariable analysis | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cases | Total | AR (%) | Cases | Total | AR (%) | RR | 95% CI | *p* | aRR | 95% CI | *p* |
| **Rice paper rolls** | | | | | | | | | | | | |
| Vegetarian | 17 | 22 | 77.3 | 11 | 23 | 47.8 | 1.6 | 1.0–3.0 | 0.04 | 1.7 | 1.01–2.8 | 0.046 |
| Chicken | 5 | 7 | 71.4 | 9 | 16 | 56.3 | 1.3 | 0.7–2.4 | 0.66 |  |  |  |
| **Sandwiches/baguettes** | | | | | | | | | | | | |
| Roast beef | 10 | 17 | 58.8 | 24 | 35 | 68.6 | 0.9 | 0.5–1.4 | 0.49 |  |  |  |
| Roast vegetable | 3 | 5 | 60.0 | 31 | 47 | 65.9 | 0.9 | 0.4–1.9 | 1 |  |  |  |
| Ham, cheese and tomato | 10 | 14 | 71.4 | 24 | 38 | 63.2 | 1.1 | 0.7–1.7 | 0.75 |  |  |  |
| Chicken | 19 | 27 | 70.4 | 15 | 25 | 60.0 | 1.2 | 0.8–1.8 | 0.43 |  |  |  |
| Egg | 19 | 24 | 79.2 | 15 | 28 | 53.6 | 1.5 | 0.99–2.2 | 0.05 | 1.2 | 0.8–1.9 | 0.34 |
| Salmon | 5 | 6 | 83.3 | 29 | 46 | 63.0 | 1.3 | 0.9–2.0 | 0.65 |  |  |  |
| **Other** | | | | | | | | | | | | |
| Sushi | 4 | 5 | 80.0 | 2 | 2 | 100.0 | 0.8 | 0.5–1.2 | 1 |  |  |  |
| Fruit | 19 | 27 | 70.4 | 15 | 25 | 60.0 | 1.2 | 0.8–1.8 | 0.43 |  |  |  |
| Sweets (tarts, slices, cakes) | 13 | 21 | 61.9 | 10 | 15 | 66.7 | 0.9 | 0.6–1.5 | 0.77 |  |  |  |

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

Table 2: Univariate and multivariable analyses of risk factors for illness at events supplied by a single caterer, Canberra, Thursday 17 November 2022

| Exposurea | Exposed | | | Not exposed | | | Univariate analysis | | | Multivariable analysis | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cases | Total | AR (%) | Cases | Total | AR (%) | RR | 95% CI | *p* | aRR | 95% CI | *p* |
| **Sushi** | | | | | | | | | | | | |
| Teriyaki chicken | 7 | 9 | 77.8 | 26 | 58 | 44.8 | 1.7 | 0.99–2.7 | 0.08 | 0.9 | 0.4–1.8 | 0.71 |
| Tuna | 6 | 7 | 85.7 | 27 | 60 | 45.0 | 1.9 | 1.1–2.9 | 0.05 | 1.5 | 0.9–2.6 | 0.11 |
| Chicken schnitzel | 7 | 10 | 70.0 | 26 | 57 | 45.6 | 1.5 | 0.9–2.5 | 0.19 |  |  |  |
| Teriyaki beef | 6 | 6 | 100.0 | 27 | 61 | 44.3 | 2.3 | 1.7–3.0 | 0.01 | 1.8 | 0.9–3.8 | 0.11 |
| Any sushi | 12 | 16 | 75.0 | 21 | 51 | 41.2 | 1.8 | 1.2–2.8 | 0.02 | 1.2 | 0.6–2.5 | 0.65 |
| **Wraps** | | | | | | | | | | | | |
| Tandoori chicken wrap | 8 | 15 | 53.3 | 25 | 52 | 48.1 | 1.1 | 0.6–1.9 | 0.71 |  |  |  |
| Roast beef wrap | 11 | 15 | 73.3 | 22 | 52 | 42.3 | 1.7 | 1.1–2.7 | 0.04 | 1.0 | 0.5–2.0 | 0.94 |
| Roast vegetable wrap | 6 | 13 | 46.2 | 27 | 54 | 50.0 | 0.9 | 0.5–1.8 | 0.80 |  |  |  |
| Any wrap | 20 | 33 | 60.6 | 13 | 34 | 38.2 | 1.6 | 0.95–2.6 | 0.07 | 1.5 | 0.8–2.9 | 0.22 |
| **Sandwiches/baguettes** | | | | | | | | | | | | |
| Roast beef | 3 | 5 | 60.0 | 3 | 5 | 60.0 | 1.0 | 0.4–2.8 | 1 |  |  |  |
| Roast vegetableb | 4 | 4 | 100.0 | 2 | 6 | 33.3 | 3.0 | 0.97–9.3 | 0.08 |  |  |  |
| Ham, cheese and tomato | 5 | 7 | 71.4 | 1 | 3 | 33.3 | 2.1 | 0.4–11.4 | 0.50 |  |  |  |
| Chicken | 5 | 9 | 55.6 | 1 | 1 | 100.0 | 0.6 | 0.3–1.0 | 1 |  |  |  |
| Egg | 6 | 8 | 75.0 | 0 | 2 | 0.0 | Inf | NaN–Inf | 0.13 |  |  |  |
| Salmon | 3 | 4 | 75.0 | 3 | 6 | 50.0 | 1.5 | 0.6–4.0 | 0.57 |  |  |  |
| **Other** | | | | | | | | | | | | |
| Hot foodc | 11 | 20 | 55.0 | 6 | 17 | 35.3 | 1.6 | 0.7–3.3 | 0.23 |  |  |  |
| Rice paper rolls | 11 | 19 | 57.9 | 8 | 22 | 36.4 | 1.6 | 0.8–3.1 | 0.16 |  |  |  |
| Fruit | 17 | 34 | 50.0 | 22 | 43 | 51.2 | 1.0 | 0.6–1.5 | 0.92 |  |  |  |
| Sweets (tarts, slices, cakes) | 14 | 25 | 56.0 | 19 | 42 | 45.2 | 1.2 | 0.8–2.0 | 0.39 |  |  |  |

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

b Multivariable analysis not performed for roast vegetable sandwiches as these were only eaten at one event.

c Hot food included mini pies, sausage rolls and quiches.

Environmental Health investigation

The proprietor had received a complaint directly from a customer and was anticipating the inspection. The premises were generally clean and well maintained. Staff were wearing gloves and hairnets during food preparation, hand washing facilities were equipped with soap and paper towels; chemical all-purpose sanitiser was present, but running low. It was noted that the business had previously been implicated in a foodborne norovirus outbreak in 2019.

There were three major issues where the business was not compliant with the *Food Act 2001*. There was no designated food preparation sink; the walk-in freezer floor was not clean and needed replacing to allow effective cleaning; and there was potential for cross contamination of food items in the freezer due to lack of organisation. Other issues that were identified included handwashing sinks in the staff toilets too small to allow effective handwashing, no documented staff exclusion policy, and inadequately maintained staff illness records.

Seven statutory food samples and 13 environmental swabs were collected from the premises. There was no remaining food from the catered events available for testing, so food available on the premises on the day of inspection was sampled. As a result of the non-compliances, an Improvement Notice was issued on 23 November 2022 and a follow-up inspection was conducted on 7 December 2022 to review progress and provide hand hygiene and food safety education.

## Laboratory investigation

### Clinical samples

Seven faecal specimens were tested from attendees at Events 1, 2 and 3; all were positive for norovirus. All specimens tested negative for other viral and bacterial pathogens. Four specimens were sent for genotyping at the Serology, Virology and OTDS Laboratories (SAViD) NSW Health Pathology Randwick: one from Event 1, two from Event 2, and one from Event 3. Three samples from two events were genomically indistinguishable. One sample had insufficient coverage breadth to call the lineage and genotype.

### Food and environmental samples

Seven food samples were tested including roast beef, sandwich egg and chicken mixes, carrot, rice and a sausage roll. Thirteen environmental samples were tested, including a tea towel and two chux cloths, two swabs for *L. monocytogenes* from the food preparation sink and sandwich preparation bench and eight swabs for *Salmonella* spp. from locations including sandwich preparation benches, the chicken mixing blade, a slicer, chopping boards and the food preparation sink.

*Salmonella* spp. and *L. monocytogenes* were not detected from any food or environmental samples. *C. perfringens* and *E. coli* were not detected at reportable limits in any of the food samples. The roast beef sample returned a marginal SPC result of 1,200,000 cfu/g and the remaining food SPC results were satisfactory. Coagulase positive *Staphylococcus* spp. was detected in the pre-prepared sandwich egg mix with a marginal count of 500 cfu/g.

# Discussion

The epidemiological and microbiological evidence provided from this investigation strongly implicates norovirus as the causative agent of this outbreak. While this outbreak did not meet the Kaplan criteria for norovirus outbreaks due to an illness duration longer than expected, it did meet the more recent and sensitive criteria from Lively et al of a fever-to-vomit-ratio < 1, proportion of cases with bloody stools < 0.1 and proportion of cases with vomiting ≥ 0.26.12,13 Norovirus was laboratory-confirmed in all seven clinical specimens by positive NAT, with genotyping indicating norovirus from two events were genomically matched, strongly suggesting a common source. The number of cases, and longer than average illness duration, represent significant morbidity and non-fatal productivity losses.1

Cohort studies revealed that illness was associated with several foods on univariate analysis; and on multivariable analysis, with vegetarian rice paper rolls on day one and no specific foods on day two. This was considered consistent with generalised contamination of foods, given there were no foods independently associated with illness by day two.

The source of the contamination was most likely an infected food handler at the catering business and not a specific ingredient as no outbreaks were detected outside of event attendees and their contacts, and there were foods with unrelated ingredients associated with illness on univariate analysis. It is also not plausible for this outbreak to be attributed to person-to-person transmission rather than food contamination, as disease onsets indicated a point source exposure, and the events were unrelated apart from the common caterer.

Large food-handler-related norovirus outbreaks associated with a centralised catering business have been described worldwide.14–17 Viruses are the most common cause of food-handler-related outbreaks, and ready-to-eat foods that don’t undergo a subsequent kill step are the most commonly implicated foods, as occurred in this outbreak.18,19 Multiple food items were suspected to be contaminated consistent with food-handler-associated outbreaks, where frequent hand contact occurs with a variety of foods during preparation and serving, as well as during manual preparation of food following cooking.14,18

Viral foodborne outbreaks may involve symptomatic or asymptomatic food handlers.18–24 In this outbreak no food handlers reported illness during the exposure period; however, one had a pre-school aged child with gastrointestinal symptoms in the week prior to the outbreak and one developed symptoms at the end of the exposure period. This first food handler was involved in the preparation of many of the foods that were found to be risk factors for illness on univariate analysis. Both food handlers may have been infectious during food preparation despite being asymptomatic. This demonstrates the importance of all food handlers always adopting effective hand hygiene and food handling practices even in the absence of symptoms.

The environmental health inspection demonstrated inadequate hand washing facilities in the staff toilets; risk of cross-contamination of foods through disorganised storage; and inadequate staff illness records, exclusion policies and procedures. It has been found that there is a high prevalence of environmental contamination among food businesses involved in viral gastroenteritis outbreaks and that norovirus is often detected on bathroom surfaces rather than food preparation areas.25 In this outbreak, the handwashing sinks were too small to allow for effective handwashing, potentially allowing transfer of viral particles via contact surfaces.

Coagulase positive *Staphylococcus* spp. in the egg sandwich mix sample was within the range of between 102 and 103 cfu/g, a marginal result as determined by the FSANZ *Compendium of Microbiological Criteria for Food*. This may be indicative of poor hand hygiene and food handling controls and proactive investigation ensuring hygiene practices and the effective implementation of temperature controls is recommended.2 The roast beef sample also had a marginally raised SPC which is an indicator of the microbiological quality of food, providing further evidence that improved hygiene and food handling processes are required.

One of the strengths of this investigation was the collection of faecal specimens from attendees at multiple events, enabling confirmation of the aetiologic agent and confirmation that viruses detected at more than one event were genetically related. This was due in part to the delivery of faecal collection kits to cases by ACT Health staff. Persons affected by similar outbreaks often do not have faecal specimens tested, the aetiological agent cannot be confirmed, and transmission patterns cannot be confirmed using genomics.15

Limitations of the investigation include the inability to test for viral contamination of foods and environmental surfaces to definitively correlate human infection with environmental and food contamination, as well as the inability to definitively confirm the suspected source of the outbreak through testing of food handlers for norovirus. The testing of food handlers for norovirus is not routinely performed as part of foodborne outbreak investigations in Australian jurisdictions but may assist public health authorities in understanding the mechanisms of contamination of large catering-associated foodborne disease outbreaks and is recommended in studies.14,15,26 This is of importance as casual workers are unlikely to admit to mild symptoms of gastroenteritis.

There were two large foodborne norovirus outbreaks reported in the ACT in 2021 and 2022.27 It has been found that knowledge of norovirus among food handlers is generally low, and lower in catering companies compared to institutional settings.28 Catering businesses in the ACT should be reminded of appropriate hand hygiene and food handling practices, as well as the exclusion from work requirements for food handlers with gastroenteritis, to assist in prevention of these outbreaks.

Finally, this norovirus outbreak was the second large foodborne norovirus outbreak attributed to this caterer in the past four years. On discussion with the proprietor of the business it was clear that they had not understood that the previous outbreak investigation in 2019 attributed that outbreak to the catering company. While it has been found that norovirus outbreaks may be associated with frequently penalised catering services, there is no literature related to services implicated in recurrent outbreaks.29 It is important that businesses implicated in foodborne disease outbreaks are informed of and understand the findings of outbreak investigations in order to modify and maintain food safety practices.

This outbreak investigation demonstrates the significant morbidity and loss of productivity that foodborne norovirus outbreaks cause and the importance of effective hand hygiene and food handling practices at all times, given asymptomatic individuals can excrete and transmit norovirus.

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We declare no conflicts of interest.

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