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ORIGINAL ARTICLE

Adherence to the Australian acute anaphylaxis clinical care standard and outcomes in a regional Queensland specialist outpatient service

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Abstract

Background: There is no published information on the recognition and management of anaphylaxis in regional Queensland. The establishment of a clinical immunology and allergy service for the Cairns and Hinterland Hospital and Health Service (CHHHS) has enabled the exploration of patient outcomes.
Aims: To analyse anaphylaxis presentations, management and outcomes in a regional Queensland cohort compared with the Australian Commission on Safety and Quality in Health Care (ACSQHC) Acute Anaphylaxis Clinical Care Standard.
Methods: A retrospective cohort study was undertaken with patients identified through clinical immunology and allergy clinic letters. All adults with a clinical immunologist and allergist diagnosis of anaphylaxis were included from service inception (1 March 2016) until 1 January 2024.
Results: Clinic letter database searching identified 636 patients with the word anaphylaxis in their problem list. A total of 220 patients (134 females, 61%) with a median age 42 years (IQR: 31–47 years) experienced 303 episodes of anaphylaxis; 350 did not meet inclusion criteria. Anaphylaxis was recognised and adrenaline was administered in 213 episodes (79%). Twenty-two of 46 patients (where site of intramuscular injection was recorded) received an adrenaline injection in the deltoid muscle. The median time to first dose of adrenaline and the duration of monitoring was 8 min and 6 h respectively. The most frequently reported causes for anaphylaxis were drugs/vaccines/contrast media (55 episodes, 18%), food (53 episodes, 17%), idiopathic (46 episodes, 15%) and venom (38 episodes, 13%).
Conclusions: The treatment of anaphylaxis generally aligned with the ACSQHC Acute Anaphylaxis Clinical Care Standard; the high proportion of patients excluded demonstrates that more research is needed regarding the diagnostic accuracy in anaphylaxis.

Introduction

Anaphylaxis is a medical emergency due to a multisystem allergic reaction and requires immediate treatment with intramuscular (IM) adrenaline to optimise patient outcomes and minimise the risk of adverse sequelae, including death. Australian-based epidemiological studies have reported that the incidence and mortality rates of anaphylaxis are increasing,[1,2] reflected in a recent systematic review.[3] In an effort to contend with increasing anaphylaxis mortality, the Australian Commission on Safety and Quality in Health Care (ACSQHC) has released the *Acute Anaphylaxis Clinical Care Standard*.[4] In the standard, ACSQHC has highlighted six key quality statements outlining the optimal management of patients with anaphylaxis[4]:

1 Prompt recognition of anaphylaxis
2 Immediate injection of IM adrenaline
3 Correct patient positioning
4 Access to a personal adrenaline autoinjector (including in health care settings)
5 Appropriate observation time post anaphylaxis

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6 Correct discharge management (including access to adrenaline autoinjectors and clinical immunology and allergy referral)

Adherence to these six statements is expected to improve outcomes for patients with anaphylaxis.

The Cairns and Hinterland Hospital and Health Service (CHHHS) provides medical care to a diverse population, with Modified Monash Model geographical rurality indexes varying from two (regional centre) to seven (very remote communities),[5] and a significant proportion (ranging from <5% to >30%) of patients identifying as Aboriginal and/or Torres Strait Islander.[6] The establishment of the first ever and only local public clinical immunology and allergy service in 2016 provided the opportunity to analyse the current treatment and outcomes of patients with anaphylaxis in this Far North Queensland population. Additionally, the publication of the *Acute Anaphylaxis Clinical Care Standard* offered the ideal framework for this analysis[4]; providing a standardised approach, key outcomes of interest, and a guide for evaluation. The data collected for this audit allowed statistical analysis of additional aspects of anaphylaxis investigation and management. As such, the question addressed in our study was:

> What are the baseline demographics, findings relating to anaphylaxis management key quality statements and episode factors affecting outcomes in adult patients with a diagnosis of anaphylaxis from the CHHHS clinical immunology and allergy service?

To address this question, the objectives of this study were to measure baseline demographics, outline key outcomes relating to the *Acute Anaphylaxis Clinical Care Standard* and assess for factors associated with additional doses of adrenaline or a particular causative allergen.

Methods

This study was designed as a single-centre, retrospective cohort study. As such, it has been reported in adherence to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) reporting guidelines (Appendix A).[7] The research itself was performed in accordance with the declaration of Helsinki,[8] with an ethics exemption granted by the Far North Queensland Human Research Ethics Committee (EX/2021/QCH/76019).

Patients were identified using a keyword search for 'anaphylaxis' in the >2100 individual patient clinic letters from the CHHHS clinical immunology and allergy service. Electronic medical records (including, where available, ambulance notes) of all identified cases were then assessed against prespecified inclusion and exclusion criteria by KL.

Inclusion criteria

Adult patients with an episode of anaphylaxis diagnosed, or confirmed diagnosed within this specialist service from its inception (March 2016) until January 2024.

Exclusion criteria

Not meeting diagnostic criteria for anaphylaxis,[9] or episodes not documented or unretrievable.

Any uncertainty regarding a patient meeting criteria for inclusion was resolved by consensus between the authors. For all included patients, a single author (KL) extracted the following data:

Baseline demographics/general information

- Age
- Country of birth
- Identification as Aboriginal and/or Torres Strait Islander
- Previous diagnosis of allergy or hypersensitivity reaction
- Total number of anaphylaxis episodes

Episode details for each anaphylaxis event

- Causative allergen
- Location
- Signs and symptoms constituting anaphylaxis
- Severity grading[10]
- Treatment, including health professional attendance, time to first dose of adrenaline, administration route and total number of doses
- Responsiveness of signs/symptoms to adrenaline
- Duration of monitoring
- Number of adrenaline autoinjectors at discharge
- Days to follow-up and year of attendance in CHHHS clinical immunology and allergy clinic

Finally, to additionally quantify the number of presentations with anaphylaxis over time, 5 years of patient-level coding data from January 2018 was obtained for all presentations to the Cairns Hospital's emergency department (ED) with a working diagnosis inclusive of keywords relating to anaphylaxis (Appendix B).

Statistics

Statistical analysis was performed in GraphPad Prism version 9.3.1. Sample size calculations were not

performed due to the exploratory nature of the study. A descriptive analysis was initially undertaken with the Shapiro–Wilk test used to determine normalcy of distribution. Data with normal distribution are presented as mean and standard deviation, whereas non-normal distribution are presented as median and interquartile range (IQR) and categorical variables as n (%). The α level was set at 0.05. Time to first dose of adrenaline was compared between first responders using the Kruskal–Wallis test. A simple linear regression model was utilised to assess for change in the number of patients attending clinic and ED with anaphylaxis presentations over time.

A subsequent exploratory statistical analysis was performed to analyse factors associated with multiple doses of adrenaline and assess for differences in causative allergens between demographic subpopulations. For 2×2 contingency tables, the χ^2 test of independence was utilised to assess for significant associations. Where df >1, the Fisher–Freeman–Halton exact test was instead employed to assess for significant associations. Missing data points were excluded from statistical analysis. Where P values are calculated, they are denoted by: $^*P < 0.05$; $^{**}P < 0.01$; $^{***}P < 0.001$; $^{****}P < 0.0001$; with ns indicating not significant.

Results

Details regarding the identification and inclusion of patients have been incorporated into Figure 1. A total of 2109 individual clinic files were interrogated for the keyword anaphylaxis. The keyword anaphylaxis was mentioned in 636 patient letters; of these, 286 patients (13.7% of patients reviewed in clinic) were diagnosed with anaphylaxis and assessed against the inclusion and exclusion criteria. With the exclusion of a further 66 patients for not meeting all criteria, 220 patients were included in the study, with experiencing 303 episodes of anaphylaxis. The baseline characteristics for included patients are shown in Table 1. Of these patients, a majority were female (61%, 134/220), with a median age of 42 years. Less than a fifth of included patients identified as Aboriginal and/or Torres Strait Islander (12%, 26/220 (nine male, 17 female)), and the most common countries of birth were Australia, England and New Zealand. Over half the patients had a previous diagnosis of allergy

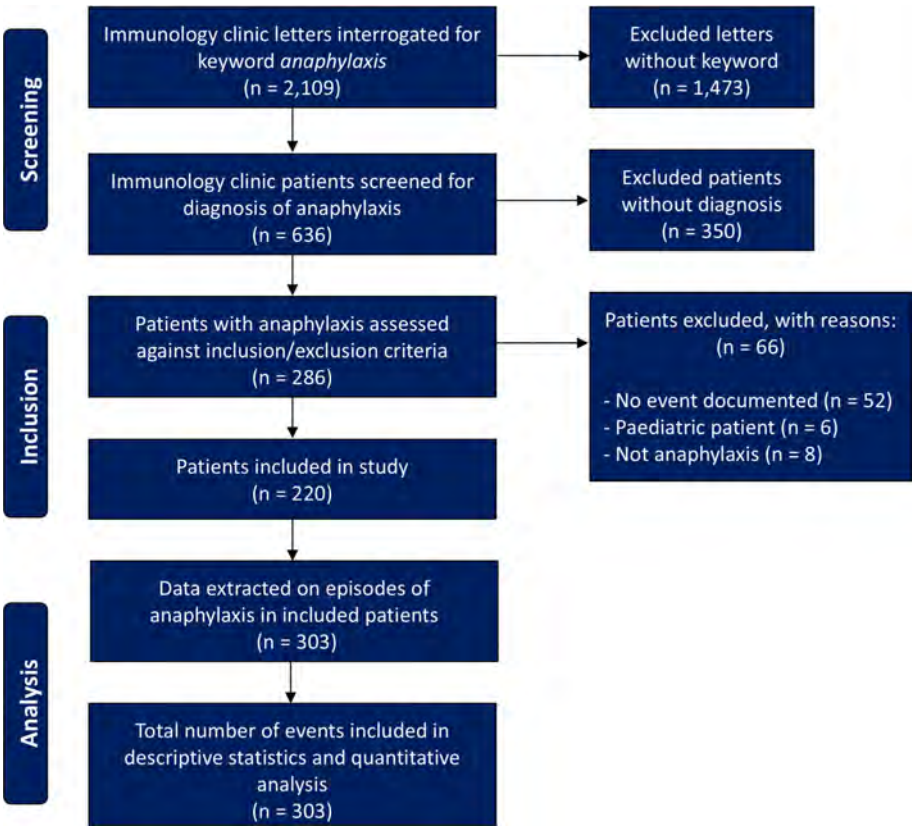

Figure 1 Flow diagram for inclusion of patients in study.

Table 1 Baseline characteristics of included patients

Patient characteristic	Number (%) ($n = 220$)
Sex	
Female	134 (61%)
Male	86 (39%)
Age (years)	
Median	42
IQR	31–57
Aboriginal/Torres Strait Islander status	
Aboriginal	13 (6%)
Torres Strait Islander	5 (2%)
Aboriginal and Torres Strait Islander	8 (4%)
Neither	194 (88%)
Country of Birth	
Australia	175 (80%)
England	9 (4%)
New Zealand	7 (3%)
Thailand	4 (2%)
Philippines	3 (1%)
Other	22 (10%)
Medical History	
Previous diagnosis of allergy	108 (49%)
Comorbid asthma	47 (21%)
Number of anaphylaxis episodes	
1	178 (81%)
2	30 (14%)
3+	12 (5%)

IQR, interquartile range.

or comorbid asthma and most experienced a single episode of anaphylaxis.

The results of key outcomes for included patients have been collated in Figure 2; however, the full record of extracted data can be found in Appendix C.

In the assessment of *prompt recognition and immediate intramuscular adrenaline administration (ACSQHC standards 1 and 2)*, patients were treated with adrenaline when indicated in most episodes (79%, 213/271). For those who did not receive adrenaline when indicated (58/271), this was primarily due to missed opportunity for standard-of-care treatment by the first responder (28%, 16/58), patients not seeking medical attention (28%, 16/58) or first responder did not recognise anaphylaxis (22%, 13/58). The first administration of adrenaline was performed by the patient in 26% of anaphylaxis episodes (55/213). Where the site of IM adrenaline was recorded (46/303), just under half were injected in the deltoid muscle (48%, 22/46). Where documented (74/303, 24%), the median time to IM adrenaline injection was 8 min and 84% (62/74) of these patients had first-episode anaphylaxis. There was no significant difference between initial treatment with either 300 or 500 μg dose ($n = 93$ vs $n = 115$) of IM adrenaline and administration of further doses ($\chi^2 = 0.552$, df = 1, $P = 0.537$).

ACSQHC standards 3 and 4: Patient positioning during anaphylaxis management and access to adrenaline autoinjectors in hospital were not documented in medical records examined for this study.

In the assessment of *appropriate observation time and discharge management (ACSQHC standard 5)*, patients were observed for a median time of 6 h after adrenaline injection; in 21% (54/250) of episodes, monitoring was for less than 4 h, and 20% (11/54) of these episodes ended in a discharge against medical advice. At the time of initial autoinjector prescription, 68% (65/95) of patients were documented to have been trained in the use of adrenaline autoinjectors and 66% (160/241) received two autoinjectors.

In the assessment of *clinical immunologist and allergist referral and diagnosis (ACSQHC standard 6)*, the median time to follow-up in the clinical immunology and allergy service was 53 days, despite all being triaged to be seen within 30 days. The most common causative allergens of anaphylaxis episodes were drugs/vaccine/contrast media, closely followed by food, idiopathic and venom (18% (55/303), 17% (52/303), 15% (45/303) and 13% (38/303) respectively). Further analysis of the food subgroup demonstrated crustaceans (5%, 15/303) and tree nuts (3%, 9/303) to be the most common allergens in this group.

The number of yearly presentations coded as anaphylaxis to the Cairns Hospital's ED, and new patients attending the clinical immunology and allergy service for anaphylaxis are described in Figure 3. Linear regression showed no significant change in ED presentations for anaphylaxis (slope = −0.7 cases/year, $R^2 = 0.018$; $P = 0.828$), but a significant increase in new patients attending the service over time (slope = 2.9 patients/year, $R^2 = 0.671$ $P = 0.013$).

Results of the detailed exploratory analysis can be found in Appendix D. For brevity, the important findings were that Aboriginal and/or Torres Strait Islander patients were significantly less likely to receive more than two doses of IM adrenaline ($\chi^2 = 4.41$, df = 1; $P = 0.036$). Conversely, there was no association between doses of adrenaline administered and injection in the deltoid muscle ($\chi^2 = 0.09$, df = 1; $P = 0.762$), female sex ($\chi^2 = 1.48$, df = 1; $P = 0.223$) or rurality of episode ($\chi^2 = 0.01$, df = 1; $P = 0.913$). While there were no sex differences in attributable allergen/cause of anaphylaxis (Fisher exact = 4.93, df = 4; $P = 0.295$), rural/remote patients were significantly more likely to experience insect venom/bite anaphylaxis (Fisher exact = 22.56, df = 4; $P < 0.001$); idiopathic anaphylaxis was significantly higher in Aboriginal and/or Torres Strait Islander patients (12%, 26/220; Fisher exact = 9.28, df = 4; $P = 0.048$). Patients allergic to drugs were significantly less likely to have a second episode of anaphylaxis

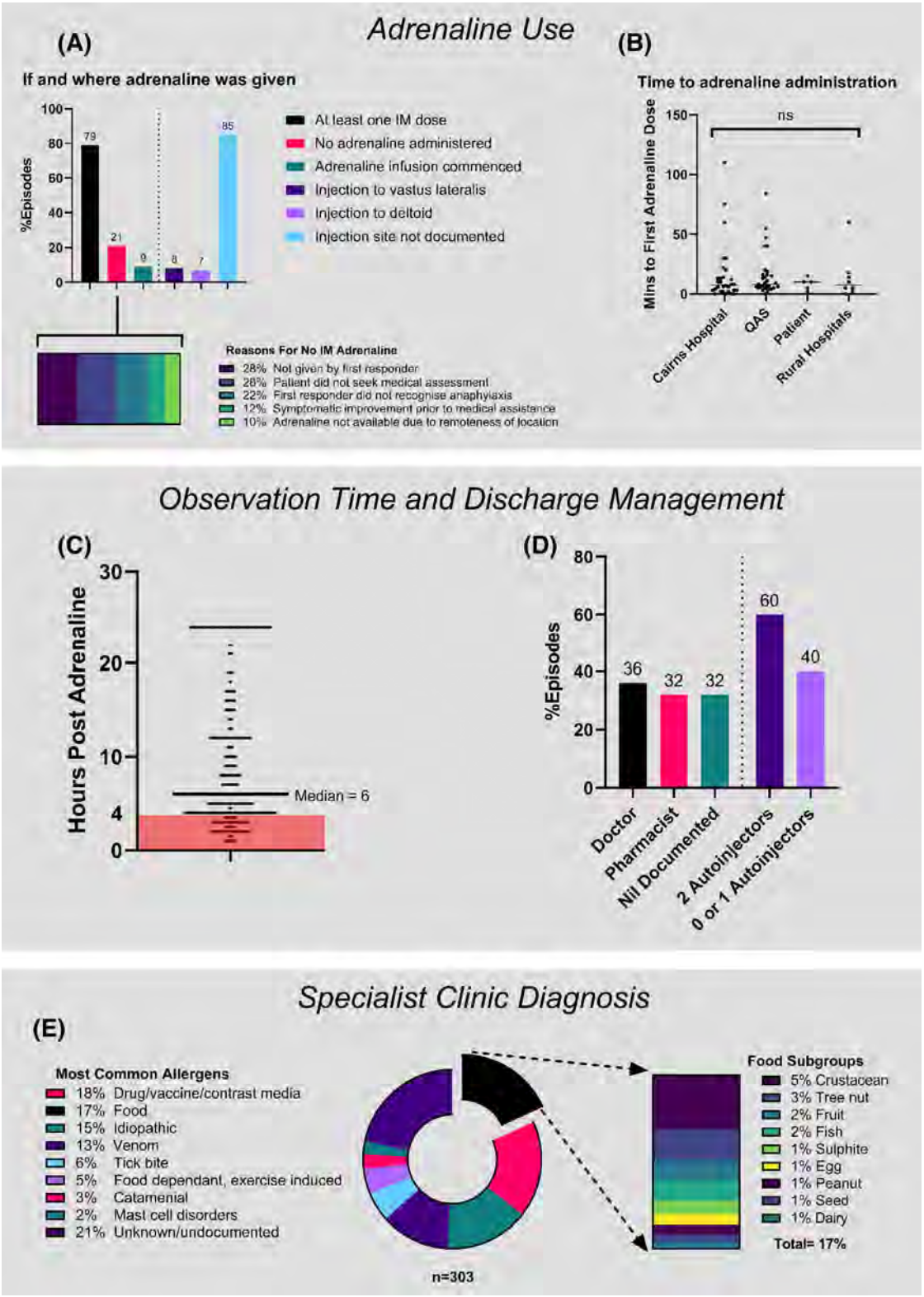

Figure 2 Results: (A) Rates of adrenaline use with site of injection and reasons for adrenaline not being administered; (B) Time to adrenaline injection, documented by first responder; (C) Hours monitored after adrenaline injection; (D) Rates and provider of adrenaline autoinjector training and number of autoinjectors on discharge;, and (E) Most common causes of anaphylaxis. QAS, Queensland Ambulance Service.

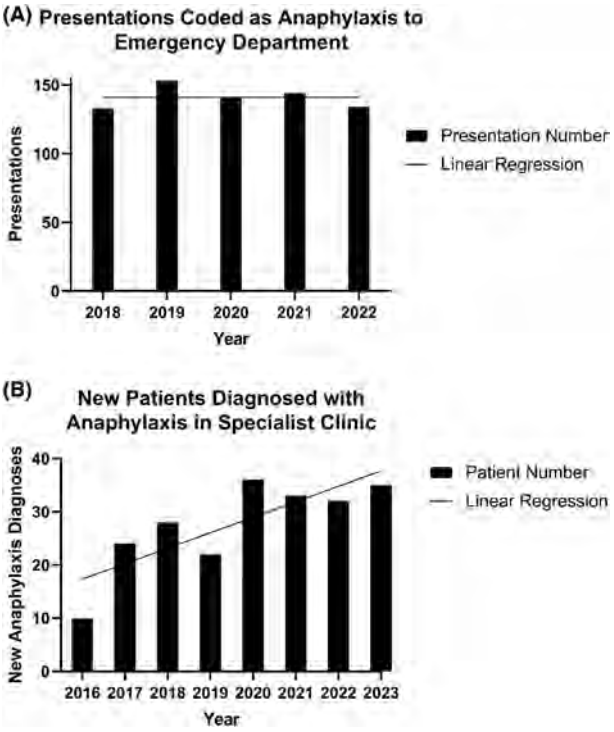

Figure 3 (A) Presentations coded as 'anaphylaxis' to the Cairns Hospital's emergency department by year and (B) new patients attending the clinical immunology and allergy service with a diagnosis of anaphylaxis by year.

(Fisher exact = 42.60, df = 4; $P < 0.001$). In the analysis of anaphylaxis manifestations, the use of more than two doses of IM adrenaline was significantly associated with persistent angioedema ($\chi^2 = 7.76$, df = 1; $P = 0.005$) and respiratory symptoms ($\chi^2 = 5.58$, df = 1; $P = 0.018$). However, there was no significant association with gastrointestinal ($\chi^2 = 0.02$, df = 1; $P = 0.885$), dermatological ($\chi^2 = 0.03$, df = 1 $P = 0.860$) or cardiovascular signs/symptoms ($\chi^2 = 0.45$, df = 1; $P = 0.504$). Furthermore, different causative allergens were not associated with particular system manifestations.

Discussion

This study used the ACSQHC Acute Anaphylaxis Clinical Care Standard as a framework and described the demographics, clinical features and outcomes for patients diagnosed with anaphylaxis in the CHHHS clinical immunology and allergy service, and analysed factors associated with multiple doses of adrenaline. From a demographics perspective, this patient cohort had a slightly higher proportion of female patients experiencing anaphylaxis compared with that reported elsewhere in Australian studies (61% in this present study vs 54% in Drewitt *et al.*,[11] and 51% in Stiles *et al.*[12]).

With respect to key outcomes outlined in the *Acute Anaphylaxis Clinical Care Standard*, where data were retrievable, local management mostly aligned with standard recommendations 1, 2, 5 and 6, but standards 3 and 4 were not assessable.

ACSQHC standards 1 and 2: Seventy-nine per cent of patients received adrenaline when indicated and available. This is similar to 71% reported by Thomas *et al.* in an analysis of ED presentations in Adelaide, Australia.[13] In the 21% who did not, reasons included the first responder either did not recognise (22%, 13/58) or did not treat anaphylaxis appropriately (28%, 16/58). This highlights the importance of increased training for first responders in the recognition and management of anaphylaxis as suggested in the 2020 World Allergy Organisation (WAO) anaphylaxis guidance statement.[14] Where documented (24%, 74/303), patients who received adrenaline did so with a median time from arrival of first responder to first dose of 8 min. Anecdotally, the CHHHS clinical immunology and allergy service has retrospectively identified numerous cases of anaphylaxis that were not recognised at the time—sometimes years later. Further auditing is currently underway of the 350 patients who were excluded from this study, as we know many were originally referred with a diagnosis of anaphylaxis that was subsequently undiagnosed by the clinical immunology and allergy service. Diagnostic accuracy can significantly reduce patient distress and unnecessary health system expenditure due to inappropriate treatment.[15] Work is currently underway to explore patient and health system factors for mislabelled anaphylaxis and the impact mislabelling has on patient wellbeing.

The site of IM adrenaline is not mentioned in the summary points of the *Acute Anaphylaxis Clinical Care Standard* but is in the supportive text. The recommended site for IM adrenaline into the vastus lateralis is in line with clinical research supporting this site for optimal absorption of IM adrenaline.[16,17] In the context of low documentation rates (15% of anaphylaxis episodes), almost half of the patients received an IM adrenaline injection into the deltoid. Acknowledging the limitations of these data, there was a lack of association between deltoid injection and administration of further doses of adrenaline or adverse outcomes.

ACSQHC standards 5 and 6: Up to one in five patients were not monitored for the recommended 4 h after adrenaline administration; however, no representations or relapse symptoms were documented following discharge. Again, within the limitations of these data, this is interesting in light of findings that monitoring time and even hospital attendance is under review internationally after decreased hospital attendance during the COVID-

19 pandemic did not correlate with increased adverse outcomes for anaphylaxis managed with adrenaline autoinjectors in the community.[18] A median wait time of 53 days until review by the clinical immunology and allergy service is almost double the intended 30-day wait for patients triaged as category one, but there were no documented adverse outcomes. Anecdotally, during this time many patients experienced prolonged anxiety related to diagnostic uncertainty after an already traumatic anaphylaxis event. An Australian study into patients with idiopathic anaphylaxis and the diagnostic and prognostic uncertainty associated with this condition has demonstrated a significantly elevated burden on mental health when compared with the general population.[19] There were no fatalities from anaphylaxis in patients after attending the clinical immunology and allergy service. The majority of written prescriptions for adrenaline autoinjectors provided outside the clinical immunology and allergy clinic service did not include explicit instructions for injection into the mid anterolateral thigh compared with all prescriptions from the specialist clinic. Seventeen per cent (41/241) of patients were only prescribed a single autoinjector. Sixty-eight per cent (65/95) of patients were documented to have received training in the use of adrenaline autoinjectors.

A literature search for anaphylaxis in Aboriginal and/or Torres Strait Islander patients did not identify any studies specifically evaluating the demographics, causes, outcomes or treatment of patients in this demographic. This study revealed that anaphylaxis events in Aboriginal and/or Torres Strait Islander patients was proportional to their population within the CHHHS catchment (12%, 26/220 patients and 36/303 events).[6] However, Aboriginal and/or Torres Strait Islander patients have significantly higher rates of poorly controlled and underdiagnosed asthma,[20] a known risk factor for mortality from anaphylaxis.[21] This information emphasises the imperative to assess for asthma in Aboriginal and Torres Strait Islander patients with anaphylaxis. An additional group of particular interest in this study were those living in rural and remote areas. A total of 13% and 5% of episodes of anaphylaxis were attributed to venom and tick-bite respectively, which is higher than 8% and <3% (other) found previously by Drewett *et al.* in a Victorian study.[11]

In contrast to multiple Australian and international studies,[1–3] we found that presentations to the ED coded as anaphylaxis are not increasing with time. Indeed, the rate of coded anaphylaxis presentations has remained constant from 2018 until 2023. This result is more reflective of findings in American[22] and German populations,[23] albeit from earlier time periods (1990s and 2000s respectively). These differences may be explained, in part, by our particular focus on adult cases of anaphylaxis with the most recent population-based Australian study finding two key groups associated with increasing anaphylaxis incidence were patients aged 5–14 and 15–24 years.[12]

Data collection for this audit revealed significant documentary evidence for underdiagnosis and misdiagnosis of anaphylaxis. This provides an opportunity to further investigate patient and health system factors contributing to diagnostic anomalies around anaphylaxis and the broader consequences.

Limitations

A primary limitation of this study is the single service retrospective design. There was at least one case of fatal anaphylaxis in a patient who had never been referred to this clinic (PB personal communication) and there may be others that are not known and thus unavailable to be included in this audit. Second, the retrospective nature associated with the use of medical records to extract data generates misclassification bias as in some cases documentation of episode features related to anaphylaxis was ambiguous, e.g. subjective symptoms. Furthermore, reliance on retrospective notes introduces recording bias in included data. For instance, if clinic doctors discover that the site of adrenaline injection was in the deltoid, they may be more likely to document this variation from standard of care.[9] The best method in which to improve quality of data, particularly with regards to site of adrenaline injection, would be to collect data prospectively.

Finally, this study was unable to capture patients who are not referred to the clinical immunology and allergy service or those who did not attend (DNA) appointments. DNA data were subsequently assessed and over the 7-year time frame of this study, 29 patients referred for anaphylaxis did not attend clinic. For patients who were suspected to have anaphylaxis at the point of referral triage, the triaging consultant proactively contacted the referring general practitioner to recommend that two adrenaline autoinjectors be provided to the patient. Nonetheless, the significant increase in new patients with anaphylaxis attending the clinical immunology and allergy service each year demonstrates increased capture of patients in the local area.

Conclusion

We have characterised management of anaphylaxis in a Far North Queensland patient cohort and found good adherence to the ACSQHC *Acute Anaphylaxis Clinical Care Standard*. Further research opportunities include patient, social and health system costs/impacts associated with mis/underdiagnosis of anaphylaxis.

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Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Supporting Information

Additional supporting information may be found in the online version of this article at the publisher's web-site:

Appendix A STROBE Checklist.
Appendix B. Included ED Working Diagnoses (SNOMED CT).
Appendix C. Full Table of Extracted Outcomes.
Appendix D. Full Exploratory Statistical Analysis.