Acute Anaphylaxis Clinical Care Standard

Implementation Guide for NSW Health Facilities

May 2024

NSW GOVERNMENT

CLINICAL EXCELLENCE COMMISSION

Contents

Background

In November 2021, the Australian Commission for Safety and Quality in Health Care published the Acute Anaphylaxis Clinical Care Standard [1]. The number of patients with serious allergies, and the rates of anaphylaxis presentations to hospital are increasing [2]. While only a small number of anaphylaxis events are fatal, they are often preventable. Despite there being clinical guidelines, before this clinical care standard, there has been no uniform, national standard for the recognition and treatment of acute anaphylaxis. Implementing this clinical care standard can help health services meet the requirements of the National Safety and Quality Health Service (NSQHS) Standards and improve the care provided to patients.

The CEC convened an Anaphylaxis Working Group to prepare this implementation guide, in response to requests from NSW Health facilities to support the ACSQHC Clinical Care Standards and requirements from *Medication Handling* Policy Directive PD2022_032 [3].

Purpose

This implementation guide outlines the **minimum requirements** for local procedures on the management of acute anaphylaxis and the use of patient's own adrenaline (epinephrine) autoinjectors. It should be utilised during a procedure development process, and by the local Drug and Therapeutics Committee prior to endorsement of a local procedure.

Acknowledgement

The CEC wishes to thank the members of the Acute Anaphylaxis Clinical Care Standard Implementation Working Group who have given their time and advice for the development of this Implementation Guide and example Audit Tool. The members of the Working Group included:

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Definitions and Symptoms of Anaphylaxis

Definition of anaphylaxis

Anaphylaxis is a potentially life threatening, severe allergic reaction that requires immediate treatment with adrenaline (epinephrine). The Australasian Society of Clinical Immunology and Allergy (ASCIA) defines anaphylaxis as [4]:

- any acute onset illness with typical skin features (urticarial rash or erythema/flushing, and/or angioedema), plus involvement of respiratory and/or cardiovascular and/or persistent severe gastrointestinal symptoms

  OR

- any acute onset of hypotension or bronchospasm or upper airway obstruction where anaphylaxis is considered possible, even if typical skin features are not present.

Symptoms

Mild or moderate reactions (may not always occur before anaphylaxis):

- swelling of lips, face, eyes
- hives or welts
- tingling mouth
- abdominal pain, vomiting – these are signs of anaphylaxis for insect sting or injected drug (medication) allergy.

Anaphylaxis – Indicated by any one of the following signs:

- difficult or noisy breathing
- swelling of tongue
- swelling or tightness in throat
- difficulty talking or hoarse voice
- wheeze or persistent cough - unlike the cough in asthma, the onset of coughing during anaphylaxis is usually sudden
- persistent dizziness or collapse
- pale and floppy (young children)
- abdominal pain, vomiting – for insect stings or systemically administered allergens.

Adapted with permission from ASCIA.

Other Definitions

In this document, the term **clinician** refers to all types of healthcare providers who deliver direct clinical care to patients, including nurses, midwives, medical practitioners, allied health practitioners and pharmacists [1].

The term **adolescent** refers to a patient aged between 12 and 17 [5].

Quality Statement 1 – Prompt recognition of anaphylaxis

A patient with acute-onset clinical deterioration with signs or symptoms of an allergic response is rapidly assessed for anaphylaxis, especially in the presence of an allergic trigger or a history of allergy.

Requirements for local procedure

Roles and responsibilities of staff

Local procedures should clearly define roles and responsibilities of different staff groups in the prompt recognition and treatment of anaphylaxis, for example:

- It is the responsibility of all clinical staff to recognise the signs and symptoms of anaphylaxis and escalate accordingly.
- It is the responsibility of staff permitted to administer in public healthcare facilities according to Medication Handling Policy Directive PD 2022_032, to administer intramuscular (IM) adrenaline (epinephrine) via autoinjector or syringe.

Note: HealthShare Food and Patient Support Services staff are trained only on food allergens and not on signs and symptoms of anaphylaxis. These staff would still be expected to raise alarm if they noticed a patient in distress. Facilities where patient food is not provided by HealthShare are to ensure provision of food allergen management training to staff conducting these duties.

Reference to guidelines on prompt recognition and treatment of anaphylaxis

ASCIA has several peer-reviewed and regularly updated resources. The following guideline includes the clinical criteria to support diagnosis of anaphylaxis:

ASCIA Guidelines Acute management of anaphylaxis - Australasian Society of Clinical Immunology and Allergy (ASCIA)

The Emergency Care Institute (ECI) has also published a guideline for use by clinicians in the immediate management of anaphylaxis:

Anaphylaxis | Emergency Care Institute (nsw.gov.au)

The Royal Children's Hospital has published a paediatric specific guideline:

Clinical Practice Guidelines: Anaphylaxis (rch.org.au)

These guidelines should be adopted as part of a locally approved procedure to ensure the prompt recognition and treatment of anaphylaxis.

Documentation

If anaphylaxis is recognised in a patient with the causative or suspected agent identified, the allergy is to be documented in the eMR with the severity of reaction listed as 'severe'. A local procedure needs to outline the requirement for a notification via ims+ for patients who have had anaphylaxis as an inpatient after treatment has occurred.

Quality Statement 2 – Immediate injection of intramuscular adrenaline (epinephrine)

A patient with anaphylaxis, or suspected anaphylaxis, is administered adrenaline (epinephrine) intramuscularly without delay before any other treatment including asthma medicines. Corticosteroids and antihistamines are not first-line treatments for anaphylaxis.

Requirements for local procedure

Processes to facilitate safe and legal administration of adrenaline (epinephrine)

The ASCIA guidelines [4] state the most appropriate treatment for acute anaphylaxis is intramuscular adrenaline (epinephrine). The use of other medications (such as antihistamines and corticosteroids) is **not recommended** and delays appropriate treatment. Adrenaline (epinephrine) needs to be available on each ward and clinical unit. Local procedures are to outline processes to facilitate safe and legal administration of adrenaline (epinephrine) in NSW health facilities. Such processes should include:

- *For patients admitted with a history of anaphylaxis* – prescribing at the point of presentation or admission an "as required" or "PRN" intramuscular adrenaline (epinephrine) at the appropriate dose in case of anaphylaxis.
- *For patients admitted with a history of anaphylaxis carrying an adrenaline (epinephrine) autoinjector device* – prescribing of both an "as required" or "PRN" intramuscular adrenaline (epinephrine) for their autoinjector device, as well as an order for use of adrenaline (epinephrine) ampoules at the appropriate dose in case of anaphylaxis.
- *For patients with unknown allergy status or no known allergies* – facilities are to have a locally endorsed nurse-initiated procedure which includes intramuscular adrenaline (epinephrine) for use when anaphylaxis is suspected. This should allow initial treatment with adrenaline (epinephrine) until Clinical Emergency Response System (CERS) treatment can be provided.

Note for Emergency Departments: In addition to facility-wide nurse-initiated procedures, Emergency Care and Assessment (ECAT) protocols include intramuscular adrenaline (epinephrine) administration where anaphylaxis is suspected.

Assessment of patient capability

Patients/carers are to be assessed as capable in their use and able to escalate to staff when using the device. Local procedures are to ensure patients/carers are educated to notify staff immediately when they need to or have used their own adrenaline (epinephrine) autoinjector device.

Adrenaline (epinephrine) autoinjector training devices are to be made available within a facility for patient training and clinician familiarity. Training adrenaline (epinephrine) autoinjector devices can be sourced through pharmaceutical company sales representatives or through hospital allergy/immunology services.

Documentation

The patient's health care record is required to have a record of any treatment given in a health care facility for anaphylaxis, and a record of any CERS activation.

All adrenaline (epinephrine) administered (by the patient or otherwise) is to be documented using the local electronic medication management (eMM) system. This is done by signing the administration of a pre-existing "PRN" order or creating an order within the eMM system record.

Quality Statement 3 – Correct patient positioning

A patient experiencing anaphylaxis is laid flat, or allowed to sit with legs extended if breathing is difficult. An infant is held or laid horizontally. The patient is not allowed to stand or walk during, or immediately after the event, until they are assessed as safe to do so, even if they appear to have recovered.

Requirements for local procedure

Current recommendations for correct positioning of patients experiencing anaphylaxis are given in the ASCIA guidelines and are available in an infographic and as a short video at How to position a person having anaphylaxis - Australasian Society of Clinical Immunology and Allergy (ASCIA).

Local procedures are to clearly outline that once staff recognise signs and symptoms of anaphylaxis, they ensure the patient is correctly positioned to minimise harm. Patients are to be lying flat or in a seated position with legs raised or extended, if unable to lie flat.

Quality Statement 4 – Access to a personal adrenaline (epinephrine) autoinjector in all healthcare settings

A patient who has an adrenaline (epinephrine) autoinjector has access to it for self-administration during all healthcare encounters. This includes patients keeping their adrenaline (epinephrine) autoinjector safely at their bedside during a hospital admission.

Requirements for local procedure

Ensuring ongoing access to patient's own adrenaline (epinephrine) autoinjectors

Each facility is required to detail in their local procedures the process for patients who are admitted to hospital with their own adrenaline (epinephrine) autoinjector including how such patients are to be identified on admission, how they will maintain access to such a device whilst an inpatient and to ensure that staff are informed of the adrenaline (epinephrine) autoinjector and its location throughout the patient's journey.

Patients who have an adrenaline (epinephrine) autoinjector device are to have both an "as required" or "PRN" intramuscular adrenaline (epinephrine) for their autoinjector device, as well as an order for use of adrenaline (epinephrine) ampoules at the appropriate dose in case of anaphylaxis.

Patient and carer capability assessment

Medication Handling Policy Directive PD2022_032 states that the patient and or carer should be assessed as capable to self-administer. This should be documented in the patient's healthcare record. Safer Care Victoria [6] established a checklist for such an assessment. This checklist has been adapted for NSW Health facilities and included in this document in Appendix A. Local procedures are to reinforce this requirement. Where there are part time or multiple carers, it is recommended that all carers are risk assessed as required. Advice on how to use an adrenaline (epinephrine) autoinjector device can be found through ASCIA: "How to give an adrenaline injector".

Device assessments

Medication Handling Policy Directive PD2022_032 specifies the requirement for a pharmacist to check the adrenaline (epinephrine) autoinjector is fit for use. Local procedures should ensure checking of a device entails:

- that the paediatric pen is the correct dose (recent weight)
- the expiry date of the device
- the "window" is clear (images should be provided to assist clinicians)
- the device has not been used
- the manner of storage i.e. the device has not been stored in hot car.

Once a device has been checked, the pharmacist should document in the patient's health care record that the device is fit for use. Devices assessed as not fit for use should be discarded and a replacement provided. Patient labels (or other locally available sticker) may be applied to indicate the device has been checked through local procedures. This should also be reflected on staff communication/handover tools, also including device location. Adrenaline (epinephrine) autoinjectors should not be left at the patient's bedside unless documented as fit for purpose.

NOTE – Medication Handling Policy Directive (PD2022_032) requires a **pharmacist** to check if an adrenaline (epinephrine) autoinjector is fit for use. The Acute Anaphylaxis Clinical Care Standard states this can be carried out by all **clinicians.** The CEC has recommended to the Ministry of Health that Medication Handling PD2022_032 be updated to state **clinician** instead of pharmacist in alignment with the Clinical Care Standard.

Storage requirements

Medication Handling Policy Directive PD2022_032 states that patients may retain their adrenaline (epinephrine) autoinjector on their person at the bedside in accordance with facility procedures. In the case where the patient has not passed a capability assessment, but their carer has passed; if the adrenaline (epinephrine) autoinjector is kept at the bedside with that carer, nursing staff must be alerted to and have access to the device when there is no longer a competent carer who can supervise the device (in addition to the adrenaline (epinephrine) kept in the ward/unit for anaphylaxis). The adrenaline (epinephrine) autoinjector is to be stored out of the access of other patients and children. In paediatric settings, the patient's own adrenaline (epinephrine) autoinjector is to travel with the child to an on-site school (if appropriate) [7].

Staff are to ensure:

- shared decision making with patient/carers on the most appropriate place to store the adrenaline (epinephrine) autoinjector device
- the location of the device is documented in the health care record
- the location of the adrenaline (epinephrine) autoinjector device is included in clinical handover
- the Nursing Unit Manager/team leader is aware of the adrenaline (epinephrine) autoinjector device and its location

Different clinical areas will have a different level of risk with relation to storage of adrenaline (epinephrine) autoinjector devices. For example, for a patient with acute behavioural disturbance, it may not be appropriate for bedside storage of an adrenaline (epinephrine) autoinjector. Procedures are to include documentation requirements of adrenaline (epinephrine) autoinjectors location and include a risk assessment to address varying needs of each unit or service. An example risk assessment is included in Appendix B – this can be adapted where required to meet individual LHD/SHN requirements based on their individual resources and service needs.

Devices stored with patients are to always be clearly labelled with the patients details and stored together with their ASCIA Action Plan for Anaphylaxis.

Supply of adrenaline (epinephrine) autoinjectors

If a patient's own adrenaline (epinephrine) autoinjector is used during their encounter with the health facility, then procedures are to be in place for timely replacement of the device. If a device is replaced, it needs to be labeled with the patient's details.

PBS authority prescriptions cannot be written by clinicians from NSW Health facilities. Arrangements are to be in place for adrenaline (epinephrine) autoinjectors to be supplied from the hospital Pharmacy Department during business hours. Arrangements are also to be in place for supply to patients being discharged after-hours. For further information on supply to patients going home, refer to Quality Statement 6 – Discharge management and documentation.

Refer to the NSW Medicines Formulary online platform to determine the current formulary status of adrenaline (epinephrine) autoinjector devices.

Quality Statement 5 – Observation time following anaphylaxis

A patient treated for anaphylaxis remains under clinical observation for at least four hours after their last dose of adrenaline (epinephrine), or overnight as appropriate according to the Australasian Society of Clinical Immunology and Allergy Acute Management of Anaphylaxis *guidelines. Observation timeframes are determined based on assessment and risk appraisal after initial treatment.*

Requirements for local procedure

A locally approved procedure needs to include information for appropriate monitoring requirements of patients. The risk of biphasic reaction (secondary onset of symptoms without re-exposure to allergen) requires at least four hours of monitoring. Local procedures should provide guidance to facilities to monitor these patients for a minimum of four hours or in some cases overnight.

A local procedure should outline criteria to assist with clinical decision making for patients presenting with anaphylaxis to the Emergency Department who might require an overnight admission or patients who may require a period of increased observation if admitted as an inpatient. These patients may include those who:

- had a severe or protracted anaphylaxis (e.g. required repeated doses of adrenaline (epinephrine) or IV fluid resuscitation)
- have a history of severe/protracted anaphylaxis
- have other concomitant illness (e.g. severe asthma, history of arrhythmia, systemic mastocytosis)
- live alone or are remote from medical care
- present for medical care late in the evening
- do not have access to an adrenaline (epinephrine) autoinjector.

Quality Statement 6 – Discharge management and documentation

Before a patient leaves a healthcare facility after having anaphylaxis, they are advised about the suspected allergen, allergen avoidance strategies and post-discharge care. The discharge care plan is tailored to the allergen and includes details of the suspected allergen, the appropriate ASCIA Action Plan, and the need for prompt follow-up with a general practitioner and clinical immunology/allergy specialist review. Where there is a risk of re-exposure, the patient is prescribed a personal adrenaline (epinephrine) autoinjector and is trained in its use. Details of the allergen, the anaphylactic reaction and discharge care arrangements are documented in the patient's healthcare record.

Requirements for local procedure

Provision of information to patients on discharge

Local procedures are to specify the education resources, referrals and documents to be provided to patients on discharge as well as the provision of ASCIA action plans. The ASCIA Action Plans are available from the ASCIA website. Procedures are to clearly outline education to patients and the provision of written materials.

Supply of adrenaline (epinephrine) autoinjectors on discharge

The supply of an adrenaline (epinephrine) autoinjector by the hospital should be clearly specified by the locally approved procedures, as the provision of a PBS authority prescription is not possible from NSW Health hospitals. Procedures should outline the process for patients to obtain adrenaline (epinephrine) autoinjectors on discharge from the Emergency Department and inpatient wards.

Provisions should be made to enable adrenaline (epinephrine) autoinjector devices to be supplied without the need for a pharmacist to dispense when patients are being discharged from the Emergency Department after-hours. If required on discharge, inpatients should wherever possible have an adrenaline (epinephrine) autoinjector dispensed to them by a pharmacist during normal business hours. This is to be documented in the patient's health care record and the supply recorded according to local procedures.

Local Drug and Therapeutics Committees should recommend the number of adrenaline (epinephrine) autoinjectors that need to be dispensed to newly diagnosed patients based on risk posed to patients. This should take into account the risk of exposure to the allergen after discharge, the ability of timely review by an immunologist or General Practitioner to obtain a prescription for dispensing under the PBS and also cost.

Education and training requirements

A process is required to ensure that clinicians are competent to recognise the symptoms of anaphylaxis and begin initial treatment. The locally approved anaphylaxis procedure is to indicate **which** clinicians in a healthcare setting require training and assessment and to what level.

Generally, two levels of education will be required.

- **All clinical staff** should be trained to recognise the signs and symptoms of anaphylaxis.
- **Clinicians** able to administer adrenaline (epinephrine) should be trained on the correct dosage and administration of adrenaline (epinephrine).

Note: Allergy management training for food services staff is addressed in Quality Statement 1.

Training and education of staff is to include:

- recognition of signs and symptoms of anaphylaxis
- initial treatment of anaphylaxis
- correct positioning of patients
- intramuscular (IM) administration of adrenaline (epinephrine)
- correct use of adrenaline (epinephrine) autoinjectors
- biphasic reactions and observation time
- how to check an adrenaline (epinephrine) autoinjector device is fit for use
- documentation requirements including charting PRN orders of adrenaline (epinephrine) for patients with a history of anaphylaxis
- documentation on discharge from health facility including communication with GP and allergy specialist
- documentation of an adverse event in ims+.

A certificate is to be generated upon completion of anaphylaxis training.

Patient/carer education requirements:

- immediately alerting clinical staff when an adrenaline (epinephrine) autoinjector is used during a hospital admission (activation of a CERS)
- education on allergen and avoidance
- how to use an adrenaline (epinephrine) autoinjector
- recognition of signs and symptoms of anaphylaxis and follow an ASCIA Action Plan
- how to access replacement adrenaline (epinephrine) autoinjectors.
- weight-based dose changes for paediatric patients

A patient information leaflet and other useful resources can be found on the ASCIA website under Information for Patient and Carers [8].

Audit and review

An audit tool (available in the Quality Audit Reporting System or QARS) has been developed to assess the management of patients who have experienced an episode of anaphylaxis. This is an example audit tool that can be accessed and adapted for local use by contacting your local QARS administrator (Questionnaire ID 14196). The example audit includes:

- adrenaline (epinephrine) autoinjector location updated and clear to all staff
- number of patients treated with IM adrenaline (epinephrine)
- proportion of patients with history of anaphylaxis charted PRN adrenaline (epinephrine)
- proportion of patients discharged with updated action plans
- patients provided education resources
- proportion of patients with communication to GP
- number of patients who develop anaphylaxis as inpatient with an ims+ notification made
- allergy information in eMR has been updated after anaphylaxis
- documentation of capability assessment.

References

1. ACQSHC Acute Anaphylaxis Clinical Care Standard November 2021 Acute Anaphylaxis Clinical Care Standard (2021) | Australian Commission on Safety and Quality in Health Care. Accessed 21 June 2023
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5. NSW Ministry of Health Guide to Understanding Inpatient Mental Health Admissions for Children and Adolescents. Accessed 01 March 2024.
6. Use of a Patients Own Adrenaline (Epinephrine) Autoinjector in Hospital Safer Care Victoria Use of patients own adrenaline autoinjector in hospital_WEB.pdf (safercare.vic.gov.au) November 2019. Accessed 21 June 2023.
7. NSW Education March 2022 Anaphylaxis and Allergy Procedures for Schools. Accessed 24 January 2024.
8. ASCIA 2024 Information for Patients and Carers. Accessed 29 January 2024.

Appendix A – Checklist: Patient's own adrenaline (epinephrine) autoinjector use during admission

Use this checklist for patients at risk of anaphylaxis, and who have an adrenaline (epinephrine) autoinjector and anaphylaxis action plan.

A: Action Plan for Anaphylaxis	
Does the patient have a copy of an up-to-date ASCIA Action Plan for Anaphylaxis available at their bedside?	Yes/No
If yes, move to section B. If no, complete Action Plan with treating medical officer or nurse practitioner prior to proceeding.	
B: Physical and cognitive assessment of the patient	
Does the patient have the physical and cognitive capability to safely self-administer their adrenaline (epinephrine) autoinjector without posing a risk to others?	Yes/No
Is the patient comfortable and willing to self-administer their adrenaline (epinephrine) autoinjector if required?	Yes/No
If yes, move to section C. If no, go to section D.	
C: Patient awareness of anaphylaxis and use of adrenaline (epinephrine) autoinjector	
Is the patient aware of the signs and symptoms of anaphylaxis?	Yes/No
Does the patient understand what they should do if they develop symptoms of anaphylaxis?	Yes/No
Can the patient confidently explain how to use their adrenaline (epinephrine) autoinjector?	Yes/No
Is the patient aware they must immediately notify staff when an adrenaline (epinephrine) autoinjector is used whilst in hospital?	Yes/No
If no to any of the above, provide education for the patient	
D: Assessment of competence of carer/family member	
Does the carer/family member have the education and capability (as per section C) to safely administer the patient's adrenaline (epinephrine) autoinjector?	Yes/No
If yes, move to section E. If no, provide education for the carer/family member.	
E: Storage of adrenaline (epinephrine) autoinjector	
Discuss with the patient (family/carer) the most appropriate place to store the adrenaline (epinephrine) autoinjector, so it is accessible to patient, family and carers.	☐
Document location of adrenaline (epinephrine) autoinjector in the patient's history and any locally agreed areas	☐
Include location of adrenaline (epinephrine) autoinjector in clinical handover.	☐
Assess the patient's adrenaline (epinephrine) autoinjector for viability. Check expiry date, manner of storage, and that the device window is clear. Replace if not viable.	☐
Check if the adrenaline (epinephrine) autoinjector has the patient's name on it. If not, attach patient's health service label.	☐
Remind patient (family or carer) to alert staff if their adrenaline (epinephrine) autoinjector is administered.	☐

Adapted from Safer Care Victoria [6].

Appendix B – Example Risk Assessment: Storage of Patient's Own Adrenaline (Epinephrine)

It is recommended that a risk assessment is repeated when circumstances change that would result in a different outcome. This can be adapted where required to meet individual LHD/SHN requirements based on their individual resources and service needs.

Question	Answer	Score
1. Is the patient/consumer under the care of a Mental Health or Drug & Alcohol team for an acute phase of illness? Clinician discretion required when scoring. (Mental Health or Drug & Alcohol to be consulted if necessary)	**Yes = 1 to 5** **No = 0**	
2. Are they a paediatric/adolescent patient?	**Yes = 1** **No = 0**	
3. Is the patient in an isolation/single room?	**Yes = 0** **No = 1**	
4. Are there any wandering patients/children, OR confused persons present on the ward/unit?	**Yes = 1** **No = 0**	
5. Are there any patients with acute behavioural disturbance on ward/unit? For units that do not commonly treat acute behavioural disturbance (i.e. general medicine, cardiology, etc.) **OR** For units that commonly treat acute behavioural disturbance (i.e. Mental Health, Drug & Alcohol, Dementia Unit, etc). Clinician discretion required when scoring.	**Yes = 3** **OR** **Yes = 1 to 3** **No = 0**	
6. Is patient in a high traffic area? e.g. emergency department / urgent care centre	**Yes = 1** **No = 0**	
Total Score: **0 = Low Risk:** Environment is assessed as safe to retain adrenaline (epinephrine) autoinjector **1 – 4 = Moderate Risk:** Environment may be safe to retain adrenaline (epinephrine) autoinjector, judgement to be used **≥ 5 = High Risk:** Environment is assessed as **unsafe** for any patient to retain their adrenaline (epinephrine) autoinjector on their person/at the bedside. The adrenaline (epinephrine) autoinjector is to be removed from patient and returned at discharge from the unit.		

Adapted from Northern Sydney Local Health District