AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

Clinical Care Standards

DRAFT FOR CONSULTATION

Acute Anaphylaxis Clinical Care Standard

October 2020

Published by the Australian Commission on Safety and Quality in Health Care
Level 5, 255 Elizabeth Street, Sydney NSW 2000

Phone: (02) 9126 3600
Fax: (02) 9126 3613

Email: mail@safetyandquality.gov.au
Website: www.safetyandquality.gov.au

ISBN: XXX-X-XXXXXX-XX-X TBC

The Commission's preference is that you attribute this publication (and any material sourced from it) using the following citation:

Australian Commission on Safety and Quality in Health Care. *Acute Anaphylaxis Clinical Care Standard:* Consultation draft. Sydney: ACSQHC; 2020

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Contents

Acute Anaphylaxis Clinical Care Standard

Quality statements

1 Prompt recognition of anaphylaxis

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

2 Immediate injection of intramuscular adrenaline

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

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 not held upright. The patient should not be 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.

4 Access to a personal adrenaline injector in all healthcare settings

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

5 Observation time following anaphylaxis

A patient with anaphylaxis is observed in a healthcare facility for at least 4 hours after their last dose of adrenaline, or overnight as appropriate according to the current ASCIA[*] *Acute Management of Anaphylaxis Guideline*. Observation timeframes are determined based on assessment and risk appraisal after initial treatment.

6 Discharge management

Before a patient leaves a healthcare facility after having anaphylaxis they are equipped to respond safely in case of a recurrence. They receive an anaphylaxis action plan, an adrenaline injector or prescription if there is risk of re-exposure to the allergen, and education on allergy management strategies. Arrangements for a consultation with their general practitioner and a clinical immunology/allergy specialist are included in the discharge care plan and explained to the patient.

[*] Australasian Society of Clinical Immunology and Allergy

Indicators for local monitoring

The following indicators will support health service organisations to monitor how well they are implementing the care recommended in this clinical care standard and are intended to support local quality improvement activities.

Indicator 1a: Evidence of a locally approved anaphylaxis management pathway that includes:

1) An assessment protocol with clinical criteria to support prompt diagnosis of anaphylaxis, and
2) Guidance on the progression of allergic reaction to anaphylaxis and triage of patients already treated with adrenaline.

Indicator 2a: Proportion of patients with anaphylaxis treated with intramuscular adrenaline.

Indicator 4a: Evidence of a locally approved policy that defines:

1) The organisation's protocol to identify patients admitted to hospital that carry an adrenaline injector(s), and
2) The organisation's protocol for a patient to maintain access to their adrenaline injector(s) for self-administration throughout their hospital stay.

Indicator 6a: Evidence of local arrangements that ensure patients diagnosed with anaphylaxis receive:

1) A completed ASCIA Action Plan for Anaphylaxis
2) An adrenaline injector, or prescription for, an adrenaline injector
3) Education on reducing their risk of anaphylaxis, how to recognise the signs and symptoms of anaphylaxis, and how to use an adrenaline injector if one has been prescribed
4) A referral to clinical immunology/allergy specialist or a recommendation to see their current specialist
5) A recommendation to see their general practitioner within the week and take their care plan with them.

The organisation's process to assess adherence to the local arrangements should be described.

Indicator 6b: Proportion of patients with anaphylaxis separated from hospital with a completed ASCIA Action Plan for Anaphylaxis.

Indicator 6c: Proportion of patients with anaphylaxis who require an adrenaline injector provided an adrenaline injector, or prescription for one, prior to separation from hospital.

The definitions required to collect and calculate indicator data are specified online [LINK TBC]. More information about indicators and other quality improvement measures is provided in Appendix A

Clinical care standards

Clinical care standards aim to support the delivery of evidence-based clinical care and promote shared decision making between patients, carers and clinicians. They aim to reduce unwarranted variation and improve the appropriateness of care for a specific clinical condition or procedure, regardless of where people are treated in Australia.

A clinical care standard contains a small number of quality statements that describe the level of clinical care expected for a specific clinical condition or procedure. Indicators are included for some quality statements to assist health service organisations monitor how well they are implementing the care recommended in the clinical care standard.

A clinical care standard differs from a clinical practice guideline. Rather than describing all the components of care for a specific clinical condition or procedure, a clinical care standard focuses on key areas of care where the need for quality improvement is greatest.

Clinical care standards aim to support improved health care by considering the various perspectives of the community, clinicians, and health service managers.

Clinical care standards are developed by the Australian Commission on Safety and Quality in Health Care (the Commission), an Australian Government agency that leads and coordinates national improvements in the safety and quality of health care, based on the best available evidence. By working in partnership with the Australian Government, states and territories, the private sector, clinical experts, and patients and carers, the Commission aims to ensure that the health system is better informed, supported and organised to deliver safe and high-quality care.

About the Acute Anaphylaxis Clinical Care Standard

Context

Despite clinical guidelines, there is no uniform, national standard of care for the recognition and treatment of acute anaphylaxis. The number of patients with serious allergies, and the rates of anaphylaxis presentations to hospital are increasing and while only a small number of anaphylaxis events result in fatality, these are often preventable.[1, 2]

This clinical care standard describes the key components of care that patients can expect when they have anaphylaxis. It supports the provision of high-quality, evidence-based care, taking into account the context in which care is provided, local variation and the quality improvement priorities of the individual health services.

Goal

The goal of the *Acute Anaphylaxis Clinical Care Standard* is to improve the recognition of acute anaphylaxis and the provision of appropriate treatment and follow-up care.

Scope

This clinical care standard relates to the care provided to adults, children and infants when they are experiencing anaphylaxis, from initial presentation to a healthcare setting or first clinical contact in the community, through to discharge including planning for follow-up care. It also applies to patients who experience anaphylaxis while in a healthcare facility.

Pathway of care

This standard applies to care provided in the following care settings:

- All hospital settings, including public and private hospitals, subacute facilities, and outpatient and day procedure services
- Emergency services, such as ambulance services
- General practice
- Other primary healthcare settings such as Aboriginal Controlled Health Services and community pharmacies.

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 professionals, paramedics and other clinicians who provide health care, and students who provide health care under supervision.

What is not covered

The *Acute Anaphylaxis Clinical Care Standard* does not include:

- Detailed assessments of allergies and their management
- Care provided by schoolteachers, bystanders or other non-medically trained people.

Evidence that underpins this clinical care standard

Key sources that underpin the *Acute Anaphylaxis Clinical Care Standard* are current clinical guidelines from the Australasian Society of Clinical Immunology and Allergy (ASCIA) guideline: Acute Management of Anaphylaxis (2020)[3], and the Safer Care Victoria Anaphylaxis Clinical Care Standard (2019).[4]

Supporting documents

The following supporting documents for this clinical care standard are available on the Commission's website at https://www.safetyandquality.gov.au/standards/clinical-care-standards/consultations-clinical-care-standards [short URL TBC]

- Acute Anaphylaxis Clinical Care Standard – Consumer Fact Sheet
- Acute Anaphylaxis Clinical Care Standard – Clinician Fact Sheet
- Acute Anaphylaxis Clinical Care Standard – Discharge checklist and discussion guide

How to use this clinical care standard

The quality statements describe the expected standard for key components of patient care. By describing what each statement means, they support:

- **Patients** to know what care may be offered by their healthcare system, and to make informed treatment decisions in partnership with their clinician
- **Clinicians** to make decisions about appropriate care
- **Health service organisations** to understand the policies, procedures and organisational factors that can enable the delivery of high quality care.

This clinical care standard should be implemented as part of an overall approach to safety and quality, incorporating the following principles and standards.

General principles of care

When applying the information contained in a clinical care standard, clinicians are advised to use their clinical judgement and to consider the individual patient's circumstances, in consultation with the patient, or their support people.

This clinical care standard aligns with key principles that are the foundation for achieving safe, high-quality care including:

- Person-centred care and shared decision making
- Informed consent
- Cultural safety for Aboriginal and Torres Strait Islander people

For more information and additional Commission resources, see Appendix A

Measurement for quality improvement

Measurement is a key component of quality improvement processes. The Commission has developed a set of indicators to support clinicians and health services organisations to monitor how well they are implementing the care recommended in this clinical care standard. The indicators are intended to support local quality improvement activities. No benchmarks are set for these indicators.

The indicators are listed with the relevant quality statements. The definitions required to collect and calculate indicator data are available online [LINK TBC]. More information about indicators and other quality improvement measures is provided in Appendix B.

Information on other quality measures including patient reported outcome measures and patient experience measures is provided in Appendix C.

Meeting the requirements of national standards and accreditation

Implementing this clinical care standard as part of a quality improvement activity can help health services meet the requirements of the NSQHS Standards

More information about clinical care standards and the NSQHS Standards is included in Appendix D.

Background information on anaphylaxis

Anaphylaxis is the most severe form of allergic reaction. Anaphylaxis is potentially life threatening if not treated immediately. Allergy occurs when a person's immune system reacts to substances (allergens) in the environment that are harmless for most people.[5] Over four million Australians live with allergies.[6] For example, food allergy occurs in around 10% of infants, 4-8% of children, and 2% of adults in Australia.[7]

The diagnosis of anaphylaxis is based on clinical findings, taking into consideration the patient's history and the physical examination.[8]

Anaphylaxis has no universally accepted definition. The Australasian Society of Clinical Immunology and Allergy (ASCIA) defines anaphylaxis as:

- 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.

Recent studies show increasing incidence of all-cause anaphylaxis in Australia, the United Kingdom and the United States.[2] In Australia, hospital admissions due to anaphylaxis have increased by 46% over 5 years from 8,098 in 2014-15 to 11,856 in 2018-19.[9] Over the same 5-year period, anaphylaxis presentations to emergency departments in public hospitals grew by 58%, to over 10,940 in 2018-19.[1]

Foods are the most common triggers for anaphylaxis presentations to hospitals, followed by medicines, insect stings, and idiopathic anaphylaxis (anaphylaxis of unknown cause).[10]

Adrenaline (epinephrine) is the first-line treatment for anaphylaxis as it causes vasoconstriction and bronchodilation, prevents and relieves airway oedema, hypotension and shock. It also has the effect of decreased mediator release, making it the only medicine that reduces the amplification of an allergic response. Adrenaline reduces hospitalisation and death.[11]

There are well recognised guidelines for the management of acute anaphylaxis. Despite this, research shows the recommended care pathway is not adhered to in the treatment of some patients. While adrenaline is the first line treatment for anaphylaxis, a study in eight Australian emergency departments found 27% of reactions consistent with anaphylaxis were not given adrenaline.[12] Analysis of 324 anaphylaxis fatalities between 1997 and 2013 found that fatalities increased in parallel with increasing hospital anaphylaxis admission rates, and highlighted delays in treatment with adrenaline.[2]

Adrenaline is the only effective treatment for anaphylaxis.[3, 11] However, studies continue to show high rates of corticosteroid and antihistamine administration for the initial treatment of anaphylaxis.[13-15] This is of concern as delayed administration of adrenaline is a risk factor for fatal anaphylaxis.[16, 17]

Globally, certain key components of care for anaphylaxis have been identified as requiring improvement. These include the prescription of an adrenaline injector with an anaphylaxis action plan, referral to an allergy/immunology specialist to confirm the suspected allergen, and patient education for ongoing management including recognition of anaphylaxis and the correct use of the injector.[17-19]

Quality statement 1

Prompt recognition of anaphylaxis

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

Purpose

To improve the time to optimal diagnosis and treatment for people with anaphylaxis.

What the quality statement means

For patients

If you have sudden difficulty in breathing, swelling of your face, tightness in your throat, persistent dizziness, hives or other symptoms that could indicate an allergic reaction, your healthcare provider will assess if you are experiencing the most severe form of allergic reaction, anaphylaxis. If you experience anaphylaxis due to an insect bite or sting you may have abdominal pain and/or vomiting.[3]

The most common triggers of anaphylaxis are food, insect bites or stings, and medicines. Your clinician will ask what you have eaten, whether you have had an insect bite or sting, or have had any medicines. A reaction can occur within minutes or several hours after exposure to a trigger (also called an 'allergen').

A mild or moderate allergic reaction may progress to anaphylaxis so be aware of the symptoms and signs of anaphylaxis so you can recognise if this is happening.

If you have an allergy or have had anaphylaxis before, it is important to let your clinician know about this. If you have asthma and are at risk of anaphylaxis and experience sudden difficulty in breathing, this should be treated as anaphylaxis.

For clinicians

Assess patients presenting with rapid development of severe respiratory and/or circulation problems, with or without/ skin and mucosal changes, immediately for possible anaphylaxis. The presence of an allergic trigger or a history of allergy should heighten suspicion even if the patient is not in severe distress. Clinical presentation of anaphylaxis is variable and skin features are not always present. The most common triggers of anaphylaxis are food, insect venom, and medicines (Table 1). After exposure to a trigger, the onset of signs and symptoms of anaphylaxis (Table 2) is usually within minutes to several hours. [3, 4, 8]

Monitor patients regularly to promptly recognise the progression of a mild to moderate allergic reaction to anaphylaxis.[2] Reactions can progress to severe involvement of more than one body organ system and rapidly become life threatening.[8] [17]

Obtain a history from the patient noting recent exposure to substances known to cause an allergic reaction, any known allergies for the patient, including previous reactions and treatment, and any history of anaphylaxis.[3] Document the time of the onset of symptoms in the patient's healthcare record.[20]

Consider patient risk factors that potentially contribute to fatal anaphylaxis (for example, older age, cardiovascular and respiratory diseases) and co-factors that are likely to amplify the severity of an allergic reaction, such as exercise or acute infection.[8, 11, 12]

Rule out other sudden-onset multisystem diseases.[21] Common differential diagnoses include acute asthma, syncope, panic attacks and septic shock.[4] However, a patient who experiences sudden breathing difficulty and has asthma and is known to be at risk of anaphylaxis should be treated as anaphylaxis.[3]

Consider the role of laboratory investigations in initial presentation of anaphylaxis as serial measurements of mast cell tryptase concentrations taken during anaphylaxis can be useful for subsequently confirming the diagnosis and identifying the trigger when reviewed after the event, usually by a clinical immunology/allergy specialist.[20]

Rehearse the anaphylaxis management protocol regularly to ensure prompt recognition of anaphylaxis for patients presenting with allergic reactions. [4, 11]

For health service organisations

Ensure that an anaphylaxis management protocol, outlining clinical criteria, is available and used consistently by clinicians. Confirm clinical staff have the skills and competency to promptly recognise the signs and symptoms of allergic reactions including anaphylaxis.[4]

Ensure that systems are in place for the continuing assessment of the patient experiencing an allergic reaction, to monitor for the possible progression of symptoms to anaphylaxis. This may include drills to ensure competency of relevant staff to the anaphylaxis management protocol.

Reporting of incidents of delayed recognition of anaphylaxis, or missed anaphylaxis as an adverse event should be included in the quality management program, for instance through incident management reporting.

Related resources

Allergy & Anaphylaxis Australia
Signs & Symptoms Video: https://allergyfacts.org.au/allergy-anaphylaxis/signs-symptoms

Indicator for local monitoring

Indicator 1a: Evidence of a locally approved anaphylaxis management pathway that includes:

1) An assessment protocol with clinical criteria to support prompt diagnosis of anaphylaxis, and
2) Guidance on the progression of allergic reaction to anaphylaxis and triage of patients already treated with adrenaline.

Table 1: Triggers of anaphylaxis

Common triggers	Less common triggers
Food • Peanuts • Tree nuts • Egg • Fish • Shellfish • Cow's milk (dairy) products • Soy • Sesame seeds • Wheat **Medicines** • Antibiotics • Anaesthetics **Insect stings** • Bees • Wasps • Jack jumper ants • Fire ants	**Other foods** • Food additives • Other foods (see common triggers) • Other milks **Topical medicines** • Chlorhexidine **Biological** • Transfusions • Antivenoms • Monoclonal therapies • Immunoglobulins **Physical** • Exercise (with/without food) • Cold **Other** • Latex • Tick bites • Contrast media • Hormonal changes[#] • Other medicines • Idiopathic (trigger not identified)

[#] Hormone allergy is an allergic reaction where the trigger is an individual's hormones.[22, 23]

Table 2: Signs and symptoms of allergic reactions [3, 24]

Symptoms of a mild to moderate allergic reaction include one or more of the following:
Rash, hives (red raised, itchy bumps) or welts
Swelling of the lips, eyes or face
Itchy or tingling mouth
Stomach pain, nausea, or vomiting
In the case of sting or bites, localised swelling at sting site
Symptoms of anaphylaxis (a severe allergic reaction) include one or more of the following:
Airway:
Swollen tongue
Difficulty swallowing or speaking
Throat tightness
Change in voice (hoarse or croaky sounds)
Stridor (high-pitched inspiratory noise caused by upper airway obstruction)
Breathing:
Difficult or noisy breathing
Sudden persistent cough
Wheeze
Shortness of breath (increased respiratory rate)
Circulation:
Increased pulse rate (tachycardia)
Low blood pressure (hypotension) with persistent dizziness or feeling faint
Collapse
Sudden onset of pallor and floppiness (in babies and young children)
Decreased conscious level or loss of consciousness
Cardiac arrest
Gastrointestinal:
Severe nausea
Severe diarrhoea
Abdominal pain or vomiting (for insect stings or injected medicine allergy)
Skin and mucosal changes can be subtle or absent in up to 20% of anaphylaxis

Quality statement 2

Immediate injection of intramuscular adrenaline

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

Purpose

To ensure immediate treatment with intramuscular adrenaline as soon as anaphylaxis is recognised or suspected, in order to prevent progression to life threatening symptoms.

What the quality statement means

For patients

In a healthcare setting, if a clinician believes you are experiencing anaphylaxis, they will immediately give you an injection of adrenaline into the outer mid-thigh muscle.

If you have an adrenaline injector and you recognise the signs of anaphylaxis (a severe allergic reaction), use the adrenaline injector without delay and call for help immediately.[25] Using your adrenaline injector when you suspect anaphylaxis can prevent the allergic reaction progressing to a life threatening reaction. If you are not sure, it is safer to use adrenaline than to wait for your symptoms to get worse.[3, 8]

Adrenaline lessens the effects of anaphylaxis by reducing throat swelling, opening the airways and maintaining heart function and blood pressure.[3, 26]

Other medicines (including non-sedating antihistamines and asthma medicines) to relieve symptoms such as itchy or red skin, and breathlessness, should only be used after adrenaline, if necessary.[3, 8]

For clinicians

Administer adrenaline intramuscularly immediately on diagnosis of anaphylaxis. If anaphylaxis is suspected in the presence of an allergy or anaphylaxis history, or exposure to a potential allergen, it is safer to administer adrenaline early rather than to wait for progression (which may be hard to reverse). Administer adrenaline via intramuscular injection into the mid-anterolateral thigh, using a needle of appropriate length. Subcutaneous or inhaled routes for adrenaline are not recommended as they are less effective.[13, 24, 26] Delayed administration of adrenaline is a risk factor for fatal anaphylaxis.[2, 27, 28]

Intramuscular (IM) injection of adrenaline is safer than an intravenous (IV) bolus injection. Adverse events have been reported in adult patients who received overdoses of IV adrenaline, but these are rare with IM adrenaline.[29, 11]. There are no absolute contraindications to adrenaline administration in anaphylaxis. [3, 11, 17, 24]

Adrenaline causes vasoconstriction, bronchodilation, increased cardiac output, reduced mucosal oedema and reduced mediator release. Therefore, adrenaline not only treats the signs and symptoms but also reduces the amplification of an allergic response. [11, 30]

Second and subsequent doses of IM adrenaline can be administered to patients with anaphylaxis whose symptoms are not relieved by the initial dose. Repeated IM adrenaline injections can be given at five minute intervals if the patient's symptoms are not improving.[3] The management for anaphylaxis in pregnant women is the same as for non-pregnant women, with appropriate positioning.[31]

Include a 'when required' (prn) order for IM adrenaline on an admitted patient's medication chart if they have a known allergy and have been prescribed an adrenaline injector, to expedite the administration of IM adrenaline if they experience anaphylaxis whilst in care.

Corticosteroids and antihistamines are not to be given as a first line of treatment as they are not effective in treating anaphylaxis. Corticosteroids have a delayed effect of 4 to 6 hours, and are adjuncts in the management of anaphylaxis but should not be used instead of adrenaline. Antihistamines are only helpful for relieving associated urticaria (hives), angioedema and itch. Do not give promethazine (for example Phenergan®), or other sedating antihistamines, as the sedating effect can mask deterioration or a biphasic reaction.[3, 13, 26]. Phenergan can also decrease blood pressure causing deterioration.

Consider the implications of the treatment provided in the healthcare facility and of communication regarding adrenaline use. Avoiding adrenaline use in the case of a severe allergic reaction, or preferentially using corticosteroids or antihistamines may inadvertently give a message to patients that they should delay using their adrenaline injector, thus increasing potential risk in a subsequent anaphylaxis.

For health service organisations

Ensure a protocol for the management of anaphylaxis is in place which supports prompt administration of adrenaline by all relevant clinicians including nurses.[4, 26] The use of protocols can significantly improve IM adrenaline injection rates for anaphylaxis.[11]

Ensure access to adrenaline for the treatment of anaphylaxis in all clinical areas and that access arrangements are specified in the protocol for the management of anaphylaxis, ensuring adrenaline is readily accessible to any clinician who may administer it, including for 'when required' (prn) charted IM adrenaline.

Ensure clinical staff have training in the management of anaphylaxis. The use of 'Anaphylaxis Management' cards for an anaphylaxis event can serve as a cognitive aid when rehearsing the protocol for an event.[4, 30]

Make sure that relevant staff are trained and practised in using adrenaline injector devices. Ensure practice devices are available.[25]

Consider providing access to adrenaline in readily identifiable anaphylaxis kits for emergency use with anaphylaxis, to reduce the time to administration of intramuscular adrenaline. To avoid confusion, the anaphylaxis kits should be easily distinguished from the intravenous adrenaline kits for cardiac emergencies. An anaphylaxis kit also reduces the risk of the inadvertent IV overdose of adrenaline for anaphylaxis.[3, 32]

Related resources

Adrenaline injector practice devices are available and are commonly sourced from: allergyfacts.org.au/shop/training-accessories

Indicator for local monitoring

Indicator 2a: Proportion of patients with anaphylaxis treated with intramuscular adrenaline.

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 not held upright. The patient should not be 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.

Purpose

To reduce adverse outcomes during or after anaphylaxis due to low blood pressure. Fatality can occur within minutes if a patient stands or sits up suddenly whilst they have inadequate perfusion.

What the quality statement means

For patients

When you are experiencing anaphylaxis you will be advised to lie flat, or sit with your legs extended if breathing is difficult. Your legs can be elevated if you feel faint. An infant should be held horizontally (lying down), and they must not be held upright.

If you stand up too quickly after anaphylaxis, your blood pressure may drop dangerously. Do not stand or walk anywhere, even to the bathroom. After you have been treated, you should wait until a clinician assesses it is safe for you to get up. This is usually after a minimum of 1 hour.[3]

For clinicians

Ensure the patient is in a supine position; do not allow them to stand or walk. Monitor the patient's blood pressure and elevate their legs if their blood pressure is low. Fatality can occur within minutes if a patient stands or sits up suddenly whilst they have inadequate perfusion.[3]

A sitting position sufficient to relieve respiratory distress is allowed while the patient is monitored carefully for any circulatory collapse. Patients who are vomiting or pregnant should be placed on their side in the left lateral (recovery) position.[3]

Infants should be held horizontally. They must not be held upright. [3]

Ensure the patient understands why they are not to stand up suddenly or walk until after they have been treated and assessed and that this is communicated to other staff caring for the patient.

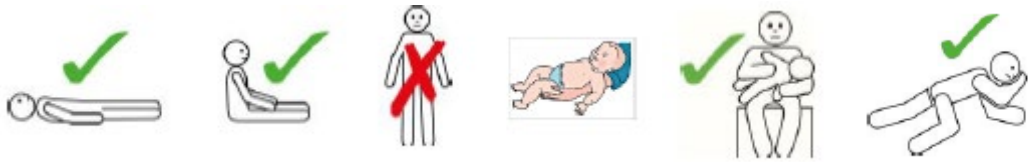
The patient must be assessed for circulatory stability after they have been adequately treated and before being allowed to mobilise. This is usually a minimum of 1 hour after 1 dose of adrenaline, and 4 hours if more than 1 dose of adrenaline is administered.[3]

For health service organisations

Ensure acute anaphylaxis management protocols are in place to provide guidance on appropriate positioning for patients with anaphylaxis, and specify that patients should not stand or walk until assessed as safe to do so, after treatment with adrenaline.

Ensure equipment and training is in place to routinely monitor patient blood pressure after an anaphylaxis event.

Figure 1: Correct positioning during and after an anaphylaxis event[3]



Quality statement 4

Access to a personal adrenaline injector in all healthcare settings

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

Purpose

To avoid harm resulting from delayed administration of adrenaline to patients with anaphylaxis who have their own adrenaline injector and could self-medicate safely during a healthcare encounter or admission.

What the quality statement means

For patients

If you normally have a personal adrenaline injector (such as EpiPen or Emerade) and know how to use it, you should be able to have it close by while you are receiving care in a health service, including a hospital, ambulance or clinic. Tell your healthcare team that you have an adrenaline injector and arrange with them to keep it near you during your care. Your healthcare team may want to confirm that you know how and when to use your adrenaline injector.[25]

If you experience symptoms, especially difficulty breathing, faintness or swelling of your tongue or throat, whilst in health care, lay down (or sit with your legs extended if breathing is difficult), use your adrenaline injector without delay and alert a staff member immediately.

For clinicians

For adrenaline to be given as soon as possible after the onset of symptoms of anaphylaxis, it is important for the patient (or their carer) to be able to immediately administer their own adrenaline injector regardless of the setting. A readily accessible adrenaline injector may also be used by a clinician if available and necessary.[25]

If a patient has an adrenaline injector, assess their capacity to safely use it during the healthcare encounter. This includes

- Their physical capability, and willingness, to use the device and their ability to recognise the symptoms of anaphylaxis
- Considering medicines administered during the healthcare visit that may impair the patient's usual ability to recognise and treat anaphylaxis
- In the paediatric setting, involve a parent, guardian or carer in the assessment
- Where a patient is cognitively impaired or lives with a disability, involve a family member or carer in the assessment if appropriate.

As part of the assessment, identify a safe place for the adrenaline injector to be stored that allows ease of access for the patient, in an unlocked location, while maximising the safety of others.[25]

The adrenaline injector should be:

- Stored with the patient's ASCIA Action Plan for Anaphylaxis
- Labelled with the patient's name.

Notify all staff that the patient has an adrenaline injector with them, including handover when the patient has scans or other tests.

For health service organisations

Ensure a policy is in place for a personal adrenaline injector to be easily accessible to the patient at all times, in a manner that is safe to others.

Related resources

The Safer Care Victoria (SCV) *Use of a patient's own adrenaline (epinephrine) autoinjector in hospital: Change package* includes an in-hospital checklist for patients own use of adrenaline injectors.
https://www.bettersafercare.vic.gov.au/reports-and-publications/use-of-a-patients-own-adrenaline-epinephrine-autoinjector-in-hospital-change-package

Indicator for local monitoring

Indicator 4a: Evidence of a locally approved policy that defines:

1) The organisation's protocol to identify patients admitted to hospital that carry an adrenaline injector(s), and
2) The organisation's protocol for a patient to maintain access to their adrenaline injector(s) for self-administration throughout their hospital stay.

Quality statement 5

Observation time following anaphylaxis

A patient with anaphylaxis is observed in a healthcare facility for at least 4 hours after their last dose of adrenaline, or overnight as appropriate according to the ASCIA *Acute Management of Anaphylaxis Guideline*. Observation timeframes are determined based on assessment and risk appraisal after initial treatment.

Purpose

Patients who have experienced anaphylaxis are observed in a setting with facilities to manage deterioration or a biphasic reaction.

What the quality statement means

For patients

When you have been treated in a healthcare facility for anaphylaxis you will be kept under medical supervision for at least 4 hours after the last injection of adrenaline. Adrenaline has a short duration of action and wears off quickly.

Occasionally some people have another episode of anaphylaxis without coming into contact with their allergic trigger, and require further treatment with adrenaline. A clinician will review your risk of re-exposure or recurrence of anaphylaxis before you are discharged.

In some cases you may need to be admitted overnight for observation after having anaphylaxis. For example, if you have received more than one dose of adrenaline to treat your anaphylaxis, have a history of severe asthma, have arrived late in the evening, live alone or a long way from health care services, or if your adrenaline injector cannot be replaced before you get home and you do not have another one.

For clinicians

Observe patients for at least 4 hours after the last injection of adrenaline following anaphylaxis. Re-assess the patient after 4 hours. Consider the severity of the reaction, concomitant conditions and history of anaphylaxis in determining a longer timeframe.[3]

Prolonged, relapsing and biphasic reactions may occur. Biphasic reactions are estimated to occur following 3 to 20% of anaphylactic reactions, and cannot be predicted. [3, 26]

Before discharge, ensure the patient has had a medical review to assess their risk of re-exposure or recurrence of anaphylaxis.

Observe the patient overnight if they:

- Had a severe reaction (hypotension or hypoxia)
- Required repeated doses of adrenaline
- Have a history of severe asthma or protracted anaphylaxis
- Have other concomitant illness, such as asthma, chest infection or arrhythmia
- Live alone or are remote from medical care
- Have known systemic mastocytosis
- Presented for health care late in the evening
- Cannot easily replace their adrenaline injector on discharge and have no other adrenaline injector.[3]

For health service organisations

Ensure protocols align with ASCIA guidelines and that systems and processes are in place for patients to undergo clinical observation for the appropriate length of time.

Ensure all patients have a medical review prior to discharge from care to assess their risk of re-exposure or recurrence of anaphylaxis.

Quality statement 6

Discharge management

Before a patient leaves a healthcare facility after having anaphylaxis they are equipped to respond safely in case of a recurrence. They receive an anaphylaxis action plan, an adrenaline injector or prescription if there is risk of re-exposure to the allergen, and education on allergy management strategies. Arrangements for a consultation with their general practitioner and a clinical immunology/allergy specialist are included in the discharge care plan and explained to the patient.

Purpose

To reduce the risk associated with a subsequent episode of anaphylaxis by ensuring that patients who have experienced anaphylaxis have access to adrenaline if required, an individualised care plan and education before they are discharged. To inform the patient and their primary care provider about the ongoing management they will require.

What the quality statement means

For patients

Before you are discharged from a health care service, your clinician will discuss with you the ongoing management for your allergy, and provide you with information about reducing the risk of anaphylaxis. Together, a clinician will develop a care plan with you in a format that you understand. It is important that you know what to do if you have another allergic reaction and that, where possible, the triggers for your anaphylaxis have been correctly identified so you can avoid it happening again. These triggers are also called allergens. For example, if you are allergic to a medicine, such as an antibiotic, you need to know its active ingredient name so that so you can avoid it, and so that it is accurately recorded on your healthcare record.

Following an anaphylaxis event you should have:

- An adrenaline injector or a prescription for one
- Information about anaphylaxis
- An ASCIA Action Plan for Anaphylaxis
- A referral or appointment to see to a clinical immunology/allergy specialist
- A care plan that describes the ongoing care required for your allergy.

If you are at risk of future exposure to your trigger, you will be given or prescribed an adrenaline injector when you are discharged from the health service organisation. If you are given a prescription, it is very important that you go to the pharmacy, preferably on the way home, to get your adrenaline injector. You will need to keep the adrenaline injector with you at all times. You will be advised on the need for medical identification jewellery.[4, 19, 26]

You and your family or carer, will be taught how to recognise the signs and symptoms of anaphylaxis so that you know when to use the adrenaline injector. You will be given instructions on how to use and store the adrenaline injector. You will be given an ASCIA Action Plan for Anaphylaxis, which explains exactly what to do if you have the symptoms and signs of anaphylaxis.

If you have not seen an allergy specialist before, you will be given a referral or an appointment. Your clinical immunology/allergy specialist can help confirm what triggers your

anaphylaxis, and explain how to prevent and manage anaphylaxis. If you already have a regular specialist, it is preferred you see them for follow-up.

Visit your general practitioner (GP) with a copy of your care plan and ASCIA Action Plan for Anaphylaxis within one week after discharge from the health service organisation. If you do not have a referral or appointment for a clinical immunology/allergy specialist, ask your GP to refer you to one as soon as possible.

Information for ongoing support services available in the community, such as the Allergy & Anaphylaxis Australia information and advice line (1300 728 000), and Australasian Society of Clinical Immunology and Allergy (ASCIA) information leaflets and website will be given to you.

For clinicians

Plan the patient's discharge to ensure adequate follow-up and preventive measures.

Complete an ASCIA Action Plan for Anaphylaxis on discharge when an environmental allergen is identified or suspected. Prescribe, or provide, an adrenaline injector. If a prescription is given to the patient, determine which pharmacy they will visit to obtain the adrenaline injector to check the pharmacy has one in stock. Ensure the patient, and family, are aware of the urgency in obtaining an adrenaline injector (ideally on the way home), and of keeping it with them at all times.

Educate the patient/carer and family on the signs and symptoms of anaphylaxis, and that anaphylaxis may present differently each time. Provide education and training as to when and how to use the adrenaline injector, and confirm patient proficiency. If the patient is at high risk of anaphylaxis, advise them to obtain medical identification jewellery that provides information about their allergy.[3, 4, 26]

Advise parents of affected children to inform all carers of the nature of the trigger for their anaphylaxis, avoidance strategies, symptoms and signs of an allergic reaction and its treatment.[26]

Document food, medicine, and sting or bite exposure in the hours before anaphylaxis. This may confirm a known allergen or indicate a new trigger. Record what caused the allergic reaction when it is known.[3, 8, 26] Upload an entry in the patients My Health Record for the anaphylaxis event.

Develop an individualised care plan with the patient that describes the ongoing care required for their allergy. This includes trigger avoidance strategies, treatment of allergic reactions and planned medical appointments. If the patient has a medicine allergy, the ASCIA drug allergy document can be completed for them (https://allergy.org.au/images/stories/drug_allergy/ASCIA_Drug_Allergy_Record_2020.pdf).

Advise the patient to see their general practitioner within one week after the anaphylaxis event with a copy of their care plan and their ASCIA Action Plan for Anaphylaxis.

Refer the patient to a clinical immunology/allergy specialist following an initial anaphylaxis event, or for review by their current specialist, who will identify and confirm the cause of anaphylaxis, provide ongoing management of, and patient education about anaphylaxis for the prevention of recurrences.[3, 8, 19]

Recognise the degree of anxiety the patient and/or their family are experiencing after the anaphylaxis event. Inform their general practitioner, or primary care provider, so they can offer ongoing care. Provide the patient information for support services available in the community, such as Allergy & Anaphylaxis Australia (https://allergyfacts.org.au/), and Australasian Society of Clinical Immunology and Allergy (ASCIA https://www.allergy.org.au/patients/information).

For health service organisations

Facilitate access to an adrenaline injector if the patient requires one, to enable the patient being discharged safely. Arrangements may include dispensing an adrenaline injector, or providing a prescription to be filled immediately on leaving the healthcare setting as appropriate to the local setting. Consider the provision of an adrenaline injector on discharge after hours.

Ensure systems are in place for clinicians to provide patients and their family with information and education on anaphylaxis, including the ASCIA Action Plan for Anaphylaxis, and education on the use of the adrenaline injector when one is prescribed or provided.

Ensure that processes are in place so that clinicians can develop an individualised care plan for the management of their allergy with patients before they leave the healthcare facility, and provide the plan to the patient and their general practitioner or ongoing clinical provider within 48 hours of discharge. Provide access to written information for clinicians to give to the patient as appropriate, for instance the *Acute Anaphylaxis Clinical Care Standard* Consumer Fact Sheet and Anaphylaxis discharge checklist and discussion guide.

Ensure processes are in place to upload an entry in the patients My Health Record for the anaphylaxis event.

Related resources

Support services available in the community include:

- Australasian Society of Clinical Immunology and Allergy (ASCIA) leaflets and website https://www.allergy.org.au/patients/information
- Allergy & Anaphylaxis Australia leaflets, videos and training https://allergyfacts.org.au/
- Allergy & Anaphylaxis Australia information and advice line - **1300 728 000**.

Indicators for local monitoring

Indicator 6a: Evidence of local arrangements that ensure patients diagnosed with anaphylaxis receive:

1) A completed ASCIA Action Plan for Anaphylaxis
2) An adrenaline injector, or prescription for, an adrenaline injector
3) Education on reducing their risk of anaphylaxis, how to recognise the signs and symptoms of anaphylaxis, and how to use an adrenaline injector if one has been prescribed
4) A referral to clinical immunology/allergy specialist or a recommendation to see their current specialist
5) A recommendation to see their general practitioner within the week and take their care plan with them.

The organisation's process to assess adherence to the local arrangements should be described.

Indicator 6b: Proportion of patients with anaphylaxis separated from hospital with a completed ASCIA Action Plan for Anaphylaxis.

Indicator 6c: Proportion of patients with anaphylaxis who require an adrenaline injector provided an adrenaline injector, or prescription for one, prior to separation from hospital.

Appendix A: General principles of care

This clinical care standard aligns with key principles that are the foundation for achieving safe, high-quality care. When implementing this clinical care standard health services should ensure quality improvement activities support these principles.

Person-centred care

Person-centred care is health care that is respectful of, and responsive to, the preferences, needs and values of patients and consumers. [33, 34]

Clinical care standards support the key principles of person-centred care, namely:

- Treating patients with dignity and respect
- Encouraging patient participation in decision making (see Shared decision making)
- Communicating with patients about their clinical condition and treatment options
- Providing patients with information in a format that they understand and encouraging them to participate in decision-making.

Shared decision making

Shared decision making involves discussion and collaboration between a consumer and their clinician. It is about bringing together the consumer's values, goals and preferences with the best-available evidence about benefits, risks and uncertainties of treatment, to reach the most appropriate healthcare decisions for that person.

Involving support people

The Australian Charter of Healthcare Rights (second edition) [35] describes the rights that consumers, or someone they care for, can expect when receiving health care.

Patients have the right to involve the people they want in planning and making decisions about their health care and treatment. This could be a family member, carer, friend, or a consumer advocate such as a social worker. Many health services employ different types of liaison officers, such as Aboriginal and/or Torres Strait Islander liaison officers, who can provide patients with advocacy, information and support.

This clinical care standard does not specifically refer to carers and family members, but statements which refer to clinicians' discussions with patients about their care should be understood to include support people if this is what the patient wishes, or a substitute decision maker if the person is unable to provide their consent.

Informed consent

Informed consent is a person's voluntary and informed decision about a health care treatment, procedure or intervention that is made with adequate knowledge and understanding of the benefits and risks to them, and the alternative options available. The Commission developed an informed consent fact sheet for consumers, available at https://www.safetyandquality.gov.au/publications-and-resources/resource-library/informed-consent-fact-sheet-clinicians.

Action 2.4 in the NSQHS Standards requires health service organisations ensure that informed consent processes comply with legislation and best practice. [33]

Cultural safety and patient safety

Cultural safety is about overcoming the cultural power imbalances of places, people and policies to contribute to improvements in Aboriginal and Torres Strait Islander health. [36]

The Cultural Respect Framework 2016-2026 {AHMAC. Cultural Respect Framework 2016-2026 for Aboriginal and Torres Strait Islander Health. 2019} commits the Australian Government and all states and territories to embed cultural respect principles into their health system. The Framework should be used to develop, implement and evaluate cultural awareness and cultural competency strategies.

Health consumers are safest when clinicians have considered power relations, cultural differences and patients' rights. Part of this process requires clinicians to review their own beliefs and attitudes. [37]

The NSQHS Standards *User Guide for Aboriginal and Torres Strait Islander Health* [37] describes six specific actions that aim to help health services improve the quality of care and health outcomes for Aboriginal and Torres Strait Islander peoples. [33]

Appendix B:
Indicators to support local monitoring

The Commission has developed a set of indicators to support clinicians and health services in monitoring how well they implement the care described in this clinical care standard. The indicators are a tool to support local quality improvement activities. No benchmarks are set for any indicator.

The process to develop the indicators specified in this document comprised:

- A review of existing Australian and international indicators
- Prioritisation, review and refinement of the indicators with the topic working group.

The data underlying these indicators are collected from local sources, through prospective data collection or retrospective chart or review of policies and protocols.

In this document, the indicator titles and hyperlinks to the specifications are included with the relevant quality statement under the heading 'Indicator for local monitoring'. Full specifications for the *Acute Anaphylaxis Clinical Care Standard* indicators can be found in the Metadata Online Registry (METeOR). [Link TBC]

METeOR is Australia's web-based repository for national metadata standards for the health, community services and housing assistance sectors. Hosted by the Australian Institute of Health and Welfare, METeOR provides users with online access to a wide range of nationally endorsed data and indicator definitions.

Appendix C:
Measuring and monitoring patient experiences

Systematic, routine monitoring of patients' experiences of, and outcomes from, health care is an important way to ensure that the patient's perspective drives service improvements and patient-centred care. This is the case in all health services.

Patient experience measures

While this clinical care standard does not include indicators specific to measuring patient experiences, the Commission strongly encourages health services to use the Australian Hospital Patient Experience Question Set (AHPEQS). AHPEQS is a 12-question generic patient experience survey that has been validated in both day-only and admitted hospital patients across many clinical settings. The instrument is available for download to both private and public sector health services.

Patient-reported outcome measures

In Australia, patient-reported outcome measures (PROMs) are an emerging method of assessing the quality of health care. The Commission is leading a national work program to support the consistent and routine use of PROMs to drive quality improvement.

PROMs are standardised, validated questionnaires that patients complete, without any input from healthcare providers. They are often administered at least twice to an individual patient – at baseline and again after an intervention, or at regular intervals during a chronic illness. The information contributed by patients filling out PROMs questionnaires can be used to support and monitor the movement of health systems towards person-centred, value-based health care.

PROMs are being used to evaluate healthcare effectiveness at different levels of the health system, from the individual level to service and system levels. There is growing interest across Australia and internationally in the routine interrogation of patient-reported outcome information for evaluation and decision-making activities at levels of the health system beyond the clinical consultation.

Appendix D: Integration with National Standards

The National Safety and Quality Health Service Standards

Monitoring the implementation of this clinical care standard will help organisations to meet some of the requirements of the NSQHS Standards (2nd ed.). [33]

The NSQHS Standards aim to protect the public from harm and improve the quality of health service provision. They provide a quality assurance mechanism that tests whether relevant systems are in place to ensure that expected standards of safety and quality are met.

Within the NSQHS Standards, the Clinical Governance Standard and the Partnering with Consumers Standard combine to form the clinical governance framework for all health service organisations that applies to all other standards.

- The Clinical Governance Standard aims to ensure that systems are in place within health service organisations to maintain and improve the reliability, safety and quality of health care.
- The Partnering with Consumers Standard aims to ensure that consumers are partners in the design, delivery and evaluation of healthcare systems and services, and that patients are given the opportunity to be partners in their own care, to the extent that they choose.

Action 1.27b and Action 1.28

Under the Clinical Governance Standard, health service organisations are expected to support clinicians to use the best available evidence, including clinical care standards (see Action1.27b) and to monitor and respond to unwarranted clinical variation (Action 1.28).

Health service organisations are expected to implement the NSQHS Standards in a way that suits the clinical services provided and their associated risks. Specific aspects of the NSQHS Standards (2nd ed.) that are relevant to this clinical care standard include:

Information about the NSQHS Standards is available at the NSQHS Standards website.

Glossary

Term	Definition
adrenaline	Adrenaline, also known as epinephrine, is a hormone and a medicine. Adrenaline is secreted by the adrenal gland in the body in response to stress or a fright. This is known as the fight-or-flight response. An adrenaline injection is used to treat anaphylaxis (a severe allergic reaction) as it reduces throat swelling, opens the airways and maintains heart function and blood pressure.
adrenaline injector	Device containing one metered dose of adrenaline (epinephrine) that is administered intramuscularly and can be done so by a non-clinical person.[4]
adverse events	An incident that results, or could have resulted, in harm to a patient or consumer. A near miss is a type of adverse event. [33]
allergy	Allergy occurs when a person's immune system reacts to substances in the environment that are harmless to most people. These substances are known as allergens and are found in dust mites, pets, pollen, insects, ticks, moulds, foods and some medicines.
anaphylaxis	Anaphylaxis is the most severe form of allergic reaction characterised by a sudden onset in which the clinical presentation is variable. Skin features are not always present.
angioedema	Angioedema is deeper swelling within the skin or mucous membranes and can be skin-coloured or red.
ASCIA	Australasian Society of Clinical Immunology and Allergy
assessment	A clinician's evaluation of a disease or condition, based on the patient's subjective report of the symptoms and course of the illness or condition and the clinician's objective findings. These findings include data obtained through laboratory tests, physical examination and medical history; and information reported by carers, family members and other members of the healthcare team. [33]
biphasic anaphylaxis	After complete recovery of anaphylaxis, a return of symptoms within 72 hours with no further exposure to the allergen. It is managed in the same way as anaphylaxis.
carer	A person who provides personal care, support and assistance to another individual who needs it because they have a disability, medical condition (including a terminal or chronic illness) or mental illness, or they are frail or aged. An individual is not a carer merely because they are a spouse, de facto partner, parent, child, other relative or guardian of an individual, or live with an individual who requires care. A person is not considered a carer if they are paid, a volunteer for an organisation, or caring as part of a training or education program. [38]

Term	Definition
clinical practice guidelines	Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. [39] Greenfield S, Steinberg E, editors. Washington, DC. Greenfield S, Steinberg E, editors. Washington, DC.
clinician	A trained health professional who provides direct clinical care to patients including registered and non-registered practitioners. Clinicians may provide care within a health service organisation as an employee, a contractor or a credentialed healthcare provider, or under other working arrangements. They include nurses, midwives, medical practitioners, allied health professionals, paramedics and other clinicians who provide health care, and students who provide health care under supervision.
consumer	A person who has used, or may potentially use, health services, or is a carer for a patient using health services. A healthcare consumer may also act as a consumer representative to provide a consumer perspective, contribute consumer experiences, advocate for the interests of current and potential health service users, and take part in decision-making processes. [40]
epinephrine	Epinephrine, also known as adrenaline, is a hormone and a medicine. The World Health Organization classifies epinephrine as an essential medicine for the treatment of anaphylaxis. See adrenaline.
healthcare record	Includes a record of the patient's medical history, treatment notes, observations, correspondence, investigations, test results, photographs, prescription records and medication charts for an episode of care. [33]
health service organisation	A separately constituted health service that is responsible for implementing clinical governance, administration and financial management of a service unit or service units providing health care at the direction of the governing body. A service unit involves a group of clinicians and others working in a systematic way to deliver health care to patients. It can be in any location or setting, including pharmacies, clinics, outpatient facilities, hospitals, patients' homes, community settings, practices and clinicians' rooms. [33]
hospital	A licensed facility providing healthcare services to patients for short periods of acute illness, injury or recovery. [34]
IM	Intramuscular; an injection deep into a large muscle to administer a medicine. Adrenaline is injected into the mid-anterolateral thigh muscle for anaphylaxis.
informed consent	A process of communication between a patient and clinician about options for treatment, care processes or potential outcomes. This communication results in the patient's authorisation or agreement to undergo a specific intervention or participate in planned care. The communication should ensure that the patient has an understanding of the care they will receive, all the available options and the expected outcomes, including success rates and side effects for each option. [41]

Term	Definition
IV	Intravenous; an injection or infusion into a vein.
mastocytosis	Mastocytosis is a condition caused by too many mast cells in the body. Mast cells are a kind of blood cell. They can build up under the skin and/or in the bones, intestines and other organs. This causes a range of symptoms, including itchy bumps on the skin, gastrointestinal issues such as diarrhoea, and bone pain.
medical practitioner	A medically qualified person whose primary role is the diagnosis and treatment of physical and mental illnesses, disorders and injuries. They include general practitioners, medical specialists, interns and residents.
medical record	See 'healthcare record'.
medicine	A chemical substance given with the intention of preventing, diagnosing, curing, controlling or alleviating disease, or otherwise improving the physical or mental wellbeing of people. These include prescription, non-prescription, investigational, clinical trial and complementary medicines, regardless of how they are administered. [42]
patient	A person who is receiving care in a health service organisation. [33]
point of care	The time and location of an interaction between a patient and a clinician for the purpose of delivering care. [33]
primary care	The first level of care or entry point to the health care system, such as general practice clinics, community health practice (for example, clinics, outreach or home visiting services), ambulance services, pharmacists, or services for specific populations (for example Aboriginal or refugee health services).
prn	"as needed". Medicines taken as needed are known as "**PRN**" medicines
procedure	The set of instructions to make policies and protocols operational, which are specific to an organisation. [33]
quality improvement	The combined efforts of the workforce and others – including consumers, patients and their families, researchers, planners, and educators – to make changes that will lead to better patient outcomes (health), better system performance (care) and better professional development. [43]
risk assessment	Assessment, analysis and management of risks. It involves recognising which events may lead to harm in the future, and minimising their likelihood and consequence. [44]
risk factor	A characteristic, condition or behaviour that increases the possibility of disease, injury or loss of wellbeing.
scope of practice	The extent of an individual clinician's approved clinical practice within a particular organisation, based on the clinician's skills, knowledge, performance and professional suitability, and the needs and service capability of the organisation. [45]

Term	Definition
shared decision making	A consultation process in which a clinician and a patient jointly participate in making a health decision, having discussed the options and their benefits and harms, and having considered the patient's values, preferences and circumstances. [46]
side effects	Unintended effects from a medicine, treatment or device.
urticaria	Urticaria is a pink or red itchy rash that may appear as blotches or raised red lumps (wheals). Hives is the common term for urticaria.
system	The resources, policies, processes and procedures that are organised, integrated, regulated and administered to accomplish a stated goal. A system: • Brings together risk management, governance, and operational processes and procedures, including education, training and orientation • Deploys an active implementation plan; feedback mechanisms include agreed protocols and guidelines, decision support tools and other resource materials • Uses several incentives and sanctions to influence behaviour and encourage compliance with policy, protocol, regulation and procedures. The workforce is both a resource in the system and involved in all elements of systems development, implementation, monitoring, improvement and evaluation. [33]

1

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Acknowledgements

Many individuals and organisations have freely given their time and expertise in the development of this document. In particular, the Commission wishes to thank the *Acute Anaphylaxis Clinical Care Standard* Topic Working Group, and other key experts who have given their time and advice. The involvement and willingness of all concerned to share their experience and expertise is greatly appreciated:

Topic Working Group

- A/Prof Andrew Wilson (Chair)
- Ms Sue Crocker
- Adj. A/Prof Alan Eade
- Dr Katie Frith
- Dr Alice Grey
- Dr Carolyn Hawkins
- Dr Preeti Joshi
- Dr Helen Kolawole
- Dr Peter Leman
- Dr Nhi Nguyen
- Maria Said
- Dr Joanne Simpson
- Dr Andrew Singer
- Ms Sandra Vale

A number of Commission staff were also involved in the writing and review of this publication, and the Commission wishes to acknowledge:

- Alice Bhasale
- Helen Dowling
- Suzanna Henderson
- Dr Robert Herkes
- Chris Leahy
- Carolyn Stewart
- Carmel Thorn
- Leslie Trainor
- A/Prof Amanda Walker

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

Level 5, 255 Elizabeth Street, Sydney NSW 2000
GPO Box 5480, Sydney NSW 2001

Phone: (02) 9126 3600
Fax: (02) 9126 3613

Email: mail@safetyandquality.gov.au
Website: www.safetyandquality.gov.au