

13 December 2020

Clinical Care Standards team
Australian Commission on Safety and Quality in Health Care
Email ccs@health.gov.au

To whom it may concern,

Re: ASCIA feedback on the draft Acute Anaphylaxis Clinical Care Standard

The Australasian Society of Clinical Immunology and Allergy (ASCIA) appreciates the opportunity to review the draft Acute Anaphylaxis Clinical Care Standard submitted for public consultation by the Australian Commission on Safety and Quality in Health Care (the Commission).

ASCIA commends this initiative, which will support a national approach to the treatment of anaphylaxis.

As the peak professional body of clinical immunology/allergy specialists in Australia and New Zealand, ASCIA has been working for the past 20 years to develop accessible, consistent and evidence-based resources for anaphylaxis management, for use throughout Australia and New Zealand.

We submit the following feedback on behalf of ASCIA (shown below in red font) on the draft Acute Anaphylaxis Clinical Care Standard.

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.

6. Does the quality statement adequately describe the quality of care that should be provided for the prompt recognition of anaphylaxis?

YES

How could the quality statement be improved?

NA

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.

7. Does the quality statement adequately describe the quality of care that should be provided to ensure the prompt administration of adrenaline as soon as anaphylaxis is recognised?

YES

How could the quality statement be improved?

- The statement regarding antihistamines and steroids should be strengthened. We suggest "Antihistamines and steroids do not treat or prevent anaphylaxis and have no role in first line treatment of anaphylaxis".
- Change wording from 'A patient with anaphylaxis...' to 'A patient having anaphylaxis...'
- There are differences if the patient is being treated in the community or is in a monitored situation in hospital where they may be given IV adrenaline, and this is unclear.
- We understand the strong emphasis on IM adrenaline but as this document covers in-patients and not just presentations to ED, IVI adrenaline is often the optimal route for intraoperative anaphylaxis. Therefore, ASCIA IV adrenaline protocols should be included if IM adrenaline is not effective.
- Regarding "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."

Feedback: This requires a lot of education involving medical and nursing staff. Would this be practically feasible in a busy hospital environment? If this is mandated, there will be a need to audit to see how much of this is done (similar to writing allergies in a drug chart).

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.

8. Does the quality statement adequately describe the correct positioning of people experiencing anaphylaxis?

YES

How could the quality statement be improved?

- Positioning of pregnant woman should be included (in the left lateral/recovery position) in the statement itself.

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.

9. Does the quality statement adequately describe a patient maintaining access and control of a personal adrenaline injector in a healthcare setting?

YES

How could the quality statement be improved?

- Adrenaline injectors should be stored safely but not in locked containers or cupboards.
- Remove Emerade as it is not currently available in Australia.

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 current Australasian Society of Clinical Immunology and Allergy (ASCIA) Acute Management of Anaphylaxis Guideline.

Observation timeframes are determined based on assessment and risk appraisal after initial treatment.

10. Does the quality statement adequately describe the quality of care that should be provided to ensure an appropriate observation time following anaphylaxis?

YES

How could the quality statement be improved?

- Definition of prolonged and relapsing anaphylaxis is required here, or in glossary.
- Greater emphasis is required to ensure information on patients at risk of anaphylaxis (both food and medication) is captured by **all** relevant patient information management systems used by hospitals. Louis Tait's death is one of the reasons we have this draft Acute Anaphylaxis Clinical Care Standard, and we are uncertain if this document would have prevented Louis being given the milk product whilst he was in hospital.
- There should be a standard waiting time for a referred patient (first anaphylaxis) to be seen by a clinical immunology/allergy specialist and appropriate indicators for local monitoring. Many of these patients are walking "time-bombs" as they may not know what triggered the 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.

11. Does the quality statement adequately describe the quality of care that should be provided for discharge management?

YES

How could the quality statement be improved?

- Discharge management could be more specific by separating out the various triggers and how they are to be investigated. For example, all drug related anaphylaxis patients to be referred to a specialist centre experienced in drug allergy testing for further investigation and correct labelling of the patient's problem.
- Details of the allergic reaction should be documented in My Health Record, and if the allergen is known it should be listed in local medical records (e.g. emr) and this should flag allergens with other non-clinical areas such as food preparation/kitchen for inpatients.
- The **ASCIA Action Plan for Anaphylaxis** is the nationally standardised action plan for anaphylaxis (used throughout Australia and New Zealand since 2003) and therefore should be stipulated. Health professionals (including EDs) should not develop their own action plans as this will create inconsistency and confusion.
- Regarding "if the statement 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."

Feedback: This may be time consuming for the clinician to call the pharmacy – hence it does not sound feasible. Suggest a possible rewording "If a prescription is given to the patient, advise the patient to check their preferred pharmacy or the closest pharmacy to ensure there is an adrenaline injector in stock".

For consumers:

12. Are there aspects of care related to anaphylaxis that are not covered by this clinical care standard that should be included?

YES

Please describe here

- For people who have anaphylaxis and have already been admitted to hospital, it is important their allergy is documented in local electronic records and steps are taken to ensure the risk of another allergic reaction is reduced, both while in hospital and on discharge.
- Health professionals should refer patients to the national support organisation for patients, consumers and carers, Allergy & Anaphylaxis Australia (A&AA), to improve management before they are seen by a clinical immunology/allergy specialist.

For clinicians and health service organisations:

13. The quality statements target areas of care that could benefit from quality improvement. Are there additional aspects of care that should be included in the quality statements?

YES

Please describe and provide evidence to support your response

- The patient's allergic reaction should be documented in local health electronic records as well as on My Health Record to ensure all healthcare providers are informed of the allergy and reaction.

Resources

14. Is the fact sheet for consumers useful?

YES

How could the fact sheet be improved?

- Information for patients, consumers and carers available in different languages would be useful.

15. Is the Anaphylaxis discharge checklist and discussion guide useful?

YES

How could the discharge checklist be improved?

- Is the care plan that is created on discharge in addition to the discharge summary, or part of it? Discharge summaries are frequently completed only after a patient is discharged, so a patient wouldn't necessarily be provided with a copy. It may be useful to have this as a separate document and a standardised template would be useful.
 - The following statement should be included "Adrenaline injectors can be purchased at full price (no PBS rebate) from most pharmacies if you have not been given a prescription".
 - EpiPen® should have a capital E and capital P and the registered symbol
 - Neither Symjepi nor Anapen adrenaline injectors are currently available in Australia, but it is possible that Anapen may be available by the time this work is completed.
 - Suggested wording change to this statement - Signs and symptoms of anaphylaxis may be different each time, so it is important that you can recognise anaphylaxis. Your ASCIA Action Plan for Anaphylaxis lists all of the possible signs and symptoms, and how to give the adrenaline injector device, so it is important to keep it with your device.
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- It could be useful to inform consumers know that adrenaline injector training devices are available from Allergy & Anaphylaxis Australia.

Indicators for local monitoring

16. Would you like to provide comments about the indicators?

YES

Indicator for 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.

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.

17. Do you agree that the indicator captures information that can be used locally to improve clinical care and support local clinical quality improvement activities?

STRONGLY AGREE

If you disagree, please briefly explain why, and suggest how the indicator can be improved?

In **table 1** we suggest:

- adding allergen immunotherapy and vaccines to the list of less common causes of anaphylaxis.
- removing 'other milks' as it is unnecessary as a less common trigger (other foods are already listed and this should encompass 'other milks'.

In **table 2**:

- Circulation – increased pulse rate (tachycardia) is not in the ASCIA definition of anaphylaxis. Tachycardia alone could not be considered to be diagnostic of anaphylaxis. There are other reasons for tachycardia including anxiety, crying or agitation. If IM adrenaline has already been given, this can also cause tachycardia and may be mistaken for recurrence of anaphylaxis. Therefore we suggest that the committee reviews this to make it clearer and add '*persistently* increased pulse rate'.
- Gastrointestinal- severe nausea and severe diarrhoea are not in the ASCIA anaphylaxis guidelines. Severe nausea and severe diarrhoea alone are insufficient signs anaphylaxis. Therefore we suggest severe, persistent abdominal pain, vomiting or diarrhoea are signs of anaphylaxis (any cause) and retain 'abdominal pain or vomiting (insect stings and injected medicines).

Indicator for 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.

Indicator 2a

Proportion of patients with anaphylaxis treated with intramuscular adrenaline.

18. Do you agree that the indicator captures information that can be used locally to improve clinical care and support local clinical quality improvement activities?

STRONGLY AGREE

If you disagree, please briefly explain why, and suggest how the indicator can be improved?

Indicator for 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.

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.

19. Do you agree that the indicator captures information that can be used locally to improve clinical care and support local clinical quality improvement activities?

SOMEWHAT AGREE

If you disagree, please briefly explain why, and suggest how the indicator can be improved?

- The organisation's protocol to identify patients admitted to hospital that carry an adrenaline injector.
- The organisation's protocol for a patient to maintain access to their adrenaline injector(s) for self administration throughout their hospital stay.
- The patient's AI is stored safely but is not locked in a drawer/cupboard at their bedside during a hospital admission.

Indicators for 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.

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

20. Do you agree that the indicator captures information that can be used locally to improve clinical care and support local clinical quality improvement activities?

SOMEWHAT AGREE

If you disagree, please briefly explain why, and suggest how the indicator can be improved?

- Regarding the statement: If you have not seen an allergy specialist before, you will be given a referral or an appointment.

Feedback: Not all hospitals have an Allergy/Immunology Department. It might be more feasible to re-word this to "If you have not seen a clinical immunology/allergy specialist before, you will be given a referral to arrange for an appointment".

- We recommend that details of the allergic reaction should be documented in My Health Record, and the allergen if known should be listed in local medical records (e.g. emr), as this should flag allergens with other non-clinical areas such as food preparation/kitchen for inpatients.
- We recommend changing the statement "They receive an anaphylaxis action plan...." to "They receive an ASCIA Action Plan for Anaphylaxis...."

Indicator 6b

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

21. Do you agree that the indicator captures information that can be used locally to improve clinical care and support local clinical quality improvement activities?

SOMEWHAT AGREE

If you disagree, please briefly explain why, and suggest how the indicator can be improved?

- It is important to include this indicator, as a completed ASCIA Action Plan for Anaphylaxis is an important clinical tool.
- Regarding the statement "Complete an ASCIA Action Plan for Anaphylaxis on discharge when an environmental allergen is identified or suspected."

Feedback: Suggest remove environmental and just state "Complete an ASCIA Action Plan for Anaphylaxis on discharge."

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.

22. Do you agree that the indicator captures information that can be used locally to improve clinical care and support local clinical quality improvement activities?

SOMEWHAT AGREE

If you disagree, please briefly explain why, and suggest how the indicator can be improved?

23. Do you know of any current or planned initiatives that could support the implementation of this clinical care standard?

YES

Please provide further comments here.

- ASCIA regularly reviews and updates ASCIA anaphylaxis e-training courses, so if this occurs at the same time or after the Acute Anaphylaxis Clinical Care Standard (CCS) is released, reference can be made to the document in the ASCIA e-training courses.
- The Acute Anaphylaxis Clinical Care Standard could be included in paramedic guidelines and accreditation processes. .

24. Do you have any other comments that you would like to make about this clinical care standard?

YES

Please provide further comments here

- There is some inconsistency regarding the mixing of singular and plural (e.g. 'A patient should see their doctor'...) that could be improved.
- Regarding biphasic anaphylaxis in glossary which says return of symptoms within 72 hours.
Feedback: Suggest inserting the average timeframe like "the majority will occur within 4-24 hours, but up to 72 hours in rare cases". This would make it in line with the recommendation for overnight admission, otherwise 72 hours may suggest a three day hospital admission.
- ASCIA appreciates the efforts made to create this important Acute Anaphylaxis Clinical Care Standard.

ASCIA thanks the Australian Commission on Safety and Quality in Health Care for this opportunity to review the draft Acute Anaphylaxis Clinical Care Standard submitted for public consultation.

Please let us know if you have any questions regarding this feedback.

Yours sincerely,



Dr Katie Frith
Chair, ASCIA Anaphylaxis committee



Jill Smith
ASCIA CEO
