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FPM

December 17, 2020

Adjunct Prof. D Picone AO
Chief Executive Officer
Australian Commission on
Safety and Quality in Health Care
GPO Box 5480
Sydney NSW 2001

By email: CCS@health.gov.au

Dear Professor Picone,

Acute Anaphylaxis Clinical Care Standard – Feedback on draft

Thank you for inviting the Australian and New Zealand College of Anaesthetists (ANZCA) to provide feedback on the Australian Commission on Safety and Quality in Health Care (the Commission) draft Acute Anaphylaxis Clinical Care Standard (the standard).

ANZCA, including the Faculty of Pain Medicine, is committed to setting the highest standards of clinical practice in the fields of anaesthesia, perioperative medicine and pain medicine. As one of the largest medical colleges in Australia, ANZCA is responsible for the postgraduate training programs of anaesthetists and specialist pain medicine physicians, in addition to promoting best practice and ongoing continuous improvement that contributes to a high quality health system.

The draft standard was circulated to a number of college committees for feedback, including the safety and quality committee and anaesthetic allergy subcommittee. These committees have identified major concerns with the document; in particular with the wording of Quality Statements 2 and 6.

Quality Statement 2 recommends intramuscular adrenaline stating “intravenous adrenaline is less safe”, without qualification. ANZCA’s position is that clinicians with appropriate training in using intravenous adrenaline, including the three critical care specialities of anaesthesia, emergency medicine, and intensive care medicine, should be permitted to use this route if the patient has appropriate haemodynamic monitoring.

Quality Statement 6 on discharge management focuses on the steps for patients with environmental allergens (e.g. exposure to a food or insect). For patients who have had anaphylaxis to a known or unknown drug (e.g. perioperative anaphylaxis), some steps are redundant, confusing and in some situations likely to cause harm. The statement should clearly separate recommendations for those experiencing anaphylaxis to environment allergens from those who have anaphylaxis to drugs, to address the different needs, management and follow-up of these two different groups.

ANZCA House
630 St Kilda Road
Melbourne VIC 3004

+61 3 9510 6299
anzca.edu.au

Australian and New Zealand
College of Anaesthetists
ABN 82 055 042 852

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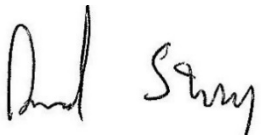
The **attached** feedback outlines a substantial number of proposed changes to the standard to address the above concerns. In order for ANZCA to endorse this standard, these concerns will need to be adequately addressed in the final version. ANZCA will require at least 4 weeks for the final standard to be reviewed by the relevant committees.

Thank you again for the opportunity to comment on the draft standard. Should you require any further information, please do not hesitate to contact the ANZCA safety and quality policy staff in the first instance at sq@anzca.edu.au

Yours sincerely



Dr Vanessa Beavis
President

Professor David Story
Chair, Safety and Quality Committee

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.

Amend to *"Anaphylaxis is considered in any patient demonstrating signs or symptoms of a severe allergic reaction and/or rapid clinical deterioration."* The presence of a trigger or history may not be obvious.

The following changes are recommended to Table 1: "Triggers" on p12:

- Remove: "Anaesthetics" and replace with "Neuromuscular blocking drugs".
- Add: "Chlorhexidine" and "Contrast media" to "Common triggers", "Medicines".

The different presentation of anaphylaxis in anaesthetised/sedated patients should be included on p11 and in the table on p13: The anaesthesia/sedation will likely preclude the reporting of any symptomatology from the patient. Drapes may make the identification of skin manifestations difficult. Haemodynamic changes may only be recorded once the Non-Invasive Blood Pressure (NIBP) monitor next cycles, but monitors reliant on a cardiac output (ETCO2 and SpO2) may alarm earlier. Other monitors may be helpful e.g. Ventricular tachycardia (Vt) and Peak Airway Pressure (PAP) alarms for those under anaesthesia.

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.

Clinicians with appropriate training in using intravenous adrenaline, including the three critical care specialities of anaesthesia, emergency medicine and intensive care medicine, should be supported in their use of intravenous adrenaline if the patient has appropriate haemodynamic monitoring. The suggested wording is:

> *A patient with anaphylaxis, or suspected anaphylaxis is administered adrenaline without delay, before any other treatment including asthma medicines. In most cases the intramuscular route is preferred. Intravenous adrenaline is only used by clinicians with appropriate training and with haemodynamic monitoring in use. Corticosteroids and antihistamines are not first line treatment for anaphylaxis.*

The following changes to p14 are also suggested:

> ***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.*
>
> ***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 or into your vein.*

For clinicians

Administer adrenaline intramuscularly, or intravenously if appropriate haemodynamic monitoring is in use in a critical care setting, 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 or intravenously if appropriate haemodynamic monitoring is in use in a critical care setting. Subcutaneous or inhaled routes for adrenaline are not recommended as they are less effective.

Delayed administration of adrenaline is a risk factor for fatal anaphylaxis.

*Intramuscular (IM) injection of adrenaline is safer than an intravenous (IV) bolus injection if appropriate haemodynamic monitoring **is not** in use or the clinician **is not** trained in the use of intravenous adrenaline. Adverse events have been reported in adult patients who received overdoses of IV adrenaline, but these are rare with IM adrenaline. There are no absolute contraindications to adrenaline administration in anaphylaxis.*

…

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.
…

Further suggestions:

- "Phenergan" refers to a brand and should be replaced with "promethazine" the generic name. (p15, line 15)
- Add the need to "call for help"/escalate care, and request assistance with management.

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.

With intravascular fluid exiting the circulation during anaphylactic reactions the resulting hypovolaemia requires optimisation of circulation and ventilation. This is best achieved by lying patients with legs elevated as well as upper body (jack-knife position).

The statement should be revised to: *"Patients are positioned to optimise cardiorespiratory function*."

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.

Amend to: *"Patients in possession of their prescribed adrenaline autoinjector have access to this at all times."*

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.

Amend to: *"Patients treated for anaphylaxis are observed in accordance with ASCIA guidelines.*"

A holistic view of the patient and their comorbidity should be considered in both assessment and discharge planning for an episode 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.

Amend to: *"Patients are provided with the necessary information and documentation for their continued care including further investigation and management as appropriate for them, following discharge."*

This standard focuses on the steps for patients with known or unknown environmental allergens. For patients who have had anaphylaxis to a known or unknown drug (e.g. perioperative anaphylaxis), some steps are redundant, confusing and in some situations likely to cause harm.

The document should distinguish between cases where there is a risk of re-exposure in the community and where the risk of re-exposure is low, such as for agents available on prescription only (e.g. antibiotics) or administered by medical practitioners only (e.g. neuromuscular blocking agent). It would not be appropriate to give an EpiPen or an ASCIA Action Plan to someone with a neuromuscular blocking agent allergy. This difference has been suggested in line 31: "*If you are at risk of future exposure to your trigger, you will be given or prescribed an adrenaline injector*", but line 25 already says you should have one.

The following amendments should also be made to reflect this:

…

For patients

Delete lines 25-30 and replace with the following:

Following an anaphylaxis event where there is a risk of re-exposure to the trigger in the community you should have:

- *An adrenaline autoinjector or a prescription for one*

- *Information about anaphylaxis*
- *An ASCIA Action Plan for Anaphylaxis (for anaphylaxis with a known allergen)*
- *A referral or appointment to see to a clinical immunology/allergy specialist*
- *A care plan that describes the ongoing care required for your allergy*
- *Received advice about the need for medical identification jewellery*

Following an anaphylaxis event where the risk of re-exposure to the trigger in the community is low you should have:

- *Information about 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*
- *Received advice about the need for medical identification jewellery*

For clinicians

Amend lines 12-18 as follows:

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

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

…

Amend lines 21-23 as follows:

If the patient is at high risk of anaphylaxis, advise them to obtain medical identification jewellery that provides information about their allergy once the trigger has been identified.

Amend lines 24-38 as follows:

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. 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.

~~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. 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). Ensure there is documentation on the patient's records of the suspect drug/drugs allergy. The patient requires clear written information with the name of the drug or possible drugs so these can be avoided until testing has occurred. This is particularly

important in perioperative anaphylaxis where multiple drugs as well as skin preparations might have been used.

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. Upload an entry in the patients My Health Record for the anaphylaxis event.

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 when an environmental allergen is identified or suspected.

Refer the patient to a clinical immunology/allergy specialist/anaesthesia (perioperative) allergy clinic 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.

The statement should also include a reminder to check the expiry of adrenaline autoinjector and replace as needed.

Fact sheet for consumers

This resource is unnecessarily wordy and difficult to understand.

The fact sheet should provide clarity around the different types of allergy (outpatient environmental vs inpatient drug/other substance), for example, the comment about adrenalin autoinjectors (which may not be needed after anaphylaxis to a drug). This wording may cause anxiety for patients who have an anaphylactic reaction during surgery, but are not given an autoinjector.

Anaphylaxis discharge checklist and discussion guide

The comments on the consumer fact sheet (above) equally apply to the checklist/discussion guide. In addition, this resource should include a reminder to consumers regarding expiration dates and replacement of autoinjectors.

INDICATORS FOR LOCAL MONITORING

Indicator for Quality Statement 2 - Immediate injection of intramuscular adrenaline

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

As outlined in the feedback on Quality Standard 2, intravenous is the preferred route for critical care areas. Therefore, the following changes should be made:

P5, line 11 and p15, line 43: *Indicator 2a. Proportion of patients with anaphylaxis treated with ~~intramuscular~~ adrenaline.*

Indicators for Quality Statement 6 - Discharge management

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.

- Point 3 should include education on how to use an adrenaline autoinjector and to replace the autoinjector every year or two years.
- Points 1-3 are not indicated for drug allergy, therefore add *"where indicated"* to each.
- Under point 4 add "anaesthesia (perioperative) allergy clinic" to the list of referrals.
- Add an additional point (6): "*Allergy documentation is included in patient record including likely or potential drugs."*
- Add an additional point (7): "*Documentation of drugs to avoid until completion of assessment.*"

Indicator 6b

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

Proportion of patients with anaphylaxis, where there is a risk of re-exposure to the allergen in the community, 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.

Change to:

As discussed, clarity is required about which patients require an adrenaline autoinjector.

General feedback

- The documents should use clear, concise language and bullet points.
- The term "Acute Anaphylaxis" suggests there is a "chronic/alternative anaphylaxis" which would involve alternative care to this standard. Anaphylaxis is only an acute event. The response is most certainly more importantly recognised as acute. As such, the phrase "acute anaphylaxis" should be replaced with "anaphylaxis" in the title and the document.
- A quality statement should be added: Escalate care promptly where appropriate, including transfer to acute care services. I.e. if in a GP/outpatients clinic, the patient needs to go to an Emergency Department.

<End of feedback>