Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis

Incorporating

Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection 1:1,000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis

<table>
<thead>
<tr>
<th>Document reference number:</th>
<th>ONMSD 2016-004</th>
<th>Document prepared by:</th>
<th>Office of the Nursing and Midwifery Services Director, Health Service Executive, in collaboration with the National Immunisation Office at the request of the Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation</th>
</tr>
</thead>
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<tr>
<th>Document approved by:</th>
<th>Name: Dr. Kevin Kelleher, Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation, HSE</th>
</tr>
</thead>
<tbody>
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<td>Signature: [Signature]</td>
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</tbody>
</table>

| Approval date:             | 9th April 2019 | Responsibility for implementation | Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation, |

| Revision date:             | This is a controlled document and may be subject to change at any time. | |
| Provisional date:          | March 2021 | |

Categories of health professionals that may administer in accordance with these Directions and Medicine Protocol:
Registered Nurses and Midwives in the voluntary and statutory services of the Health Service Executive who are expected to deal with an anaphylaxis
<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>Purpose</td>
<td>3</td>
</tr>
<tr>
<td>2.0</td>
<td>Scope</td>
<td>3</td>
</tr>
<tr>
<td>3.0</td>
<td>Definition of Anaphylaxis</td>
<td>3</td>
</tr>
<tr>
<td>4.0</td>
<td>Recognition of Anaphylaxis: General Principles</td>
<td>3</td>
</tr>
<tr>
<td>5.0</td>
<td>Recognition of Anaphylaxis</td>
<td>5</td>
</tr>
<tr>
<td>6.0</td>
<td>Treatment of Anaphylaxis</td>
<td>6</td>
</tr>
<tr>
<td>7.0</td>
<td>Follow up</td>
<td>9</td>
</tr>
<tr>
<td>8.0</td>
<td>Storage of Epinephrine (Adrenaline)</td>
<td>9</td>
</tr>
<tr>
<td>9.0</td>
<td>Caution</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection 1:1,000 by IM injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>References</td>
<td>17</td>
</tr>
</tbody>
</table>
Directions for nurses and midwives for the management of a patient who develops Anaphylaxis or suspected anaphylaxis

1.0 Purpose
The purpose of this direction is to provide information on the safe and effective management of anaphylaxis to ensure patients are promptly diagnosed, treated and managed after onset of symptoms of anaphylaxis.

2.0 Scope
This direction applies to registered nurses and registered midwives in the voluntary and statutory services of the HSE who are expected to deal with anaphylaxis.

3.0 Definition of Anaphylaxis
Anaphylaxis is a potentially life threatening allergic reaction to foreign protein antigens such as food and bee stings. It is a very rare complication of immunisation (0.4-2 per million doses) (Immunisation Guidelines for Ireland, National Immunisation Advisory Committee, available at http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/)

4.0 Recognition of anaphylaxis- General Principles
Anaphylaxis must be distinguished from fainting (vasovagal episode), anxiety and breath-holding episodes, which are significantly more common. See Table 1 below.

**Table 1 Differentiating Vasovagal episode and Anaphylaxis**

<table>
<thead>
<tr>
<th>Onset</th>
<th>Vasovagal episode</th>
<th>Anaphylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin</td>
<td>Generalised pallor; cold, clammy skin</td>
<td>Itch, generalised erythema, urticaria or angio-oedema (localised swelling of face, mouth, etc.)</td>
</tr>
<tr>
<td>Respiratory</td>
<td>Normal or shallow, not laboured</td>
<td>Cough, wheeze, stridor, tachypnoea, recession, cyanosis</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Bradycardia but strong carotid pulse. Hypotension corrected when lying down</td>
<td>Tachycardia, weak/absent pulse. Sustained hypotension unless specific treatment</td>
</tr>
<tr>
<td>Neurological</td>
<td>Light-headed. Possible loss of consciousness, improves on lying down</td>
<td>Severe anxiety and distress, loss of consciousness</td>
</tr>
</tbody>
</table>

Source: http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/

Those experiencing an anxiety spell may appear fearful, pale and sweaty, and complain of light-headedness, dizziness and numbness or tingling of their hands or feet. Hyperventilation is usually present.

During a breath-holding episode an infant or child is suddenly silent but obviously agitated. Facial flushing or pallor can occur as breath-holding continues. Some episodes end with a resumption of crying, but others can be followed by a brief period of unconsciousness during which breathing resumes.
Swelling and an urticaria rash may appear at the injection site but are not always caused by an allergic reaction and may disappear without additional treatment. However, if any other symptoms occur, even if considered mild (sneezing, nasal congestion, coughing, etc.), Epinephrine (Adrenaline) should be given. There is little risk with the unnecessary use of Epinephrine (Adrenaline), whereas delay in its administration in anaphylaxis may result in severe anaphylaxis and death. The features of severe disease include obstructive swelling of the upper airway, marked bronchospasm and hypotension.
5.0 Recognition of anaphylaxis

5.1 Anaphylaxis is likely when all of the following 3 criteria are met:

5.1.1 a. Sudden onset

b. Rapid progression of symptoms

c. Involving two or more organ systems.

- The patient will feel and look unwell
- Most reactions occur within several minutes. Rarely, reactions may be delayed in onset
- The time of onset of anaphylaxis depends on the type of trigger
- The patient is usually anxious and can experience a "sense of impending doom"

5.1.2 Life-threatening Airway and/or Breathing and/or Circulation problems (Resuscitation Council (UK) 2008)

- Patients can have some or all of the following; (use the ABCDE approach to recognise these)

Airway problems:

- Airway swelling e.g. mouth, tongue and throat swelling (pharyngeal/laryngeal oedema). The patient has difficulty in breathing and swallowing and feels that the throat is closing up
- Shortness of breath – Hoarse voice
- Stridor (a high-pitched inspiratory noise caused by upper airway obstruction)

Breathing problems:

- Increased respiratory rate
- Wheeze
- Confusion caused by hypoxia
- Cyanosis (appears blue). This is usually a late sign.
- Respiratory arrest

Circulation problems:

- Signs of shock – pale, clammy
- Increased pulse rate (tachycardia)
- Low blood pressure (hypotension)
- Decreased conscious level or loss of consciousness
- Anaphylaxis can cause myocardial ischaemia and electrocardiograph changes even in patients with normal coronary arteries
- Cardiac arrest

The circulatory effects do not respond, or only respond transiently, to simple measures such as lying the patient down and raising the legs. Patients with anaphylaxis can deteriorate if made to sit or stand up.

Disability Problems
The above Airway, Breathing and Circulation problems can all alter the patient’s neurological status causing Disability problems because of decreased brain perfusion. There may be confusion, agitation and loss of consciousness.

Patients can also have gastro-intestinal symptoms (abdominal pain, incontinence, vomiting).

5.1.3 Skin and/or mucosal changes (flushing, urticaria, angioedema)

**Exposure**

- Skin and mucosal changes should be looked for
- They are often the first feature and are present in over 80% of patients with anaphylaxis
- They can be subtle or dramatic
- There may be just skin, just mucosal or both skin and mucosal changes
- There may be erythema (a patchy or generalised red rash)
- There may be urticaria, which may appear anywhere on the body
- Angioedema is similar to urticaria but involves swelling of deeper tissues, commonly in the eyelids and lips, and sometimes in the mouth and throat

Skin changes alone, without airway, breathing or circulation problems, do not signify anaphylaxis. Most patients who have skin changes caused by allergy do not go on to develop anaphylaxis.

5.2 The following supports the diagnosis:

5.2.1 Recent exposure to a known allergen for the patient. The patient should be observed for immediate adverse reactions.

5.2.2 Following administration of any vaccine the patient should be observed for 15 minutes to allow monitoring for any immediate reaction including possible anaphylaxis, as typically the onset of anaphylaxis occurs within minutes.

6.0 Treatment of Anaphylaxis

6.1 As soon as anaphylaxis is suspected, **call for help**. Get a member of the team to dial 999 or 112 and state that there is a suspected case of anaphylaxis.

6.2 **Treating a patient with anaphylaxis in the community will not be the same as in an acute hospital. Out of hospital, an ambulance must be called immediately and the patient transported to an emergency department.**

6.3 **Patient positioning:** The patient should be placed in a comfortable position. The following factors should be considered:

- The patient with Airway and Breathing problems may prefer to sit up as this may make breathing easier.
- Lying flat with or without leg elevation is helpful for the patient with low blood
pressure (Circulation problem). If a patient feels faint, do not sit or stand them up –
this can cause cardiac arrest.

- The patient who is breathing and unconscious should be placed on their side
  (recovery position).

6.4 **Breathing:** If the patient stops breathing, mouth to mouth or preferably bag valve mask
ventilation should be performed.

6.5 **Epinephrine (Adrenaline):** If the patient has clinical signs of shock, airway swelling or
breathing difficulties, they should be given Epinephrine (Adrenaline) 1:1,000 administered
by intramuscular injection. See National Immunisation Advisory Committee *Anaphylaxis:*
*Treatment in the Community* (available at

6.6 **Cardiac Arrest:** If the patient has a cardiac arrest discontinue administration of IM
Epinephrine (Adrenaline), initiate CPR and continue it until medical assistance arrives.
Algorithm for Emergency Management of Anaphylaxis - National Immunisation Advisory Committee – Immunisation Guidelines for Ireland

Anaphylaxis: Treatment in the Community

Anaphylaxis is likely if a patient who, within minutes of exposure to a trigger (allergen), develops a sudden illness with rapidly progressing skin changes and life-threatening airway and/or breathing and/or circulation problems.

1. Get help
2. Call ambulance
3. Assess airway, breathing, and circulation
4. Send, wheeze, respiratory distress or clinical signs of shock
5. Lie patient flat with legs raised (unless vomiting or respiratory distress increases)

EpiPen

- 0.5 - 0.75 mg (500 micrograms)
- 0.5 - 0.75 mg (600 micrograms)

Use 27-30 gauge needle for those ≤ 100 kg

Repeat every 5-10 mins, up to 3 doses
Remember urgency of hospital transfer

1. Ambulance will be equipped with oxygen, Salbutamol and fluids.
2. If profound shock judged immediately life threatening, give CPR/BLS if necessary.
3. If respiratory distress present, elevate head.
4. IM into middle third of anterolateral thigh; maximum effect 10 minutes after IM injection.

NOTE: Immediate administration of adequate doses of epinephrine will decrease patient mortality and morbidity. All patients with signs of an anaphylactic reaction, especially hypotension, airway swelling, or difficulty breathing, should receive immediate intramuscular (IM) epinephrine in the anterolateral thigh.

The anterolateral thigh is superior to IM administration in the deltoid or subcutaneous injection.

Suggested Anaphylaxis Kit

- Copy of "Anaphylaxis: Treatment in the Community" from Immunisations Guidelines for Ireland
- 3 x 1ml ampoules of Epinephrine (1:1,000, 1mg/ml) or
- 6 x Epinephrine auto-injectors, 150 mcg, 300 mcg and/or 3 x 500 mcg* (depending on age of vaccinees)
- 3 x 1 ml syringes
- Needles 3 x 16mm, 3 x 25mm, 3 x 37 – 40mm
- 1 pocket mask
- Sphygmomanometer (optional)
- Stethoscope (optional)
- Pen and paper to record time of administration of Epinephrine

The kits should be kept closed to ensure the drugs are not exposed to light and stored at room temperature. The kits require regular checking to replace drugs before their expiry date.

*Ensure that 500mcg auto-injectors have 25mm needles
7.0 Follow up

7.1 Following immediate management, all patients must be referred to hospital for observation, even if it appears that they have made a good recovery. Biphasic or late phase reactions occur in up to 20% of cases. They can be more difficult to treat than the initial episode. Patients should therefore be observed in hospital for at least 12 hours after severe anaphylaxis.

7.2 Record all actions taken including drug, dose, route, time and site of administration in patient notes.

7.3 In Ireland the Health Product Regulatory Authority (HPRA) is responsible for monitoring adverse reactions to medicines and vaccines. Of particular importance are all suspected reactions to newly authorised products, serious reactions to established products and all suspected reactions to vaccines.

7.4 The incident and all actions taken must be promptly recorded and the relevant National Incident Management Report Form completed (National Incident Report Form (HC NIRF 01 – VO2)) (April 2017) (available at https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v10-person.pdf)

7.5 The HPRA must be informed using the Adverse Reaction Report (Yellow) Card System available at www.hpra.ie.

8.0 Storage of Epinephrine (Adrenaline)

8.1 Epinephrine (Adrenaline) is light sensitive and so should always be stored in its box until required. The carriage of loose ampoules of Epinephrine (Adrenaline) is not recommended. It should be protected from heat, but does not require storage in a fridge. Check expiry date.

9.0 Caution

9.1 Do not administer Epinephrine (Adrenaline) intravenously. The IV route should be reserved for specialist use in hospital.

9.2 Epinephrine (Adrenaline) is available in different strengths and preparations. Each ml of solution for IM injection contains 1 mg of Epinephrine (Adrenaline).
Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection 1:1000 concentrate by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis.

This medicine protocol is a specific written instruction for the administration of Epinephrine (Adrenaline) by intramuscular injection to groups of patients who may not be individually identified before presentation for treatment.

This medicine protocol enables registered nurses and midwives in the voluntary and statutory services of the HSE who have undertaken the relevant education programmes to administer Epinephrine (Adrenaline) 1:1000 with reference to the Nursing and Midwifery Board of Ireland professional guidance, National Immunisation Advisory Committee and National Immunisation Office, HSE and in accordance with Summary of Product Characteristics for Epinephrine (Adrenaline) 1:1,000 as detailed by the Health Product Regulatory Authority (HPRA) at [www.hpra.ie](http://www.hpra.ie).

- Health Services Executive (2018) *Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis incorporating Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection BP 1:1,000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis.* Dublin: Health Service Executive
- Nursing and Midwifery Board of Ireland (2015) *Practice Standards for Midwives* Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2015) *Recording Clinical Practice. Professional Guidance* Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2015) *Scope of Nursing and Midwifery Practice Framework* Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2014) *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives.* Dublin: Nursing and Midwifery Board of Ireland

The Nursing and Midwifery Board of Ireland defines medicine protocols as "written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medicine when a medicine protocol is in effect" (An Bord Altranais, 2007, p35).
Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection 1:1,000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis

1.0 Critical Elements

<table>
<thead>
<tr>
<th>Name of Organisation where medicine protocol applies</th>
<th>Health Service Providers across the voluntary and statutory services of the Health Service Executive (HSE).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date the medicine protocol comes into effect</td>
<td>March 2019</td>
</tr>
<tr>
<td>Date for review of medicine protocol</td>
<td>March 2021</td>
</tr>
<tr>
<td>This is a controlled document and may be subject to change at any time.</td>
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</tr>
<tr>
<td>Names and Signatures of the employing authority who is authorising the implementation of the medicine protocol</td>
<td>Name: <strong>Dr. Kevin Kelleher</strong>, Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation, HSE</td>
</tr>
<tr>
<td>“On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation”</td>
<td>Signature: [Signature]</td>
</tr>
<tr>
<td>Name: <strong>Dr Colm Henry</strong>, Chief Clinical Officer, HSE</td>
<td></td>
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Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis and Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection 1:1,000 by IM Injection by registered nurses and registered midwives. Version 3. 2019
### 2.0 Clinical Criteria

| Clinical Condition for use of the medicine protocol (World Health Organisation 2009): | Epinephrine (Adrenaline) Injection is used to provide rapid relief of hypersensitivity reactions to drugs and other allergens, and in the emergency treatment of anaphylaxis. Anaphylaxis can be described as a severe, systemic (whole body) allergic reaction. Signs and Symptoms of anaphylaxis: Possible early warning signs:  
- Itching of skin, rash and swelling around the injection site  
- Dizziness and general feeling of warmth  
- Painless swelling in parts of the body e.g. face or mouth  
- Flushed, itchy skin, nasal congestion, sneezing, tears  
- Hoarseness,  
- Swelling of the face, difficulty breathing  
- Nausea, vomiting, abdominal pain  
Life threatening symptoms:  
- Wheezy, difficulty breathing, collapse, low blood pressure, weak pulse  

*It is important that anaphylaxis is differentiated from other more common and less serious reactions to vaccination, e.g. simple faints (Vasovagal episode), anxiety attacks and breath holding episodes.* |

| Circumstances in which the medicine protocol applies | This medicine protocol applies in the management of a patient with anaphylaxis or suspected anaphylaxis. |
| Inclusion criteria for patient/service user treatment using the medicine protocol | This medicine protocol applies to treatment of:  
- Adults  
- Children |
| Exclusion criteria for patient/client treatment using the medicine protocol | None |
| Actions to be taken for those who are excluded from the medicine protocol | Not applicable |
| Referral arrangements if further advice or consultation is required | As soon as anaphylaxis is suspected, **call for help.** Get a member of the team to dial 999 or 112 and state that there is a case of anaphylaxis. |
| Documentation required to support implementation of the medicine protocol | - HPRA Adverse Reaction Report Form (available at [www.hpra.ie](http://www.hpra.ie))  
|---|---|
| 3.0 Details of Medicine to be supplied | - Epinephrine (Adrenaline) Injection 3P 1:1,000, 1ml ampoule (1mg)  

**Route/Method of Administration:** Intramuscular injection. The anterolateral thigh is superior to IM administration in the deltoid or subcutaneous injection.  

**Dose and Frequency of Administration**  

**Dose by age:**  
- 0 – 5 years: 0.15ml (150micrograms)  
- 6 – 12 years: 0.3ml (300micrograms)  
- > 12 years: 0.5ml (500 micrograms)  
- Adult: 0.5 – 0.6ml (500 – 600micrograms)  
- Use 21G 37-40mm needle for those ≥ 100Kgs  

See Algorithm for Emergency Management of Anaphylaxis NIAC Guidelines |
| Name of Medicine | - Tachycardia  
- Palpitations  
- Dyspnoea  
- Tremor  
- Headache  
- Dizziness  
- Cold extremities |
| Potential adverse reactions. |
The RNP registered nurse or midwife should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out online at [http://www.hpra.ie](http://www.hpra.ie) (“Report an Issue” tab) or through use of the downloadable or post-paid yellow card options. Downloadable forms may be completed manually and submitted to the HPRA via “freepost”. Yellow cards are available on request from the HPRA at **01 6764971**.

- Suspected adverse reactions must be reported in accordance with criteria outlined by the HPRA. This includes any suspected adverse reactions brought to the attention of the registered nurse or midwife. HPRA reporting of suspected adverse reactions may be carried out online at [http://www.hpra.ie](http://www.hpra.ie) or through use of the yellow card system which is available in a downloadable format from the HPRA website, or on request from the HPRA. You may request adverse reaction forms via
  - Telephone number +353-1-6764971
  - Fax number +353-1-6767836
  - Email: [info@hpra.ie](mailto:info@hpra.ie)

The incident and all actions taken must be promptly recorded in accordance with the *Management of a Patient with Anaphylaxis: Treatment in the Community* (National Immunisation Advisory Committee 2019) – available online at [https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf](https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf)

| Procedure for the reporting and documentation of errors and near misses involving the medicine | - In the case of medication errors that directly involve the patient/service user, i.e. wrong medicine/patient/dose/route being administered or another medication error, the registered nursing/midwifery staff must remain with the patient and closely monitor the patient/service user for any adverse reactions. Vital signs should be recorded and the patient should be reviewed by the registered nurse/midwife and medical practitioner.
- The incident and all actions taken must be recorded and the relevant National Incident Management Report Form (NIRF) completed as soon as is practicable after the event occurs and within one working day. (National Incident Report Form (NIRF 01 – V10)) (May 2018), available at [https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v10-person.pdf](https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v10-person.pdf)
- The incident must be reported to the relevant line manager as soon as possible.
- The incident and all actions taken must be promptly recorded in the patient’s documentation/notes.
- The patient/service user and/or significant others should be informed of the incident.
- Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above. |
| Mechanisms for storage of medicine | - Keep the container in the outer carton  
- Epinephrine (Adrenaline) is light sensitive and so should always be stored in its box until required.  
- Do not store above 25°C  
- Keep out of reach of children  
- Nature and Content of Container: 1ml, clear glass ampoules.  
- Pack size: 10 x 1ml ampoules  
- Single use only. If only part used, discard the remaining solution  
Any waste material should be disposed of in accordance with the “Healthcare risk waste management segregation packaging and storage guidelines for healthcare risk waste” 4th edition November 2010, available at  
- available at [http://www.lenus.ie/hse/handle/10147/120929](http://www.lenus.ie/hse/handle/10147/120929) . |
| Resources and equipment required | - Disposable kidney dishes/trays  
- Gauze swabs, tape/plasters  
- Sharps bins, and bags for disposal of other hazardous waste materials  
- Alcohol hand rinse  
- Access to telephone |
| Audit process to identify appropriate use of the medicine protocol or unexpected outcomes | - All documentation to be held for review and audit purposes.  
- Team meetings are advisable to review the use of the medicine protocol. |
### 4.0 Patient/service-user care information

| Advice to be given to the patient/service user and/or carer before and/or after treatment | - Patient should be transported to an emergency department as soon as possible  
- All who had anaphylaxis should be advised of the benefits of wearing a device such as a bracelet that will inform bystanders of their anaphylaxis history  
- Advise the patient to contact their General Practitioner for follow up. |
| Details of any necessary follow-up, action and referral arrangements | - Patient is transferred to the nearest emergency department as soon as possible. |

### 5.0 Staff authorised to use medicine protocol

| Professional qualifications, training, experience and competence relevant to this medicine protocol | Professional Qualifications:  
- Registered as a nurse or midwife on the live Register of the Nursing and Midwifery Board of Ireland  

Training, Experience, Competence:  
- Basic Life Support for Health Care Workers within the last two years  
- Approved Anaphylaxis Treatment Training programme initially, with updates as required to maintain individual competence  
- Education programme for nurses and midwives on the use of the following medicine protocol:  
  - Medicine Protocol for the administration of Epinephrine (Adrenaline) Injection 1:1000 by Intramuscular Injection by registered nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis (2019). |

Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis and Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection 1:1000 by IM Injection by registered nurses and registered midwives. Version 3. 2019
References


Epinephrine (Adrenaline) 1:1,000 Summary of Product Characteristics available at: http://www.hpra.ie


