Public Health England

NHS England

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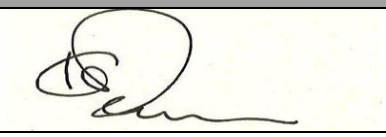
Patient Group Direction for administration of Adrenaline (Epinephrine) 1:1000 injection 1mg in 1ml

IN ALL CASES OF SUSPECTED ANAPHYLAXIS
DIAL 999 IMMEDIATELY AND STATE THAT THERE IS A CASE OF SUSPECTED ANAPHYLAXIS

Immediate access to adrenaline (Epinephrine) injection 1mg in 1ml and the equipment to administer it is a requirement when vaccines are being administered. This PGD provides a framework to guide healthcare professionals on the appropriate use of adrenaline and informs them about their training requirements.

Any person able to recognise anaphylactic reaction is permitted to administer intramuscular adrenaline injection for the purpose of saving life, whether they are a healthcare professional or not. There is no need to be signed up to this PGD to treat patients in an emergency.

Approved By

NHS England and Staffordshire Area Team	Name	Signature
Medical Director	Dr Ken Deacon	
LPN Pharmacy Chair	Dr Manir Hussain	
Head of Public Health Commissioning	Rebecca Woods	

Date of patient group direction approved	Nov 2014
Date this patient group direction becomes due for review	March 2016

STAFF CHARACTERISTICS

- Provider of NHS services within NHS England (Shropshire & Staffordshire Area Team)
- Registered nurse with current NMC registration

Specialist competencies or qualifications:

- The health care professional must have a good understanding of the NICE Good Practice Guidance on Patient Group Directions[1].
- The NICE competency framework: For health professionals using Patient Group Directions should be used by health care professionals planning to work under this PGD to identify any gaps in their knowledge. The gaps should be addressed before the healthcare professional is authorised to work under this PGD.
- The clinical manager/ lead GP/commissioner must have evidence that the health care professional has undertaken training to carry out clinical assessment of patient leading to confirmation that the patient requires treatment according to the indications listed in the PGD.
- The healthcare professional must provide evidence of training, appropriate annual updates and continued professional development undertaken to support their competence for administration of this treatment.
- The clinical manager/ lead GP must have assessed the competency of the healthcare professional to work to this Patient Group Direction. The NICE competency framework: For health professionals using Patient Group Directions should be used to support this assessment.
- The health care professional must have undertaken training and annual updates in the recognition and treatment of anaphylaxis, including practical in Basic Life Support and has immediate access to an in-date supply of adrenaline 1mg in 1ml (1:1000) at the time of the consultation. (The practitioner must be deemed competent in basic life support and in emergency administration of adrenaline)
- The health care professional must have access to all relevant sources of information e.g. information issued by the Department of Health (Green Book), British National Formulary (BNF), Summary of Product Characteristics (SPC), and the clinical guideline concerning medicine(s) within this Patient Group Direction (PGD).
- The registered health care practitioner is professionally accountable for supply or administration under the PGD as defined in their own profession's Code of Professional Conduct and Ethics.

YOU MUST BE AUTHORISED BY NAME BY YOUR CLINICAL LEAD UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

CLINICAL CONDITION	
Clinical need addressed	Emergency treatment of allergic manifestations of acute anaphylaxis. Anaphylaxis is likely when all of the following three criteria are met: • Sudden onset and rapid progression of symptoms • Life-threatening airway and/or breathing and/or circulation problems • Skin and/or mucosal changes (flushing, urticaria, angioedema) Use an Airway, Breathing, Circulation, Disability, and Exposure (the ABCDEs) approach to assess and treat the patient. **Appendix 1** **NB: If in doubt assume anaphylaxis and treat.**
Inclusion criteria	All individuals who show signs and symptoms of an anaphylactic or anaphylactoid reaction (Consent to treatment - if the patient is unable to give consent due to a life-threatening situation, or if parents or guardians are not present, adrenaline (epinephrine) should be administered where treatment is judged to be in the best interests of the patient).
Exclusion criteria (for full details of interacting medicines refer to current Summary of Product Characteristics (SPC) www.medicines.org.uk & BNF)	The absence of an anaphylactic reaction. In severe genuine anaphylaxis there is NO exclusion criteria Anaphylactic reaction should be distinguished from for example fainting (syncope) and panic attacks
Caution/need for further advice /Interactions	**There are no absolute contraindications to treatment as this product is intended for use in life-threatening emergencies.** • If adrenaline has already been self-administered by the client (e.g. Epipen) this should be taken into account when determining the timing and dosage of administration. • Caution – atopic individuals, hyperthyroidism, diabetes, ischaemic heart disease, hypertension. (*However, the benefits of treatment will probably outweigh any risks associated with cautions)*. • Do not give repeated doses in hypothermic clients.
Management of excluded patients	If there is uncertainty as to whether anaphylaxis is present if possible seek immediate advice from another clinician. However if anaphylactic reaction is suspected immediate treatment is a priority and this should not be delayed unnecessarily. For all excluded patients monitor carefully over at least 30 minutes to ensure they are not progressing to anaphylaxis. Refer to medical practitioner or A&E if necessary.
Action for patients not wishing to receive care under this PGD	Ring 999 and transfer urgently to A&E with a paramedic crew. The patient, parent or guardian should be advised of the potential risks
Treatment and Drug details	

<table>
<tr><td>Name form and strength of medicine</td><td>Adrenaline (Epinephrine) 1 in 1000 injection (1mg in 1ml)</td></tr>
<tr><td>Legal classification</td><td>POM – Prescription only medicine.
(restriction does not apply to adrenaline injection 1mg/ml where administration is for life saving emergency)</td></tr>
<tr><td>Black triangle warning
Suspected adverse reactions. Should be reported using the Yellow Card reporting scheme (www.yellowcard.gov.uk).</td><td>No</td></tr>
<tr><td>Method of obtaining supply</td><td>Licensed NHS supplier
Community pharmacy</td></tr>
<tr><td>Site for treatment</td><td>• GP surgeries
• Community Pharmacies
• Patient’s home</td></tr>
<tr><td>Route/method</td><td>Intramuscular injection (preferably anterolateral thigh)</td></tr>
<tr><td>Dose</td><td>Adrenaline 1:1000 injection (1mg/1ml)

<table>
<tr><th></th><th>Adrenaline Dose</th><th>Volume to Administer (IM)</th></tr>
<tr><td>Adult</td><td>500 micrograms</td><td>0.5ml</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td>Child more than 12 years</td><td>500 micrograms</td><td>0.5ml</td></tr>
<tr><td>Child more than 12 years – small or pre-pubertal</td><td>300 micrograms</td><td>0.3ml</td></tr>
<tr><td>Child 6-12 years</td><td>300 micrograms</td><td>0.3ml</td></tr>
<tr><td>Child less than 6 years</td><td>150 micrograms</td><td>0.15ml*</td></tr>
</table>

An anaphylaxis pack normally containing two ampoules of adrenaline (epinephrine) 1:1000, four 23G needles and four graduated 1ml syringes (*syringes should be suitable for measuring a small volume). Packs should be checked regularly to ensure the contents are within their expiry dates.</td></tr>
<tr><td>Number of times treatment may be administered</td><td>If there is no clinical improvement, the dose may be repeated after 5 minutes. Monitor individual patient’s response- blood pressure, pulse and respiratory function. Depending on the individual’s response subsequent doses may be given if there is a delay in obtaining medical/paramedical support.

Health professionals working to this PGD should follow the Resuscitation Council (UK) guidance which currently advises that the dose can be repeated after 5 minutes. Manufacturer’s product information for auto injectors may advise a longer time interval between doses, however the Resuscitation Council provides guidance that these products may also be repeated after 5 minutes.</td></tr>
</table>

	In the event of any individual suffering from anaphylactic reaction, the patient must be admitted to the hospital via the emergency services for observation and further assessment. 999 must be called in all cases.
Quantity to be supplied or administered	The dose as detailed above can be repeated at intervals of 5 minutes until the patient improves or emergency medical services /ambulance have arrived. Initiate CPR at any stage if appropriate
Side effects *Full details of side effects are available in the SPC.* *www.medicines.org.uk* *Suspected adverse reactions to drugs including vaccines should be reported on the yellow card available at the back of the BNF. Also at www.yellowcard.gov.uk*	Possible side effects: - Tachycardia, angina, hypertension & ventricular arrhythmias. Anxiety, headache, cerebral bleeding. Nausea and vomiting. Sweating, weakness, dizziness & hyperglycaemia.
Additional Information (including storage and disposal)	Facilities and supplies Anaphylactic pack containing: • Adrenaline 1:1000 (10 amps) • 1ml syringes (suitable for measuring small volumes) • Needles • Gloves • Direct access to telephone emergency 999. Desirable resources within Health Centres, clinics and GP practices • Oxygen/ tubing/ mask • ECG machine • Automated defibrillator, ambu bag & pocket mask. • Guedel airways Storage and disposal • Store in an accessible location (all medical staff must be aware of local of emergency anaphylaxis pack) • Store in original packaging • Store below 25^0C • Protect from light • Equipment used for treatment should be disposed of by placing in a proper, puncture-resistant 'sharps' box according to local authority regulations and guidance in Health Technical Memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013) Suspend vaccination session until anaphylaxis pack has been replenished
Advice to patient/carer	**BEFORE TREATMENT:** • Prior to the administration of adrenaline the patient should receive an explanation that they are having an allergic reaction and that IM adrenaline is going to be administered to relieve the symptoms and help reverse the reaction. • Advise patient of possible side effects (although this may not always be

	possible) **AFTER HOSPITAL TREATMENT:** Refer patient to GP for appropriate follow-up advice.
Follow up	**URGENT HOSPITALISATION VIA 999** Explain the course of action and the need for urgent medical attention to the patient and any carer. Highlight any known medical history to emergency services. To help confirm the diagnosis of anaphylaxis and identify the most likely trigger it is useful to have: • A description of the reaction with circumstances and the timings to help identify potential triggers. • A list of administered treatments • Copies of relevant patient records Inform the patient's GP of the incident and the substance implicated in causing the anaphylactic reaction. Patients must be fully informed about the reaction when sufficiently recovered. What caused the anaphylaxis should be discussed as should measures to avoid a further episode of anaphylaxis.
Suspected adverse reactions	If any medication is implicated in causing the anaphylactic reaction, the incident must be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card scheme at http://yellowcard.mhra.gov.uk
Error reporting	Any incidents or near-miss issues must be reported via the organisation's internal reporting system
RECORD KEEPING	
Documentation needed/treatment records to be kept for audit purposes *A computer or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes.*	Full entry in patients record and patient held record to include: • Patient's name, address, date of birth and registered GP • Manufacturer, product name, batch number(s), expiry date(s) • Dose(s) administered • Number of doses administered • Date / time administered • Anatomical site of administration • Route of administration • Advice given to patient (including follow up advice) • Details of staff who administered (sign and print name) • Details of any adverse drug reactions resulting in suspected anaphylaxis. • Record as supplied via Patient Group Direction (PGD) in patient's clinical record All records should be clear, legible and contemporaneous. This information should be recorded as appropriate in the patient's General Practitioner record or other patient record, depending on location of treatment A computerised or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes.

	If treatment has been administered by a provider other than the GP practice, timely communication to the GP practice to enable the patient's record to be updated must be completed. Any noted adverse effects following vaccination must also be reported to the GP practice. Clinical records must be kept for at least 8 years following completion of treatment. In patients who are aged under 17 years, clinical records must be kept until the patient's 25th birthday, or for 8 years following a child's death. Data must be stored in accordance with Caldicott guidance and the Data Protection Act. • Reconciliation – stock balances should be reconcilable with receipts, administration records and disposal.

Register of practitioners qualified to administer and/or supply Adrenaline (Epinephrine) 1:1000 injection 1mg in 1ml under this Patient Group Direction	
Name of clinical manager/GP Lead/Commissioner	
Signature of clinical manager/GP Lead / commissioner	Date:
A copy of this page should be retained by the authorising manager for 2 years for audit purposes	
Please state clinical area where this PGD is in use	

Healthcare professional individual declaration

I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD

- **PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY**.
- It is the responsibility of each professional to practice only within the bounds of their own competence.
- All practitioners operating in accordance with this PGD should have a current, signed copy of it readily available for reference.
- If a practitioner is asked to supply, or administer a medicine not covered by this or any other PGD then a patient specific direction is required from a doctor, dentist or independent prescriber.

Name of professional (please print)	Signature	Authorising Manager (Must sign against each entry)	Date of authorisation

Appendix 1

Patient assessment (Resuscitation Council UK 2008)

Patients can either have an airway, breathing or circulation problem or any combination.

Airway problems
- Airway swelling, e.g. throat and tongue swelling
- Hoarse voice
- Inspiratory stridor

Breathing problems
- Shortness of breath
- Wheeze
- Confusion caused by hypoxia, patient becoming tired
- Cyanosis – late sign
- Respiratory arrest
- Acute irreversible asthma

Circulation problems
- Signs of shock, pale, clammy
- Increased pulse rate
- Low blood pressure, feeling faint, collapse
- Decreased conscious level or loss of consciousness
- Cardiac arrest

Other symptoms can include:
- Angioedema, commonly eyelids and lips
- Sense of impending doom
- Skin and/or mucosal changes. Can be subtle or dramatic and present in over 80% of reactions. Changes may be just skin, just mucosal or both.
- Abdominal pain, incontinence, vomiting
- Erythema
- Urticaria anywhere on the body. Pale pink/red weals, usually itchy

Disability
Common causes of unconsciousness include profound hypoxia, hypercapnia, cerebral hypoperfusion due to hypotension, or the recent administration of sedative or analgesic drugs.

Exposure
To examine the patient properly, full exposure of the body is necessary. Skin and mucosal changes after anaphylaxis can be subtle. Minimise heat loss. Respect the patient's dignity.

Appendix 1

Resuscitation Council (UK)

Anaphylactic reactions – Initial treatment

Anaphylactic reaction?

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Airway, Breathing, Circulation, Disability, Exposure

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Diagnosis - look for:
- Acute onset of illness
- Life-threatening Airway and/or Breathing and/or Circulation problems [1]
- And usually skin changes

↓

- **Call for help**
- Lie patient flat
- Raise patient's legs (if breathing not impaired)

↓

Intramuscular Adrenaline [2]

1 Life-threatening problems:

Airway:	swelling, hoarseness, stridor
Breathing:	rapid breathing, wheeze, fatigue, cyanosis, SpO_2 < 92%, confusion
Circulation:	pale, clammy, low blood pressure, faintness, drowsy/coma

2 Intramuscular Adrenaline

IM doses of 1:1000 adrenaline (repeat after 5 min if no better)

• Adult	500 micrograms IM (0.5 mL)
• Child more than 12 years:	500 micrograms IM (0.5 mL)
• Child 6 -12 years:	300 micrograms IM (0.3 mL)
• Child less than 6 years:	150 micrograms IM (0.15 mL)

March 2008

Reference Sources

- Adrenaline (Epinephrine) Injection BP 1 in 1000 SPC (eMC)
  www.medicines.org.uk

- Medical emergencies in community: British National Formulary
  www.bnf.org

- Resuscitation Council UK Emergency treatment of anaphylactic reactions
  www.resus.org.uk/pages/reaction.pdf (accessed on 14.10.2014)

- Immunisation against infectious disease. The Green Book
  https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147868/Green-Book-Chapter-8-v4_0.pdf
  (accessed 14.10.2014)

Acknowledgement: Medicines Management Team, Telford & Wrekin CCG for developing the PGD.