

Patient Group Direction For The Administration Of Adrenaline (Epinephrine) In Cases Of Suspected Anaphylactic Reactions By Approved Healthcare Professionals Working within NHS Grampian

Lead Author: Medicines Management Specialist Nurse NHSG	Consultation Group: See relevant page in the PGD	Approver: Medicines Guidelines and Policies Group
Signature:		Signature:

Signature:	Signature:
& Adamon.	

NHSG Identifier: NHSG/PGD/Adrenaline/ MGPG1199	Review Date: October 2023	Date Approved: October 2021
	Expiry Date: October 2024	

NHS Grampian have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Board. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 6.01 (Amended April 2022)

Revision History:

·

Date of change	Summary of Changes	Section heading
August 2021	2 yearly review following updated UK anaphylaxis guidance.	
August 2021	Removal of previous Appendix 4. Additional information on recognition of anaphylaxis as no longer available from the UK Resuscitation Council.	
August 2021	Exclusions updated.	Exclusion criteria
August 2021	Precautions and special warnings updated.	Precautions and special warnings
August 2021	Dose table updated to include those under 6 months of age.	Dosage/ maximum total dose
August 2021	Diagram added for clarity of position for administration and the route of administration.	Route/Method of administration
April 2022	Minor amendment to Authorisation of Administration section due to omission of occupational therapist, orthoptist/prosthetists, radiographers and speech and language therapists to include all registered health care professionals that main be authorised to operate under PGD.	Authorisation of administration

NHGS Identifier: NHSG/PGD/Adrenaline/MGPG1199

Keyword(s): PGD Patient Group Direction dental nurse

pharmacist physiotherapist podiatrist

radiographer nurse midwife Emerade EpiPen

Minijet Jext auto-injector

Policy Statement: It is the responsibility of the individual healthcare professionals and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document: Drafted: August 2021

Completed: September 2021

Approved: October 2021 (published – November 2021)

Amended and April 2022

reauthorised:

Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by;

Medical practitioner	Name: Dr Fiona Warrick
mourous praemaene.	Health Board: NHSG
	Title: Consultant Anaesthetist and Clinical Lead for Resuscitation Team
	Contact email: fiona.warrick@nhs.scot
	Signature How Die
	Date Signed: 23/11/2021
Senior representative of the	Name: Jan Short
professional group who will	Health Board: NHSG
provide care under the direction	Title: Senior Resuscitation Officer
anection	Contact email: jan.short@nhs.scot
	Signature Shout
	Date Signed: 11/10/2021
Lead author	Name: Frances Adamson
Loud ddillol	Health Board: NHSG
	Title: Medicines Management Specialist Nurse
	Contact email: frances.adamson@nhs.scot
	Signature & Adoma.
	Date Signed : 28/10/2021
la la	Date digited : 26/10/2021
Pharmacist	Name: Anne Marshall
	Health Board: NHSG
, ,	Title: Community Pharmacist
	Contact email: anne.marshall5@nhs.scot
	Signature Mades

Approved and authorised for use within NHSG by;

Medicines Guidelines and Policies Group Chair	Signature	Date Signed
Lesley Coyle	- AS	28/10/2021
	7	A

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	Title:
Frances Adamson Anne Marshall	Lead Author: Medicines Management Specialist Nurse Pharmacist: Community Pharmacist
Dr Fiona Warrick	Medical Practitioner: Consultant Anaesthetist and Clinical Lead for Resuscitation Team
Jan Short	Senior Representative: Senior Resuscitation Officer
Lisa Lawrie	Lead Nurse Aberdeen City CHP
Alexandra Lowe	Dental Clinical Lead
Sarah Buchan	Pharmaceutical Care Services Manager

Patient Group Direction For The Administration Of Adrenaline (Epinephrine) In Cases Of Suspected Anaphylactic Reactions By Approved Healthcare Professionals Working Within NHS Grampian

Clinical indication to which this PGD applies

Definition of situation/Condition

This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to administer adrenaline (epinephrine) by intramuscular injection (IM) to individuals suffering from suspected hypersensitivity and anaphylactic reactions.

Individuals particularly at increased risk are those with existing hypersensitivity and immune disorders such as asthma, haemolytic anaemia, thyroiditis, systemic lupus erythematosus and rheumatoid arthritis.

This PGD should be used in conjunction with the recommendations in the current <u>British National Formulary (BNF)</u>, <u>British National Formulary for Children (BNFC)</u>, individual Summary of Product Characteristics (SmPC) and The Resuscitation Council (UK) <u>Anaphylaxis Guidelines</u>.

Inclusion criteria

Administration of IM adrenaline (epinephrine) should be considered for individuals who show signs and symptoms of an anaphylactic reaction. Medical advice must be sought as soon as possible from a doctor if any individual develops any signs of hypersensitivity. If there is a delay in medical support arriving and the condition of the individual is deteriorating then an emergency ambulance must be called on (9) 999 or direct via ambulance control, or dial 2222 (hospital internal) according to local procedure, or seek urgent medical advice.

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) (only 20% will experience cutaneous changes).

Note: Skin or mucosal changes alone are not a sign of anaphylaxis. Skin and mucosal changes can be subtle or absent in 10–20% of reactions (e.g. some patients present initially with only bronchospasm or hypotension).

	A single set of criteria will not identify all anaphylactic reactions. There are a range of signs and symptoms, none of which are entirely specific. See Appendix 3 for the Airway, Breathing, Circulation, Disability and Exposure (ABCDE) approach to assess and treat an individual which should be followed, as individuals can have an airway, breathing or circulation problem or any combination which is life threatening. See Appendix 4 for an anaphylaxis algorithm (adapted from the Resuscitation Council (UK) – Anaphylaxis Algorithm May 2021). Individuals displaying the previously described signs and symptoms may receive the administration of adrenaline (epinephrine) if they are: Hospital in-patients Hospital out-patients attending out-patient or diagnostic departments Visitors or members of staff (if possible check with individual to ascertain if they have already self-administered adrenaline using an auto-injector) Individuals receiving care in the community, including minor injury units, GP practices, dental practices, health centres clinics, schools, pharmacies, individual's own houses and other community settings.
Exclusion criteria	 The absence of an anaphylactic reaction. In severe genuine anaphylaxis there are no exclusions and contra-indications are relative as adrenaline is being administered in an emergency situation.
Precautions and special warnings	 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).
Action if excluded from treatment	Call (9) 999 Emergency services and/or refer to doctor as appropriate. If within the acute hospital setting dial 2222 (hospital internal) according to local procedure, or seek urgent medical advice. Ensure all actions/decisions are documented.

	Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	Not considered likely however; If the individual is unable to give consent due to a life-threatening situation adrenaline (epinephrine) should be administered where treatment is judged to be in the best interests of the individual.

Description of treatment available under the PGD

1	,	
Name form and strength of medicine	Adrenaline (epinephrine) 1mg/1mL (1 in 1,000) solution for injection ampoules.	
medicine	Adrenaline (epinephrine) 500micrograms/0.5mL (1 in 1,000) solution for injection ampoules.	
	Adrenaline (epinephrine) 500micrograms (single dose) (1 in 1,000) solution for injection (pre-filled syringe) autoinjector.	
	Adrenaline (epinephrine) 300micrograms (single dose) (1 in 1,000) solution for injection (pre-filled syringe) autoinjector.	
	Adrenaline (epinephrine) 150micrograms (single dose) (1 in 1,000) solution for injection (pre-filled syringe) autoinjector.	
Legal status	Adrenaline (epinephrine) is a Prescription-only Medicine (POM).	
	Note: Exemption to legal category – POM restriction does not apply to the IM administration of up to 1mg of adrenaline injection 1 in 1000 (1mg/1mL) for the emergency treatment of anaphylaxis.	
Dosage/Maximum total dose	Adults - 500micrograms (0.5mL) of adrenaline (epinephrine) 1 in 1,000 (1mg/mL).	
	Table reference - Emergency Treatment of Anaphylactic Reactions. (2008). Resuscitation Council (UK)	

Age	Dose of Adrenaline	Volume of 1 in 1,000 (1mg/mL) solution
Under 6 months	100-150micrograms IM	0.1 – 0.15mL
6 months to 6 years	150micrograms IM	0.15mL
Age	Dose of Adrenaline	Volume of 1 in 1,000 (1mg/mL) solution
6 - 12 years	300micrograms IM	0.3mL
Adult and child over 12 years	500micrograms IM (300micrograms IM if the individual is small or pre-pubertal)	0.5mL (0.3mL)

Infants and Children - The scientific basis for the recommended doses is weak. The recommended doses are based on what is considered to be safe and practical to draw up and inject in an emergency.

Proprietary adrenaline auto-injectors.

Healthcare professionals should be familiar with the use of the most commonly available auto-injector devices. The dose recommendations for adrenaline in this guideline are intended for healthcare providers treating an anaphylactic reaction.

If an adrenaline auto-injector is the only available adrenaline preparation when treating anaphylaxis, healthcare providers should use it. **Note:** Some adult auto-injectors only contain 300micrograms (0.3mL).

Maximum number of doses: No limit – (determined by individual response)*. Repeat the IM adrenaline dose if there is no improvement in the individual's condition. Further doses can be given at 5 minute intervals according to the individual's response.

*For additional information, refer to the Resuscitation Council (UK) Emergency Treatment of Anaphylactic Reactions (2021).

Frequency of dose/Duration of treatment

The same dose can be repeated as necessary at intervals of 5 minutes if there is no improvement in the individual's condition or on further assessment of ABCDE of the individual.

Continue treatment until the individual's condition improves and no further doses of adrenaline are deemed necessary, or until medical help arrives.

Maximum or minimum treatment period	N/A				
Route/Method of administration	Intra-muscular (IM) injection (preferably mid-point in anterolateral thigh, see diagram below). However, in an emergency where this site cannot be accessed, adrenaline can be administered into the deltoid muscle of the arm). Where safely possible you should lay the individual down and elevate their legs (as per the diagram below). Inject at anterolateral aspect—middle third of the thigh middle third of the third of t				
Quantity to be administered	See Dosage/Maximum total dose and Frequency of dose/Duration of treatment sections above.				
Storage requirements	Store at less than 25°C and protect from light. Do not freeze.				
Follow-up (if applicable)	Hospital in-patients require close observation on the ward. They may need to be transferred to a high dependency facility depending on the severity of reaction and medical decision. Any affected hospital out-patients, staff or visitors, individuals in the community or those attending clinics/health centres need to be transferred to a hospital. The medical practitioner in charge of the individual's care should be informed.				
Advice (Verbal)	If conscious, prior to the administration of adrenaline (epinephrine) the individual should receive an explanation that they are having a severe reaction and that IM adrenaline (epinephrine) is going to be administered to relieve the symptoms and help reverse the reaction.				
Advice (Written)	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual/person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.				

Identifying and managing possible adverse reactions

Adverse effects are extremely rare with correct doses injected intramuscularly. The adverse effects of adrenaline mainly relate to the stimulation of both alpha and beta-adrenergic receptors. The occurrence of undesirable effects depends on the sensitivity of the individual and the dose involved.

The following are possible adverse effects:

- Tachycardia, angina, hypertension and ventricular arrhythmias
- Anxiety, headache, cerebral bleeding
- Nausea and vomiting
- Sweating, weakness, dizziness and hyperglycaemia.

There are **no absolute contraindications** to the administration of adrenaline under this PGD with any concurrent medication, as adrenaline is intended for use in a life threatening emergency.

However, there is large inter-individual variability in the response to adrenaline. In clinical practice, it is important to monitor the response; start with the recommended dose and give further doses if no response. This approach will therefore allow the management of any effects of interacting medicines, e.g. tricyclic antidepressants, cardiac glycosides.

Non selective beta blockers - individuals taking these may not respond to the adrenaline injection and may require intravenous salbutamol or aminophylline, however this must be prescribed by a medical practitioner.

This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.

BNF/BNFC:

BNF British National Formulary - NICE
BNF for Children British National Formulary - NICE

SmPC/PIL/Risk Minimisation Material:

Home - electronic medicines compendium (emc)

MHRA Products | Home

RMM Directory - (emc)

If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.

Report any severe reactions using the Yellow Card System. Yellow Card Scheme - MHRA

Facilities and supplies required

The following are to be available at sites where the medicine is to be administered:

- Appropriate storage facilities
- An acceptable level of privacy to respect individual's right to confidentiality and safety
- Basic airway resuscitation equipment (e.g. bag valve mask)
- Access to a working telephone
- Another competent adult, who can summon urgent emergency support if required should ideally be present
- Access to medical support (this may be via the telephone)
- Approved equipment for the disposal of used materials
- Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel
- A copy of this current PGD in print or electronically.

Characteristics of staff authorised to administer medicine(s) under PGD

Professional qualifications

Those registered healthcare professionals that are listed and approved in legislation as able to operate under Patient Group Directions as follows:

- Nurses, midwives and health visitors currently registered with the Nursing and Midwifery Council (NMC)
- Pharmacists currently registered with the General Pharmaceutical Council (GPhC)
- Chiropodists/podiatrists, dieticians, occupational therapists. orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC)
- Dental hygienists and dental therapists registered with the **General Dental Council**
- Optometrists registered with the General Optical Council.

Specialist competencies

Approved by the organisation as:

- Competent to assess the individual's/person with parental responsibilities capacity to understand the nature and purpose of the medicine administration in order to give or refuse consent
- Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual
- Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD

	 Competent to undertake administration of the Medicine. Note: Health care professionals should be trained in the use of auto-injectors to avoid inadvertent self-administration and IM administration technique Competent to work under this PGD.
Ongoing training and competency	 All professionals working under this PGD must: Have undertaken PGD training as required/set out by NHSG Have undertaken basic life support training face to face updated in-line with Board requirements Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis in-line with Board requirements Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct Have knowledge and familiarity of the following; SmPC for the medicine(s) to be administered in accordance with this PGD.
Responsibilities of professional manager(s)	Professional manager(s) will be responsible for; Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to administer the medicine(s) specified in this direction.

Documentation

Authorisation of administration

Template Version NHSG v6

Qualified healthcare professionals working within NHS Grampian listed and approved in legislation as able to operate under PGD can be authorised to administer the medicine specified in this PGD.

Nurses, midwives and health visitors can be authorised by their line manager.

Pharmacists can be authorised by their Director of Pharmacy (DoP) and have completed any requirements for service registration.

The following list of healthcare professionals can be approved by their line manager/head of service or vaccine coordinator.

Chiropodists, dental hygienists, dental therapists, dieticians, midwives, occupational therapists, optometrists, orthoptists, orthotist/prosthetists, paramedics, physiotherapists, podiatrists, radiographers and speech and language therapies.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1).

A Certificate of Authorisation (<u>Appendix 2</u>) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed locally.

Record of administration

An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:

- Date and time of administration
- Individuals name and CHI
- Exclusion criteria, record why the medicine was not administered (if applicable)
- Record that valid consent to treatment under this PGD was obtained
- The name, dose, form, route (batch number, expiry date and site where appropriate for injectable medicines) of the medicine administered
- Advice given, including advice given if excluded or declined treatment under this PGD
- Signature and name in capital letters of the healthcare professional who administered the medicine
- Record of any adverse effects (advise individuals GP/relevant medical practitioner).

Note: If the situation requires a 2222 call for the Clinical Emergency Team in hospital or a (9) 999 call requesting an ambulance to attend, staff must complete a Clinical Emergency DATIX inputting the following fields:

Category – Implementation of care and ongoing monitoring. Sub- category – Possible delay or failure to monitor. Details – Clinical Emergency

Documentation of the event must also be recorded in individual's medical records. The incident must always be reported to the medical practitioner in charge of the individual's care.

	All serious adverse events related to medicines should be					
	reported to the MHRA via the Yellow Card Scheme or on the website at www.yellowcard.gov.uk .					
Audit	All records of the medicine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.					
References	Electronic Medicines Compendium http://www.medicines.org.uk					
	Medicine	Date of Revision of SmPC	Date Accessed			
	Adrenaline (epinephrine) 1mg/1mL (1 in 1,000) solution for injection ampoules (Martindale)	February 2019	03/08/21			
	Adrenaline (epinephrine) 1mg/1mL Injection (1 in 1,000) for Anaphylaxis (glass prefilled syringe) (Martindale)	11/02/20	03/08/21			
	Adrenaline (epinephrine) 500micrograms (single dose) (1 in 1,000) solution for injection (pre-filled syringe) auto-injector. (Emerade)	20/01/20	03/08/21			
	Adrenaline (epinephrine) 300micrograms (single dose) (1 in 1,000) solution for injection (pre-filled syringe) auto-injector. (Emerade)	20/01/20	03/08/21			
	Adrenaline (epinephrine) 150micrograms (single dose) (1 in 1,000) solution for injection (pre-filled syringe) auto-injector. (Emerade)	20/01/20	03/08/21			
	British National Formulary and British National Formulary for Children https://about.medicinescomplete.com/ accessed 03/08/21.					
	Resuscitation Council (UK) Emergency treatment of anaphylaxis: Guidelines for healthcare providers, May 2021. https://www.resus.org.uk/media/337/download					



Appendix 1

Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

l:		(Insert name)
Working within:		e.g. Area, Practice
Agree to administer the medici Direction:	ine(s) contained within the following F	Patient Group
(Epinephrine) İn Case	tion For The Administration Oes Of Suspected Anaphylactic Professionals Working Within	Reactions By
administer the medicine(s) unc	ate training to my professional standa der the above direction. I agree not to out with the recommendations of the	act beyond my
Signed:	_	
Print Name:		
Date:		
Profession:		
Professional Registration number/PIN:		



Appendix 2

Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.

The Senior Nurse/Professional who approves a healthcare professional to administer the medicine(s) under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.

The Healthcare Professional that is approved to administer the medicine(s) under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.

Patient Group Direction For The Administration Of Adrenaline (Epinephrine) In Cases Of Suspected Anaphylactic Reactions By Approved Healthcare Professionals Working Within NHS Grampian

Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction For The Administration Of Adrenaline (Epinephrine) In Cases Of Suspected Anaphylactic Reactions By Approved Healthcare Professionals Working Within NHS Grampian

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date



Appendix 3

The ABCDE approach:

Airway

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

Breathing

- Increased respiratory rate.
- Shortness of breath.
- Wheeze.
- Hypoxia- which can lead to confusion/agitation.
- Cyanosis (appears blue) this is usually a late sign.
- Individual becoming tired.

Circulation

- Signs of shock pale, clammy.
- Increased pulse rate (tachycardia).
- Low blood pressure (hypotension) feeling faint (dizziness) which may lead to collapse.
- Decreased conscious level or loss of consciousness.
- Anaphylaxis can cause myocardial ischaemia and electrocardiograph (ECG) changes even in individuals with normal coronary arteries.

Disability

- Airway, Breathing and Circulation problems can all alter the individual's neurological status because of decreased brain perfusion. Using the Alert, responds to Vocal stimuli, responds to Painful stimuli, or Unresponsive to all stimuli (AVPU) method of assessment can determine an individual's conscious level.
- Individuals can also have gastro-intestinal symptoms (abdominal pain, incontinence, vomiting).

Exposure

- The individual must be exposed ensuring dignity to observe for skin and/or mucosal changes. This is often the first feature and present in over 80% of anaphylactic reactions.
- 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 (also called hives, nettle rash, weals or welts), which can appear anywhere on the body. The weals may be pale, pink or red, and may look like nettle stings. They can be different shapes and sizes and are often surrounded by a red flare. They are usually itchy.
- Angioedema is similar to urticaria but involves swelling of deeper tissues, most commonly in the eyelids and lips, and sometimes in the mouth and throat.

ANAPHYLAXIS CAN RESULT IN RESPIRATORY AND CARDIAC ARREST



Appendix 4 - Anaphylaxis Algorithm

