

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

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

Signature:	Signature:
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NHSG Identifier: MGPG/PGD/Adrenaline/ 1477	Review Date: February 2026	Date Approved: February 2024	
	Expiry Date: February 2027		

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 Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 7

Revision History:

PGD that has been supersededPGD supersedes NHSG/Ad Version 6.01		PGD supersedes NHSG/Adrenaline/MG Version 6.01	PG1199,
Date of change	Summary of Changes		Section heading
November 2023	Updated onto NoS Template v9.		
November 2023	0		Dosage/Maximum total dose
February 2024	Vaccination centres added. Inclusion		Inclusion Criteria
February 2024	Pregnant women position added.		Route/Method of administration

NHGS Identifier:	MGPG/PGD/Adrenaline/1477
Keyword(s):	PGD Patient Group Direction adrenaline epinephrine suspected
	anaphylactic

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: Completed: Approved: Amended and	November 2023 January 2024 February 2024 (published – April 2024)
	Amended and re-authorised:	

Patient Group Direction For Use Within NHS Grampian

Organisational Authorisations

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

PGD Developed/Reviewed by;

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Approved and authorised for use within NHSG by;

Medicines Guidelines and Policies Group Chair	Signature	Date Signed
Lesley Coyle		19/04/2024
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Management and Monitoring of Patient Group Direction

Title:

PGD Consultative Group

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

Name:

Jodie Allan	Lead Author: Medicines Management Specialist Nurse
Anne Marshall	Pharmacist: Community Pharmacist
Dr Fiona Warrick	Medical Practitioner: Consultant Anaesthetist and Clinical Lead
	for Resuscitation Team
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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</u> (BNF), <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 <u>Appendix 3</u> for the Airway, B reathing, C irculation, D isability and E xposure (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 <u>Appendix 4</u> 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, vaccination centres, individual's own houses and other community settings. Prior to the administration of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current NHSG consent policy.
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. Individuals for whom no valid consent has been received.
Precautions and special warnings	There are no absolute contraindications to treatment as this product is intended for use in life threatening emergencies
Special warnings	 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. Medical advice must be sought – refer to relevant medical practitioner. 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. Inform/refer to the relevant medical practitioner if individual/parent/carer declines treatment. Document that the administration was declined, the reason and advice given in appropriate clinical records.

Description of treatment available under the PGD

Name form and strength of medicine	Adrenaline (epinephrine) 1mg/1mL (1 in 1,000) solution for injection ampoules.
	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) auto-injector.
	Adrenaline (epinephrine) 300micrograms (single dose) (1 in 1,000) solution for injection (pre-filled syringe) auto-injector.
	Adrenaline (epinephrine) 150micrograms (single dose) (1 in 1,000) solution for injection (pre-filled syringe) auto-injector.
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.

Is the use out with the SmPC?	N/A		
Dosage/Maximum total dose	Adults - 500micrograms (0.5mL) of adrenaline (epinephrine) 1 in 1,000 (1mg/mL).		
	Table reference - Emergency Treatment of Anaphylactic Reactions. (2021). 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
	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)
	*Give 300 micro prepubertal	ograms IM (0.3mL) in a	child who is small or
	Infants and Children - The scientific basis for the recommended doses is weak. The recommended doses a based on what is considered to be safe and practical to drup and inject in an emergency.		commended doses are
re	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) this dose is still appropriate to use.		healthcare providers
	Maximum number of doses: No limit – (determined by individual response) (see <u>table above</u> for dosing information). 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.		
		nformation, refer to the cy Treatment of Anaphy	Resuscitation Council lactic Reactions (2021).

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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.	
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).	
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.	
Additional Information	N/A	
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)	 Advise individual/parent/carer what to expect and of the possible side effects and their management. 	

	 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. If serious adverse or persistent effects occur, the individual/parent/carer should be advised to contact their GP/Accident and Emergency department/NHS24. Individuals/carers should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the <u>Yellow</u> <u>Card reporting scheme</u>.
Advice (Written)	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual/parent/carer. 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. Document in accordance with locally agreed procedures in the individual's record	
	individual's record. Report any suspected adverse reactions using the Yellow Card System. <u>Yellow Card Scheme - MHRA</u>	
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 Competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions 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 and authorised by name as an approved person to work under the terms of the PGD.
Ongoing training and competency	 All professionals working under this PGD must: Have undertaken NoS PGD module training on <u>TURAS</u> Learn Have attended basic life support training either face to face or online and 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. Note: All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the medicine. If any training needs are identified these should be discussed with those responsible for authorisation to act under the PGD

	 Have knowledge and familiarity of the following; <u>SmPC</u> for the medicine(s) to be administered in accordance with this PGD.
Responsibilities of professional	Professional manager(s) will be responsible for;
manager(s)	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	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 (<u>Appendix 1</u>).
	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 must be completed to allow audit of practice.

An electronic/HEPMA record of the screening and subsequent administration, or not of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic/HEPMA recording processes.
If a paper record is used for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this PGD. 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 anatomical site where appropriate for injectable medicines) of the medicine(s) 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, and who undertook the assessment of the individual's clinical suitability for the administration/supply of the medicine Record of any adverse effects and the actions taken (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.
Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate:
 BadgerNet – Digital Maternity Notes Child Health Information Services if appropriate Hand–held records such as red book if appropriate Individual's GP records if appropriate Secondary Care Medical Notes HEPMA
Occupational health systemsIndividual service specific systems.

	Local policy should be followed with respect to sharing information with the individual's General Practitioner.			
	All records should be clear, legible and contemporaneous and in an easily retrievable format.			
	All serious adverse events related reported to the MHRA via the Yello website at <u>https://yellowcard.mhra.</u>	w Card Sch		
Audit	All records of the medicine(s) 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	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)	24/09/19	09/11/23	
	Adrenaline (epinephrine) 1mg/1mL Injection (1 in 1,000) for Anaphylaxis (glass prefilled syringe) (Martindale)	13/02/20	09/11/23	
	Adrenaline (epinephrine) 500micrograms (single dose) (1 in 1,000) solution for injection (pre-filled syringe) auto-injector. (Emerade)	01/03/22	09/11/23	
	Adrenaline (epinephrine) 300micrograms (single dose) (1 in 1,000) solution for injection (pre-filled syringe) auto-injector. (Emerade)	20/01/20	09/11/23	
	Adrenaline (epinephrine) 150micrograms (single dose) (1 in 1,000) solution for injection (pre-filled syringe) auto-injector. (Emerade)	20/01/20	09/11/23	

British National Formulary and British National Formulary for Children <u>https://about.medicinescomplete.com/</u> accessed 09/11/23.
Resuscitation Council (UK) Emergency treatment of anaphylaxis: Guidelines for healthcare providers, May 2021. <u>https://www.resus.org.uk/media/337/download</u>



Appendix 1

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

Working within: e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Administration Of Adrenaline (Epinephrine) In Cases Of Suspected Anaphylactic Reactions By Approved Healthcare Professionals Working Within NHS Grampian – Version 7

I have completed the appropriate training to my professional standards enabling me to administer the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed:	
Print Name:	
Date:	
Dale.	
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 they are 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 they understand and are 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 their individual code of professional practice and conduct.

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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

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			Version /		
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).

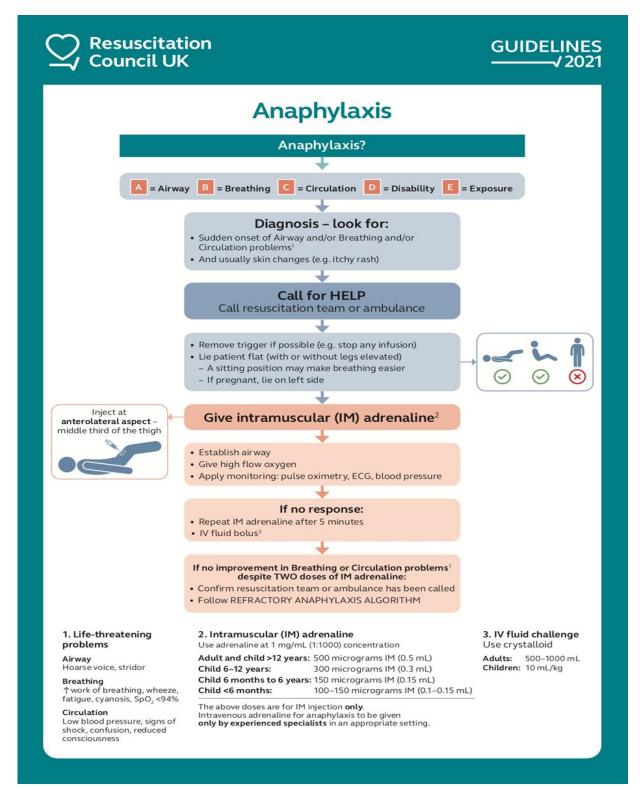
Exposure

- 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



- 18 -Review Date: February 2026 Identifier: MGPG/PGD/Adrenaline/1477 PGD For The Administration Of Adrenaline (Epinephrine) In Cases Of Suspected Anaphylactic Reactions – Version 7 Template NHSG v9