Gibraltar Health Authority

PATIENT GROUP DIRECTION

Issued Under Part 2 of the Medicines (Prescriptions Only) Regulations, 1987 by the Director of Public Health with the consent of the Minister for

ADRENALINE (EPINEPHRINE)

LEGAL STATEMENT			
Protocol Issuer	Director of Public Health Gibraltar Health Authority St. Bernard's Hospital Gibraltar Contact Telephone: +(350) 20079160		
Date effective	11th April 2025		
Date of expiry	11th April 2027		
Staff characteristics	See below (section 1)		
Professional Authorisation		SIGNATURE	DATE
Lead Doctor	Dr Helen Carter Director of Public Health [1]		
In Consultation with		SIGNATURE	DATE
Lead Pharmacist	Ms Melanie Gordon Chief Pharmacist		
Lead Nurse	Ms Sandra Gracia Director of Nursing		
Legal Authorisation		SIGNATURE	DATE
With the consent of Minister	The Honourable Minister for Health Gemma Arias-Vasquez[2] MP		

[1] A Patient Group Direction issued shall only have effect if it is signed by the Director of Public Health with the consent of the Minister.

[2] See footnote 1.

1. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses or midwives currently registered with the Gibraltar Nursing Registration Board (GNRB) • practitioners currently registered with the Gibraltar Medical Registration Board (GMRB) Anyone deemed by the Director of Public Health to be competent who meets the additional requirements below
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the 'Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, obtain informed consent (or 'best interests' decision in accordance with the Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016) and to discuss issues related to vaccination. • must be competent in the handling and storage of vaccines, and management of the cold chain • must be competent in the recognition and management of anaphylaxis • must have access to the PGD and associated online resources **IMMEDIATE ACCESS TO OXYGEN IS NOT A NECESSITY** • should fulfil any additional requirements defined by local policy **THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT**

Continued training requirements	• Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). • Practitioners should be constantly alert to any subsequent recommendations from the GHA, UKHSA and/or NHS England and NHS Improvement and other sources of medicines information. **Note:** The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	This Patient Group Directive (PGD) will authorise all qualified health professionals to administer adrenaline (Epinephrine) by intramuscular injection (IM) to patients suffering from suspected hypersensitivity and anaphylactic reactions. Patient groups 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 British National Formulary (BNF), British National Formulary for Children (BNFC), individual Summary of product Characteristics (SPC) and the Resuscitation Council (UK) Anaphylaxis Guidelines.

Criteria for inclusion	Administration of IM adrenaline (epinephrine) should be considered for individuals who shoe signs and symptoms of an anaphylactic reaction. Medical advice must be sought as soon as possible from a doctor if any individual develops and 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 according to GHA procedure, or seek urgent medical advice. Anaphylaxis is likely when all of the following three criteria's are met: • Sudden onset and rapid progression of symptoms. • Life threatening AIRWAY and BREATHING and/or Circulation problems.

	• Skin and/or mucosal changes (flushing, urticarial, angioedema). (only 20% will experience cutaneous changes). **NOTE: 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 http://www.resus.org.uk/EasySiteWeb?GatewayLink.aspx?alId=824 And Appendix 1 for the Airway, Breathing, Circulation, Disability and Exposure (ABCDE) approach to assess and treat a patient which should be followed, as patients can have an airway, breathing or circulation problem or any combination which is life threatening. See Appendix 2 for an anaphylaxis algorithm (adapted from the Resuscitation Council (UK) – Anaphylaxis Algorithm March 2008) Patients 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). • Patients receiving care in the community, including minor injury units, GP practices, Health Centres, clinics, schools, pharmacies, patient's own houses and other community settings.

Criteria for exclusion[3]	• Previous allergy to adrenaline (if known about) • Other contra-indications are relative, as adrenaline is being administered in an emergency situation. • Patient declines treatment. **MANAGEMENT OF EXCLUDED PATIENTS** Call 999 Emergency ambulance services and/or refer to the doctor as appropriate. If within the acute hospital setting dial according to GHA procedure, or seek urgent medical advice. Ensure all actions/decisions are documented. The reason why the patient was excluded under the PGD will be documented in the patient's medical notes.

[3] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

Cautions including any relevant action to be taken	Current guidance: Emergency Treatment of Anaphylactic Reactions, Resuscitation Council (UK) January 2008, annotated with links to NICE guidance July 2012, is to monitor the response, start with a safe dose and give further doses if a greater response is needed, i.e. titrate the dose according to effect. **IMMEDIATE ACCESS TO OXYGEN IS NOT A NECESSITY UNDER THIS PGD. BASIC LIFE SUPPORT AND CALLING EMERGENCY SERVICES IS SUFFICIENTFOR IMMEDIATE RESUSCITATIN.**

Action to be taken if the patient is excluded	Call 999 Emergency Ambulance services and/or refer to the doctor as appropriate. If within the acute hospital setting dial according to GHA procedure, or seek urgent medical advice. Ensure all actions/decisions are documented. The reason why the patient was excluded under the PGD will be documented in the patients medical notes.

Action to be taken if the patient or carer declines treatment	Not considered likely however; Call 999 Emergency Ambulance services and/or refer to doctor as appropriate. If within the acute hospital setting dial according to GHA procedure, or seek urgent medical advice. Ensure all actions/decisions are documented.
Arrangements for referral for medical advice	As per local GHA policy

3. Description of treatment

Name, strength & formulation of drug	Adrenaline/Epinephrine (1 in 1000) • Adrenaline (epinephrine) 1mg/1ml (1 in 1,000) solution for injection ampoules. • Adrenaline (epinephrine) 500mcg/0.5ml (1 in 1,000) solution for injection ampoules. • Adrenaline (epinephrine) 500mcg (single dose) (1 in 1,000) solution for injection (pre-filled syringe) auto-injector. • Adrenaline (epinephrine) 300mcg (single dose) (1 in 1,000) solution for injection (pre-filled syringe) auto-injector. • Adrenaline (epinephrine) 150mcg (single dose) (1 in 1,000) solution for injection (pre-filled syringe) auto-injector.
Legal category	Prescription only medicine (POM)
Black triangle	No
Route / method of administration	Intra-muscular (IM) injection (preferably mid-point in anterolateral thigh).

<table>
<tr>
<td>Dose and frequency of administration</td>
<td>
Non-proprietary adrenaline
Adults- 500mcg (0.5ml) of adrenaline (epinephrine) 1 in 1,000 (1mg/ml).

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.

Table reference- Emergency Treatment of Anaphylactic Reactions. (2008). Resuscitation Council (UK)

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.

<table>
<tr><th>Age</th><th>Dose of Adrenaline</th><th>Volume of 1 in 1,000 (1mg/ml) solution</th></tr>
<tr><td>Under 6 years</td><td>150mcg IM</td><td>0.15ml</td></tr>
<tr><td>6-12 years</td><td>300mcg IM</td><td>0.3ml</td></tr>
<tr><td>Over 12 years</td><td>500mcg IM

(300mcg IM if the patient is small or pre-pubertal)</td><td>0.5ml

(0.3ml)</td></tr>
</table>

If an adrenaline auto-injector is the only available adrenaline preparation when treating anaphylaxis, healthcare providers should use it. N.B. some adult auto-injectors can only contain 300mcg (3.0ml)

Maximum number of treatments: No limit_ (determined by patient response) *Repeat the IM adrenaline dose if there is no improvement in the patients condition. Further doses can be given at about 5-minute intervals according to the patient’s response.

*For additional information, refer to the Resuscitation Council (UK) Emergency Treatment of Anaphylactic Reactions (2008).
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<tr>
<td>Storage</td>
<td>Store at less than 25°C and protect from light. DO NOT FREEZE.</td>
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<tr>
<td>Disposal</td>
<td>Follow local clinical waste policy and GHA/NHS standard operating procedures and ensure safe and secure waste disposal.

Equipment used including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely and securely according to local GHA arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).</td>
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Drug interactions	There are no absolute contraindications to the administration of the adrenaline under this PGD with any concurrent medication, as adrenaline is intended for use in a life-threatening emergency. However, there is a 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 a greater response is needed. This approach will therefore allow the management of any effects of interacting drugs, e.g. tricycle antidepressants, cardiac glycosides. Non selective beta blockers- patients taking these may not respond to the adrenaline injection and may require intravenous salbutamol or aminophylline, however this would be prescribed by a medical practitioner.
Adverse effects	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 patient and 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. This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SPC for details of all potential adverse reactions. BNF/BNFC: http://www.medicinescomplete.com/mc/bnf/current/ http://www.medicinescomplete.com/mc/bnfc/current/ SPCs/PILs: http://www.medicines.org.uk/emc/ http://www.mhra.gov.uk/spc-pil/index.htm
Reporting procedure of adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store and send a copy of the Yellow card to the Director of Public Health. Any adverse reaction to a vaccine should also be documented in the individual's record and the individual's GP should be informed.

	INFORM GIBRALTAR DIRECTOR OF PUBLIC HEALTH IMMEDIATELY IF SEVERE ADVERSE REACTION IS SUSPECTED
Information to be given to patient or carer	If conscious, prior to the administration of adrenaline (epinephrine) the patient 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 to help reverse the reaction. The patient information leaflet contained in the medicine(s) should be made accessible to the patient, parent, guardian, or person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. Copies of the Patient Information Leaflets and SPCs for all medicines can be found at http://www.medicines.org.uk or http://www.mhra.gov.uk/spc-pil/index.htm
Patient advice / follow up treatment	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, patients in the community or those attending clinics/health centres need to be transferred to a hospital. The medical practitioner in charge of the patients care should be informed.

Records	An electronic and/or paper record for the administration of the drug specified in this PGD must be completed in order to allow audit of practice. This should include: • that valid informed consent was given or a decision to administer made in the individual's best interests in accordance with the Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016 • Name and address of patient. • Patient GHA No and date of birth.

	• Details of parent/guardian, or person with parental responsibility where applicable. • Consultant/General Practitioner details. • Risk group, if appropriate. • Findings of physical examination, if appropriate. • Exclusion criteria, record why drug not administered. • Reason for giving. • Consent to the administration (if not obtained elsewhere). • Drug manufacturer, batch number and expiry date. • Site where drug administered, dose and route of administration. • Signature and name in capital letters of practitioner who administered the drug. • Date drug given. • Record of any adverse effects (advice patients doctor). A record of administration must be made. This can either be done electronically or into the patients case notes or an out-patient report form completed giving full details of the incident and the treatment given. The incident must always be reported to the medical practitioner in charge of the patients care. The health professional involved must ensure that the use of the drug specified in this PGD is recorded appropriately and reported to the appropriate manager. If the anaphylactic reaction was caused by a drug/medication being administered to a patient, the event should be recorded on Datix, where this available. The event should also be recorded on a Document of Resuscitation Form and then filed in the patients medical records. 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. These records should be retained: **For children and young people**, retain until the patients 25th birthday or 26th if the young person was 17 years old at the conclusion of treatment. **For 17 years and over,** retain for 6 years after last date of entry, for 3 years after death, or in accordance with GHA policy, where this is greater than above.

Key references	Electronic Medicines Compendium http://www.medicines.org.uk British National Formulary current online version http://www.medicinescomplete.com/mc/bnf/current/ British National Formulary for Children current online version http://www.medicinescomplete.com/mc/bnfc/current/ Resuscitation Council (UK) guidelines http://www.resus.org.uk/

5. Practitioner authorisation sheet

Adrenaline/Epinephrine (1 in 1000):
PGD valid from 11th April 2025 until 11th April 2027

Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

Practitioner

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of the **GHA** for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.