University Hospitals of Derby and Burton
NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration of NALOXONE INTRAMUSCULAR INJECTION in a non-medical setting

By Registered Nurses, Emergency Nurse Practitioners (ENP), Emergency Care Practitioners (ECP) and Emergency Physiotherapy Practitioners (EPP) In Minor Injuries departments at Samuel Johnson and Sir Robert Peel community hospitals

Documentation details

Reference no:	UHDB245
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Change history

Version number	Change details	Date

Glossary

Abbreviation	Definition

1. PGD template development (PGD Working Group)

PGD Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who can work under a PGD, or manages the staff who do). If this is a review of existing PGD, replace previous names with the individuals involved for this version

Name	Designation
Dr Venkat Thungala	Doctor
James Kerr	Pharmacist
Alannah Davies	Representative of RNMHP Group

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

Name of antimicrobial pharmacist	Designation	Date Reviewed
n/a	n/a	n/a

2. Organisational authorisations

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

University Hospitals of Derby & Burton NHS Foundation Trust authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
Minor Injuries departments at Samuel Johnson and Sir Robert Peel community hospitals
Limitations to authorisation
The dosing regimen in this PGD is only suitable for use in a non-medical setting (in the absence of an immediately-available medical* prescriber). The doing is consistent with BNF advice in this scenario. Prescribers are preferred when available as there can be a judgment on the most appropriate dose regimen ('High' or 'Low' regimens as per BNF or following UHDB guidelines). A non-medical prescriber with training/experience in emergency treatment of opioid overdose would also be preferential to using this PGD to ensure dose tailored to specific patient need.

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	James Hooley	**Signed copy held in Pharmacy**	**26/05/2023**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Divisional Pharmacist *Clinical Pharmacist from PGD working group*	James Kerr	**Signed copy held in Pharmacy**	**04/05/2023**
Consultant *Doctor*	Dr Venkat Thungala	**Signed copy held in Pharmacy**	**23/05/2023**
Interim Matron Acute Medicine QHB *Registered Professional representing users of the PGD*	Danielle Murphy	**Signed copy held in Pharmacy**	**26/04/2023**

Local enquiries regarding the use of this PGD may be directed to UHDB.PGDgovernance@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered professional with current professional registration operating within their usual scope of practice. Must be a profession permitted by current legislation to practice under a patient group direction.
Initial training	- Completion of all Essential-to-role training as outlined in the UHDB PGD policy. - Individual has read and understood full content of this PGD and signed authorisation (section 7) - Completion of Medicines Management Drug Assessment - Deemed competent by their line manager to undertake the clinical assessment of a patient leading to a diagnosis that requires treatment according to the indications listed in this PGD.
Competency assessment	Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.
Ongoing training and competency	- Annual Medicines Safety Training (essential to role) - Review/repeat initial training above when this PGD is revised - The registered healthcare practitioner will ensure Anaphylaxis/CPR training is kept updated yearly. - The registered healthcare professional must actively take part in CPD and annual individual performance reviews. - Regular training and updating in safeguarding children and vulnerable adults as per trust policy
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	• Acute opioid overdose in a non-medical setting
Criteria for inclusion	• History or evidence of suspicion of opioid poisoning/overdose in patients over 16 years of age only, before 999 ambulance transfer to A&E as indicated by: - Pinpoint pupils - Respiratory depression - Reduced level of consciousness *N.B. Use in pregnancy is not prohibited but use only if potential benefit outweighs risk – consider exclusions and cautions below*
Criteria for exclusion	• Children under 16 years of age • Patient with known hypersensitivity to naloxone • Patients who have received longer term opioid/opiate treatment (i.e. receiving palliative care/treatment of chronic pain • Patients who are physically dependant on opioid/opiates
Cautions including any relevant action to be taken	• Dial (9) 999 for emergency transfer or call 2222 for resuscitation team • Immediate resuscitation support must be available • Continuous monitoring as soon as possible (Pulse, blood pressure, ECG, pulse oximetry) • Naloxone must be given with caution to patients who have received high doses of opioids or are physically dependent on opioids. Too rapid reversal of the opioid effect can cause an acute withdrawal syndrome in such patients. Hypertension, cardiac arrhythmias, pulmonary oedema and cardiac arrest have been described. • Patients who respond satisfactorily to naloxone hydrochloride must be closely monitored. The effect of opioids can be longer than the effect of naloxone hydrochloride and further doses may be necessary. • Naloxone hydrochloride is not effective in central depression caused by agents other than opioids. Reversal of buprenorphine-induced respiratory depression may be incomplete. If an incomplete response occurs respiration should be mechanically assisted hence need for urgent referral as below.
Action to be taken if the patient is excluded	• ***Dial 9-999 for URGENT transfer to A&E***
Action to be taken if the patient or carer declines treatment	• Discuss urgent need for treatment • Document advice given • Advise patient on alternative treatment
Arrangements for referral for medical advice	• Dial 9 999 immediately for urgent transfer to emergency department from MIU

5. Description of treatment

Name, strength & formulation of drug	Naloxone 400micrograms/1ml Intramuscular Injection
Legal category	POM
Route / method of administration	**Intramuscular Injection (IM)** to be injected into deltoid region or anterolateral thigh.
Indicate any off-label use (if relevant)	*None*
Dose and frequency of administration	**As per limitation to this PGD detailed above. This dosing regimen is suitable for use in a non-medical setting in the absence of an immediately-available medical prescriber (or suitably trained non-medical prescriber):** 400 micrograms every 2–3 minutes, each dose given in subsequent resuscitation cycles if patient not breathing normally, continue until consciousness regained, breathing normally, medical assistance available, or contents of syringe used up; to be injected into deltoid region or anterolateral thigh. BNF Online accessed at https://www.medicinescomplete.com/#/content/bnf/_953600571?hspl=Naloxone#content%2Fbnf%2F_953600571%23pot-prescribingAndDispensingInformation
Duration of treatment	STAT
Quantity to be supplied (leave blank if PGD is administration ONLY)	*n/a*
Storage	Store below 25°C and protect from light. Do not refrigerate or freeze. Keep the ampoules in the outer carton in order to protect from light. Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: *Available from the electronic Medicines Compendium website accessed:* *https://www.medicines.org.uk/emc/product/6344/smpc#gref* *Accessed on 14/12/21*
Drug interactions	Doses used in acute opioid overdose may not be appropriate when there is risk of acute withdrawal (e.g. chronic opioid use), or when a continued therapeutic effect is required (e.g. postoperative use, palliative care).
Adverse reactions	• Common or very common Arrhythmias; dizziness; headache; hypertension; hypotension; nausea; vomiting

	• Uncommon Diarrhoea; dry mouth; hyperhidrosis; hyperventilation; tremor • Rare or very rare Cardiac arrest; erythema multiforme; pulmonary oedema
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use.
Written information to be given to patient or carer	Give marketing authorisation holder's patient information leaflet (PIL) provided with the product.
Patient advice / follow up treatment	• Reassure patient • Dial 9 999 for urgent transfer to acute hospital setting for further treatment and observation due to risk of respiratory depression • Monitor BP, ECG, Pulse oximetry • If required, commence CPR
Records	Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following: • name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • name of registered health professional • name of medication supplied/administered • date of supply/administration • dose, form and route of supply/administration • quantity supplied/administered • batch number and expiry date (if applicable e.g. injections and implants) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • Confirm whether supplied and/or administered and that this was done via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled e-records). All records should be clear, legible and contemporaneous. If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals receiving treatment under this PGD should also be in the clinical area for audit purposes as per UHDB PGD policy.

6. Key references

Key references	• *Electronic Medicines Compendium: Available at: https://www.medicines.org.uk/emc/product/6344/smpc#CONTRAINDICATIONS, Accessed 6/12/21* • *Electronic BNF, Available at:* https://www.medicinescomplete.com/#/content/bnf/_953600571?hspl=Naloxone#content%2Fbnf%2F_953600571%23pot-prescribingAndDispensingInformation *Accessed 6/12/21* • *NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2* • *https://medusa.wales.nhs.uk*

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7. Registered health professional authorisation sheet

PGD Name [version]: MIU SJCH and SRP – Naloxone Intramuscular Injection [v1]
PGD ref: UHDB245

Valid from: 26/05/2023 **Expiry date: 25/05/2026**

Before signing check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read MUST match this authorisation form.

Registered health professional
By signing this patient group direction you are indicating that

a) You agree to and understand all content and commit to only work within this framework.
b) You have completed any core PGD e-Learning or training records on My Learning Passport or within your department.
c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this PGD.

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 / Assessor

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of University Hospitals of Derby & Burton NHS Foundation Trust 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 registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet must be retained by a manager in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD.