University Hospitals Bristol and Weston NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply/Administration of naloxone for the treatment of opioid overdose

Documentation details

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Change history

Version number	Change details	Date
2.0	New template	03/12/2020

Glossary

Abbreviation	Definition
BRI	Bristol Royal Infirmary
ED	Emergency Department
HCPC	Health and Care Professions Council
NMC	Nursing and Midwifery Council
UHBW	University Hospitals Bristol and Weston NHS Foundation Trust

1. PGD template development

Developed by:	Name	Date
Pharmacist	[redacted]	09.10.2023
Doctor	[redacted]	
Registered Professional representing users of the PGD	[redacted]	

PGD Working Group Membership

Name	Designation
[redacted]	Drug Specialist Nurse BRI
[redacted]	Charge Nurse, Emergency Department
[redacted]	Consultant Physician, ED, BRI
[redacted]	Medicines Information Pharmacist

2. Organisational authorisations

UNIVERSITY HOSPITALS BRISTOL AND WESTON authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
UHBW Specialist Drug Team and Adult ED BRI
Limitations to authorisation

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Senior Consultant Physician	[redacted]		
Deputy Chief Nurse	[redacted]		
Chief Pharmacist	[redacted]		

Local enquiries regarding the use of this PGD may be directed to [redacted]

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD. Alternative authorisation sheets/templates may be used where appropriate in accordance with local policy.

3. Characteristics of staff

Qualifications and professional registration	Nurses with current NMC registration employed by UHBW and currently working within the Drug Specialist Team at the BRI or Adult Emergency department (ED) registered nurses involved in the Take home Naloxone Interventions Study (TIME) Or Adult Emergency Department (ED) Paramedics registered with the HCPC. -
Initial training	• Have completed the UHBW Trust learning package for PGDs. • Have the competencies to undertake the clinical assessment of patients leading to diagnosis that requires treatment according to the indications listed in this PGD. • Have read and understood the PGD and have the competencies for supplying and administering medicines for this specific PGD. • Have a full understanding of the process for supplying, administering and recording of drugs issued under a PGD. • Have demonstrable, detailed knowledge of the drug being supplied or administered. Additionally, the minimum requirement for staff is: • SMMGP online e-learning https://www.smmgpelearning.org.uk/course/index.php?categoryid=2 • ROADS Overdose Awareness and Use of Naloxone Training. • All staff must be signed off as competent by the service Naloxone Lead, or relevant manager. The Naloxone Lead will be responsible for keeping a register of staff and volunteers appropriately trained in supply of naloxone.
Competency assessment	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	The practitioner must be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up to date with continued professional development.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and the Medicines Code	

4. Clinical condition or situation to which this PGD applies.

Clinical condition or situation to which this PGD applies	For use in adult clients over the age of the 18 years for the treatment of coma or respiratory depression (bradypnoea) due to actual or suspected overdose due to an opioid substance, to reverse the action of opioids such as heroin, methadone, morphine (incl. MST®), pethidine, dihydrocodeine (DF118) or buprenorphine (Temgesic®, Subutex®). It does not matter which opioid was taken or whether it was legal or not.
Criteria for inclusion Use BNF/BNFC/SPC. Take into account any clinical guidelines or policies that are available locally or nationally, e.g. BASHH/NICE/JCVI	For use in clients 18 years and over who meet the following criteria: (1) Opioid dependent adult clients who admit opiate use and are therefore at risk of overdose. And/or (2) Opioid dependent adult clients , friends and relatives who are not already in receipt of an emergency supply of Naloxone through a prescription, but where this would constitute normal practice as part of the care pathway. Client must receive advice and support about overdose treatment with Naloxone including an appropriate leaflet, (provided by drug agency)
Criteria for exclusion	Clients aged under 18 years of age: Any patient under this age must be referred to the Young Peoples Drug & Alcohol services. Naloxone Injection should not be given to patients who are known to be hypersensitive to the drug or any of the ingredients. when it is unclear if Naloxone injection forms part of the care pathway for the client, and the use of Naloxone injections has not been discussed with the client and/or s/he has not received advice or support about the use of Naloxone, or assessment of suitability or competence. Client is pregnant or breast-feeding. These patients should be referred to the Medic in charge.
Cautions including any relevant action to be taken	• Naloxone should be used with caution in patients with pre-existing cardiac disease or patients who have received medications with potential adverse cardiovascular effects, such as hypotension, ventricular tachycardia or fibrillation and pulmonary oedema. • Caution in patients with liver cirrhosis [a small study showed naloxone concentrations to be approximately 6 times higher - SPC] • These patients should be referred to the Medic in charge. Note: • Physical dependence on opioids – naloxone may precipitate

	withdrawal (see symptoms under adverse effects) • Naloxone is not effective against respiratory depression caused by non-opioid drugs. Reversal of buprenorphine-induced respiratory depression may be incomplete. If an incomplete response occurs, respiration should be mechanically assisted.
Action to be taken if the patient is excluded	• Advise that they should contact the community service about prescription of a supply of Naloxone injection.
Action to be taken if the patient or carer declines treatment	• If appropriate, acknowledge the client's right to decline treatment under this PGD, ensuring they understand the risks involved in delaying treatment and the alternative treatments available. • document refusal
Arrangements for referral for medical advice	Refer to the appropriate medical practitioner–

5. Description of treatment

Name, strength & formulation of drug	Naloxone hydrochloride injection as 1mg/1mL solution for injection prefilled syringe (2mL syringe)
Legal category	Prescription Only Medicine (POM) For Immediate use in emergency situation only
Route / method of administration	Intramuscular injection - to be injected into deltoid region or anterolateral thigh
Indicate any off-label use (if relevant)	N/A
Dose and frequency of administration	Inject 400 micrograms of naloxone injection using the pre-filled syringe.400 micrograms of naloxone may be repeated every 2 to 3 minutes until: the patient is breathing normally; or consciousness is regained; or the contents of a syringe are used up. The injection may need to be repeated more than once if the desired degree of improvement in respiratory function and level of consciousness is not obtained. Use once and discard any remaining solution after use.
Duration of treatment	For immediate use in emergency situation only
Quantity to be supplied	1 syringe
Storage	Stock must be securely stored in a locked cupboard according to organisation Medicines Code Do not store above 25°C. Store in the original container in order to protect from light.
Drug interactions	• No relevant interactions identified. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website:

	www.medicines.org.uk
Identification & management of adverse reactions	An ambulance should be called if opioid overdose is suspected, and naloxone is used. Paramedics will be able to assist with any adverse reactions. • Increased or decreased blood pressure • Dizziness • Headache • Arrhythmias • Ventricular tachycardia and fibrillation • Pulmonary oedema (has occurred in post-operative patients with pre-existing cardiac disease, hypertension, and patients receiving ß2 agonist therapy) • Hyperventilation • Opiate withdrawal symptoms e.g. nausea, vomiting, sweating, tremor, aggression Very rare: cardiac arrest (may also be caused by opioid toxicity itself) A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
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. • Report via Datix.
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	Provide client / relative / friend with information given on adverse reactions and show how to use the device. Provide client with a copy of consent form if under the care of the Drug Specialist Nurses. **Having identified an overdose:** 1. Call an ambulance 2. Give rescue breaths if the person is not breathing 3. Put them in the recovery position 4. Inject the initial recommended small amount of naloxone (usually 400 micrograms), wait (2-3 minutes). If unresponsive, inject another small amount. Repeat as necessary. 5. Stay with the person at least until the ambulance arrives

	6. After administration, place injection back in the outer packing and close. This forms its own crash box. Please hand the kit in to the paramedic for disposal. Those supplied with take home naloxone are advised that the dosage given (400 microgram) is sufficient to effect some clinical improvement in an individual with opioid toxicity but should not precipitate severe opioid withdrawal (in those with opioid dependence) or acute circulatory stress. Individuals who refuse to be transported to the ED should be monitored by the person who administered the naloxone and/or ambulance staff. Opioid toxicity may result in respiratory depression/arrest and cardiac arrest. In this situation CPR should be commenced until the individual's condition improves or an ambulance arrives. All patients with suspected or actual opioid overdose must be referred to emergency services. This is especially important with methadone in view of its very long duration of action. Patients who have received naloxone hydrochloride to reverse the effects of opioids should be warned to avoid driving ,operating machinery or engaging in other activities demanding physical or mental exertion for at least 24 hours, since the effect of the opioids may return. Clients to present to Bristol Drug Project (BDP) for further supply of naloxone if expires or has been used.
Records	Record: • that valid informed consent was given. • name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • name and signature of registered health professional • name of medication supplied/administered, batch number and expiry date. • dose, form and route of administration • quantity supplied/administered. • date and time of supply/administration • advice given, including advice given if excluded or declines treatment. • details of any adverse drug reactions and actions taken • supplied 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. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	• *Electronic Medicines Compendium http://www.medicines.org.uk/* • *Electronic BNF https://bnf.nice.org.uk/* • *Public Health England https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/669475/phetake-homenaloxoneforopioidoverdoseaug2017.pdf* • *NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2*

7. Registered health professional authorisation sheet

PGD257 Naloxone **Valid from:** **Expiry:**

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

Registered health professional

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 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 BRISTOL AND WESTON 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 should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

All UHBW PGDs can be accessed via the intranet at the following [redacted]

APPENDIX ONE:

Consent, Agreement and Data Collection Form for the Supply of Take-home Naloxone for use by the Drug Specialist Nurses

Complete this form when issuing take-home Naloxone Injection

Name:			
Service user / carer / family member / hostel worker / other (delete as appropriate)		DOB (service user only):	
Telephone:		Mobile:	
Address or Work Base:			
GP (Service user only):			

By signing the form I confirm that:

I have been given training in the dangers of opiate overdose, basic resuscitation and the appropriate intramuscular administration of Naloxone Injection	
I am aware of online naloxone Injection resources and have been advised to revisit them for a review	
I have been given printed guidance about naloxone Injection	
I am aware that naloxone Injection is to be administered in suspected opiate overdose only	
I am aware that the naloxone pre-filled syringe has an expiry date and that it will need to be replaced before that date	
I agree that my participation at the training and the issuing and use of naloxone Injection (naloxone hydrochloride) may be audited	
I confirm that I am to my knowledge not allergic to naloxone hydrochloride naloxone Injection	
I understand that all medicine should be kept in a safe place, i.e. out of reach of children	
I give permission for my details to be passed onto the Bristol Drugs Project	

Name	Signature	Date
Batch Number	Expiry date	Name recorded on label (tick)
Name of person supplying naloxone	Signature of person supplying naloxone	Date of issue recorded on label (tick)