Supply of Naloxone 2mg/2mL Injection to Patients or Nominated Representatives of a Named Patient or Staff Members Working for Services in Contact with People at Risk of Opioid Overdose
Protocol Number 373 version 5

Date protocol prepared: September 2016

Date protocol due for review: September 2018

This patient group direction must be signed by all health care professionals involved in its use. NHS Forth Valley should hold the original signed copy. The PGD must be easily accessible in the clinical setting.

Organisation	NHS Forth Valley

Job Title	Name	Signature	Date
Director of Nursing	Angela Wallace	Signed by Angela Wallace	3/11/16
Medical Director	Tracey Gillies	Signed by Tracey Gillies	3/11/16
Director of Pharmacy	Gail Caldwell	Signed by Gail Caldwell	4/11/16

This document authorises the supply of prefilled syringes of **naloxone hydrochloride injection for intramuscular use 2mg/2mL** by appropriately trained nurses and pharmacists to patients or nominated representatives of a named patient or staff members working for services in contact with people at risk of opioid overdose who meet the criteria for inclusion under the terms of the document.

Practitioners seeking to supply prefilled syringes of **naloxone hydrochloride injection for intramuscular use 2mg/2mL** must ensure that they assess all clients to make sure they meet the criteria before supplying the product.

The purpose of this Patient Group Direction is to help patients, by ensuring that they have ready access to a quality assured service which provides a timely, consistent and appropriate supply of prefilled syringes of **naloxone hydrochloride injection for intramuscular use 2mg/2mL.**

Signatures of those developing the Patient Group Direction

Job Title	Name	Signature	Date
Doctor	**Dr Claire McIntosh**	**Signed by Claire McIntosh**	**25/10/16**
Pharmacist	**Josef Elias**	**Signed by Josef Elias**	**2/11/16**
Nurse	**Tracy Coyle**	**Signed by Tracy Coyle**	**2/11/16**
Microbiologist (if appropriate)			
Paediatrician (if appropriate)			

Approval from Patient Group Directions Group

	Chair	Signed on behalf of group	Date
Patient Group Directions Group	**Gail Caldwell**	**Signed by Gail Caldwell**	**4/11/16**

Signature of **one** GP on behalf of Practice **OR** Head of Service **OR** Employer to indicate that other professionals may undertake the work within the confines of the Patient Group Direction

Name	Signature	Date

The following Patient Group Direction for the supply of naloxone 2mg/2mL injection to patients or nominated representatives of a patient or staff members working for services in contact with people at risk of opioid overdose may be used from the following business/practice:

Name:

Address:

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

CLINICAL CONDITION

Indication	To allow appropriately trained nurses and pharmacists to supply naloxone hydrochloride injection 2mg/2mL without a prescription in order to reduce the risk of fatality in named patients identified to be at risk of future opioid overdose.
Inclusion Criteria	Patients, aged 16 and over at risk of opioid overdose, who have demonstrated an awareness and understanding of the naloxone supply and related training programme (Heartstart Training programme or alternative locally approved training programme). Nominated representatives of a named patient who have demonstrated an awareness and understanding of the naloxone supply and related locally approved training programme (Heartstart Training programme or alternative locally approved training programme). Patient's named representatives are identified and confirmed by the patient. Patient consent for representatives to act on their behalf should be recorded. Members of staff working for services in contact with people at risk of opiate overdose who have demonstrated an awareness and understanding of the naloxone supply and related locally approved training programme (Heartstart Training programme or alternative locally approved training programme). Such supply should be in accordance with the Lord Advocate's Guidelines issued in March 2011.
Exclusion Criteria	Naloxone will not be supplied to patients, their nominated representatives or staff members who have not attended the approved course, except in exceptional circumstances determined at the discretion of the pharmacist or nurse making supply. Under 16 years of age. Patients with hypersensitivity to naloxone hydrochloride or to any

	of the excipients of this medicinal product. There are no exclusions from treatment where the risk of opiate overdose is suspected. Exclusion may result in the death of a patient. Where valid consent for supply is not obtained.
Caution/ Need for further advice	Refer to the SPC of Prenoxad inj. (http://www.medicines.org.uk) and current edition of the British National Formulary (BNF) for further information on cautions (http://www.bnf.org). Patients, their nominated representatives and staff members must understand the short acting nature of naloxone and an apparently successful outcome after injection of naloxone may be followed later by recurrence of an overdose state. They should be advised of the requirement to contact the emergency services wherever opioid overdose is suspected. Naloxone may affect the foetus in pregnant women and should be used with caution. The requirement for naloxone and the risk of death to the patient needs to outweigh the possible risk to the foetus. Specialist training should be considered for pregnant drug users at risk of an opiate overdose. Naloxone may cause hypersensitivity reactions in a small number of susceptible individuals. Medical advice must be sought as soon as possible if a recipient develops any signs of hypersensitivity.
Action if patient declines or is excluded	It will be explained to the patient/nominated representative/staff member that if naloxone cannot be supplied under the requirements of the PGD, it cannot be supplied under the requirements of the FV ADP Naloxone Competency Framework either. Record the reason for the exclusion and any advice given. Patients/nominated representatives/staff members who are not eligible to receive a supply of naloxone may still attend courses. They should be advised of further opportunities to attend approved courses. The patient/nominated representative/staff member should be advised of the need to contact the emergency services at the earliest opportunity if they have identified someone showing signs of opioid overdose. Advice should be given on alternative strategies including harm reduction and overdose prevention. Advise patients on available treatment services.

DRUG DETAILS

Name, form & strength of medicine	Naloxone hydrochloride Prefilled syringe of naloxone injection for intramuscular use: 2mg/2mL Labelled in accordance with the POM requirements of the Medicines Act. (Supplied as a kit)
Legal Status	POM
Route/ Method	Intramuscular injection into the outer thigh muscle. May be administered through clothing if necessary. Must not be given by intradermal or intravenous injection.
Dosage	See SPC (http://www.medicines.org.uk) and http://www.naloxone.org.uk for details of dosing of naloxone inj. Recommended dose: • 0.4 ml (0.4 mg) intramuscularly into the outer thigh muscle or muscles of the upper arm, through clothing if necessary • can be repeated every 2-3 minutes, if necessary
Frequency	See above.
Duration of treatment	Immediate emergency treatment in advance of the arrival of emergency services. It is essential that when an opioid overdose is suspected, and naloxone administered, that the ambulance services are contacted immediately.
Maximum or minimum treatment period	Administration of immediate dose naloxone from prefilled syringe.
Quantity to Supply	One prefilled syringe of naloxone injection for intramuscular use: 2mg/2mL syringe.
Side Effects	Refer to the SPC (http://www.medicines.org.uk) and current edition of the British National Formulary (BNF) for further information on side effects (http://www.bnf.org). See section "Caution/Need for further advice" re. possible withdrawal effects that can be precipitated.Nausea is very common; dizziness, headache, ventricular tachycardia, hypotension, hypertension, and vomiting are common.All adverse reactions should be reported to the MHRA through the Yellow Card Scheme. Yellow cards, guidance and information on adverse events are available in the current edition of the BNF (www.bnf.org).
Advice to patient/carer/staff member	Patient/nominated representative/staff member should be advised of the requirement to contact the emergency services by dialling on 999, wherever opioid overdose is suspected. Ensure the patient, patient's nominated representative or staff member is competent in basic life support as specified by the

	Naloxone Training Programme (see also http://www.naloxone.org.uk). Explain treatment and course of action. Information about quickly antagonising the opioid injection and the consequences. Information about the short acting nature of naloxone, approximately 20-minutes, and that it is imperative to call an ambulance. Give a copy of information leaflets: guidelines for administering naloxone 400 micrograms for opioid overdose and on basic life support procedures. Advise on safe storage and handling of the product: Store in a cool, dry place; protect from light; keep syringe in sealed outer container; use within expiry date on product. Advise on the safe disposal of needles following naloxone injection. (Individuals will be trained in safe storage and handling of the product and on the safe disposal of needles.) Advise on procedures to obtain resupplies of used, lost or expired naloxone.
Follow up	**Patient/ patient's nominated representative/ staff member:** Contact emergency services. Inform emergency services of doses given. Inform emergency services and service supplying naloxone if an adverse effect to naloxone is suspected. Return to service supplying naloxone to obtain further supply.

STAFF CHARACTERISTICS

Qualifications	Nurse with current appropriate registration, currently employed by NHS Forth Valley. Pharmacist with current appropriate registration, working within NHS Forth Valley.
Specialist competencies or Qualifications	Has undertaken appropriate approved training (Naloxone Programme Training), to carry out clinical assessment of patient leading to identification that the patient requires treatment according to the indications listed in the PGD. Attend training updates as appropriate. Has undertaken appropriate training for working under PGDs for the supply of medicines. Has undertaken training appropriate to this PGD.

Continuing Training & Education	Up to date knowledge in therapeutic area. The practitioner should be aware of any change to the recommendations for naloxone. It is the responsibility of the individual to keep up to date with continued professional development.

REFERRAL ARRANGEMENTS & AUDIT TRAIL

Referral arrangements	All opioid overdoses should involve contacting the emergency services.
Records/audit trail	Details of the PGD supply should be recorded: Patient's name, address, date of birth and gender. Agreement of Trust/Consent to Share form completed. Written patient consent for supply to a nominated representative should be recorded. Contact details of GP/ other relevant prescriber (if registered). Diagnosis. In the case of staff members working for services in contact with people at risk of opioid overdose, name of staff member and address of service should be recorded. Dose, form, expiry date and batch number of supply. Advice given including side effects and contraindications. Signature/ name of practitioner who supplied the medication. Date drug supplied. If appropriate, details of an adverse drug reaction and actions taken including documentation in the patient's medical record. Referral arrangements (including self-care). A computer or manual record of all patients (along with the patient's representative's name, if appropriate) and staff members working for services receiving naloxone under this PGD should be kept for audit purposes. Repeat supplies monitored from distribution sites. The GP or other relevant prescriber (where applicable) should be informed in writing.
Reference sources and comments	SPC - Summary of Product Characteristics BNF – British National Formulary National Training Manual for Naloxone Supply

PATIENT GROUP DIRECTION AUTHORISATION DOCUMENT

Patient Group Direction for Supply of Naloxone 2mg/2mls Protocol number 373 version 5

Name of Premises _____

Address of Premises_____

PROFESSIONAL AGREEMENT

I have read and confirm that I have understood the above named protocol. I confirm that I have the necessary competency and training. A copy of the protocol is available in the clinical situation in which the supply or administration will occur.

Name of Professional	Job Title	Signature	Date

The above people have been authorised to use this protocol

Signature of CHP Nurse Advisor/ Clinical Nurse Manager/ GP (for Practice Nurses) Professional Lead for PGDs pertaining to other professions

Name	Signature	Date