Background

In 2015 legislation was passed to allow the supply of naloxone, a Prescription only Medicine, without the need for a prescription or Patient Group Direction. The legislation is specific to services which provide drug treatment i.e. provide Opioid Replacement Therapy (ORT) or Injecting Equipment Provision (IEP).

This framework relates only to the supply of naloxone hydrochloride injection for lay administration and includes actions which must be followed. You must be authorised by name and have undertaken local naloxone supply competency framework training, under the current version of this framework to be able to issue supplies of Take Home Naloxone.

Authorisation to supply using this framework only allows supplies to be made under the framework as specified; supplies issued on prescription or by patient group directive (PGD) must be made by the appropriate professional.

What is naloxone?

Naloxone reverses the effects of opioid drugs such as methadone and heroin. In the event of a suspected opioid overdose it can temporarily reverse the effects of opioids by blocking the receptors in the brain where the opioids work for approximately 20-30 minutes. Naloxone does not remove opioids from the body, after this time the opioids can reattach and there is a risk that the overdose state could return.

Naloxone hydrochloride is used to reduce the risk of fatality in individuals identified to be at risk of future opioid overdose.

Naloxone has no psychoactive properties and has no intoxicating effects or dependence potential.

Who can receive a supply of naloxone?

- People at risk of opioids overdose, their friends and carers and workers who have regular contact with people at risk
- Individuals aged 16 years and over as defined by local Health Board or Alcohol Drug Partnership (ADP) area.
- All individuals receiving a supply of naloxone must be able to demonstrate a basic awareness of opioid overdose, basic life-support and naloxone use.
- There are no exclusions from administering naloxone where the risk of opioid overdose is suspected as failure to administer naloxone may result in the death of

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an individual. There is legislation in place which allows administration of naloxone by any person where opioid overdose is suspected.

Who cannot receive a supply of naloxone?

- Individuals who are under 16 years of age.
- Individuals who are unable to demonstrate sufficient knowledge on the use of naloxone to be safely given a supply.
- Individuals who have not consented to receiving a supply.
- Individuals with a known allergy to naloxone.

Action to be taken if an individual cannot receive a supply

- Explain that naloxone can only be provided at this stage under the requirements of the framework.
- Advice should be given on alternative treatment strategies including harm reduction and overdose prevention.
- Advise the individual to dial 999 in the event of a suspected opioid overdose.
- Refer to an appropriate healthcare professional and/or advise on available treatment services if appropriate.
- Record any action.

Supply/Resupply Details

Individuals should be issued with a take home pack of naloxone hydrochloride 2mg/2ml Pre-filled Syringe for Injection. This will be in the form of **Prenoxad® Injection**. Always ensure Prenoxad® is the product supplied as generic versions do not contain needles or the appropriate information leaflet and would be unable to be used in an emergency.

Individuals at risk of future opioid overdose can receive:

- One prefilled syringe Naloxone injection for intramuscular use: 2mg / 2ml syringe (Prenoxad ®).
- One additional prefilled syringe may be issued to the individual to hold as a spare supply if required.

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Individuals identified as family members or carers of someone at risk of future opioid overdose can receive:

 One prefilled syringe Naloxone injection for intramuscular use: 2mg / 2ml syringe (Prenoxad®).

Services in contact with those at risk of opioid overdose can receive:

 An appropriate number of kits for the size and activity of the service. Care Inspectorate guidance should be followed.

Dosage

One dose (containing 0.4mg in 0.4mls) of injection solution is to be injected into the outer thigh muscle. There are five doses in each syringe. If there is no response after 2-3 minutes a further dose should be administered. This should be repeated until either:

- 1. The person regains consciousness or
- 2. All 5 doses have been used or
- 3. The emergency services arrive and take over

The number of doses required will depend on individual need and response to treatment.

Side Effects

As with other types of medicines, naloxone can cause side effects such as:

Very Common

Very rare

- Feeling sick
- Being sick, dizziness, headache, fast heart beat, increased blood pressure
- Sweating, tremor, decreased or irregular heart rhythm, diarrhoea, faster or deeper breathing
- Fits
- Allergic reaction

Symptoms of withdrawal

Symptoms of withdrawal are commonly experienced when administering naloxone in opioid overdose. The individual should be reassured that these effects will be short lived as naloxone will begin to wear off after 20-30 minutes. They should be strongly advised against the use of additional substances which will increase the risk of a further overdose.

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Cautions for use of naloxone

There are no exclusions from administering naloxone where opioid overdose is suspected as not administering may result in the death of the person. However it is important to note the following cautions for use and reassure trainees of the appropriate course of action.

Naloxone may affect the foetus in pregnant women and may also cause issues for people with pre-existing cardiac disease. In overdose situations, the risk of death to the individual generally outweighs the associated risks.

Provision of the naloxone supply to individuals

All relevant details should be recorded on the appropriate database/<u>paperwork</u> including where known:

- Individual's name
- Address
- DOB
- Whether supply is to a person at risk, family/friend or worker
- First supply, spare supply or repeat supply, including the reason for repeat e.g. used for overdose, lost or damaged kit.
- Dose and form (Naloxone 2mg in pre filled syringe for injection 2mg/2ml). This is pre printed on the naloxone audit form.
- Details of staff member(s) providing the training/supply and the service they are supplying from

Other factors to consider

- Ensure that the individual is 16 years of age or over.
- Ensure that the individual is not allergic to naloxone. Any details of an adverse drug reaction should be recorded using the Yellow card Scheme found at www.bnf.org
- Is the individual at risk pregnant?
- Does the individual at risk have any heart/ renal or liver problems?

If the answer is yes to either of these a naloxone supply can still be made and the individual advised that naloxone can be administered for the purposes of saving a life. The importance of calling an ambulance should be reinforced.

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The individual receiving the supply should receive a brief intervention on basic life support, overdose causes, signs and symptoms and how to assemble and safely administer naloxone. However if the person is at high risk of overdose and is unwilling to receive a full brief intervention, instruction on naloxone use only may be given.

Explain the treatment and course of action of naloxone.

- Naloxone will only work on opiate based drugs such as heroin or methadone.
- The effects will only last for around 20 30 minutes.
- Naloxone does not remove opiates from the body and there is a risk that someone could go back into an overdose state.
- Always call 999 and ask for an ambulance.
- It is important someone does not take more drugs to negate the effect of withdrawal that naloxone has precipitated..

Additional information to be provided:

- Keep the pack sealed until needed. Never use a damaged or opened kit unless they are positive it contains naloxone
- Store in a cool, dry place, protected from light.
- Return for a resupply when the expiry date on the product is reached.
- How to dispose of the pack.
- Where to access further training and re-supplies of lost, used or expired kits.

The individual will be provided with the following leaflets:

- Patient information leaflet (PIL) which will be contained within the pack.
- NHS Lothian A5 orange PIL for administering naloxone and basic life support. (Appendix C)

The member of staff making the supply of naloxone should ensure that the correct product has been selected.

It is recommended that a second check should be obtained from another staff member where applicable (this individual does not need to be signed onto the supply framework).

There are no labeling requirements.

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Monitoring

Recording must be completed using the <u>NHS Lothian audit form</u>. Forms should be returned promptly to the following:

For Edinburgh based services:

Andrew O'Donnell, Harm Reduction Team, Spittal St Centre, 22-24 Spittal St, Edinburgh EH3 9DU or by secure email to Andrew.odonnell@nhslothian.scot.nhs.uk

For East and Midlothian based services: Dave Gasparini, MELD, 6A Newmills Road, Dalkeith, EH22 1DU or by secure email to <u>davegasparini@meld-drugs.org.uk</u>

For West Lothian services:

lan Davisdon, West Lothian Civic Centre, Howden South Road, Livingston, EH54 6FF or by secure email to ian.davidson@nhslothian.scot.nhs.uk

Verbal consent can be sought to share the other copies of the form with a GP or other relevant service.

Staff Characteristics

The staff member as a minimum requirement should be able to respond to questions relating to aspects of the local training programme, info about the basic effects of naloxone and know where to refer to for further professional advice.

Staff directly issuing supplies of naloxone to individuals must:

- Be identified to make naloxone supplies by the drug treatment service manager.
- Adhere to any relevant professional registration body standards.
- Have undertaken the <u>NHS Lothian's Take Home Naloxone Training for Trainers</u> day in order to use this framework. Prior to this, the Learn Pro module on Overdose Prevention and naloxone should be completed

Continuing Education and Training

- Staff 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.

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Further Information Sources

NHS Lothian Take Home Naloxone page https://services.nhslothian.scot/harmreductionteam/NaloxoneFramework/Pages/default.aspx

Department of Health, Medicines Healthcare and Regulatory Authority and Public Health England "Widening the availability of Naloxone (Nov 2015) <a href="https://www.gov.uk/government/publications/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone/widening-the-availability-

Current edition of the British National Formulary (BNF) http://www.bnf.org/

Prenoxad ® Summary of Product Characteristics (SPC) http://www.medicines.org.uk/emc/medicine/27616

Prenoxad ® Patient Information Leaflet (PIL) http://www.medicines.org.uk/emc/medicine/27594

Prenoxad® Injection http://www.prenoxadinjection.com/

Care Inspectorate "Health Guidance: National Naloxone Programme" http://hub.careinspectorate.com/media/52169/naloxone-guidance-aug-2013.pdf

NHS Lothian's Substance Misuse and Harm Reduction Training Programme. Contains information on THN training for trainers.

http://www.nhslothian.scot.nhs.uk/Services/A-Z/HarmReductionTeam/Pages/HRTTraining.aspx

Further Contacts

Mandy Hart, Specialist Pharmacist in Substance Misuse Amanda.J.Hart@nhslothian.scot.nhs.uk

Andrew O'Donnell Naloxone Lead and Trainer for NHS Lothian Andrew.odonnell@nhslothian.scot.nhs.uk

LOCAL AUTHORISATION

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Authors		Designation and Contact Details	
Name: Gary Todd		Designation: Principal Pharmacist	
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Name: Andrew O'Donnell		Designation: NHS Lothian Naloxone Lead	
Signature:	Date: 19 th July 2018	E-mail address: Andrew.Odonnell@nhslothian.scot.nhs.uk	
Name:		Designation	
Signature:	Date:	E-mail address:	

Appendix A

Naloxone Supply Competency Framework Training Record

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Drug Treatment Centre Name					
This training record should be retained within the drug treatment centre and kept up to date by the service manager.					
I have read and understood the Naloxone Supply Competency Framework and agree to supply this medicine in accordance with the framework.					
Staff Member (please print)	Signature	Date			

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