Portsmouth City Council

SERVICE SPECIFICATION
FOR
'PILOT' FOR THE PROVISION OF
TAKE HOME NALOXONE
IN
Portsmouth

Contents

Prenoxad (Naloxone) Supply Standard Operating Procedure (SOP)

1. Aims and intended service outcomes

1.1. To pilot the provision of take home Naloxone in the Portsmouth City Council area.

1.2. To increase awareness and the availability of training and supply of Naloxone.

1.3. To provide training and supply of Naloxone to clients at risk of opiate overdose.

1.4. To provide clients with a convenient supply of replacement injectable naloxone following emergency use or date expiry.

1.5. To help clients who use the service to access other health, voluntary and social care services where appropriate to facilitate behaviour change in their journey toward recovery.

1.6. This specification should be read alongside Public Health England guidance on take home naloxone:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/669475/phetake-homenaloxoneforopioidoverdoseaug2017.pdf

2. Service outline

2.1. The service will be offered to suitable Substance Misuse and Needle Exchange service users.

2.2. Naloxone will be offered to anyone over 18 years:

- Currently using illicit opiates, such as heroin;
- Receiving opioid substitution therapy;
- Leaving prison/rehab with a history of drug use; and
- Who has previously used opiate drugs (to possess in the event of a relapse).

2.3. Naloxone will also be offered to a family member, carer, peer or friend, with consent of anyone identified in 2.2.

2.4. All clients will be offered brief training in recognising the symptoms of opioid overdose, how to respond appropriately and how to administer naloxone.

2.5. The training and naloxone supply can be delivered by any member of the pharmacy team who must have completed the approved naloxone training.

2.6. All clients will be provided support, advice and information, including signposting or referral to other health and social services. These will include:

- Harm reduction service drop ins;
- Local substance misuse treatment services; and
- Services for BBV testing and treatment.

2.7. Assessment, intervention and Naloxone Supply

2.7.1. All clients attending the service should be asked some basic information about the naloxone programme to ensure their needs are met. The client must be given training on:

- Risks and signs of opiate overdose;
- Basic life support; and
- Naloxone administration.

2.7.2. Verification of the clients' knowledge and understanding of all aspects of the service should be confirmed, via the customer training checklist (page 17).

2.7.3. Only in exceptional circumstances (based on professional judgement) should a supply of naloxone be refused. Reasons for refusal should be recorded.

2.7.4. For those clients who have been training onsite and when the Pharmacist is assured that the client understands:

- The risks and signs of opiate overdose;
- How to administer basic life support; and
- Naloxone administration.

The Pharmacist will make a supply of ‘take home naloxone’ as determined by their suitability.

2.7.5. Written and Verbal information about the Naloxone Service, benefits, harm reduction, signs of opiate overdose and basic life support will be given.

2.8. Date recording & information sharing
2.8.1. The pharmacy should maintain appropriate records on Pharm Outcomes to ensure effective on-going service delivery and audit.

2.8.2. The pharmacy will be expected to ensure secure systems and records to prevent misuse of service, and to ensure the confidentiality for service users.

2.8.3. The pharmacy will create a record on Pharm-Outcomes using the initials / identifier provided by the service user (initials, mm/yy e.g. AA0271) and first part of their post code e.g. PO5.

3. Accessibility
3.1. The service will be available on an open access basis with no requirement for service users to be referred from another agency.

3.2. The service user will determine:

- Which delivery site they access;
- The frequency of engagement; and
- Which interventions they access.

4. Service requirements
4.1. The pharmacy will ensure the service is user friendly, non-judgemental, person-centred and confidential at all times.

4.2. The pharmacy has a duty to ensure that pharmacists and staff involved in the provision of the service are aware of and operate within local protocols.

4.3. The pharmacy must ensure that pharmacists and staff involved in the provision of the service have relevant knowledge and are appropriately accredited in the operation of the service, including sensitive, client centred communications skills and confidentiality.

4.4. The pharmacy must ensure that the Contract Manager is informed of any changes to personnel such that the service becomes unavailable at the pharmacy.

4.5. Where a pharmacist leaves a community pharmacy currently accredited to provide this service, the community pharmacy must assess the impact to service delivery and ensure that the Contract Manager is informed of service issues as soon as possible. Every effort should be made to ensure service continuity.

5. Duration
5.1. This Service Specification is valid from 1st June 2018 - 31 March 2020

6. Safeguarding and governance
6.1. It is implicit in the service being provided that it is delivered to the standard specified, and complies with the legal and ethical boundaries of the profession.

6.2. Should an issue be identified either through a visit of the Contract Manager or through any other means an action plan will be produced. The pharmacy will identify any issues and create an action plan with the named pharmacist. The timescales will be agreed according to the level of risk and the Contract Manager will send a written report to the named pharmacist within two weeks of the visit, summarising what action needs to be taken and by when. The Contract Manager will contact the pharmacy again once the agreed timescales have elapsed to confirm that the action plans has been completed. If any further action needs to be taken, this will be documented and new timescales agreed.

6.3. If the issues remain unresolved after this, the option to withdraw the service from the pharmacy may be exercised.

6.4. Please note that the pace with which the process progresses will be determined by the level of risk. In addition, any serious professional matters identified may be escalated to Public Health England or GPhC.

6.5. Pharmacy staff must be aware of local child, and vulnerable adult, protection procedures. These must be followed at all times.

7. Training requirements
7.1. Before they can distribute Naloxone, pharmacists/staff are required to complete either face to face Naloxone training delivered by the Recovery Hub (substance misuse treatment service), or SMMGP FreeLearn - Naloxone Saves Lives (you will need to register prior to completing the course) http://www.smmgp-elearning.org.uk/course/index.php?categoryid=2

7.2. The declaration for reading and signing the Standard Operating Procedure (SOP) found at **Appendix A** of this specification needs to be confirmed on PharmOutcomes before starting the service.

7.3 The pharmacy shall engage with the Public Health team to promote service development, update knowledge and inform the pilot.

8. Use of Locum Pharmacists
8.1. The pharmacy has a duty to ensure that staff and other pharmacists (including locums) involved in the provision of the service have relevant knowledge and are appropriately trained in the operation of the service to ensure the smooth continuation of the service in their absence.

8.2. Where possible, the pharmacy should ensure it is staffed by a regular pharmacist/s. Should the pharmacy be in a position where the pharmacy will be run on different locum pharmacists for more than a month, the Contract Manager must be informed.

8.3. The council has the right to withdraw the service from a pharmacy that is not staffed with regular pharmacists. Alternatively, the council may impose additional conditions on the pharmacy in order for the pharmacy to remain providing the service.

8.4. The pharmacy should ensure that there is adequate support staff, including staff specifically trained to support this service in the pharmacy at all times in order to support the pharmacist (including locum pharmacist) in the operational elements of the service and to help ensure the safe and smooth running of the service.

8.5. The pharmacy will ensure that appropriate professional indemnity insurance is in place.

8.6. It is a requirement for pharmacies signing up to this agreement to comply with all the requirements of the essential services of the NHS Community Pharmacy Contractual Framework.

9. Premise

9.1. The service must be provided from a designated consultation area in the pharmacy that meets, as a minimum, the national standards required for the provision of the Medicines Use Review Service.

9.2. The consultation area will provide sufficient privacy (both auditory and visual) and safety for delivery of the service. Hand washing facilities will be required within the consultation area or nearby. The pharmacy contractor must ensure that NHS infection control standards are complied with at all times.

9.3. The pharmacy will have appropriate health promotion material available for the users of the service and promotes its uptake.

9.4. Ensure internet access to use Pharm Outcomes.

10. Quality standards

10.1. The pharmacy should ensure the following:

- Pharmacists and staff involved in the provision of the service must be aware of and operate within any locally agreed protocols and operate to Standard Operating Procedures (SOPs) for the delivery this Service Specification. A SOP is provided at **Appendix 1**;
- The pharmacy is making full use of promotional material;
- The pharmacy can demonstrate that pharmacists and staff involved in the provision of the service have undertaken some CPD relevant to this service on at least an annual basis;
- The pharmacy has a complaints procedure in place and will report any complaints, comments or concerns to the Contract Manager as soon as possible by email or phone;
- Co-operation with any review of the client experience

10.2. The quality standards for the pharmacist are:

- Accreditation by commissioner

- Training completed and verified

10.3. Reportable incidents (including dispensing errors and suspected breaches of the Controlled Drugs Regulations 2013) will be reported to Public Health in line with national guidelines.

11. Audit
11.1. The Contract Manager may employ mystery shoppers as part of audit.

11.2 The Contract Manager may telephone pharmacies to audit quantities of stock in store, pharmacies will provide this information.

12. Reporting incidents
12.1. The Pharmacy is required to have a robust accident/incident reporting and investigation procedure in place for all clinical and non-clinical incidences.

12.2. Any incidents pertinent of this service should be reported using the Pharmacy's normal incident reporting procedure and a copy of this report should be sent to the Contract Manager.

13. Payment arrangements
13.1. Payment and Reimbursement Structure
- Naloxone supply: £
- Payments will be made on a monthly basis.

13.1.2. There is a limited supply of 400 kits available over twenty two months for the Take Home Naloxone Pilot, which will be delivered across six or seven pharmacies.

14. Claims for Payment
14.1. Payments will be made monthly upon input onto Pharm Outcomes. Invoices will be generated automatically by Pharm Outcomes on the 5th of the month. The service contract and financial details will have needed to be completed and returned before any payments will be made.

14.2. Evidence of your bank details, for example a paying in slip, will be required for payment.

15. Local contact information
15.1. Contract Manager: Matthew Barton, Commissioning Contracts Officer, Public Health, Portsmouth City Council. Tel: 023 9283 4403
email:matthew.barton@portsmouthcc.gov.uk

Prenoxad (Naloxone) Supply Standard Operating Procedure (SOP)

1.1 Purpose

This SOP aims to provide guidance on the supply of take home naloxone, in the form of Prenoxad prefilled syringe pack, to service users, family members, hostels, carers and other groups for the purpose of temporarily reversing opioid overdose. It is intended as a framework for the supply of naloxone injections by specialist services operating throughout Portsmouth. This applies to all staff, volunteers and peers within Substance Misuse services who have direct contact with service users.

1.2 Background

Britain continues to have a high number of drug-related deaths with opiate overdose remaining a major cause of death among injecting drug users. In England and Wales 765 deaths were registered in 2013 in which heroin or morphine were mentioned on the death certificate: An average of two every day, and a significant increase of 32% compared to those registered in 2012. This increase brings the number of deaths relating to heroin and/or morphine to similar levels to 2010. Portsmouth has one of the highest rates of drug related deaths in England.

Naloxone is a drug which temporarily reverses the effects of opioids such as heroin, methadone and morphine. For many years, naloxone has been used within emergency medical settings to reverse the effects of opioid overdose and prevent death. UK Guidelines on Clinical Management of Drug Misuse fully endorses the use of naloxone in overdose management and prevention.

On the first of October 2015 The Human Medicines (Amendment) (No. 3) Regulations 2015 (2015/1503) came into force. This allows naloxone to be supplied by:
Persons employed or engaged in the provision of drug treatment services provided by, on behalf of or under arrangements made by one of the following bodies– a) an NHS body; (b) a local authority; (c) Public Health England; or (d) Public Health Agency. This includes pharmacies which are commissioned by local authorities to deliver needle and syringe exchange programmes, and those delivering supervised consumption of opiate substitute medication.

It can be supplied to anyone in the course of lawful drug treatment services and only where required for the purpose of saving life in an emergency. For explanatory memorandum see:
http://www.legislation.gov.uk/uksi/2015/1503/pdfs/uksiem_20151503_en.pdf

2.1 Policy

Public Health Portsmouth will facilitate overdose awareness and use of naloxone training to staff, in line with local and national guidelines to help reduce the numbers of local drug related deaths from opioid overdose. This training will be delivered by the Recovery Hub (Solent NHS Trust). Trained staff will then disseminate the training to customers. Alternatively e-learning is an option. Service users and concerned others will sign a responsibility deal agreeing to appropriate use.

2.2 Staff competence

Staff supplying naloxone should have been appropriately trained. All staff should complete the SMMGP online learning package (available at: http://www.smmgpelearning.org.uk/course/index.php?categoryid=2) or attend training delivered by the Recovery Hub. A record of staff trained will be sent to the Public Health Portsmouth (Contract manager).

2.3 Eligibility criteria
Naloxone can be supplied to anyone:

- Currently using illicit opiates, such as heroin;
- Receiving opioid substitution therapy;
- Leaving prison with a history of drug use; and
- Who has previously used opiate drugs (to protect in the event of relapse).

2.4 Training service users, carers and identified others in overdose management
Training on how to recognise opioid overdose, overdose management, and administration of naloxone injection must be given before naloxone is supplied. The training may be delivered on an individual or group basis. The training is not time consuming, taking five to ten minutes, but must cover recognition of an opioid overdose and that the procedure is to:

- Ensure personal safety first;
- Call an ambulance;
- Place the casualty in the recovery position, or on their side if breathing;
- Place the casualty on their back if not breathing;
- Commence chest compressions and rescue breaths if not breathing;
- Inject naloxone into the thigh or upper arm muscle;
- Repeat chest compressions and rescue breaths until breathing commences;
- Repeat naloxone injections at 2 minute intervals in doses of 0.4mg until breathing commences;
- If patient is still non-responsive and ambulance services have not arrived Naloxone can continue to be given at 2 minute intervals if there are other kits available to use; and
- Wait with the casualty until the ambulance arrives and safely dispose of the naloxone kit to paramedics.

The process of using the naloxone kit must be explained and demonstrated and minimum data entered into Pharm Outcomes. This should be done each time a kit is given out or replaced.

One naloxone pre-filled syringe/pack for intramuscular use will be supplied. Each pack will include one naloxone injection 1mg/ml as a 2ml pre –filled syringe. Each 2ml syringe is marked out with 5 x 0.4mg doses - the minimum effective dose which can be given in an attempt to reverse the effects of opioid overdose. Should there be an identified need for more than one kit, this should be discussed with the Recovery Hub (tel: 023 9229 5573), who can provide additional packs directly to the customer.

The used syringe and needle should be replaced in cradle in the yellow Naloxone kit box when no longer required and the box shut to become a temporary sharps container. Used or partially used kits should be given to the emergency services attending (police, ambulance, and fire) for safe disposal. If no emergency services attend then used kits should be returned to the service of issue for bearer re-supply and recording of details of use.

Naloxone can be issued to pregnant women where the potential benefit is deemed to outweigh the risk Naloxone can be issued to young people under 18 by an appropriately acting professional acting within a suitable clinical governance framework after careful consideration and on a case by case basis. Account should be taken of Fraser guidelines and the mental capacity of the young person to understand the issues

involved, together with adherence to guidance relating to consent and safeguarding in children and young people.

2.5 Collection and audit
The supply of naloxone must be recorded on Pharm Outcomes.

If it is a replacement kit, details should be recorded on Pharm Outcomes, This will record valuable information about the use of the naloxone kit and the situation in which it was used.

Those who have used naloxone should be encouraged to share and record their story with appropriate specialist staff, which can then be transcribed. Stories of people who have used naloxone to save a life provide useful learning for staff, carers and service users and can be helpful in evidencing the effectiveness of take home naloxone. An email with this information (anonymised) can be sent to Matthew.barton@portsmouthcc.gov.uk Section 2.10 details the information that could be shared.

2.6 Supply, storage and stock control
On 30th June 2015, naloxone was reclassified under article 7 of Prescription Only Medicines Order, by Parliament. Naloxone is now on the list of prescription only medicines that can be administered parentally (by injection) by anyone for the purpose of saving a life.

Take home naloxone will be supplied as pre-packed Prenoxad kit containing:

- 1 x 2ml pre-filled syringe (Naloxone Hydrochloride (Prenoxad) 1mg/1ml);
- 2 x 23G 1.25” needles for intramuscular injection; and
- Product instruction sheet/s.

Naloxone has been subjected to stability studies at 40 degrees centigrade which showed the product shelf life was fully compliant at this temperature for up to 6 months however it should be protected from light. Inappropriate storage and handling may shorten the shelf life. Service users must be advised to keep the take home naloxone out of reach of children and pets and encouraged to return for replacement dose should they have used or lost the medication or when it has expired. Service users must be advised of the safe disposal of needles following the use of the take home naloxone.

Prenoxad kits have a low potential for misuse however carriers should be discouraged from opening kits to use needles for other purposes, understanding that police will remove unsealed kits from service users if found during searches.

Used sharps and syringes should be replaced in the Naloxone kit box and shut before being given to attending emergency services or returned to the specialist service of issue for safe clinical waste disposal. Un-used, unwanted, used or partially used, found and expired stock should also be returned to service of issue or handed to the ambulance service staff who attend a suspected overdose situation for safe disposal. Supplies of Naloxone should be ordered by pharmacies from the Portsmouth Recovery Hub. These can be requested by telephoning 023 92 4573 or email XXXXXX (t.b.c). Orders for between up to 20 kits can be requested, as we do not want unused stock left to expire. If a pharmacy has unused stock the Recovery Hub should be informed so they can collect this.

Each specialist issuing service will attach a self-adhesive label to the kit when issued stating name of issuing service, trained bearers name and date of issue. Care should be taken over the placement of this label to ensure it does not obscure the product expiry date pre-fixed label.

Services should avoid holding more stock than they need as held stock expiry dates will be eroding.

Budget for Naloxone supplies is not finite and services are requested to carefully consider the appropriateness of issue to a service user. Naloxone is designed to help save the lives of opiate users, many of whom will be known to services to be at high risk of overdose through chaotic behaviour or to have overdosed before and for service users in known high risk situations such as recent exit from custody or discharge from inpatient stay.

It is not necessary or appropriate for all injecting drug users such as NPS or steroid users to be issued with it unless they are known to also be using opiates. Services are asked to order and issue Naloxone with caution, given financial constraints, and only to service users where they identify it will be beneficial and effective.

2.7 Expired supplies
Naloxone has a maximum shelf life of 3 years. When naloxone is supplied this should be explained to the client and the expiry date noted and told to them. Recipients of take home naloxone should be encouraged to return the naloxone to the service before the expiry date to collect a further supply. Recipients should be made aware of stock recall procedures should a product recall be issued for a specific batch. Expired supplies should immediately be placed in sharps collection bins for clinical waste collection and disposal. Returned sealed kits can be used for demonstration or staff training purposes.

2.8 Product Recall
Should a product recall alert be received from the supplier to the Public Health Portsmouth, the lead officer will cascade the alert and notify batch numbers to the specialist services who issue the product. Specialist services are responsible for making every attempt possible to contact the bearer of the recalled batch and encouraging them to return their supply. Recalled supplies should be stored separate to other stock. Returned stock is to be labelled appropriately and quarantined, awaiting supplier collection and replacement, in line with MHRA guidance:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/403210/A_guide_to_defective_medicines.pdf

The specialist service is responsible for contacting the supplier direct for pick up and replacement of such stock. Record should be made of quantity of recalled stock received and batch numbers and of the new batch number of supply issued to replace that recalled. Re-issue should otherwise follow standard procedure.

2.9 Naloxone Project process

2.10 Pharmacy Naloxone Customer Training Checklist

Customer Identifier (Initials, Month and year of birth i.e. JS0278) :
First part of postcode (i.e. PO5):
Date: **Tick when trained**

The customer has been made trained and can identify the following

What are the signs of a suspected opiate overdose

Pinpoint pupils; Loss of consciousness and casualty unresponsive to stimuli (e.g. a shout or a shoulder shake); Breathing problems such as slow/shallow or infrequent breaths, snoring/rasping sounds, or not breathing at all; Cyanosis (blue tinge to the lips, tip of the nose, eye bags, fingertips or nails)

Name some overdoes myths

The following actions are myths and will not help the person to survive, you should not:
Inject or administer stimulants
Walk the person around
Put the person in a bath of cold water to shock the person awake
Run away, the person is at risk of dying., in most cases the police will not attend in an overdose situation
Slap the person who has overdosed in the face
These actions could increase risk of death and will only delay the right action.

What you should do with a suspected overdose

Attempt to rouse the casualty by shouting and or shaking their shoulders; Call 999; Assist the casualty into recovery position; Provide basic life support

What is naloxone

Naloxone is an opioid antagonist, it rapidly reverses the effects of opioids such as heroin, morphine, methadone, codeine and dihydrocodeine. One of the effects that can be reversed is respiratory depression. It does not remove opiates from the body, but temporarily blocks the effects, giving enough time for the emergency services to arrive.

How to assemble the naloxone injection and how to administer

There are some common elements for the use of the intramuscular (IM) injection: Once the IM injection has been prepared and assembled, it should be held in a similar manner to a pen. It should be injected into either the deltoid muscle (upper arm) or outer thigh muscle. The needle should be held at 90° to the surface of the skin and then inserted into the muscle through the clothes if necessary. The plunger should be pushed down slowly and steadily to administer one dose. The needle should be withdrawn from the casualty and placed in a safe place. No attempt should be made to re-sheath the needle. The used kit should be given to the paramedics on arrival for safe disposal.

How often you should administer naloxone

Naloxone can be administered every 2-3 minutes until the casualty regains consciousness or the paramedics arrive. If the casualty is not breathing, emergency life support should continue in-between doses

Why you should stay with the person

You need to ensure they are in the recovery position and if required receive basic life support. When the paramedics arrive they should be told which drugs have been used, if known, and they should be given the naloxone kit and advised how many doses have been administered.