Guidance For Drug Treatment Services In Grampian Undertaking Supply Of Naloxone To People At Risk Of Opioid Overdose, Significant Others And Services In Contact With Those At Risk

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<th>Co-ordinators:</th>
<th>Consultation Group:</th>
<th>Approver:</th>
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<td>Specialist Pharmacists</td>
<td>See page 7</td>
<td>Medicine Guidelines and Policies Group</td>
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Version 1

Executive Sign-Off

This document has been endorsed by the Director of Pharmacy and Medicines Management

Signature: ____________________________
Title: Guidance For Drug Treatment Services In Grampian Undertaking Supply Of Naloxone To People At Risk Of Opioid Overdose, Significant Others And Services In Contact With Those At Risk

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Hospital/Interface services: Assistant General Managers and Group Clinical Directors
Operational Management Unit: Unit Operational Managers

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Review: This policy will be reviewed in two years or sooner if current treatment recommendations change
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Responsibilities for disseminating document as per distribution list: Specialist Pharmacists in Substance Misuse

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* Changes marked should detail the section(s) of the document that have been amended, i.e. page number and section heading.
## Guidance For Drug Treatment Services In Grampian Undertaking Supply Of Naloxone To People At Risk Of Opioid Overdose, Significant Others And Services In Contact With Those At Risk

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1. Introduction

The Human Medicines (Amendment) (No. 3) Regulations 2015 brought about a change in legislation to allow the supply of naloxone without the need for a Patient Group Direction (PGD) or Patient Specific Direction (PSD).

The legislation allows supply of naloxone to be made by clinical and non-clinical staff employed by commissioned drug treatment services. Further information regarding the change in legislation and its intent can be found in the joint Department of Health, Medicines and Healthcare Products Regulatory Agency (MHRA) and Public Health England Guidance "Widening the availability of naloxone". These amendments have been introduced in a bid to reduce deaths due to opioid overdose by making naloxone more easily accessible in communities for use on those at risk.

The unique nature of this legislation has relaxed the usual measures which apply to Prescription-only Medicines. This document aims to ensure that a clear framework of clinical governance remains in place within commissioned Drug Treatment Services delivering naloxone supplies in Grampian.

1.1 Objectives

To increase access to naloxone supply in a bid to reduce the number of deaths associated with opioid overdose by:

- Widening the range of services and professionals (clinical and non-clinical) eligible to undertake naloxone supply.
- Removing barriers to significant others and services in contact with people at risk of opioid overdose receiving a naloxone supply.

To provide a clinical governance framework for drug treatment services involved in the supply of naloxone in the absence of a PGD or PSD.

NB: This guidance does not prevent the supply of naloxone (Prenoxad®) by prescription if this is the preferred route. The aim is to increase access and facilitate supply.

1.2 Definitions

Naloxone: A drug which can temporarily reverse the effects of opioid drugs such as heroin and methadone in overdose situations.

Naloxone Take Home Programme (Scotland): Scottish Government supported initiative which made naloxone kits available to people at risk of overdose, significant others and services in contact with those at risk in a bid to reduce the risk of drug related death. It includes components of training on overdose awareness, basic life support and naloxone administration.
Drug treatment services: For this purpose drug treatment services are provided by, on behalf of, or under arrangements made by an NHS body, local authority or Public Health Agency. In Grampian, authorisation to supply naloxone through non-clinical services will be explicitly agreed with the commissioning organisation. Injecting Equipment Providers (IEPs) and Community Pharmacies which dispense Opioid Replacement Therapy are included under this definition.

Drug workers: For this purpose professionals employed by a drug treatment service to deliver care for people who use drugs. Staff can be clinical or non-clinical.

1.3 Clinical Situations

This guidance document refers to the supply and use of naloxone in the event of a suspected opioid overdose in community settings. It does not refer to suspected opioid overdose managed by healthcare workers in clinical settings.

1.4 People Who Can Make A Supply Of Naloxone Under This Guidance

Drug workers working for a commissioned Drug Treatment Service who have successfully completed training by an approved Grampian trainer may make naloxone supply in line with this guidance.

1.5 People Who Can Receive A Supply Of Naloxone Under This Guidance

- People at risk of opioid overdose.
- The significant others of people at risk of opioid overdose.
- Services in contact with people at risk of opioid overdose (non-clinical settings) e.g. hostels, homeless shelters, etc.

Prior to making a supply of naloxone the person receiving the supply must be able to demonstrate a basic awareness of opioid overdose, basic life support and naloxone use to the drug worker.

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

1.6 Guidance On Supply To Children And Young People

“Any drug treatment service considering providing a child or young person under 18 with training on overdose management or on the use of naloxone, or considering direct supply of naloxone, should always act in line with established clinical principles for the treatment of children and young people. This is the case whether the goal of such consideration is to reduce risks to a young person who is using drugs or to reduce risk for others (such as an opioid-using parent).

While there is no legal restriction under the new legislation on the supply to children or young persons of naloxone by a drug treatment service, such a decision would
need very careful consideration and oversight and would need to be made on a case by case basis.

An appropriately competent professional acting within a suitable clinical governance framework would have to consider the needs of each child or young person, taking account of potential benefits to the child of the intervention and any risks. They are expected always to take proper account of the child or young person’s ability to understand the issues involved and to provide suitable consent. In the case of a child who exercises a carer role for a drug-using parent, consideration of the interests of the child can be quite complex.

The drug treatment service and competent drug workers should take account of any relevant guidance (including that relating to consent in children and young people and regarding child safeguarding).

1.7 People Who Cannot Receive A Supply of Naloxone Under This Guidance

- People who are unable to demonstrate a basic understanding of opioid overdose, basic life support and naloxone use to the drug worker.
- People who are deemed by the drug worker as having insufficient capacity to agree to, or who has not provided consent to receive, a supply of naloxone.
- Any person who expresses a known allergy to naloxone.

2. Evidence Base

The supply of naloxone as described forms a key component of national and international policies aimed at reducing the incidence of drug related deaths. It is included in guidance documentation from the World Health Organisation, Advisory Council on the Misuse of Drugs, MHRA, Department of Health and Public Health England. The supply forms part of a national programme introduced and evaluated by the Scottish Government.

3. Competence Of Drug Workers

All drug workers undertaking naloxone supply must have successfully completed NHS Grampian approved naloxone training. The drug treatment service manager is responsible for ensuring that participating drug workers have undergone training and remain competent. As a minimum requirement the drug worker should be able to respond to questions relating to aspects of the local training programme, information about the effects of naloxone and know where to refer to for further professional advice or support if required.

The drug treatment service manager should ensure that all staff are updated on any changes to this guidance and should retain a record of staff trained and eligible to make a supply of naloxone. Competence should be assured annually and may take the form of team discussion, one-to-one review during appraisal or attendance of refresher training as deemed appropriate by the service manager.
4. **Training Requirements (People At Risk, Significant Others, Services In Contact With Those At Risk)**

Prior to making a naloxone supply, drug workers should cover the detail outlined in NHS Grampian’s One-to-One Naloxone Checklist (Appendix 1) to assure that people receiving a supply of naloxone have sufficient knowledge on its use.

5. **Naloxone Supply Information**

Drug workers involved in making the supply of naloxone should maintain a good working knowledge of the following information and be competent in conveying this.

5.1 **The Prenoxad® Kit**

The branded product Prenoxad® (naloxone hydrochloride 2mg/2mL pre-filled syringe for injection) should be supplied to the people or services outlined in this guidance document. Prenoxad® is currently the only form of naloxone licensed for use by lay people. In addition to the pre-filled syringe, the pack contains a patient information leaflet and two needles. The second needle is included as a back-up should the first one become damaged. It is not necessary to change needles between injections. The kit is packaged within a hard shell case which should be used to contain and dispose of the syringe and needles following use. Other versions of naloxone do not contain any needles or the appropriate information leaflet and would be unable to be used in an emergency.

People at risk of future opioid overdose can receive:

- One Prenoxad® kit for intramuscular use.
- One additional Prenoxad® kit to hold as a spare supply if required and circumstances support this, e.g. splits time between family home and other property.

People who are identified as a significant other of someone at risk of future opioid overdose can receive one Prenoxad® kit for intramuscular use.

Services in contact with those at risk of future opioid overdose may also be provided with an appropriate number of kits for the size and activity of the service. Care Inspectorate Guidance should be followed. It is the responsibility of the service receiving the supply to ensure that they have processes and protocols in place which meet its recommendations.

Practical information that should be discussed when making a naloxone supply include:

- It is not necessary to keep Prenoxad® in a fridge.
- The pack should remain sealed until needed. It may be confiscated by the police if unsealed and they cannot verify the contents.
- Where to access further training and resupplies of lost, used or expired kits (see list of participating services).
- Used or expired kits can be returned to any community pharmacy for disposal.
• A “Naloxone Can Be A Lifesaver” And Tear Off Prenoxad® “Assembly And Administration Guide” leaflet should be given with each supply (orderable from NHS Grampian Health Information Resources Service).

5.2 Contraindications To The 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.

5.3 Dosage Information And Route Of Administration

Naloxone is classified under Article 7 of Prescription-only Medicine Order, by Parliament which means that it can be administered by injection by anyone for the purpose of saving a life.

One dose (400 micrograms in 0.4mL) of naloxone should be injected into the outer thigh muscle. The syringe contains five doses which are clearly marked as such. If there is no response after 2-3 minutes a further dose should be administered. This should be repeated until either:

• The person regains consciousness or
• All 5 doses have been used or
• The emergency services arrive and take over.

5.4 Managing Symptoms Of Opioid Withdrawal

The most common side effect of naloxone is opioid withdrawal. In a person who is physically dependent on opioids this is often likened to severe influenza. Symptoms may include but are not limited to: body aches, diarrhoea, rapid heart rate, fever, runny nose, sneezing, sweating, yawning, nausea, vomiting, restlessness, irritability, shivering, trembling, abdominal cramps and weakness.

When making supplies, drug workers should advise that, although symptoms of withdrawal can be experienced when administering naloxone, they will generally be short lived. If faced with an overdose situation the casualty should be reassured that the effects of naloxone will begin to wear off after 20-30 minutes and strongly advised against the use of additional substances. Further substance use will significantly increase the risk of further overdose.

5.5 Data Recording And Monitoring

NHS Grampian “Record of Naloxone Training, Supply and Resupply” (Appendix 2) should be used to record details of training and supply. This should subsequently be recorded using the approved data collection system which is currently neo360® (May 2017). The consent of the person being trained should be gained for recording details of supplies made and sharing this data anonymously for the purposes of project monitoring.

The drug treatment service manager is responsible for ensuring confidentiality of the records to enable verification of service provision.
5.6 Stock Management

Services should ensure that they have adequate protocols in place for the ordering, monthly date checking and rotation and disposal of stock. Stock must be ordered from an approved supplier. Services may be requested to produce protocols and demonstrate compliance to commissioners and/or the Grampian naloxone co-ordinator. Prenoxad® has a relatively short expiry date of 3 years from date of manufacture. To maximise the effective lifespan of stock, no more than one month’s supply of Prenoxad® should be kept in hand at any one time and stock ordered frequently. Third sector drug treatment services should contact NHS Grampian’s naloxone co-ordinator for advice on stock management.

6. Consultation

Seonaid Anderson, Consultant Psychiatrist, Aberdeen Integrated Alcohol Service
Helen Cheyne, Nurse Manager, Specialisms, NHS Grampian Mental Health Service
Bruce Davidson, Consultant Psychiatrist and Clinical Lead, NHS Grampian Substance Misuse Services
Fraser Hoggan, Development Officer, Aberdeen City Alcohol and Drug Partnership
Kirsten Horsburgh, National Naloxone Co-ordinator, Scottish Drugs Forum
Elizabeth Kemp, Principle Pharmacist, NHSG Pharmacy and Medicines Directorate
Lynsey Murray, Lead Nurse, Moray Integrated Drug and Alcohol Services (NHS)
Tara Shivaji, Public Health Consultant, NHS Grampian
Rhona Stewart, Lead Social Worker, Drugs, Aberdeen City Council
Lynn Sutherland, Development Officer, Aberdeenshire Alcohol and Drug Partnership
NHS Grampian Acute Substance Misuse Group
NHS Grampian Mental Health Operational Medicines Management Group

7. Distribution List

Aberdeen City, Aberdeenshire and Moray Alcohol and Drug Partnerships
NHS Grampian Mental Health Services
NHS Grampian Acute Services
Primary Care Contracts Team (Community Pharmacies and GP Surgeries)

8. References

1. The Human Medicines (Amendment) (No. 3) Regulations 2015. S.I. Medicines. 2015/1503


### Appendix 1 - One to One Naloxone Checklist

<table>
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<tr>
<th>Person’s Name &amp; CHI/Date of Birth</th>
<th>Person’s Address (inc. postcode)</th>
<th>Name of GP Surgery</th>
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<th>Identification – Does the person currently have a Naloxone supply?</th>
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**Q. Have you received a naloxone kit yet?**

**A. Yes** - Check if still in possession/used, check expiry date, consider need for refresh of training

**No** – Ask “What do you know about Naloxone”?

Person still uncertain? “We’re trying to get as many supplies into the community as we can”, “Unlikely to use on yourself/more likely to be used on somebody else”. Discuss high risk times – low tolerance – not a reflection of how the person is currently doing, etc.

The person should be able to demonstrate an understanding of the following:

**Is aware of the most common drugs present in drug deaths**

**Compare against substances and combination used by the person/significant other, etc.**

**Combination of depressants** is the most common cause of Drug Deaths in Grampian.

- Opioid drugs including heroin, methadone, dihydrocodeine
- Benzodiazepines/“Benzos” e.g. diazepam
- Alcohol.
- Unknown/unpredictable substance include gabapentin/pregabalin, New Psychoactive Substances e.g. phenazepam, etizolam, etc (often no idea what these substances actually contain).

**Is aware of risk factors for overdose**

Tailor discussion to your knowledge of the person’s own circumstance. May include, but not restricted to:

- Polysubstance use (depressant combinations above including alcohol).
- Lowered tolerance, e.g. missed doses of methadone.
- Using alone (consider isolation and loneliness.)
- Poor physical or mental health.
- Recent hospitalisation, prison sentence, following rehabilitation or detoxification.
- Adverse life events e.g. bereavement, relationship difficulties or other social circumstances, e.g. housing issues, job loss, etc.

**Knows how to identify an overdose:**

**Q. How would you know someone has overdosed?**

**Q. What action would you take?**

Check for understanding and recognition of following:

- Unresponsive
- Unconscious
- Breathing problems (slow/stop/snore)
- Blue skin/lips
- Pinpoint pupils (discuss why not that helpful).

**Identify any misconceptions about the action required in overdose situations.**

e.g. walking round room, inflicting pain, shocking with cold water/bath, etc

**Discuss and correct as required.**
Knows the recommended actions to take when faced with overdose.

Discuss and where necessary demonstrate the following components to confirm appropriate knowledge and skills:

- Ensure environment is safe for you to take action (needles, dogs, etc).
- Shake shoulders firmly and ask if the person can hear you.
- Check if they are breathing (look along chest, feel for breath on face – no longer than 10 seconds).
- Call 999 for ambulance. Tell the operator where you are and that you are with a person who is either....

A. “...UNCONSCIOUS BUT BREATHING”

* ACTION TO TAKE - Put in recovery position and administer naloxone.

B. “...UNCONSCIOUS AND NOT BREATHING” (No breath felt in 10 seconds)

* ACTION TO TAKE - start basic life support (BLS) and administer one dose of naloxone after the first cycle of BLS.
  (One cycle = 30 chest compressions at a rate of 1 per second followed by 2 breaths).

• Continue to administer one dose of naloxone every 2-3 minutes if there is no response.
• Stay with person until the ambulance arrives.

Check knowledge and understanding of how naloxone works:

Q. Can you tell me? If not explain that naloxone:

- Temporarily reverses the effects of opioid drugs.
- Doesn’t remove opioid drugs from the body.
- Won’t work on non-opioid drugs such as benzodiazepines, alcohol or gabapentin, etc.
- Will begin to wear off after around half an hour.
- After this the effects of opioid drugs may return as drugs reattach to receptors in the brain.

NB: If the person comes round, encourage them not to use any further drugs.

Check knowledge of when and how to physically administer naloxone:

- Keep in wrapper unless you need to use the kit (prevent confiscation).
- Remove wrapper and twist box to open.
- Explain contents (5 doses, 2 needles, barrel and leaflet).
- Twist grey cap off and.
- Remove needle from wrapper, twist needle onto barrel and remove the needle cover.
- Inject into outer thigh muscle one dose at a time.
- Place in yellow box between injections and after used (acts as a cradle/sharps bin).
- Give used kit to paramedic or a pharmacy for disposal.
- Ask your drug worker, doctor or pharmacy for a new kit.

The above person has demonstrated an understanding and awareness of opiate overdose, the use of naloxone, calling 999, the recovery position and basic life support and is eligible to receive a supply of take home naloxone

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Appendix 2 - Grampian Naloxone Take Home Program - Record of Training and Supply

TRAINING (ONE TO ONE CHECKLIST COVERED)

☐ Person at risk  ☐ Family Member/Friend  ☐ Service Worker  Sex: ☐ M  ☐ F

CHI/Date of Birth: ........................................... Unit Number (SMS only)...............................

Trainee Name: ..........................................................................................................................

Address: ...................................................................................................................................

.................................................................................................................................................... Postcode: .......................................

Declined training? ☐ No  ☐ Yes – Reason* ......................................................................................

* e.g. Received training elsewhere (record details of service & date of training below if known)

Date Trained: ............................ Prison Release date (if applicable): .............................

Name of Training Service: ...........................................................................................................

Name of Trainer: ..........................................................................................................................

I consent to:

• Details of this training/supply being recorded on the electronic database
• Anonymous sharing of data with the NHS for purpose of reporting and research

Signed (trainee): .................................................................

Signed (trainer): ............................................................... Date: ......................................

NALOXONE SUPPLY/RESUPPLY

Declined supply of naloxone?  ☐ No  ☐ Yes - Reason .................................................................

Date Naloxone kit supplied (if different from above): ..........................................................

Batch number: ................................................. Expiry Date: ...............................................

Member of staff making supply (if different): ............................................................................

☐ 1st supply  ☐ Spare supply  ☐ Used on self (Complete reverse)  ☐ Used on other (Complete reverse)

☐ Expired  ☐ Confiscated  ☐ Damaged  ☐ Lost  ☐ Not known
NALOXONE RESUPPLY – Where the naloxone kit has been used on somebody

When did the overdose occur? (Approximate date):

Who administered the kit?
- ☐ Self
- ☐ Paramedic
- ☐ Another person
- ☐ Unknown

Where did the overdose occur?
- ☐ My own home
- ☐ Somebody else’s home
- ☐ Another indoor location
- ☐ Outdoors
- ☐ Other (state)

What was the outcome?
- ☐ Opioid reversed, person went to hospital
- ☐ Opioid reversed, person did not go to hospital
- ☐ Person did not survive
- ☐ Kit not used
- ☐ Not known

Additional Information: