Standard Operating Procedure (SOP) and Competency Framework for the supply of Take Home Naloxone (THN) by North Yorkshire Horizons

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Approved by:	ICGB Board
Signed:	*Julie Fleetwood (chair)*
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Purpose

This SOP aims to provide guidance on the supply of Take Home Naloxone (THN) by North Yorkshire Horizons (NYH) to service users, family members, carers and other groups for the purpose of temporarily reversing opioid overdose. This SOP is intended as a framework for the supply of THN injections by staff and applies to all paid employees, volunteers and peer mentors within the NYH partnership. It should be read in conjunction with the Spectrum Community Health PGD on the use of Naloxone, the NYH Standard Operating Procedure for the Administering of Naloxone and relevant NYH shared policies.

This SOP is based on:

- 'Take-home naloxone for opioid overdose in people who use drugs' PHE Feb 2015 (updated July 2017): http://www.nta.nhs.uk/uploads/phetake-homenaloxoneforopioidoverdoseaug2017.pdf
- Statutory Instruments: The Human Medicines (Amendment) (No 3) Regulations 2015 no 1503

Introduction

The key aims of the implementation of Take Home Naloxone (THN) are to:

- Reduce morbidity and mortality associated with drug use
- Promote harm reduction by disseminating appropriate equipment and information
- Improve health and social care for drug users and their carers
- Enhance service provision for service users
- Provide consistent communication about the acute risks of drugs

Naloxone is an opioid antagonist. It can reverse the effects of opioids and prevent death if used within a short period following an opioid overdose. The effects of Naloxone in reversing opioid overdose last for about 20 minutes. As this is shorter than the duration of opioid effects, the person may return to overdose state when the effects of Naloxone wear off. Mixed agonist/antagonist opioids such as Buprenorphine are only partially reversed by Naloxone, but less likely to cause respiratory depression than heroin or methadone.

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Research has shown that a high proportion of overdoses are witnessed, yet medical help is often not sought or is sought too late. Witnesses at an overdose event are however, often willing to intervene so providing training in cardiopulmonary resuscitation, recognition of overdose and the use of Naloxone by service users and/or their carers, can improve chances of an individual surviving an opioid overdose. Studies indicate that at least 50% of opiate users will have experienced a non-fatal overdose at some point in their lives, and are at increased risk of suffering a fatal overdose.

Naloxone administration can precipitate withdrawal symptoms in someone who is opioid dependant, increasing the likelihood of aggression and further opioid ingestion. Close monitoring is therefore required for several hours after an overdose reversed by Naloxone, preferably within a medical setting (e.g. hospital). In a small number of cases, severe but short-term complications have been reported, including cardiac problems and potential adverse effects on a foetus where victims are pregnant. North Yorkshire Horizons will ensure that THN is provided and that those supplied with THN are aware that it should not be used as a substitute for calling emergency medical services.

Legislation

Under changes to the Human Medicines Regulations (2015); there is now no need for Naloxone to be supplied on prescription. Naloxone can be provided by substance misuse services to specified individuals, without prescription, Patient Group Direction, or Patient Specific Direction. Naloxone can be administered by injection by trained individuals for the purpose of saving a life.

Which services can dispense Naloxone?

Take Home Naloxone (THN) can be supplied by any substance misuse service provider, including:

- Primary care drug services
- Needle exchange services including pharmacies
- Pharmacies dispensing under supervised consumption contracts

A drug service cannot supply stocks to another service or organisation. Under the new legislation:

- A hostel that is not a commissioned drug treatment service cannot supply naloxone to individuals
- A drug treatment service can’t supply naloxone to a hostel, which is an organisation

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- However, a drug service can supply a named individual in a hostel (or other facility where drug users gather and might be at risk of overdose), which could be a hostel manager or other member of staff

Which individuals can dispense Naloxone?

Take Home Naloxone (THN) can be dispensed by people employed or engaged in drug treatment services who will be able to supply naloxone where it is required for saving life in an emergency.
These staff can supply THN to individuals in the following groups:

- An individual who is using or has previously used opioids (illicit or prescribed) and is at potential risk of overdose
- A carer, family member of friend who may witness an individual overdose
- A named individual/ staff member in a hostel (or other facility where drug users gather and might be at risk of overdose)

Trained NYH Outreach Workers would also be able to carry stocks of naloxone and supply it to drug users.

For individual scenarios not allowed by the new regulations, prescribing of naloxone is still available (either by prescriber, or nurse/other worker under Patient Group Direction or Patient Specific Direction).

Provision of Take Home Naloxone (THN) in NYH

Determination of individuals to be offered THN has been identified in line with NICE guidelines in relation to identifying higher risk groups i.e. injecting, street homeless and/or opiate users recently released from prison. The following criteria has been documented and agreed by NYH partners at the ICGB:

- Users of illicit opiates
- Known affiliation with illicit opiate users
- Currently homeless
- Prison/detox/rehab/hospital leaver (within last 2 weeks)
- Recent overdosed
- Known affiliation with another person who has recently overdosed
- Recent abstinence
- Recent IV use
- Recent poly drug use
- Recent significant life event (e.g. death of a friend, child removal, relationship breakdown, etc.)
- Concern of health or social vulnerability

Recent in the above list is defined as being within the last 12 months

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Identification of potentially eligible individuals can come from within the NYH treatment caseload (by NYH staff), harm reduction services, local agencies and/or carers/family members with consent from the individual. Determination of eligibility (in line with criteria set at ICGB) and decision to supply an individual will then be agreed by NYH's relevant (by hub area) Lead Practitioner and relevant NYH Recovery Coordinator and/or hub Open Access & Engagement Worker. Consideration will be taken for those individuals possibly pregnant who will be required to attend a clinical appointment to discuss specific risk factors. Supply can then be made by suitably trained staff once all training/ competency frameworks have been completed (see appendices).

Training, support and governance for staff supplying THN

Supplies of THN will be made by NYH staff, volunteers or peer mentors who have been signed off by the Harm Reduction Coordinator and added to the THN Staff Training Record (see Appendix A) by completing the following:

- A half-day 'train the trainer' delivered by Martindale Pharma
- Completed all sections of the THN Staff Training Matrix (See Appendix B) with NYH Harm Reduction Coordinator, Lead Practitioner (if suitably trained) or Clinical Lead (either on a one to one or group PDG basis)
- Has read and understood the NYH Take Home Naloxone SOP and any additional training documents

Initially training will be provided to NYH Open Access & Engagement (OA & E)Workers and Lead Practitioners. New OA&E staff will be trained within 12 weeks of commencement and additional staff will be trained should the service require. Each trained member of staff will be required to complete 'refresher' training documented on the training record on an annual basis. Any issues arising from non-compliance with the SOP will trigger the submission of a Serious Untoward Incident (SUI) so that learning can be drawn and trends identified by the Quality and Performance and Senior Management Team. Training will be applied to those areas and team meetings to share best practice. Any identified errors or omissions by individual staff members will be addressed through usual professional development, supervision and performance management by the Lead Practitioner.

Training, supply, recording and administration of THN to service users, carers and eligible others

Training

Training and supplies (to service users) should only be made by NYH staff, volunteers or peer mentors who have been signed off to do so. 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 all aspects of the Prenoxad information and instructions included within the THN kit, including:

- What Prenoxad injection is used for
- When and how Prenoxad injection is given
- Possible side effects
- Storing Prenoxad
- Contents of the THN kit (one naloxone injection 1mg/ml as a 2ml pre –filled syringe, 2 needles and an information leaflet)
- Recognition of an overdose and that the procedure is to: call an ambulance, place the victim in the recovery position, inject Naloxone into the thigh or upper arm muscle, wait with the victim until the ambulance arrives and safely dispose of the Naloxone kit to paramedics (having enclosed both used and unused needles, as well as the syringe, within the yellow THN container)

The above areas and the process of using the Naloxone kit must be explained and demonstrated using a sample kit and the individual's understanding documented on the Service User Training Checklist (see Appendix C). This should be done each time a kit is given out or replaced. Where there is a chance a service user may be pregnant, they will also be encouraged to attend an appointment with a NYH clinician to further discuss potential short-term effects of Naloxone on a foetus.

Supply

Each eligible individual will be supplied one Prenoxad pre-filled syringe/pack as supplied by Martindale Pharma and ordered by the Harm Reduction Coordinator from Orion Medical. Each pack includes one Naloxone injection 1mg/ml as a 2ml pre –filled syringe and Prenoxad information and instructions sheet. Each 2ml syringe is marked out with 5 x 0.4mg doses which is the minimum effective dose which can be given in an attempt to reverse the effects of opioid overdose. When supplied with a THN kit, individuals will need to sign two copies of the Take Home Naloxone Agreement (see Appendix D) to acknowledge receipt of the kit and understanding of their responsibilities around its use and the recording and evaluation of THN provision by NYH.

Recording

The supply of THN must be recorded using the approved SystmOne (if registered) template for North Yorkshire Horizons and should include:

- Details of the THN supplied (batch number, expiry date, kit number)
- Date training was provided, by who and who to (if a carer)
- Details of additional and/or clinical appointments/discussions (if applicable i.e. where service user is pregnant)

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- Signed copy of THN Agreement attached to the service user record (if on SystmOne)

Where naloxone has been used, the following should be recorded where possible:

- Circumstances of the overdose: who, when, where, etc.
- Whose naloxone was used by whom
- How many naloxone doses were given and their effects
- Advice given to the overdosed person/outcome of the overdose and its treatment (i.e. whether individual attended hospital)

This will be recorded initially on the THN Feedback Form (see Appendix F) and transferred on to the THN template on SystmOne by the staff member completing the form.

Where supplies are made to individuals not present on the case management system i.e. hostel managers or NEX only individuals, the above will be documented and managed by the Harm Reduction Coordinator and stored securely within the NYH network. All supplies should be recorded by the relevant hub on their Supply of THN Register (see Appendix E).

Administration

Used THN kits will be replaced by NYH wherever possible. Replacement kits will be supplied to individuals following the same process as the initial supply and recorded in the same way and indicating on the record as a re-supply. Lead Practitioners and the Harm Reduction Coordinator will take responsibility for ensuring that hubs are suitably stocked with THN kits following the initial batch order and roll out of THN provision by the service.

THN kits have a shelf life of 3 years. No THN kit supplied by NYH will carry an expiry date of before January 2020. NYH will undertake regular audits of the take-up and use of THN within the contract timescale and will provide information and recommendations to commissioners and partners regards need for continued provision under future drug treatment contract arrangements in North Yorkshire. NYH will ensure that individuals supplied with THN are aware of the need to dispose of used or expired kits through the correct channels (i.e. paramedics, needle exchange{NEX}/pharmacy needle exchange{PNEX}).

Storage of THN

Where THN is stored will differ from site to site. For this reason, it will be the responsibility of hub Lead Practitioners to ensure that:

- Supplies for emergency use for suspected overdose on site (refer to relevant SOP) are kept separate from supplies of THN (preferably in one of the clinical rooms)
- THN should be kept in it's original container and in stored in a cool, dry place (good practice guideline not to exceed25 degrees C), protected from light
- Trained staff are aware of the location of THN within their hub

Safe storage of THN for individuals supplied with THN is included within the training and signed off on the relevant checklist and THN Agreement.

Transportation of THN

Transportation of THN between NYH hubs (following the initial batch order), will be carried out by approved staff and recorded by the Harm Reduction Coordinator. Additional THN stock for individual hubs will be ordered (from Orion Medical) by the Harm Reduction Coordinator or Lead Practitioner and delivered to the relevant site.

Preferably, THN will be issued to service users on site and service users advised to take home their THN immediately for storage in a safe place. Where THN must be transported to service users, this should be done only by approved staff. THN kits must not be left unattended at any time during transport. A record of the transport of THN by the persons issuing, transporting and receiving the THN should be captured on the THN Agreement signed by the service user and NYH issuer.

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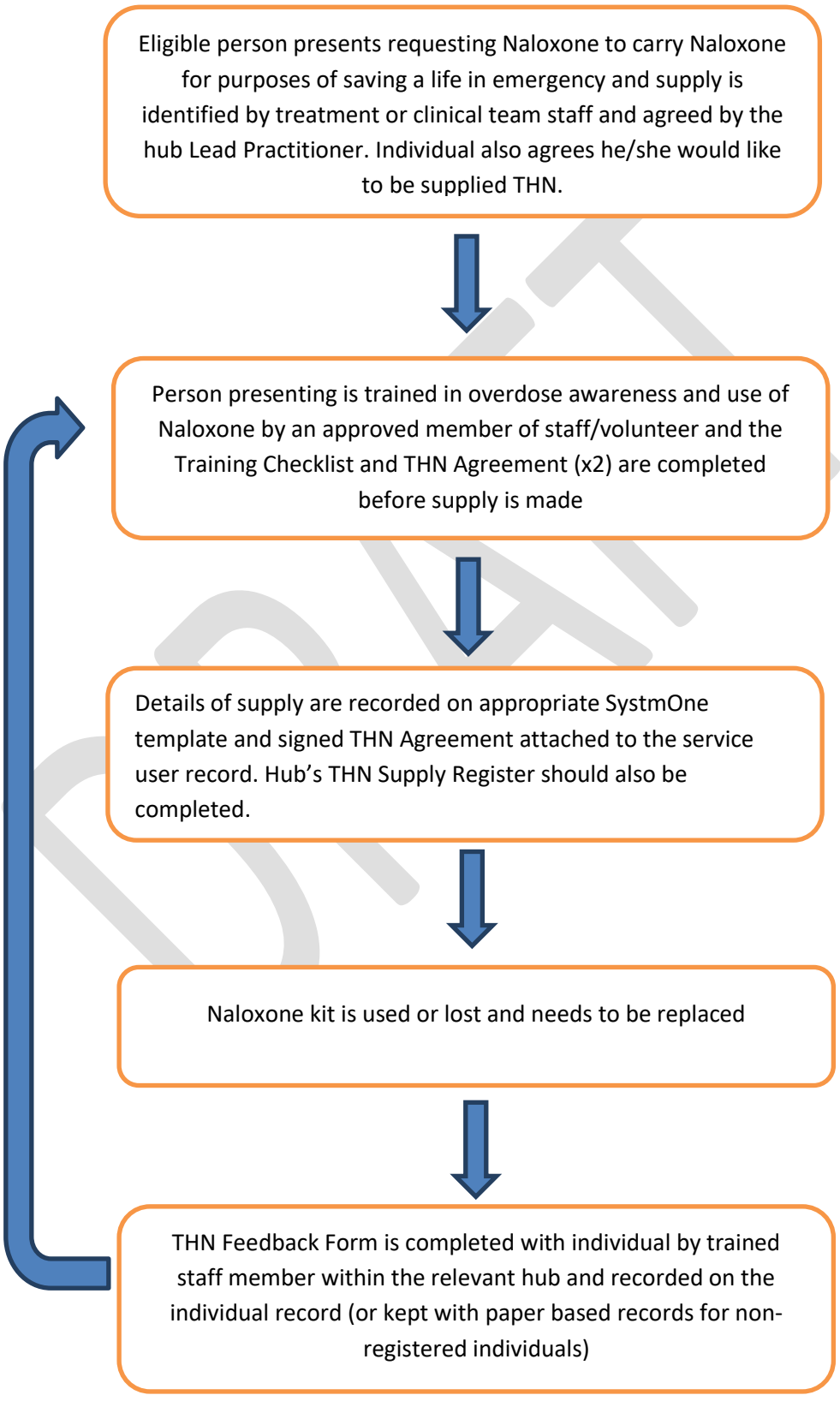
NYH THN Process Map



Appendix A: NYH Training Record

This training record should be retained within North Yorkshire Horizons and updated by the Harm Reduction Coordinator once approve staff have completed all aspects of the Take Home Naloxone Training and completed the THN Training Checklist.

Staff Member (please print)	Signature	Date

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Appendix B: NYH THN Staff Training Matrix

Name of staff: …… Assessment completed by…… Date of assessment: ……

Opiate overdose context issues	Date when competent	Not applicable	Comments	Refresher date
Knows approximate numbers of opiate related deaths and how/when reports are published				
Is aware of trends in the UK and locally related to own area				
Is aware of the fact that most overdoses which include the use of opioids are witnessed and how this relates to harm reduction opportunities and saving of life				
Is aware of the risk factors in overdose – including popular myths				
Has a good understanding of which are high risk times for individuals who use opioids				

Policy and procedure	Date when competent	Not applicable	Comments	Refresher date
Has read and understood the NYH THN SOP				
Understands the procedures and any PSD or PGD that applies to the supply of Naloxone and has been signed off as competent				

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(separate document), if relevant to their role.				
Understands the requirements of audits and gaining consent according to policies				
Knows the procedure for ordering new supplies of Naloxone if this is relevant to their role				
Can correctly record receipt of supplies of Naloxone if this is relevant to their role.				
Management of emergency situations	**Date when competent**	**Not applicable**	**Comments**	**Refresher date**
Knows about the procedure required if an overdose of opioids were to occur on premises and who would take responsibility for managing the incident				
Understands the signs and symptoms of an opioid overdose				
Correctly understands the immediate assessment of consciousness and breathing in someone suspected of an opioid overdose				
Shows good knowledge and skills in: • Placing an individual in the recovery position • How and when to call for assistance • How to administer basic life support and cardio-pulmonary resuscitation, demonstrating assessment, good technique and management of an emergency situation • The properties and action of Naloxone • The administration of Naloxone				

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Understands the requirement around recording and completing incident reports if required				
Recorded observations (include what has been observed)	**Date when completed**	**Comments**		
Is able to deliver sessions/advice to service users on the management of opioid overdose and administration of Naloxone				
Is aware of all supporting literature available when advising service users and/or their carers and can demonstrate how this supports verbal guidance				

By signing below you agree this person has met all the criteria above and is competent to deliver opioid overdose training/advice to service users and supply them with Naloxone to take home.

Signature of Manager: …… Date: ……
Signature of staff member: …… Date: ……
Date of review: ……

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Appendix C: **NYH THN Service User Training Checklist**

Service user name:……. Date of birth:…….....

Representative name (if applicable):……..

Evidence of understanding	Assessor's signature
What are the signs and symptoms of suspected opioid overdose? Unconscious, not responding to touch or noise, breathing difficulties, heavy snoring, rasping sounds, pinned pupils, blue tinge to lips, nose, fingertips.	
How and when would you call an ambulance? Dial 999. Prenoxad is not an alternative to calling an ambulance.	
Describe what resuscitation you would provide? Recovery position/CPR specify different actions depending whether patient is breathing or not breathing.	
When would you inject Prenoxad? When the person will not wake, shows signs of overdose and they have been put into the recovery position. Call ambulance first.	
How long do the effects of Prenoxad last? 20 – 30 minutes. Overdose may return after this, especially if the person uses opioids again.	
Describe what Prenoxad is and how it works? Opioid antagonist, antidote to heroin, reverses effects of heroin temporarily, does not reverse alcohol or benzos, quick acting 2-8 min.	
How do you inject Prenoxad? Assemble the injection as shown on the leaflet provided. Inject 0.4ml (up to the first black line) into the muscle of the outer thigh or upper arm. Repeat another 0.4ml dose every 2-3 minutes until the person wakes up or the ambulance arrives	
Are you aware of the importance of staying with the person and handing over to the paramedics when they arrive? Tell the paramedics what the person has taken if you know, hand the Prenoxad kit to the paramedics.	

I confirm that the above named service user or representative has had Prenoxad training, has demonstrated sufficient understanding of overdose and using Prenoxad and has been provided with a Prenoxad kit and Prenoxad information:

Staff sign:……Service user sign:……

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Appendix D: NYH Take Home Naloxone Agreement
(2 copies: one for individual being supplied and one to be stored by the service)

- I understand I have been given a supply of Naloxone to use if I suspect an individual has overdose on opiates
- I understand that it is my responsibility to store and transport Naloxone safely and appropriately
- It is my responsibility to call for emergency services immediately. Using Naloxone is NEVER instead of seeking emergency medical help.
- I have been given training in the dangers of opiate overdose, basic resuscitation and the appropriate administration of Naloxone
- I am aware that the needles supplied are strictly for Naloxone use **only**
- I understand that Naloxone is a treatment specific drug that reverses the effect of overdose and needs to be used only for the purpose of saving lives
- I agree to be contacted at a later date to assess my knowledge and/or use of overdose training and Naloxone
- I give my consent that information regarding take home Naloxone being supplied to me may be stored by NYH on their case management system and shared between relevant parties e.g. service providers, commissioners
- I understand that it is my responsibility to update NYH on the use, loss, damage or other to the THN kit I have been issued as soon as possible

Individual being supplied name	
Signature	
Date	
Approved practitioner name	
Signature	
Date	

Drug: Naloxone HCL 2ml pre filled syringe 1ml/1mg	Quantity issued:	Issued by:	Date	

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Appendix E: NYH Take Home Naloxone Register

HUB:

Date:	Supplied by (staff):	Quantity supplied	Batch Number and Expiry date:	Name & ID of Service User/ eligible other:	Treatment client, NEX only client, Hostel staff or carer??	Kit no.	Re-supply Y or N?

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Appendix F: NYH Take Home Naloxone Feedback Form

Service user's name: ……

Date: ……

Take home naloxone kit used on: **SERVICE USER** or **SOMEONE ELSE**

How much was given (0.4mg per black line, total 2mg):

1 DOSE or **2 DOSES** or **3 DOSES** or **4 DOSES** or **ALL**

What was the outcome: ……

Was the ambulance called: **YES** or **NO**

If NO can you please state why: ……

How was the used kit disposed of: ……

Has a new kit been given: **YES** or **NO**

Would the service user like to tell us anything else about their experience of using take home naloxone:

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Staff name: ……

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