



Llywodraeth Cynulliad Cymru
Welsh Assembly Government

Guidance and Training Protocol for the Development of the Introduction of Take Home Naloxone

JUNE 2009

Contents	Page Number
Introduction	3
Introducing take home Naloxone locally	4
Training Guidance	5-7
Patient Group Direction/Patient Specific Direction, Data Collection	8
ANNEX A – National Working Group membership	9-10
ANNEX B – Training Protocol	11-15
ANNEX B (APPENDIX 1) Training Presentation	16-19
ANNEX B (APPENDIX 2) - Opiate Overdose and use of Naloxone Information Sheet, In Order to Dispense	20-21
ANNEX C – Example Patient Group Direction, Patient Specific Direction	22-31
ANNEX D – Consent Form, Data Collection Form, Replenishing used and out of date stock	32-34

Introduction:

This guidance is for Community Safety Partnerships and Service Treatment Providers to assist them in the introduction of take home Naloxone. The guidance has been developed and agreed with the National Working Group whose membership is at Annex A. This document will be reviewed and refreshed in the light of the lessons learned arising out of the demonstration sites.

In the Welsh Assembly Government's new strategy for tackling substance misuse "Working Together to Reduce Harm", there is a commitment to take actions which focus on reducing the number of drug related deaths and near fatal drug poisonings. One of those key actions contained in the strategy's 3 year implementation plan is the development of guidance and protocols to introduce Naloxone. In December 2008 the Welsh Assembly Government announced its intention to establish demonstration sites for take home Naloxone.

This guidance provides detailed advice on the various elements that will need to be addressed for the successful introduction of take home Naloxone.

The key aims of the implementation of take home Naloxone 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
- Assist the Regional Confidential review Panels in monitoring overdose incidents
- Enhance service provision for service users
- Provide consistent communication about the acute risks of drugs

For further information please contact: Rhian Hills – National Lead for Naloxone
E mail: Rhian.Hills@wales.gsi.gov.uk
Phone: 01495761423

Who Can Administer Take Home Naloxone

Naloxone is a prescription-only medicine and must be prescribed for a named patient or supplied to an individual by means of a Patient Group Direction (PGD). However, it can be administered by anyone to another person for the purpose of saving life.¹

¹ Department of Health (England) and the devolved administrations (2007). *Drug Misuse and Dependence: UK Guidelines on Clinical Management*. London: Department of Health (England), the Scottish Government, Welsh Assembly Government and Northern Ireland Executive

Cycle of overdose management

In order to reduce the risk of overdose, and minimise the harm caused by such incidents, overdose management should be regarded as a cyclical process and one that offers a number of opportunities for individuals and agencies to intervene effectively at different points.

Figure 1 sets out the cycle of overdose management that has been constructed from the Glasgow Naloxone Pilot, whereby evidence was provided by people who have experienced overdose, witnessed overdose, police, ambulance staff and A&E Consultants. It sets out the process and action points which represent both the optimal overdose survival pathway and a learning cycle to prevent future overdose.²

Figure 1



Introducing Take Home Naloxone Locally:

The National Working Group has identified three key elements that need to be addressed to effectively implement and deliver take home Naloxone

- 1) Appropriate training of individuals who will be administering Naloxone
- 2) The establishment of locally agreed protocols (Patient Group Direction/Patient Specific Direction) for the supply and administration of Naloxone
- 3) Robust data collection

² *Reducing Drug Users' Risk of Overdose* (2008), Part 7, Scottish Parliament, The UK Parliament, National Assembly for Wales, Northern Ireland Assembly

Training

Ethos of Training:

Not all overdoses are preventable; however training service users allows appropriate help to be available which can save lives. In this context it is not only the use of Naloxone that is essential, first aid skills can also be vital. In addition to this it is paramount to dispel myths of dealing with overdose and provide service users with the necessary skills to allow them to recognise when an individual has gone into an overdose state. Essentially when people are in overdose, outcomes for individuals can be substantially improved by individuals administering Naloxone – a drug that immediately reverses the effects of the opiate. This drug can restore consciousness and provide enough time for the ambulance to arrive.

Aim of Training:

The aim of the training is to reduce the vulnerability of injecting drug users through both first aid skills and the provision of Naloxone. The training will attempt to do this by:

- Developing targeted first aid learning for injecting drug users focusing on the key skills most likely to make a difference in crisis situations that learners are likely to encounter
- Providing access to Naloxone and education in its use

Who to Target

- **All drug users**, but especially those most at risk of overdose, e.g. people leaving prison, those in or due to leave residential detoxification or residential rehabilitation, homeless people and people who are not in contact with mainstream services.
- **Poly-drug users**. There is a general awareness that using more than one drug at a time increases the chance of overdose; however many overdoses occur when people have, for example, used their normal amount of main drug but also drink alcohol, take benzodiazepines (such as diazepam) etc. There is a general consensus that a drug used several hours ago is no longer effective. Service users need to understand that a drug used several hours ago will still be in their system and increases the chances of overdose.
- **Hard to reach drug users** who are usually homeless and not in touch with mainstream services. These users are usually more chaotic and have fewer support networks in place.
- **Long-term users** who have a high tolerance level and may have become complacent about the risks of overdose.

- **Staff**, some of whom may witness overdoses themselves. It is useful for staff to have a good understanding of overdose prevention so they can advise service users and also attract people into the training. It will often be the frontline staff who are relied upon to do so. Staff can be included in training where there is capacity or a separate staff-only session may be preferable.

As a minimum, service treatment providers must consider the following:

- Drug workers should receive updated overdose information and training as part of their continuous professional development. This may allow for improvement in cascading information to client groups and those most at risk.
- Telephone response staff should be provided with information regarding the management of overdose including guidance on the use of Naloxone.
- Overdose awareness training should be made available to all police, ambulance staff and clinical staff working in primary care and hospitals. This should cover the prevention and management of overdose as well as the principles of harm reduction.

How to attract drug users

- Advertise training sessions through posters and flyers in local drug projects and needle exchange services, outreach sessions, hostels, squats, word of mouth and newsletters such as The Big Issue and Drink and Drug News (DDN)
- Pay participants' travel and offer refreshments.
- Consider ways to encourage involvement, such as paying participants to attend the training, i.e. give a voucher. In some pilot schemes (e.g. South Gloucester), all clients were paid £10 for attending training.
- Make the training accessible to service users. Ideally the training should be taken to them. If training sessions are being run in a treatment service, the training sessions could be arranged to coincide with clinic times or service user meetings so that people only have to make one journey.
- Experience in delivering basic harm reduction advice has shown that the length of training can affect learning outcomes. It is therefore suggested that as a minimum training should last one to two hours. Demonstration sites are introducing a variety of training packages ranging from in house training to training in collaboration with the British Red Cross. All decisions on training length and content should be discussed at a local level.

Learning outcomes

Service treatment providers should ensure service users are competently trained in order to participate in the provision of take home Naloxone. As a minimum, training sessions must cover the following headings:

- Overview of the main risk factors for drug overdose
- How to recognise when someone has overdosed
- Overview of the most common myths and dangerous practices in response to overdose
- Information on Naloxone, its use, safe keeping of Naloxone, disposing of equipment and replacement Naloxone
- Question and answer session

A model training protocol can be found at Annex B accompanied by a suggested presentation for training purposes at Appendix 1.

Following the presentation, the training should include practising injecting techniques (most agencies use oranges for this purpose).

At the end of the training session participants should be able to:

- Summon medical assistance appropriately and confidently
- Identify the key risks for accidental overdose
- Recognise the signs and symptoms of a drug overdose
- Keep themselves safe, e.g. look out for used needles if dealing with someone who has overdosed
- Assess vital life signs and prioritise actions to provide first aid
- Place someone in the recovery position
- Give mouth to mouth resuscitation
- Provide cardio-pulmonary resuscitation (CPR)
- Outline common myths and dangerous practices in overdose response
- Discuss what has been covered in the session.
- Have in depth knowledge of Naloxone and its effects
- Practised injecting Naloxone
- Each individual must complete a consent form (A suggested format can be found at Annex D)

At the end of the training session you will need to issue an information sheet to each individual. A model is at Appendix 2 of Annex B.

Patient Group Direction (PGD)/Patient Specific Direction (PSD)

Before take home Naloxone can be issued by anyone other than a prescriber a PGD and/or PSD must be agreed by the NHS Trust and/or Local Health Board (LHB). A PGD is a written instruction for the supply and administration, or administration, of medicines to groups of patients who may not be individually identified before presentation for treatment.

A PSD enables the supply of a Prescription Only Medicine (POM) to be made within the course of the business of an NHS Trust, LHB or other NHS body in accordance with the written directions of an appropriate practitioner for a specific patient i.e. a named individual.

Welsh Assembly Guidance on PGD's and PSD's are contained in Welsh Health Circular WHC 2000/116.

All agencies are strongly advised to engage their appropriate pharmaceutical colleagues at the earliest possible opportunity. An example of a PGD/PSD is at Annex C. Please note this is a suggested format only based upon PGDs/PSDs currently in development by members of the National Working Group. All PGD/PSDs must be developed and agreed locally through existing protocols.

Naloxone Preparations

The preparations available at the time of producing this guidance are the ampoule and the minijet. Due to a manufacturing problem, the minijet preparation is currently unavailable. Decisions on the use of preparations are a local matter which will need to be addressed in the development of the PGD/PSD. It is strongly recommended that service users are consulted on their preferences.

Data Collection

It is important to ensure that sufficient information is collected to assist in the evaluation of how Naloxone has helped individuals. This is also an opportunity to identify and respond to other critical harm reduction messages e.g. Blood Borne Virus. An evaluation protocol is being developed and will include measuring the number of Naloxone preparation issued and to whom. All service treatment providers need to ensure they keep up to date records of training and dissemination of take home Naloxone in order to participate in the evaluation process. An example data collection form can be found at Annex D.

Membership of the National Working Group

Karen Eveleigh	Welsh Assembly Government (Chair)
Dr Sarah Watkins	Welsh Assembly Government - Senior Medical Officer
Diane Heath	Welsh Assembly Government - Pharmacy Division
Rhian Hills	Welsh Assembly Government – Naloxone Project Lead
Tim Powell	Welsh Assembly Government – Secretariat to the group
Robert Willis	Welsh Assembly Government – Social Justice -Senior Research Officer
David Evans	Swansea City Council – representing Swansea Community Safety Partnership
Erica Painter	Cardiff City Council – representing Cardiff Community Safety Partnership
Ian Price-Jones	Newport City Council – representing Newport Community Safety Partnership
Ceriann Tunnah	Conwy County Council – representing Conwy Community Safety Partnership
David Ashworth	North Wales Police
Alison Fisher	South Wales Police
Chris Moore	Welsh Ambulance Service
Alex Paterson	National Offender Management Service
Rowena Williams	National Leadership And Innovation Agency for Healthcare
Dorothy Edwards	Swansea Local Health Board
Vanessa Morton	Swansea Local Health Board
Jill Timmins	North Wales NHS Trust
Ravi Vadrhi	Cardiff and the Vale NHS Trust
Neville Brooks	Crime Reduction Initiative
Glyn Davies	South Wales Drug Intervention Programme – Assistant Manager
Jeff Evans	GPwSI Consortium (Community Prescribing Service)

	Gwent)
Ifor Glyn	Swansea Drugs Project
Nathan Greig	Crime Reduction Initiative
Andrew Hopkins	Gwent Specialist Substance Misuse Service
Gareth Hopkins	South Wales Drug Intervention Programme - Manager
Dr Julia Lewis	Gwent Specialist Substance Misuse Service
Mike Mallett	Gwent Specialist Substance Misuse Service
Francine Miles	Kaleidoscope
Dr Rosanna Oretti	Cardiff Addictions Unit
Alison Palmer	Gwent Specialist Substance Misuse Service
Katy Playle	Drug Intervention Programme Manager for North Wales Probation.
James Varty	Kaleidoscope
Lyn Webber	Gwent Drug Intervention Programme Manager
Rowan Williams	Gwent Open Access Local Service
John Charles	Wicked Wales – Service User Group
Sian Heke	Wicked Wales – Service User Group
Phil Williams	Wicked Wales – Service User Group

Training Protocol

The following questionnaire should be used at the start of the training session to test individuals' knowledge of overdose.

This should then be repeated on completion of the session to gauge level of understanding. Any gaps or misunderstandings should be addressed by the Trainer before issuing an individual with the Naloxone pack.

Pre and Post Training Naloxone Questionnaire³

Trainers Notes:

The purpose of this questionnaire is to dispel the myths about overdose and Naloxone. Individuals/groups should be told it is not a test but is designed to prompt discussion and identify the facts.

The following questions require true/false answers. The correct answer is underlined.

Naloxone is used for:

1. Helping someone get off drugs
2. Bringing someone back from a cocaine overdose.
3. Bringing someone back from a heroin or methadone overdose
4. None of the above.

Your risk of overdose increases when you:

1. Mix opiates with other downers like alcohol or benzos (diazepam, Temazepam etc)
2. Use after your tolerance has gone down (because you were in prison or drug treatment, for instance).
3. Use a stronger (more pure) product than usual
4. All of the above.

You can tell when someone's overdosing (not just really high) when

1. They don't respond to loud calls or being shook
2. Their lips and nail beds look blue
3. They emit a deep gurgling sound
4. All of the above

Which one of these methods is a good way to deal with a person when overdosing?

³ Overdose Prevention Resources www.psi.org/HIV/IDU/overdose

1. Put the person in a cold bath
2. Hit them hard to shock them awake
3. Put them in the recovery position and call 999
4. Inject them with cocaine or salt water

Injecting Naloxone can reverse a cocaine overdose:

1. True
2. False

Naloxone should be injected:

1. Under the skin
2. Into the stomach
3. Into a big muscle like the upper arm, butt, calf
4. Into a vein

After you inject the Naloxone, it is important to:

1. Call 999 or make sure someone does
2. Stay with the person or make sure someone does
3. All of the above

An overdose can outlast a dose of Naloxone, so you should dial 999 and ask for an ambulance and stay with the person until it arrives

1. True
2. False

You can overdose on Naloxone

1. True
2. False

Staff Initial:_____

Training Protocol (Continued)

Service treatment providers should ensure that individuals are competently trained in order to participate in the provision of take home Naloxone. As a minimum, training sessions must cover the following topics:

Overview of the main risk factors for drug overdose

- Main risk 'groups', i.e. people leaving prison and detoxification, or having recently stopped the use of Naltrexone⁴
- Injecting drugs
- Longer history of injecting
- Poly-drug use. Risks associated with using combinations of depressant drugs, e.g. mixing heroin with other sedative drugs or mixing with alcohol

How to recognise when someone has overdosed

- Deep snoring/'gurgling' noises
- Not able to wake, not responsive to noise or pain, e.g. pinching earlobe
- Turning blue
- Not breathing
- No pulse

Overview of the most common myths and dangerous practices in response to overdose

Allow the group to discuss common misconceptions about how to respond when someone overdoses, such as:

- Putting them in cold baths
- Walking them around the room
- Taking them outside for 'fresh air'
- Hitting them

⁴ an oral antagonist against the action of opiates

- Injecting salt water

Emphasise that if someone is overdosing, they cannot be **'forced'** into regaining consciousness.

What is Naloxone?

An opioid antagonist – It **temporarily** reverses the effects of opioids.

How does a patient respond to Naloxone?

Duration and type of effect from Naloxone depends on:

1. Which opioid has been used
2. How much opioid is being used e.g. methadone v's heroin
3. By what means was it taken, i.e. oral, IV
4. Any other drugs or alcohol taken

If someone has taken an opioid overdose, a single dose of Naloxone **buys time**. The patient still needs to go to hospital. Please dial 999 for an ambulance

Where should it be kept?

- a. Carried by the patient on their person
- b. A specific place at home or the place where you use drugs. You should also let others know where it is kept

What about safety?

Naloxone should be kept out of the reach of children. The expiry date also needs to be checked intermittently, if it is out of date you need to return to the drug agency to collect another dose of Naloxone

How is the Naloxone syringe assembled?

Instructions leaflets are included in the take home Naloxone pack. There are dummy or (out of date) syringes available which can be used to practice assembling the syringe. It is important to emphasise that care must be taken when placing the vial on the plunger needle as it is easy to eject Naloxone accidentally.

Where should Naloxone be Injected ?

It is quicker and easier to give into a muscle, i.e., intramuscular. It takes 2-5 minutes to have an effect given intramuscularly. Intramuscular injection is the usual way it is given in Accident & Emergency Departments and by paramedics.

What should be done with the syringe after use?

The syringe should be placed in a sharps bin e.g. in the Ambulance which is called. In addition in areas where ampoule packs are being used the used needle can be placed in the container and given to the ambulance staff or taken back to the service treatment provider.

How to get a replacement dose of Naloxone?

When a replacement dose is needed due to the current dose being used or out of date, an individual should return to the agency where they were originally trained and supplied with the Naloxone pack. If this is not possible, individuals can enquire with any local agency where they can obtain a new Naloxone pack or ring the national helpline DAN 24/7 on 0800 6 33 55 88. When replenishing Naloxone, Agencies must ensure that a consent form and replenishing stock form is completed (Annex D refers). In addition, it is essential that the individual's knowledge is still up to date – it is strongly recommended that the individual be asked to complete the questionnaire at Annex B.

Calling an Ambulance

Throughout the training session it is imperative to emphasise the following:

- Advocate that service users must dial 999 and call an ambulance to assist.
- Naloxone is a short acting drug and lasts between 20 minutes and 1 hour. An overdose can last up to 8 hours; therefore a person may go back into overdose state.
- Police are not routinely called to overdoses, if they do attend this will be to assist the paramedic, with the purpose being to save a life.
- **PLEASE NOTE: The Naloxone pack should not be opened unless it is to administer to someone in an emergency overdose situation. If the pack is opened for any other reason the prescription is invalid and could be removed from an individual if stopped by the Police**

Question and answer session

Give all participants the opportunity to ask questions⁵

⁵ Preston A, Hunt N and Derricott J (2001) *Preventing Overdose Exchange Campaigns* / Department of Health.

SUGGESTED PRESENTATION TO USE AS PART OF THE TRAINING SESSION

What is Naloxone ?

- Naloxone is an opiate antagonist which works by displacing opioids from their receptor sites.
- It is indicated for coma or respiratory depression caused by opioids.
- Naloxone can reverse the effects of overdose if used within a short period following an opioid overdose.

How long does it last ?

- It lasts at least 20 mins and up to an hour.
- It has a shorter duration of action than most opioids.
- Opioid reversing effects of naloxone may end before the effects of the opioid end.
- Therefore a person may return to overdose state.
- Close monitoring is required for several hours after overdose.
- Monitoring should be carried out within a medical setting (e.g. hospital)

Who can use Naloxone ?

- On 30th June 2005, 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.
- This means that naloxone can be given by any member of the public (including all drug service/hospital staff) to a person suspected of having an opioid overdose.

Opioid overdose information

- Opioids include drugs such as heroin and methadone.
- Opioid overdose can occur in anyone using opioids and may lead to death.
- Opioid overdose deaths are frequently related to respiratory depression.
- There has been an increase in opioid overdose deaths in recent years.
- Most opioid overdoses are witnessed by others.

How to Recognise Opiate Overdose



Person unconscious, and cannot be woken – **UNROUSABLE**



CYANOSIS – **BLUE** lips or tongue



Not breathing at all or breathing slowly – deep snoring.



Pin point pupils

Opioid overdose management including use of Naloxone

- Try to wake person – if not responsive....
- **CALL AMBULANCE** – say suspected opioid overdose, and trigger words “ Naloxone Pilot “
- Check airway – clear if blocked.
- Check breathing – give 2 mouth to mouth breaths if not breathing.
- Place in recovery position if breathing.
- Inject naloxone into muscle – thigh, upper buttock or upper arms.
- Continue with basic life support until ambulance arrives.

Actions on Discovering Overdose



CALL AMBULANCE



Check **Airway** – clear if blocked, Check **breathing**.



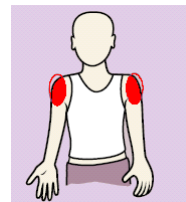
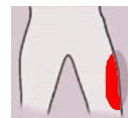
If breathing, place in **recovery** position – if not breathing, begin basic life support or place in **recovery position** to maintain a good airway and prevent them from choking



Administer **naloxone**

Naloxone Administration

- Quickest route of injection is intravenous
- **However INTRAMUSCULAR injection recommended as easier.**
- Inject into a muscle
- Upper outer buttock, thigh area or upper arm.
- Hold needle 90 degree above skin
- Insert needle into muscle
- **Slowly** and **Steadily** push plunger all the way down



APPENDIX 2

OPIATE OVERDOSE AND USE OF NALOXONE INFORMATION SHEET AND ORDER TO DISPENSE

Name:	Date Trained:
-------	---------------

- Opiates are drugs such as heroin and methadone
- An opiate overdose can be fatal
- A death from an opiate overdose may be prevented with Naloxone and ambulance assistance

How do I recognise an opiate overdose?

- Person unconscious (sleepy or difficult to arouse)
- Breathing rate slow
- Pinpoint pupils
- Cold to touch or blue colour of lips/skin

What should I do if I suspect an opiate overdose?

1. Try to wake the person
2. Call an AMBULANCE if not waking
3. Check airway – clear if blocked
4. Check breathing
5. Place in recovery position
6. Inject Naloxone into muscle, thigh, upper outer buttock or upper arms
7. Continue with basic life support until ambulance arrives

What should I do after I use Naloxone?

1. Place the used syringe into the Naloxone pot or sharps bin
2. Give the container to Ambulance personnel or return it to the agency that trained you
3. Contact the agency that trained you to give feedback on the use of Naloxone

By contacting the agency you will be given a replacement dose of Naloxone to take away.

What should I do if my naloxone has gone out of date?

1. Contact the agency who trained you
2. Take your out of date dose back to the agency

Naloxone Checklist and Order to Dispense

Overdose prevention techniques

Educate those you use with! Tolerance, Gradual injecting, Risk factors, Mixing drugs, abstinence, use of naltrexone

Signs of Overdose

Sleepiness, slower breathing, non responsive to verbal/touch, turning blue

CALL FOR HELP → **CALL 999**

A & B of Life – no one dies from opiate overdose if they can be kept breathing!

Clear airway, remove gum, food, anything from the mouth; put in the recovery position.

IF YOU HAVE BEEN TRAINED IN BASIC LIFE SAVING TECHNIQUES YOU CAN CARRY OUT RESCUE BREATHS

Rescue Breathing

On back, lift up back and neck – tip chin to open airway

Remember to clear mouth and pinch off nose, seal your mouth over theirs

Two quick breaths to begin, then one breath every 5 seconds

Naloxone – store away from light and room temperature

Keep Naloxone with you when you are using

Inject into shoulder, buttock cheek or thigh

Breathe for them until the Naloxone works

WAIT FOR AMBULANCE

Return of overdose – Naloxone lasts for between 20 minutes and 1 hour, you need to call an ambulance in case they go back into an overdose

Disp: batch No..... Exp Date.....

Date..... Nurse/Dr.....

NB: IT IS IMPORTANT TO ALWAYS PHONE 999 IF AN OVERDOSE IS SUSPECTED. NALOXONE SHOULDN'T BE USED IN ISOLATION

EXAMPLE: PATIENT GROUP DIRECTION (PGD)/PATIENT SPECIFIC DIRECTION (PSD)



PATIENT GROUP/SPECIFIC DIRECTION

Patient Group/Specific Direction for the supply of Naloxone Hydrochloride as a take home medication to those individuals deemed to be at high risk of future opioid overdose.

NB: Where the patient is known in advance

The patient group direction allows authorisation of the delegation of the supply of the above drug (in the absence of an individual prescription) by a nurse or other qualified practitioner. A **Patient Specific Direction (PSD)** is required to treat people who are known or expected prior to presentation. A PGD may be converted into a PSD by adding the specific names and addresses (or names and date of birth) and having it signed and dated by a doctor (See references for further information)

Role of this Patient Group/ Specific Direction (PGD/PSD) within ABM University NHS Trust/LHB:

This PGD/PSD allows named professionals to **supply** take home naloxone to those individuals deemed to be at high risk of future opioid overdose. The named professional will **supply** naloxone 0.4mg to individuals who have attended a training program run in conjunction with ABMU Substance Misuse Services on overdose prevention, CPR techniques and the administration of naloxone.

ANNEX C Continued

***Patient Group/Specific Direction for the supply of
Naloxone Hydrochloride as a take home medication to those
individuals deemed to be at high risk of future opioid overdose***

Name and address of organisation:	ABM University NHS Trust/LHB One Talbot Gateway, Port Talbot SA12 7BR
Date PGD comes into effect	May 2009
Review/expiry date:	May 2011
Name of Medicine Approved name:	Naloxone injection 400 micrograms/ml
Professionals to whom PGD applies	Registered nurses holding current registration with NMC employed by ABM University NHS Trust/LHB
Lead Doctor signatureDr Christine Brown
Lead Pharmacist signatureCheryl Davies
Lead Nurse signatureGavin Thomson
On behalf of ABM University NHS Trust/LHB Medical Director (or deputy)Dr Bruce Ferguson

ANNEX C Continued

**The Chief Pharmacist should hold the original signed copy of all PGDs.
A copy of the PGD should be easily accessible in the clinical setting and should be read by all health care professionals designated to administer this treatment. If a PSD, a copy should be placed in the patients notes
The Trust through the Directorate must maintain a list of Healthcare Professionals who are authorised to administer treatment under this Direction.**

***Patient Group/Specific Direction for the supply of
Naloxone Hydrochloride as a take home medication to those
individuals deemed to be at high risk of future opioid overdose***

(Adapted from the PGD developed by Avon and Wiltshire NHS Trust)

Define situation/condition	<p>To provide a take home supply of Naloxone Hydrochloride to named individuals with opioid dependence that are deemed at risk of future opioid toxicity.</p> <p>Naloxone can be used to reverse the action of opioids such as heroin, methadone, morphine (inc. MST[®]), pethidine, dihydrocodeine (DF118) or buprenorphine (Temgesic[®], Subutex[®]).</p>
Criteria for inclusion	<p>Opioid dependent individuals aged 16 years and over who reside within the locality of the ABM University NHS Trust/LHB who are deemed to be at risk of future episodes of opioid toxicity</p> <p>Supply will only be made after attendance of the training programme provided in conjunction with ABMU Substance Misuse Services and in conjunction with a signed consent form.</p>
Criteria for exclusion	<ul style="list-style-type: none"> • No Valid consent • Non attendance of training programme • Clients under 16 years of age • Hypersensitivity to Naloxone or any component of the preparation <p>Caution</p> <ul style="list-style-type: none"> • Naloxone may cause cardiac irritability and should be used with caution in those with cardiovascular disease or receiving potentially cardiotoxic medication. • Naloxone should be used with caution in pregnant women and the need for naloxone needs to outweigh the possible risk to the foetus. There is no information in respect of breastfeeding. <p>Refer to the current edition of British National Formulary www.bnf.org for the latest information on cautions and</p>

	contraindications of naloxone.
Action if excluded	<ul style="list-style-type: none"> • Seek advice from appropriate healthcare professional. • Advise an alternative treatment strategy for that individual (emphasis on harm reduction and overdose PREVENTION) • Record all decisions and actions in the individual's notes, where applicable. • Update the Welsh Assembly Database for take home Naloxone accordingly
Action for individuals who decline care under protocol	<ul style="list-style-type: none"> • Individuals have the right to refuse to attend the training programme and/or to decline the supply of take home Naloxone. • An attempt should be made to communicate with the individual. If appropriate, acknowledge the individual's right to decline treatment under this direction, ensuring they understand the risks and the alternative treatments available. • Refer to doctor if applicable • Record all decisions and actions in the individual's notes, where applicable. • The Welsh Assembly Database for take home Naloxone will be updated accordingly.
Seek further advice:	<ul style="list-style-type: none"> • Seek advice from the appropriate healthcare professional
Description of Treatment:	
Name of medicine	Naloxone injection 400 micrograms/ml
Legal status of medicine	POM
Form	Pre-filled syringe or ampoule
Strength	400micrograms in 1ml
Dose/range criteria for dose	<u>Supply:</u> Only 1 ml (400 micrograms) can be supplied to individuals with opioid dependence.
Method/route of administration	Intramuscular injection (not intravenous). Note that the onset of action following intramuscular injection is slightly slower than for intravenous injection but will still have effect within minutes.
Frequency of administration	Naloxone is short acting (the half life, in adults, ranges between 30-80 minutes Individuals supplied take home naloxone will be always advised as part of the training programme that: <ol style="list-style-type: none"> 1. Only <u>one</u> 400 micrograms dose of naloxone will be supplied. This is to avoid acute opioid reversal, seen with large dosages of naloxone, which can lead to circulatory stress with cardiac arrest and rarely seizures (see adverse outcomes below). 2. It is imperative that when opioid toxicity is suspected and naloxone is administered that an ambulance is called immediately. In this situation, the naloxone can offer

	<p>sufficient improvement in the individual in question until the ambulance arrives and further medical assistance can be offered (see follow up below).</p>
Total dose	<p>400 micrograms of naloxone. Further doses may be given by emergency services upon arrival.</p> <p>N.B. The dose of naloxone required in acute opioid overdose in <u>non-tolerant</u> individuals may be much lower than that needed in those with tolerance to opioids, such as those receiving palliative care or in opioid dependent users.</p>
Adverse reactions	<ul style="list-style-type: none"> • Nausea, vomiting, sweating, tachycardia, tremor and hyperventilation may occur due to abrupt reversal of narcotic depression. • Hypotension, hypertension, pulmonary oedema, atrial and ventricular arrhythmias and cardiac arrest have been reported in some patients, particularly in those with pre existing cardiac abnormalities. • Seizures have occurred rarely. <p>Refer to current edition of British National Formulary www.bnf.org for latest information on adverse events.</p>
Reporting procedure of adverse reactions:	<ul style="list-style-type: none"> • Individuals who have administered take home naloxone will be encouraged to return to their local service to have their naloxone replaced by a suitably trained ABMU employed nurse (see supplies and storage). Upon return, they will be asked information for the Welsh Assembly Database which will include any reports of adverse reactions noted and the circumstances surrounding the use of naloxone. • All adverse reactions should be documented in the medical records and the GP informed; • Reactions should be reported to the Commission on Human Medicines (CHM) using the yellow card system. Guidance on its use is available at the back of the BNF or can be accessed via the CHM website www.yellowcard.gov.uk
How is consent obtained / documented	<p>Consent to supply needs to be documented on the pro-forma attached, which also confirms attendance at training and suitability of supply</p>
Written and verbal advice for patient/ carer:	<ul style="list-style-type: none"> • Provide Patient Information Leaflet included in pack • Provide information on possible side effects and their management. • Individuals must be advised to call an ambulance immediately after they have administered the naloxone for further follow up
Follow-up	<p><u>Supply:</u> Those supplied with take home naloxone are advised that the dosage given (400 micrograms) is sufficient to effect some clinical improvement in an individual with opioid toxicity but will not hopefully precipitate severe opioid withdrawal (in those with opioid dependence) or acute circulatory stress. However, the ambulance must be called immediately, irrespective of initial improvement, and the individual transported to A/E (as above). Individuals who refuse to attend A/E need to be monitored by the person who has administered the naloxone and/or ambulance staff.</p> <p>Opioid toxicity may result in respiratory depression/arrest and cardiac</p>

	<p>arrest. In this situation, CPR should be commenced until the individual's condition improves or until emergency help arrives.</p> <p>These aspects, including how to undertake CPR, will be covered in the training programme provided.</p>
Supplies and storage	<ul style="list-style-type: none"> Supply will be in the form of a pre-packed emergency naloxone kit The agreed contents will be <ul style="list-style-type: none"> 1 x ampoule naloxone (400mcg/ml) 1 x ampoule snapper 1 x syringe (2.5 or 1ml) 1 x 25mm needle for intramuscular injection 1 x skin prep wipe 1 x instruction sheet. <p>N.B. the ampoule, needle and syringe may be replaced by a pre filled syringe naloxone (400mcg/ml) dependent on supply</p> <ul style="list-style-type: none"> Individuals will be trained as regards safe storage and handling. Store at room temperature (15-30°C) and protected from light. The shelf life of naloxone (usually in excess of 18 months) will be compromised by inappropriate storage and handling. Prior to administration visually inspect the drug for any particulate matter, cloudiness and/or discolouration. In such cases and/or if the vial is cracked or damaged, the naloxone needs to be discarded. Individuals will be advised to keep the medication out of reach of children and pets. Individuals will be encouraged to return for replacement naloxone should they have used or lost the medication and when the naloxone has expired. Individuals will be trained in respect of the safe disposal of needles following the use of naloxone.
Arrangements for referral for medical advice.	<p>Persons supplying the drug must be able to identify and contact a named medical practitioner who should respond appropriately.</p>
Records of supply for audit:	<p>The Welsh Assembly Database for take home Naloxone will be completed for all individuals who are supplied Naloxone. This will include demographic information.</p> <p>The GP and /or other relevant prescriber will be informed in writing.</p> <p>Monitoring of use of the PGD will be undertaken at least annually by service staff. The standard to be achieved is full compliance with all the criteria.</p> <p>Actual mechanism for audit will be service specific, dependant on documentation process in use in each service.</p>
Characteristics of Staff:	
Qualifications required	<p>Registered nurses holding current registration with NMC employed by ABM University NHS Trust/LHB</p>
Specialist qualification or	<ul style="list-style-type: none"> Demonstrates evidence of competency

competencies	<ul style="list-style-type: none"> • Familiar with the BNF and SPC entries for this product • Recognises the adverse drug reactions associated with this product • Have undertaken ELS training • Have undertaken in-house training for the supply of naloxone
Continuing training education	<ul style="list-style-type: none"> • Annual attendance at an appropriate course to update on resuscitation skills and the management of anaphylaxis • Evidence of continued professional development • Relevant update training • Aware of any updates made to the product in the BNF or SPC • Evidence of ongoing professional development and education in the use of PGD/PSDs and in the pharmacology related to the medicines included in this protocol.
Additional information	
References	<ul style="list-style-type: none"> • Current edition of BNF http://www.bnf.org.uk • Summary Product Characteristics for Naloxone injection 400 micrograms/ml • NMC (2007) Standards for Medicines Management; • NMC (2008) Code of Professional Conduct; • The Resuscitation Council UK 2008

ANNEX C Continued

***Patient Group/Specific Direction for the supply of
Naloxone Hydrochloride as a take home medication to those
individuals deemed to be at high risk of future opioid overdose***

COMPETENCY STATEMENT

Name of Nurse.....

<i>Competency statement</i>	<i>Met</i>	Comments
Any specific requirements for the direction		
Demonstrates understanding of the law in relation to the direction		
Demonstrates awareness of limitation of safe practice		
Demonstrates understanding of drugs covered by the direction and possible side effects		
Describes correct procedure for seeking medical/pharmaceutical advice		
Describes action to be taken in event of drug error or reaction		
Demonstrates correct documentation procedure		
Has undertaken trust intravenous drug administration study day if IV preparation		
Demonstrates ability to review patient's allergy history		

Name of Assessor.....

Designation.....

Date.....

Review Date.....

To be filed in individual nurse CPD record

ANNEX C Continued

***Patient Group/Specific Direction for the supply of
Naloxone Hydrochloride as a take home medication to those
individuals deemed to be at high risk of future opioid overdose***

This Patient Group Direction is to be read, agreed and signed by all registered nurses authorised to operate the PGD. One copy should be given to each nurse; the original signed copy should be kept by the nominated GP / doctor with responsibility for PGDs within the area.

I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct.

Name of Authorised Nurse	Signature of Authorised Nurse	Nominated GP / doctor with responsibility for PGDs	Signature of nominated GP / doctor	Date Approved

The document may be converted to a Patient Specific Direction by adding the patient's name, doctor's signature and date



CONSENT FORM

Supply of Naloxone under a Patient Group/Specific Direction (PGD/PSD)

Please read each statement below and tick the box after the statements that you agree with. If you are able to tick all the boxes, please then sign the bottom of this form. If you are unable to tick all the boxes, please discuss this with the approved professional, as it may mean that you will not be able to have treatment under this direction. If this is the case, staff will discuss alternative methods of treatment with you if you wish.

- I confirm that I am not to my knowledge allergic to Naloxone hydrochloride (or any of its ingredients)
- I understand that my GP (and any other prescriber of medication that I have) will be informed of the treatment that I am being offered (this is necessary in case of any problems).
- I have had an opportunity to ask all the questions that I need to ask about Naloxone and the possible risks and benefits.
- I have attended the training programme and have been supplied with a written information pack.
- I confirm that I am happy to have the Naloxone. I am signing this form voluntarily and without pressure.
- I agree to be contacted at a later date to update my knowledge on overdose training, CPR and Naloxone.

Print your name here

Date

Signature

Printed name of Professional

Date

Signature

If the patient is unable to sign for themselves, a witness must also sign to confirm that this form has been understood by the patient.

Witness signature

Date

Signature

Place the signed consent form in the individual's notes and/or Naloxone audit file, a copy **can** be given to the individual.

**CONSENT FORM, DATA COLLECTION FORM,
REPLENISHING USED/OUT OF DATE STOCK**

SERVICE USER CONSENT FORM FOR SUPPLY OF TAKE HOME NALOXONE

(3 copies: one for client case notes if applicable, one for Naloxone data collection file and one for the service user if they would like one)

NALOXONE HYDROCHLORIDE

Name:..... DOB.....

Address:..... Tel:.....

..... Mobile:.....

.....

Referrer:.....

Tel:..... Keyworker.....

Drug	Issued By	Date & Time	Batch No & Expiry
Naloxone			

- I have been given training in the dangers of opiate overdose, basic resuscitation and the appropriate administration of Naloxone
- I am aware that the needle supplied is 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 solely 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

Signed..... Date.....

Witnessed..... Date.....

ANNEX D (CONTINUED)

TAKE HOME NALOXONE DATA COLLECTION

Name		Worker			
Address					
			Post code		
DOB		Age			
Ethnic Group		Gender	Male	Female	
Age first use of opiates		Age first needle use			
Which opiate using (please circle):		Heroin	Methadone	Other	
How much		Is this (please circle)	Daily	Occasional	
In the past year how many times have you gone 3 or more days without any opiates and why? (rehab, prison etc)					
In the past 6 months which other drugs have you used regularly (please circle)			Cocaine Alcohol Benzo's Amphetamines Other		
Number of times you have overdosed		On what			
Number of times you have witnessed		Taken to hospital			
Number of times witnessed a death					
Are you taking any medication	Yes	No	If so, what		
Have you had a BBV test	Yes	No	Want to	Yes	No

ANNEX D (CONTINUED)

PROFORMA FOR RECORDING THE USE OF TAKE HOME NALOXONE AND REPLENISHING STOCK

This form is to be completed by agencies when replenishing take home Naloxone. This form should be completed along with a consent form (see Annex C)

Name of person who administered dose:					
Administered to:			self (by another)/ friend/ relative/ unknown individual/ known client		
Was CPR used:	yes	no	Recovery position used:	yes	no
Did patient attend A&E:	yes	no	Was ambulance called	yes	No
Overdose of:	Heroin/ methadone/ other opiate specify..... unknown				
Situation in which overdose occurred:					
Where was patient when overdose occurred?: Please ask what area they were in e.g. Ely, Cardiff					
Date and time of overdose:					
Naloxone Re-issued by:					
Date and Time:					
Batch Number & Expiry:					