

RECOGNITION OF OPIOID TOXICITY AND MANAGEMENT WITH NALOXONE FOR ADULT HOSPITAL PATIENTS

This guidance does not override the individual responsibility of health professionals to make an appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

Introduction

This document guides Worcestershire Acute Hospitals NHS Trust health care professionals to recognise and manage opioid toxicity in adult hospital patients. Management of both severe (potentially life-threatening) opioid toxicity with respiratory compromise and opioid toxicity without respiratory compromise are covered. It is written in conjunction with current UK guidelines which are referenced and linked for additional information where needed.

This guideline is for use by the following staff groups :

Trust wide adult nursing and medical staff in Worcestershire Acute Hospitals NHS Trust.

Lead Clinician(s)

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Additional thanks to Dr Kath Newton

Approved by:	
Palliative Care Team Business Meeting:	18 th January 2023
Haematology / Palliative Care Directorate:	18 th January 2023
SCSD Divisional Governance:	23 rd January 2023
Medicines Safety Committee:	8 th March 2023
Clinical Governance Group:	2 nd May 2023
Review Date:	2 nd May 2026
This is the most current document and should be used until a revised version is in place	<i>Or prior to this in event of new national guidance being released which alters management</i>

Key amendments to this guideline

Date	Amendment	Approved by:
May 2023	New document published	Palliative Care Team Business Meeting, Haematology/ Palliative Care Directorate, SCSD Governance, MSC, CGG

RECOGNITION OF OPIOID TOXICITY AND MANAGEMENT WITH NALOXONE FOR ADULT HOSPITAL PATIENTS

Introduction

This document guides Worcestershire Acute Hospital NHS Trust health care professionals to recognise and manage opioid toxicity in adult hospital patients. Management of both severe (potentially life-threatening) opioid toxicity with respiratory compromise and opioid toxicity without respiratory compromise are covered. It is written in conjunction with current UK guidelines which are referenced and linked for additional information where needed. This guideline has been produced in response to clinical incidents that have highlighted the need for improved recognition of, and management approaches when, opioid toxicity is suspected. Serious opioid toxicity can be life-threatening and is a potentially reversible cause for deterioration in clinical condition.

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1. Recognition of Opioid Toxicity and Management with Naloxone for Adult Hospital Patients

1.1 TARGET AUDIENCE

This guideline is intended to be used by all generalists who are treating adult patients, who are opioid toxic, in the hospital setting. However, it is recognised that clinicians with expert experience on opioid use may chose alternative approaches after appropriate assessment of the patient.

1.2 GENERAL PRINCIPLES

Opioid toxicity can be a life threatening reversible medical emergency which can be triggered by any opioid, administered via any route and at any dose. It can occur at any time even when the patient has been on regular opioids for a long period of time.

Life-threatening opioid induced respiratory compromise is a medical emergency and rapid titration of naloxone may be required.

Naloxone should be used with caution in chronic opioid use (whether prescribed or recreational). Patients are at risk of acute withdrawal symptoms, including agitation and an abrupt return of pain that is difficult to control.

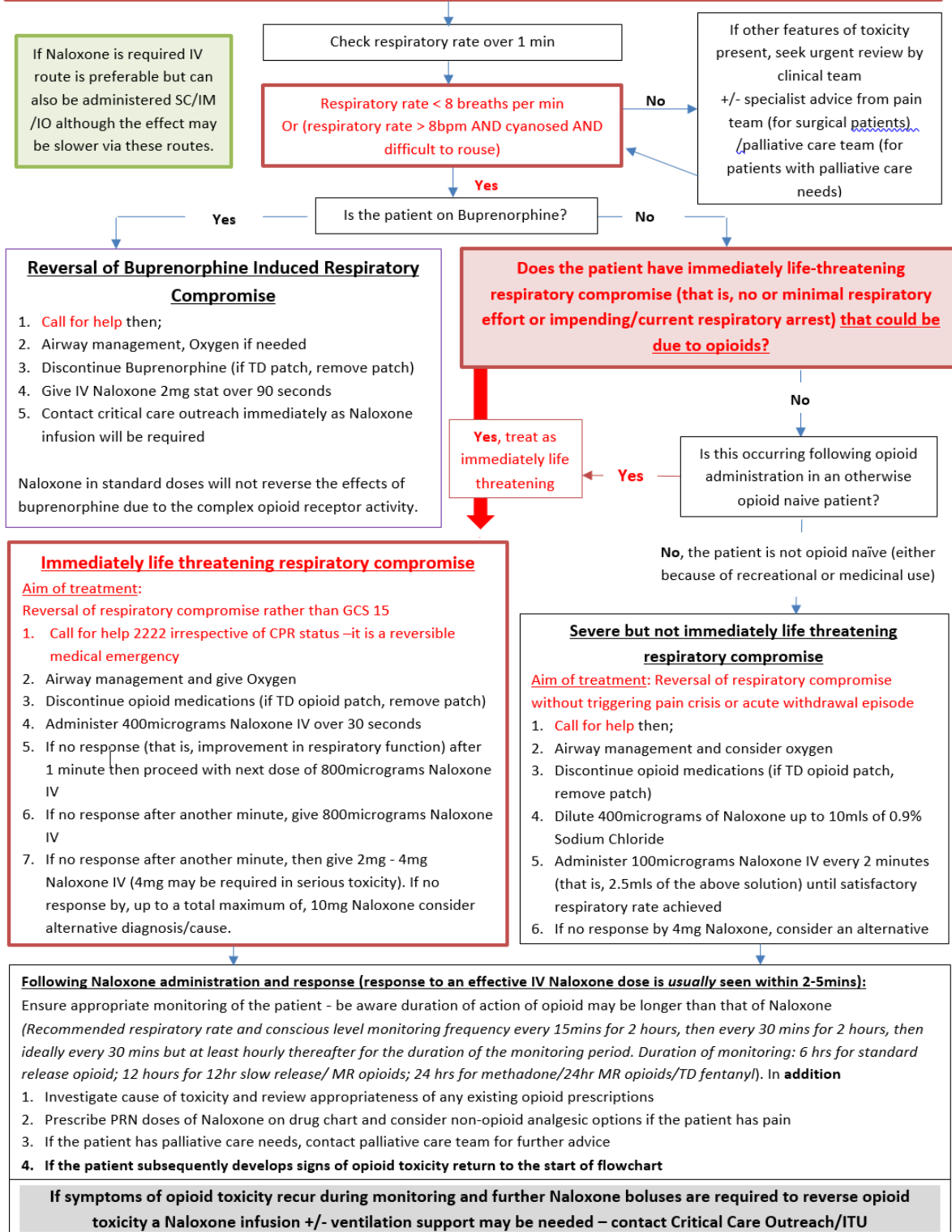
- Important factors that may increase the risk of toxicity in a patient using opioids include:
 - Opioid naïve patients (see section 1.5)
 - Renal dysfunction
 - Co-administration of other analgesics such as amitriptyline, gabapentin or pregabalin
 - Recent alternative intervention for pain relief such as radiotherapy or a nerve block.
 - Recent changes in opioid drug, dose or route of administration
- Patients with chronic pain or palliative care needs who are on long-term prescribed opioids are at risk of an acute pain crisis following the use of naloxone. Following use of naloxone in these patients, urgent advice from relevant clinical specialists is essential to review on-going pain management.
- Naloxone is not indicated for:
 - patients on opioids who are dying as a natural result of their disease progression
 - symptoms induced by non- opioids e.g. barbiturates, benzodiazepines
 - opioid induced drowsiness and/or delirium which is not life threatening
- It is recognised that a number of clinical conditions can also present with signs and symptoms found in opioid toxicity. These conditions can also occur in conjunction with opioid toxicity.

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1.3 FLOW CHART

This flowchart is to be used in conjunction with the content of this guideline:

Initial approach for an adult hospital patient with potential opioid toxicity features
 Opioid toxicity can occur with *any* opioid, that is used for *any* reason, administered by *any* route, and occur at *any* dose.
 Features of opioid toxicity include: confusion/falling GCS, myoclonus, pin point pupils, respiratory compromise



1.4 DIAGNOSIS OF OPIOID TOXICITY

Opioid toxicity can occur with any opioid, at any dose, that is used for any reason, administered by any route, and it can occur at any time.

WARNING SIGNS that opioid toxicity may be occurring include:

- Persistent drowsiness
- Confusion or hallucinations
- Falling GCS (Glasgow Coma Scale)
- Myoclonus
- Pin point pupils
- **Respiratory compromise** (when severe toxicity occurs this can be life-threatening.)

Respiratory compromise due to opioid toxicity is a REVERSIBLE medical emergency (irrespective of the patient's CPR status.)

1.4.1 RECOGNISING RESPIRATORY COMPROMISE

Respiratory rate is one sign that clinicians will use to assess for respiratory compromise in opioid toxicity. In practice, dependent on the clinical scenario, additional information about respiratory function (including, peripheral oxygen saturations monitoring and blood gas monitoring) may be required to assess the level of respiratory compromise.

Respiratory compromise, that could be due to opioids, is indicated by:

- Respiratory rate < 8 breaths per mins (bpm), or
- Respiratory rate > 8bpm AND cyanosed AND difficult to rouse

Immediately life threatening respiratory compromise would be indicated by no/minimal respiratory effort or impending/current respiratory arrest.

Opioid toxicity may also need to be considered in patients who have hypercapnia and/or respiratory acidosis.

1.5 DEFINING 'OPIOID NAIVE'

There is no consensus agreement in the medical literature on the definition of 'opioid naïve'. For the purposes of this guideline the authors would define an opioid naïve patient as 'a patient who does not have a history of regular, frequent use of strong opioids for chronic pain, palliative care needs, or recreational drug use.'

1.6 PRIORITISATION OF CALLING FOR HELP AND SENIOR DECISION MAKER INPUT

It is recognised that, even for patients with a DNACPR (do not attempt cardiopulmonary resuscitation) or CPR not recommended decision in place, treatment of reversible conditions prior to the onset of respiratory arrest is likely to be appropriate. There may be **exceptional** circumstances when it is not appropriate to treat. However, this requires senior level (StR or above) face-to-face clinical decision making and clear documentation of the rationale. Calling the emergency medical response team (2222) facilitates the urgent input of these decision makers.

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1.7 TREATMENT OF OPIOID TOXICITY WITH NALOXONE (GENERAL PRINCIPLES ON INDICATIONS, DOSE AND AIMS)

Naloxone acts as an opioid antagonist.

- The *indication* for treatment of opioid toxicity with Naloxone is respiratory compromise (as outlined in section 1.4).
- The *dose* of Naloxone used will vary as per the clinical context (as outlined in sections 1.8, 1.9 and 1.10).
- The *aim* of treatment with Naloxone is satisfactory reversal of respiratory compromise. A satisfactory response in respiratory function is not exclusively related to an improvement in respiratory rate. A respiratory rate > 8bpm can only be regarded as an appropriate response to treatment of opioid toxicity in the context of the individual patient circumstances. Dependent on the clinical context, satisfactory response in respiratory function may also include the maintenance of a safe airway without the need for adjuncts, and a rate and depth of breathing that would prevent and/or improve any new respiratory failure believed to be due to the opioid toxicity. In certain circumstances the O₂/CO₂ levels may need to be considered to determine what would constitute a worsening respiratory failure for that patient. **Overall the aim of treatment with Naloxone is to ensure the airway and breathing is safe within the context of the patient's background conditions.**

1.8 MATERNITY/ PREGNANCY

As per the advice in the British National Formulary Naloxone should be used only if the benefit outweighs the risk.

1.9 MANAGEMENT OF OPIOID TOXICITY CAUSING LIFE-THREATENING RESPIRATORY COMPROMISE

Management of immediate life-threatening respiratory compromise

Aim of treatment: Reversal of respiratory compromise rather than GCS 15

1. Call for help 2222 irrespective of CPR status –**it is a reversible medical emergency**
2. Airway management and give oxygen
3. Discontinue opioid medications (if transdermal opioid patch, remove patch)
4. Administer 400micrograms Naloxone IV over 30 seconds
5. If no response (improvement in respiratory function) after 1 minute then proceed with next dose of 800micrograms Naloxone IV
6. If no response after another minute, give 800micrograms Naloxone IV
7. If no response after another minute, then give 2mg - 4mg Naloxone IV (4mg may be required in serious toxicity). If no response, by up to a total maximum of 10mg Naloxone, consider alternative diagnosis/cause

1.10 MANAGEMENT OF OPIOID TOXICITY CAUSING SEVERE BUT NOT IMMEDIATE LIFE-THREATENING RESPIRATORY COMPROMISE

Management of severe but NOT immediate life-threatening respiratory compromise

Aim of treatment: Reversal of respiratory compromise without triggering pain crisis or acute withdrawal episode

1. Call for help
2. Airway management and consider oxygen
3. Discontinue opioid medications (if transdermal opioid patch, remove patch)
4. Dilute 400micrograms of Naloxone up to 10mls of 0.9% Sodium Chloride
5. Administer 100micrograms Naloxone IV (2.5mls of the above solution) every 2 minutes until satisfactory respiratory rate achieved
6. If no response by 4mg Naloxone, consider alternative diagnosis/causes.

1.11 BUPRENORPHINE

Due to very strong receptor affinity (reflected in its high relative potency with morphine), Naloxone in standard doses does not reverse the effects of Buprenorphine and higher doses of Naloxone must be used. Buprenorphine can be given via a transdermal patch, orally or via injection. Management needs to be individualised for these patients.

Management of Buprenorphine Induced Respiratory Compromise

1. Call for help
2. Airway management, Oxygen if needed
3. Discontinue Buprenorphine (if transdermal opioid patch, remove patch)
4. Give IV Naloxone 2mg stat over 90 seconds
5. Contact critical care outreach immediately as Naloxone infusion will be required

1.12 MANAGEMENT OF OPIOID TOXICITY NOT CAUSING RESPIRATORY COMPROMISE

Patients showing signs of mild to moderate opioid toxicity WITHOUT evidence of respiratory compromise can usually be managed without the use of Naloxone. (Omission of the next dose of opioid with a possible overall reduction in the total daily opioid, or opioid switching may be required, and will be determined following individual assessment of the patient).

Seek urgent review from the clinical team, including specialist advice from acute pain team (for surgical patients) or the palliative care team (for patients with palliative care needs) where appropriate.

Continue to monitor closely for changes in the patient's condition, and act appropriately if respiratory compromise subsequently occurs.

1.13 ONGOING MANAGEMENT FOLLOWING NALOXONE ADMINISTRATION

Response to an effective dose of IV Naloxone is usually seen within 2-5mins. If no improvement in the patient's respiratory function *despite adequate naloxone* doses then an alternative diagnosis should be sought.

1. Ensure appropriate monitoring of the patient. The duration of action of most opioids is longer than that of Naloxone, so symptoms may recur following initial treatment with Naloxone.

Recommended Guidelines for Duration of Monitoring post Naloxone Administration

Monitor respiratory rate and conscious level: every 15 mins for 2 hours ; then every 30 mins for 2 hours; then ideally every 30 mins but **at least hourly** thereafter for the duration of the monitoring period). Continue for:

- 6 hours for standard release opioid
- 12 hours for 12hr slow release/ MR (modified release) opioids
- 24 hours for Methadone/24hr MR (modified release) opioids/TD (transdermal) Fentanyl

2. Investigate cause of toxicity and review appropriateness of any existing opioid prescriptions
3. Prescribe PRN doses of Naloxone on drug chart and consider non-opioid analgesic options if the patient has pain.
4. If the patient has palliative care needs, contact the palliative care team for further advice
5. If the patient subsequently develops recurrence of signs of opioid toxicity return to the start of the flowchart
6. If symptoms of opioid toxicity recur during monitoring and further doses of Naloxone are administered, a Naloxone infusion with possible respiratory/ventilation support may be needed - **contact Critical Care Outreach/ITU.**

1.13.1 PULMONARY OEDEMA IN OPIOID TOXICITY

Rarely an opioid overdose is complicated by pulmonary oedema. Signs may be absent until Naloxone is given at effective dose. If unexpected breathlessness or hypoxia continues despite effective naloxone treatment, then consider this additional diagnosis. Treatment with oxygen, furosemide and nitrates is usually effective. Delayed onset (48 hrs) post treatment with Naloxone) has been reported

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1.13.2 SIDE EFFECTS AND DRUG INTERACTIONS

Side effects can include:

- Dizziness; headache; hypertension; hypotension; nausea and vomiting; tremor; arrhythmias; rarely, Pulmonary odema (see above)
- Cardiovascular effects occur more frequently in post-operative patients, patients with pre-existing cardiac disease or patients on medications known to cause these effects

Important drug interactions:

- Clonidine – can cause severe hypertension if naloxone administered in cases of clonidine overdose induced coma
- Alcohol – in case of mixed intoxication with opiate and alcohol the onset of the effect of naloxone may be less rapid.

1.14 PATIENTS REQUIRING NALOXONE INFUSION / DRUG INFORMATION ABOUT NALOXONE

For patients requiring Naloxone infusion to support their recovery from an episode of opioid toxicity please **review Medusa** for information regarding this.

The initiation or discontinuation of Naloxone infusions should take place with specialist support/advice from Critical Care Outreach/ITU or other appropriately experienced clinicians. Clear plans for ongoing monitoring (such as, frequency of observations) and management of the patient in the event of further recurrence of toxicity should be documented in the medical notes when infusions are initiated/discontinued.

Infusion doses are based on approximately 60% of the resuscitative dose.

Resuscitative dose: IV bolus that was sufficient to maintain the patient with satisfactory ventilation for 15 minutes.

If a continuous infusion is necessary, use regimen A.

If the initial resuscitative dose was more than Naloxone 1200 micrograms use regimen B. NB: This is rare event and generally for suspected opioid overdose only, or in severely fluid restricted patients.

- **Regimen A**

Continuous IV infusion: Dilute Naloxone 2mg to 500ml using Sodium Chloride 0.9% or Glucose 5% (**that is, 4 microgram Naloxone/ml diluent**)

Naloxone dose to maintain ventilation for 15 minutes	Initial hourly rate of infusion	Volume per hour (of 4microgram/ml soln)
100 micrograms	60 micrograms /hr	15mls/hr
200 micrograms	120 micrograms/ hour	30mls/hr
400 micrograms	240 micrograms/ hour	60mls/hr

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600 micrograms	360 micrograms/ hour	90mls/hr
800 micrograms	480 micrograms/ hour	120mls/hr
1000 micrograms	600 micrograms/ hour	150mls/hr

- **Regimen B**

Continuous IV infusion if higher resuscitative dose required: Dilute Naloxone 10mg in 50ml or 4mg in 20ml (unlicensed concentration of 200micrograms per ml) with Sodium Chloride 0.9% or Glucose 5% (that is, **200mcg Naloxone/ml diluent**)

Naloxone dose to maintain ventilation for 15 minutes	Initial hourly rate of infusion	Volume per hour (of 200microgram/ml soln)
1200 micrograms (1.2mg)	720 micrograms/hr	3.6ml/hr
1600 micrograms (1.6mg)	960 micrograms/hr	4.8ml/hr
2000 micrograms (2mg)	1200 micrograms/hr	6ml/hr
2400 micrograms (2.4mg)	1440 micrograms/hr	7.2ml/hr
2800 micrograms (2.8mg)	1680 micrograms/hr	8.4ml/hr
3200 micrograms (3.2mg)	1920 micrograms/hr	9.6ml/hr

Monitoring during infusion

- Monitor respiratory rate regularly
- Titrate in 100microgram-200 microgram/hr increments to maintain respiratory rate > 10 breaths per minute.
- Once respiratory rate and appropriate level of consciousness maintained for > 2 hours, titrate down the infusion and continue to monitor respiratory rate.
- All patients should be observed for 6 hours after the last bolus dose or after the infusion has stopped for reoccurrence of CNS and respiratory depression.
- Patients who have received high doses of opioids or who are physically dependant on opioids are at risk from acute withdrawal syndromes/ return of pain if the opioid effect is reversed too rapidly.
- Excessive doses of naloxone should be avoided post surgery as it may cause excitement, increase in blood pressure and clinically important reversal of analgesia.

Other resources that provide further information about opioid toxicity and its management

- Toxbase (password for access to TOXBase can be provided by the Emergency Department Staff)
- WM SPAAG Specialist Palliative Care Audit and Guidelines Group (SPAGG)
- Palliative Care Formulary

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Monitoring Tool

This should include realistic goals, timeframes and measurable outcomes.

How will monitoring be carried out?

Who will monitor compliance with the guideline?

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: <i>(Responsible for also ensuring actions are developed to address any areas of non-compliance)</i>	Frequency of reporting:
	WHAT?	HOW?	WHEN?	WHO?	WHERE?	WHEN?
	These are the 'key' parts of the process that we are relying on to manage risk. We may not be able to monitor every part of the process, but we MUST monitor the key elements, otherwise we won't know whether we are keeping patients, visitors and/or staff safe.	What are we going to do to make sure the key parts of the process we have identified are being followed? (Some techniques to consider are; audits, spot-checks, analysis of incident trends, monitoring of attendance at training.)	Be realistic. Set achievable frequencies. Use terms such as '10 times a year' instead of 'monthly'.	Who is responsible for the check? Is it listed in the 'duties' section of the policy? Is it in the job description?	Who will receive the monitoring results? Where this is a committee the committee's specific responsibility for monitoring the process must be described within its terms of reference.	Use terms such as '10 times a year' instead of 'monthly'.
<p>Notes on Monitoring:</p> <p>An annual audit compliance of the use of the guidance would be appropriate if the cohort of patients requiring this could be identified. Currently there is no easy way of identifying all patients who receive Naloxone for Opioid Toxicity (this is due to this being regarded as an emergency drug and held in stock on the wards but may not be utilised). A cohort may be identifiable through Datix reporting system which could be used the basis of audit for compliance but as use of Naloxone is not a mandatory Datix event this is unlikely to provide an accurate representation cohort. The Trust is planning to introduce electronic prescribing in May 2023; at this point this cohort may be easily identifiable and review of appropriate monitoring (such as annual audit) would take place at that point with reporting of learning via medicines safety. In the interim period signposting will occur on the hospital palliative care team intranet page / where appropriate in annual junior doctor medical teaching.</p>						

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References

- British National Formulary 82
- Eds: Twycross R, Wilcock A, Howard P. Palliative Care Formulary 7th edition. Palliativedrugs.com Ltd, Nottingham (2020) page 488
- National Poisons Information Service. TOXBase <http://www.npis.org/toxbase.html>
- Guidelines for the use of naloxone in palliative care patients. West Midlands Specialist Palliative Care Audit and Guidelines Group (SPAGG) (<http://www.wmcares.org.uk/wp-content/uploads/Guidelines-for-the-Use-of-Naloxone-in-Palliative-Care-Adult-Patients-2017-final-version-m.pdf>)
- Scottish Palliative Care Guidelines Naloxone (<https://www.palliativecareguidelines.scot.nhs.uk/guidelines/medicine-information-sheets/naloxone.aspx>)

Contribution List

This key document has been circulated to the following individuals for consultation;

Designation
Mr Tony Chopra Pharmacist (2019)
Dr Elma Wong , Consultant Anaesthetics (May 2019)
Dr Kath Newton, Palliative Medicine (2019)
Dr Abi Lal, Consultant in Respiratory Medicine (July 2020)
Mrs Sarah Pittaway, Pharmacist (March 2022/ January 2022)
Hospital Palliative Care Team (November / December 2021)
Dr David Brocklebank, Acute Medicine Clinical Director (December 2021)
Dr Sabina Moola, Acute Medicine Clinical Lead (December 2021)

This key document has been circulated to the chair(s) of the following committee's / groups for comments;

Committee
Palliative Care Team Business Meeting 18/1/23
Haematology / Palliative Care Directorate Meeting – Approved 18/1/23
SCSD Divisional Governance Meeting –
Medicine Safety Committee

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Is this:	<input checked="" type="checkbox"/> Review of an existing activity <input type="checkbox"/> New activity <input type="checkbox"/> Planning to withdraw or reduce a service, activity or presence? NB: Designed to replace previous Naloxone Monograph
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.)	Please see document for references / committees involved in review.
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	N/A
Summary of relevant findings	N/A

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale.**

Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential <u>positive</u> impact	Potential <u>neutral</u> impact	Potential <u>negative</u> impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age		X		Neutral as replacing/updating and existing document (Naloxone Monograph). No specific issues related to equality groups is identified.
Disability		X		
Gender Reassignment		X		
Marriage & Civil Partnerships		X		
Pregnancy & Maternity		X		
Race including Traveling Communities		X		
Religion & Belief		X		
Sex		X		

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Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Sexual Orientation		X		
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)		X		
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)		X		

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
	Nil identified			
How will you monitor these actions?	N/A			
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)	At next planned review of guidance			

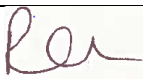
Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	 Dr R Bullock (GMC: 6073187)
Date signed	14/12/22
Comments:	
Signature of person the Leader Person for this activity	
Date signed	
Comments:	



Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	no
2.	Does the implementation of this document require additional revenue	no
3.	Does the implementation of this document require additional manpower	no
4.	Does the implementation of this document release any manpower costs through a change in practice	no
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	no
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval.