Management of intravenous remifentanil Patient Controlled Analgesia (PCA) for maternity service users in the labour ward delivery suite

Classification:	Guideline
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Guideline to be followed by (target staff):

To be read in conjunction with the following documents:

Milton Keynes University Hospital NHS Foundation Trust (2022) Controlled Drugs Standard Operating Procedures Controlled Drugs Standard Operating Procedures. PHARM/SOP/01. Version 1 [Online] Available at: https://mkuhcloud.sharepoint.com/:b:/r/sites/TrustDocumentation/Trust%20Documentation%20%20policies%20guideslines%20patient/Medicines%20Management/Controlled%20Drugs/Controlled%20Drugs%20Standard%20Operating%20Procedures%20(CD%20SOPs).pdf?csf=1&web=1&e=D07hJ0

Milton Keynes University Hospital NHS Foundation Trust (2022) Unlicenced Medication Use: Policy. DOC104. Version 6 [Online] Available at: https://mkuhcloud.sharepoint.com/sites/TrustDocumentation/Trust%20Documentation%20%20policies%20guideslines%20patient/Medicines%20Management/Medicines%20Management%20Polices%20and%20Guidelines/Unlicenced%20Medicines%20Policy%20062020.pdf (Accessed 20 February 2023)

Are there any eCARE implications? No

CQC Fundamental standards:

Regulation 9 – person centered care
Regulation 10 – dignity and respect
Regulation 11 – Need for consent
Regulation 12 – Safe care and treatment
Regulation 13 – Safeguarding service users from abuse and improper treatment
Regulation 14 – Meeting nutritional and hydration needs
Regulation 15 – Premises and equipment
Regulation 16 – Receiving and acting on complaints
Regulation 17 – Good governance
Regulation 18 – Staffing
Regulation 19 – Fit and proper

Disclaimer -

Since every patient's history is different, and even the most exhaustive sources of information cannot cover every possible eventuality, you should be aware that all information is provided in this document on the basis that the healthcare professionals responsible for patient care will retain full and sole responsibility for decisions relating to patient care; the document is intended to supplement, not substitute for, the expertise and judgment of physicians, pharmacists or other healthcare professionals and should not be taken as an indication of suitability of a particular treatment for a particular individual.

The ultimate responsibility for the use of the guideline, dosage of drugs and correct following of instructions as well as the interpretation of the published material **lies solely with you** as the medical practitioners

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Guideline Statement

Remifentanil PCA provides an alternative method of analgesia for labour, particularly for maternity service users who are unable to choose an epidural. This guideline outlines the safe management of intravenous Remifentanil PCA for maternity service users in labour, on the delivery suite.

Executive Summary

Remifentanil is a potent opioid with a fast onset and fast offset time, which makes it an option for intravenenous analgesia for labour via PCA. It can also cause sedation and respiratory depression. This guideline is to facilitate safe practice in the use of Remifentanil PCA for labour analgesia.

Remifentanil is a Controlled Drug and use in PCA is outside the Product Licence. The Trust acknowledges the clinical advantages of this use over potential risks.

Definitions

AVPU – Alert, Verbal, Pain, Unresponsive
BMI - Body Mass Index
BVM – Bag Valve Mask
CIG – Clinical Improvement Group
CTG – Cardiotocography
IUD – Intra Uterine Death
IV – Intravenous
NACS – Neonatal and Adaptive Capacity Scores
NRFHR – Non-reassuring Fetal Heart Rate
PCA – Patient-controlled analgesia
SPO2 – Oxygen Saturation
TENS – Transcutaneous Electrical Nerve Stimulation
VAS – Visual Analogue Score
PCA – Patient Controlled Analgesia BMI - Body Mass Index
IUD – Intra Uterine Death
TENS – Transcutaneous Electrical Nerve Stimulation

1.0 Roles and Responsibilities:

Midwifery Team - Ensure adequate staffing levels to provide one-to-one care and monitoring.
Anaesthetic Team - Set up the PCA and provide an explanation on how to use it, be present for the initial 5 boluses. Troubleshoot complications.
Pharmacy Team - Ensure adequate supply of Remifentanil and emergency drugs.

2.0 Implementation and dissemination of document

The guideline has been approved through maternity guidelines group and pharmacy CIG. Dissemination of the minutes throughout maternity staff and with a guideline monthly memo.

The guideline is available on the intranet and accessible by all hospital staff.

3.0 Processes and procedures

3.1 Rationale

Traditionally, the pharmacological options for labour analgesia are self-administered entonox via a mouth-piece, intramuscular pethidine administered by a midwife or an epidural sited by an anaesthetist.
Entonox on its own may not provide adequate pain relief for all maternity service users. Nitrous oxide is also a potent greenhouse gas.
Pethidine has well recognized side-effects which include sedation, gastric stasis and hypoventilation in the maternity service user[2,12]. Furthermore, pethidine readily crosses the placenta and may cause prolonged sedation in the newborn. Due to the above reasons, some maternity service users may not wish to have pethidine.

Epidurals provide excellent pain relief but there is a risk of post-dural puncture headache, nerve damage and an increased incidence of assisted vaginal delivery. Due to the above reasons, many maternity service users may not wish to have an epidural. Also some are unable to choose an epidural due to reasons such as clotting disorders or previous spine surgery.

Remifentanil PCA offers an alternative to the above-mentioned labour analgesia options. The intravenous administration of remifentanil via a patient- controlled device is advantageous for following reasons:

1. It matches the time course of labour as it has a rapid onset and offset. It takes 20 seconds for remifentanil to reach the brain (one arm-brain circulation time) and 1 minute to reach peak effect.
2. It is non-cumulative in the mother and baby and therefore has very few extended maternal or neonatal side-effects[5].
3. Transient loss of variability in CTG trace may occur in a small number of cases[7]. However, they are less frequent than those observed during systemic administration of other opioids and rarely require intervention[8,10,12].
4. Administration of remifentanil PCA has been shown to be safe, provided there is continuous monitoring. When compared to intramuscular pethidine, PCA remifentanil has better pain scores, greater maternal satisfaction, less maternal desaturation, fewer CTG abnormalities, higher neonatal and adaptive capacity scores (NACS) at 30 minutes and lower incidence of non-reassuring fetal heart rates (NRFHRs) requiring interventional delivery[2,12].
5. Results from the RESPITE Trial[13] have confirmed that pain scores and maternal satisfaction is better with remifentanil PCA. In comparison to pethidine, median VAS (Visual Analogue Score) pain scores were 13.91 points lower for remifentanil. 86% of women thought remifentanil gave effective pain relief as compared to 71% with pethidine.
6. Most importantly, the RESPITE Trial[13] showed a significant reduction in conversion to epidural analgesia as well as a decrease in assisted vaginal deliveries with remifentanil PCA as compared to pethidine. Caesarean rates were not affected.
7. As with any intravenous PCA system, the maternity service user benefits from a greater sense of control over their pain management, an important psychological effect which contributes to the success of this technique[1,7].
8. The safety profile of remifentanil PCA has been studied and published in various journals[1,6,7,11]. Comparison studies on the basis of efficacy and side-effects favour Remifentanil over Pethidine[2,5,11].

9. Remifentanil PCA for labour analgesia has been safely used for many years across many obstetric units across the United Kingdom[5,9].

3.2 Special Consideration (Fetal malposition, Extremes of Maternal BMI)

Although there are many perceived benefits, it must be recognised that administering a potent systemic opioid like remifentanil has the potential risk of causing profound sedation and respiratory depression[5].

Prompt recognition and treatment of side-effects of remifentanil is only possible by close and continuous monitoring of the maternity service user in order to prevent complications. Therefore, this analgesic option must only be offered if constant midwifery presence and continuous pulse oximetry can be guaranteed.

Unlike an epidural, remifentanil PCA will not provide a complete form of labour analgesia.

Maternity service users are unable to sleep when using remifentanil PCA as they have to remain awake to press the PCA button. When labour is anticipated to be longer and more painful (e.g., induction of labour in a primipara with an occipito-posterior baby) or when they are exhausted and needing to sleep, an epidural may be more appropriate.

Epidural analgesia is often recommended in maternity service users with a BMI > 40 as this can be topped up for theatre if required. Furthermore, they are at risk of respiratory depression. Therefore, this cohort can have a remifentanil PCA, but only after discussion with the consultant obstetric anaesthetist on call or if previously documented in the anaesthetic clinic, key concerns being airway safety and reduced tolerance to an apnoeic episode.

Maternity service users with twin pregnancies should be encouraged to opt for an epidural rather than a remifentanil PCA as it allows internal podalic version of the second twin.

In maternity service users who weigh< 50 kg, a reduced starting bolus of 20 micrograms should be used. For use in BMI<18, discuss with the consultant anaesthetist on call.

3.3 Consent

Whenever possible, maternity service users should be given prior opportunity to familiarise themselves with the different analgesic options available and ask questions to the anaesthetist.

While written consent is not necessary, it is important to inform the maternity service user of the following:

1. Unlicensed indication – This does not mean that it is unsafe, but using remifentanil as a labour analgesic is outside the terms of its UK licence. The Trust acknowledges the potential clinical advantages over lesser effects of licensed treatment options.
2. Sedation, itching, nausea.
3. Respiratory depression, need for continuous pulse oximetry, may require oxygen support.
4. Incomplete analgesia – option to convert to epidural, if feasible.
5. Although this method is being used in many other trusts in the UK, this is a relatively new technique with limited experience in this Trust.

3.4 Indications

Remifentanil PCA is an alternative form of analgesia for maternity service users who do not want pethidine or an epidural. It may be used when epidural analgesia is contra-indicated and/or when other forms of analgesia are insufficient.

Remifentanil PCA may also be preferred in maternal service users with:

Coagulopathies and bleeding disorders
Anatomical difficulties of spine, failure to site an epidural
Previous spine surgery
Neurological diseases that preclude siting an epidural
Sepsis

3.5 Contra-indications

3.5.1 Absolute contra-indications: - Allergy to Remifentanil

3.5.2 Relative contra-indications: - Gestation < 36 weeks

- Other long-acting opioid in the preceding 4 hours - Severe heart or lung disease
- Extreme BMI: <18 or > 40 - Intra-uterine death

Relative contra-indications can be overridden, but only after discussion with a consultant obstetric anaesthetist or if previously documented in the obstetric anaesthesia clinic.

3.6 Initiating a PCA

The decision to commence an IV PCA using remifentanil should be taken by an obstetric anaesthetist in liaison with the midwifery coordinator. The midwife caring for the patient should have undergone local training and be familiar with the working of a PCA pump and competent in recognising the side effects of remifentanil.

Continuous pulse oximetry monitoring and constant midwifery presence are a pre-requisite to using remifentanil PCA and lack of the above would preclude offering this option to the maternity service user.

It is the responsibility of the obstetric anaesthetist to set up the PCA and program it appropriately. Drug preparation (in the absence of prefilled syringes/bags) must be done only by the obstetric anaesthetist.

The pumps should be programmed such that it will not allow clinician boluses, loading doses or background infusions.

3.7 Pump set up

Equipment required:

- 50 ml BD syringe (Luer lock)
- 50 ml 0.9% sodium chloride
- 2 mg remifentanil
- PCA pump
- Extension set
- Nasal O2 cannulae (with end tidal CO2 monitoring when available)
- One-way/anti-syphon valve

Drug concentration	40 micrograms /ml
Default Bolus dose	40 micrograms (1 ml)
In < 50 kg	20 micrograms (0.5 ml)
Lockout time	2 minutes
Continuous infusion	None
Loading dose	None

Prophylactic dose of IV Ondansetron 4 mg.

3.8 Conduct

Refer to Quick Reference Guideline 10-point checklist (Appendix A).

The maternity service user must have 2 IV cannulas: a 20G IV cannula dedicated to Remifentanil PCA only and a 16G/18G IV cannula for IV fluids.

The PCA should be connected directly to the 20G IV cannula with no intermediary extensions or connectors. No other drugs or IV fluids should be given through this cannula.

The Blood Pressure cuff should be on the opposite arm, to avoid drug trapping and subsequent release of large boluses.

Do not flush a Remifentanil PCA cannula that is attached to the maternity service user.

The following items must be readily available:
- Self inflating bag-valve-mask (BVM)
- Non rebreather mask
- Nasal oxygen cannulae - Oxygen supply (Wall)
- Naloxone 0.4 mg - Atropine 0.6 mg
- Ephedrine 30 mg (Pre-filled 3 mg/mL)

These drugs should be available in the drug room and the epidural trolley.

It is the responsibility of the anaesthetist to show the maternity service user in labour how to use the PCA device i.e., to press the demand button at the first subjective sign or in anticipation of a contraction. It will take 20 seconds for remifentanil to reach the brain (one arm-brain circulation time) and 1 minute to reach its peak effect.

The maternity service user should be made to understand that only they can operate the handset. No one else, including the members of staff, is allowed to operate the PCA on their behalf. This must be emphasised to the relatives as well. It is important that the maternity service user does not press the demand button in between contractions.

The anaesthetist should be in the room for the first five boluses to ensure the maternity service user is not over sedated and is maintaining their oxygen saturation level.

No other opiate should be administered whilst the PCA is in progress.

TENS/Entonox may be used in conjunction with the Remifentanil PCA.

While on remifentanil PCA, only clear/isotonic/non-carbonated liquids are allowed, due to the risk of aspiration if there is an episode of reduced consciousness.

3.9 Monitoring

Essential monitoring:
- Pulse oximetry (continuous)
- Heart rate (continuous, from pulse oximeter)
- Respiratory Rate – every 15 minutes for 1 hour, then every 30 minutes
- Non-invasive Blood Pressure – every 15 minutes for 1 hour, then every 30 minutes - Sedation score (AVPU) – every 15 minutes for 1 hour, then every 30 minutes
- Continuous fetal CTG monitoring

A full set of baseline observations should be recorded prior to initiating the PCA. The initiating anaesthetist should ensure the first set of observations has been recorded.

The maternity service user must be monitored continuously and remain in the delivery suite. Systemic opioids can cause drowsiness and therefore, if the maternity service user wishes to mobilise off the bed, the PCA must be stopped for 5 minutes until the effects have completely resolved.

Once the PCA is initiated, one to one continuous care is essential. If the midwife has to leave the room and is unable to find someone to relieve her, the PCA button must be removed from the maternity service user and disconnected from the pump. Furthermore, the maternity service user should not be left unattended in the 5 minutes after the PCA button was last used.

Alternatives, such as entonox, can be used till one-to-one care resumes.

3.10 Discontinuation and removal of PCA

The remifentanil PCA should be stopped when the vertex is visible. This will allow time for any fetal remifentanil to be metabolised before delivery.

The remifentanil PCA should normally be disconnected once the placenta is delivered.

However, it is acceptable for the maternity service user to use the device, if they were using it for labour, to facilitate perineal repair under local anaesthetic infiltration.

The IV cannula should be removed on discontinuation of the PCA. Do not flush a remifentanil PCA cannula. This could lead to significant respiratory depression. Please discuss with the anaesthetist if it is deemed necessary to retain the IV cannula.

It is the duty of the labour ward staff to thoroughly clean the pump and handset after use.

3.11 Management of side-effects

3.11.1 Low oxygen saturation - SpO2 < 94% for more than 15 seconds and Respiratory Rate < 8 per minute

Action:
- Remove PCA handset.
- Administer Oxygen 2-4 L/min via nasal cannula.
- If SpO2 improves to > 94%, PCA may be restarted.

3.11.2 Respiratory depression – Respiratory Rate < 8 per minute Action:

- Remove PCA handset.
- Make every attempt to wake the maternity service user up (shake/shout) if respiratory depression is associated with excessive sedation.
- Prop the patient to a semi-upright position.
- Administer Oxygen 15 L/min via non-rebreather mask.
- Call the anaesthetist, but do not leave the patient unattended.
- Pull the emergency alarm if SpO2 is falling to less than 90%.
- If Respiratory Rate remains less than 8 per minute, Anaesthetist to administer Naloxone 400 micrograms IV.

3.11.3 Over sedation – sedation/AVPU score P or U Action:
- As for respiratory depression above, if no response then give IV Naloxone 400 micrograms.
- If sedation is refractory to the above measures, in addition to Remifentanil overdose, consider other causes like hypoglycemia, hypoxia, hypercarbia and cerebrovascular event.

3.11.4 Bradycardia and/or Hypotension – Maternal heart rate < 50 per minute and/or Systolic Blood Pressure < 90 mmHg
Action:
- Remove the PCA handset.
- Call the Anaesthetist but do not leave the maternity service user unattended. - If heart rate fails to recover rapidly, treat with Atropine 0.6 mg IV
- If hypotensive and heart rate < 50 per minute, give 500 ml Hartmann's solution stat - Anaesthetist may give IV Ephedrine
- Pull emergency alarm if patient is drowsy or unresponsive.

3.11.5 Nausea and vomiting:
Administer prescribed anti emetic.

3.11.6 Pruritis:
Administer prescribed anti-histamine.

3.11.7 Fetal bradycardia:
Stop the PCA, Inform Anaesthetist and Obstetrician immediately.

3.11.8 Chest Wall Rigidity:
Action:
- Stop PCA
- Call anaesthetist immediately. - Consider 2222

3.11.9 Trouble-shooting for Anaesthetists:

If attempts to rouse the patient fail:

- Administer IV Naloxone up to 400 micrograms.
- Provide airway and respiratory support as clinically indicated.
- Ensure Remifentanil PCA use is suspended until maternity service user is fully awake and responsive.

Subsequent management:

- Ensure the maternity service user does not use the PCA in between contractions.
- If the episode of respiratory depression recurs despite above measures, decrease the dose of Remifentanil to 20mcg/dose or stop the use of PCA and seek advice from on call Consultant Anaesthetist. Alternative analgesia will be required.

Appendix A – Quick Reference Guide

Quick Reference Guideline

10-point checklist when initiating remifentanil PCA for labour analgesia:

1. Confirm indication/contra-indication for remifentanil PCA for labour analgesia.

2. Confirm no opiates in the past 4 hours.

3. Check with midwife-in-charge/coordinator regarding safe staffing levels.

4. Verbal consent taken by anaesthetist after explaining pertinent points as mentioned in the guideline.

5. Dedicated 20G IV cannula with no intermediary connectors and an anti-syphon valve.

6. Anaesthetist to prescribe and set up PCA.

7. Anti-emetic prescribed.

8. Ensure the following are readily available: - Self-inflating bag-valve-mask
- Non-rebreather face mask (with reservoir bag) - Nasal oxygen cannulae
- Oxygen wall-supply
- Naloxone 400 micrograms - Atropine 600 micrograms -
Ephedrine 30 milligrams

9. Anaesthetist must be present for initiation and first 5 boluses.

10. Midwife to record observations as per guideline.

4.0 Statement of evidence/references

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You may also be interested in this clinical trial:

ClinicalKey (2016) Pain Relief and Progress of Labour With Remifentanil Patient-controlled Analgesia Versus Combined Spinal-epidural Analgesia in Multiparous Women: a Prospective Observational Study [Online] Available from: https://www.clinicalkey.com/#!/content/clinical_trial/24-s2.0-NCT02963337 (Accessed 02 March 2023)

5.0 Governance

5.1 Document review history

Version number	Review date	Reviewed by	Changes made
1	Jun 2022	J John, E Tyagi	Created Document

5.2 Consultation History

Stakeholders Name/Board	Area of Expertise	Date Sent	Date Received	Comments	Endorsed Yes/No
Donna James	Midwife	16/6/22	17/6/22	Does not believe that 1:1 midwifery care for remifentanil PCA will be feasible in the current climate	No, safety issue
Jessica Matson	Midwife	15/6/22	17/6/22	Why can't they eat	Explanation included on risk of aspiration
Anja Johansen-Bibby	Consultant Obstetrician	15/6/22	17/6/22	Phrasing and terminology	Yes
Sanyal Patel	Consultant Obstetrician	15/6/22	17/6/22	No capnography monitoring on labour wards	Yes
Trevor Jenkins	Pharmacy			Remifentanil for labour off-license indication	yes

5.3 Audit and monitoring

Audit/Monitoring Criteria	Tool	Audit Lead	Frequency of Audit	Responsible Committee/Board
Audit of people having remifentanil PCA for labour	Audit of notes	Anaesthetic Consultant	12 months	Anaesthetics

5.4 Equality Impact Assessment

As part of its development, this Guideline and its impact on equality has been reviewed. The purpose of the assessment is to minimise and if possible remove any disproportionate impact on the grounds of race, gender, disability, age, sexual orientation, religion or belief, pregnancy and maternity, gender reassignment or marriage and civil partnership. No detriment was identified. Equality Impact assessments will show any future actions required to overcome any identified barriers or discriminatory practice.

Equality Impact Assessment			
Division	Surgery	Department	Anaesthetics
Person completing the EqIA	Eleanor Tyagi	Contact No.	Via email
Others involved:		Date of assessment:	13/6/22
Existing policy/service	No	New policy/service	Yes

Will patients, carers, the public or staff be affected by the policy/service?	Yes
If staff, how many/which groups will be affected?	Service users, midwives, anaesthetists

Protected characteristic	Any impact?	Comments
Age	NO	Increases the analgesic options available to pregnant people. Positive impact as the policy aims to recognise diversity, promote inclusion and fair treatment for patients and staff
Disability	NO	
Gender reassignment	NO	
Marriage and civil partnership	NO	
Pregnancy and maternity	YES	
Race	NO	
Religion or belief	NO	
Sex	NO	
Sexual orientation	NO	

What consultation method(s) have you carried out?
Guideline review group
How are the changes/amendments to the policies/services communicated?
Will need including in PROMPT
What future actions need to be taken to overcome any barriers or discrimination?

What?	Who will lead this?	Date of completion	Resources needed
Review date of EqIA	Jun 2025		