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REMIFENTANIL PATIENT CONTROLLED ANALGESIA FOR LABOUR POLICY

SUMMARY POINTS

This Policy :

- describes remifentanil PCA and who it may be suitable for as a labour analgesic
- outlines necessary steps in patient preparation and setting up the PCA syringe
- details the responsibilities of the midwife and observations that must be performed during its use
- highlights safety aspects to be adhered to during use

DOCUMENT DETAILS

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Signed:	
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Chairman:	1) Mr Daniel Webster 2) Dr Richard Day
Signed:	
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DOCUMENT HISTORY

Date of Issue	Version No.	Next Review Date	Date Approved	Director Responsible for Change	Nature of Change
Mar 2013	1.1			Mr D Webster Dr R Isaacs	First draft
Apr 2013	1.2	Apr 2016	Apr 2013	Deirdre Terrot, Dr B Parker	BP added to observations. Amended CIs, reconstitn, observations, competency assessment table and PIL (put into Trust template)
Jan 2016	1.3			Dr C Fortescue, Dr R Tunney	Updated training, disposal, prescription

TABLE OF CONTENT

1. RELEVANT TO

- All registered healthcare professionals with a responsibility to obstetric patients

2. PURPOSE

- To provide guidance as to when a remifentanil PCA is indicated and contra-indicated, how to set up the PCA and the observations that must be performed by the midwife once the PCA is in use. Training and safety issues are discussed

3. DEFINITIONS

- Remifentanil – an opiate drug with a rapid onset and offset time
- PCA – patient controlled analgesia
- CTG – cardiotocography (monitoring of baby's heartbeat)
- CD – controlled drug

4. DOCUMENT DEVELOPMENT

- Remifentanil has been identified as a safe and effective option of analgesia for use in labour pain. Its rapid onset of action within 1-2 mins, fast offset and potent analgesia makes it suitable for use for pain relief during labour. Analgesia effects peak at about 1 minute and can be timed to coincide with peak contraction pain by the woman during regular contractions
- PCA remifentanil has been shown to be superior to either i.m. or i.v. pethidine. In obstetric units where PCA remifentanil is used routinely, the conversion rate to epidurals is around 9% which indicates that although it has superior analgesia to pethidine, in some cases, analgesia is inadequate
- Remifentanil is broken down by enzymes in the plasma (tissue esterases) in both the mother and the fetus. It does not accumulate in either the mother or the fetus/neonate so, regardless of the length of time the drug has been used, the rate of elimination is the same. This is a unique property compared to other opioids. The effects wear off after approximately 3 minutes. The effective biological half-life is 3-10 minutes and duration of action can be 5-10 minutes[3]
- When considering the fetus or neonate, no investigations to date have found an excess of non-reassuring CTG traces with remifentanil use. There were fewer non-reassuring CTG traces and better neurobehavioural scores in neonates in the remifentanil group when compared to pethidine[4]
- Remifentanil PCA thus has a role as a labour analgesic, especially in cases where epidural analgesia is contra-indicated or refused by the parturient

5. REFERENCES

- The information contained within this document has been adapted principally from guidelines from:

1. The Ulster Hospital South Eastern Health- Guideline 66-2005

2. Social care Trust, Belfast NHSCT/12/519(2012), with permission from Dr. David Hill and from other centres

3. Martindale: The Complete Drug Reference, 2nd quarter 2013 update (via medicines complete)

4. Blair J M, Dobson G T, Hill D A et al. Patient controlled analgesia for labour: a comparision of remifentanil patient controlled analgesia in labour. Int J Obstet Anesth 2001;10:86-90

6. CONSULTATION

- These guidelines have been agreed upon by all obstetric anaesthetic consultants

- They have also been approved by Pharmacy and Midwifery departments (latter by Dawn Minden,

7. TRAINING

- Midwives should attend the local theory session as part of their training and be supervised for use of remifentanil PCA in at least three women in labour (Appendix 1)

- Novice anaesthetic trainees will need to complete a WBPA (Manages remifentanil PCA for a women in labour) prior to starting on call in Obstetrics (Appendix 2)

8. REMIFENTANIL PCA

8.1 INDICATIONS FOR REMIFENTANIL PCA

- Remifentanil PCA is an alternative to pethidine in patients who do not want, or cannot have, an epidural e.g. coagulopathy, local infection, spina bifida etc

- Remifentanil is currently not licensed for use via PCA and so must be prescribed by an anaesthetist. Only midwives who have undergone a period of supervised practice and have been deemed competent by anaesthetists (Appendix 1) may administer this infusion

8.2 CONTRAINDICATIONS FOR REMIFENTANIL PCA

- Allergy or sensitivity to opioid drugs
- Multiple pregnancy
- Other parenteral opioid administration within preceding four hours
- Pre-existing respiratory disease (discuss with anaesthetist prior to commencing a PCA)
- Maternal refusal
- Inability to co-operate, or operate the PCA pump

8.3 CRITERIA FOR USE

- In general, any woman being offered remifentanil PCA should be more than 36 weeks' gestation and be in established labour
- If remifentanil is being considered for use at a gestation of less than 36 weeks a senior obstetrician must document in the clinical notes either the non-viable status of the fetus or specify the reason for requesting remifentanil in that case
- Entonox® (50% nitrous oxide in 50% oxygen) may be used in addition if required
- Oxygen saturation (SpO_2) monitoring must be established before the woman starts using the PCA and must be monitored continuously while the remifentanil PCA is being used
- A remifentanil observation chart must be completed while the PCA is in situ (Appendix 5)
- **A designated, trained midwife must be assigned to give one to one care**

8.4 PREPARATION and SETTING UP

- **Preparation of the woman:**
  - The woman should be issued with, and have read, the remifentanil PCA patient information leaflet (Appendix 3)
  - The woman should be informed of the possible side-effects including drowsiness, itching, nausea, dizziness, respiratory depression and hypotension
  - In particular the woman should be informed that approximately one woman in ten using remifentanil PCA will experience transient lowered oxygen saturation levels requiring the administration of additional oxygen via nasal specs (this is not dissimilar to those using Entonox®)
  - A dedicated intravenous cannula (22g Blue or 20g Pink) is required
  - The woman should be shown how to use the PCA and should be told to press the button just before or at the start of a contraction
  - The woman should be told that nobody else must be allowed to press the button for pain relief and she should be the sole controller (safety feedback control)
  - A pulse oximeter (oxygen saturation) probe must be attached before the PCA is started (finger or ear probe)

- **Equipment required:**
  - 50 ml IV luer lock syringe (to fit CME Medical TPCA pump)
  - 2 mg ampoule of Remifentanil (checked and signed out of CD register by two registered midwives)
  - Drug additive label
  - Dedicated remifentanil PCA pump set to deliver 1ml (40 mcg) bolus over max. 5 seconds with a 2 min lockout e.g. TPCA machine by CME Medical
  - Sims-Graseby "Flo-Safe" extension set or equivalent

- **Syringe preparation:**
  - Remifentanil solution to be reconstituted by anaesthetists only. Remifentanil PCA-trained midwives may provide a second check (see Appendix 1).
  - Dissolve 2mg Remifentamil in 2ml Sodium chloride 0.9%. Make up to a final volume of 50ml with Sodium chloride 0.9%.
  - Final solution concentration to be 40 micrograms/ml of Remifentanil base (1mg Remifentanil base equivalent to approximately 1.1mg Remifentanil hydrochloride)

- N.B. Remifentanil is stable for 24 hours at room temperature after reconstitution

- Anaesthetists should sign the prescription of Remifentanil which is on the Observation chart (Appendix 5)

8.5 OBSERVATIONS

- Remifentanil PCA observation sheet to be completed for all women using Remifentanil (Appendix 5)

- A sedation score is to be recorded every 30 minutes (see sedation scale below)

- Continuous SpO_2 monitoring must be established prior to starting PCA and recorded on observation sheet every 30 minutes along with respiratory rate, BP and pain score

- If SpO2 fall below 94%, oxygen should be administered via nasal cannulae at 2-3 L/min

- CTG monitoring is not required unless clinically indicated

- **NOTE**: Sedation score is recorded on a scale from 1-5:-

    1. *Fully awake*
    2. *Drowsy*
    3. *Eyes closed but rousable by voice*
    4. *Eyes closed but rousable by physical stimulus*
    5. *Eyes closed and not rousable*

8.6 INDICATIONS FOR CONTACTING THE ANAESTHETIST AND STOPPING REMIFENTANIL

- A sedation score of 3, 4 or 5
- Respiratory rate of less than 8 breaths per minute.
- SpO2 remaining below 90% despite oxygen via nasal specs at 2-3L/min

8.7 DISPOSAL OF REMIFENTANIL PCA

- Disposal of the remifentanil should be by **anaesthetists only**
- The midwife should contact the anaesthetist when the PCA pump is no longer required
- The anaesthetist can use this as an opportunity to complete the Remifentanil audit sheet (Appendix 5) which should then be returned to the box in the anaesthetic office

8.8 POINTS OF SAFETY

- A midwife deemed competent to monitor women receiving remifentanil PCAs must be present throughout PCA use and can only be relieved by another midwife also deemed competent
- **ALWAYS** use a dedicated cannula
- **DO NOT** give any other drugs via the PCA cannula (dedicated line)
- **ONLY** the woman using the PCA is to use the PCA button to administer a bolus dose
- The PCA button is **NOT** to be pressed by any other staff or the woman's relatives to preserve the safety feedback loop controlled solely by the woman
- **ALWAYS** flush the cannula after the PCA is removed with 5 ml sodium chloride 0.9%. The patient should be monitored for at least 10 minutes after this due to the remaining remifentanil solution flushed through from the cannula

9. APPROVAL PROCESS

- To be approved by East Dorset Maternity Approved Documentation Group, and the Drug and Therapeutics Group

10. DISSEMINATION

- This policy will be available on the intranet and within central delivery suite

11. REVIEW AND REVISION ARRANGEMENTS INCLUDING VERSION CONTROL

- The policy will be reviewed again in 2016, or sooner if required

12. MONITORING COMPLIANCE AND EFFECTIVENESS

- An audit form will be completed by the midwife following delivery for all cases where remifentanil PCA has been used. These will be collected by the anaesthetic team and progress continuously monitored. Any adverse events will be reported in the standard manner via an AIRS form

APPENDIX 1 – COMPETENCY ASSESSMENT: MONITORING OF WOMEN RECEIVING A REMIFENTANIL P.C.A INFUSION

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COMPETENCY ASSESSMENT: MONITORING OF WOMEN ON A

REMIFENTANIL 50 ML P.C.A. SYRINGE INFUSION

NAME OF MIDWIFE: _____

Date of attending Theory session ……/……/……..

Anaesthetist _____

PCA to be reconstituted, prepared and discarded by anaesthetists only.

Supervised practice Monitoring and Managing Women Receiving a Remifentanil PCA infusion:

	DATE	NAME OF RECIPIENT	DRUGS DRAWN UP BY (Signature)	SIGNATURE OF ANAESTHETIST
1				
2				
3				

I hereby confirm that the above-named midwife has carried out, under supervision, the monitoring and management of women receiving a Remifentanil PCA infusion and has reached a satisfactory level of competence.

Signature of Anaesthetist: _____ Date: _____

Signature of Midwife: _____ Date: _____
(Please return to delivery suite manager on completion)

APPENDIX 2 – COMPETENCY ASSESSMENT FOR ANAESTHETISTS

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Obstetrics Initial Assessment of Competence

Minimum clinical learning outcomes:

- To pass the formal practical initial assessment of competence in obstetric anaesthesia and, having achieved this, be able to provide analgesia and anaesthesia as required for the majority of the women in the delivery suite
- To understand the management of common obstetric emergencies and be capable of performing immediate resuscitation and care of acute obstetric emergencies [e.g. eclampsia; pre-eclampsia; haemorrhage], under distant supervision but recognising when additional help is required

All of the following needs to be completed before the Obstetric Initial Assessment of Competence certificate can be signed off.

A-CEX

- ☐ Conduct epidural analgesia for labour
- ☐ Conduct regional anaesthesia for caesarean section
- ☐ Conduct general anaesthesia for caesarean section

DOPS

- ☐ Top up epidural for labour analgesia
- ☐ Top up epidural for caesarean section
- ☐ Perform spinal anaesthesia
- ☐ Manages a remifentanil PCA for a woman in labour

CBD

- ☐ Discuss how changes in the anatomy and physiology due to pregnancy influenced the conduct of anaesthesia
- ☐ Discuss whether pregnancy influenced the choice of drugs used during anaesthesia
- ☐ Discuss how the conduct of general anaesthesia is affected by late pregnancy
- ☐ Examine the case records of a patient that the trainee has anaesthetised for operative delivery in a situation where major haemorrhage might be expected. Discuss the factors that influence the likelihood of major obstetric haemorrhage, the precautions that should be taken to deal with it and the principles of its management.
- ☐ Examine the case records of a patient with pregnancy associated hypertension that the trainee has treated. Discuss how this influences anaesthetic management.
- ☐ Examine the case records of a patient for whom the trainee provided extradural analgesia for normal labour. Discuss the methods of pain relief available for normal delivery.

Initial Assessment of Competence in Obstetric anaesthesia Certificate completed

Date _____

APPENDIX 3 – PATIENT INFORMATION LEAFLET

Remifentanil Patient Controlled Analgesia (PCA) for Labour

What is Remifentanil PCA?

Remifentanil is a very short-acting pain relieving drug rather like pethidine. It's pain relieving effect comes on very rapidly, and also wears off very quickly afterwards. A small dose of the remifentanil is given into a drip in your arm at your request by pushing a button on a PCA pump.

Who can use Remifentanil?

Any woman in labour can request to use remifentanil PCA. We would advise women with an allergy to morphine, pethidine or other related drugs not to use remifentanil. Remifentanil may be useful also in certain situations where for one reason or another, women cannot have an epidural. You may also wish to use remifentanil if you do not wish to have an epidural.

How is it given?

To use remifentanil you will need to have a cannula ("drip") placed in a vein, usually on the back of your hand or arm. The drip is connected to an electronic pump, which delivers a small dose of remifentanil once you press the hand-held button. The pain relieving effect is felt usually in 20 to 30 seconds, and wears off again within a few minutes.

You are in control and you get the drug when you need it and not in between contractions. **It is very important that you alone press the button for pain relief and nobody else for safety reasons.** There is a safety feature built into the pump so that you can only get a fixed amount of the drug within a set time period so you cannot give yourself too much of the drug. You can use the pump at any time right up to your delivery if you wish, and the effects will still wear off very quickly when you stop using the pump after your baby has been born.

Are there any side effects?

Some women can get sleepy between contractions, and occasionally your breathing may slow down. However, even if you are drowsy, this will wear off very quickly after you stop using the pain relief. As part of our routine observations with remifentanil your midwife will measure your oxygen level using a sensor (like a peg) on your finger, as well as your level of pain relief and drowsiness at regular intervals. Otherwise all observations and treatment is the same as for any other woman on labour ward.

Remifentanil does cross the placenta to the baby in a similar way to pethidine but unlike pethidine, any effect wears off much more quickly. This type of pain relief has now been used in large numbers of women in labour with no side effects to the baby.

When can I ask for Remifentanil?

You can request remifentanil at any time during your labour. If the anaesthetist agrees that it is safe for you to use, your midwife will organise to get the pump set up. This may take a few minutes, but you will be able to use it immediately once you are given the button to push.
You can still ask for 'gas and air' at the same time as the remifentanil PCA pump.

References

Remifentanil Patient Controlled Analgesia for Labour policy, Professor M Wee and Dr R Isaacs, April 2013; updated Jan 2016 by Dr C Fortescue Dr R Tunney.
Poole Hospital NHS Foundation Trust intranet

Contact details

Central Delivery Suite
Telephone number **01202 442308**

For further general health-related information, please ask the relevant department for an Information Prescription or contact:

The Health Information Centre
Poole Hospital NHS Foundation Trust
Longfleet Road
Poole
Dorset
BH15 2JB
Telephone: 01202 448003

www.poole.nhs.uk

Author: Dr M Wee, Dr R Isaacs, Dee Terrot
Date: April 2013
Updated January 2016 by Dr C Fortescue and Dr R Tunney
Review date: January 2019
Version number: to be applied by Patient Information Team
Ward sister/head of department: Sandra Chitty

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If you wish to make any comments or to ask about any research evidence used to write this leaflet, please contact the Patient Information Team confidentially: phone 01202 448003, write to the Health Information Centre (address above), or email patient.information@poole.nhs.uk.

APPENDIX 4 – REMIFENTANIL PCA AUDIT SHEET

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Remifentanil PCA Audit Form

Date _____

Gravidae in labour	**P0**	**P1**	**P2**	**P3+**	
Labour type	**Spontaneous**		**Augmented**		**Induced**
Satisfaction	**Very Satisfied**	**Satisfied**	**Dissatisfied**		**Very Dissatisfied**
Pain before PCA	**No Pain**	**Mild**	**Moderate**	**Severe**	**Unbearable**
Pain with PCA	**No Pain**	**Mild**	**Moderate**	**Severe**	**Unbearable**
Entonox used with PCA	**Yes**	**No**			
Supplementary O2 used	**Yes**	**No**			
Adverse effects	**Itching**	**Nausea**	**Other** _____		

CTG	**Normal**	**Suspicious**	**Pathological**		
Mode of delivery	**NVD**	**Ventouse**	**Forceps**	**LSCS**	
APGARS	**1 min** _____		**5 min** _____		
Fetal resuscitation?	**Yes**	**No**			
Stopped PCA	**Yes**	**No**			
Reason for stopping	**After delivery**				
	Pain	**Drowsiness**	**Desaturation**		**Pushing**
	FTP, going to theatre		**Syringe empty**		
	Technical problem				
	Other				
Alternative analgesia used	**None**	**Entonox**	**Epidural**	**CSE**	**Spinal**
If theatre	**Spinal**	**Epidural Top Up**		**GA**	

When complete please return to the anaesthetists office. Thank you.

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REMIFENTANIL P.C.A. ANALGESIA OBSERVATION CHART

Patient Label

Pain Score
0 No pain
1 Slight pain
2 Fair pain
3 Moderate pain
4 Severe pain
5 Extreme pain

Sedation Score
1 Fully aware
2 Drowsy
3 Eyes closed but rousable by voice
4 Eyes closed but rousable by physical stimulus
5 Eyes closed and not rousable

PCA PRESCRIPTION Remifentanil 2mg in 50ml 0.9% saline, final concentration 40mcg/ml: for PCA use, 1ml bolus, 2 minute lockout

Anaesthetist signature: _____ Name (print):_____ Date: _____

	OBSERVE CONTINUOUSLY – RECORD OBSERVATION AND SEDATION SCORE EVERY 30 MINUTES																	
Time																		
O_2 Saturation																		
Resp Rate																		
Pain Score																		
BP																		
Sedation Score																		