Remifentanil Patient Controlled Analgesia (PCA) for a Woman in Labour

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Applicable for which staff members?	All clinicians in maternity including access holder lead maternity carers (LMCs)
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1. Purpose of guideline

The purpose of this guideline is to facilitate the safe and effective use of remifentanil patient controlled analgesia (PCA) for a woman in labour.

Although remifentanil is a category C drug for use in pregnancy, it is increasingly being recognised as a valid form of analgesia for a woman who may be unable to have an epidural for labour, for either medical reasons or maternal preference.

Once prescribed, in accordance with the Auckland DHB 'Medications – Prescribing' policy, any medication should be administered and documented in accordance with the Auckland DHB 'Medications – Administration' policy (see associated Auckland DHB documents section).

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2. Definitions

PCA	Patient controlled analgesia
IV	Intravenous
Bolus dose	Amount of medication the woman receives when the demand button is pressed
Lock out	The time between one successful bolus and until the woman can have the next bolus dose
Anti-reflux valve	A valve device placed within an IV line to prevent inadvertent backflow and potentially an inadvertent bolus of the drug from the infusion
Anti-syphon valve	A valve to reduce the risk of inadvertent free flow which may be due to lack of complete syringe engagement within the pump

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3. Pharmacodynamics and pharmacokinetics

Metabolism of remifentanil occurs via non-specific esterases (enzymes) within the blood and tissues. Liver or renal dysfunction does not affect metabolism of remifentanil, and its clearance generally correlates to total body water.

After some degree of maternal metabolism, remifentanil crosses the placental barrier and can cause respiratory depression in a newborn. A neonate has the same ability to metabolise remifentanil as the mother, so any effects of the drug from placental transfer is short-lived. There is very little evidence assessing the impact of remifentanil on breast-feeding success, but because the half-life is extremely short, it is unlikely to cause any prolonged effects in a breastfed newborn, unlike pethidine labour analgesia.

Remifentanil is a short acting opioid analgesic drug. It provides effective labour analgesia following intravenous administration via a patient controlled analgesia (PCA) pump and is maximally effective within 1-2 minutes, with an onset within 30 seconds.

Whilst remifentanil crosses the placenta, it is readily metabolised by the mother and the baby. It may be associated with transient respiratory depression in the newborn, which improves within minutes. Approximately 10 minutes after a PCA dose has been administered, there is virtually no drug effect, regardless of how long the PCA is used.

It may cause side effects such as drowsiness, respiratory depression, itching, nausea and vomiting.

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4. Indications and contraindications for remifentanil PCA

Remifentanil PCA may be offered to a woman in whom an epidural is contraindicated or refused, or where other forms of pain relief are not appropriate or have provided insufficient analgesia.

Prior to institution, the use of the remifentanil PCA should be discussed between the obstetric, anaesthetic and midwifery carers of the woman.

Indications

Analgesia during labour when one or more of the following conditions exist:

- Contraindications to regional anaesthesia (epidural or spinal anaesthesia)
- Coagulopathy, thrombocytopenia or anti-coagulation
- Sepsis
- Spinal cord pathology
- Intrauterine death or termination of pregnancy for fetal abnormalities
- Maternal request
- Perineal tear repairs in conjunction with local anaesthetic infiltration, where regional anaesthesia is contraindicated.

Contraindications

- Allergy to remifentanil (or other opioids)
- Inability to provide 1 to 1 midwifery care or lack of provision for monitoring throughout labour
- Administration of opioids (e.g. pethidine) in the preceding 4 hours
- Epidural and intrathecal administration

Precautions

- Special consideration should be given to a woman with severe cardiac or respiratory disease, or obstructive sleep apnoea
- Entonox can be used concurrently with a remifentanil PCA; however, care must be taken to ensure that the woman does not become excessively sedated.
- Remifentanil PCA can be used throughout labour and delivery and can be used to augment local infiltration for perineal repair.

Side effects

- Drowsiness
- Skeletal muscle rigidity
- Bradycardia
- Hypotension
- Respiratory depression and apnoea
- Nausea and vomiting
- Pruritus
- Shivering

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5. Patient education and consent

Since remifentanil is not licensed for pregnancy and labour, informed consent should be taken prior to commencing a remifentanil PCA. This should be facilitated by consulting the 'Pain Relief in Labour – Remifentanil Patient Controlled Analgesia (PCA)' information leaflet (see associated Auckland DHB documents section).

Ideally, discussion about the use, risks, side effects and benefits associated with a remifentanil PCA should be discussed with the woman antenatally. However, there may be late presentation or changes in the maternal clinical condition that precludes an epidural for labour. In this situation, the woman should be counselled about the safety profile and benefits of the remifentanil PCA. A woman considering this form of analgesia should be given the 'Pain Relief in Labour – Remifentanil Patient Controlled Analgesia (PCA)' information leaflet.

The PCA should be described in terms that the woman can understand and include the following points:

- Unlicensed indication
- potential side effects and reporting these to the midwife
- potential side effects on the neonate
- oxygen
- how and when to press the PCA button i.e. at the ***start*** of the contraction, as the remifentanil peak effect is within 1-2 minutes, with a rapid offset

Document the discussion with the patient in the clinical record, including her consent.

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6. Preparing the woman and a dedicated IV line

A woman requiring remifentanil PCA for labour should be permitted only clear fluids during her labour, in addition to regular ranitidine until the delivery of the placenta (see associated Auckland DHB documents section).

Baseline monitoring should be commenced and documented on the CR5782: Adult Observations Chart ***before*** the PCA is started, including the level of consciousness. If baseline oxygen saturations on air are below 93%, it should be discussed with the duty consultant anaesthetist, prior to commencement of the PCA.

Ability to administer oxygen is mandatory whilst the PCA is insitu. Oxygen administration at 2 L/min via nasal cannulae should be applied to the woman ***prior*** to the commencement of the PCA.

A non-rebreather mask should be present in the delivery room, and an AmbuBag should be present on the resuscitation trolley.

No other systemic opioids should be administered in the preceding 4 hours prior to commencing the remifentanil PCA, or whilst the PCA is in progress.

A PCA requires a dedicated IV line with an extension set with antireflux and antisyphon valves. No drugs or other fluids, including flushes, should be administered via this dedicated line, thus preventing inadvertent bolus administration of the drug.

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7. Prescribing the remifentanil PCA and setting up the dedicated pump

The duty anaesthetist is responsible for prescribing the PCA, which should be prescribed using 'CR8675: Patient Controlled Intravenous Analgesia' (PCIA prescription) and should be inserted into the woman's medication chart.

Only the anaesthetist may institute changes in the remifentanil bolus dose. Any such changes to the dosing of the bolus dose should be clearly documented and timed on the prescription. This is the responsibility of the duty anaesthetist.

The remifentanil PCA for labour follow up form (kept with the pump) should be completed and returned to the 'epidural follow-up tray' on the Delivery Unit.

An ampoule of naloxone (400 mcg/mL) should be prescribed in conjunction with the PCA, for administration to the woman should her respiratory rate be <8/min.

The dedicated remifentanil PCA pump is kept in the silver case in the anaesthetic department on Level 9. The plug can be found with the pump. The pump and the plug should be returned to the department as soon as possible after use.

A copy of instructions on how to set up the pump is found within the dedicated silver case in which the pump is stored, and on the L9 Anaesthesia Intranet site.

The duty anaesthetist is responsible for setting up the remifentanil PCA pump: 40 mcg/mL concentration of remifentanil (2 mg diluted into 50 mls 0.9% NaCl). This should be labelled appropriately. An extension set with a dedicated antisyphon and antireflux valve should be used in conjunction with the ***dedicated infusion line*** to prevent inadvertent siphoning or bolus of drug to the woman.

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

The demand dose is based on ***lean body weight***, rather than total body weight. This can be determined with the following calculation.

Estimated lean body weight (kg) = height (cm) - 100

e.g. 165 cm patient: 165 -100 = 65 kg lean body weight

The bolus dose range is 0.2 – 0.8 mcg/kg with a fixed lockout time of 3 minutes*.

The regimen should be commenced at a 0.2 mcg/kg bolus dose and be increased incrementally as needed. Adequacy of analgesia and dosage should be regularly reviewed as the labour progresses.

(*Hinova/Fernando 2009; Muchatuta 2013)

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8. Monitoring during the use of the remifentanil PCA

A midwife who is aware of the potential complications of a remifentanil PCA ***must*** be present in the room ***at all times***.

The anaesthetist should remain with the patient for 20 - 30 minutes after the PCA is set up and whilst analgesia is being established, and for the same period after dose changes have been instituted. The anaesthetist should continue to review the woman during her labour to ensure that there are no adverse effects and that she has adequate pain relief, and provide support to the midwifery and obstetric team.

Only the woman is permitted to press the PCA button.

Observations should be recorded on the CR5782: Adult Observations Chart and must include level of consciousness and respiratory rate in addition to oxygen saturations, blood pressure and heart rate.

Observations should initially be recorded at 5 minute intervals for the first 30 minutes, or when further changes in the PCA prescription are instituted. If the initial observations are satisfactory, then they may be continued at 30 minute intervals.

Continuous pulse oximetry is mandatory for the duration, and for 30 minutes after the cessation of the PCA. Oxygen via nasal cannulae (minimum 2 L/min) should be continued throughout the duration of the remifentanil PCA regardless of the oxygen saturations.

If such monitoring is unable to be provided then the PCA cannot be commenced or should be discontinued.

If there are any concerns regarding the PCA, side effects or patient observations, the duty anaesthetist or Delivery Unit anaesthetic consultant should be contacted.

Fetal monitoring should be carried out as for any labouring woman receiving opioid analgesia.

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9. When to contact the anaesthetist and troubleshooting

When to contact the anaesthetist (duty anaesthetic registrar or consultant)

- Level of consciousness correlating to 'responds to voice' or less; or she is frequently drowsy
- RR < 10/min
- Oxygen saturations of < 95% despite administration of oxygen
- Bradycardia HR < 50/min or systolic BP <90 mmHg
- PCA pump troubleshooting
- When the PCA pump contains less than 15 mL (so as to ensure that there is timely replacement of the remifentanil PCA syringe, and to ensure that the woman is not subject to a period of inadequate analgesia)

If concerned about patient observations:

- Remove PCA handset from the woman
- Rouse the woman and ask her to take deep breaths, administer oxygen via non-re-breather mask
- If the woman is hypotensive or has a bradycardia then she should be placed into full left lateral position and a fluid bolus considered
- Check blood pressure at 2.5 minute intervals
- Call anaesthetic registrar or consultant to attend
- If respiratory rate < 8/min or excessive sedation administer naloxone 400 mcg IV at 1 minute intervals until there is improvement
- In the unlikely event of respiratory arrest a 'code blue' should be called

Other trouble-shooting

- If the woman is still in pain or is developing side effects, such as itching or nausea contact the anaesthetic registrar or delivery unit anaesthetic consultant

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10. Discontinuing the remifentanil PCA

Once discontinued, the PCA line should be disconnected and the IV line removed, ***without flushing the line*** (as this may cause inadvertent bolus of the any remaining remifentanil, which may be present in the line). Monitoring should continue 30 minutes after cessation of the PCA.

When the remifentanil PCA is discontinued, appropriate ongoing analgesia should be considered for the woman.

The completed remifentanil PCA follow up form, with a patient sticker, should be placed in the epidural follow up tray for follow up by the pain team the next day.

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11. Supporting evidence

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- Tveit TO, Halvorsen A, Seiler S, Rosland JH. Efficacy and side effects of intravenous remifentanil patient-controlled analgesia used in a stepwise approach for labour: an observational study. Int J Obstet Anesth. 2013; 22(1):19-25
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- Ultiva ®(Remifentanil) Data Sheet. Auckland: GlaxoSmithKline NZ Ltd, 2014.
- International Journal of Anthropology. 1989 Dec; 4: 295-298.

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12. Associated Auckland DHB documents

- Intravenous Fluid Prescription - Adult
- Medications - Administration
- Medications - Allergies & Adverse Drug Reactions (ADRs) Identification, Documentation & Reporting
- Medications - Intravenous & Infusions Administration
- Medications - Prescribing
- Patient Controlled Intravenous Analgesia (PCIA) - Adult
- Ranitidine and Fasting in Labour (awaiting approval)

Clinical forms

- Remifentanil PCA follow up form
- CR5782: Adult Observations Chart
- CR8675: Patient Controlled Intravenous Analgesia (PCIA prescription)

Patient information

- Pain Relief in Labour – Remifentanil Patient Controlled Analgesia (PCA)

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13. Disclaimer

No guideline can cover all variations required for specific circumstances. It is the responsibility of the health care practitioners using the Auckland DHB guideline to adapt it for safe use within their own institution, recognise the need for specialist help, and call for it without delay, when an individual patient falls outside of the boundaries of the guideline.

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14. Corrections and amendments

The next scheduled review of this document is as per the document classification table (page 1). However, if the reader notices any errors of believes that the document should be reviewed ***before*** the scheduled date, they should contact the owner or the Clinical Policy Advisor without delay.

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