This information was up to date at the time of release to the Heads of Midwifery.
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Updating arrangements for the formulary should be decided upon and implemented at a local level.

Naloxone (Maternal)

Legal status (GSL, P or POM on exemption list, or PGD)	▪ POM - midwife may administer as medicine is on midwives exemptions list
Patient group	Women with respiratory and other CNS depression resulting from the administration of opioid analgesia during labour.
Clinical indication	Reversal of respiratory depression in women who have received an opioid analgesic during labour.
Pharmacology (Onset and duration of action where appropriate)	Naloxone is a semi-synthetic morphine derivative that is a specific opioid antagonist. The onset of action by IM is slower than IV (that is more than 2 minutes) but lasts between 45 minutes to 4 hours.
Pharmaceutical form, strength, route of administration	Injection contains naloxone hydrochloride 400micrograms in 1ml ampoule supplied in packs of 5 or 10 x 1ml ampoules. Use undiluted.
Dose, frequency and maximum number of doses or period of time for administration or supply	400microgram IM or IV. Can be repeated within 1-2 hours depending on the type, dose and frequency of opioids. Observe closely as repeated doses may be required within 1-2 hours as the duration of action of opioids is longer than naloxone.
Contra-indications/exclusion criteria	▪ hypersensitivity to naloxone or any of the included excipients ▪ severe cardiovascular disease ▪ known substance misuser ▪ mother is on long term opiates for chronic painful condition ▪ check for and document any allergies ▪ check and document past medical and drug history and current medication to ascertain potential for overdose ▪ if an exclusion applies consult with a doctor ▪ document consultation in maternity record

Naloxone (Maternal)

Cautions and action that will be taken if a caution applies	▪ too rapid reversal of opioid effects can cause an acute withdrawal syndrome - hypertension, cardiac arrhythmias, pulmonary oedema and cardiac arrest have been described (particularly if high dose of opiates used or physically dependent). ▪ following the use of opioids during surgery, excessive dosage of naloxone should be avoided, because it may cause excitement, increase in blood pressure and clinically important reversal of analgesia ▪ reversal of opioid effects achieved too rapidly may induce nausea, vomiting, sweating or tachycardia ▪ use with caution in pre-existing cardiac disease or patients who have received medications with potential adverse cardiovascular effects, causing symptoms such as hypertension, hypotension, ventricular tachycardia or fibrillation and pulmonary oedema, cardiac arrest ▪ reversal of buprenorphine-induced respiratory depression may be incomplete ▪ prior to the administration of naloxone it is essential that basic CPR measures are initiated if required: **Airway** - ensure an adequate clear airway. **Breathing** - initiate artificial ventilation. **Circulation** - initiate cardiac massage. ▪ check for and document any allergies ▪ check and document past medical and drug history and current medication to ascertain potential for overdose ▪ if a caution applies consult with a doctor ▪ document consultation in maternity record
Drug interactions and action that will be taken if a patient is taking a medicine that may interact	▪ tricyclic antidepressants, calcium channel blockers, beta-blockers and digoxin may induce hypotension, hypertension, ventricular tachycardia, fibrillation cardiac arrest and pulmonary oedema ▪ if there is a clinically significant drug interaction, consult with a doctor before administration or supply ▪ document consultation in maternity record ▪ refer to current BNF for latest information on interactions

Naloxone (Maternal)

Potential adverse reactions and side effects including actions to be taken if adverse drug reaction is suspected	▪ *naloxone can precipitate acute withdrawal symptoms in babies of substance misusing mothers* ▪ *abrupt postoperative reversal of opioid depression may result in nausea, vomiting, sweating, tremulousness, tachycardia, increased blood pressure, ventricular tachycardia, fibrillation, pulmonary oedema, and cardiac arrest which may result in death.* ▪ *it may be associated with risk of intraventricular haemorrhage in babies less than 34 weeks gestation at birth* ▪ *local irritation and inflammation can occur after IM use* ▪ *common side effects - dizziness, headache, tachycardia, hypotension, hypertension, nausea and vomiting and post op pain.* ▪ ▪ *Uncommon side effects - diarrhoea, dry mouth, tremor, sweating, hyperventilation, arrhythmia and bradycardiaRare side effects – seizures, tension* ▪ *very rare side effects - erythema multiforme, urticaria, rhinitis, dyspnoea, , anaphylactic reactions, shock, fibrillation, cardiac arrest and pulmonary oedema have been reported* ▪ *if a serious adverse reaction is suspected please report to the MHRA Yellow Card Scheme http://yellowcard.mhra.gov.uk/*
Overdose	▪ higher than recommended dosage in postoperative use can lead to the return of pain, hyperventilation, agitation and tension ▪ immediate assessment/treatment is essential - refer to medical staff ▪ manage in accordance with established treatment guidelines ▪ for further advice contact National Poisons Centre 0344 892 0111
Action if patient declines	▪ refer to authorised prescriber or doctor ▪ document in maternity record
Additional advice and information	▪ supply the manufacturer's patient information leaflet if requested
Patient monitoring arrangements during and after treatment and follow-up required	Monitor for the return of respiratory depression or lethargy and pain as the duration of action is shorter than opioids. If naloxone is ineffective or inadequate discuss with a doctor. Document decision in maternity record.
Particular storage requirements	▪ Store at room temperature below 25ºC in the original carton and protect from light.

References

1. SPC for Naloxone 400mcg in 1ml ampoules Hameln Pharmaceuticals ltd.Text revision 6.2.2019. Accessed 16.12.19 www.emc.medicines.org.uk
2. http://www.bnf.org