STANDARDS, LIMITS and CONDITIONS for PRESCRIBING, ORDERING and ADMINISTERING CONTROLLED SUBSTANCES

Approved with implementation pending amendment of Provincial & Territorial Regulations

The following are national standards for midwives to independently prescribe, order and administer controlled substances to women and, where indicated, newborns in their care, as designated under federal and provincial/territorial regulation.

Standards for Control & Prevention of Diversion or Abuse of Controlled Substances in Midwifery Practice

Hospital Practice
When a drug is identified for in-hospital use only it must be signed out of the locked drug cupboard on a dose-by-dose basis. Midwives are required to following hospital protocols and record-keeping and security procedures for all in-hospital prescribing, ordering, administering or disposing of controlled substances.

Out-of-Hospital Practice
Security: Any out-of-hospital supply of a controlled substance must be kept secure and protected against theft or diversion for inappropriate use.

Writing Prescriptions: Prescriptions must be written on regulator approved duplicate prescription pads in a manner so that they are difficult to alter. Prescription pads should be stored out of sight in a secure location in the office and never left unattended in a medical bag. Verbal prescriptions are not permitted. No refills are allowed.

Controlled Substance Log: Midwives must maintain a record of all purchasing, receiving, prescribing, ordering, administering or disposing of controlled substances, including keeping a current accurate inventory of any controlled substances transported or stored outside of a hospital. This record must be kept in a controlled substance log maintained in a form prescribed by their midwifery regulatory body. .

Destroying Out-of-Date Drugs & Substances: Out-of-date controlled drugs and substances, or those no longer needed, must be destroyed by the midwife who must be witnessed by another midwife, a physician, a registered nurse, nurse practitioner or a pharmacist. Unwanted supplies of these drugs may also be surrendered to the pharmacist from whom they were obtained. The means of destruction and the witness must be recorded in the midwife's controlled substance log.

Protection Against & Reporting of Loss or Theft: Midwives must take reasonable steps to protect controlled substance from loss or theft. Any losses or thefts must be reported to Health Canada's Office of Controlled Substance, to the midwife's provincial or territorial midwifery regulatory body and if required, to a law enforcement agency.

Ethics: It is unethical and prohibited for a midwife to prescribe or administer any of these controlled substances to herself/himself or to a member of her/his immediate family.

Demonstrating Competence: Currently practicing midwives will need to demonstrate their knowledge and competence to their respective provincial and territorial midwifery regulators prior to being authorized to independently prescribe, order and administer these controlled substances. Applicant for registration will have their knowledge and competence to independently prescribe, order and administer designated controlled substances assessed through the Canadian Midwifery Registration Examination.

Standards, Limits and Conditions for Prescribing, Ordering and Administering Controlled Substances in Midwifery Practice

The standards below provide midwifery indications, routes of administration and upper dosage limits where appropriate, adverse effects and contraindications for the use of these drugs. Midwives may only prescribe, order or administer the following controlled substances within the standards set out in this document and to a woman under their professional treatment where the drug is required for the purposes outlined below.

Controlled Substances for Use in Prodromal Labour and in the Early Postpartum Period

Lorazepam

(Ativan®). Lorazepam is a benzodiazepine, an anti-anxiety agent and sedative which binds to benzodiazepine receptors on the postsynaptic neuron at several sites within the central nervous system.

Indications and Clinical Use:
Midwives may only prescribe, order or administer Lorazepam on their own authority for
1) therapeutic rest in prodromal labour and/or for
2) the short term management of excessive anxiety during the postpartum while the midwife is arranging for consultation with a physician for further diagnosis and ongoing treatment.
Lorazepam may be used to promote therapeutic rest during prodromal labour and in the early postpartum period, particularly where anxiety and/or insomnia due to anxiety or transient stress are factors and non-pharmacologic measures have been ineffective. Administration under any other circumstance must be on the order of a physician.

Contraindications:
Lorazepam[1] should not be taken in conjunction with alcohol or other sedating medications. Benzodiazepines[2] should not be used with women who have the following medical conditions: glaucoma, liver or kidney impairment, hyperkinesias, hypoalbuminaemia, myasthenia gravis, or any type of organic brain disorder. Benzodiazepines should not be given to women with a history of drug abuse or dependency. Benzodiazepines are contraindicated in the first trimester of pregnancy because of the potential for congenital malformations. Women taking

[1] Hale, T.W,(2010). *Medications and Mother's Milk*. (14th Edition). Amarillo, TX: Hale Publishing.
[2] Drug information. *Lorazepam, Oxazepam* drug information. Retrieved March 19, 2012 from Up to Date

these drugs to treat anxiety disorders should be advised of the risk and offered alternate approaches to therapy.

Warnings and Precautions:
All practitioners caring for an individual taking a benzodiazepine should be aware that long term use can result in dependency and withdrawal symptoms when the medication is discontinued. Prolonged doses of benzodiazepines during pregnancy and/or the postpartum period may cause physical dependence with resulting withdrawal symptoms in the newborn. Before prescribing, ordering or administering a benzodiazepine to a woman with a depressive, chronic psychotic, phobic or obsessive behavioral disorder or potential suicidal tendencies, consultation with a physician is required.

While benzodiazepines may be prescribed for postpartum psychosis, these medications do enter breast milk and, if used by nursing mothers, midwives should watch for possible sedation, feeding difficulties and weight loss in the newborn. Hypoglycemia and respiratory problems in the neonate may occur following exposure late in pregnancy. Elimination of benzodiazepines in the newborn infant following in-utero exposure can be slow. Lorazepam is considered an intermediate acting benzodiazepine with a half-life of (9-16 hrs) and term infants may excrete Lorazepam for up to 8 days following birth.

Benzodiazepines have been associated with anterograde amnesia; may impair physical or mental abilities; may cause hypotension; may cause hyperactive or aggressive behavior. Use with caution in women with hepatic impairment, renal impairment, respiratory disease, a history of drug abuse, alcoholism, personality disorders, or depression.

Women taking this medication should not operate machinery or drive a vehicle.

Pregnancy:
Category D

Lactation:
Category L3

Adverse Reactions:
Benzodiazepines may cause drowsiness, blurred vision, dizziness and impair concentration. Other potential side effects include lack of muscle coordination, nausea, constipation, visual disturbances, skin rash, and loss of bladder control. If breathing difficulties, fainting, rash or hypotension are experienced a physician should be contacted immediately.

Clinical judgement should be exercised as Lorazepam does cross the placental barrier. Should labour progress more rapidly than anticipated, Flumazenil, a benzodiazepine receptor antagonist, may be required and should be readily available for administration to the mother or neonate. Immediately after administration physician consultation is required. (Please refer to the section on Flumazenil at the end of the benzodiazepine section).

Dosage and Administration:
Usual dose is 1-2 mg sublingually.
Lorazepam by injection should not be used in an obstetric situation.

In prodromal labour the dose may be repeated 12 hours later if needed and labour is not yet active. No more than two consecutive doses should be given when used in labour.
In treating postpartum anxiety the dose may be given every 12 hours for no more than 3 days or a maximum of six doses. Once postpartum treatment is initiated physician consultation must be arranged. The sublingual tablet, when placed under the tongue will dissolve in approximately 20 seconds. The woman should not swallow for at least 2 minutes to allow sufficient time for absorption.

Onset of Action:
After sublingual use: 15-30 minutes
Peak action: 2 hours

Duration of Action:
Half-life: 9 to 16 hours: Half-life: conjugate - 16 to 20 hours

Excretion:
Urine as metabolites

Oxazepam

(Serax®). Oxazepam is a benzodiazepine, an anti-anxiety agent and sedative which binds to benzodiazepine receptors on the postsynaptic neuron at several sites within the central nervous system.

Indications and Clinical Use:
Midwives may only prescribe, order or administer Oxazepam on their own authority for 1) therapeutic rest in prodromal labour and/or for 2) the short term management of excessive anxiety during the postpartum while the midwife is arranging for consultation with a physician for further diagnosis and ongoing treatment. Oxazepam may be used for therapeutic rest during prodromal labour and the early postpartum period, particularly where anxiety or insomnia due to anxiety or transient stress are factors and non-pharmacologic measures have been ineffective. Administration under any other circumstance must be on the order of a physician.

Contraindications:
Oxazepam should not be taken in conjunction with alcohol or other sedating medications. Benzodiazepines should not be used with women who have the following medical conditions: glaucoma, liver or kidney impairment, hyperkinesias, hypoalbuminaemia, myasthenia gravis, or any type of organic brain disorder. Benzodiazepines should not be given to women with a history of drug abuse or dependency.

Benzodiazepines are contraindicated in the first trimester of pregnancy because of the potential for congenital malformations. Women taking these drugs to treat anxiety disorders should be advised of the risk and offered alternate approaches to therapy.

Warnings and Precautions:
All practitioners caring for an individual taking a benzodiazepine should be aware that long-term use can result in dependency and withdrawal symptoms when the medication is discontinued. Prolonged doses of benzodiazepines during pregnancy and/or the postpartum

period may cause physical dependence with resulting withdrawal symptoms in the newborn. Before prescribing, ordering or administering a benzodiazepine to a woman with a depressive, chronic psychotic, phobic or obsessive behavioral disorder or potential suicidal tendencies, consultation with a physician is required.

While a benzodiazepine may be prescribed for postpartum psychosis, these medications enter breast milk and, if used by nursing mothers, midwives should watch for possible sedation, feeding difficulties and weight loss in the newborn. Hypoglycemia and respiratory problems in the neonate may occur following exposure late in pregnancy. While elimination of benzodiazepines in the newborn infant following in utero exposure can be slow, Oxazepam is considered a short-acting benzodiazepine (less or equal to 12 hrs) and the least lipid soluble, so levels in breast milk tend to be low. Thus Oxazepam is considered safer during lactation than other benzodiazepines, especially if its use is short-term or intermittent.

Benzodiazepines have been associated with anterograde amnesia; may impair physical or mental abilities; may cause hypotension; may cause hyperactive or aggressive behavior. Use with caution in women with hepatic impairment, renal impairment, respiratory disease, a history of drug abuse, alcoholism, personality disorders, or depression.

Women taking this medication should not operate machinery or drive a vehicle.

Pregnancy:
Category D

Lactation:
Category L3

Adverse Reactions:
Benzodiazepines may cause drowsiness, blurred vision, dizziness and impair concentration. Other potential side effects include lack of muscle coordination, nausea, constipation, visual disturbances, skin rash, and loss of bladder control. If breathing difficulties, fainting, rash or hypotension are experienced a physician should be contacted immediately.

Clinical judgement should be exercised as benzodiazepines do cross the placental barrier. Should labour progress more rapidly than anticipated, Flumazenil, a benzodiazepine receptor antagonist, may be required and should be readily available for administration to the mother or neonate. Immediately after administration physician consultation is required. (Please refer to the section on Flumazenil at the end of the benzodiazepine section).

Dosage and Administration:
Usual dose is 15 or 30 mg orally. (not available as an injection)
In prodromal labour the dose may be repeated 8 or 12 hours following first dose if active labour is not yet established. No more than two consecutive doses should be given. In treating postpartum anxiety the dose may be repeated every 8 to 12 hours in the postpartum period for no more than 3 days or a maximum of six doses. Once postpartum treatment is initiated physician consultation must be arranged.

Onset of Action:
Peak of action is 2-4 hours

Duration of Action:
Half-life: 4 to 14 hours

Excretion:
Urine as metabolites

Flumazenil

(Anexate®, Romazicon®) **is not** a controlled substance but has been included here for reference purposes. Flumazenil is a benzodiazepine receptor antagonist and acts as an antidote in reversing the CNS depressant effects of benzodiazepine compounds. Flumazenil has no effect on CNS depression from other causes such as opioids, alcohol, barbiturates or general anesthetics. Flumazenil if required should be readily available for administration to the mother or neonate.

Indications for Clinical Use:
For reversal of benzodiazepine use during procedure, or known isolated benzodiazepine overdose in women who are not taking benzodiazepines chronically

Contraindications:
Hypersensitivity to flumazenil or benzodiazepines or to any component of the formulation

Warnings and Precautions:
Flumazenil may not reverse respiratory depression as well when longer acting benzodiazepines have been used. There is a need to monitor in the event that respiratory depression or sedation returns. Flumazenil may not reverse amnesia. Immediately after administration physician consultation is required.

Pregnancy:
Category C

Lactation:
It is not known whether flumazenil is excreted in human milk

Adverse Reactions:
Headache; fatigue; tremor; weakness; diaphoresis; agitation; seizure although rare.

Dosage and Administration:
0.1mg/ml injectable solution
IV: 0.2 mg over 15-30 seconds
If there is no response after the initial dose, then 0.3 mg given over 15-30 sec 1 min later, if no response then again 0.5 mg IV over 15-30 sec to maximum cumulative dose of 3 mg/hr.

Onset of Action:
30-60 minutes

Duration of Action:
Half Life: 53 minutes

Elimination:
Liver

Controlled Substances for Use in Active Labour

Fentanyl citrate

Fentanyl Citrate (Fentanyl) is a short-acting opioid which binds with receptors at many sites within the CNS, alters pain reception, increases pain threshold. Fentanyl has no active metabolites and produces less maternal sedation, nausea, and vomiting than morphine.

Indications and Clinical Use:
Midwives may only prescribe, order or administer fentanyl on their own authority for the purpose of pain relief in labour in hospital and not for any other purpose. Fentanyl is administered intravenously as an analgesic for pain relief in labour. Fentanyl is useful in early active labour with cervix at least 3-4 cm dilated and effacing, when a multiparous woman having a rapid, intense labour is requesting analgesia, and for women who wish pain relief, who do not want or have a contraindication to epidural analgesia or where epidural is not available. Administration under any other circumstance must be on the order of a physician.

Contraindications:
Fentanyl should not be used when the woman has PIH, is hypotensive or hypovolemic, has liver or kidney disease, is obese (BMI greater than 35), in preterm labour, at high risk of emergency caesarean delivery (e.g. breech) or has respiratory compromise (e.g. severe asthma, cystic fibrosis) or allergy or prior intolerable side effects to Fentanyl (hallucinations) or known hypersensitivity to Fentanyl.

Fentanyl should not be used in the presence of atypical or abnormal fetal heart tones or in the second stage of labour. Fentanyl should be used with caution in multiple pregnancy, where a woman has a history of difficult intubation or who has already received more than one dose of a longer acting narcotic in labour.

Fentanyl should not be administered within one hour of anticipated delivery.

Warnings and Precautions:
Naloxone should be readily available for administration to the mother or neonate. Physician consultation immediately after administration is required if Naloxone needs to be given.

Fentanyl may cause CNS depression which may impair physical or mental abilities. Use with caution in women with hepatic dysfunction, renal impairment, pre-existing respiratory compromise (hypoxia and/or hypercapnia), a history of drug abuse or acute alcoholism.
.
One to one care must be provided. Monitor maternal vital signs, including respirations, and sedation scores for 30 minutes after IV Fentanyl administration, then hourly for 4 hours.

Monitor maternal oxygen saturation for 5 minute periods if bolus dose of 2 mcg/kg or total doses greater than 200mcg/hr are used *or* if morphine or meperidine has been administered

IM in the 3 hours preceding IV fentanyl administration. A physician should be consulted if oxygen saturations fall below 94%

Pregnancy:
Category C

Lactation:
Category L2.

Adverse Reactions:
Fentanyl can depress maternal and newborn respiration. Extra caution should be observed if fentanyl use continues for more than 5 hours or a total dose of 300 mcg has been administered. The larger the maternal dose, the more likely the neonate is to be depressed. O2 saturation monitoring of the newborn is advised for at least 2 hrs after birth whenever more than 250 mcg has been given. As with any narcotic, watch for aspiration, drowsiness, hypotension, obtunded reflexes in addition to respiratory depression.

Dosage and Administration:
Dilute 100 micrograms (2mLs – 2mL ampoule) into 8mLs normal saline to obtain 10mL solution (concentration 10mcg/mL) and give IV during a contraction. The recommended weight-based dose is 0.5 mcg/kg over 30 seconds waiting 5 minutes for effect and repeating every 5 minutes until satisfactory pain relief or a total maximum dose of 2mcg/kg/hr (or 200mcg/hr, or 4 doses in 1 hr) has been given. Alternatively, with continuous maternal O2 saturation monitoring, doses up to 1mcg/kg (max 100mcg) can be given initially with repeat dosing every 15 -20 minutes to a total of 200mcg/hr (or 2 doses). Once a total dose of 3mcg/kg has been administered epidural or other alternate pain relief measures should be considered.

Onset of Action:
3-5 minutes, peak effect in 5-15 minutes

Duration of Action:
Less or equal > to 1hour, a maternal half-life of less than >1 hour and a neonatal half-life of 1-6 hours.

Morphine sulphate

Morphine sulphate (morphine) is an opioid. It binds to opiate receptors in the CNS, causing inhibition of pain pathways, altering perception and pain response; producing generalized CNS depression. Morphine has a similar analgesic action as Demerol® (Meperidine), but with less nausea and fewer significant side effects for the neonate.

Indications and Clinical Use:
Midwives may only prescribe, order or administer morphine on their own authority for the purpose of pain relief in labour in hospital and not for any other purpose.
Administration under any other circumstance must be on the order of a physician. Morphine can be administered intramuscularly as an analgesic for pain relief in labour.
Morphine is often administered with dimenhydrinate (Gravol®) to counteract the side effects of nausea and vomiting. (The two drugs are compatible in a syringe for only 15 minutes.)

As morphine is more sedating and has a longer half life than fentanyl, it should be reserved for early labour analgesia when intramuscular administration will provide longer relief, or for women who do not want IV access in labour.

Contraindications:
Hypersensitivity to morphine sulfate or any component of the formulation; acute alcoholism, seizure disorders.

Morphine should not be used in the presence of atypical or abnormal fetal heart tones, in late first stage, active labour, or the second stage of labour.

Warnings and Precautions:
Naloxone should be readily available for administration to the mother or neonate. Physician consultation immediately after administration is required if Naloxone needs to be given.

Morphine should be used with caution in patients with a history of drug abuse or acute alcoholism with severe hepatic impairment, in patients with renal impairment, with pre-existing respiratory compromise (hypoxia and/or hypercapnia), with seizure disorders or with thyroid dysfunction. Assess maternal and fetal well-being prior to and after morphine administration. Determine cervical dilation prior to administration; generally a nullipara should be less than 7 cm and a multipara less than 4 cm. As with other opioids, morphine can depress maternal and newborn respiration. The larger the maternal dose, the more likely the neonate is to be depressed. As with any narcotic, watch for aspiration, drowsiness, hypotension, obtunded reflexes, in addition to respiratory depression and urinary retention.

Monitoring: Assess maternal and fetal well-being prior to morphine administration 15 minutes post administration and every 1 to 4 hours thereafter. Determine cervical dilation prior to administration. Generally a nulliparous woman should be less than 7 cm and a multipara less than 4 cm. With IM administration, protocols in some centers allow the woman to be discharged home in early labour if both mother and fetus are well.

Pregnancy:
Category C

Lactation:
Category L3

Adverse Reactions:
Circulatory depression, flushing, shock , bradycardia, hypotension, drowsiness, dizziness, confusion, headache, pruritus, chest pain, hypertension, tachycardia, vasodilation, amnesia, anxiety, hallucination, nervousness, restlessness, seizure, slurred speech, rash.

Dosage and Administration:
10 – 15 mg IM every 4 hours or
3 – 5 mg dose IV bolus every 10 minutes prn for 1 -2 hours of relief
IV administration may be particularly appropriate for the nulliparous woman seeking pain relief in early active first stage. Morphine should **not** be administered subcutaneously as consistency of uptake and effectiveness cannot be determined. Morphine is often

administered with dimenhydrinate (Gravol®) to counteract the side effects of nausea and vomiting. (The two drugs are compatible in a syringe for only 15 minutes.)

Onset of Action:
15 – 20 minutes, peak effect is in 40-50 minutes

Duration of Action:
3 – 4 hours
Morphine has a maternal half life of 1 hour and a neonatal half life of 6 hours. It has no active metabolites. Morphine may be used up to 4 hours prior to anticipated delivery. Most infants delivered 3 hours after a dose have been found to have no detectable cord levels.

Dimenhydrinate

(Gravol®) is **not** a controlled substance but has been included here for reference purposes as it is often given with morphine to counteract the side effects of nausea and vomiting.

Dimenhydrinate is categorized in a class of drugs called antihistamines. It competes with histamine for H_1-receptor sites on effector cells in the respiratory tract, gastrointestinal tract and blood vessels; blocks chemoreceptor trigger zones.

Indications and Clinical Use:
Dimenhydrinate can be administered intramuscularly as an analgesic for pain relief in labour and is often given with morphine to counteract the side effects of nausea and vomiting. (The two drugs are compatible in a syringe for only 15 minutes.) While it is considered safe, dimenhydrinate may produce some sedation.

Contraindications:
Hypersensitivity or previous reactions to dimenhydrinate or any component of the formulation.

Warnings and Precautions:
Use with caution in patients with asthma, peptic ulcer or cardiac arrhythmias and thyroid dysfunction.

Pregnancy:
Category B

Lactation;
Category L2

Adverse Reactions:
Palpitations, hypotension, confusion, nervousness, restlessness, headache, insomnia, tingling, heaviness and weakness of hands, vertigo, dizziness, blurred vision, nasal stuffiness, dryness of nose and throat; nausea, vomiting, diarrhea, constipation, dry mouth; tightness of chest, wheezing.

Dosage and Administration:
Usual Concentration: each ml contains 50mg
50 – 100 mg PO every 4-6 hours, maximum dose 400 mg/day
25 - 50 mg IM or IV every 4 hours, maximum dose 100mg every 4 hours
25 mg IV should be administered slowly over 2 min

Onset of Action:
20 to 30 minutes

Duration of Action:
3 to 6 hours

Meperidine

(Demerol®) Synthetic narcotic agonist-analgesic of opiate receptors; inhibits pain pathways causing alteration in response to pain; produces analgesia, sedation and generalized CNS depression.

Indications and Clinical Use:
Midwives may only prescribe, order or administer meperidine on their own authority for the purpose of pain relief in labour in hospital and not for any other purpose. Meperidine is no longer a drug of choice for labour as it has active metabolites which affect the newborn. It should only be used if fentanyl and/or morphine are not available or cannot be tolerated. Meperidine is used for the relief of moderate to severe pain during the early stages of labour.

As meperidine is sedating and has a long half life, it should be reserved for early labour analgesia when intramuscular administration will provide longer relief, or for women who do not want IV access in labour. Administration under any other circumstance must be on the order of a physician.

Contraindications:
Hypersensitivity to meperidine or to any component of the formulation; in patients with severe respiratory insufficiency.

Warnings and Precautions:
Prolonged use may increase the risk of toxicity such as seizures from the accumulation of meperidine metabolites. It may cause nausea and vomiting. Meperidine crosses the placenta and may cause respiratory depression in the newborn particularly if birth progresses quickly within two hours of drug administration.

Pregnancy:
Category C

Lactation;
Category L2

Adverse Reactions:
Meperidine crosses the placental barrier and can produce depression of respiration and psycho-physiologic functions in the newborn. Extra caution should be observed because of meperidine's long half-life. The larger the maternal dose, the more likely the neonate is to be depressed. O2 saturation monitoring of the newborn is advised after birth. As with any narcotic, watch for aspiration, drowsiness, hypotension, obtunded reflexes in addition to respiratory depression.

Dosage and Administration:
IM/SC (IM is the preferred route): 50 – 100 mg repeated every 1-3 hours

Onset of Action:
Rapid

Duration of Action:
2-4 hours
Half life: 2.5-4 hours
Peak plasma time: IM 30-50 minutes; SC 40-60 minutes

Elimination:
Urine as metabolites

Naloxone Hydrochloride

(Narcan®) Opioid antagonist. Naloxone Hydrochloride is **not** a controlled substance but has been included here for reference purposes

Indications and Clinical Use:
Naloxone should be given to a newborn with respiratory depression as a result of administration of a narcotic analgesic to the mother in labour. Physician consultation immediately after administration is required if Naloxone needs to be given.
Naloxone Hydrochloride (Naloxone) is used to reverse narcotic-induced depression in the neonate caused by maternal intrapartum intake of opiates such as fentanyl and morphine taken close to the time of delivery or from narcotic dependent mothers.

Contraindications:
Hypersensitivity or previous adverse reaction to naloxone or any component of the formulation.

Warnings and Precautions:
Consultation with a physician is required after the administration of a narcotic antagonist. Naloxone causes release of catecholamines and, for newborns of narcotic dependent mothers, naloxone may cause symptoms of acute neonatal opioid withdrawal. Naloxone is not effective in reversing respiratory depression due to non-opioid drugs.

Pregnancy:
Category C

Lactation:
Category L3

Adverse Reactions:
Adverse reactions are related to reversing dependency and precipitating withdrawal symptoms. Withdrawal symptoms may include convulsions, excessive crying, shrill cry, failure to feed, and hyperactive reflexes[3]

[3] Drug information. *Naloxone Hydrochloride*. Retrieved March 15, 2012 from Up to Date.

Dosage and Administration:
The usual newborn dose is 0.1 mg/kg. (Neonatal Resuscitation Program Standard). Give rapidly by IV as the preferred route. IM is also acceptable, but onset of action will be delayed. Dosage may be repeated at 2-3 minute intervals.

Naloxone is available in concentrations of 0.4 mg/mL and 1 mg/mL. Choose 1 mg/mL concentration when available as this will result in a smaller volume to be administered.

Concentration	Dosage	Weight	Total dose	Total mL
0.4 mg/mL	0.1 mg/kg 0.25 mL/kg	3 kg	0.3 mg	0.75 mL
1.0 mg/mL	0.1 mg/kg 0.1 mL/kg	3 kg	0.3 mg	0.3 mL

Onset of Action:
IV, IM: Within 2-5 minutes

Duration of Action:
20-60 minutes: repeated doses are usually needed
Half-life: 2-3 hours

Elimination:
In urine as metabolites.

Controlled Substance and Related Medications for Use in the Postpartum

Acetaminophen with Codeine

(Tylenol® with Codeine No.3[4]) An analgesic, combined opioid which peripherally blocks pain impulses as synthesis of prostaglandins in the central nervous system is inhibited.
Bind to opiate receptors in the CNS, altering perception and response to pain. Causes generalized CNS depression.

Indications and Clinical Use:
Acetaminophen and codeine combined is used to relieve moderate to severe pain in the postpartum period following vaginal and/or operative delivery.

Note: a number of non-codeine-containing pain medications given with regularly scheduled intervals in the first few days post-partum often will provide adequate pain relief without the risks or side effects of codeine exposure.

Contraindications:
Hypersensitivity to acetaminophen, codeine, or any component found in the formulation. Contraindicated in patients with respiratory depression, bronchial asthma, hypercapnia,

[4] Drug information. *Tylenol with Codeine*. Retrieved January 14 , 2013 from Up to Date

paralytic ileus, or known CYP2D6 ultra-metabolizers who are breastfeeding due to risk of neonatal poisoning.

Warnings and Precautions:
Due to the potential adverse effects of codeine on breastfeeding babies, mothers who are breastfeeding should take acetaminophen with codeine for a maximum of four days. If a longer course of a pain medication is required, a different medication should be prescribed.[5] Acetaminophen and codeine may also contain caffeine which can cause CNS and cardiovascular stimulation. Use with caution in patients with a history of peptic ulcer or GERD. May cause hepatotoxicity in the following: with excessive use >4g/day of acetaminophen containing medications; with alcohol use; pre-existing liver disease; chronic daily use.

Caution:
Metabolism of the codeine portion is variable. Codeine must be metabolized to active morphine to have pain-relieving effect. Some people are rapid metabolizers, and may experience enhanced effect but also enhanced adverse effects such as drowsiness and sedation. Where there is a genetic predisposition to rapid metabolizing and increased conversion to morphine, breastfeeding babies can be at significant, even life-threatening, risk. Given that an ultra-rapid metabolizer genotype occurs in 1% in Caucasians and up to 30% in some parts of Asia and Africa, this polymorphism is clinically important.[6] One case of infant death has been reported. Breastfeeding babies should be monitored closely and breastfeeding mothers should take acetaminophen with codeine for a maximum of four days. Some people cannot metabolise codeine, so for these people, codeine is not effective.

Pregnancy:
Category C

Lactation:
Category L3
L5 in rapid metabolizers

Adverse Reactions:
In greater than 10%: Dizziness, lightheadedness, sedation, nausea, vomiting, dyspnea.
In 1% to 10%: Dysphoria, pruritus, abdominal pain, constipation.

Dosage and Administration:
Acetaminophen 300mg and codeine phosphate 30mg;
Based on codeine (30 -60 mg/dose) every 4-6 hours, maximum dose: codeine 240mg/24hours and acetaminophen 4000 mg/24 hours;
Dose adjustment/titration should be made according to appropriate analgesic effect as long a maximum dose is not exceeded.

Onset of Action:

[5] P Madadi, M Moretti, N Djokanovic, P Bozzo, I Nulman, S Ito, G Koren, Guidelines for maternal codeine use during breastfeeding, Canadian Family Physician, November 2009 vol. 55 no. 11, 1077-1078

[6] G. Koren, J. Cairns D. Chitayat, A. Gaedigk, S. J. Leeder, Pharmacogenetics of Fatal Morphine Poisoning in a Breastfed Neonate of a Codeine Using Mother, Retrived April 8, 2013 from MotherRisk

15–30 minutes
Time to peak effect: 60–90 minutes

Duration of Action:
P.O. 0.5-1 hour: 10-60 min: 3-8 hours (dose dependent)
Half-life: 2–3 hours - ranges from 1.5 to 3.5 hours for acetaminophen, 1.5 to 4 hours for codeine and from 2.5 to 4.5 hours for caffeine.

Elimination:
In urine as metabolites

Acetaminophen with Oxycodone

(Endocet®, Percocet®[7,8]) An analgesic combined opioid which blocks pain perception in the cerebral cortex by binding to opiate receptors in the CNS. The binding inhibits the flow of pain sensations and peripherally blocks pain impulses as synthesis of prostaglandins in the central nervous system is inhibited. Produces antipyresis and binds to opiate receptors in the CNS altering perception and response to pain.

Indications and Clinical Use:
Acetaminophen and oxycodone combined is used to relieve moderate to severe pain in the postpartum period following vaginal and/or operative delivery. **Midwives may only prescribe, order or administer acetaminophen with oxycodone on their own authority for the purpose of postpartum pain relief in hospital and not for any other purpose.** If a longer course of a pain medication is required, a non-narcotic medication should be prescribed upon discharge or the woman can be referred to a physician to determine if continued use of acetaminophen with oxycodone seems appropriate.

Contraindications:
Hypersensitivity to oxycodone, acetaminophen, or any component found in the formulation. Contraindicated in patients with respiratory depression, bronchial asthma, hypercarbia, paralytic ileus.

Warnings and Precautions:
May cause CNS depression, impairing mental or physical abilities. Use with caution in patients with known G6PD deficiency. May cause hepatotoxicity in the following: with excessive use >4g/day of acetaminophen containing medications; with alcohol use; pre-existing liver disease; chronic daily use. A woman's history, including any history of misuse or abuse of narcotic drugs, should be considered before prescribing or ordering oxycodone as it is an opioid agonist of the morphine-type and can be abused in a similar manner as other opioid agonists, legal or illicit.

Pregnancy:
Category C

Lactation:

[7] Drug information. *Acetaminophen with Oxycodone*. Retrieved February 11, 2013 from Up to Date
[8] Medscape Reference. *Acetaminophen with Oxycodone*. Retrieved February 11, 2013 from Medscape

Category L3

Adverse Reactions:
Allergic reaction, dizziness, light-headedness, nausea, vomiting, constipation, dysphoria, respiratory depression, sedation, skin rash.

Dosage and Administration:
Usual initial dose for mild to moderate pain: Oral 2.5 mg/325 mg – 5 mg/325 mg (oxycodone 2.5 – 5 mg/acetaminophen 325 mg
Usual initial dose for severe pain: Oral 7.5 mg/325 mg – 10 mg/325 mg or 7.5 mg/500 mg or 10 mg/650 mg
Doses should be given every 4-6 hours as needed and titrated accordingly based on appropriate analgesic effects.
The initial dose is based on the oxycodone content and the maximum daily dose is based on the acetaminophen content.
The total daily dose of acetaminophen should not exceed 4 grams.
The total daily dose of oxycodone should not exceed 2.5 mg – 5 mg (12 tablets), 7.5 mg (8 tablets), 10 mg (6 tablets)

Onset of Action:
Rapid onset

Duration of Action:
4 hours
Half-life: Ranges from 1.5 to 3.5 hours for acetaminophen
Half-life: Ranges from 1.43 to 3.51 hours for oxycodone

Elimination:
In urine as metabolites

Hydromorphone

(Dilaudid-HP®, Dilaudid®[9]) A potent semisynthetic narcotic analgesic which binds to opioid receptors in the CNS, inhibiting ascending pain pathways which in turn alters the response and perception of pain.

Indications and Clinical Use:
Hydromorphone is used to relieve moderate to severe pain in the postpartum period following vaginal and/or operative delivery. It is more potent than morphine by approximately 7-10 times, but used in lower doses. **Midwives may only prescribe, order or administer hydromorphone on their own authority for the purpose of postpartum pain relief in hospital and not for any other purpose.** If a longer course of a pain medication is required, a non-narcotic medication should be prescribed upon discharge or the woman can be referred to a physician to determine if continued use of hydromorphone seems appropriate.

Contraindications:

[9] Drug information. *Hydromorphone*. Retrieved February 11, 2013 from Up to Date
[9] Medscape Reference. *Hydromorpone*. Retrieved February 11, 2013 from Medscape

Hypersensitivity to hydromorphone or any component found in the formulation.
Contraindicated in patients with respiratory depression, acute or severe asthma.

Warnings and Precautions:
May cause CNS depression impairing mental or physical abilities. May cause potentially life threatening respiratory depression. Use with caution in patients with a history of seizure disorder, hypovolemia, cardiovascular disease, drug abuse. A woman's history, including any history of misuse or abuse of narcotic drugs, should be considered before prescribing or ordering hydromorphone as it is a highly addictive morphine-type drug and can be abused in a similar manner as other opioid agonists, legal or illicit.

Pregnancy:
Category C

Lactation:
Category L3

Adverse Reactions:
Bradycardia, hyper/hypotension, vasodilation, tachycardia, CNS depression, confusion, dizziness, hallucinations, headache, memory impairment, mood alterations, seizure, GI disturbances,

Dosage and Administration:
For moderate pain: PO (immediate release) 2-4 mg every 4-6 hours
For severe pain: PO (immediate release) 4 mg every 3-6 hours
IV: 0.2 mg – 1 mg every 2-3 hours
Give slowly over 2-3 minutes
Rectal suppository: 3 mg every 6-8 hours.

Onset of Action:
Oral: 15-30 minutes; peak effect: 30-60 minutes
IV: 5 minutes; peak effect: 10-20 minutes
Extended release tablet: 6 hours; peak effect: 9 hours

Duration of Action:
Oral, IV: 3-4 hours
Extended release tablet: 13 hours
Time to peak: Immediate release tablet: $\leq$ (less than) 1 hour
Extended release tablet: 12-16 hours

Elimination:
Half-life elimination: Immediate release formulations: 2-3 hours
Half-life elimination: Extended release tablets: 8-15 hours
In urine as glucuronide conjugates

References

Abuse and Diversion of Controlled Substances: *A Guide for Health Professionals*, Health Canada, 2006CM0700 Appendix A – *Fentanyl Protocol for Labour,* Fetal Maternal Newborn and Family Health Policy and Procedure Manual, BC Children's and Women's Health Centre

CM0700 Appendix B – *Morphine Protocol for Labour,* Fetal Maternal Newborn and Family Health Policy and Procedure Manual, BC Children's and Women's Health Centre

Drug information. *Acetaminophen with Oxycodone*. Retrieved February 11, 2013 from Up to Date

Drug information. *Flumazenil.* Retrieved Ma7 7, 2013 from Up to Date

Drug information. *Hydromorphone*. Retrieved February 11, 2013 from Up to Date

Drug information. *Lorazepam, Oxazepam*. Retrieved May 7, 2013 from Up to Date

Drug information. *Naloxone Hydrochloride*. Retrieved March 15, 2012 from Up to Date.

Drug information. *Tylenol with Codeine*. Retrieved January 14, 2013 from Up to Date

Enkin M, Kierse, MJNC, et al, A Guide to Effective Care in Pregnancy and Childbirth (3rd ed.) (2000) Oxford University Press. ISBN 019263173

Hale W. Hale, PH.D., Medications and Mothers' Milk (Fourteenth Edition) (2010) Hale Publishing. ISBN 9780982337998

G. Koren, J. Cairns D. Chitayat, A. Gaedigk, S. J. Leeder, Pharmacogenetics of Fatal Morphine Poisoning in a Breastfed Neonate of a Codeine Using Mother, MotherRisk Retrived April 8, 2013

Medscape.*Acetaminophen with Oxycodone*. Retrieved February 11, 2013 from Medscape

Medscape Reference. *Hydromorpone*. Retrieved February 11, 2013 from Medscape

P Madadi, M Moretti, N Djokanovic, P Bozzo, I Nulman, S Ito, G Koren, Guidelines for maternal codeine use during breastfeeding, Canadian Family Physician, November 2009 vol. 55 no. 11, 1077-1078

PSBC *Support Tool No.5 Discomfort and Pain in Labour,* Perinatal Services BC, 2011