

Maternity Unit Medicine Directives (Includes Midwives Exemptions and Protocols)

Issue Date	Review Date	Version
November 2020	November 2023	8

Purpose

- The purpose of this Policy is to ensure that practising midwives safely administer those medicines which their legal status exempts them from the need for a prescription from an authorised prescriber or without the need for a specific Patient Group Direction (PGD) to women during the antenatal, labour and postnatal periods and to neonates.
- To list medicines that midwives can administer in the course of their professional practice under Medicines Act exemptions i.e. without the need for a prescription from an authorised prescriber or without the need for a specific PGD.
- Medicines not included in this list will require a prescription from an authorised prescriber on the official Trust In-patient, Lloyds Out-patient Prescription, or other authorised prescribing charts or may be given under the terms of a specific PGD.

Who should read this document?

- All midwives employed by University Hospitals Plymouth NHS Trust in that capacity, working in either the Maternity Unit or the community setting are entitled to administer medicines without medical prescription under midwives exemptions, pharmacy only and general sales list (GSL) medicines described in this document if they hold the professional qualification of Registered Midwife, and have received appropriate training in the safe handling and administration of medicines. Training in the safe handling, and appropriate use of all drugs listed in the protocol is provided during midwifery training. It is also expected that those midwives will complete the e learning program covering PGDs on an annual basis as part of their mandatory training.

Core accountabilities

Owners	Dr Reshma Gandechea Senior Deputy Chief Pharmacist and Sheralyn Neasham, Matron for Maternity Inpatient Services
Review	Medicines Utilisation and Assurance Committee
Ratification	Sally Mayell
Dissemination (Raising Awareness)	Sheralyn Neasham, Matron for Maternity Inpatient Services
Compliance	Sheralyn Neasham, Matron for Maternity Inpatient Services

Links to other policies and procedures

- UHPNT Medicines Management Policy
- Procedures For Administering Injectable Medicines
- Medicines for Human Use (Miscellaneous Amendments) order 2010 – Midwives Exemptions List
<http://www.legislation.gov.uk/uksi/2010/1136/contents/made>
- The Medicines (Pharmacy and General Sale – Exemption) Order 1980, No.1924, Part 4
<http://www.legislation.gov.uk/cy/uksi/1980/1924/made>

Annexe 2 to NMC Circular 07/2011 Changes to Midwives Exemptions

Version History	
Version 5	July 2015
Version 6 Changes :	<ul style="list-style-type: none"> • Protocol for IV Oxytocin Infusion During Labour removed as not supported by NMC guidance under Midwives' Exemptions (Ref. Annexe 2 to NMC Circular 07/2011). • Protocol for Morphine 10mg/5ml oral solution removed as, under closer inspection, the legislation for Midwives' Exemptions only relates to parenteral morphine. The PGD for Morphine 10mg/5ml oral solution has been reinstated for administration of single doses. A copy of this will be kept with the other Midwives' PGDs.
Version 7	<ul style="list-style-type: none"> • Amendments made to the monographs for oxytocin and Syntometrine® in accordance with the updated UHPNT intrapartum guidelines. • 5-10ml bolus added to the sodium chloride 0.9% monograph for flushing after IV medicines and for flushing newly sited venous cannulas.
Version 8 Changes:	<ul style="list-style-type: none"> • Hartmann's IV solution added for emergency use in PPH • Ergometrine changed to IM

The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

**An electronic version of this document is available on Trust Documents.
Larger text, Braille and Audio versions can be made available upon
request.**

Contents

The Patient group Directions (PGDs) for Midwives are now kept separately as a collection of stand-alone documents in the office of the Matron for Maternity.

Section A – Midwives Exemptions	
	Page
Adrenaline	5-6
Diamorphine	7-8
Diclofenac	8-9
Ergometrine	9-10
Hartmann’s Infusion	10-11
Sodium Chloride 0.9% Infusion	12
Lidocaine	13
Oxytocin Intravenous Infusion Post-delivery	14
Oxytocin Intravenous Bolus Post-delivery	15-16
Phytomenadione Injection	16-17
Phytomenadione Oral	17-18
Prochlorperazine	18-19
Syntometrine	19-20
Anti D Immunoglobulin	20-22

Section B – Pharmacy Only (P) Medicines	
	Page
Entonox	23-24
Clotrimazole Cream	24
Clotrimazole Pessary	24-25
Compound Macrogol Oral Powder, eg. Laxido or Movicol	25-26
Lidocaine 2.5% with 2.5% Prilocaine Cream eg. Emla	26-27

Section C – General Sales List (GSL) Medicines	
	Page
Calamine lotion	27
Peptac	28
Ispaghula Husk eg. Fybogel	29
Glycerol Suppository	29-30
Lactulose	30
Magnesium Trisilicate	30-31
Sodium Citrate Micro-enema	31
Oxygen	31-32
Paracetamol	32
Simple Linctus	32-33

Appendix 1 -Document accountability, responsibility and dissemination	
Accountability	34
Overall Responsibility for These Policies and Guidelines	34
Dissemination and Implementation	34

1 Clinical Condition Being Treated

- **Low risk** patients presenting during pregnancy with particular emphasis on the intrapartum and immediate postpartum period. Where there are restrictions to administration these are specified in the schedule's special instructions.
- Patients with known allergies or previous adverse reactions to any of the listed drugs, or with significant medical or obstetric problems **must** be referred to a doctor for advice and provision of treatment.
- Patients excluded from the group protocols must be referred to a doctor for advice and provision of treatment.
- If the patient is receiving any concomitant medication or treatment it is the responsibility of the health professional identified in the staff group to ensure that treatment with the drug detailed in these group directives is appropriate. In case of any doubt further advice must be sought from the appropriate health professional and recorded as having been sought before the drug is given.

2 General instructions for use of the medicine directives for midwives

- Midwives must not administer any drugs **not** listed above, unless prescribed by a medical practitioner or a UHPNT-approved non-medical independent prescriber.
- Each dose of administered medication is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. In addition, use of oxytocin for the management of induction, augmentation of labour or management of post-partum haemorrhage is to be recorded on the intravenous fluid chart. Administration of Controlled Drugs also needs to be recorded in the Controlled Drugs' Register. The indication for the choice of drug should also be documented.
- All records of administration should clearly bear the signature and name of the midwife, the words "Midwives' Exemption" where this applies, and a second checker in the case of administration of intravenous injections/infusions or Controlled Drugs, or administration to a neonate.
- The midwife cannot delegate the administration of a medicine to a support worker or registered nurse.
- The midwife must ensure the medicines are taken before leaving the patient. Medicines must not be left on the patient's bedside table/locker to administer themselves
- Any midwife has the right to refuse to administer a drug under a midwives exemption, pharmacy only and GSL medicine.
- Medicines Law allows registered midwives to administer and supply any Pharmacy-Only or GSL medicine to a patient in the course of their professional work, without the need for a prescription or a PGD.

Section A – Midwives Exemptions

Protocol for Adrenaline 1 in 1,000 (1:1,000) IM injection	
Comes into effect	October 2020
To be reviewed	October 2025
Administration of	Adrenaline 1 in 1,000 (1:1,000) intramuscular injection
Legal Classification	POM, Listed under Midwives Exemptions
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	<ul style="list-style-type: none"> • Emergency treatment of anaphylaxis. • If the reaction may have been triggered by a drug or intravenous fluid (eg gelofusine or blood product) which has been administered to the patient then this should be stopped immediately. • The Medical Emergency Team must be called.
Clinical criteria for inclusion	<ul style="list-style-type: none"> • Patient is an adult or adolescent older than 12 years presenting with sudden-onset and rapidly progressing life-threatening signs and symptoms of anaphylaxis. <p>Anaphylaxis is likely when all of the following three criteria are met:</p> <ul style="list-style-type: none"> • Sudden onset and rapid progression of symptoms. • Life-threatening airway and/or breathing and/or circulation problems. • Skin and/or mucosal changes (flushing, urticaria, angioedema). <p>Use the ABCDE approach to assess the patient:</p> <p><u>Airway problems:</u></p> <ul style="list-style-type: none"> • Airway swelling eg. throat and tongue swelling. The patient has difficulty in breathing and swallowing and feels that their throat is closing up. • Hoarse voice. • Stridor (high-pitched inspiratory noise due to upper airway obstruction). <p><u>Breathing problems:</u></p> <ul style="list-style-type: none"> • Shortness of breath, increased respiratory rate. • Wheeze. • Patient becoming tired. • Confusion caused by hypoxia (SaO₂ <92) • Cyanosis – this is usually a late sign. <p><u>Circulation problems:</u></p> <ul style="list-style-type: none"> • Signs of shock – pale, clammy. • Tachycardia. • Hypotension – dizziness, faintness, collapse. • Decreased consciousness or loss of consciousness. • ECG changes indicating myocardial ischaemia. <p><u>Disability:</u></p> <ul style="list-style-type: none"> • Altered neurological status: confusion, agitation, loss of consciousness. <p><u>Exposure:</u></p> <ul style="list-style-type: none"> • Erythema, flushing, generalized rash, urticaria. • Angioedema is similar to urticaria but involves swelling of deeper tissues, most commonly in the eyelids and lips, and sometimes in the mouth and throat.
Criteria for exclusion	<ul style="list-style-type: none"> • Patient is 12 years or younger • Patient is allergic to adrenaline or sodium metabisulphite

Reasons for seeking urgent advice from doctor	<ul style="list-style-type: none"> • Patient is excluded from treatment with adrenaline under this protocol. • Patient is pregnant or breastfeeding. • Immediately after the first dose has been given. • The midwife is unhappy to treat for whatever reason.
Dosage	0.5ml of 1:1,000 adrenaline injection (500 micrograms).
Route of administration	Intramuscular injection, preferably into the anterolateral aspect of the middle third of the thigh (or upper arm).
Frequency of administration	May be repeated once after 5 minutes if patient is no better
Period of administration	Maximum 2 doses under this protocol.
Warnings/Monitoring	<ul style="list-style-type: none"> • Avoid inadvertent intravenous administration. • Inform the doctor immediately after giving the first dose of adrenaline if the patient is known to be taking drugs that potentially interact with adrenaline : alpha-blockers, non-cardioselective beta-blockers eg. propranolol, cocaine, tricyclic antidepressants eg. amitriptyline. • Continue to monitor using the ABCDE approach: to include pulse oximetry, ECG, blood pressure. • Patients who are breathing but unconscious should be placed in the recovery position. Pregnant patients should lie on their left side to prevent caval compression. • If the patient is not breathing or has no pulse, commence cardiopulmonary resuscitation using current guidelines. • Possible side effects include anxiety, nausea, tremor, tachycardia, vomiting, headache and cold extremities.
Advice to patient/carer	<ul style="list-style-type: none"> • Explain the condition and the treatment involved if appropriate. • Explain the need for adjuvant treatment i.e. oxygen, fluids, IV chlorphenamine, IV hydrocortisone and salbutamol if appropriate. • If appropriate, inform the patient of potential side effects and ask them to alert the clinician should they occur.
Arrangements for referral	<ul style="list-style-type: none"> • Inform medical team or on-call doctor of the action taken. Instruct ward or department staff to monitor patient closely for at least 8 hours.
Details of records to be kept	<ul style="list-style-type: none"> • Document on once only prescriptions on the front of the drug chart, signed by the midwife administering in accordance with the protocol. <p>Records/audit trail to be recorded in patient's notes</p> <ul style="list-style-type: none"> • Full details of the event with time-course of the reaction. • Dose and form administered • Resuscitative measures. • Patient's response to treatment. • Signature/ Name of staff who administered or supplied the medication <p>Details of any adverse drug reaction and actions taken including documentation in the patients' medical record</p> <ul style="list-style-type: none"> • Where the trigger substance/drug/fluid/food for the anaphylaxis is known or strongly suspected, a record of this should be made on the drug chart, in the medical notes and on the patient's wrist band. • The attending doctor should be encouraged to complete a "Yellow Form" from the BNF for all severe drug reactions and send it to the CSM.
Reference	<ul style="list-style-type: none"> • https://www.resus.org.uk/pages/reaction.pdf

Protocol for Diamorphine injection	
Comes into effect	October 2020
To be reviewed	October 2025
Administration of	Diamorphine injection 5-10mg
Legal Classification	POM, CD, Listed under Midwives Exemptions
Black Triangle?	No
Outside terms of SPC?	Yes, For acute pain, diamorphine is licensed to be repeated 4-hourly if necessary, not as frequently as 2-hourly.
Clinical situations for which medicine is to be used	Pain relief in labour or latent phase of labour
Clinical criteria for inclusion	<ul style="list-style-type: none"> • Pain relief in labour or latent phase of labour • The patient's Booking Weight is at least 50kg
Criteria for exclusion	<ul style="list-style-type: none"> • Acute respiratory depression • Acute alcoholism • Severe renal impairment • Acute diarrhoeal conditions • Patient taking other opiates (prescribed or illicit use) • Known pheochromocytoma • Known raised intracranial pressure • Taking a Monoamine Oxidase Inhibitor (MAOI), cimetidine or selegiline. • Allergy to morphine, codeine or diamorphine
Reasons for seeking further advice from doctor	<ul style="list-style-type: none"> • The patient is excluded from treatment under this protocol. • Emergency administration of Naloxone required in the event of respiratory depression • If the patient has been given the maximum dosage of 15mg under this protocol and is still in pain, then a doctor should review the patient and prescribe further diamorphine as appropriate.
Dosage	5-10mg
Route of administration	IM
Frequency of administration	<ul style="list-style-type: none"> • Dose repeated as required up to a maximum of 15mg before medical review is necessary. • The minimum interval after giving 5mg diamorphine before giving another dose of diamorphine, or morphine sulphate 10mg/5ml oral solution (Oramorph®) is 2 hours. • The minimum interval after giving 10mg diamorphine before giving another dose of diamorphine, or morphine sulphate 10mg/5ml oral solution (Oramorph®) is 4 hours. • Do not administer diamorphine within 2 hours after a dose of morphine sulphate 10mg/5ml oral solution (Oramorph®).
Period of administration	As clinically indicated up to a maximum of 15mg in divided doses.
Warnings	Can cause respiratory depression see BNF or Summary of Product Characteristics
Follow-up	None
Arrangements for referral	None
Details of records to be kept	<ul style="list-style-type: none"> • Each dose of administered diamorphine is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. In addition, administration of diamorphine also needs to be recorded in the Controlled Drugs' Register. The indication for the choice of drug should also be documented. • All records of administration should clearly bear the signature and name of the midwife and a second checker, and the words "Midwives

	Exemption”.
Additional comments	Narcotics appear to be a major factor in delaying stomach emptying. If used women should stop eating and drinking and be offered sips of water only. NB. Diamorphine is a superior analgesic over pethidine with significantly fewer long-term neonatal and maternal complications
Reference	Summary of Product Characteristics for Diamorphine 5mg Injection https://www.medicines.org.uk/emc/product/1466/smpc last updated 29/04/2020

Protocol for Diclofenac 50mg tablets / 100mg suppositories	
Comes into effect	October 2020
To be reviewed	October 2025
Administration of	Diclofenac suppositories 100mg, Diclofenac tablets 50mg
Legal Classification	POM, Listed under Midwives Exemptions
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	Postnatal pain relief, inflammatory pain, back pain, soft tissue disorders
Clinical criteria for inclusion	For use in postnatal period only
Criteria for exclusion	<ul style="list-style-type: none"> • History of hypersensitivity to diclofenac, its ingredients, aspirin or other NSAIDs. • Renal or hepatic disorders • Pregnancy-Induced Hypertension – can be given via medical prescription following clinical review – must have no evidence of renal failure and a recorded normal platelet count • Active peptic ulceration or history of peptic ulceration or gastrointestinal bleeding related to NSAIDs. • Third trimester of pregnancy • Known inflammatory bowel disease • Known congestive heart failure, ischaemic heart disease, cerebrovascular disease or peripheral arterial disease • Asthmatic patients who have never used NSAIDs before. • History of aspirin or NSAID induced asthma, angioedema, urticarial rash or rhinitis • Do not use in combination with NSAIDs taken on a regular basis • Avoid in sepsis without medical prescription
Reasons for seeking further advice from doctor	The patient is excluded from treatment under this protocol.
Dosage	50mg tablet or 100mg suppository
Route of administration	Oral or Rectal
Frequency of administration	2 to 3 divided doses in 24 hours for the tablets. Minimum interval between 100mg suppositories of 16 hours.
Period of administration	Maximum of 150mg in 24 hours via all routes
Warnings	<ul style="list-style-type: none"> • Diclofenac can reversibly inhibit platelet aggregation. • The following adverse effects can occur in more than 1% of patients • Epigastric pain, other Gastrointestinal disorders (e.g. nausea, vomiting, diarrhoea, abdominal cramps, dyspepsia, flatulence, anorexia). Headache, dizziness, or vertigo. Rashes or skin eruptions. • Hypersensitivity reactions have been reported following treatment with NSAIDs.

	<ul style="list-style-type: none"> These consist of (a) non-specific allergic reactions and anaphylaxis (b) respiratory tract reactivity comprising of asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura angioedema and, more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).
Details of records to be kept	<ul style="list-style-type: none"> Each dose of administered medication is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. All records of administration should clearly bear the signature and name of the midwife and the words "Midwives' Exemption". The indication for the choice of drug should also be documented.
References	<ul style="list-style-type: none"> Summary of Product Characteristics (SPC) for diclofenac 50mg tablets https://www.medicines.org.uk/emc/product/4515/smpclast date last update 26/08/2020 SPC for Voltarol suppositories last updated 26/08/2020

Protocol for Ergometrine injection	
Comes into effect	October 2020
To be reviewed	October 2025
Administration of	Ergometrine injection, 500mcg
Legal Classification	POM, Listed under Midwives Exemptions
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	Post-partum haemorrhage
Clinical criteria for inclusion	Post-partum haemorrhage in the absence of contraindications
Criteria for exclusion	<ul style="list-style-type: none"> Prior to delivery of anterior shoulder of infant Severe hypertension (diastolic \geq 100mm Hg or systolic \geq 160mm Hg) Severe pre-eclampsia Severe cardiac, occlusive vascular, renal or hepatic disease Known allergy to ergometrine or maleic acid
Reasons for seeking further advice from doctor	<ul style="list-style-type: none"> Patient is excluded for treatment under this protocol The patient has been taking any of the following inhibitors of hepatic enzymes: macrolide antibiotics (e.g. troleandomycin, erythromycin, clarithromycin), HIV protease or reverse transcriptase inhibitors (e.g. ritonavir, indinavir, nelfinavir, delavirdine), or azole antifungals (e.g. ketoconazole, itraconazole, voriconazole) which should be avoided, since these can result in ergot toxicity (vasospasm and ischaemia of the extremities and other tissues).
Dosage	500mcg
Route of administration	Intramuscular
Frequency of administration	Once only
Period of administration	
Warnings	<ul style="list-style-type: none"> Use with caution where moderate degrees of conditions noted in exclusion criteria above .

Follow-up	None
Arrangements for referral	None
Details of records to be kept	<ul style="list-style-type: none"> • Each dose of administered medication is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented. • All records of administration for ergometrine should clearly bear the signature and name of the midwife, and a second checker, and the words "Midwives' Exemption".
Reference	https://www.medicines.org.uk/emc/product/6265/smpc last updated 01/04/2020

Protocol for Compound Sodium Lactate (Hartmann's) Intravenous Fluid	
Comes into effect	October 2020
To be reviewed	October 2025
Administration of	Compound Sodium lactate (Hartmann's) intravenous infusion
Legal Classification	POM, Listed under Midwives Exemptions
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	To run concurrently with syntocinon infusion for augmentation of labour or when epidural sited. To be administered intravenously in an emergency situation of PPH where a bolus of IV fluid is required
Clinical criteria for inclusion	As above
Criteria for exclusion	<ul style="list-style-type: none"> • Impaired renal function • Cardiac failure • Hypertension • Severe liver disease • Peripheral and pulmonary oedema • Pre-eclampsia.
Reasons for seeking further advice from doctor	<ul style="list-style-type: none"> • The patient is excluded from being given Compound Sodium Lactate infusion under this protocol. • Signs of sodium depletion or fluid overload
Dosage	1000ml over 8 hours Emergency 1000ml over 4 hours
Route of administration	Intravenous
Frequency of administration	As appropriate
Period of administration	During labour
Warnings	Administration of large doses may give rise to sodium depletion and oedema
Follow-up	None
Arrangements for referral	None
Details of records to be kept	<ul style="list-style-type: none"> • Each bag of administered Hartmann's is to be recorded on the Intravenous fluids section of the prescription sheet, partogram (if in use) and the maternity records. The indication for administration of Hartmann's should also be documented. • All records of administration should clearly bear the signature and name of the midwife, and a second checker, and the words "Midwives' Exemption".
Reference	https://www.medicines.org.uk/emc/product/1812 last updated Dec 2018

Protocol for Intravenous Sodium Chloride 0.9 %	
Comes into effect	October 2020
To be reviewed	October 2025
Administration of	Sodium chloride 0.9 % intravenous infusion
Legal Classification	POM, Listed under Midwives Exemptions
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	To run with 40 iu oxytocin as infusion for post-partum haemorrhage prevention or treatment. To use as a flush prior to giving any intravenous medication or following the insertion of a peripheral IV cannula.
Clinical criteria for inclusion	As above
Criteria for exclusion	Impaired renal function, cardiac failure, hypertension, peripheral and pulmonary oedema, pre-eclampsia.
Reasons for seeking further advice from doctor	Signs of fluid overload or hyponatraemia
Dosage	500ml over 4 hours 5-10ml bolus
Route of administration	Intravenous
Frequency of administration	As appropriate
Period of administration	Infusion during or following the 3 rd stage of labour 5-10ml bolus following siting of any peripheral IV cannula or prior to giving any IV medication
Warnings	Administration of large doses may give rise to sodium depletion, oedema and hyperchloraemic acidosis.
Follow-up	If a patient requires regular IV medication then sodium chloride 0.9% needs to be prescribed by a doctor or prescriber on page 16 of the adult drug prescription chart.
Arrangements for referral	None
Details of records to be kept	<ul style="list-style-type: none"> • Each bag or bolus of administered Sodium Chloride 0.9% is to be recorded on the Intravenous fluids section of the prescription sheet, partogram (if in use) and the maternity records. The indication for administration of Sodium Chloride 0.9% should also be documented. • All records of administration should clearly bear the signature and name of the midwife, and a second checker, and the words "Midwives' Exemption".
Reference	https://www.medicines.org.uk/emc/product/1871/smpc last updated Dec2018

Protocol for Lidocaine 1% injection	
Comes into effect	October 2020
To be reviewed	October 2025
Administration of	Lidocaine injection 1%
Legal Classification	POM, Listed under Midwives Exemptions
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	To provide percutaneous local anaesthesia of the skin prior to performing an episiotomy or a repair of perineal trauma or insertion of a peripheral IV cannula.
Clinical criteria for inclusion	As above
Criteria for exclusion	<ul style="list-style-type: none"> • Hypovolaemia • Heart block or severe hypotension • Known Wolff-Parkinson-White Syndrome. • Known Stokes-Adams syndrome. • Bradycardia with a heart rate below 50 bpm • Allergy to lidocaine or other amide-type local anaesthetics.
Reasons for seeking further advice from doctor	<ul style="list-style-type: none"> • The patient is excluded from treatment with lidocaine under this protocol. • Patient experiences any severe side effect listed below. • The treatment has failed to produce adequate local anaesthesia.
Dosage	5ml to perform episiotomy or insert peripheral IV cannula. 15-20ml for perineal repair Total maximum must not exceed 20ml
Route of administration	Percutaneous
Frequency of administration	Divided dose for episiotomy and subsequent repair
Period of administration	As above
Warnings	Great care must be taken to avoid intravascular injection. If Lidocaine enters the circulation it can cause toxicity within 10 to 25 minutes so careful surveillance for toxic effects necessary during the first 30 minutes after injection. Toxic effects include light-headedness, sedation, twitching; In severe reactions convulsions and cardio-vascular collapse may occur very rapidly.
Follow-up	None
Arrangements for referral	None
Details of records to be kept	<ul style="list-style-type: none"> • Each dose of administered medication is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented. • All records of administration for lidocaine should clearly bear the signature and name of the midwife, and the words "Midwives' Exemption".
Reference	https://www.medicines.org.uk/emc/product/4781/smpc last updated 16/04/2019

Protocol for Oxytocin IV Infusion Post-Delivery

Comes into effect	October 2020
To be reviewed	October 2025
Administration of	Oxytocin 10 IU/ hour, intravenous
Legal Classification	POM, Listed under Midwives Exemptions
Black Triangle?	No
Outside terms of SPC?	Yes, maximum licensed concentration is 20IU in 500ml 0.9% sodium chloride.
Clinical situations for which medicine is to be used	Post-partum haemorrhage
Clinical criteria for inclusion	Post-partum haemorrhage in the absence of contraindications
Criteria for exclusion	<ul style="list-style-type: none"> • Prior to delivery of anterior shoulder of infant • Known allergy to oxytocin or any of the excipients in the injection.
Reasons for seeking further advice from doctor	<ul style="list-style-type: none"> • The patient is excluded from being treated with oxytocin under this protocol. • The patient's condition is not responding to treatment. • The patient suffers a severe adverse reaction to the oxytocin.
Dosage	40iu in 500mls over 4 hours = 10iu/125mls/hour
Route of administration	Intravenous Prepare and administer 40iu Oxytocin in 500ml 0.9% sodium chloride intravenously over 4 hours via an IV pump.
Frequency of administration	As above
Period of administration	As medically indicated
Warnings	Do not infuse via the same IV line/catheter as blood or plasma, or solutions containing sodium metabisulphite.
Follow-up	None
Arrangements for referral	None
Details of records to be kept	<ul style="list-style-type: none"> • Each 500ml infusion of administered Oxytocin is to be recorded on the Intravenous fluids section of the prescription sheet, partogram (if in use) and the maternity records. The indication for administration of Oxytocin infusion should also be documented. • All records of administration of Oxytocin should clearly bear the signature and name of the midwife, and a second checker, and the words "Midwives' Exemption".
Reference	https://www.medicines.org.uk/emc/product/9334 last updated 14/06/2018

Protocol for Oxytocin Bolus Injection Post-Delivery	
Comes into effect	September 2018
To be reviewed	September 2023
Administration of	Oxytocin 10 IU intramuscular (unlicensed)
Legal Classification	POM, Listed under Midwives Exemptions
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	<ul style="list-style-type: none"> • Active management of 3rd stage of labour • Post-partum haemorrhage
Clinical criteria for inclusion	<ul style="list-style-type: none"> • Administered to mother not before delivery of anterior shoulder in cephalic presentation • After delivery of the baby for breech or other presentations • After delivery of all babies in multiple births • Post-partum haemorrhage
Criteria for exclusion	Prior to delivery of anterior shoulder of infant
Reasons for seeking further advice from doctor	As clinically indicated
Dosage	10 IU
Route of administration	intramuscular
Frequency of administration	As above
Period of administration	Administer and repeat the dose as clinically indicated.
Warnings	
Follow-up	None
Arrangements for referral	None
Details of records to be kept	<ul style="list-style-type: none"> • Each dose of administered medication is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented. • All records of administration for oxytocin should clearly bear the signature and name of the midwife, and a second checker, and the words "Midwives' Exemption".
Reference	UHPNT General principles of intrapartum care and cord bloods. Next review

Protocol for Phytomenadione (Konakion MM Paediatric®) Injection 2mg in 0.2ml																
Comes into effect	October 2020															
To be reviewed	October 2025															
Administration of	Phytomenadione intramuscular injection															
Legal Classification	POM, Listed under Midwives Exemptions															
Black Triangle?	No															
Outside terms of SPC?	No															
Clinical situations for which medicine is to be used	Routine administration at birth, if not given orally															
Clinical criteria for inclusion	As above															
Criteria for exclusion	Parental refusal															
Reasons for seeking further advice from doctor																
Dosage	<p>Weight and gestation dependent Gestation > 34 weeks 1mg < 34 weeks refer to weight</p> <p>Weight</p> <table border="1"> <thead> <tr> <th>Wt</th> <th>Dose of Vit K</th> <th>Inj. volume</th> </tr> </thead> <tbody> <tr> <td>1kg or less</td> <td>0.4mg</td> <td>0.04ml</td> </tr> <tr> <td>1~ 1.5kg</td> <td>0.6mg</td> <td>0.06ml</td> </tr> <tr> <td>1.5 ~ 2kg</td> <td>0.8mg</td> <td>0.08ml</td> </tr> <tr> <td>Over 2kg</td> <td>1.0mg</td> <td>0.1ml</td> </tr> </tbody> </table>	Wt	Dose of Vit K	Inj. volume	1kg or less	0.4mg	0.04ml	1~ 1.5kg	0.6mg	0.06ml	1.5 ~ 2kg	0.8mg	0.08ml	Over 2kg	1.0mg	0.1ml
Wt	Dose of Vit K	Inj. volume														
1kg or less	0.4mg	0.04ml														
1~ 1.5kg	0.6mg	0.06ml														
1.5 ~ 2kg	0.8mg	0.08ml														
Over 2kg	1.0mg	0.1ml														
Route of administration	Intramuscular injection															
Frequency of administration	Single dose															
Period of administration	Single dose at birth															
Warnings	None															
Follow-up	None															
Arrangements for referral	None															
Details of records to be kept	<ul style="list-style-type: none"> Each dose of administered medication is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented. All records of administration for phytomenadione should clearly bear the signature and name of the midwife, and a second checker, and the words "Midwives' Exemption". 															
References	<ul style="list-style-type: none"> PHNT Neonatal Intensive Care Unit Guidelines: Vitamin K monograph next due for review June 2022 https://www.medicines.org.uk/emc/product/9754 															

Protocol for Phytomenadione (Konakion MM Paediatric®) 2mg in 0.2ml oral solution

Comes into effect	October 2020
To be reviewed	October 2025
Administration of	Phytomenadione oral solution
Legal Classification	POM, Listed under Midwives Exemptions
Black Triangle?	Yes
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	Routine administration at birth, if not given intramuscularly
Clinical criteria for inclusion	As above
Criteria for exclusion	Parental refusal
Reasons for seeking further advice from doctor	
Dosage	2mg doses
Route of administration	Oral
Frequency of administration	2 ~ 3 repeated doses First dose at birth Second dose at 4 ~ 7 days Continue monthly doses of 2mg until formula fed If baby vomits within one hour of dose a repeat dose should be given.
Period of administration	As above
Warnings	None
Follow-up	None
Arrangements for referral	None
Details of records to be kept	<ul style="list-style-type: none"> • Each dose of administered medication is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented. • All records of administration for phytomenadione should clearly bear the signature and name of the midwife, and a second checker, and the words "Midwives' Exemption".
References	<ul style="list-style-type: none"> • PHNT Neonatal Intensive Care Unit Guidelines: Vitamin K monograph next due for review June 2022 • https://www.medicines.org.uk/emc/product/9754 •

Protocol for Prochlorperazine Injection

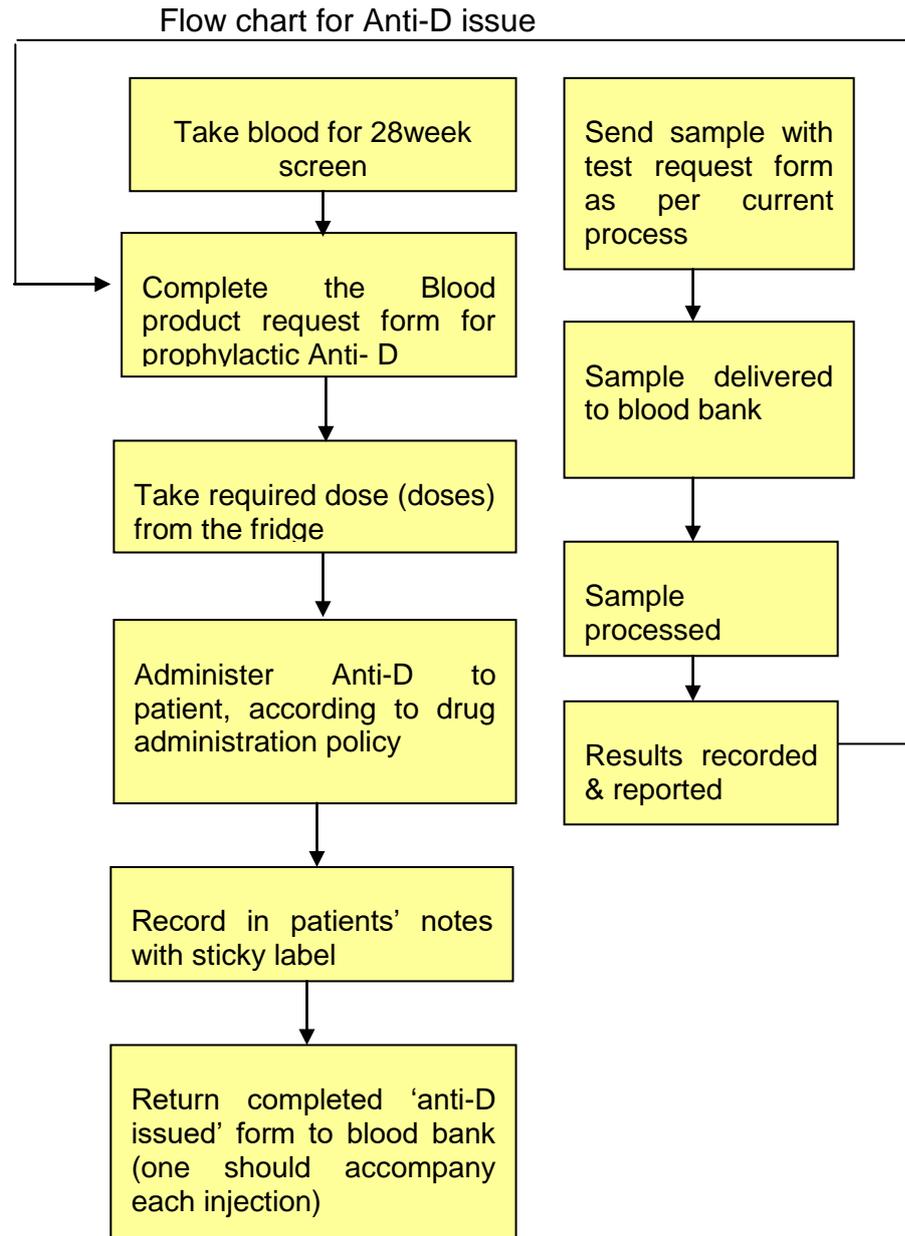
Comes into effect	October 2020
To be reviewed	October 2025
Administration of	Prochlorperazine injection 12.5mg
Legal Classification	POM, Listed under Midwives Exemptions
Black Triangle?	No
Outside terms of SPC?	Not for a single dose. Yes for repeated 6-8 hourly dosing by injection, although this is common practice in medicine.
Clinical situations for which medicine is to be used	Anti-emetic
Clinical criteria for inclusion	For patients in labour or latent phase of labour. May be administered with diamorphine or morphine
Criteria for exclusion	<ul style="list-style-type: none"> • Do not administer within six hours of administration of Promethazine. • Hypersensitivity to Prochlorperazine, other ingredients or other phenothiazines. • Hepatic, cardiac and renal disease. Hypothyroidism, myasthenia gravis, phaeochromocytoma, Parkinson's disease, history of narrow-angle glaucoma or agranulocytosis. • Arrhythmias or patients taking anti-arrhythmic drugs • Use of any other drug which may affect QT interval • Use of other phenothiazines.
Reasons for seeking further advice from doctor	<ul style="list-style-type: none"> • The patient is excluded from being treated with prochlorperazine under this protocol. • The patient's nausea and/or vomiting is not responding to treatment. • The patient suffers a severe adverse reaction to the prochlorperazine.
Dosage	12.5mg
Route of administration	Intramuscular
Frequency of administration	6-8 hourly
Period of administration	As clinically indicated.
Warnings	<p>Many of the adverse effects are related to multiple doses or long-term use. The following may occur after single doses: Sedation and acute dystonic reactions – uncontrollable movements of the tongue, mouth, arms and/or legs; hypotension (usually postural), pain or nodule formation at the injection site, dry mouth, respiratory depression, akathisia (urge to move about constantly), nasal stuffiness. Neuroleptic Malignant Syndrome (hyperthermia, rigidity, autonomic dysfunction, altered consciousness) is a rare but serious adverse effect.</p> <p>Possible adverse effects on the neonate include lethargy or paradoxical hyper excitability, tremor and low apgar score.</p>
Follow-up	None
Arrangements for referral	None
Details of records to be kept	<ul style="list-style-type: none"> • Each dose of administered medication is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented. • All records of administration for prochlorperazine injection should clearly bear the signature and name of the midwife, and the words "Midwives' Exemption".
Reference	https://www.medicines.org.uk/emc/product/6623

Protocol for Syntometrine® Injection	
Comes into effect	September 2018
To be reviewed	September 2023
Administration of	Syntometrine®, intramuscular injection, 1 amp (syntocinon 5units, Ergometrine 500mcg)
Legal Classification	POM, Listed under Midwives Exemptions
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	<ul style="list-style-type: none"> • Active management of 3rd stage of labour • Post-partum haemorrhage
Clinical criteria for inclusion	<ul style="list-style-type: none"> • Administered to mother not before delivery of anterior shoulder in cephalic presentation • After delivery of the baby for breech or other presentations • After delivery of all babies in multiple births • Post-partum haemorrhage in the absence of contraindications
Criteria for exclusion	<ul style="list-style-type: none"> • Prior to delivery of anterior shoulder of infant • Severe hypertension (diastolic \geq 100mm Hg or systolic \geq 160mm Hg) • Severe pre-eclampsia • Severe cardiac, occlusive vascular, renal or hepatic disease • Known allergy to oxytocin, syntocinon or any of the excipients in the injection.
Reasons for seeking further advice from doctor	<ul style="list-style-type: none"> • Patient is excluded for treatment under this protocol • The patient has been taking any of the following inhibitors of hepatic enzymes: macrolide antibiotics (e.g. troleandomycin, erythromycin, clarithromycin), HIV protease or reverse transcriptase inhibitors (e.g. ritonavir, indinavir, nelfinavir, delavirdine), or azole antifungals (e.g. ketoconazole, itraconazole, voriconazole) which should be avoided, since these can result in ergot toxicity (vasospasm and ischaemia of the extremities and other tissues).
Dosage	1 ampoule (syntocinon 5units, Ergometrine 500mcg)
Route of administration	Intramuscular
Frequency and period of administration	Repeat the dose as clinically indicated.
Warnings	<ul style="list-style-type: none"> • Use with caution where moderate degrees of conditions noted in exclusion criteria above
Follow-up	None
Arrangements for referral	None
Details of records to be kept	<ul style="list-style-type: none"> • Each dose of administered medication is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented. • All records of administration for Syntometrine should clearly bear the signature and name of the midwife, and the words "Midwives' Exemption".
Reference	https://www.medicines.org.uk/emc/product/865

Protocol for Anti-D Immunoglobulin Injection	
Comes into effect	October 2020
To be reviewed	October 2025
Administration of	Anti-D immunoglobulin by deep intramuscular injection
Legal Classification	POM, Listed under Midwives Exemptions
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	<ul style="list-style-type: none"> • Routine antenatal prophylaxis • Prophylaxis following a sensitising event • Postpartum prophylaxis if baby is Rhesus positive
Clinical criteria for inclusion	<ul style="list-style-type: none"> • As above • Within 72 hours, but up to 10 days, following a sensitising event ~ if less than 12 weeks pregnant only administer if patient undergoing evacuation, bleeding is persistent and heavy, has diagnosis of ectopic pregnancy or undergoing medical TOP • At 28 weeks routine antenatal prophylaxis, with no cut off point up to delivery • Within 72 hours as postpartum prophylaxis if baby is Rhesus positive
Criteria for exclusion	<ul style="list-style-type: none"> • Patient already has anti-D antibodies • Known allergy to anti-D Immunoglobulin • Woman declines treatment • Woman declines blood products, e.g. Jehovah's witness • IgA deficiency • Disorder of Haemostasis • Less than 12 weeks pregnant, unless patient undergoing evacuation or bleeding is persistent and heavy
Reasons for seeking further advice from doctor	<ul style="list-style-type: none"> • Anaphylaxis can occur but is rare. In the event of anaphylaxis the midwife should seek emergency medical assistance • Local pain and tenderness • Any suspected side effects should be reported the patients GP, Lead Obstetrician if Consultant led care and Consultant haematologist. The Consultant Haematologist will advise in subsequent treatment
Dosage	<p>cffDNA – if performed in pregnancy and fetus confirmed as negative, no further doses of Anti -D required in the event of a sensitising event.</p> <p><u>Sensitising event at less than 12 weeks gestation</u> if fetus confirmed as positive</p> <p>500 iu anti-D Immunoglobulin as directed by Blood bank</p> <p><u>Sensitising event at 12 weeks or more gestation</u> if fetus confirmed as positive</p> <p>500 iu anti-D Immunoglobulin as directed by Blood bank</p> <p>Give within 72 hours, but up to 10 days, following a sensitising event.</p> <p>Cord and maternal bloods to be taken for all mothers who are Rh negative, regardless of cffDNA result.</p>

	<p><u>Post-partum prophylaxis if baby is Rhesus positive:</u></p> <p>500iu anti-D Immunoglobulin within 72 hours of delivery. NB if more than 72 hours has passed anti-D should be given as there may be some benefit for up to 10 days from exposure.</p>
Route of administration	Deep intramuscular (Deltoid)
Period of administration	Single doses
Warnings	<ul style="list-style-type: none"> • Anaphylaxis can occur but is rare. In the event of anaphylaxis the midwife should seek emergency medical assistance, therefore, can only be administered where emergency care is available. It must not be administered in the patient's home. • Patient must remain in environment with emergency equipment for at least 20 min post-administration
Follow-up	Blood sample for Kleihauer testing after a sensitising event following routine prophylactic administration of Anti-D to assess the need for further prophylaxis
Patient advice	MMR vaccine may be given in the postpartum period with Anti-D as long as separate syringes and different limbs. If this is not possible then MMR should be deferred for three months.
Arrangements for referral	None
Details of records to be kept	<ul style="list-style-type: none"> • Each dose of administered medication is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented. • All records of administration for Anti-D Immunoglobulin should clearly bear the signature and name of the midwife, and a second checker, and the words "Midwives' Exemption".
References	<ul style="list-style-type: none"> • UHPT Antenatal Guidelines No.3 Administration of Anti-D Immunoglobulin for Rh negative women, Version 8 July 2023 • UHPT Maternity Standard Operating Procedure. Cell free fetal DNA (cffDNA) testing for Rhesus Status typing HD type, version 1 November 2020 • https://www.medicinescomplete.com/#/content/bnf/_204952084?hspl=anti-d&hspl=immunoglobulin#DMD4993011000001106

Process for administration of prophylactic Anti D at 28 weeks gestation if cffDNA result inconclusive not performed or fetus confirmed as positive.



Section B

P

Pharmacy Only Medicines

Entonox	
Comes into effect	October 2020
To be reviewed	October 2025
Administration of	Entonox gas for inhalation
Legal Classification	Pharmacy only
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	To provide pain relief
Clinical criteria for inclusion	As above
Criteria for exclusion	<ul style="list-style-type: none"> • Entonox should not be used in any condition where gas is entrapped within a body and where its expansion might be dangerous, such as with air embolism or pneumothorax. • Use with caution with: <ol style="list-style-type: none"> 1. <u>Oxytocin</u> Effects of Oxytocin potentially reduced, with enhanced risk of hypotensive effect and risk of cardiac arrhythmias. 2. <u>Antihypertensives</u> Risk of enhanced hypotensive effects.
Reasons for seeking further advice from doctor	
Dosage	Administer via suitable anaesthetic apparatus with facemask and bacteria filter. Ensure scavenging operation while in use and for 45 minutes after discontinuing use within the hospital environment.
Route of administration	Inhalation
Frequency and period of administration	As appropriate
Additional comments	<ul style="list-style-type: none"> • Community Midwives carrying Entonox cylinders should ensure they are stored in a secure manner in the midwife's car and have a 'hazardous gases' sign displayed at all times when transporting cylinders. In cold weather the gases will separate. In the event of exposure to cold the cylinder will need to be warmed. This can be done by immersing the cylinder in warm water and then inverting the cylinder a few times to mix the gases. • Entonox may affect the patient's ability to drive. Advise do not drive for 12 hours. • The high level of oxygen in Entonox (50% O₂) may depress respiration in a small proportion of chronic obstructive pulmonary disease patients who have chronically raised carbon dioxide levels. If this occurs withdrawing Entonox will reverse the condition.
Follow-up	None
Arrangements for referral	None
Details of records to be kept	Administration of Entonox is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be

	documented.
Reference	Summary of Product Characteristics for Entonox® last updated 8/11/2018

Clotrimazole 1% Cream	
Comes into effect	October 2020
To be reviewed	October 2025
Administration of	Clotrimazole 1% cream
Legal Classification	GSL
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	Vaginal and vulval candidiasis
Clinical criteria for inclusion	As above
Criteria for exclusion	Spontaneous rupture of membranes, APH
Reasons for seeking further advice from doctor	If initial treatment not effective
Dosage	Clotrimazole 1% cream
Route of administration	Topical
Frequency of administration	Apply to the affected area(s) 2-3 times daily.
Period of administration	Supply one tube to complete treatment.
Additional comments	Patient to seek medical advice if the candidiasis persists beyond seven days treatment.
Follow-up	None
Arrangements for referral	None
Details of records to be kept	Administration and/or supply of clotrimazole cream is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented.

Clotrimazole 500 mg Pessary	
Comes into effect	October 2020
To be reviewed	October 2025
Administration of	Clotrimazole 500 mg pessary
Legal Classification	Pharmacy Only
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	Vaginal and vulval candidiasis
Clinical criteria for inclusion	As above

Criteria for exclusion	Spontaneous rupture of membranes, APH
Reasons for seeking further advice from doctor	If initial treatment not effective
Dosage	500 mg once only
Route of administration	Vaginal
Frequency of administration	Single dose
Period of administration	
Additional comments	
Follow-up	None
Arrangements for referral	None
Details of records to be kept	The administration and/or supply of a clotrimazole pessary is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented.

Compound Macrogol Oral powder, eg. Laxido® or Movicol®	
Comes into effect	October 2020
To be reviewed	October 2025
Administration of	Compound macrogol oral powder – sachet
Legal Classification	Pharmacy Only
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	Constipation
Clinical criteria for inclusion	As above
Criteria for exclusion	Intestinal perforation or obstruction, paralytic ileus, inflammatory conditions of intestines
Reasons for seeking further advice from doctor	If treatment not effective Evidence of untoward side-effects
Dosage	2 sachets
Route of administration	Oral
Frequency of administration	Once or twice daily
Period of administration	As needed
Additional comments	
Follow-up	None
Arrangements for referral	None
Details of records to be kept	The administration and/or supply of Laxido is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented.

Lidocaine 2.5% with Prilocaine 2.5% Cream (eg. Emla®)	
Comes into effect	October 2020
To be reviewed	October 2025
Administration of	Lidocaine 2.5% with prilocaine 2.5% cream
Legal Classification	Pharmacy Only
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	To provide, when required, percutaneous local anaesthesia of the skin prior to insertion of peripheral intravenous cannulas.
Clinical criteria for inclusion	<ul style="list-style-type: none"> The patient is over 16 years of age. The intended site of application is intact, normal skin.
Criteria for exclusion	<ul style="list-style-type: none"> Known hypersensitivity or allergy to lidocaine, prilocaine, other amide-type local anesthetics, excipients in the cream, or occlusive dressings. Infected, inflamed or broken skin at the intended site of use. Known complete heart block Known history of methaemoglobinaemia. Patients with atopic eczema affecting the area to which the cream will be applied. Patient has had Lidocaine with Prilocaine cream applied to the same area in the last 5 hours.
Reasons for seeking further advice from doctor	<ul style="list-style-type: none"> The patient experiences significant adverse effects from the cream. The cream is failing to provide adequate local anaesthesia. If the patient needs application of Lidocaine with Prilocaine cream to facilitate IV cannula insertion, but she is excluded from treatment under this protocol. Two failed attempts at cannulation at different sites using Lidocaine with Prilocaine cream.
Dosage	2g of Lidocaine with Prilocaine cream (approximately half a tube) over each site where IV cannulation will be attempted.
Route of administration	Topical
Frequency and period of administration	<ul style="list-style-type: none"> Apply in a thick layer around and over the intended site of venous cannulation. Cover with an occlusive dressing for a minimum of 1 hour and a maximum of 5 hours before removing and attempting the insertion of a venous cannula. Care should be taken when applying Lidocaine with Prilocaine cream to patients with atopic dermatitis. A shorter application time, 15-30 minutes, may be sufficient. Application times of longer than 30 minutes in patients with atopic dermatitis may result in an increased incidence of local vascular reactions.
Warnings	<ul style="list-style-type: none"> Watch for possible adverse effects: <ul style="list-style-type: none"> Erythema, itching or swelling at site of application Blistering of the skin (very rare) Allergic reactions (very rare) Patients treated with anti-arrhythmic drugs class III (eg, amiodarone) should be carefully monitored and ECG monitoring considered as cardiac effects may be additive.
Follow-up	None
Arrangements for referral	None
Details of records to be kept	Use of Lidocaine with Prilocaine cream is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for using Lidocaine with Prilocaine cream should also be documented.
Reference	Summary of Product Characteristics for Emla® Cream last updated

Section C

GSL

General Sales List Medicines

Calamine lotion	
Comes into effect	October 2020
To be reviewed	October 2025
Supply/Administration of	Calamine lotion
Legal Classification	GSL
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	Pruritis
Clinical criteria for inclusion	As above
Criteria for exclusion	Insect stings
Reasons for seeking further advice from doctor	A systemic disease can cause pruritis in pregnancy. Any suspected pathological conditions should be investigated and treated
Dosage	Apply liberally
Route of administration	Topical
Frequency of administration	As appropriate
Period of administration	
Warnings	
Follow-up	None
Arrangements for referral	None
Details of records to be kept	Administration and/or supply of calamine lotion is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented.

Peptac	
Comes into effect	October 2020
To be reviewed	October 2025
Supply/Administration of	Peptac
Legal Classification	GSL
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	Gastro-oesophageal reflux
Clinical criteria for inclusion	As above
Criteria for exclusion	Diabetics
Reasons for seeking further advice from doctor	Persistent or worsening of condition
Dosage	5-10ml
Route of administration	Oral
Frequency of administration	QDS
Period of administration	As needed
Warnings	
Follow-up	None
Arrangements for referral	None
Details of records to be kept	Administration and/or supply of peptac is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented. https://www.medicines.org.uk/emc/product/8799/smpc#gref

Ispaghula Husk Sachets eg. Fybogel®	
Comes into effect	October 2020
To be reviewed	October 2025
Supply/Administration of	Fybogel
Legal Classification	GSL
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	Constipation
Clinical criteria for inclusion	As above
Criteria for exclusion	<ul style="list-style-type: none"> • Intestinal obstruction • Colonic atony • Fecal impaction • Difficulty in swallowing • Allergy to peanut or soya • Phenylketonuria
Reasons for seeking further advice from doctor	If constipation persists
Dosage	1 sachet in water
Route of administration	Oral
Frequency of administration	BD, after meals
Period of administration	As needed
Warnings	
Arrangements for referral	None
Details of records to be kept	Administration and/or supply of Ispaghula Husk sachets is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented.

Glycerol Suppository 4g	
Comes into effect	May 2015
To be reviewed	May 2020
Supply/Administration of	Glycerol suppository 4g
Legal Classification	GSL
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	Constipation
Clinical criteria for inclusion	As above
Criteria for exclusion	Anal fissure Haemorrhoids
Reasons for seeking further advice from doctor	If constipation persists
Dosage	One 4g suppository
Route of administration	Per rectum
Frequency of administration	Once only
Period of administration	
Warnings	
Follow-up	None
Arrangements for referral	None
Details of records to be kept	Administration of a glycerol suppository is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented.

Lactulose	
Comes into effect	October 2020
To be reviewed	October 2025
Supply/Administration of	Lactulose
Legal Classification	GSL
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	Constipation
Clinical criteria for inclusion	As above
Criteria for exclusion	Galactosaemia Intestinal obstruction
Reasons for seeking further advice from doctor	As clinically indicated
Dosage	15ml
Route of administration	Oral
Frequency of administration	BD, then adjust as required to a maximum of 15ml TDS
Period of administration	As needed
Warnings	
Follow-up	None
Arrangements for referral	None
Details of records to be kept	Administration and/or supply of Lactulose is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented.

Magnesium Trisilicate Mixture B.P.	
Comes into effect	October 2020
To be reviewed	October 2025
Supply/Administration of	Magnesium Trisilicate mixture B.P.
Legal Classification	GSL
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	Relief of indigestion
Clinical criteria for inclusion	As above
Criteria for exclusion	Hypophosphataemia Diarrhoea
Reasons for seeking further advice from doctor	Persistent or worsening of condition
Dosage	10ml
Route of administration	Oral
Frequency of administration	TDS
Period of administration	As needed
Warnings	
Follow-up	None
Arrangements for referral	None
Details of records to be kept	Administration and/or supply of Magnesium Trisilicate Mixture is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented.

Sodium Citrate Micro-Enema	
Comes into effect	October 2020
To be reviewed	October 2025
Supply/Administration of	Micro-enema
Legal Classification	GSL
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	Constipation
Clinical criteria for inclusion	As above
Criteria for exclusion	Anal fissure Haemorrhoids
Reasons for seeking further advice from doctor	If constipation persists
Dosage	One suppository
Route of administration	Per rectum
Frequency of administration	Once only
Period of administration	
Warnings	
Follow-up	None
Arrangements for referral	None
Details of records to be kept	Administration of a sodium citrate micro-enema is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented.

Oxygen	
Comes into effect	October 2020
To be reviewed	October 2025
Supply/Administration of	Oxygen
Legal Classification	GSL
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	Resuscitation of the infant in accordance with Resuscitation Council Newborn Life Support Guidelines.
Clinical criteria for inclusion	As above
Criteria for exclusion	
Reasons for seeking further advice from doctor	
Dosage	Up to 100% set at 4 ~ 6 L / min
Route of administration	Facial or via mask / t-piece
Frequency and period of administration	As appropriate
Additional comments	
Follow-up	None
Arrangements for referral	None
Details of records to be kept	Use the Oxygen section of the prescription chart to record administration of oxygen, to include the details of the concentration used, the flow rate and the device used. Also record on the partogram (if in use) and the maternity records. Also record the indication for administering oxygen.

Paracetamol	
Comes into effect	May 2015
To be reviewed	May 2020
Supply/Administration of	Paracetamol tablets 500mg
Legal Classification	GSL
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	Mild/ moderate pain relief and pyrexia
Clinical criteria for inclusion	As above Be aware of other analgesics prescribed that may contain paracetamol
Criteria for exclusion	Caution with hepatic or renal impairment
Reasons for seeking further advice from doctor	
Dosage	500 ~ 1000mg
Route of administration	Oral
Frequency of administration	4 ~ 6 hours Maximum of 4g in 24 hours
Period of administration	As needed
Warnings	
Follow-up	None
Arrangements for referral	None
Details of records to be kept	Administration and/or supply of paracetamol is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented.

Simple Linctus	
Comes into effect	October 2020
To be reviewed	October 2025
Supply/Administration of	Simple Linctus
Legal Classification	GSL
Black Triangle?	No
Outside terms of SPC?	No
Clinical situations for which medicine is to be used	Upper respiratory tract irritation
Clinical criteria for inclusion	As above
Criteria for exclusion	
Reasons for seeking further advice from doctor	Persistent cough or worsening of condition
Dosage	5ml
Route of administration	Oral
Frequency of administration	TDS - QDS
Period of administration	As needed
Warnings	
Follow-up	None
Details of records to be kept	Administration and/or supply of Simple Linctus is to be recorded on the Once-Only section of the prescription sheet, partogram (if in use) and the maternity records. The indication for the choice of drug should also be documented.

Dissemination Plan			
Document Title	Maternity Unit Medicine Directives (Includes Midwives Exemptions and Protocols)		
Date Finalised	November 2020		
Previous Documents			
Action to retrieve old copies	Remove previous version saved/uploaded on Trust Folders or specific Maternity Unit Drives.		
Dissemination Plan			
Recipient(s)	When	How	Responsibility
Upload document into a "Midwives Directives" subfolder of the "Maternity" folder in the Trust Document Library			Information Governance Team

Review Checklist		
Title	Is the title clear and unambiguous?	Yes
	Is it clear whether the document is a policy, procedure, protocol, framework, APN or SOP?	Yes
	Does the style & format comply?	Yes
Rationale	Are reasons for development of the document stated?	Yes
Development Process	Is the method described in brief?	
	Are people involved in the development identified?	Yes
	Has a reasonable attempt has been made to ensure relevant expertise has been used?	Yes
	Is there evidence of consultation with stakeholders and users?	
Content	Is the objective of the document clear?	Yes
	Is the target population clear and unambiguous?	Yes
	Are the statements clear and unambiguous?	Yes
Evidence Base	Is the type of evidence to support the document identified explicitly?	
	Are key references cited and in full?	
	Are supporting documents referenced?	
Approval	Does the document identify which committee/group will review it?	Yes
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	
	Does the document identify which Executive Director will ratify it?	
Dissemination & Implementation	Is there an outline/plan to identify how this will be done?	Yes
	Does the plan include the necessary training/support to ensure compliance?	
Document Control	Does the document identify where it will be held?	Yes
	Have archiving arrangements for superseded documents been addressed?	Yes
Monitoring Compliance & Effectiveness	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	
	Is there a plan to review or audit compliance with the document?	
Review Date	Is the review date identified?	Yes
	Is the frequency of review identified? If so is it acceptable?	
Overall Responsibility	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes

Core Information	
Date	November 2020
Title	Maternity Unit Medicine Directives (Includes Midwives Exemptions and Protocols)
What are the aims, objectives & projected outcomes?	<ul style="list-style-type: none"> • The purpose of this Policy is to ensure that practising midwives safely administer those medicines which their legal status exempts them from the need for a prescription from an authorised prescriber or without the need for a specific Patient Group Direction (PGD) to women during the antenatal, labour and postnatal periods and to neonates. • To list medicines that midwives can administer in the course of their professional practice under Medicines Act exemptions i.e. without the need for a prescription from an authorised prescriber or without the need for a specific PGD.
Collecting data	
Race	There is no evidence to suggest that there is an impact on race regarding this policy. Data collected from Datix incident reporting and complaints will ensure this is monitored.
Religion	There is no evidence to suggest that there is an impact on religion regarding this policy. Data collected from Datix incident reporting and complaints will ensure this is monitored.
Disability	There is no evidence to suggest that there is an impact on disability regarding this policy. Data collected from Datix incident reporting and complaints will ensure this is monitored.
Sex	There is no evidence to suggest that there is an impact on sex regarding this policy. Data collected from Datix incident reporting and complaints will ensure this is monitored.
Gender Identity	There is no evidence to suggest that there is an impact on gender identity regarding this policy. Data collected from Datix incident reporting and complaints will ensure this is monitored.
Sexual Orientation	There is no evidence to suggest that there is an impact on sexual orientation regarding this policy. Data collected from Datix incident reporting and complaints will ensure this is monitored.
Age	There is no evidence to suggest that there is an impact on age regarding this policy. Data collected from Datix incident reporting and complaints will ensure this is monitored.

Socio-Economic	There is no evidence to suggest that there is an impact on socio-economic status regarding this policy. Data collected from Datix incident reporting and complaints will ensure this is monitored.
Human Rights	There is no evidence to suggest that there is an impact on human rights regarding this policy. Data collected from Datix incident reporting and complaints will ensure this is monitored.
What are the overall trends/patterns in the above data?	Nothing of concern.

Involving and consulting stakeholders				
Internal involvement and consultation	Not required			
External involvement and consultation	Not required			
Impact Assessment				
Overall assessment and analysis of the evidence	Approved			
Action Plan				
Action	Owner	Risks	Completion Date	Progress update
Specific issues and data gaps that may need to be addressed through consultation or further research	None			