

Midwives Exemptions Management

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Departments/Group this Document applies o:	Maternity

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Review Date:

Guideline to be followed by (target staff): Registered Midwives and Student Midwives under the direct supervision of their Practice Supervisor / Assessor

To be read in conjunction with the following documents:

- Milton Keynes University Hospital NHS Foundation Trust. *Guidelines for supply of discharge medicines use of TTO pre-packs.* PHARM/GL/26. Version 3, 2021.
- Milton Keynes University Hospital NHS Foundation Trust. *Medicines management policy*. PHARM/GL/19. Version 8, 2020.
- Milton Keynes University Hospital NHS Foundation Trust. *Procedure for the ordering, supply, storage, prescribing and administration of mifepristone on labour ward policy.* PHARM/GL/23. Version 4, 2018.
- Milton Keynes University Hospital NHS Foundation Trust. Procedure for the use of patients own drugs (Pods). PHARM/GL/24. Version 3, 2020.
- Milton Keynes University Hospital NHS Foundation Trust. Controlled Drugs Standard Operating Procedure (CD SOPs). PHARM/SOP/01. Version 1. 2020.
- Milton Keynes University Hospital NHS Foundation Trust. *Vitamin K Prophylaxis in Newborn Babies*. MIDW/GL/117. Version 5, 2019.

Are there any eCARE implications? No

CQC Fundamental standards:

Regulation 9 – person centered care

Regulation 10 – dignity and respect

Regulation 11 – Need for consent

Regulation 12 – Safe care and treatment

Regulation 13 – Safeguarding service users from abuse and improper treatment

Regulation 14 - Meeting nutritional and hydration needs

Regulation 15 – Premises and equipment

Regulation 16 - Receiving and acting on complaints

Regulation 17 – Good governance

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Regulation 18 – Staffing Regulation 19 – Fit and proper

Disclaimer

Since every patient's history is different, and even the most exhaustive sources of information cannot cover every possible eventuality, you should be aware that all information is provided in this document on the basis that the healthcare professionals responsible for patient care will retain full and sole responsibility for decisions relating to patient care; the document is intended to supplement, not substitute for, the expertise and judgment of physicians, pharmacists or other healthcare professionals and should not be taken as an indication of suitability of a particular treatment for a particular individual. The ultimate responsibility for the use of the guideline, dosage of drugs and correct following of instructions as well as the interpretation of the published material **lies solely with you** as the medical practitioner.

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Guideline Statement

Medicines management is defined by the MHRA as:

"Medicines management, also referred to as medicines optimisation, has been defined by the Medicines and Healthcare Products Regulatory Agency 2004 as: "The clinical, cost effective and safe use of medicines to ensure patients get the maximum benefit from the medicines they need, while at the same time minimising potential harm." (RCN, 2020, p.5)

Additionally, the NMC state that:

Midwives must "demonstrate knowledge and understanding of the principles of safe and effective administration and optimisation of prescription and non-prescription medicines and midwives' exemptions and demonstrate the ability to safely supply and administer medicines listed in Schedule 17 of the Human Medicines Regulations (midwives' exemptions) and any subsequent legislation and demonstrate the ability to check the list regularly".

Nursing and Midwifery Council (2019) *Standards of proficiency for midwives*. [Online] Available from: https://www.nmc.org.uk/globalassets/sitedocuments/standards/standards-of-proficiency-for-midwives.pdf [Accessed 17 March 2020]

Executive Summary

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The purpose of this guideline is to:

- Present clearly and effectively the standards by which Milton Keynes University Hospital expect registrants within a maternity setting to manage the use of medicines on the wards and in community. It is based on standards from medicines management published by the Royal Pharmaceutical Society and Nursing and Midwifery Council (2019).
- Ensure that practicing midwives safely administer those medicines which their exemptions allow them to administer without the need for a prescription or specific Patient Group Direction to women during the antenatal, labour, and postnatal period and in some cases neonates.
- List medicines that midwives may administer during their professional practice under the Medicines Act 1968 exemptions listed in Schedule 17 of the Human Medicines Regulations 2012 (as amended) that MKUH trust have deemed appropriate.



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Definitions

Midwives Exemptions

The current legislation which provides for midwives' exemptions from medicines rules is the Human Medicines Regulations 2012.

The Human Medicines Regulations 2012, amended in 2016, ("the Regulations") consolidated many of the pre-existing pieces of legislation related to the administration, sale and supply of medicinal products for human use. The Regulations govern the ways that medicines can be lawfully sold and supplied in the UK.

The Regulations set out the rules for prescription, supply and administration of medicines by midwives with reference to patient-specific directions (PSD), patient-group direction (PGD) and midwives' exemptions.

Registered midwives may supply and administer, on their own initiative, any of the substances that are specified in medicines legislation under midwives' exemptions, *provided it is during their professional practice.* They may do so without the need for a prescription or patient-specific direction (PSD) from a medical practitioner.

Provided the requirements of any conditions attached to those exemptions are met, a patient group direction (PGD) is not required. Medicines not included in the midwives' exemptions require a prescription, a patient-specific direction (PSD), or a patient-group direction (PGD). Registered midwives must only supply and administer those medicines, including analgesics, in which they have received the appropriate training as to therapeutic use, dosage, side effects, precautions, contra-indications and methods of administration.

When supplying or administering medicines under midwives' exemptions, midwives must ensure their practice is evidence based (Human Medicines Regulations, 2012). It is important that every midwife reviews this information regularly as the list can change and it is important that they keep this area of their knowledge and competence up to date.

(Practising as a Midwife in the UK, NMC 2017. Updated: 6 Jan 2020)

Use of the word 'patient'

Throughout this document where the word 'patient' is used this refers to whoever the medication may be administered to, for example, patient, client, user, or woman (midwifery).

Use of the word 'registrant'

Throughout this document where the word 'registrant' is used this refers to nurses, midwives and specialist community public health nurses who are registered on the NMC register.

Abbreviation List

BNF British National Formulary

CD Controlled drug

GSL General Sales List Medicine

MHRA Medicines and Healthcare products Regulatory Agency

ME Midwife Exemption

NKDA No Known Drug Allergies

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NIRAC Oniversity Hospital NHS Foundation Hust

NMC Nursing and Midwifery Council

P Pharmacy medicine
PGD Patient Group Direction
POM Prescription Only Medicine
PSD Patient Specific Direction

1.0 Roles and Responsibilities:

This policy applies to all Registered Midwives employed by Milton Keynes University NHS Hospital Trust.

Midwives acting under this guideline must ensure:

- That they understand and adhere to their scope of practice and work within it.
- Have a clear understanding of documentation they are required to complete.
- Have a working knowledge of locally agreed guidelines and policies in relation to the supply and administration of medicines
- Have a working knowledge of the therapeutic uses, normal doses, side effects, precautions and contraindications of the medicines being administered

2.0 Implementation and dissemination of document

This guideline will be implemented by Registered Midwives employed by Milton Keynes University Hospital NHS Trust. All Agency Midwives shall be expected to adhere to these guidelines. It is important that every midwife reviews this information regularly as the list can change and it is important that they keep this area of their knowledge and competence up to date

This guideline should be used in conjunction with PHARM/GL/19 – Medicines Management Policy. The foregoing information is in addition to this Policy.

3.0 Processes and procedures

3.1 Standards for practice of administration of medicines

Midwives can supply and administer (but not sell)

- All General Sales List (GSL) Medicines
- All Pharmacy (P) Medicines

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Some Prescription Only Medicines (POM) which include some controlled Drugs (CDs)

Only a Registered Midwife can supply and administer medicines against midwives' exemption orders.

Student Midwives may administer medicines on the exemption list, except controlled drugs, under the direct visual supervision of the midwife.

Students must never be given drug cupboard keys to access medicines without direct supervision of the supervising midwife.





3.2 Administration

The midwife must be confident of the woman's or neonates' identity prior to administration of the medicine by both confirmation of their identity wristband and verbal checking.

The Midwife must be aware of the plan of care established for the patient and medicines administered only within the context of the patient's care plan.

The patient shall have allergies/known adverse drug reactions confirmed prior to medication administration.

<u>Prior to administration, the Midwife should scan the patient's ID band and verbally confirm the</u> details to ensure:

- the right patient
- the right drug
- the right dose
- the right route
- the right time

In addition, the Midwife should scan the drug box and check the contents and packaging for its expiry date, and any signs of damage or tampering.

The Midwife must observe the medicines being taken by the patient before leaving them. At no point should medicines be left for patients to self-administer on lockers.

Prescription Only Medicines shall only be administered with a prescription unless they appear on the Midwives Exemption List in **Appendix 1**

A record of the medicine administered and/or taken by the patient shall be recorded on eCare prescription chart.

Administration of drugs including phytomenadione (Konakion ® MM Paediatric) to a neonate must be undertaken having been second checked independently with a second registrant, and then recorded on eCare.

A midwife cannot delegate administration of a midwife's exemption drug to a care assistant or registered nurse.

Except for Controlled Drugs and IV Medication, student midwives may administer any of the medicines on the midwife's exemption list **(Appendix 1)** under direct supervision of a registered midwife.

Where a drug is to be administered intravenously, TWO registered practitioners must check the drug prior to administration, the process in its entirety must be checked by the second registered practitioner independently. In the event that a midwife is working alone (i.e. at a homebirth) and encounters an emergency, it is acceptable in this instance to administer IV drugs without reference



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to a second registrant. The registrant should perform a second check themselves. Rationale for this decision must be clearly documented on eCare.

Where medication is not given, the reason for not doing so must be recorded on eCare selecting one of the appropriate reasons.

3.3 Documentation

Midwives must keep accurate and detailed records of the supply and administration of medicines which are accurate, timely and contemporaneous.

Midwives who administer medicines should ensure that these are always recorded on eCare. Neonatal drugs (other than phytomenadione (Konakion ® MM Paediatric) must be recorded on eCare and documented in the red child health book and purple postnatal notes that the family take home.

All midwives should ensure that:

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- Relevant allergies and adverse drug reactions (including NKDA) are completed on eCare
- Any medicine administered under Midwives Exemption is clearly documented on eCare under the midwives' exemptions section.

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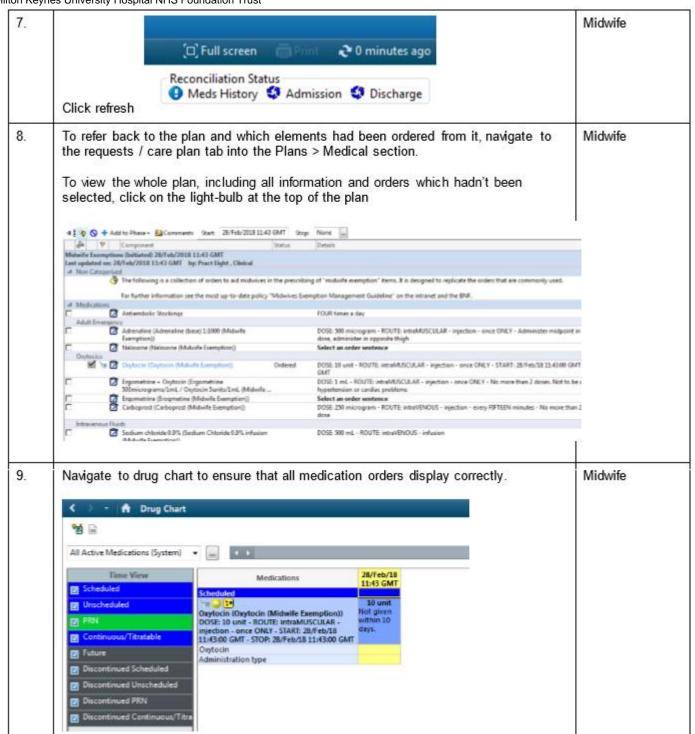
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How to document on eCare:

).	- Midwife Exemptions			
	Action			Responsibility
	From the Request / Care Plans tab in Power exemption" to find the Plan South Advanced Options Advanced Options Michael Caren New	Type 📵 Impried	*Midwife	Midwife
	Click on the Powerplan and select	to open the plan		Midwife
	The Plan has been created into section e.g. Navigate to the relevant section and click to			Midwife
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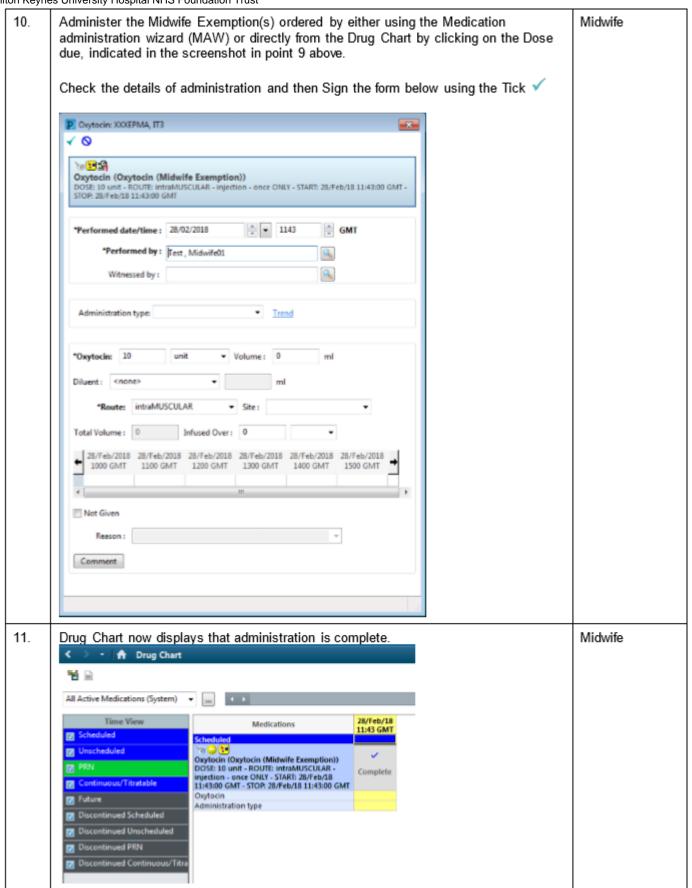


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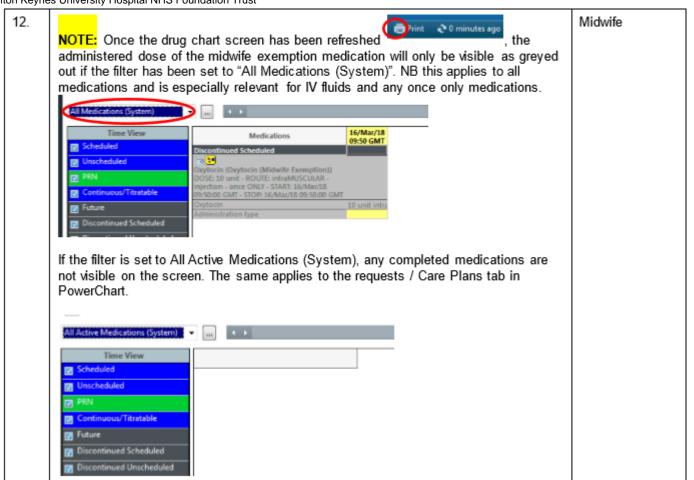


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3.4 Adverse Incidents

If an error or near miss occurs, the Midwife must take appropriate action to prevent any potential harm to the woman or neonate and report as soon as is practicable to their line manager. Inform the Doctor as it may be necessary to obtain medical review. An incident report should be submitted via the Trust incident reporting system and duty of candour completed.

Following an adverse reaction to a medicine, the registrant must take such action as is necessary to obtain help and protect the patient. An incident report should be completed, and the report reference number recorded in Assessments/Fluid Balance/Patient Safety.

3.5 Controlled drugs

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These should be administered in line with relevant legislation and MKUH Controlled Drugs Standard Operating Procedures (CD SOPs).

Registrants should ensure that patients prescribed Controlled Drugs are administered these in a timely fashion in line with the standards for administering medication to patients, the Medicines Management Policy and CD SOPs. Registrants should comply with and follow the legal requirements and approved local standard operating procedures for Controlled Drugs that are appropriate for their area of work.

A second signatory on eCare is required for administration of controlled drugs. The second signatory should witness and independently second check the whole administration process for both the safety of the patient and the registrant.



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Details of the administration of Controlled Drugs should be entered into the Controlled Drugs register which must be clearly signed for by the midwife and the second checker.

Student Midwives must not administer any Controlled Drugs however may participate in the checking and preparation of the drugs. They may not be the second checker.

All Controlled Drugs prepared and not used must be destroyed in the presence of the second registered midwife as per the Trust's CD SOPs. An entry should be made in the Controlled Drugs register and signed by both parties or solely in the case of a community midwife as per MKUH CD SOPs, Medicine management guideline and guidance for waste disposal.

4.0 Statement of evidence/references

References:

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N.B. Please note the text of the Regulations on this website is as made in 2012 and does not include later amendments.

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5.0 Governance

5.1 Document review history

Version number	Review date	Reviewed by	Changes made
2	09/2021	Emma Mitchener /	Full review
		Manish Nathwani	
1	2017	Anna- Marie Madeley	New Document

5.2 Consultation History

Stakeholders Name/Board	Area of Expertise	Date Sent	Date Received	Comments	Endorsed Yes/No
Manish Nathwani	Pharmacy	07/2020	08/2021	Comments Endorsed	
Jayne Plant	Library	07/2020		References incorporated	Yes
Zainab Ali	Pharmacist		10/2021	Comments endorsed	Yes
Women's digital group	Maternity	11/2021	23/11/2021		
Pharmacy CIG	Pharmacy		10/2021	Comments Endorsed	Yes
Guideline group	Maternity	11/2021			
Maternity CIG	Maternity	11/2021			

5.3 Audit and monitoring

Audit/Monitoring Criteria	Tool	Audit Lead	Frequency of Audit	Responsible Committee/Board
To be completed		Labour ward co-Ordinator / Ward	Case by case	Labour ward forum
		Manager		



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5.4 Equality Impact Assessment

As part of its development, this Guideline and its impact on equality has been reviewed. The purpose of the assessment is to minimise and if possible, remove any disproportionate impact on the grounds of race, gender, disability, age, sexual orientation, religion or belief, pregnancy and maternity, gender reassignment or marriage and civil partnership. No detriment was identified. Equality Impact assessments will show any future actions required to overcome any identified barriers or discriminatory practice.

	Eq	uality	/ Impact As	sessmen	t		
Division	Womer	n and	l children		Department	Maternity	
Person completing the EqIA	Erica P	Erica Puri			Contact No.	Ex 87153	
Others involved:	No	No			Date of assessment:	11/2021	
Existing policy/service	Yes	es			New policy/service	No	
Will patients, carers, the publ be affected by the policy/serv		ff	Yes				
If staff, how many/which grou affected?	ps will be	е	All staff				
Protected characteristic	А	ny im	pact?	Commer	nts		
Age			NO		impact as the policy ai		
Disability			NO	_	e diversity, promote in		
Gender reassignment			NO	rair treat	ment for patients and s	starr	
Marriage and civil partnersh	nip	NO					
Pregnancy and maternity		NO					
Race		NO					
Religion or belief		NO					
Sex		NO					
Sexual orientation			NO				
What consultation method(s)		u car	ried out?				
face-to-face meetings, email							
How are the changes/amend	ments to	the p	policies/servi	ces comn	nunicated?		
Email and teams meetings							
What future actions need to be							
What? Who	will lead	this?	Date of co	ompletion	Resources nee	eded	
Review date of EqIA 11/20)24						





Appendix 1: Midwives Exemptions List

	Clinical Indication	Dose, Route, frequency	Legal Basis for supply and administration	Conditions of use	Practice Points
Adult Emergency					
Adrenaline 1:1000 Injection	Anaphylaxis	500 microgram IM (0.5mL 1:1000) stat.	POM	Emergency treatment for anaphylaxis Do not give IV In pregnancy can reduce placental perfusion and delay 2 nd stage.	Administer midpoint in anterolateral thigh. If repeating dose, administer in opposite thigh
Oxytocics					
Oxytocin 5 units/ml and 10 units/ml Injection	Active management of 3 rd stage of labour	10units/1mL IM 5units/1mL IV	POM	Low risk of PPH Women who opt for active 3 rd stage with existing hypertension	
Syntometrine (Ergometrine 500micrograms/ml /Syntocinon5unit/ml)	Active management of 3 rd stage of labour Management of PPH	1 mL IM as a single dose	POM	Active 3 rd stage moderate to high risk of PPH No more than 2 doses (1 mg Ergometrine)	Not to be used in women with hypertension or cardiac problems
Ergometrine Maleate	Management of PPH	500 micrograms IM or slow IV	POM	Management of PPH No more than 2 doses (1mg Ergometrine)	Not to be used in women with hypertension or cardiac problems
Carboprost Injection (as Carboprost trometamol) 250 microgram per 1 ml	Management of PPH	250 micrograms IM	POM	Repeat every 15 minutes as necessary, no more than 2mg (8 Doses)	
Intravenous Fluids					
0.9% Sodium Chloride	Maternal Resuscitation	500mls	POM	Maternal resuscitation	
0.9% Sodium Chloride	IV Flush	5ml	POM	Flush of IV Cannula	Before and after the administration of IV Medication
			T =	_	
Entonox (Nitrous oxide 50% + Oxygen 50%)	Established Labour	PO - Self-administered inhalational analgesic PRN	P		
Diclofenac	Postpartum pain relief and perineal anti inflammatory	50mg or 100mg PR Max 150mg daily in divided doses	POM	Postpartum only up to 48hours Oral: take with or after food.	Avoid in those with stomach problems Can NOT be given by a student midwife
Paracetamol	Mild to moderate pain relief	1g every 4-6hrs (QDS) PO	Р	Max 4g in 24hrs	Period of no more than 4 days
lbuprofen	Postpartum pain relief	400mg 8hrly (TDS) PO	Р	To be taken with or after food. Use with caution in asthmatic patients	Check when Diclofenac used – not to be administered within 12 hrs.
Pethidine Hydrochloride	Pain relief in labour	50-100mg 3-4hrly IM	CD POM	Max 400mg in 24hrs	Can NOT be administered by a student midwife

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Drug Name	Clinical Indication	Dose, Route, frequency	Legal Basis for supply and administration	Conditions of use	Practice Points
Diamorphine	Pain relief in labour	5mg IM or SC Repeat doses of 2.5mg-5mg 4 hourly if needed	CD	Early labour/ 1 st stage of labour	Administration to upper central aspect of thigh NOT buttock Can NOT be administered by a student midwife
Morphine Sulfate	Pain relief in labour	10mg I M every 4hrs adjusted according to response to a maximum of 40mg in 24hrs	CD		Can NOT be administered by a student midwife
Anesthetics					
Lidocaine Hydrochloride 1%	Perineal infiltration	Up to 20mls SC/IM	POM		
Instillagel (Lidocaine Hydrochloride 2% + chlorhexaidine 0.5%)	Prior to urinary catheterization	6-11ml Intraurethrally	GSL	Catheterisation	
Opiate reversal					
Naloxone Hydrochloride	Reversal of respiratory depression in adult following opioid administration	Initial dose of 0.4mg, then 0.8mg for up to 2 doses at 1-minute intervals if no response to preceding dose, then increased to 2mg for 1 dose if still no response (4mg dose may be required in seriously poisoned patients) The dose in this table is for opioid overdose.	POM	Only for administration to reverse effects of opioid use	
Laxatives, anal, vaginal and Bowel prep					
Senna 7.5 mg tablets	Constipation	2-4 tablets daily, usually taken at night PO	GSL		
Lactulose Solution	Constipation	15ml BD PO titrate to according to response accordingly	GSL	Caution in history of lactose intolerance	If for postnatal 3 rd /4 th tear TTO, must be prescribed

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Drug Name	Clinical Indication	Dose, Route, frequency	Legal Basis for supply and administration	Conditions of use	Practice Points
Glycerol Suppositories	Constipation	4g PR PRN	GSL		May be moistened with water prior to use
Movicol Liquid (Macrogol)	Chronic Constipation	25mL of Movicol liquid diluted in 100mL of water 1- 3 times a day.	Р		Use up to 2 weeks
Micralax Microenema	Constipation	5mls PR as a single dose	Р		
Clotrimazole 1% cream	Treatment of vaginal and vulval candidiasis	Apply BD - TDS Topical	Р	Likely to require 7-day course	
Clotrimazole Vaginal Pessary	Treatment of vaginal candidiasis	500mg pessary at night PV	P		Do not use vaginal applicator
Fybogel Sachets	Constipation	One sachet BD PO	GSL		Dose to be given in water preferably taken after food, morning, and evening.
Nystatin (100 000 units/mL)	Treatment of oral or intestinal thrush	400 000–600 000 units (4-6mL) 4 times a day PO	POM	Usually for 7 days, and continued for 48 hours after lesions have resolved	Divide administration of the dose between both sides of the mouth. Can NOT be administered by a student midwife.
Anusol cream	Hemorrhoids	Apply to the affected area at night, in the morning and after each evacuation until the condition is controlled.	GSL	Relief from symptom of hemorrhoids including pruritus	
Antiemetics, antacids and digestion					
Cyclizine lactate	Antiemetic	50mg up to TDS IM	POM	Management of actual or potential nausea and vomiting	Avoid in severe Liver conditions Caution in Epileptics
Prochloperazine maleate (Stemetil)	Antiemetic	12.5mg IM PRN (Max TDS), to be followed, if necessary, after 6 hours by an oral dose 5-10mg PO up to TDS	POM	Management of actual or potential nausea and vomiting	Oral dose can be given 6 hours after IM dose
Gaviscon Advance	Relief of Heartburn/ indigestion/antenatally and postnatally	5-10mls PO after meals and at bedtime	GSL	Inpatients only	
Cough prep					
Simple Linctus	Dry Cough	5mls PO 3-4 time per day	GSL	Avoid in allergy to saccharin, sodium benzoate and citric acid	

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Drug Name	Clinical Indication	Dose, Route, frequency	Legal Basis for supply and administration	Conditions of use	Practice Points
Iron Supplementation Ferrous Sulphate	Antenatal/ postnatal iron supplementation for low Hb	200mg BD/TDS PO	Р	Supply and administer as inpatient only	Antenatal low Hb defined by NICE as <11g/dl prior to 12 weeks and < 10.5g/dk at 28/30 week
Maternal Prophylaxis					
Anti D Immunoglobulin	Maternal use only to protect against haemolytic disease of newborn	1500units IM routine antenatal prophylaxis For sensitizing events 1500iu	POM	To be administered in the deltoid muscle Routine prophylaxis offered to all non –sensitised pregnant women who are Rh D-ve Postnatal administration dependent on kleihauer result	See Prophylactic Anti D immunoglobulin guideline via the intranet for further information
Neonatal Drug Administration					
Phytomenadione 2mg in 0.2ml (Konakion ® MM Paediatric)	Prophylaxis of Vitamin K deficiency bleeding	Healthy neonates 36 weeks (irrespective of birthweight) 1mg IM (single STAT dose) 2mg PO, Dose will need to be repeated on day 4 – 7 of life and for exclusively breastfed babies an additional dose at 1 month of age Babies at high risk – refer to guideline	POM	Babies at high risk – see guideline If IV phytomenadione is required a neonatologist must prescribe; administration may be by a neonatal nurse Preterm babies <37 weeks and weighing <2.5kg a prescription for phytomenadione is required – See guideline	See Vitamin K prophylaxis in neonates' guideline – via the intranet for full guidance Can NOT be administered by a student midwife
Naloxone Hydrochloride	Reversal of respiratory depression in neonates following opioid administration to mother	10micrograms/kg IV/IM	POM	Naloxone <u>must not</u> be given to any infant of a mother on regular opiates or illicit drugs.	To only be administered after discussion with neonatologist See Neonatal Resuscitation guideline via the intranet for further information
Hepatitis B Immunoglobulin	Protection against Hepatitis B	200units IM ASAP after birth			See Hepatitis B Screening of Pregnant Women and Immunisation of Babies at risk guideline for further information

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