Royal Devon University Healthcare NHS Foundation Trust

Title
Medicines Policies

Reference Number: RDF1914-23
Date of Response: 02/11/2023

Further to your Freedom of Information Act request, please find the Trust's response(s) below:

Please be aware that the Royal Devon University Healthcare NHS Foundation Trust (Royal Devon) has existed since 1st April 2022 following the integration of the Northern Devon Healthcare NHS Trust (known as Northern Services) and the Royal Devon and Exeter NHS Foundation Trust (known as Eastern Services).

Please may I request all Trust current policies that include information on the checking of medicines when they are being administered to patients, and any associated documents e.g. medicines policy, specific medicine/ clinical area policies, codes, appendices to the relevant policies etc.

Please find attached the following:

- Medicines_management_policy_2021_v7.0_final_for_hub_Redacted
- Admin of Meds prof guidance

Please note: The Trust has applied the following Exemption to this FOI response:

Section 40(2) – Personal Information

The Trust has redacted any details of Trust staff in the attached documents (when indicated). The data redacted is relating to a named individual and if held by the Trust, would be exempt under Section 40(2) of the Freedom of information Act 2000, which exempts the release of personal information. The Trust believes that the release (if held) of such information meets the definition of personal data and disclosing the information would contravene Principle (a and b) as set out in Article 5 of the UK GDPR as the processing would not be lawful, fair and transparent.

Royal Devon University Healthcare NHS Foundation Trust

Medicines Management Policy

Post holder responsible for Procedural Document	[redacted], Chief Pharmacist
Author of Policy	[redacted] Medication Safety and Deputy Chief Pharmacist
Directorate/Department responsible for Procedural Document	Specialist Services - Pharmacy
Contact details:	x[redacted]
Date of Original Document:	14th June 2010
Current Version Published	V7.0 February 2022 (RDE)
Ratifying body and date ratified:	Clinical Effectiveness Committee 25 January 2022
Review date:	July 2025
Date document becomes live:	Immediate

Please *specify* standard/criterion numbers and tick ✓ other boxes as appropriate

Monitoring Information		Strategic Directions – Key Milestones	
Patient Experience	✓	Maintain Operational Service Delivery	
Assurance Framework	✓	Integrated Community Pathways	
Monitor/Finance/Performance		Develop Acute services	
CQC Fundamental Standards - Regulation: SAFE		Infection Control	
Other (please specify):			
Note: This policy has been assessed for any equality, diversity or human rights implications			

Full History:		Status: Final	
Version	Date	Author	Reason
1.0	June 2010	Pharmacy Clinical Governance Lead	*Review of all policies relating to Medicines Management in the Trust and amalgamation of documents into one policy.*
2.0	Sep 2011	Pharmacy Clinical Governance Lead	*Update to patient self-administration form.*
3.0	October 2012	Pharmacy Clinical Governance Lead	*Update to new Trust format* *Update section 2.7 with more explicit prescribing instructions for medicines to treat cancer* *Update section 3.1 to bring in line with Trust Training Needs Assessment* *Incorporation of High Strength Potassium Policy, Midazolam Policy and Lithium Policy into the main Policy.* *Add Clyst to wards that are permitted to keep high strength midazolam as stock.* *Addition of standards for medicines administration in outpatient clinics* *Expand policy for homecare services* *Update appendix to specify medication administration to all neonates* *Change to reflect changes to pharmacy discharge service.*
4.0	February 2014	Pharmacy Clinical Governance Lead	*Added reference to GMC Prescribing Guidance* *Update locations permitted to keep high strength potassium* *Update details about midazolam storage and permitted locations* *Update Self-Medication form to highlight risk of needle stick injury* *Added new requirement for CD stock lists for clinical areas* *Expanded the section on the role of the witness when checking CDs* *Added that serious prescribing errors must be escalated to Associate Medical Director* *Addition of appendix for procedure for CD administration* *Addition of appendix for review and investigation of medication incidents.*
4.1	Sep 2015	Medication Safety and Deputy Chief Pharmacist	*Addition of a section relating to midwives exemptions (moved from another historic Policy).* *Changed 'Drug and Therapeutics' to 'New Drugs' Group.* *Addition of list of professions whom may use PGDs.* *Change to CD schedule status and requirements for temazepam, ketamine and tramadol.* *Addition of line referring to CD Accountable Officer (CDAO).* *Update of joint formulary official name and link.* *Change Medical Records Governance Group to Document Approval Group.* *Statement to include CD authorised signature list storage in pharmacy.*

			Inclusion of anti-epileptics as a group of medicines that may need to be prescribed by brand (link to MHRA guidance). *Management of liquid medicine expiry dates on wards (10.11).* *Change to new Trust Policy Template including the addition of a 'Communication Plan' (appendix 12) and standard Trust failure to comply policy statement (see 1.3).* *Addition of section expiry dates for medicines (see 10.11)*
4.2	July 2016	Medication Safety and Deputy Chief Pharmacist	*Revision of covert medicines administration section (section 9.0) with two new supporting appendices and related hyperlinked references/local policies.* *Update of verbal orders section so more in line with NMC guidance (section 8.7)* *Indexing update.*
4.3	October 2016	Medication Safety and Deputy Chief Pharmacist	*Link updates*
4.4	November 2017	Medication Safety and Deputy Chief Pharmacist	*Addition of ibuprofen and a statement about P and GSL medicines to the midwives exemption (section 10.1.1-10.1.3 and appendix).* *Clarification about records required for wards when receiving patient's own supplies of CD's requiring safe storage (section 11.7.3-11.7.5).* *Preference for 2 members of staff to undertake ward CD stock checks (11.5.4) and to make more explicit that CD's must not be transferred between wards (11.11.3).* *Clarification of methotrexate process in community units where consultant visits are reduced/absent (7.1.7).* *Outlining which non-medicine products may be written up onto drug (PMAR) charts by specific professional groups (6.4.14).* *Specifying which prescription forms to use when prescribing for outpatients (6.6.2).* *Confirmation that lithium levels should be checked routinely on admission for non-elective patients as per CEC meeting 9th Nov 2017 (7.5.1).* *Rewording of paragraph relating to drug errors (18.7).* *Hyperlinks updated to HUB intranet.*
4.5	June 2018	Medication Safety and Deputy Chief Pharmacist	*Midwives exemptions (appendix) – updated list of medicines.*
5.0	January 2019	Medication Safety and Deputy Chief Pharmacist	*New template, expanded definitions, including PMAR, allergy prescriber responsibilities (6.4.4), approval via MMG for Trust-wide PMARs; discharge summary prescribing clarity, outpatient prescribing section expanded. Multiple additions in order to assimilate community practices where different. FP10 prescription form type clarified and NMP FP10 access process updated.* *Reference to Nursing Associates, a new professional group, scope of practice (appendix 9). New TTO-pack procedure (appendix 4), updated CD cupboard and lock construction requirements (British*

			Standards), revised covert section, references and associated policies updated.
6.0	October 2020	Medication Safety and Deputy Chief Pharmacist	*Hyperlinks, terminology and reference refresh. Medicines reconciliation update: definition, standards expanded responsibilities, meds rec on discharge. FP10 pad security and responsibilities expanded. New section on opiates and Trust PILs re chronic use. Anticoagulant high-risk section including INR testing in community settings and information communication. Transcription of prescriptions – new subsection based on national guidance. Revised section on ordering/supply of medicines (incl. CDs in community hospitals). Additional info about removal or disposal of patient's own medicines when in patient's home. Supply of discharge medicines – moved to more logical place in policy. Detail on storage requirements for medicines in clinical areas (environmental and construction standards). Addition line about clinical trial investigative medicines (12.1.3); Appendix 3: Inclusion of gabapentinoids in CD double checking requirements (in-line with legislative schedule changes) Appendix 4: Revised TTO pack process terminology.*
6.1	November 2020	Medication Safety and Deputy Chief Pharmacist	Removal of self-administration consent forms which have been replaced with nursing checklists in the Epic Trust EPR.
7.0	January 2022	Medication Safety and Deputy Chief Pharmacist	*Changes required as a result of Epic EPR implementation including removal of references to paper forms such as drug charts and inclusion of EPR functions.* • *Additional definitions.* • *Inclusion of allergy recording in line with NICE guidance (& EPR).* • *Additional section on remote prescribing (linking to GMC guidance). Verbal orders section updated.* • *Updated self-prescribing section adding clarity that this includes prescriptions and EPR 'orders' as well as not prescribing for family members.* • *Removal of requirement for consultant to prescribe/countersign methotrexate orders for inpatients when continued from home for non-SACT indications.* • *Reworded valproate section (pregnancy prevention programme)* • *Tramadol injections now require ward register entries of stock ward balances (incl. receipt and administration etc) unlike oral.* • *Clarification on disposal of part doses of liquid CDs in ward areas including the absorptive gel product incl. signposting ordering.* • *Updated permitted role-based medication related tasks for nursing associates and unregistered staff table (appendix 9) following approval via nursing midwifery & AHP workforce group.* • *Second check for SACT requirement.* • *TTO pack flow diagram updated to match local descriptors and Epic EPR terminology.*

Associated Trust Policies / Procedural Documents:	Advance Decision to Refuse Treatment Policy Approval, Prescribing and Supply of Unlicensed and Off-label Medicines Clinical Guideline: Basic Principles of Analgesic Administration for Acute Pain (2016) Clinical Guideline for Meds Reconciliation and Completion of MAR Chart in a Non-hospital Setting (2021). Discretionary Medicines SOP Guideline for the Safe Discharge of Patients with Complex Medication Needs Delayed or Omitted Medication - Guideline Delirium Guideline Identification of Patients Policy Incident Reporting, Analysing, Investigating and Learning Policy Injectable Medicines Policy (previously 'IV Policy') Just in Case Trust Guidance on HUB Management of Adult Inpatients with Established Opioid Dependence and Known Substance Misuse (2018) Management of hypoglycaemia in the new-born: labour ward and post-natal ward – clinical guideline. Management of Keys Policy Medical Gas Cylinder Storage and Use - Guideline (2016) Medication Administration by Skilled and Competent Non-Registered Staff in Hospital Settings Policy Medication Administration Process - Direction to administer Nasogastric and Oro-gastric Feeding Tubes in Adults, Paediatrics and Neonates Policy New Drug Policy Non-Medical Prescriber Policy New Drugs Policy Policy for the Approval, Prescribing and Supply of Unlicensed and Off-label Medicines Pharmacist Prescription Amendments Guideline Rapid Tranquilisation of Adults Guideline Safe Use of Medical Gases Policy Safeguarding Adults at Risk & Mental Capacity Act Intranet Trust Resources Substance Misuse in Pregnant Women - Maternity Guideline. Skilled and Competent Non-Registered Support Workers Medicines Policy. Temperature Monitoring of Medicines Storage In Clinical Areas (ambient and refrigerated).– Guideline Waste Management Policy
Key Words:	Medicines Management Policy, MMP, drug, medicine, medication, CD, controlled drug, lithium, valproate, warfarin, prescribing, administration, medicines reconciliation, meds rec, FP10, methotrexate, potassium, anticoagulant, anticoag, covert, midwives exemption, midwives-exemption, self-administration, self-administration, transcription

In consultation with and date:

V7.0 Medicines Management Group – 01/12/2021
Director and Assistant Directors of Nursing - 09/12/2021
Associate Medical Directors - 09/12/2021
RDE Medical Director – 09/12/2021
Governance Managers - 09/12/2021
Quality Assurance- 25/01/2022
Clinical Effectiveness Committee (CEC)– 25/01/2022
Nursing midwifery and AHP workforce group – June 2021 (appendix 9 specifically)

Contact for Review:	Medication Safety and Deputy Chief Pharmacist
Executive Lead Signature:	[redacted] Medical Director, Adrian Harris

CONTENTS

KEY POINTS OF THIS POLICY

This policy gives guidance on the use of medicines at the Royal Devon and Exeter NHS Foundation Trust (hereafter referred to as the Trust). It sets out the framework in which medicines can be prescribed, dispensed, administered and managed. This policy applies to all staff dealing with medicines and all areas and services that are the responsibility of the Trust. It does not cover Castle Place GP Practice.

1. INTRODUCTION

1.1 This document takes into account statutory requirements for the handling of medicines and also other guidance on the safe use of medicines in hospitals, including the requirements set out by the Care Quality Commission and the Health and Social Care Act 2012. It also takes account of good practice guidance for medical practitioners, non-medical prescribers, registered nurses and midwives and registered pharmacists.

1.2 **Failure to comply with this policy could result in disciplinary action.**

2. PURPOSE

2.1 To set out the principles and standards on all aspects of medicines handling, from supply and storage, to prescribing, administration and disposal of medicines in line with the relevant legislation for medicines.

2.2 To set out the standards and principles on all aspects of handling of Controlled Drugs in line with the relevant legislation for Controlled Drugs.

3. DEFINITIONS

3.1 **Medicines**: For the purpose of this policy, Medicines are defined as those substances included in the Human Medicines Regulations 2012 as medicinal products. This document also governs the use of other products, such as certain chemicals and medical devices supplied by the pharmacy department.

3.2 **Prescription**: Instructions by an authorised prescriber to supply or administer a medicine to an individual patient.

3.3 **Authorised Prescriber**: Staff authorised to instruct the supply or administration of medicines by way of a prescription.

3.4 **Medicines reconciliation:** (IHI), is the process of identifying an accurate list of a patient's current medicines and comparing them with the current list in use (e.g. on a PMAR), recognising any discrepancies, and documenting any changes, thereby resulting in a complete list of medicines, accurately communicated.

3.5 **My Care** – Trust project to launch the Epic electronic patient record (EPR) system.

3.6 **EPR** – Electronic Patient Record. Electronic system which include medication prescribing, dispensing and administration and are an evidence-based method to reduce patient harm from medicines.

3.7 **Patient Group Direction (PGD)**: Authorisation to supply or administer medicines against a protocol for groups of patients, as opposed to individual patients in line with the Human Medicines Regulations 2012.

3.8 **Patient Specific Direction (PSD):** A written instruction by a Doctor, Dentist or Non-Medical Prescriber for medicines to be supplied and/or administered to a named patient, after the prescriber has assessed the patient on an individual basis. This is could be either paper based for example a drug chart, or electronic such as a medication order in the EPR system.

3.9 **Medication order** – synonymous with the Trust EPR system where it describes an electronic process for prescribers to request that a medication is administered to a specific patient by Trust staff.

3.10 **Controlled Drug**: Those medicines defined in the Controlled Drugs (Supervision of Management and Use) Regulations 2013.

3.11 **Nursing Associates** are a new NMC registered professional group distinct from registered nurses.

3.12 **Drugs of Diversion**: Those drugs that can lead to habituation (for example codeine, benzodiazepines) which are commonly from a lower schedule of controlled drugs (in legislation) and no legal requirement for CD cupboard storage or ward register entries.

3.13 **Homecare Medication Services** a service that delivers medicine supplies and associated care directly to a patient's home or other chosen location. There are different levels of homecare services from simple dispensing and delivery of oral medicines (low tech) to more complex injectable aseptic preparations and the inclusion of nurse administration.

3.14 **Medication Administration Record** (MAR) – a record (paper or electronic) designed to record the administration of medication doses to a specific patient. This is not an authority to administer a medicine and is therefore not signed by a prescriber.

3.15 **Prescription and Administration Record** (PMAR) – a document on which both a prescriber can specify which medicine(s) that a patient should be administered and administration can be recorded. Although these paper records have been largely superseded with the introduction of the EPR, paper PMARs are still in use in the in non-hospital settings e.g. palliative care including *just- in-case* and syringe driver forms in the patient's home.

3.16 **Medication Error** - any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional or patient. Such events may relate to professional practice, healthcare products, procedures, and systems, including prescribing, ordering, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use". (WHO, 2016)

3.17 **TTO-Pack** – a prepared pack of a medicine which has standardised instructions printed onto the dispensing label so that it can be given to the patient for discharge. No changes/amendments must be made to the instructions, only additions of patient name, date of supply and in some cases course length may be added by hand.

3.18 **D-DOC** – Devon Doctors Ltd provides the urgent out-of-hours GP service in Devon.

3.19 **Transcription** - is the copying of previously prescribed medicine details (usually in writing) to enable their administration in line with legislation (i.e. in accordance with the instructions of a prescriber).

4. DUTIES AND RESPONSIBILITIES OF STAFF

4.1 It is the responsibility of the **Medical Director** to ensure all aspects of this policy are fully implemented.

4.2 The **Medical Director** appoints an appropriate individual to be the Trust Accountable Officer who is responsible for the safe and legal management of controlled drugs (CDs). It is a statutory requirement for the Trust to have an Accountable Officer.

4.3 It the responsibility of the **Chief Pharmacist** to ensure that Pharmacy staff promote the safe and effective use of medicines in the Trust in accordance with the principles set out in this policy.

4.4 The **Chief Pharmacist** is the Accountable Officer for Homecare Medication Services and all Homecare Medical Services must be commissioned and supervised by pharmacy.

4.5 It is the responsibility of **prescribers** to comply with the requirements for prescribing set out in this policy and to comply with the requirements of their professional registration. Non-medical prescribers must also comply with the requirements set out in the Non-Medical Prescribing Policy.

4.6 It is the responsibility of those **registered healthcare professionals** in charge of clinical areas to ensure that all principles relating to aspects of medicines handling, administration and disposal are adhered to by all staff working in that area.

4.7 It is the responsibility of the **Medicines Management Group** to ensure this policy is up to date and in line with statutory requirement and best practice guidance. It is also the responsibility of the Medicines Management Group to ensure adherence to the policy.

5. GENERAL PRINCIPLES

5.1 Medicines from Trust stock must only be administered or supplied to patients who are cared for on Trust premises or by Trust staff. Trust medication cannot be supplied to or used by staff, volunteers or visitors except in emergency situations.

5.2 In the hospital setting medicines must only be used if they have been supplied by the Trust's pharmacy department. Medicines must not be obtained or distributed by any other route than the pharmacy procurement or clinical trials department except where the use of FP10s has been approved.

5.3 Patient's own medicines may also be used both in the hospital and non-hospital setting (e.g. patient home) but must only be used for the individual patient for whom they have been dispensed and remain that patient's property.

6. PRESCRIBING

6.1 General Principles

6.1.1 Prescribers must ensure that their prescribing is appropriate, responsible and in the best interest of their patients. Patients should be involved in any prescribing decisions. When prescribing medicines, prescribers must ensure they consider the patients' existing medical conditions, allergy status, previous adverse drug reactions, age, personal preferences, cultural and religious beliefs and any other medication taken by the patient.

6.1.2 Prescribers must ensure that they are familiar with the medicine they prescribe and that relevant guidance is sought, such as the British National Formulary (BNF), BNF for Children, NEW Devon Joint-Formulary, National Institute for Health and Care Excellence (NICE) guidance. Trust policy and local prescribing protocols in clinical areas must also be adhered to.

6.1.3 Professional regulatory bodies including the GMC have published guidance or standards on prescribing which registrants must adhere to. (GMC, 2021)

6.1.4 Prescriptions and prescribers' orders for medicines should be created in the Trust EPR unless it is a process where the use of paper prescription form or document has been approved as an acceptable exception.

6.1.5 Where paper prescriptions are required they must be written in black indelible ink. The prescription must be unambiguous and include **all** of the following:

- Prescriber's signature (handwritten or digital)
- Printed prescriber's name (stamps are permitted) in addition to a signature
- Contact number or bleep
- Date

6.1.5 When using handwritten or typed paper charts, prescribers can use stamps with their name and professional registration number, but the prescription also has to be also signed by hand and the contact number added.

6.1.6 If changes to a paper PMAR prescribed drug entry are made, the entire existing prescription entry must be crossed-out, and signed then a new entry made. Correction fluid must not be used. These changes must also be documented in the patients' care record and on the discharge summary along with clear rationale behind the decision.

6.1.7 Prescription and order directions should be in English although some specific Latin abbreviations are considered appropriate for paper prescription forms only. (Approved abbreviations are listed in the BNF online).

6.1.8 Full, generic drug names must be used, except for those medicines where it is appropriate to use the brand-name due to differences in bioavailability or formulation (see Appendix 1 for examples). Abbreviations must not be used.

6.1.9 In order to avoid ambiguity and reduce the risk of errors, quantities must be prescribed as follows:

- 1 gram or more: prescribe as 1 g etc.
- Less than 1 gram: prescribe as milligram (500 mg, not 0.5 g)
- Less than 1 milligram: prescribe as microgram (100 microgram, not 0.1 mg)
- Do not abbreviate micrograms, nanograms or units
- If using decimals, always use the zero, i.e. 0.2 ml, not .2 ml
- Use ml for volumes
- Do not use trailing zeros (5 mg, not 5.0 mg)

6.2 Standards for Medicines Reconciliation

6.2.1 Medicines reconciliation is an organisational responsibility and it should be carried out by a trained and competent health professional – normally a pharmacist, pharmacy technician, nurse or doctor – with the necessary knowledge, skills and expertise.

6.2.2 When patients are admitted for inpatient care, it is the responsibility of the admitting healthcare professional (usually medical staff) to undertake medicine reconciliation by documenting an accurate medication-history, including information about allergies and/or previous adverse drug reactions.

6.2.3 Where available, this must be documented in the Trust EPR as 'prior to admission' (PTA) medicines. Where the EPR is not available (exceptionally) a Trust approved medication clerking proforma (example) must be used to ensure clear and complete documentation.

6.2.4 Medicines reconciliation may need to be carried out on more than one occasion during the admission – for example, when the patient is admitted, transferred between care settings or discharged from hospital.

6.2.5 In an acute setting, completion of medicines reconciliation should be within 24 hours or sooner if clinically necessary. This ensures medicines-related patient safety incidents are less likely.

6.2.6 The following standards must be met:

- All medication must be documented as fully as possible, including dose, frequency and route and, where appropriate, brand names (see Appendix 1)
- Include medicines which may not be in the GP records such as those issued via:
  - Hospital clinics e.g. oral chemotherapy or subcutaneous injections
  - Homecare company medicines (delivered to the patient's home)
  - Self-selected/purchased medicines e.g. from a pharmacy
  - Herbal medicines
- Include medicines taken irregularly e.g. PRN or seasonal medicines
- Medicines recently commenced, stopped or changed.
- Source(s) of the drug history must be documented. At least 2 sources should be used. (see Appendix 2 for a breakdown of commonly used sources and their advantages, common drawbacks and cautions).
- Historical allergies and adverse drug reactions must be documented, including
  - drug name,
  - signs, symptoms and severity of the reaction,
  - date when the reaction occurred where possible
- Recreational drugs.

6.2.7 In the event of difficulties in obtaining a reliable drug history (e.g. on the weekend), it is the responsibility of the admitting healthcare professional to clearly document that further information sources must be consulted at the next opportunity (e.g. the next working day). This should be part of the treatment plan for that patient.

6.2.8 In exceptional cases where allergy status cannot be confirmed reliably this should be documented as such using the term ''unable to assess' (document it as soon as the information is available). in the patient's medical record, so it is updated as soon as this information is available.

6.2.9 Patients with communication difficulties should be given additional support as appropriate to communicate which drugs they usually take and when and how they take them.

6.2.10 Any discrepancies identified must be documented and resolved as soon as possible to ensure complete medicines reconciliation.

6.2.11 Any intentional changes to patients' usual medication must be recorded in the Trust EPR.

6.2.12 Patient concordance should be reviewed on admission and any concerns documented.

6.2.13 It is recommended that, whenever possible, complex drug histories are referred to a pharmacist for verification and clinical review.

6.2.14 Medicines reconciliation must also be completed prior to a patient discharge or transfer to ensure that an accurate documented medication list is communicated to the patient, main carer, GP and/or onward care provider.

6.3 Authorised Prescribers

6.3.1 Only Registered Medical Practitioners or those holding recognised Non-Medical Prescribing (NMP) qualifications are permitted to prescribe. NMPs can only practice in a service where this has been approved by the NMP Lead and Chief Pharmacist and where a 'Non-Medical Prescribing Registration and Self-Assessment Form' has been signed and acknowledged by the Medicines Management Group.

6.3.2 Medical students cannot prescribe under any circumstances. Foundation Year 1 (F1) doctors are provisionally registered with the General Medical Council (GMC) and they are only permitted to prescribe on internal prescription forms and discharge forms. They are not permitted to prescribe for outpatients or prescribe on community prescriptions (FP10HNCs).

6.3.3 All prescribers, including non-medical prescribers, must adhere to the prescribing guidelines contained in this policy and any limits imposed by their prescribing qualification and professional experience and expertise.

6.4 Prescribing for inpatients

6.4.1 Medicines prescribed for inpatients must be ordered in the Trust EPR.

6.4.2 It is the prescriber's responsibility to ensure that the patient's allergy and sensitivity status is clearly recorded in their EPR prior to prescribing medicines (including the medication, type of allergic reaction and the source of the information). If there is no allergy annotate with 'No Known Drug Allergy' (see also 6.2.4) in the patient EPR.

6.4.3 Allergies and sensitivities must always be checked in the EPR before ordering any new medicine for administration.

6.4.4 When prescribing or changing a prescription in the Trust EPR the prescriber must check carefully the start time and date to ensure this is appropriate and doses are not scheduled inappropriately leading to duplication or omission or delayed doses.

6.4.5 All adult patients must have a venous thromboembolism (VTE) risk assessment completed in the EPR and appropriately actioned on admission and reassessed regularly or when the clinical condition changes.

6.4.6 All antibiotics prescribed or ordered in the Trust EPR must have a stop or review date and the indication for the antibiotic stated. See Antimicrobial Policy

6.4.7 The Trust EPR must be used to prescribe/order ALL medicines for administration in the hospital setting including: 'once-only medicines', antibiotics, oxygen and other medical gases, variable dose instruction medicines, 'when required' medicines and infusions; irrespective of route. In addition, 'when required' medicines should have

instructions about the criteria that staff should use when deciding to administer the medicine and state the maximum frequency or dose to be given in 24 hours.

6.4.8 Where the prescriber intends for certain doses not to be administered, those doses must be held in the Trust EPR and the MAR checked to ensure it is as intended. Prescribers must not assume that the staff administering it will know when or when not to give a medicine. The intention of the prescriber must be clear at all times (e.g. when drugs should be omitted or given prior to surgery).

6.4.9 Prescribers must regularly review in-patient medication orders in the EPR and review or action any medication review notes made by the clinical pharmacy team.

6.4.10 The Trust approves specific named groups of registered professionals who are not qualified as prescribers to order administration of a limited range of products in the EPR This is only permitted for products which are NOT licensed medicines and are within the scope of their professional role/expertise. Currently the approved staff and products are:

- Dietitians – oral and enteral dietary supplements* e.g. *Ensure Plus liquid*
- Speech and Language Therapists – thickener* products e.g. *Thick & Easy*

(* where NOT a licensed medicinal product –)

6.4.11 Pharmacists, who are not independent prescribers, are permitted to make a limited range of amendments to inpatient medication orders which are outlined in the Trust *Pharmacist Prescription Amendments Guideline*.

6.5 Prescribing for discharge or leave

6.5.1 Discharge medication must be prescribed via the Epic system. For safety reasons, pharmacy will not dispense discharge medication against non-approved systems.

6.5.2 Discharge documentation supplied to the patient must be written clearly so that the patient can understand which medicines they will be taking following discharge and also the directions including frequency and route. This includes writing the medication list in English and in full. Latin abbreviations and anacronyms must be avoided.

6.5.3 It is the responsibility of the doctor discharging the patient to ensure that any changes to the patient's medication since admission are clearly recorded on the discharge documentation and the reason for the change is given. Additional requirements may be needed for some types of medications e.g. anticoagulants (see section 7.9). When a discharge letter is validated it must be the final version and contain the latest medication list.

6.5.4 It is also the responsibility of the doctor discharging the patient to ensure that the patient or their carer has sufficient knowledge and understanding to safely take the medicines that are given to them on discharge or leave. This might involve explaining any changes to their usual medication, educating them about new medicines, how to take them, any side effects that might occur and the benefits expected from the medicines (for example issuing the 'yellow booklet' for warfarin). The doctor may delegate this task to another suitably qualified member of staff (nurse, midwife, pharmacist, pharmacy technician), but the prescriber retains overall accountability.

6.5.5 To avoid unnecessary delay to a patient's discharge, the discharge documentation should be written 24 hours before the planned discharge whenever possible.

6.5.6 Incomplete or inaccurate discharge documentation causes unnecessary delay and inconvenience for patients and the prescriber discharging the patient must ensure that the medicines detailed are unambiguous and accurate.

6.5.7 RD&E Pharmacy will issue 28 days' supply as standard for discharge medicines unless stated otherwise by the prescriber. When discharging patients using medicines that are already labelled for the patient ('one-stop-dispensing') a minimum supply of 14 days must be available for the patient to take home.

- Short-term courses will be supplied as specified (e.g. antibiotics).
- Eye drops, creams, inhaler and similar products will be issued in original containers.
- Sip feeds and enteral feeds will be issued on discharge, but only in small amounts that can reasonably be transported.

6.5.8 Medicines can only be supplied to patients on discharge if they have been prescribed on the discharge documentation. Patients should be encouraged to continue using their own supply of medicines unless there has been a change in treatment.

6.5.9 The use of paper FP10 forms is not usually permitted for discharges unless it has specifically been authorised by the Site Manager, Chief Pharmacist or Community Hospital Matron when there is a risk of delayed discharge. The medicines prescribed on discharge must be included in the discharge documentation to the GP and should be annotated as 'supplied via FP10'.

6.6 Prescribing for outpatients

6.6.1 Where a patient attending an outpatient appointment has an immediate clinical need for medication it must be supplied.

6.6.2 A sufficient supply to last at least until the point at which the outpatient clinic letter can reasonably be expected to have reached the patient's GP, when the GP can accept responsibility for subsequent prescribing and also allow patients sufficient time to contact staff at their general practice.

6.6.3 In most case a minimum of 7 days and a maximum supply of 28 days must be made, unless it is more practical to supply an entire course length e.g. reducing 6-week course of steroids; or a shorter course length is required.

6.6.4 If the hospital consultant is assuming clinical and prescribing responsibility for the long-term care of a patient, a longer supply can be made.

6.6.4 Funding approval may be required where a clinician wishes/needs to take prescribing responsibility on a longer-term basis.

6.6.5 Outpatient prescribed medicines will not start to be prepared by the outpatient dispensary until either the patient attends the dispensary and flags the prescribed medicine to the dispensary staff. Alternatively, where the patient is not attending the dispensary immediately, for example in virtual clinics, the clinical service should inform the dispensary team of the need for the supply and the day on which the patient will collect the dispensed medicine or when a delivery to nearest Boots store has been authorised.

6.6.5 Prescribers and clinical teams working in outpatient areas should ensure patients leaving clinic to collect medicines clearly understand that the supply will not be ready on arrival at the dispensary and that the preparation will only commence once they've presented themselves to the outpatient dispensary staff.

6.6.7 Where a supply is <u>not</u> indicated i.e. not immediate clinical need the patient should be informed by the clinical area that they must leave a minimum of a 7 days before contacting their GP surgery for a supply or appointment about the supply.

6.7 Remote Prescribing

6.7.1 With the introduction of an electronic patient record remote prescribing becomes technically possible but there are important governance considerations and significant risks that all prescribers should be aware of in doing so.

6.7.2 Following the COVID-SARS2 pandemic remote consultations have increased markedly and, in some settings, may be appropriate e.g. outpatient settings for routine follow ups.

6.7.3 Before prescribing you must consider how the patient will access any prescribed medication either by arranging with them to collect from the RDE Boots pharmacy or detailing where their medicines may be available.

6.7.4 The GMC offers detailed good practice guidance on remote prescribing which must be followed, including:

- You must only prescribe if it is safe to do so. It's not safe to prescribe if you don't have sufficient information about the patient's health or if the mode of consultation is unsuitable to meet their needs.

- Before prescribing, you must consider whether the information you have is sufficient and reliable enough to enable you to prescribe safely. You should only prescribe medicines if you have adequate knowledge of the patient's health and you are satisfied that the medicines serve the patient's needs.

- Refer to the GMC guidance for more detailed information. Link

6.7.5 Remote prescribing for inpatients, where the prescriber is unfamiliar with the patient, must not be done routinely where it might compromise the care provided. Remote prescribing for patients in community settings (including community hospitals) may be required in exceptional situations e.g. where no prescriber is at the remote site.

6.8 Ordering, storage and use of FP10 forms

6.8.1 FP10 prescription forms are issued to specific clinical areas for the purpose of outpatient prescribing (see section 6.6) and, in exceptional circumstances, discharge prescribing (see section 6.5). FP10 forms are only issued to those clinical areas where the use of the forms has been agreed between the Chief Pharmacist and Cluster or Department Manager.

6.8.2 FP10 forms must only be used for the prescribing of medicines that have previously been approved for use in the Trust. This method of prescribing must not be used to obtain medicines for patients that have not previously been approved for use in the Trust and to bypass the Joint Formulary.

6.8.3 It is the responsibility of prescribers to use FP10 forms in a cost-effective manner. The prescribing of high-cost drugs, and in particular unlicensed 'specials', must be avoided, as the hospital pharmacy can usually supply the product at a much cheaper price.

6.8.4 All staff ordering, storing or using FP10 forms must ensure that they are fully aware of the potential for fraudulent use of these prescription forms and that they are controlled stationary for that reason.

6.8.5 The following procedures apply:

- Hospital FP10 pads must be ordered from the General Pharmacy Administration Office (ext. 2441).
- The pads must be collected by a member of staff carrying Trust identification. The member of staff must sign for the receipt of the pads.
- FP10 prescription pads must be stored securely when not in use e.g. in a CD cupboard or other locked drawer/cupboard with controlled access. FP10 prescription security is the responsibility of the nurse/midwife in charge of the clinical area (or the NMP to whom that pad has been issued) and they must maintain a written record of which member of staff each pad has been issued to.
- Each prescription form issued must be recorded on the audit sheet that pharmacy supplies. The fully completed audit form must be returned to Pharmacy before a new pad is issued.
- Any losses of prescriptions or pads must be reported to the nurse in charge and the Chief Pharmacist and a Trust incident form must be completed. The report must include the identity number of the lost prescriptions. In cases where theft of prescription forms or pads is suspected, the police and Trust Security Management Service must be informed immediately.
- Named NMP prescription pads must be ordered via the Trust NMP Lead and they will be contacted when available to collect from the General Pharmacy Office. To collect the prescription pad, the staff member must show Trust ID badge and sign for them.

6.8.6 It is the responsibility of the prescriber to ensure that medicines prescribed on FP10 forms are usually available from community pharmacies (e.g. that the medicine is not a 'hospital-only' medicine). Patient name and address details must be completed in ink. Patient ID stickers must **not** be used.

6.8.7 It is the responsibility of each speciality to monitor the appropriate and cost-effective use of FP10 prescriptions.

6.8.8 It is the responsibility of a line manager to ensure that all prescriber specific FP10 prescription pads including those issued to non-medical prescribers are returned when that member of staff is leaving the Trust or prescribing role.

6.9 Prescribing Licensed and Unlicensed Medicines

6.9.1 The Trust has a separate policy for the Approval, Prescribing and Supply of Unlicensed and Off-Label Medicines which can be found on the Trust intranet.

6.9.2 Prescribers must ensure that they are aware when prescribing medicines outside of their marketing authorisation or when prescribing unlicensed medicines. Prescribing outside the recommendations of the marketing authorisation alters the prescriber's professional responsibility and potential liability and may require written patient consent.

6.9.3 Unlicensed medicines prescribing in the Trust EPR applies a prefix to all drugs of 'ULM' which can clearly be viewed when ordering and in the MAR.

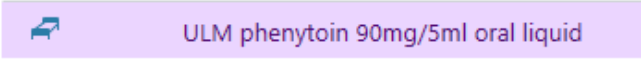

Figure 6.10 unlicensed medicine 'ULM' prefix

6.10 Prescribing Formulary and non-formulary medicines

6.10.1 Prescribing in the Trust must comply with the list of approved medicines in the North & East Devon Joint Formulary. The Formulary contains a list of agreed medicines

across the healthcare community in Devon. Non-formulary drugs should only be used when formulary options have been tried and failed, have unacceptable side effects or where there is no formulary alternative. In those cases where a patient is admitted on a non-formulary medicine they should be encouraged to provide their own supply or change to a formulary alternative.

6.10.2 Non-formulary prescribing on outpatient prescriptions will not be accepted and a formulary alternative should be used. It is not appropriate to ask GPs to start non-formulary medicines as an alternative supply route.

6.10.3 If the only option is to continue or start a non-formulary alternative the prescriber will be expected to make an application to the New Drugs Group using the appropriate application form in the New Drugs Policy.

6.11 Self-Prescribing or for Family Members

6.11.1 Prescribers should normally obtain any prescription medicines for their own use from their General Practitioner (GP). In exceptional circumstances it might be beneficial for a doctor to be able to get a dispensed supply from the hospital site in order to continue working. They may not prescribe any medication for anyone they have a close personal relationship including family members.

6.11.2 Under no circumstances should the prescriber access their own EPR record in order to self-prescribe or for anyone they have a close personal relationship with including family members. This is not permitted and can result in disciplinary action.

6.11.3 The prescription must be written on Trust approved self-prescribing paper prescription forms available to print off from HUB.

6.11.4 The paper prescription form must be signed by the doctor for whom the supply is required, and be for a course length normally no longer than 7 days. National standard prescription charges will be levied. Such a prescription must be taken to the Pharmacy's *main* dispensary during opening hours (9am – 5pm).

6.11.5 Prescriptions are **not** allowed in the following circumstances:

- For themselves for chronic conditions, the management of which should be by their GP
- For their family who should be under the care of a GP
- For colleagues and friends
- Where a prescriber is a non-medical prescriber
- Controlled drugs or Drugs of Diversion

6.11.6 The supply of medicines that are self-prescribed will be under the discretion of the pharmacist in charge and can only be dispensed by the RDE inpatient pharmacy.

6.11.7 Although this section deals primarily with the use of prescription forms for the supply of medicines, for clarity 'ordering' medicines for administration e.g. in the Epic EPR is also not allowed for themselves or family or anyone the prescriber has a close personal relationship with. Please also refer to the GMC prescribing guidance.

6.12 Prescribing new medicines and pharmaceutical samples

6.12.1 New medicines must be authorised by the New Drugs Group before pharmacy can purchase them. The application form can be found on the Trust intranet. In order to ensure a timely supply of new medicines it is recommended that clinicians contact the relevant clinical pharmacist early in the process of seeking approval for new medicines so the procurement specific are clearly understood.

6.12.2 Medicine samples offered by pharmaceutical representatives must not be used for patients at this Trust. Any new medicines a clinician wishes to introduce must follow the application process with the New Drugs Group or be provided as part of an approved clinical trial.

7. SPECIAL PROVISIONS FOR PRESCRIBING HIGH RISK MEDICINES

7.1 Methotrexate

7.1.1 Methotrexate is used to treat certain autoimmune diseases and some cancers (acute lymphoblastic leukaemia). It is used orally, subcutaneously (s.c.) or intrathecally.

7.1.2 Methotrexate is a safe drug when used correctly. However, patients have come to harm when they were prescribed oral methotrexate incorrectly (e.g. once daily instead of once weekly), the wrong strength was dispensed (10 mg instead of 2.5 mg tablets) or when patients continued to be given the drug despite suffering from toxicity.

7.1.3 Where an overdose of methotrexate is given, by any route, for non-cancer treatment that is more than the intended once weekly dose; with an electronic prescribing system (see footnote 3 on previous page).

7.1.4 When methotrexate is used for treatment of **cancer**, the initiation and continuation of treatment must only be prescribed by a specialist in that field and must comply with section 7.2.

7.1.5 Methotrexate for non-cancer indications can only be initiated only by a specialist consultant or registrar in the main therapeutic fields. This includes (not exhaustive) rheumatology, gastroenterology, dermatology and related paediatric specialities.

7.1.6 All prescriptions (inpatient, outpatient, discharge) have to clearly state:

- the dose of methotrexate in milligrams (mg)
- that the dose is a ONCE WEEKLY dose

7.1.7 All inpatient prescriptions in addition have to comply with the following:

- State the DAY of the week that it is to be given.
- The days of the week that methotrexate is NOT to be given have to be crossed out.

7.1.8 Folic acid is usually prescribed on the 6 days that methotrexate is not given and the day that it is not given must be crossed out on the inpatient chart.

7.1.9 It is the responsibility of the prescriber discharging a patient on methotrexate to ensure that the patient receives appropriate patient information and that any patient held record book is up-to-date when the patient is discharged.

7.1.10 Pharmacy will always issue multiples of 2.5 mg tablets for non-cancer use. 10 mg tablets will only be issued for paediatric patients or for cancer treatment in adults.

7.1.11 For inpatients being ***commenced*** on methotrexate, pharmacy will only issue a supply of methotrexate if the in-patient prescription is signed by a consultant or a registrar from the relevant speciality. Pharmacy will only issue a one-week supply at a time.

7.1.12 Nurses must not administer methotrexate unless the inpatient prescription complies fully with the requirements.

7.1.13 Methotrexate can be ordered for individual patients (if patients' own drugs cannot be used). Any unused methotrexate should be returned to pharmacy and not kept in the drug cupboard. Wards must not keep any methotrexate as a stock item.

7.2 Medicines for the treatment of Cancer

7.2.1 Patients receiving chemotherapy are sometimes admitted to areas of the hospital other than cancer services. Chemotherapy for haematology or oncology diseases may only be prescribed by an authorised prescriber from haematology or oncology (pharmacy holds a complete list of authorised prescribers).

7.2.2 Under no circumstances may anyone else prescribe chemotherapy for haematology or oncology diseases. If a patient requires a prescription for these drugs the on-call Haematology or Oncology Consultant or Registrar should be contacted via switchboard.

7.2.3 This restriction includes, but is not limited to:

- Continuation of chemotherapy the patient is on at admission
- Discharge prescriptions for patients who have been on chemotherapy during their admission, even if they were on that medication at admission and no changes have been made during admission
- Chemotherapy with which the prescriber may be familiar from other disciplines (e.g. cyclophosphamide and renal medicine).

7.2.4 This is to ensure that it is safe and appropriate to continue the chemotherapy in light of whatever brought the patient into hospital, to minimise the risk of prescribing error, to ensure adequate monitoring and follow up arrangements, to provide an opportunity to identify side-effects or interactions that might not be apparent to someone not familiar with the chemotherapy drug.

7.2.5 Examples of such restricted drugs include, but are not limited to: hydroxycarbamide, cyclophosphamide, thalidomide, lenalidomide, capecitabine, erlotinib, sunitinib, imatinib, gefitinib, pomalidomide, vismodegib, chlorambucil, vinorelbine.

7.2.6 This restriction does not apply to medicines that are not usually called chemotherapy, mostly hormone antagonists, such as finasteride, letrozole or tamoxifen, which can be continued without specialist review if this is considered appropriate. If in doubt, prescribers should ask pharmacy for advice and pharmacy hold a list of drugs exempted from the restrictions above.

7.3 Potassium Injection High Strength

7.3.1 High strength potassium is a high-risk drug and there have been fatal incidents where the undiluted solution has been accidentally administered after being mistaken for water for injection. To minimise the risk of accidental use of high strength potassium, the ampoules are treated as full CDs in the Trust and they have to be ordered, stored and recorded in line with the Controlled Drug requirements in this policy.

7.3.2 High strength potassium can only be ordered using a controlled drug order book.

7.3.3 The highest risk of accidental administration arises when ampoules are left by the bedside and are mistaken for water for injection or saline ampoules. High strength potassium ampoules must therefore not be left unattended but must be used immediately or destroyed.

7.3.4 High strength potassium ampoules **must not** be transferred to clinical areas outside of those authorised to store them.

7.3.5 The following areas are permitted to keep high strength potassium and staff in those areas are trained in the safe use of high strength potassium:

- Emergency Department
- Intensive Care Unit
- Coronary Care Unit
- Paediatric High Dependency Unit
- Neonatal Unit
- Yarty Ward
- Antenatal (Labour Ward)

7.4 Midazolam

7.4.1 Midazolam is a Schedule 3 Controlled Drug (CD) that is mainly used for conscious sedation and also for the treatment of terminal agitation in palliative care. Accidental overdosing with higher strength midazolam has led to deaths. For safety reasons, high strength midazolam (10mg in 2 ml = 5mg in 1 ml) is restricted to those areas that regularly require it for palliative care and it must not be used for the purpose of conscious sedation.

7.4.2 It is the responsibility of the healthcare professional in charge of the clinical area to ensure that flumazenil is available to reverse over-sedation and ensure that staff are aware where to find the reversal agent. Staff preparing midazolam syringes must use the orange pre-printed labels for Midazolam. These labels are available from EROS 45183. H203 DRUG LABEL

7.4.3 The following strengths are available:

- 1mg/mL in 2mL ampoules = 2mg in 2 mL
- 1mg/ml in 5mL = 5 mg in 5 mL
- 5mg/mL in 2mL ampoules = 10mg in 2 mL

7.4.4 **2 mg in 2 ml** ampoules can be stocked in any clinical area where its use is required, flumazenil is available and relevant staff have been trained in the use of midazolam.

7.4.5 **10 mg in 2ml** ampoules can only be stocked in the following areas/wards for the purpose of palliative care:

- Ashburn
- Community hospital wards
- Torridge
- Bolham
- Hospice
- Yeo (in Just in Case Bags)
- Clyst
- Okement
- Yarty

7.4.6 And for other specialist purposes:

- Otter ward (for the purpose of treating patients with carotid artery haemorrhage)
- ITU (for the purpose of sedating children on ventilation according to Bristol Children's Hospital Guidelines)
- All other clinical areas can request the 10mg in 2ml ampoules for individual patients for the purpose of palliative care.

7.4.7 Process for ordering 10mg in 2mL ampoules for palliative care:

- During Pharmacy opening hours, a controlled drug requisition book should be sent to Pharmacy. A supply will be made for that patient where it is ordered on the patients EPR.
- On those occasions where midazolam is required out-of-hours, ampoules should be obtained from Yeo ward with each dose recorded in Yeo's CD book including a reference to the ward the patient is currently on.
- Any remaining ampoules that are no longer required have to be returned to pharmacy. They must not be kept as stock for other patients.

7.5 Lithium

7.5.1 Lithium can cause harm if treatment is not monitored adequately. The following steps should be taken when patients who are on lithium are admitted as inpatients:

- Check lithium levels on admission for all non-elective admissions and at other times when considered necessary.
- Assess for any signs of toxicity.
- The specific brand of lithium the patient is taking should be documented in the clerking and prescribed by brand name (e.g. Priadel®, Camcolit®, Liskonum®).
- NG or PEG tube:
- A liquid preparation can be administered via an NG tube or PEG. Please note:
  - Lithium tables are formulated with lithium carbonate; lithium liquid is formulated with lithium citrate.
  - A 5mL (520 mg) dose of Priadel® Liquid is equivalent to 200 mg Priadel® Tablets
  - Give in two divided doses (if possible during feeding breaks)
- Monitor levels five days following any formulation change.
- A purple, oral syringe must always be used for liquid medication administered or measurement. Intravenous syringes must not be used.

7.5.2 Discontinuation of lithium can cause a possible relapse if abrupt so patients should be warned about this when stopping. If lithium is stopped or discontinued abruptly, consider changing therapy to an atypical antipsychotic or valproate (this may require specialist review). The risk of relapse is significantly increased in patients whose lithium is abruptly stopped.

7.5.3 Lithium **interacts** with several other drugs (including ACE inhibitors, NSAIDs and various diuretics). Check BNF for details. Dehydration is an important risk factor for lithium toxicity and adequate hydration must be maintained.

7.5.4 Discharge: On discharge, the discharge summary must state the results of any lithium monitoring that has been carried out during the inpatient stay. If the patient is carrying a purple lithium card and record book, these details must also be entered in the record book.

7.5.5 The Psychiatric liaison team can also be contacted for further advice There is also a Shared Care Service Guideline available on the NEW CCG website here.

7.6 Valproate in Women of Childbearing Potential

7.6.1 Valproate containing medicines are indicated for the treatment of epilepsy, bipolar disorder and migraine headache (unlicensed).

7.6.2 Valproate is known to be highly teratogenic and use in pregnancy leads to physical birth defects in 10% and neurodevelopmental disorders in approximately 30 to 40% of children.

7.6.3 Following various national safety initiatives and alerts the use of valproate in girls and women of childbearing potential is now subject to the requirements/conditions of the *Pregnancy Prevention Programme*, *PREVENT.*

7.6.4 For the purpose of PREVENT, a woman of childbearing potential is defined as *a pre-menopausal female who is capable of becoming pregnant*.

7.6.5 In girls and women of childbearing potential, valproate must only be initiated and supervised by a specialist and only when other medications have not been tolerated or have been found to be ineffective.

7.6.6 For hospital specialists PREVENT conditions includes the following aspects:

- Risks must be discussed with the patient (or parent/caregiver etc.).
- Pregnancy must be excluded in women of childbearing potential (by serum pregnancy test) before the first prescription is issued.
- Ensure that highly effective contraception is in place for women of childbearing potential before the first prescription is issued.
- Complete annually the Annual Risk Acknowledgment Form with the patient (or parent/caregiver/responsible person); give them a copy & send a copy to the GP.
- See the patient urgently (within days) if referred back in case of unplanned pregnancy or if she wants to plan a pregnancy.
- Provide a copy of the Patient Guide to the patient (or parent / carer / responsible person).

7.6.7 Further information and resources are available via the MHRA website here [link].

7.7 Continuous Infusion Syringe Pumps/Drivers for Palliation

7.7.1 Where patients in the hospital setting are palliative and are being treated with a subcutaneous infusion with a syringe pump this should be prescribed on the EPR.

7.8 Opiates

7.8.1 Opiates should be prescribed and used with care. Please refer to the pain management service Basic Analgesic Guideline and NPSA guidance for reducing errors for further information.

7.8.2 Patients should be provided with information about their opioid therapy including written information such as the Pain Team leaflet 'The Use of Opioid Drugs in Managing Chronic Pain' which can be found here.

7.9 Anticoagulants

7.9.1 Anticoagulants are high risk medicines and increase the risk of bleeding. They include the following oral drugs:

- Vitamin K antagonists (VKAs): warfarin, phenindione and acenocoumarol.
- DOACs (direct-acting oral anticoagulants): dabigatran, rivaroxaban, apixaban and edoxaban.
- Heparins (low molecular weight heparins & unfractionated)

7.9.2 Refer to the Trust *Anticoagulation Policy* for important information and guidance. Guidance is also available in the Joint Formulary.

7.9.3 VKAs such as warfarin require INR monitoring to ensure the dose is therapeutic. In community settings point-of-care testing equipment can be used where available and Trust approved. Refer to the laboratory point of care testing SOPs for further information here. Specific SOPs for the following devices are here: Coaguchek XS-Plus, Coaguchek XS.For further advice/info refer to the laboratory team via this webpage.

7.9.4 All patients on an oral anticoagulant need to receive appropriate verbal and written information especially on initiation and discharge. This includes an anticoagulant book. All patients admitted on a VKA must have an INR test within 24 hours of admission or transfer.

7.9.5 In community settings INRs greater than 6 must be incident reported on Datix and appropriate actions taken.

7.9.6 When discharging patients on VKAs the discharge summary must include indication, duration of therapy, target INR and recommended monitoring. A copy of the anticoagulation PMAR chart should normally also be provided (where necessary).

7.9.7 When starting or changing anticoagulants, prescribers must review the EPR's MAR to ensure the timing of future doses are as intended. This will avoid ordering doses too close together (overdoses) and ordering them too far apart (delayed or omitted doses)

8. ADMINISTRATION

8.1 General Principles

8.1.1 Healthcare professionals (HCPs) involved in the administration of medicines must use their professional judgement in the context of the care of each individual patient.

8.1.2 Medication can only be administered or supplied against a Trust approved, valid and current:

- Prescribers 'order' in the Trust EPR (Epic).
- Medicines Act Exemptions -
  - Patient Group Directions (PGD)
  - National Protocols
  - Local drug Protocols, including those listed in the Discretionary Medicines SOP (Trust wide)
  - Midwives exemptions (see appendix 11)
- Written Instructions (Occupational Health only)
- Paper Patient Specific Directions (community settings only) e.g. direction to administer form

8.1.3 These principles must be followed at all times when administering medicines to patients and when supervising patient self-administration.

8.1.4 If there are any concerns about a prescribed medicines, dose or instructions, the nurse or midwife must contact the prescriber for a review before administering. If they are unable to contact the prescriber or they are not satisfied that their concerns have been addressed, the matter must be referred to a senior nurse or midwife in charge of the clinical area. The nurse or midwife must not allow several doses to be missed because there is an unresolved query with the prescriber.

8.1.5 The nurse, midwife or other registered healthcare professional administering medicines must ensure that they can be identified as the administrator from the medicines administration record (MAR). In the EPR this means that they must only record administration when logged into the system themselves.

8.1.6 All medicines should be administered at the time specified on the EPR's MAR. Certain medicines must be administered at specified times as a matter of priority, including antibiotics, Parkinson's disease medication, Epilepsy medication and insulin. Please refer to the Delayed and Omitted Medicines Guideline.

8.1.7 If a medicine is administered at a different time to that specified by the prescriber then this should be indicated clearly on the MAR and/or other EPR clinical documentation as appropriate. Certain activities require double checking. Appendix 3 summarises all double-checking requirements for medicines.

8.2 Authorised personnel

8.2.1 Nurses, midwifes, nursing associates and other registered healthcare professionals are authorised to administer medicines in their area of competence provided that the healthcare professional in charge of the clinical area has agreed that they are competent to do so.

8.2.2 Intravenous medicines must only be administered by nurses and midwives and other registered healthcare professionals who have been signed-off as competent in the administration of intravenous medicines and the use of infusion devices and the Trust Injectable Medicines Policy must be adhered to at all times.

8.2.3 Non-registered staff are only permitted to administer medicines in accordance with the authorisation of a prescriber where a competency framework is in place that has been agreed by the Medicines Management Group and approved by the appropriate ratifying committee. Refer to the following Policies for correct approval and governance processes:

- *Administration of Medicines by Skilled and Competent Non-Registered Staff (in the Hospital Setting Policy) link.*
- *Medicines Policy for Skilled and Competent Non-Registered (SNR) Community Staff (in a non-hospital setting) link*

8.2.4 Nurses and midwives in training should be encouraged to observe and participate in the administration of medicines appropriate to their level of training and experience. The registered nurse or midwife retains overall accountability for the actions of a student nurse or midwife and should countersign alongside the student to record administration.

8.2.5 Administration of medicines via a PGD or PGD-like drug-protocols cannot be delegated.

8.2.6 Staff administering medicines should remain competent to do so. Competency to administer medicines is checked annually through the PDR / appraisal process. If the staff member's role involves medicine management, the reviewer should ask at every PDR for evidence to demonstrate competency to carry out medicine management as part of their role. Trust-wide competencies are available for medicine management administration are available for registered staff on the Trust intranet both for acute and community staff where required.

8.3 Transcription (of a prescription)

8.3.1 In certain circumstances trained and competent registered healthcare professionals (normally a registered nurse or midwife) may transcribe a prescription onto an approved form to facilitate administration.

8.3.2 Transcription is only permitted to be undertaken by registered staff caring for patients in their own home where paper records are used to record administration of medicines.

8.3.3 Transcribing must only be used in the patient's best interests to ensure safe and continuous care; ensuring medication is administered accurately, without delay.

8.3.4 Transcription must neither be used to alter/change any current prescriptions nor add new medicines. This can only be done by a prescriber.

8.3.5 Transcription errors must be incident reported on the Trust incident reporting system.

8.3.6 Medicines must not be transcribed where the original prescription details are illegible, unclear, ambiguous or incomplete. Particular care must be taken in transcribing details of high-risk medicines including insulin, anticoagulants, cytotoxic, or controlled drug.

8.3.7 The following items must not be transcribed: palliative care medicines including 'just-in-case' medicines, those used in syringe pumps or 'when required' medicines.

8.3.8 Refer to the clinical guideline for transcription of current medicines into a paper MAR form to facilitate medicine administration in the patient's home.

8.4 Patient Group Directions

8.4.1 Certain medicines may be administered or supplied to patients without a prescription under a Patient Group Direction (PGD). The healthcare professional authorised to administer a medicine are specified in each PGD and only specified and registered professionals are permitted to administer medicines under a PGD. Medicines can only be administered or supplied by the person authorised to provide a medicine under a PGD; the administration cannot be delegated to other staff.

8.4.2 It is the responsibility of the healthcare professional in charge of a clinical area to ensure that only those staff authorised to administer medicines under a PGD do so.

8.4.3 The administration of a medicine under a PGD must be recorded in the patient's EPR MAR. Where the EPR is not available it must be recorded on other Trust approved patient specific documentation or national IT record systems e.g. NIVs where authorised.

8.4.4 Details on current PGDs in use and how to implement a new PGD can be found on PGD pages of the Trust intranet including a proposal form.

8.4.5 There are specific named healthcare professional groups which are legally permitted to use PGDs to give medicines (MHRA, 2014) which are:

- Chiropodists & podiatrists
- Dental hygienists
- Dental therapists
- Dieticians
- Midwives
- Nurses*
- Occupational therapists
- Optometrists
- Orthoptists
- Orthotists and Prosthetists
- Paramedics
- Pharmacists
- Physiotherapists
- Radiographers
- Speech and Language Therapists

8.4.6 Note ODPs & *Nursing-Associates are not currently permitted to use PGDs (not exhaustive – refer to NICE guidance for further information).

8.5 Injectable medicines

8.5.1 The administration of medicines via the intravenous route is governed by the Trust Injectable Medicines Policy.

8.6 Feeding tubes and oral syringes

8.6.1 In circumstances where patients are unable to swallow the standard solid formulation of a medicine or when patients have feeding tubes in place, healthcare professionals must find appropriate alternative products that will allow patients to receive the medicines that have been prescribed. Pharmacists and pharmacy technicians can provide advice on such queries. In addition, the help of the nutrition support team or dietician can also be sought.

8.6.2 Tablets must not be crushed and capsules must not be opened unless this has been prescribed and confirmed to be acceptable by pharmacy staff or appropriate reference sources. Staff must also be aware that crushing tablets or opening capsules is likely to be outside of the product's 'marketing authorisation' and therefore an off=license use (also see section 6.8).

8.6.3 Feeding and medicines timing should be discussed with pharmacy and dietetics if required.

8.6.4 When discharging a patient with a feeding tube, the medication requirements must be discussed with pharmacy before writing the discharge documentation to identify the most suitable medicines and formulation for the patient.

8.6.5 All oral liquid medication must be administered using oral syringes (with purple plungers) or medicine spoons. Intravenous syringes must never be used for oral medicines due to the risk of intravenous administration of oral medicines or products.

8.6.6 The Trust has a Policy for the Nasogastric and Orogastric Feeding Tubes in Adults, Paediatrics and Neonates, which can be found on the Trust intranet.

8.7 Verbal orders

8.7.1 In certain emergency situation e.g. resuscitation, the administration of medicines might be required before a prescription or order can be written. In those circumstances it is appropriate that the items are prescribed after the emergency has taken place. A full record of medicines prescribed and administered must be made as soon as possible after the event.

8.7.2 In areas using the Trust EPR, there should no requirement for verbal orders other than as outlined in 8.7.1. Please also see section 6.7 on remote prescribing.

8.7.3 For out-of-hours services provided to community hospitals by DDOC Ltd. The DDOC doctors have access to the EPR and must prescribe in the system.

8.7.4 In community non-hospital settings e.g. patient's home, there may be exceptional circumstances where it is necessary for a prescriber to give a verbal order to alter the medications to be administered (as the Trust EPR is not available). This includes stopping and amending current prescriptions as well as starting new medicines. Sections 8.7.5 – 8.7.9 refer only to these settings.

8.7.5 The prescriber must confirm this order in writing including the use of information technology (such as fax, text message or email) and the medication administration record (MAR) updated before it is administered.

8.7.6 Amendments to the MAR should be taken wherever possible by a prescriber, registered nurse or pharmacy professional. It is good practice for this to be witnessed. The witness can be non-registered competent staff.

8.7.7 In exceptional circumstances (in the patient's home setting only) the MAR chart amendment can be made by an unregistered member of staff following receipt of the written verbal order. This must be checked by a registered nurse or pharmacy professional who is responsible for all the MAR changes made.

8.7.8 Verbal orders are not permitted for controlled drugs (CDs) or discharge/leave medication.

8.8 Administration of medicines in clinics

8.8.1 All medicines administered as part of outpatient or day-case clinic procedures must be order by authorised prescribers on the Trust EPR, or given against a current and approved Patient Group Direction. Staff administering medicines in clinics must be competent in the administration of the medicines (see 8.2). The administration must be documented as a medicine administration in the EPR and in line with this policy.

8.9 Administration in a Non-Hospital Community Setting

8.9.1 Medicines in the community/home setting are the property of the person for whom they are prescribed and dispensed. Registered and non-registered staff have a supportive, educational and monitoring role in patient self-administration. However, some medication will require administration by appropriately trained staff:

- Community Nursing staff must ensure that they have access to a valid direction to administer (DTA) e.g. PSD, from which to administer in the non-hospital setting e.g. patient home. Please refer to the DTA flow chart on the Trust intranet here.
- Non-registered staff in the Urgent Community Response (UCR) teams who administer medication must do so in line with the *Medicines Policy for Skilled and Competent Non-Registered (SNR) Community Staff (in a non-hospital setting) link.*
- Staff must ensure that the medication is available within the home/community environment.
- Registered practitioners delegating the administration of a medicinal product must ensure that team members have the appropriate competence to undertake the procedure and the relevant information to enable the task to be performed safely.
- A signed record of any drug administration (including CDs), must be maintained as per 11.11.4.

8.10 Patient self-administration

8.10.1 In certain circumstances it might be beneficial for patients to administer their own medicines during their in-patient stay. Self-administration of medicines can provide a sense of continuity and support self-management when not in an inpatient setting.

8.10.2 Patients might manage their medicines competently at home, but might struggle whilst unwell in hospital.

8.10.3 Self-administration of medicines is only suitable for patients who have been assessed as capable and competent to do so by a health care professional competent in medication administration e.g. registered nurse or midwife or alternatively by a member of the pharmacy team. Special care should be taken when assessing patient's ability to manage their own insulin administration.

8.10.4 The patient must agree to self-administration and the assessment must be documented in the patient EPR using the 'self-administration flow sheet'.

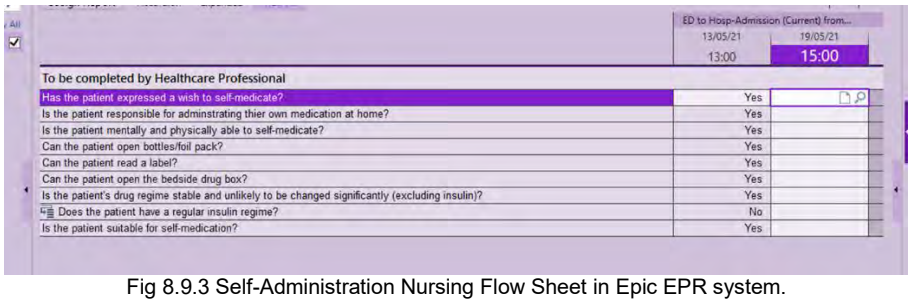

Fig 8.9.3 Self-Administration Nursing Flow Sheet in Epic EPR system.

8.10.5 It is good practice to review this every day. If a patient is sedated for a procedure, self-administration should be discontinued.

8.10.6 Medicines for self-administration must be stored in a locked cupboard, for example the patient bedside locker. Certain medicines that might be used frequently or urgently (e.g. inhalers, creams or GTN sprays) are permitted to be kept outside of a locked cupboard. Self-administration of medicines is only permitted if all medicines in the patient locker are labelled for the patient with instructions that match the prescription. Stock items must not be kept in the locker if the patient is self-administering medicines.

8.10.7 New polymer bedside lockers with RFID card operated medication compartments were introduced to many wards during 2021. These can be configured to permit patient access to one or both of the lockable compartments. Where a patient is only self-administering those medicines in frequent/urgent use, they should be secured in the upper small lockable compartment separately to all other medicines and the patient given access to this single drawer. Please refer to this information on HUB.

8.10.8 The nurse, midwife or other healthcare professional caring for the patient retains responsibility for the administration of medicines, must ensure the patient correctly takes their medicines and must record in the Trust EPR MAR when medicines have been taken by selecting 'self-administered' in the admin action box. Alternatively where paper charts are in use (no EPR) this can be done by writing 'self' into the administration box.

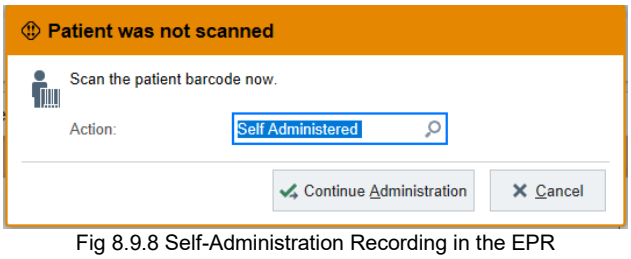

Fig 8.9.8 Self-Administration Recording in the EPR

8.10.9 Recording self-administration correctly in the EPR will clearly mark those doses as such in the EPR's MAR as shown below.

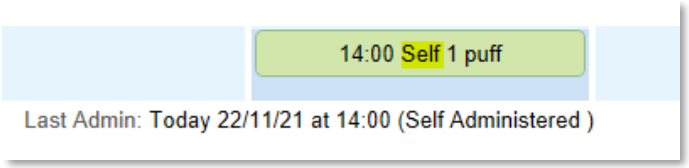

Fig 8.9.9 Self-administration record in the MAR when recorded correctly

9. COVERT ADMINISTRATION

9.1 Covert Administration Introduction

9.1.1 Covert administration can be defined as medicines deliberately disguised without the knowledge or consent of the patient receiving them, for example in food or in a drink. In exceptional circumstances, the covert administration of medicines can be considered to ensure that patients who lack capacity to understand the necessity of their medicines still receive essential treatments.

9.1.2 The Trust has extensive guidelines covering the issues of mental capacity, delirium and consent and these guidelines and standards must be adhered to at all times. The decision to administer medicines covertly must be within the correct legal framework. A best interest meeting must be had if the person lacks capacity and must involve the multidisciplinary team, including at least a doctor, a nurse and ideally also a pharmacist. How best to achieve covert administration must be clearly recorded in the patient's medical notes and the decision must be regularly reviewed.

9.1.3 The process detailed in this policy must be followed every time covert medication is considered and/or used. Policies and guidance relating to covert administration and the principles underpinning good practice can be found here:

- Mental Capacity Act 2005 (MCA 2005).
- Trust Delirium Guideline
- MCA Code of Practice (www.gov.uk)
- GMC Good Medical Practice Guidance:
    a. Prescribing & Managing Medicines and Devices (2013)
    b. 0-18 Years: Guidance for all Doctors
- RCGP MCA toolkit
- Social Care Institute for Excellence - Covert Medicines: Legal & Practice Guidance
- Trust - Safeguarding Adults at Risk & Mental Capacity Act Intranet Resources
- UK Medicines Information (UKMI) – Covert Medicine Administration Guidance

9.2 Covert Administration in Young People including Children

9.2.1 Covert administration of medicines to children (0 to 18 years) is not recommended and healthcare professionals must not administer medicines to them covertly. However, in practice explaining to the child or young person of the benefits and the rationale as to why the medicine is prescribed in appropriate language for their age may reduce the risk of treatment refusal.

9.2.2 Where there is an identified need to mask the medication flavour (i.e. disguise the flavour with food or drink) this should be discussed with the child and any agreement documented. It is also good practice to check with a pharmacist that the food or drink employed does not affect the efficacy of the medicine.

9.2.3 GMC advice is that respect for young people's views is important in making decisions about their care. If they refuse treatment, particularly treatment that could save their life or prevent serious deterioration in their health, this presents a challenge that staff need to consider carefully.

9.2.4 Parents cannot override the competent consent of a young person to treatment that you consider is in their best interests. But staff can rely on parental consent when a child lacks the capacity to consent. In England, the law on parents overriding young people's competent refusal is complex. Staff must seek legal advice if treatment is thought to be in the best interests of a competent young person who refuses.

9.2.5 Staff must carefully weigh up the harm to the rights of children and young people of overriding their refusal against the benefits of treatment, so that decisions can be taken in their best interests. In these circumstances, staff should consider involving other members of the multi-disciplinary team, an independent advocate, or a named or designated doctor for child protection. Legal advice may be helpful in deciding whether you should apply to the court to resolve disputes about best interests that cannot be resolved informally.

9.2.6 Staff should also consider involving these same colleagues before seeking legal advice if parents refuse treatment that is clearly in the best interests of a child or young person who lacks capacity, or if both a young person with capacity and their parents refuse such treatment. For further guidance on these issues see GMC guidance on consent and treatment and care towards the end of life.

9.3 Legal and Ethical Context of Covert Administration

9.3.1 Covert medication is a complex issue which involves the fundamental principles of patient/client autonomy and consent to treatment, which are set in common law and statute and underpinned by the Human Rights Act (1998). All qualified staff should be aware of the law and of their professional duties around treatment and medication.

9.3.2 Any mentally competent adult has the right to give or refuse consent to treatment or nursing intervention. If the patient lacks capacity under the Mental Capacity Act (2005) however, or is detained under the Mental Health Act (1983) then in certain circumstances covert medication can be justified and be both legal and ethical.

9.4 Procedure for Use of Covert Medication

9.4.1 The use of covert medication should be a last resort and not a routine measure should the patient not agree to take their medication. This Policy incorporates these requirements and must be followed by all healthcare practitioners within the Trust before covert medication is commenced.

9.4.2 A capacity assessment should take place with the patient in relation to their medicines and recorded using the Trust Mental Capacity Assessment Form and filed in the patient's clinical record in accordance with MCA (2005). It should be determined that if the patient is unable to do any of the following then capacity is lacking:

- Understand information relevant to the decision (e.g. the risks from not taking it).
- Retain this information for at least the duration of the conversation.
- Weigh up the information / risks involved.
- Communicate their decision.

9.5 Establishing Patient Capacity to Agree to Take Medication

9.5.1 This should be via discussion with the patient about their medicines. If the patient has capacity to make the decision about whether to take medicines or not, their wishes MUST be respected and covert administration must not be used.

9.5.2 If the patient lacks capacity to make decisions about taking their medicines the principles of the MCA (2005) should be followed and medication given in their 'best interest' (see below).

9.5.3 **All Reasonable Efforts** must be made to help the patient understand.

9.5.4 It should be recognised that many people's capacity fluctuates throughout the day and an optimal time to have discussions should be chosen. In some cases, several attempts may be required. Methods used to help overcome any communication issues including use of an interpreter should be recorded in the patient's clinical record. See the Trust intranet and the RCGP toolkit where further guidance on assessing and recording capacity can be found.

9.5.5 If the patient is able to understand, retain, weigh-up and communicate the decision then they should be assumed to possess the mental capacity to make the decision themselves, even if their decision appears unwise. In these circumstances, the decision must be respected and covert medication cannot be given. It is important that this process is followed as presumptions about a patient's mental capacity cannot be based solely on a patient's diagnosis (MCA, 2005).

9.6 Discussing Best Interests (in relation to covert administration)

9.6.1 Having established that the patient lacks capacity a decision about whether covert medication is in the patient's best interests should be had in an open and inclusive way. All staff involved in the decision-making process should be aware that covert medication is often not always appropriate or in line with what the patient would have wanted.

9.6.2 What is suitable for one patient may not be for another. The decision to give medication covertly should therefore only be made following a detailed examination of the patient's circumstances. The Balance Sheet should be used (see appendix 7) in conjunction with the Trust's Best Interests Checklist which may help inform a discussion.

9.6.3 The views of people involved in the patient's care should be sought, as it is important that the decision to administer medication covertly is not an isolated one. Members of the multi-disciplinary team, the patient's family (unless the patient expressed for them not to be involved at an earlier date when they had capacity), people closest to them and, if applicable, their GP, Learning Disability Liaison Nurse, care home manager, advocate or IMCA should all be invited to express a view.

9.6.4 If there is a registered Lasting Power of Attorney for Health and Welfare (and not just financial), this person can make the decision on the patient's behalf. If the patient lacks capacity and is "un-befriended" (only has paid carers to represent or advocate for them regardless of the length of time or closeness of the relationship) then an IMCA is necessary.

9.6.5 It is crucial that a decision is reached which is based on what the patient would have wanted, not necessarily what is best for their physical or mental health. Where consensus cannot be reached a second opinion from a formal best interest meeting (chaired by an independent person with knowledge of adult safeguarding) should be considered.

9.6.6 If an advance decision regarding refusal for medication exists, this must be respected as it is legally binding (see Advance Decision to Refuse Treatment Policy).

9.6.7 **Ensure that alternatives have been explored**. Alternative preparations should be offered, and flexibility (where possible) given e.g. frequency, formulation, timing etc. Research shows that medication concordance is improved when the patient has been involved in the decision-making process and has been empowered to have some control over what is prescribed.

9.6.8 **Establish that the medication is essential.** The medication that the patient is declining must be deemed to be essential for the patient's health and wellbeing, or for the safety of themselves or others and this must be documented in the patient's clinical record.

9.6.9 **Pharmacist** advice must be sought when crushing and /or mixing any medication with food or drink. This is to ensure that the medications the patient takes are safe to be given in this way and recommendations can be made about use of alternative formulations or medications, as necessary. Any changes to the patient's medication including rationalisation of which medicines are deemed essential, after a plan for covert medication is put in place should also be discussed with pharmacy.

9.7 Documentation of Covert Administration

9.7.1 In order to be transparent and to provide a clear audit trail all people receiving covert medication should have details recorded in the patient's clinical record detailing:

- The patient's lack of capacity
- Necessity to administer medicines covertly
- How the decision for covert administration was made
- Any best interest decisions
- Methods which have been attempted/could be considered to improve compliance/concordance.
- The Trust Mental Capacity Assessment Form must be completed

9.7.2 The initial decision alongside any best interest decision to use covert administration must be recorded on Datix as an incident using the categorisation as outlined below, even when done correctly. This should be reviewed by speciality governance groups to ensure it is in line with the requirements set out in this Policy.

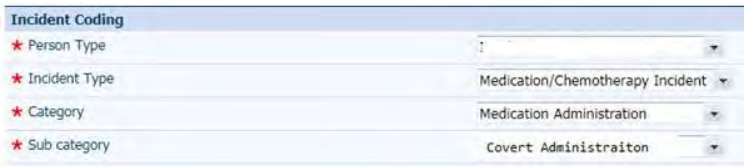

Fig 9.7.2 How to record occurrences of covert administration on Datix

9.7.3 Covert medication is treatment without consent therefore interferes with Article 5 and Article 8 of the Human Rights Act (the right to liberty and respect of private life), this is very relevant to Deprivation of Liberty as the person is seen in the eyes of the law to be under constant supervision and control (AG vs. BMBC). If covert medication is deemed to be necessary using the best interest process then an application for DoLS needs also to be completed by the ward staff clearly stating the use of covert medication in the care plan (see safeguarding intranet here). The medicine can be given before DoLS is authorised as long as there is clear documentation in the notes that the person lacks capacity and that a best interest meeting has taken place in accordance with the Mental Capacity Act 2005.

9.7.4 If covert administration is felt to be necessary after discharge, then arrangements should be made to communicate clearly the covert medication plan with the family/care home manager, prescriber (e.g. GP) for example on the discharge documentation as well as highlighting the need for this to be regularly reviewed.

9.8 Covert Prescribing

9.8.1 When prescribing medicines which have been deemed necessary to give covertly, this must be stated **explicitly** on the Drug Administration Chart, for example by adding 'COVERT ADMINISTRATION' in the admin instructions field in the EPR. (see figure 9.8.1 below).

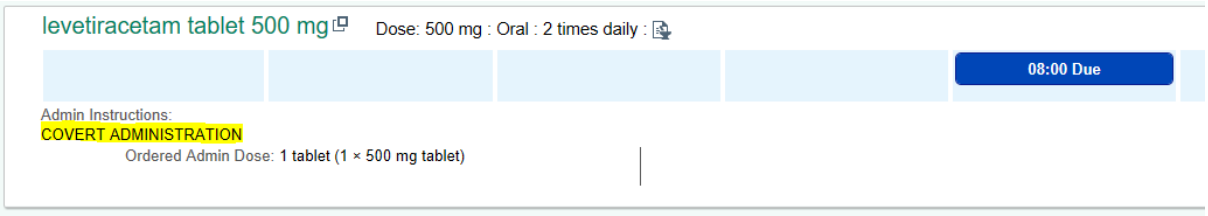

Fig 9.8.1 Drug Chart Prescribing of a Drug to be given covertly.

9.9 Administration (Covert)

9.9.1 Administration of medicines given covertly must be recorded clearly in the EPR by selecting the appropriate administration action (see fig 9.8.1) in the MAR.

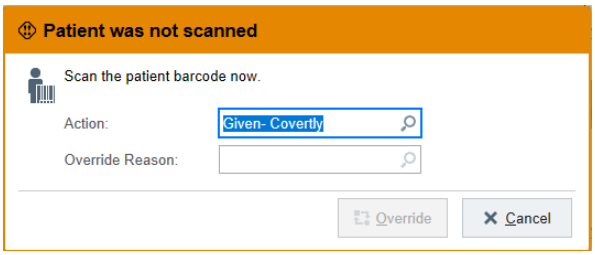

Fig 9.9.1 Recording A Covert Administration on the MAR in the EPR

9.9.2 This will show clearly on the MAR after administration with additional 'cover' text.

9.10 Review of Covert Administration

9.10.1 On-going attempts to encourage compliance are essential. As far as possible, a reason for refusal must be sought and documented appropriately in the patient's clinical record. Once taken, the decision to administer covertly must be reviewed at agreed intervals appropriate to the patient's clinical condition and/or when there is reason to believe mental capacity has changed.

9.10.2 The opportunity to offer the patient their medicines non-covertly should be considered but not if this has the potential to cause upset or distress to the patient. Covert administration should not be considered a long-term solution except in exceptional circumstances.

9.11 Exceptions to Procedure

9.11.1 Extreme Situations

9.11.2 When an emergency arises in a clinical setting and it is not possible to determine a patient's wishes, they can be treated without their consent, provided that the treatment is immediately necessary to save their life or to prevent a serious deterioration of their condition. The treatment provided must be the least restrictive option available. Any medical intervention must be considered in the patient's best interest and should be clearly recorded noting, who took the decision, why the decision was taken and what treatment was given.

9.12 Patients Detained Under the Mental Health Act (1983)

9.12.1 For patients detained under the Mental Health Act, the principles of "consent" continue to apply to any medication for conditions not related to the mental disorder for which they are detained. The assessment of their capacity to consent or refuse such medication therefore remains important.

9.12.2 However, medication for the mental disorder for which the patient has been detained, can be given against a patient's wishes during the first 3 months of treatment order or afterwards if sanctioned by a Second Opinion Approved Doctor (SOAD). If in doubt, refer to the Liaison Psychiatry Team.

9.13 Covert Administration in Summary

9.13.1 Where covert medication is used the following principles should be seen as good practice:

- **Lack of capacity,** must be established.
- **Last resort**, covert medication should only be used when all other options have been tried
- **Time limited**, it should be used for as short a time as possible
- **Regularly reviewed**, the necessity of covert medication plan should be regularly reviewed
- **Transparent**, the decision-making process should be easy to follow and clearly documented
- **Inclusive**, all decisions should be made in the patient's best interests, having undertaken a holistic assessment of the impact of covert administration.

9.13.2 Covert medication is not the same as rapid tranquilisation, which has separate Trust guideline and can be found on the Trust intranet here.

9.13.3 Use of covert medicine within a care plan must be clearly identified within Deprivation of Liberty Safeguards (DoLS) application.

9.13.4 A DoLs authorisation is not necessary to *give* the medication which is prescribed via the Mental Capacity Act 2005 in the individual's best interests however patients in hospital who lack capacity to make treatment decisions are likely to need a Deprivation of Liberty Authorisation. Further guidance on DoLS can be found via the Trust Intranet including information on the Deprivation of Liberties and Mental Capacity Act.

10. MIDWIVES' EXEMPTIONS

10.1.1 Registered midwives may supply and administer any of the substances that are specified in medicines legislation under midwives exemptions, provided it is in the course of their professional midwifery practice. This includes all General Sales List (GSL) and Pharmacy (P) medicines, as well as a limited range Prescription Only Medicines (POM) which are specifically listed in legislation.

10.1.2 They may do so without the need for a prescription or patient-specific direction from a prescriber. Provided the requirement of any conditions attached to those exemptions is met, a PGD is not required. If a medicine is not included in the midwives exemptions a PGD or prescription will be required (NMC 2010).

10.1.3 The midwives' exemption list can be found in Appendix 11. Note this does not explicitly list every P or GSL product.

10.1.4 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 (NMC 2010).

10.1.5 In July 2011 medicines legislation was amended to enable student midwives to administer medicines on the exemption list, except controlled drugs, under the direct supervision of a midwife.

10.1.6 The administration shall be only in the course of a midwife's professional practice and in the case of lidocaine and lidocaine hydrochloride shall only be while attending on a woman in childbirth.

10.1.7 Under the Medicines Act 1968 medicines are classified as:

- **GSL**- General Sales List medicines, sold more widely through retail outlets.
- **P** – Pharmacy medicines sold or supplied only through registered pharmacies by or under the supervision of a pharmacist.
- **POM** – Prescription only medicines.

10.1.8 Midwives can only supply and administer medicinal products in accordance with a specified process. In the provision of maternity care these processes will primarily be through midwives exemptions but the other methods being via patient specific directions (like those ordered by a prescriber for administration in the EPR) or patient self-administration (see section 8.9).

10.1.9 All medication administered to a patient under a midwife exemption must be recorded as an administered medicine in the EPR system. All midwife exemption medicines must be ordered so that they can be administered against in the EPR's MAR. All midwife exemption medicines are built in the EPR with a prefix of 'MWEM' (as shown below) which can be used to search for these items.

Fig 10.1.9 Searching for a midwife exemption medicines 'order' in the EPR using 'MWEM' prefix

11. CONTROLLED DRUGS

11.1 General Principles

11.1.1 The management of Controlled Drugs (CDs) is governed by the Controlled Drugs (Supervision of Management and Use) Regulations 2013. Additional statutory measures for the management of CDs are laid down in the Health and Social Care Act (2012) and its associated Regulations. This chapter has also been written in accordance with the Care Quality Commission (CQC) 'Safer Management of Controlled Drugs 2014'.

11.1.2 CDs are defined for the purpose of this document as those drugs that come under Schedule 2 and 3 of the Misuse of Drugs Regulations. These CDs are identified in the BNF-online with a sub heading of the relevant schedule for each medicinal form.

11.1.3 The registered nurse, midwife or Operating Department Practitioner (ODP) in charge of a clinical area is responsible for the safe and appropriate management of CDs in that area.

11.1.4 Each clinical area must have a list of CD stock items agreed between the nurse, midwife or ODP in charge and pharmacy. This stock list should be reviewed annually or when other clinical change requires a review. Pharmacy staff carry out regular checks of CD stock in all clinical areas.

11.1.5 Certain processes described require a witness or second checker. The witness or second checker must be 'suitably trained to carry out this task, so that they are able to challenge any step of the checking process if procedures are not followed or records do not tally. The second checker does not have to be a registered healthcare professional. See appendix 3 for a list of processes that require a witness and appendix 5 for the correct procedure for administration of a CD.

11.1.6 The Trust has a Controlled Drug Accountable Officer (CDAO) who is responsible for all controlled drug handling and governance issues in organisation. The current CDAO can be identified on the Trust intranet.

11.2 Exceptions to CD rules

11.2.1 All CDs as identified in the BNF are treated in the same way according to the rules laid out in this chapter. However, for some CDs certain rules do not apply or other additional rules may apply and are summarised below:

- Midazolam see section 7.4
- Morphine oral solution (10mg in 5ml) is a schedule 5 CD and not schedule 2 or 3 in legislation, However, for security reasons, CD requirements apply for the purpose of ordering and storing oral morphine (10mg in 5ml). None of the other CD requirements apply (i.e. it is not necessary to keep a written record in the CD register, administration can be carried out by one single qualified practitioner and none of the disposal requirements for CDs apply). In addition, prescriptions for discharge or outpatients do not have to follow CD requirements.
- High strength oral morphine (20mg in 1ml) is a Schedule 2 CD.
- Where morphine oral solution (10mg in 5ml) is administered as part of an 'Enhanced Recovery' pathway, staff in specified areas are permitted to remove morphine oral solution (10mg in 5ml) bottles from the CD cupboard for the duration of the drug round. The bottles must not be left unattended and must be returned to the CD cupboard immediately after the drug round. Such exemption must be approved by the Medicines Management Group (current exemption: Dyball East, Dyball West and Tavy).

- Ketamine is a now a schedule 2 CD in legislation therefore requires appropriate ordering, prescribing and storage.

- Temazepam and phenobarbitone require CD prescription requirements (e.g. total supply quantity in words and figures etc.) for outpatients or discharge prescriptions.

- Oral Tramadol is a schedule 3 CD, and prescription writing and ordering requirements apply. It should be stored in a CD cupboard (not a legal requirement); however, it is not necessary to keep a written record in the CD register and administration can be carried out by one single qualified practitioner. Tramadol brought into hospital by a patient can be stored in their bedside locker (must be locked) where there is a need to have the supply close to the patient e.g. self-administration of medicines.

- Injectable Tramadol is a schedule 3 CD but unlike oral tramadol also requires a written record in the CD register in addition to the other requirements. It may not be stored in the patient bedside locker under any circumstances.

- Gabapentin and pregabalin became a schedule 3 CDs from 1st April 2019. Safe storage requirements are not be legally required but are recommended where practically possible. See this bulletin on HUB for summary of requirements.

11.2.2 The registered nurse, midwife or Operating Department Practitioner (ODP) in charge of a clinical area can decide to apply additional requirements. The requirements described above are minimum requirements.

11.3 Controlled stationery

11.3.1 All CD transactions must be recorded in approved books to ensure that the Trust complies with legal requirements and a clear audit trail for CDs is in place. Pharmacy issue four CD books for use in the Trust:

- CD Requisition Book
- CD Record Book for Theatres
- Stock CD Record Book
- Patient's Own (POD) CD Record Book

11.3.2 Only one Requisition Book and one Record book must be used by a clinical area at any one time and all controlled stationery must be stored in the CD cupboard.

11.3.3 The only exception to this is for remote community units/hospitals who are permitted to use a maximum of two CD requisition books at a time.

11.3.4 Completed books must be kept in the clinical area for a minimum period of two years after the last entry. The nurse, midwife or ODP in charge is responsible for keeping the CD record book up to date and in good order.

11.3.5 A future electronic process may be introduced which permits the ordering of controlled drugs via the EPR system. This will negate the need for CD requisition books.

11.4 Ordering and supply of CDs

11.4.1 The ordering of CDs is the responsibility of the nurse, midwife or ODP in charge of the clinical area. The task of ordering CDs can be delegated to other qualified nurses, midwives or ODPs. Orders must be made in the CD Requisition Book using separate requisitions for each CD to be ordered. The order must be signed by a registered nurse, midwife or ODP.

11.4.2 The person signing the order must be an authorised signatory. It is the responsibility of the nurse, midwife or ODP in charge to ensure that pharmacy department has a current list of all authorised signatories listed on the designated Pharmacy form and that each entry in this list is counter-signed by the person in charge. Master lists of authorised signatures for an area are retained in the Pharmacy Department. The authorising nurse, midwife or ODP in charge must have their signature countersigned on the form by a member of pharmacy staff before authorising others.

11.4.3 The requisition book can be taken to pharmacy by any member of staff working in the clinical area, the ward pharmacist or the porters. For community hospitals the CD Order book must be sent in designated pharmacy box or green bag.

11.4.4 Each clinical area has an agreed CD Stock List. This is agreed between pharmacy and the nurse, midwife or ODP in charge of the clinical area. The stock list can be found in the back of an area's CD Order Book, and details CD medications forms and strengths. When ordering items that are not on the approved stock lists, the order has to be approved by a pharmacist (either on the ward or by sending the drug chart to pharmacy). CDs that are not on the stock list will be labelled by pharmacy as 'Temporary Stock' and must be returned to pharmacy by a member of the pharmacy team when they are no longer needed.

11.4.5 In addition, pharmacists are permitted to order CDs using the CD requisition book and pharmacy staff are permitted to make changes to the CD order in those cases where the order is unclear or incomplete. Any changes made to the order must be clearly documented on the requisition form and signed.

11.4.6 CDs will be delivered to clinical areas in sealed tamper proof bags or boxes, usually by pharmacy porters. Ward staff (including non-qualified staff) can also collect CDs from pharmacy providing they wear a Trust identification badge and sign for the receipt of the CDs. The sealed bag must be taken to the clinical area immediately and handed to the nurse, midwife or ODP in charge.

11.4.7 Wherever practicable, different persons should be responsible for requisitioning and receipt of CDs. The CDs received must be checked against the requisition. Any discrepancies in CDs ordered and CDs supplied must be immediately reported to pharmacy.

11.4.8 If the received amount is correct, the requisition form must be signed and the CDs must be immediately placed into the CD cupboard and entered into the CD Record Book and countersigned by a witness. CD bags must never be left unattended.

11.4.9 Only remote Trust sites e.g. community hospitals are permitted to email urgent stock CD orders to pharmacy. Emailed orders must only be used when there is an urgent need e.g. risk of harm due to omitted or delayed doses. Before emailing urgent CD requisitions the member of staff must mark the original requisition form with "**Emailed to pharmacy <date> <sign>**".

11.5 Collection of Controlled Drugs (CDs) in the non-hospital setting:

11.5.1 Staff working in the community should not routinely become involved in the delivery or custody of prescribed medicines and only in exceptional circumstances should community staff transport CDs, where patients or their carers / representatives are unable to collect them, provided the nurse is conveying the CD to a patient for whom the drug has been prescribed and dispensed (for example from a pharmacy to the patient's home). The registered practitioner will be asked to sign and prove their identity to the community pharmacist. Any CDs must be kept secure and out of sight within their vehicle and taken directly to the patient's home.

11.6 Storage of CDs, stock checks and record keeping

11.6.1 CDs must be stored in CD cupboards at all times. CD cupboards must conform to the construction standards specified in the Misuse of Drugs (Safe Custody) Regulations 1975 including British Standard reference BS2881:1989 (level 1) and be otherwise approved by pharmacy.

11.6.2 CD cupboards must be:

- only be accessed by staff authorised to do so (nurses, midwives, ODPs, pharmacists or pharmacy technicians)
- not used to store other medicines or other items not approved in this Policy
- locked at all times when not in use
- secured in cupboards using locks that are not common with any other lock in the Trust and conform to BS3621.
- Should not have any signs or labels to indicate that CDs are inside.

11.6.3 CDs that have been issued by pharmacy for discharge must be stored in the CD cupboard until they are issued to the patient. If they need to be stored overnight e.g. where discharge is delayed they must be entered into the POD CD record book. Other non-CD discharge medicines must be stored separately from CD stock.

11.6.4 It is the responsibility of the nurse, midwife or ODP in charge of the clinical area to ensure that the CD record book accurately reflects the stock level in the CD cupboard. Stock checks including expiry date checks should be undertaken by 2 members of staff one of whom must be registered and the second who is a competent witness. It must include both stock and patient's own CDs.

11.6.5 CD checks must be carried out twice daily, unless an alternative frequency has first been approved by the Medicines Management Group and Director of Nursing. All CD checks must be documented in the CD Record Book or a provided CD checking record book. Stock levels should be checked each and every time a CD is removed or added to the CD cupboard.

11.6.6 If a mistake is made it should be bracketed in such a way that the original entry is still clearly legible. This should be signed, dated and witnessed. The entry should not be crossed through.

11.6.7 If a discrepancy between actual stock levels and recorded stock levels is identified, the following steps must be taken by the nurse, midwife or ODP in charge:

- Check the record book and stock to ensure the discrepancy is not due to recording errors (e.g. incorrectly counted stock, administration of CD not recorded, requisitions not added)
- If the error can be reconciled, the nurse, midwife or ODP in charge must make an entry in the record book the reasons for the adjustment and the correct balance. This entry must be witnessed and counter signed.
- If the error cannot be reconciled, the Chief Pharmacist and Accountable Officer must be informed at the earliest opportunity (e.g. the next working day if the error was detected out of hours) and a Trust incident form must be completed
- The nurse, midwife or ODP in charge must consider that any discrepancy might be due to diversion of CDs by staff or patients. If diversion of CDs is suspected, the nurse, midwife or ODP in charge should urgently contact the Senior Matron, Assistant Director of Nursing or, if the error is detected out of hours, the Site Practitioner.
- CD Cupboards, contents and registers are audited at least every 3-6 months by a member of the pharmacy team

11.7 CD Key-Holding and Missing Keys

11.7.1 The registered nurse, midwife or ODP in charge of a clinical area is responsible for the CD keys in that area. Key-holding may be delegated to other suitably-trained, registered healthcare professionals but the legal responsibility rests with the registered nurse, midwife or ODP in charge.

11.7.2 Ward areas may only have ONE CD key in use at any one time. Spare keys where available should be labelled clearly and securely stored in pharmacy.

11.7.3 CD keys may also be stored in a secure safe or other approved CD Cupboard. This is essential for those areas which are closed at night or over weekends where no staff as per 11.7.1 are continually present.

11.7.4 If CD keys are lost, the steps described in section 12.14 must be followed. In addition, due to the addition risk relating to CDs, the following steps must also be taken:

- The Senior Matron, Lead Nurse or Site Practitioner should be contacted immediately. They will then decide if security and/or the police should be informed.
- Inform the Accountable Officer and the Chief Pharmacist (the next working day if the keys are lost out of hours).
- Report on Datix under the medication incident > Breach of Controlled Drug > Missing / Lost CD Cupboard Keys.

11.7.5 Once the CD cupboard has been opened, a stock check must immediately be carried out to check if any items are missing. This stock check must be recorded in the CD record book.

11.8 Patients' Own CDs

11.8.1 In most cases it is advisable to use CDs from stock for patient care. However, patients' own CDs can be used for administration during their hospital stay if needed, provided the CDs have been prescribed and have been assessed as suitable for use according to section 8.9.

11.8.2 It is preferable that patient's own CDs should be returned to the patient's home via a responsible adult or pharmacy should be informed to request safe destruction. The CDs remain the patient's property and patients have to consent to their destruction. This should be recorded in the CD POD record book.

11.8.3 If patients' own CDs are stored in the CD cupboard temporarily until they can be destroyed or returned to the patient's home, they must be segregated from other CD stock items by placing them into a bag which is marked with the patient's ID label. All patients' own CDs stored in the CD cupboard MUST be recorded in the POD CD Record Book (and not the Stock CD Record Book).

11.8.4 Patient's own controlled drugs should never be used to treat other patients.

11.8.5 When patients' own CDs are used for treatment, a record must be made in the Patients Own CD Record Book under a separate entry to ward stock. When patient's own CDs are transferred between clinical areas the CDs must be checked by the nurse, midwife or ODP in charge before leaving one area and then be rechecked by the nurse, midwife or ODP in charge on arrival in the new area. Any discrepancies must be reported to the Pharmacy department and an incident form completed.

11.8.6 When any patient who is using their own CDs is discharged from a ward an entry must be made in the Patients Own CD record book. This entry must state the total quantity of CDs returned to the patient and the closing balance that remains on the ward. This will usually be zero.

11.9 Prescribing CDs for Inpatients

11.9.1 CDs for inpatient administration must be ordered/prescribed in the EPR in the same way that non-CDs are (see section 2). No additional requirements apply.

11.10 Prescribing CDs for Discharge and Outpatients

11.10.1 Discharge and outpatient prescriptions must comply with the legal requirements for CDs (also see BNF online guidance section for details) in addition to complying with all prescribing requirements in section 6. This applies to hospital discharge and outpatient prescriptions.

11.10.2 Pharmacy is not permitted to dispense a CD unless all the information required by the law is provided including:

- Name and address of the patient
- Form and strength of the preparation (even where only one form/strength exists)
- Total quantity of the preparation of the number of dose units to be supplied, both in words and figures
- Dose to be taken
- The words 'for dental treatment only' (in the case of dental prescriptions).
- Signed & dated by the prescriber, including printed name and bleep number.

11.10.3 It is acceptable for the information to be electronic, but the prescriber's signature must be handwritten. The Trust EPR provides a preconfigured controlled drugs supply form which must be printed off in order for a supply to be made. The prescriber need only add the total quantity in words and figures and sign and date the form once printed.

11.10.4 Incorrectly written prescriptions cause unnecessary duplication of work and inconvenience for patients. It is the responsibility of the prescriber to avoid this by correctly writing and signing a CD prescription for dispensing and administration.

11.10.5 Temazepam and oral morphine solution (10 mg in 5 ml) are excluded from the CD prescribing requirements for outpatients or discharge.

11.10.6 On collection of CDs for discharge, they must be stored in the ward CD cupboard until the patient is leaving. An entry needs to be made in the POD CD Register only when it is being stored overnight or longer.

11.11 Prescribing CDs in Non-Hospital Community Settings

11.11.1 If CDs are required to be prescribed out of hours in community settings DDOC should be contacted who will prescribe the required medication on a community approved administration record and deliver by DDOC transport to the practitioner for administration.

11.12 Administration of CDs

11.12.1 The administration of CDs must follow the procedure as set out in appendix 5.

11.12.2 The administration of medicines must not only follow the requirement for CDs but also the requirements for the safe administration of injectable medicines and other relevant policies where applicable (i.e. the preparation and administration of an intravenous CD via a pump must be witnessed as a CD and the prescription and pump setting must fully double-checked and signed for by a second registered professional under all circumstances within the hospital setting).

11.12.3 A record must be made in the ward or department CD Record Book when a CD is removed from the CD cupboard. The following details should be recorded:

- Date and time when dose administered
- Name of patient
- Quantity administered
- Form (name, formulation and strength) in which administered
- Name/signature of nurse/authorised person who administered the dose
- Name/signature of witness (where there is a second person witnessing administration)
- Balance in stock

11.12.4 If part of a vial or ampoule is administered to the patient, the registered nurse, midwife or registered health professional must record the amount given and the amount wasted (e.g. '2.5 mg given and 2.5 mg wasted'). The disposal must be witnessed; see section 11.13 for guidance on the correct disposal of CDs.

11.12.5 Two practitioners must be involved in the administration of CDs, one of them must be a registered nurse, midwife, doctor or ODP (or a pharmacist in exceptional circumstances). The other person must be competent to witness the administration, but does not have to be a registered practitioner. Both practitioners must be present during the whole of the administration procedure. They must both witness:

- The preparation of the CDs to be administered.
- The CD being administered to the patient.
- The destruction of any surplus drug (e.g. part of an ampoule not required).

11.13 Controlled Drug Record Keeping in Non-Hospital Community Settings

11.13.1 If Trust staff are required to administer controlled drugs (CDs) in other provider settings such as care homes then the controlled drugs procedures for that provider must be followed for CD record keeping (i.e. the Controlled Drugs Record Book for that care-home/provider is completed and signed as a record of the administration, detailing the patient / resident's name, the dose and time administered, together with the running balance).

11.14 Emergency access to CDs

11.14.1 Every effort should be made to ensure that adequate stock levels are maintained to meet likely needs in all clinical areas. It is the responsibility of the nurse, midwife or ODP in charge of the clinical area to ensure that stock levels are adequate and adjusted according to specific circumstances (e.g. before bank holidays).

11.14.2 Should the need arise to access a CD outside of pharmacy opening hours from another clinical area, the nurse or midwife caring for the patient can sign out individual doses from the other area's CD record book. They must take the prescription to the clinical area, accompanied by a witness and use CD stock for the individual dose from that area. The CD Record Book in the other areas must clearly show the location of the patient and the entire process must be witnessed as described in section 11.10. In addition, the registered nurse or midwife in charge of the clinical area where the CD item is taken from must also counter-sign the CD record book.

11.14.3 CD stock items must NOT be transferred between areas and balances transferred between ward CD record books.

11.14.4 In community settings emergency access to CDs out of hours is via D-DOC.

11.15 Use of CDs during patient transfer

11.15.1 Exceptionally, a patient might require a CD during an emergency transfer to another location outside of the Trust before the medication supply can be organised.

11.15.2 In this instance, the prescriber must order the medication in the EPR. The CDs are then dispensed from the CD cupboard and an entry is made the record book, including the note: 'For Patient Transfer'.

11.15.3 It is the responsibility of the prescriber or nurse or other registered health care professional to keep these medicines secure until administration or return.

11.15.4 When the medication is administered, a record of that administration must be recorded including dose, time and date. This should be recorded in the Trust EPR MAR where available, and, where practicable, witnessed and signed by a second health care professional. Where the EPR is not accessible it must be recorded on a paper form and transcribed into the EPR at the earliest opportunity. The receiving hospital must be provided with full details of any medicines administered during transit.

11.15.5 The healthcare professional who administered the dose must then also make a entry in the CD record book detailing the actual dose given to the patient. A second signature by the nursing staff is not required, unless he/she witnessed the administration. Any unused medication is returned to stock and recorded accordingly.

11.16 Disposal of CDs

11.16.1 CDs should usually be returned to pharmacy for destruction by wards/clinical areas at the Wonford site. Community hospitals must not return unwanted patient's own CDs or expired CD stock to Pharmacy. The CDAO has authorised registered Trust employed pharmacists to witness the destruction of CDs in community hospitals by a registered nurse using a destruction kit (available from EROS). Stock suitable for reuse should where possible be returned to the main pharmacy department at Wonford by the Community Services Pharmacy team.

11.16.2 In community hospitals registered pharmacy technicians can also witness the destruction of Schedule 3 CDs and Patients Own CDs by a registered ward nurse. Records of destruction must be made in the appropriate CD registers.

11.16.3 The only exception to this is the disposal of small amounts of individual doses of CDs that are prepared, but not administered, in a clinical area. Such small amounts of CD can be disposed of in sharps bin for mixed pharmaceutical waste. Two staff must witness the disposal (one of them must be a nurse, midwife or ODP) and an entry must be made in the CD Record Book, including the names of the two people involved in the destruction.

11.16.4 CDs being disposed of (as per 11.16.3) MUST be fully discharged from the container they are in e.g. syringe into the sharps bin along with the container so that the CD is irretrievable.

11.16.5 Absorbent gel granules must be used in sharps bins to render liquid controlled drugs irretrievable when disposing of them. These can be provided via ward top up from NHS supplies using code HFL8661. They must be securely stored away from patients as they are harmful if swallowed. Multiple sachets may need to be used depending on the sharps bin size.

Figure 11.16.4 – Absorbent gel for disposal of liquid controlled drugs

11.16.6 All other CDs no longer needed in the clinical area (such as expired or unwanted stock or patient's own CDs) must be returned to pharmacy. Only pharmacists or pharmacy technicians are authorised to return unwanted CDs to pharmacy. Pharmacy staff will record any CDs that are removed from the clinical areas and ask a suitable witness to sign for the removal of CDs.

11.16.7 When returning CDs to pharmacy, an entry must be made in the ward CD Register, signed by the nurse, midwife or ODP in charge and the pharmacist or pharmacy technician involved in the return process.

11.17 Destruction of Patient's Own CDs in the Patient's Home

11.17.1 Patients own CDs are and remain the property of that person. Staff working in the community should not routinely remove unwanted or expired medicines, including CDs from a patient's home or possession, either during their care or after the death of a patient. The patient, their representative or family member should be advised to return unwanted or expired medicines to the local community pharmacy or dispensing practice for safe disposal, unless directed otherwise by the Coroner, or it is deemed not appropriate to do so (e.g. where there may be a risk of misuse).

11.17.2 In exceptional circumstances, and for non-coroner cases, where the risks have been considered the medication will be denatured and the destruction witnessed by a competent witness (which may include a family member where it is appropriate to do so, and this will not cause additional distress). In such circumstances it is advisable to obtain written consent for the destruction of medication. All actions taken must be documented, and a signature obtained from the witness (where, if a family member, carer or other non-registrant will not cause additional distress).

11.17.3 When a proportion of a controlled drug (CD) remains on renewing a syringe driver or giving set, the residual CD must be denatured on the premises and be recorded in the patient's clinical records.

11.18 CDs in operating theatres

11.18.1 In addition to the requirements above, the following additional guidance must be adhered to:

- Each theatre must have their own CD record book and CD cupboard
- Specific CD record books for theatres should be requested from pharmacy

- The practice of issuing “active stock” to the anaesthetist and then returning the unused portion to stock is not permitted. An amount should be issued to the anaesthetist for a specific patient and any surplus drug must be destroyed and the destruction witnessed and signed in the CD record book.

11.19 Illegal substances

11.19.1 The Trust has a duty under the Misuse of Drugs Act 1971 to ensure that its premises are not used for the possession or supply of illegal substances. Illegal substances are, for example, Schedule 1 CDs, such as cocaine or cannabis, or other controlled drugs that have not been issued for treatment by prescriber, as well as psychoactive drugs (see Psychoactive Substances Act 2016).

11.19.2 Illegal substances might be brought into the Trust by patients, visitors or staff. Anyone suspecting or knowing that illicit substances have been brought to the premises, must follow the following key principles:

- Senior staff must be informed immediately (including the patient’s consultant if a patient is involved)
- Patient confidentiality must be maintained
- Patient care must not be compromised
- A written record should be kept of any actions taken
- Anyone in possession of an illegal substance should be encouraged to surrender it. It must then be transferred immediately to pharmacy for safe disposal, or at the earliest opportunity if pharmacy is closed. The substance can be stored in the CD cupboard in a sealed bag until safe transfer to pharmacy is possible
- Senior staff might consider informing the police if it is suspected that the illegal substance has been brought into the Trust for the purpose of supply to others or if the person refuses to surrender the substance or refuses to leave the Trust’s premises
- Illegal substances must never be returned to a patient or visitor as this constitutes the supply of an illicit substance, which is a serious criminal offence
- An incident form must be completed.

12. ORDERING, SUPPLY & STORAGE OF MEDICINES

12.1 General Principles

12.1.1 Only medicines supplied by the hospital pharmacy are permitted to be used in the Trust, with the exception of patients’ own drugs.

12.1.2 It is the responsibility of the nurse or midwife or other authorised healthcare professional in charge of a clinical area to ensure that medicines are ordered, stored and disposed of in line with this policy. This includes responsibility for the safe custody of medicines and accountability for their use.

12.1.3 Medicines used as part of a *clinical trial of an investigational medicinal product* (CTIMP) will be stored in the Clinical Trials Pharmacy unless the protocol dictates that urgent and/or out of hours access to the drug is required. If this is the case then storage arrangements and supply processes will be discussed with the research team and risk assessed by the pharmacy clinical trials team.”

12.2 Ordering Stock Medicines

12.2.1 Any urgent medicine ward stock supply requests must be made via the Trust EPR system if available via the 'med stock request' workflow which can be accessed normally via the quick link menu bar.

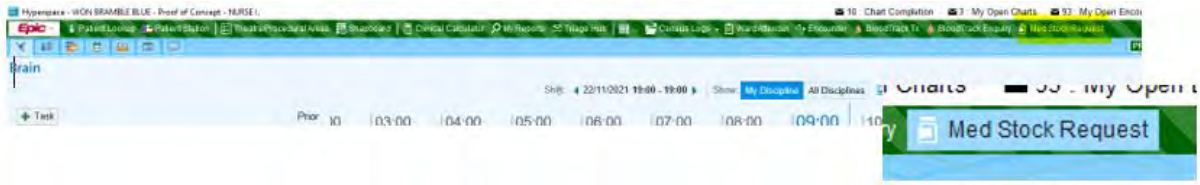

Fig 12.2.1 Ordering stock medicines in the EPR system via 'Med Stock Request' function

12.2.2 Wards must not order items on top-up days or as routine stock replacement as this will be actioned by pharmacy staff as part of a top-up service. Any requests must only be for medication needed where stock is inadequate to meet ward demands. The pharmacy team may reject any supply requests if they are duplicated, non-urgent or ordered on top-up days.

12.2.3 Alternatively for areas/staff without access to the EPR, stock items can also be ordered via an approved stock request form, which can be scanned and emailed to the pharmacy distribution team. Order requests for limited numbers of lines may also be telephoned through to the distribution team on ext. 2453 (Monday to Friday 08:30 to 17:00 & weekends 09:00 to 16:00).

12.2.4 Weekly orders for community hospital are obtained by completing the ward profile stock list on a designated day. This must be sent with 24 hours' notice to the RDE pharmacy for next day delivery Monday to Friday.

12.3 Pharmacy stock top-up

12.3.1 Most clinical areas have a pharmacy-led top-up service and a list of stock medicines, which is agreed in writing between the nurse or midwife in charge, the ward pharmacist and distribution manager. For wards without pharmacist cover, the pharmacy technician or a senior pharmacist may agree the list. The content of the stock list is reviewed at least annually.

12.3.2 Pharmacy staff will replenish stock and maintain the stock contents of the cupboard on a schedules programme to the agreed profile levels and put away stock, leaving an issue advice notice. This notice should be reviewed by the nurse or midwife in charge to monitor what has been supplied to the clinical area and to identify potential supply problems.

12.3.3 Pharmacy staff ensure that the ward medicines cupboard is topped-up at the agreed times, stock is adequately rotated and regular expiry checks are carried out.

12.3.4 Community hospitals/units do not receive a top-up service from pharmacy and must follow weekly profile checks and order processes.

12.4 Assessment of Patient's Own Drugs

12.4.1 Patients are encouraged to bring with them (or a relative/carer) all their current medication when they come into hospital and use them where appropriate and there has not been a change in treatment. This applies to planned and un-planned admissions where practicable. They remain the patient's property.

12.4.2 It is the responsibility of the nurse or midwife caring for the patient to ensure that patient's own drugs have been assessed and found to be suitable for use before they use them. Where a pharmacy medicines management technician service is available, the assessment will be carried out by the pharmacy technician. Where no pharmacy service is available, the check must be carried out by the nurse or midwife caring for the patient. The responsibilities for ensuring patient's own medicines are suitable for use remains the nurse's or midwife's caring for the patient.

12.4.3 The criteria for assessing patient's own drugs are suitable for use, are shown in appendix 6.

12.4.4 Pharmacy technicians will annotate the drug chart to show that patient's own drugs have been checked by stating the date of the check and the number of remaining tablets, capsules or other items.

12.4.5 If fewer than seven days' supply of patient's own drug remains, further supplies must be ordered from pharmacy without delay.

12.4.6 The person assessing the patient's own drugs must ask the patient's permission to remove any unsuitable items before disposing of them appropriately. For documenting removal of a patient's own medicines from their own home for disposal, this must be recorded on the following form.

12.4.7 Patient's own drugs held in safe custody is considered part of the deceased patient's estate. Where relatives request that medicines are disposed of following a death in hospital staff should follow waste management policy. However, should destruction not be requested the medicines should be returned to the patient's relatives with the advice to retain the drugs for 7 days before returning to them to their community pharmacy for safe disposal. This should be recorded in the patient health record.

12.4.8 Any medicines which might be relevant to the cause of death in Coroner cases must be handed to the Police.

12.4.9 Patient's own drugs must never be used for other patients or put into stock.

12.4.10 Patient's own drugs must only be administered if they have been prescribed.

12.5 Ordering of Inpatient Supplies

12.5.1 Those clinical areas where a pharmacy technician service is in place, any drug required that is not held in stock will be ordered by the pharmacy technician.

12.5.2 Wards with no pharmacy technician support or outside their visiting times, must request medicine supplies by the nurse or doctor caring for the patient. Supply requests must be placed via the Trust EPR.

12.5.3 For community hospitals/units, inpatient items should be requested in the same way via the EPR.

12.5.4 It is the responsibility of the nurse caring for the patient to ensure that inpatient items are requested from pharmacy in a timely manner and that any additional requirements (such as controlled drug order book) are sent with the request. Requisition forms should be sent as soon as practical, but before 16:00 Monday to Friday to ensure same-day delivery.

12.5.5 For community hospitals/units the inpatient supplies will be made on the following day and orders should be placed by 2pm to ensure next day delivery

12.5.6 Pharmacy will usually issue all medicines fully labelled for that patient so that they can be issued on discharge if required.

12.5.7 Some medicines are not usually dispensed with full instructions as they often change or stop prior to discharge:

- Antibiotics for short courses
- Prednisolone for variable dosing
- Other variable or reducing dose medicines
- Therapy involving dose titration
- Medicines not usually used after discharge

12.6 Ordering of Discharge Items

12.6.1 When a discharge medicine is required for supply, the items must be ordered from pharmacy.

12.6.2 Supply requests are made in the Trust EPR by ward staff (mostly nursing) undertaking the discharge supply check workflow. This is available for all inpatients who have had their discharge medicines reconciliation completed by a prescriber and allows the nurse to confirm which of the prescribed items are required for supply.

12.6.3 Ward staff undertaking supply checks must also inform the pharmacy of the need for a discharge supply. The pharmacy department operates a discharge bleep service Monday to Friday 08.30-17:00. After 17:00 during the week and at the weekend the need for supply of discharge medicines must be communicated to the pharmacy inpatient dispensary team

12.6.4 Ward stock must never be given to patients on discharge. Staff on the ward are not permitted to change, annotate or write labels for medicines for discharge.

12.6.5 Additional prescribing requirements apply for controlled drugs on discharge prescriptions. Further details can be found in section 11.9.

12.6.6 Blister packs require 24- and 48-hours' notice (Monday to Fridays) for Acute and Community wards respectively. These should be considered the minimum notice periods as these discharge supplies are complex to dispense and all aspects in the Complex Medication Needs Guideline must be satisfied.

12.6.7 Community wards/units must request discharge medicine supplies from the Pharmacy before 2pm to ensure next day delivery (Mon-Fri).

12.7 Supply of discharge or leave medication

12.7.1 It is the responsibility of the nurse or midwife caring for a patient to ensure that the patient is discharged with all of the appropriate medicines that they are of the appropriate quality e.g. labelled, in date etc. and that patient is educated particularly with respect to new / changed / stopped medicines.

12.7.2 Nurses and midwives should encourage patients to ask questions about their medicines and must either explain them to the patient/relative/carer. If they do not feel competent to do so they must refer back to the prescriber discharging the patient to clarify.

12.7.3 Medicines must only be issued to patients against a valid EPR After Visit Summary.

12.7.4 Final checking of discharge medicines must be done against the after-visit summary discharge documentation from the Trust EPR within 24 hours before discharge to ensure the accuracy of the supplied medicines.

12.7.5 Where supplies of medicines are required at the point of discharge clearly annotate the discharge prescription/summary with next to the required items.

12.7.6 Medicines must only be given to patients on discharge if they are appropriately labelled for the correct patient. These can either be medicines which are:

- Dispensed by pharmacy specifically for the named patient,
- Pre-labelled medicines packs kept as ward stock ('TTO pack' to-take-out),
- Patient's own medicines brought into hospital.

12.7.7 Under no circumstances can medicines be supplied to patients on discharge directly from unlabelled ward stock. No staff other than pharmacy staff are permitted to print/write labels for medicines with the exception of completing blank fields such as date and patient names to pre-dispensed TTO pack labels.

12.7.8 Under no circumstances can medicines be transferred from one container to another or the labels amended on the ward. Only pharmacy staff are permitted to make such changes.

12.7.9 The nurse or midwife must take particular care to ensure that the patient is only given those medicines that are labelled for them and no additional items are given to them from the patient's locker such as stock medicines.

12.7.10 When a supply of TTO-medicines are given from a ward or department to a patient there must be a record made in their EPR. TTO pack labels must be correctly completed according to the instructions on the prescription. The TTO pack label must not be amended by hand to meet the dose requirements. Refer to appendix 4.

12.7.11 When urgent discharge medications are required outside of pharmacy opening hours, the use of FP10 forms can be authorised for use by Site Management/CH Matron as described in section 6.5. The discharging doctor must consider the availability of medicines in community pharmacies before writing a FP10 prescription.

12.7.12 Discharge medicines must not be requested to be dispensed by a retail/community pharmacy without a FP10 prescription being supplied by the hospital, or be prescribed by the patient's GP.

12.7.13 Refer to the Complex Medication Needs Guideline for patients requiring medication reminder charts, blister packs and/or other compliance aids on discharge.

12.7.14 Patients/carers/relatives should be encouraged to return any medicines at home which are no longer needed e.g. those discontinued during admission to a community pharmacy for disposal following discharge.

12.7.15 Following death of a patient, the patients medicines are considered to be part of their estate. Relatives should be offered the safe disposal of the medicines, but they can take the medicines with them. In this case, relatives should be advised to safely dispose of the medicines at a community pharmacy.

12.8 Onward Care Management of Medicines

12.8.1 If a medicine is required to be administered following discharge and the patient is unable to do this themselves e.g. injections, arrangements must be made with appropriate nursing teams for this to be provided (e.g. via GP surgery).

12.9 Out of Hours Supply/Delivery

12.9.1 The following options are available if a medicine is required urgently outside of pharmacy opening hours:

- Emergency drug cupboard at Wonford hospital– this can be accessed by contacting the Site Practitioner.
- Other clinical areas – staff can search for medicines on the Trust network.
- Contacting the on-call pharmacist (via switchboard)
- Community Hospital – use FP10 to be dispensed by a local retail pharmacy

12.10 Delivery

12.10.1 Stock and inpatient items are placed in reusable pharmacy sealed delivery bags with tamper proof tabs and are usually delivered to the clinical area by a member of the pharmacy team. For remote sites such as community hospitals this will be via hospital transport in a sealed box/bag. Ward staff are also permitted to collect the bags from pharmacy, provided they wear their Trust identification badge. Some ward areas are required to sign for collections.

12.10.2 Medicines deliveries to the clinical area must be unpacked as soon as possible, to ensure patients receive any urgent medicines, fridge items are placed in the fridge and to ensure the security of the medicines is not compromised.

12.10.3 The ‘Air Tube’ system may be used to deliver urgent items to clinical areas on the Wonford site. CDs, fragile items, liquids, cytotoxic medicines or anything containing glass must not be delivered in this way. Returns to pharmacy must never be made using the air tube system.

12.10.4 In community hospitals/units, on receipt of drugs of diversion they must be signed into the drugs of diversion record book and locked in a designated cupboard.

12.11 Storage

12.11.1 It is the responsibility of the nurse or midwife in charge to ensure that all medicines are stored appropriately according to the manufacturer’s guidance and secure in locked medicines cupboards so that access is restricted. This also applies to the storage of patients’ own drugs.

12.11.2 The following types of cupboards may be used:

- Controlled drug cupboard.
- Medicine cupboard.
- Reagent cupboard.
- Locked medicine fridge.
- Locked medicines trolley.
- A designated locked/secure area for the storage of large volume fluids (e.g. intravenous, irrigation, etc). This should be a domestically clean area that is lockable.
- Patient’s own (bedside locker) drug cupboards.

12.11.3 To ensure medicine storage is secure, all cupboards must be secured to permanent fixtures. In the case of trolleys (including COWs and WOWs) they should be (locked and) secured to a wall when not in use. For POD lockers these may alternatively be fixed to a patient's bedside locker.

12.11.4 Medication must be stored in appropriate conditions, including temperature, most commonly:

- Refrigerated (2-8C)
- Room temperature / ambient (<25C)

12.11.5 Medicine fridges must be temperature monitored according to the guidelines on the Trust intranet here; which also provides advice on monitoring ambient medicine storage.

12.11.5 A limited range of medicines for life threatening emergencies may be kept on a resuscitation trolley so that they are available for immediate use.

12.11.6 Refer to 8.10.6 for medicines which may by kept outside of a locked cupboard for patients who are self-administering,

12.11.7 The keys for the medicine cupboards must be kept in the personal custody of a registered nurse, midwife or ODP.

12.11.8 All medicine cupboards and storage units being newly fitted in clinical areas must comply with both of the security standards detailed in BS2881:1989 (cupboard construction) and BS3681 (lock). (RPS, 2018) (NHSEI, 2021).

12.11.9 Keypads where a number is shared with multiple users are not suitable for medicine cupboards.

12.11.10 See section 11.5.2 for further information relating to CD storage requirements.

12.11.11 Medicine storage must be used solely for the storage of medicines. Internal medicines e.g. tablets, external medicines e.g. creams and injectable medicines should all be stored in separate distinct locations within the storage cupboards.

12.12 In-Use Shelf-Life for Medicines

12.12.1 For licensed medicines, the licence holder (manufacturer) must specify the storage conditions and any requirements as to the shelf-life in use. For example, reconstituted antibiotic liquids will have defined storage and in-use shelf-life information specified on the products labelling.

12.12.2 Other examples of medicines with in-use shelf lives include: *Oramorph* oral solution, dipyridamole MR capsules, GTN tablets, chlorpromazine syrup, *Gastrocote* liquid, risperidone liquid etc. Note, the product labelling/packaging should always be referred to for up-to-date advice regarding these requirements.

12.12.3 For **internal** (i.e. oral) **liquid** medicines, if an in-use expiry is not specified, they should be given a 6-month in-use expiry date. On opening, the date opened and the expiry should be clearly stated on the label. Stickers can be ordered for this purpose from EROS (product code 14517 rolls of 500).

Fig 12.12.3 Expiry Date Medicine Sticker

12.12.4 Medicines specifically prepared in pharmacy for individual patients or for a ward's use, will be allocated an expiry date by pharmacy, this should never be exceeded or changed.

12.13 Loss of Medicines

12.13.1 Anyone suspecting the loss or misappropriation of medicines from clinical areas must immediately inform the Senior Matron, Assistant Director of Nursing or Site Practitioner. The Chief Pharmacist must be informed the next working day. Senior staff might also decide to contact Trust security or the police. An incident form should be completed by senior staff using the *medication handling / storage incident category/subcategory under medication type.*

12.13.2 It is the responsibility of the nurse or midwife in charge of a clinical area to decide when a medicines loss should be reported to senior staff.

12.14 Loss of Medicine Keys

12.14.1 If Controlled Drug cupboard keys are missing or lost, additional requirements apply as described in 11.6.

12.14.2 The loss of a medicine key is a serious incident. If keys cannot be found then urgent efforts should be made to retrieve the keys as speedily as possible, for example by contacting nursing, midwifery or ODP staff who have just gone off duty and by thoroughly searching the clinical area. It must be reported as an incident on Datix.

12.14.3 For medicine keys other than controlled drug keys categorise the incident form using *medication handling / storage incident > missing / lost medicine key*. See 11.6 for how to report CD key loss on Datix.

12.14.4 If the key cannot be found shortly after the loss was discovered, and not more than six hours later, the nurse, midwife or ODP must immediately inform the Senior Matron, Assistant Director of Nursing or Site Practitioner. The Chief Pharmacist must be informed on the next working day. Senior staff might also decide to contact Trust security or the police. An incident form must be completed. Ensure patient care is not compromised by obtaining access to alternative supplies.

13. HOMECARE MEDICATION SUPPLY

13.1 General Principles

13.1.1 Homecare is defined as a service that delivers medicine supplies and associated care directly to a patient's choice of location. There are different levels of homecare services from simple dispensing and delivery of oral medicines (low tech) to more complex injectable aseptic preparations and the inclusion of nurse administration (high tech).

13.1.2 The Trust Chief Pharmacist is the accountable for the governance of medicines supplied via Homecare.

13.1.3 The Trust New Drugs Group approves homecare services and receives annual reports on homecare services from the Chief Pharmacist.

13.1.4 The use of homecare services does not alter the Trust's duty of care to patients. The Trust's clinical team retains responsibility for the clinical aspects of care.

13.2 Contracting, Service Level Agreements and Financial Governance

13.2.1 Homecare services must only be used where a Service Level Agreement (SLA) is in place. This is usually signed by the Lead Clinician for the service, the Chief Pharmacist and a representative for the Homecare Company.

13.2.2 The Trust has agreements with a limited number of companies to provide Homecare services. These companies have successfully tendered for these services and they have been vetted and approved as part of a regional contracting exercise.

13.2.3 Areas of responsibility should be clearly defined for all parties within the agreement, in either the specification or the service level agreement for the service. The quality of the service must be given high priority and reflected in the specification. The specification should include a set of key performance indicators and management information reports.

13.2.4 Homecare services should consider the impact of a range of financial parameters e.g. NHS medicine contracts (local, regional and national), national tariffs (PBR status of medicine, activity tariff), local service costs to the provider and VAT.

13.2.5 Each prescription should be accompanied by an official order generated through the hospital pharmacy computer system. Invoices should be matched against this and the proof of delivery.

13.3 Patient Consent

13.3.1 Homecare may not be suitable for all patients or therapies and the decision to opt for this course of treatment must be part of a multidisciplinary approach involving the patient, the responsible clinician, the pharmacy service and where appropriate service commissioners and primary care. An assessment of suitability for homecare must be undertaken which may include an assessment of the home environment, availability of carers and impact of any homecare service on them, presence of disability and support, and medication concordance.

13.3.2 A patient must fully understand the benefits and risks of a homecare service before providing consent. Patients preferring to receive care and supplies direct from the hospital despite the existence of homecare services should not be prevented from doing so. A patient must provide formal written consent to use a homecare service arrangement by completing and signing a patient registration form in addition to the usual treatment consent procedures.

13.3.3 A patient's GP must be informed when medicine Homecare services have been agreed.

13.4 Approval Process for Homecare Supply

13.4.1 All requests for homecare services must be sent to the Chief Pharmacist.

13.4.2 The following stakeholders must be consulted prior to introducing a new homecare service: Patients and Carers, Consultants, Nurses/Specialist Nurses, Chief Pharmacist and Pharmacy Procurement, Divisional or Service Managers, Accountants and Commissioners.

13.4.3 All Homecare services must follow the normal medicines governance procedures within the Trust.

13.4.4 Standard Operating Procedures (SOPs) should be prepared to govern the operational management of each homecare service.

13.4.5 Regular review meetings must be held between the service provider, the clinical service and pharmacy to review the performance of the service against the requirements set out in the SLA.

14. PRIVATE PATIENTS AND PAYMENT-BY-RESULT EXCLUSIONS

14.1 Private Patients, Top-up/Co-Payment Patients

14.1.1 The pharmacy department supplies medicines for private patient and for 'top-up' (co-payment) patients. Any request for the pharmacy department to supply medicines for private use must be made by a consultant and should be clearly marked as 'private' or 'private top-up'. NHS stock must not, under any circumstances, be used for private work or private supplies.

14.1.2 Refer to the Trust Private Patients Policy for further information.

14.2 Exclusions from 'payment-by-result'

14.2.1 There are a number of high cost drugs that are excluded from the 'Payments by Results' (PbR) tariff. The Trust must request payment for the use of these high cost drugs outside of the usual tariff. In order to ensure that all issues of these drugs can be identified, all excluded PbR drugs must be prescribed on a named patient basis allowing a clear route for reimbursement. In exceptional cases where this is not possible (e.g. vials used for multiple patients) a separate agreement must be arranged with the Pharmacy Operations and Business Manager.

15. DISPOSAL OF MEDICINES

15.1 Detailed information about waste management in the Trust can be found in the Waste Management Policy on the intranet.

15.2 The safe and legal disposal of CDs is described in section 11.15 – 11.16.

15.3 Return of Medicines to Pharmacy

15.3.1 Medicines no longer needed in a clinical area or out-of-date medicines must be returned to pharmacy for disposal. These items must be placed in the 'Return to Pharmacy' tray and will be collected by pharmacy staff or in community hospitals returned in Pharmacy department delivery boxes.

15.3.2 Cytotoxic and cytostatic waste must not be returned to pharmacy, but disposed of in sharps bins with purple lids.

15.4 Disposal of Medicines in Clinical Areas

15.4.1 Medicines and equipment contaminated with medicines can be disposed of in clinical areas using the sharps bins with yellow lids.

15.4.2 Cytotoxic and cytostatic waste must be disposed of in sharps bins with purple lids. These medicines are identified on the ward stock list with a 'C' and the tray in the medicine cupboard is clearly identified with a cytotoxic sticker.

16. DEFECTIVE MEDICINES

16.1 The Trust is required to comply with strict procedures for the notification of defects in medicinal products. Defects may involve, for example, inadequate or incorrect labelling, ineffective packaging, contamination or discolouration of the medicine and broken tablets. Anyone discovering a defective medicine must contact pharmacy immediately. If the defect is of a potentially serious nature the on-call pharmacist should be contacted.

16.2 If a potentially defective medicine has been given to a patient, the patient's consultant should also be informed.

16.3 The defective item and any associated equipment must be retained and sent to pharmacy.

16.4 An incident form must be completed.

16.5 Where pharmacy is notified of a defective medicine from an external organisation (e.g. the Medicines and Healthcare Products Regulatory Authority - MHRA), pharmacy staff will instigate the 'product recall procedure' and ensure the removal of any affected medicines from Trust premises.

17. REPORTING ADVERSE REACTIONS

17.1 Healthcare professionals are encouraged to report any suspected adverse reactions to medicines that patients might have experienced. This is particularly important for new medicines (marked in the BNF with a black triangle), but reporting is encouraged for any adverse reactions.

17.2 Adverse reactions must be recorded in the patient's notes and communicated to GP's e.g. on a discharge summary or other relevant document.

17.4 Adverse reactions can also be reported on the MHRA website or using the yellow card scheme in the back of the BNF. Reports can also be made by contacting the pharmacy medicines information service.

17.5 Datix can be also used to record significant medication adverse drug reactions as well as suspected allergies.

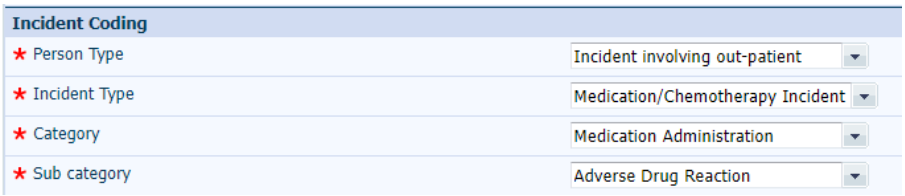

Fig 17.4 Datix reporting categories to be used for adverse drug reaction reporting

18. REPORTING MEDICINES RELATED INCIDENTS

18.1 The Trust encourages all staff to report incidents according to the Trust Incident Reporting Policy, including medicines related incidents and 'near-miss' medication incidents. This includes prescribing, dispensing or administration errors or any incident related to the safe and legal use of medicines.

18.2 The incident form should specify clearly the medicines involved, the location, the nature of the incident and, if a patient was involved, if the patient came to any harm.

18.3 The reporting of incidents can help the Trust learn from mistakes and ensure that similar errors are avoided in future.

18.4 Where prescribing errors are detected, every effort should be made to inform the prescriber of the error as well as completing an incident form. Serious prescribing errors, even if the medicine has not been administered to the patient, must also be reported to the patient's consultant and the nurse or midwife in charge of the clinical area and a record should be made in the patient's notes. Where appropriate, serious or potentially serious prescribing errors should be escalated to the relevant Associate Medical Director.

18.5 Dispensing errors can either originate from pharmacy or from clinical areas (e.g. where incorrect discharge medication was given to a patient). The incident form should clearly state where the error occurred. Dispensing errors from pharmacy should be reported immediately to the pharmacy department as well as completing an incident form.

18.6 Administration errors include: wrong patient, wrong medicine, wrong dose, wrong route or missed/delayed doses.

18.7 Where medication errors occur the form shown in appendix 10 should be completed to facilitate personal reflection and learning from the incident. This is irrespective of type of error e.g. prescribing or administration and profession of the member of staff involved to ensure a standardised approach to medication errors. Serious or potentially serious errors should also be reported to the patient's consultant.

18.8 More information on the reporting and investigation of incidents can be found on the Safety, Risk and Patient Experience section of Trust intranet here.

19. ARCHIVING ARRANGEMENTS

The original of this policy, will remain with the author Deputy Chief Pharmacist, Pharmacy. An electronic copy will be maintained on the Trust Intranet, P – Policies – M – Medicines Management. Archived electronic copies will be stored on the Trust's "archived policies" shared drive, and will be held indefinitely. A paper copy (where one exists) will be retained for 10 years.

20. MONITORING COMPLIANCE & EFFECTIVENESS PROCESS OF THE POLICY

20.1 In order to monitor compliance with this policy, the auditable standards will be monitored as follows:

What areas need to be monitored?	How will this be evidenced?	Where will this be reported and by whom?
Medicines must be prescribed accurately and safely	Annual pharmacy audit report to Medicines Management on errors found on drugs chart by pharmacists	MMG – Clinical Pharmacy Manager / Medication Safety Pharmacist
Medication incidents and must be reported in line with the Trust incident reporting policy via Datix	Quarterly report to the Medicines Management Group of Medication incidents	MMG – Medication Safety Pharmacist
Medication incidents must be appropriately graded and investigated and any actions identified must be completed	Quarterly report to the Medicines Management Group of Medication incidents	
Compliance with safe handling of medicines requirements.	Annual audit report from Care Quality Assessment Tool (CQAT) to Medicines Management Group	
Controlled Drug related incidents	Quarterly CDLIN report	MMG – Medication Safety Pharmacist

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APPENDIX 1: MEDICINES THAT MUST BE PRESCRIBED BY BRAND NAME

Note - This list is not exclusive and branded products available on the market might change at any time.

Amphotericin
Intravenous amphotericin is available in different formulations. Only the lipid formulation AmBisome® is available for general prescribing. The non-lipid deoxycholate complex (Fungizone®) can only be obtained by authorisation of the pharmacist in charge.

Antiepileptic Medicines
The MHRA has offered guidance on the risk associated with switching manufacturers of this group of drugs in 2013 and can be found here.

Valproate is available as *valproic acid* (also known as semisodium valproate) which is not interchangeable with *sodium valproate*.

Ciclosporin
Because of differences in bioavailability, the brand of oral ciclosporin should be specified by the prescriber.

Lithium
Priadel®, Liskonum®, Camcolit®

Nifedipine and Diltiazem
Many different modified release preparations are available and this should be prescribed by brand name.

Tacrolimus
Patient should stay on the product they were started on. None of the different tacrolimus brands are interchangeable.

Theophylline and Aminophylline
The rate of absorption from modified release preparations can vary between brands. Patients should be maintained on one brand.

https://improvement.nhs.uk/resources/patient-safety-alerts/

APPENDIX 2: GUIDANCE FOR MEDICINES RECONCILIATION

Source	Advantage	Common problems	Caution
Patient / Carer	Patient/Carer can explain what medicines they actually take, including over-the-counter medicines and herbal medicines	Confused patients	Patient might sound confident, but does not actually understand their medicines
Patient's Own Medication	Clearly shows what was dispensed	Patient not actually taking the medicines as dispensed. Not all medicines brought into hospital	Carefully check that drug belongs to patient
Patient's Own Compliance aids (e.g. blister packs)	Clearly shows what was dispensed, timing of medicines and some insight into compliance.	Not all medicines are suitable for inclusion in a blister pack e.g. PRN, unstable for inclusion, non-oral meds.	Check date and if there are other medicines taken that are not in the pack.
Patient's medical alert bracelet	Highlights a particular important allergy status or condition.	Limited to a single condition or allergy	Carefully check that bracelet belongs to patient (often is not named)
GP repeat prescription slip	Shows repeat medication	Might not show acute medication	Check date last dispensed – some repeat slips show old drugs no longer used.
GP fax/print-out	Most up-to-date list, usually includes allergies	Not available out of hours	
Care home (MAR) Sheet copy OR medicines reminder chart	Up-to-date list of medicines actually given to patient in care home	Drug might be discontinued recently, but still shows on MAR Sheet	Check drug currently given
Previous Hospital Records Discharge summaries Summary Care Record (SCR)	Usually available in hospital notes or computer records	Medication has been changed since last admission	Use with caution if more than 3-4 weeks old
Community pharmacy	Accurate record of what was dispensed	Might not include all drugs patient takes. Patient might not take drugs as labelled	Consider patient confidentiality and consent before contacting pharmacy

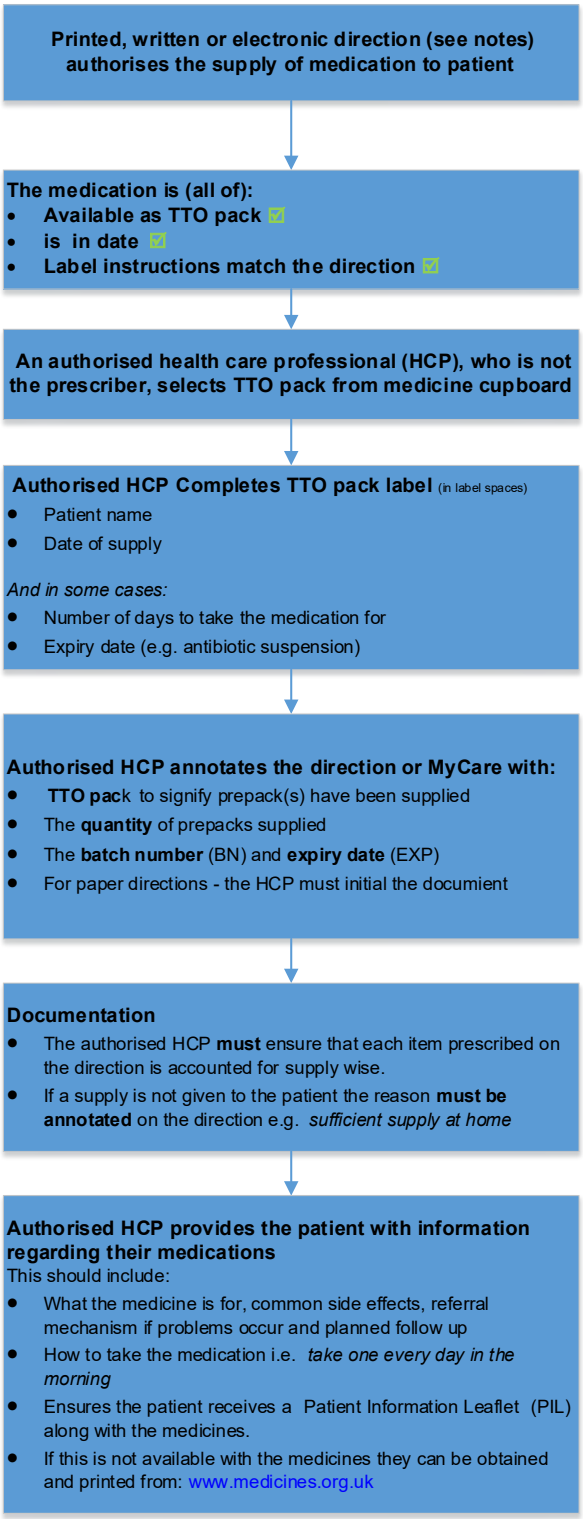
It is good practice to use two sources of information, especially if one source is less reliable or not current (e.g. hospital records). Patients should be prompted to also mention creams, ointments, eye drops, inhalers and vitamins or supplements as they might otherwise be missed. Some medicines require further details prior to prescribing on the inpatient drug chart:

- Warfarin (and other VKAs): State patient's usual dose (if known) and recent INR result(s)
- Dabigatran, rivaroxaban, apixaban and edoxaban: These new fixed-dose oral anticoagulants should be prescribed under the 'anticoagulation' section of the main drug chart.
- Insulin: State exact type of insulin and usual administration device.
- Inhalers: State name, strength and usual device (including spacers).
- Once/twice weekly drugs (e.g. bisphosphonates): state day of week usually taken.
- Oral chemotherapy: Obtain specialist review and DO NOT prescribe.

APPENDIX 3: DOUBLE CHECKING REQUIREMENTS

Activity	Double check required?	Authorised person to double check	Type of check
Controlled Drugs			
- Receipt of CDs in clinical area	Yes	Any competent person	Witness and sign in CD Record Book
- Administration of CDs	Yes	Any competent person	Full check of the entire administration process and sign CD Record Book
- Administration of Oramorph 10mg in 5 ml Tramadol Pregabalin or Gabapentin	No		
- Destruction of small amounts of CDs in clinical area (e.g. part ampoules)	Yes	Any competent person	Witness and sign in CD Record Book
- CD Ward Stock Checks	Preferred		
Injectable medicines administration	See Injectable Medicines Policy		
Systemic Anti-Cancer Therapy (SACT)	Yes	As per Policy for Safe Use of Systemic Anti-Cancer Therapies (SACT) in the Treatment of Cancer	
Intrathecal administration of cytotoxic drugs	Yes	As per Intrathecal policy	
Administration of medicines to neonates	Yes	Any competent person	Full check of entire administration process

APPENDIX 4: TTO-PACK SUPPLY PROCEDURE



Notes

What is a direction?

- A discharge note or AVS OR outpatient prescription in the My Care EPR system written by a Trust prescriber.
- Patient group direction (PGD)

What is a prepack (TTO pack)?

- A medicine with a pharmacy dispensing label attached that includes details of the drug, form, strength, quantity, intended dosage and any relevant BNF warning labels.
- Under no circumstances must the dosage instructions be changed
- Only the patient name and date of supply (and if appropriate number of days of treatment and expiry date) must be written on the label

Who can be an authorised HCP?

- All Health Care Professionals who are registered with their professional body and are competent in managing medicines.

They must:

- Have 6 months experience working in the clinical area, and have successfully completed a period of preceptorship or induction.
- Maintain continuing professional development pertaining to their area of practice (including written directions) and in line with current evidence.
- Has read and understand the process outlined in this appendix.
- Proven competent to administer drugs against a prescription.
- Be named on the official Ward/ Unit list of staff authorised to supply PP drugs.

Note - individuals may appear on more than once on the list

Only Professionally Registered Staff from the following groups may supply TTO packs to patients: Pre-requisite for

- Nurses, Midwives or Nursing Associates
- Pharmacist / Pharmacy Technician
- Podiatrists
- Paramedics
- Doctors
- Non-medical prescribers
- Any registered professional listed in a Trust approved PGD.

Storage of the direction

- Discharge documentation (notes and AVS) and outpatient orders/prescriptions are an integral park of the MyCare EPR system.
- PGD - supply to be recorded as outlined in the PGD

APPENDIX 5: ADMINISTRATION PROCEDURE FOR CD'S IN HOSPITAL SETTINGS
(excl. Theatres)

Two practitioners must be involved in the administration of CDs. One of them is the registered professional who is clinically responsible for the administration of the medicine. The **other practitioner acts as the witness**, but is not clinically responsible and does not need to be a registered practitioner.

Where CDs are administered by intravenous infusion or infused by other routes, or where complex calculations are required, two registered practitioners must be involved in the administration process and **both practitioners are independently accountable** for the administration. Injectable medicines can only be administered staff who have completed the Trust injectable medicine training.

Equipment required:

1) Medication Administration Record 2) CD Key 3) CD Record Book

Additional equipment optionally required:

1) Injectable Medicine Reference (e.g. Medusa) 2) Calculator
3) Diluents 4) Infusion pumps or syringe drivers

The following steps must be followed by both practitioners

In the preparation area:

1) Identify the CD required from the prescription
2) Check the appropriateness of the prescription details, including drug, dose, route and time/date of administration required and check the prescription is signed and valid.
3) Select the CD required from the appropriate CD storage location
4) Remove the appropriate quantity required from the outer box
5) Check the selected CD outer box and inner packaging (e.g. vial, ampoule, tablet strip, patch) against the prescription to ensure it is the correct drug, form and strength
6) Check the expiry date
7) Select the correct page in the CD Ward Record Book
8) Sign-out the required quantity of the CD Ward Record Book
9) Both practitioners must sign CD Ward Record Book to confirm the quantity booked out
10) Stock check the drug to confirm remaining quantity of drug matches that in CD Record Book
11) Return remaining stock to the CD cupboard

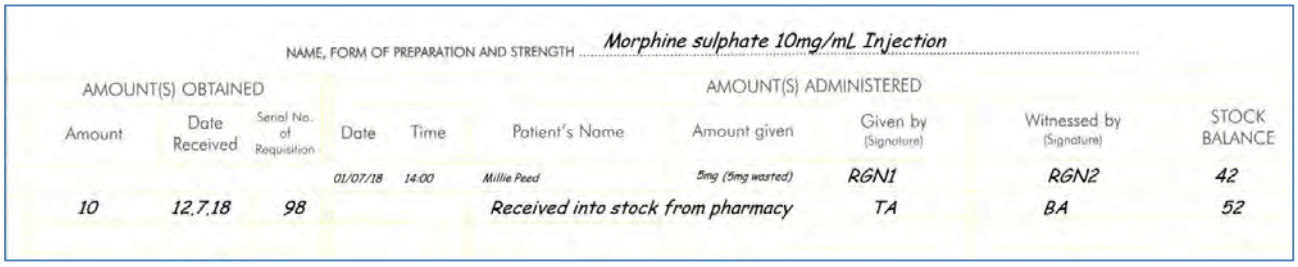
At the patient bed-side:

12) Take the CD to the patient
13) Both practitioners to positively identify the patient as per Trust Policy:
14) Both practitioners witness administration (as much as practically possible) and sign for the administration on the drug chart
15) Where infusion devices are involved, both registered practitioners must check the infusion settings on the device.

Where there are wasted CDs (e.g. use of part vials or ampoules when preparing an infusion):

1) The amount used must be clearly stated in the CD Record Book.
2) The amount wasted must also be clearly stated in the CD Record Book as a separate entry.
3) Both practitioners must sign to confirm the amount used and the amount wasted.
4) Waste CDs MUST be fully discharged from syringe or bag into a sharps bin so that they are irretrievable.

The entry in the CD Record Book must contain the following information:



NAME, FORM OF PREPARATION AND STRENGTH *Morphine sulphate 10mg/mL Injection*

AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED						
Amount	Date Received	Serial No. of Requisition	Date	Time	Patient's Name	Amount given	Given by (Signature)	Witnessed by (Signature)	STOCK BALANCE
			01/07/18	14:00	Millie Peed	5mg (5mg wasted)	RGN1	RGN2	42
10	12.7.18	98			Received into stock from pharmacy		TA	BA	52

APPENDIX 6: CRITERIA FOR THE ASSESSMENT OF PATIENTS' OWN DRUGS

	Use:	Do not use:
Type of medicine	Tablets Capsules Inhalers Creams/Ointments Liquids in original containers	Liquids in amber bottles Eye drops/ointments open longer than 4 weeks Medicines in trays and compliance packs
Appearance	Clean and dry	Mixed tablets/capsules Dirty label/box Broken tablets
Age of medicine	Loose tablets within 6 months of dispensing Commercially blister-packed medicines within the expiry date	Out of date items
Labelling	Correct patient name Correct instruction	Wrong patient No or incorrect instructions Handwritten or amended labels

APPENDIX 7: COVERT MEDICATION BALANCE SHEET TOOL

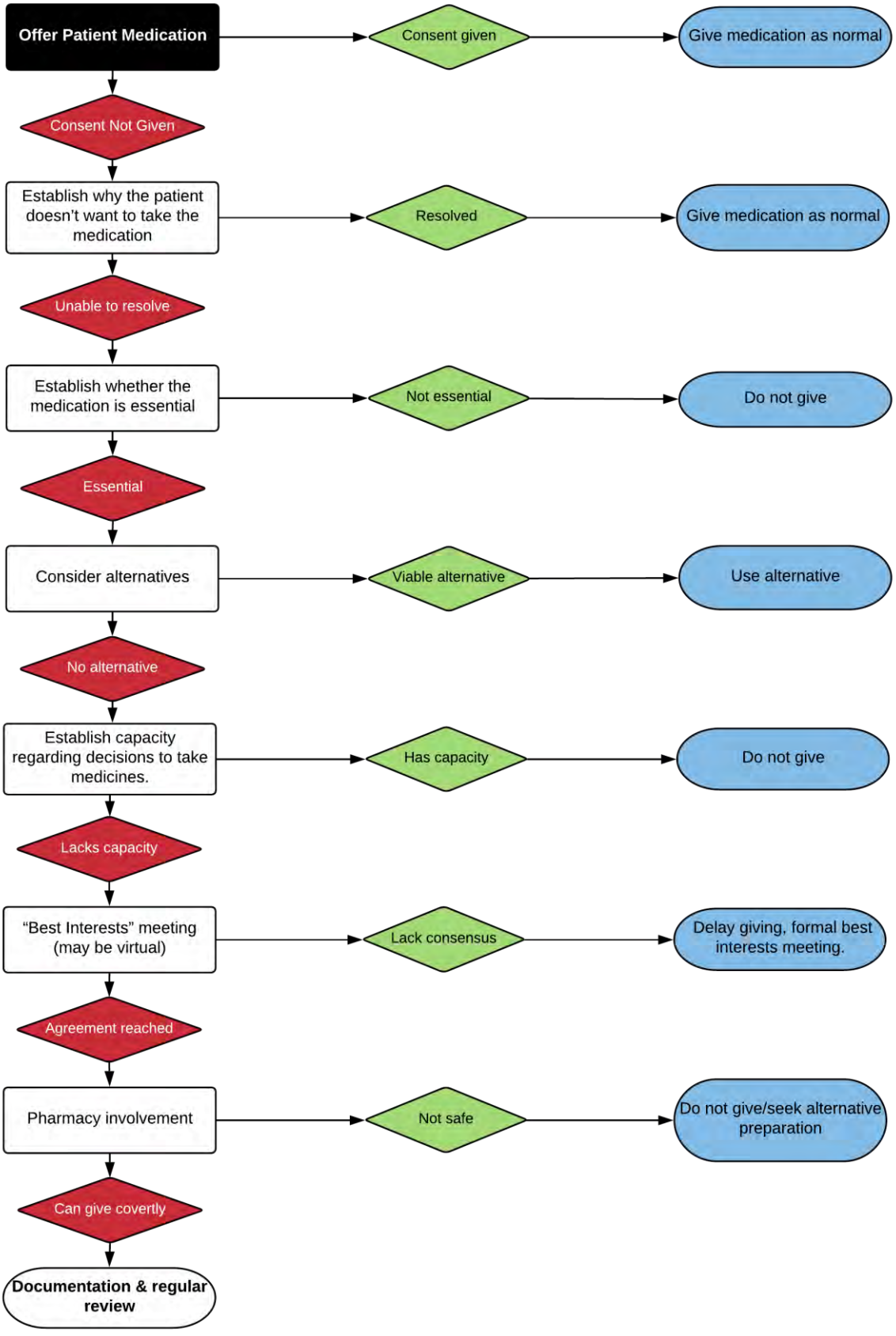
This balance sheet can be used as a tool to assist decision making when covert medication is being considered, especially where there may be lack of consensus within the team.

Questions for consideration by the team:

- How urgent is the medical need?
- Will the medicine cause side effects that are unacceptable to the patient?
- What are the changes of the medication successfully treating the condition?
- What were the patient's prior beliefs about medication?
- Will it affect the therapeutic relationship?
- Will it affect the level of trust that the patient has in the team?
- Is the condition likely to improve without medication?
- Have alternatives been tried?
- Is capacity likely to return?

Pros of giving medicines covertly	Cons of giving medicines covertly

APPENDIX 8: FLOWCHART FOR THE USE OF COVERT MEDICATION



APPENDIX 9: PERMITTED SCOPE OF MEDICATION PRACTICE – NURSING ASSOCIATES AND UNREGISTERED STAFF

Administration Related Task		Unregistered Staff (skilled & competent)	Nursing Associate (Registered)	Registered Nurse
Use Patient Group Directions (PGDs)		✘*	✘*	✓*
Intramuscular (IM) injections		✘+	✓*#	✓
Oral, topical and inhalation routes		✘+	✓*#	✓
Administer and monitor medications using enteral equipment e.g. nasogastric or RIG or PEG tubes.		✘+	✓◊	✓
Administer of Subcutaneous (SC) Injections		✘+¥	✓#*	✓
INTRAVENOUS	Administer ready to use products	✘+	✓◊	✓◊
	Via volumetric pumps	✘+	✓◊	✓◊
	Prepare IVs (e.g. reconstitute)	✘+	✓◊	✓◊
	Prepare IV Infusions (add drug to bulk fluid)	✘+	✓◊	✓◊
	Via Syringe Drivers	✘	✓◊	✓◊
Intrathecal		✘	✘	✘
Hold Medication Cupboard/Fridge Keys (not CD)		✘+	✓◊	✓
Hold CD keys		✘	✓◊	✓
Second Check of CD - balance check		✓#	✓◊	✓
Second Check of CD - administration check (not injectables)		✘+	✓◊	✓
Second check of complex injectable medicines (calculation, equipment and administration) including controlled drug IVs		✘	✓◊	✓
Flushing cannulas after cannula insertion		✘+	✓◊	✓
Discretionary medicines		✘	✓◊ (but not PGDs)	✓ (via PGD or SOP/Policy)
Administration or management of medicines in isolation from registered staff/nurses		✘+	✓◊	n/a
Preparation and supply of medicines discharge or transfer		✘	✓◊	✓

* Based on legislation, national guidance, or Nursing Associate Curriculum Framework.

Where competent.

◊ Where competent AND has completed any necessary Trust approved [competency] training.

¥ Delegated administration (in community settings) by a registered nurse following Trust SOP / Policy.

+ Trust process to permit unregistered staff to administer named medicinal products by exceptional cases/scenarios (refer to one of the Administration of Medicines by Non-registered Staff Policies for hospital and non-hospital settings).

APPENDIX 10: MEDICATION ERROR REVIEW FORM (link to electronic form on HUB)

Name(s) of staff involved in incident:	Ward/Specialty where incident occurred:
Datix reference (Datix must be completed):	DWI-
DETAILS OF ERROR/INCIDENT	
What was prescribed (drug, dose, route, time) e.g. incorrect dispensing, administration	
What was given/omitted (drug, dose, route, time)	
Effect on patient: (remember duty of candour)	
Was any intervention required?	
Why do you think the error/incident happened?	
Where any other staff consulted about the medicine prior to the error/incident? (e.g. doctor, pharmacist, nurse):	
Any support required for member of staff involved?	Occupational Health referral: Yes ☐ No ☐
List actions agreed between member staff involved in error/incident and manager: (e.g. training; supervision; reflection, …)	
I agree that this is an accurate reflection of the error/incident and I agree with the actions above: Member of staff involved: Sign:…… Date: ……	I agree that this is an accurate reflection of the error/incident and I agree with the actions above: Manager/Supervisor/Clinical Lead: Sign: …… Date: ……

APPENDIX 11: MIDWIVES EXEMPTION MEDICATION LIST

(note not all P or GSL medicines are explicitly listed – see section 10 for further information).

#	Drug	Use	Route	NMC Advice for professional practice	Method of supply or administration	Recommended Dosage Instructions	Legal Class
1	Anusol cream	Adult	Topical	For the treatment of haemorrhoids in the antenatal and postnatal period.	Midwives exemption to supply tube for patient to apply themselves or can apply for patient.	Apply night and morning and after a bowel movement. Use for a maximum of 7 days	P
2	Anusol Suppository	Adult	PR	For the treatment of haemorrhoids in the antenatal and postnatal period.	Midwives exemption to supply for patient to insert themselves or can administer for the patient.	1 suppository night and morning and after a bowel movement. Use for a maximum of 7 days.	P
3	Adrenaline 1:1000 Injection	Adult	IM	For use in anaphylaxis only	Midwives exemption to administer.	500micrograms (0.5ml). Can be repeated after 5 mins if no improvement.	POM
4	Anti-D immunoglobulin Injection	Adult	IM	For antenatal and postnatal use to protect against haemolytic disease of the new-born.	Midwives exemption to administer.	1500units at 28 weeks gestation 500units post delivery In cases of a de-sensitising event in the antenatal period or a very large feto-maternal haemorrhage: refer to medical staff.	POM
5	Carboprost Injection	Adult	IM	For the treatment of postpartum haemorrhage	Midwives exemption to administer	250 micrograms repeated if necessary after 15 mins. Maximum of 5 doses.	POM
6	Clotrimazole cream 1%	Adult	Topical	For the treatment of thrush	Midwives exemption to supply tube for patient to apply themselves or can apply for patient.		P
7	Clotrimazole Vaginal tablet 200mg	Adult	PV	For the treatment of thrush	Midwives exemption to supply box for patient to insert themselves or can administer to patient.	ONE pessary at night for 3 consecutive nights	P
8	Clotrimazole Vaginal tablet 500mg	Adult	PV	For the treatment of thrush	Midwives exemption to supply box for patient to insert themselves or can administer to patient.	ONE pessary at night as a single dose.	P

9	Cyclizine tartrate Injection	Adult	IM	For the management of actual or potential nausea and vomiting	Midwives exemption to administer	50mg up to 3 doses a day	POM
10	Diamorphine Injection	Adult	IM	For pain relief in labour	Midwives exemption to administer **May NOT be administered by a Student Midwife**	5mg. A maximum of 2 doses at least 3 hrs apart.	**CD** POM
11	Diclofenac Tablets	Adult	Oral	For postpartum, pain relief up to 48 hours after birth.	Midwives exemption to administer	150 mg daily in 2 or 3 divided doses.	POM
12	Diclofenac Suppositories	Adult	PR	For postpartum, pain relief up to 48 hours after birth.	Midwives exemption to administer	150 mg daily in 2 or 3 divided doses.	POM
13	Entonox Medical Gas	Adult	Inhalation	For analgesia in labour	Midwives exemption		P
14	Ergometrine Maleate Injection	Adult	IM/IV	For the treatment of postpartum haemorrhage. IV use with caution –risk of hypertension	Midwives exemption	0.5mg.	POM
15	Ferrous sulphate tablets	Adult	Oral	For the treatment of anaemia	Midwives exemption to supply box for patient to self-administer	200mg. 2-3 times per day	POM
16	Gelofusine infusion	Adult	IV	For maternal resuscitation	Midwives exemption	500ml-1000ml	POM
17	Glucose gel 40%	Neonate	Oral (mucosa)	For the EMERGENCY treatment of hypoglycaemia. (refer to HUB guideline here)	Midwives exemption to administer. To inner cheek and massage gel into the mucosa using latex-free gloves.	Weight of Baby (kg) / Volume of Gel (mL) 1.5 – 1.99 / 1.0 2.0 – 2.99 / 1.5 3.0 – 3.99 / 2.0 4.0 – 4.99 / 2.5 5.0 – 5.99 / 3.0	Food Supple-ment (i.e. .not a medicine)
18	Hartmann's solution Infusion	Adult	IV	For maternal resuscitation	Midwives exemption	1000ml	POM
19	Hepatitis B Vaccine	Neonate	IM	For use in protection against Hepatitis B	Midwives exemption	10 micrograms	POM
20	Hepatitis B Immuno-globulin	Neonate	IM	For use in protection against Hepatitis B	Midwives exemption	200 units	POM
21	Ibuprofen	Adult	PO	Analgesia	Midwives exemption	200-400mg TDS	P
22	Lidocaine injection	Adult	SC/IM	For perineal infiltration	Midwives exemption	5-20 mls 1.0%	POM

23	Lidocaine Hydrochloride injection	Adult	SC/IM	For perineal infiltration	Midwives exemption	5-20 mls 1.0%	POM
24	Miconazole Gel	Neonate	Oral	Oral thrush	Midwives exemption	Smear small amount on affected area with a clean bud 4 times daily for 5-7 days (continue for 48hrs after lesions healed).	POM
25	Morphine injection	Adult	IM	Pain relief in labour	Midwives exemption **May NOT be administered by a student midwife.**	5mg. A maximum of 2 doses at least 3 hrs apart.	**CD** POM
26	Naloxone Hydrochloride Injection	Adult	IM	For reversal of respiratory depression resulting from opioid administration	Midwives exemption	100-200 micrograms. Inform medical staff if you have had to give as has short half-life and repeated doses may be required.	POM
27	Naloxone Hydrochloride Injection*	Neonate	IM	For reversal of respiratory depression resulting from opioid administration to the mother	Midwives exemption	200 micrograms ***CAUTION** – see Management of pregnant substance misusing women guideline	POM
28	Nystatin	Neonate	Oral	Oral thrush	Midwives exemption	1ml 4 times per day (after feed), usually for 7 days (Continue for 48hrs after lesions have resolved).	POM
29	Oxytocin injection (natural & synthetic)	Adult	IM/IV	For the active management of the third stage of labour and the treatment of Postpartum haemorrhage	Midwives exemption	Dosage dependant on preparation and reasons for usage. Please see Policy	POM
30	Paracetamol tablets	Adult	Oral	For analgesia	Midwives exemption	500mg -1g 4 hrly. Max dosage of 4g/ 24hrs.	GSL P POM
31	Peppermint water	Adult	Oral	For the treatment of indigestion	Midwives exemption	10 mls diluted with 10 mls of water	GSL
33	Peptac // Gaviscon Mixture	Adult	Oral	For the treatment of heartburn	On Trust approved PGD	10-20 mls *Contains GSL ingredients but only licensed for sale from a pharmacy only.	P*

33	Pethidine Hydrochloride Injection	Adult	IM	For pain relief in labour	Midwives exemption **May NOT be administered by a student midwife**	50-100mg. A maximum of 2 doses at least 3 hrs apart.	**CD** POM
34	Phytomenadione	Neonate	Oral	Prophylactic use to prevent Vit K deficiency bleeding	Midwives exemption	Initial dose 2mg to be given before 4hrs of age. Follow up dosage regime varies according to method of feeding. Please refer to administration chart.	POM
35	Phytomenadione injection	Neonate	IM	Prophylactic use to prevent Vit K deficiency bleeding	Midwives exemption	Dose dependant on baby's weight. Please refer to administration chart.	POM
36	Prochlorperazine injection	Adult	IM	For management of actual or potential nausea and vomiting	Midwives exemption	at least 6hrs apart.	POM
37	Simple linctus	Adult	Oral	For the treatment of a cough	Midwives exemption	5 ml	GSL
38	Sodium Chloride 0.9% injection	Adult	IV	For maternal resuscitation and IV Flush	Midwives exemption	3-5 mls for an IV flush. 500-1000 mils for maternal resuscitation	POM
39	Strepsils	Adult	Oral	For the treatment of a sore throat	Midwives exemption to supply strip for patient to self-administer.		GSL

APPENDIX 12: COMMUNICATION PLAN

Royal Devon and Exeter NHS
NHS Foundation Trust

The following action plan will be enacted once the document has gone live.

Staff groups that need to have knowledge of the strategy/policy	Pharmacy Staff Prescribers Nurses Midwives
Key changes if a revised policy	New template, expanded definitions, including PMAR, allergy prescriber responsibilities (6.4.4), approval via MMG for Trustwide PMARs; discharge summary prescribing clarity, outpatient prescribing section expanded. Multiple additions in order to assimilate community practices where different. FP10 prescription form type clarified and NMP FP10 access process updated. Reference to *nursing associate's* new professional group added and scope (appendix 9). New TTO-pack procedure (appendix 4), updated CD cupboard and lock construction requirements (British Standards).
The key objectives	Sets out the standards and principles on all aspects of medicines handling, from supply and storage, to prescribing, administration and disposal of medicines in line with the relevant legislation for medicines. States standards and principles on all aspects of handling of Controlled Drugs in line with the relevant legislation for Controlled Drugs.
How new staff will be made aware of the policy and manager action	Email Cascade Notice on Intranet
Specific Issues to be raised with staff	Locating midwife exemptions – this has been relocated policy wise into the Medicines Management Policy.
Training available to staff	Support available for clinical/ward areas from the relevant specialist pharmacist, or deputy chief pharmacist.
Any other requirements	Nil
Issues following Equality Impact Assessment (if any)	None
Location of hard / electronic copy of the document etc.	The original of this policy, will remain with the author Deputy Chief Pharmacist, Pharmacy. An electronic copy will be maintained on the Trust Intranet, P – Policies – M – Medicines Management. Archived electronic copies will be stored on the Trust's "archived policies" shared drive, and will be held indefinitely. A paper copy (where one exists) will be retained for 10 years. 'Pharmacy Administration' Shared Drive

APPENDIX 13: EQUALITY IMPACT ASSESSMENT TOOL

Name of document	Medicines Management Policy
Division/Directorate and service area	Trust wide
Name, job title and contact details of person completing the assessment	Joe Maguire, Medication Safety and Deputy Chief Pharmacist, 402427
Date completed:	December 2021

The purpose of this tool is to:

- **Identify** the equality issues related to a policy, procedure or strategy
- **Summarise the work done** during the development of the document to reduce negative impacts or to maximise benefit
- **Highlight unresolved issues** with the policy/procedure/strategy which cannot be removed but which will be monitored, and set out how this will be done.

1. **What is the main purpose of this policy / plan / service?**
   Govern unlicensed medicines

2. **Who does it affect?**
   Carers ☒ Staff ☒ Patients ☒ Other (please specify)

3. **Who might the policy have a 'differential' effect on, considering the "protected characteristics" below?** (By *differential* we mean, for example that a policy may have a noticeably more positive or negative impact on a particular group e.g. it may be more beneficial for women than for men).

Protected characteristic	Relevant	Not relevant
Age	☒	☐
Disability	☒	☐
Sex - including: Transgender, and Pregnancy / Maternity	☒	☐
Race	☐	☒
Religion / belief	☐	☒
Sexual orientation – *including:* Marriage / Civil Partnership	☐	☐

4. **Apart from those with protected characteristics, which other groups in society might this document be particularly relevant to**… (e.g. those affected by homelessness, bariatric patients, end of life patients, those with carers etc.)?

None identified.

5. **Do you think the document meets our human rights obligations?** ☒

Feel free to expand on any human rights considerations in question 6 below.

A quick guide to human rights:
• **Fairness –** how have you made sure it treat everyone justly? • **Respect –** how have you made sure it respects everyone as a person? • **Equality –** how does it give everyone an equal chance to get whatever it is offering? • **Dignity –** have you made sure it treats everyone with dignity? • **Autonomy –** Does it enable people to make decisions for themselves?

6. **Looking back at questions 3, 4 and 5, can you summarise what has been done during the production of this document and your consultation process to support our equality / human rights / inclusion commitments?**

Only positive impacts identified. • It is important to encourage prescribers to consider of a patient's, **pregnancy** status and communication difficulties when prescribing/de-prescribing medicines. This is considered good practice professionally and will minimize the risk of discrimination. • Parents cannot override the competent consent of a **young** person to treatment that you consider is in their best interests. However, they can where the child lacks capacity. • If a patient lacks capacity (Mental Capacity Act (2005)) or is detained (Mental Health Act (1983)) then in certain circumstances covert medication can be justified, legal & ethical.

7. **If you have noted any 'missed opportunities', or perhaps noted that there remains some concern about a potentially negative impact please note this below and how this will be monitored/addressed.**

"Protected characteristic":	None identified as having negative impact.
Issue:	n/a
How is this going to be monitored/ addressed in the future:	n/a
Group that will be responsible for ensuring this carried out:	n/a

ROYAL PHARMACEUTICAL SOCIETY

Royal College of Nursing

JANUARY 2019
REVIEW DATE JANUARY 2023

Professional Guidance on the Administration of Medicines in Healthcare Settings

ENDORSED BY

THE ROYAL COLLEGE OF MIDWIVES

Association of Pharmacy Technicians UK

RCGP Royal College of General Practitioners

Pharmacyforum Leading Promoting Supporting

Introduction

This professional guidance has been co-produced by the Royal Pharmaceutical Society (RPS) and Royal College of Nursing (RCN) and provides principles-based guidance to ensure the safe administration of medicines by healthcare professionals.

One of the roles of a professional body is to develop professional standards and guidance that are supportive, enabling and professionally challenging. The importance of professional standards and guidance alongside regulatory standards in supporting patient safety has been repeatedly emphasised. [1,2,3]

The guidance was developed in response to the announcement of the withdrawal of the Medicines Management Standard by the Nursing and Midwifery Council and will be hosted on the RPS and RCN websites.

Application of this guidance is a multidisciplinary responsibility. All staff groups involved in the administration of medicines should be involved in developing organisational policies and procedures.

In addition to corporate and clinical governance responsibilities, registered healthcare professionals are personally responsible for putting patients first and for a commitment to ethics, values, principles and improvement. They are also responsible for practicing within their own scope and competence, using their acquired knowledge, skills and judgement.

The Royal Pharmaceutical Society (RPS) is the body responsible for the leadership and support of the pharmacy profession within England, Scotland and Wales.

The Royal College of Nursing is a professional body and a trade union representing nursing staff working in the public, private and voluntary sectors.

How the guidance was developed

This guidance was developed following an eight-week consultation as part of the project on the Safe and Secure Handling of Medicines and was overseen by a multidisciplinary Task and Finish group including service users. Details of those who responded to the consultation and of those individuals involved in the development of this guidance are acknowledged in the Professional Guidance on the Safe and Secure Handling of Medicines.

If you have any comments on this guidance please contact RPS Professional Support team at support@rpharms.com. If you have suggestions for additional resources or practice guidance please contact RCN Advice Team: 0345 772 6100.

Scope

The guidance is aimed at registered healthcare professionals; the principles however, can be applied in any healthcare setting by any persons administering medicines.

The clinical elements of the prescribing of medicines (such as choice of medicine, treatment duration and method of administration) are beyond the scope of this guidance.

The guidance applies across the UK.

1 Francis R. (2013). Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry.

2 Berwick D. (2013). A promise to learn - a commitment to act: improving the safety of patients in England.

3 Dementia Services Development Centre. (2014). Trusted to Care: An independent review of the Princess of Wales Hospital and Neath Port Talbot Hospital at Abertawe Bro Morgannwg University Health Board.

Administration of medicines

1 Medicines are administered in accordance with a prescription, Patient Specific Direction[4], Patient Group Direction[5] or other relevant exemption specified in the Human Medicines Regulations 2012 (Schedules 17 and 19, as amended).[6]

Medicines that are not Prescription Only Medicines may be administered according to a locally agreed homely remedy protocol.[7,8]

The different legal mechanisms that are used for the prescribing, supply and administration of medicines are described in *Medicines Matters*.[9]

2 Organisational policies define who can administer medicines, or when appropriate delegate the administration of medicines, within a particular setting.

3 The organisation has a policy for self-administration of medicines. Patients maintain responsibility for the administration of some or all of their medicines, during a stay in the healthcare setting, unless a risk assessment indicates otherwise.

4 The risk assessment incorporates elements such as any risks to the patient or others, the patient's ability to manage the tasks involved and consent. Such risk assessments are repeated as necessary.

4.1 The assessment determines whether:

4.1.1 the storage and administration of the patients' medicines remain under the supervision of a healthcare professional

4.1.2 the patients' medicines are stored under the supervision of a healthcare professional and the patient self-administers under supervision

4.1.3 the patient assumes full responsibility for the storage and self administration of the medicine.

5 Records are kept of any assessment undertaken and the outcome. The record includes details, including the time and date, of the patient's agreement to assume responsibility of the self-administration of their medicines, where appropriate.

6 Processes are in place to ensure that the patient has access to an adequate supply of the correct medicines taking into account any changes made to patients' medicines whilst in the healthcare setting. These are appropriately stored so that they are fit for use, and so that the medicines cannot be subject to unauthorised removal e.g. by other patients or visitors.

7 Registered healthcare professionals who administer medicines, or when appropriate delegate[10] the administration of medicines, are accountable for their actions, non-actions and omissions, and exercise professionalism and professional judgement at all times.

8 Those administering medicines are appropriately trained, assessed as competent and meet relevant professional and regulatory standards and guidance.

9 There are organisational policies and procedures in use for the medicines administration process. (See also 15 below.)

10 Wherever possible, the actions of prescribing, dispensing/supply and administration are performed by separate healthcare professionals. Exceptionally, where clinical circumstances make it necessary and in the interests of the patient, the same healthcare professional can be responsible for the prescribing and supply/administration of medicines. Where this occurs, an audit trail, documents and processes are in place to limit errors.

4 Specialist Pharmacy Service. (2013). Questions about Patient Specific Directions (PSD).

5 Specialist Pharmacy Service. (2017). To PGD or not to PGD that is the question.

6 Medicines and Healthcare products Regulatory Agency. (2014). Rules for the sale, supply and administration of medicines for specific healthcare professionals.

7 National Institute for Health and Care Excellence. (2014). Guideline SC1: Managing medicines in care homes.

8 Regional Medicines Optimisation Committee (Midland and East). (2018). Homely Remedies – Position Statement.

9 Department of Health. (2006). Medicines Matters: A guide to mechanisms for the prescribing, supply and administration of medicines. (NB: This document is under review by Specialist Pharmacy Services.)

10 Nursing and Midwifery Council. Delegation and accountability. (Accessed online 28/06/18)

11 The organisation has a procedure to minimise the risks associated with the handling or administration of a medicine.

12 Suitable equipment and devices which aid the administration of medicines are available.

13 Sufficient information about the medicine is available to enable identification and correct use of the medicine.

14 Before administration, the person administering the medicine must have an overall understanding of the medicine being administered and seeks advice if necessary from a prescriber or a pharmacy professional.

15 The organisation's administration procedure is followed. This may include, but **is not limited to**, checking the following:

15.1 The identity of the patient

15.2 The prescription or other direction to administer meets legal requirements, is unambiguous and includes where appropriate the name, form (or route of administration), strength, and dose of the medicine to be administered

15.3 That issues around consent have been considered [11,12,13,14,15,16,17,18,19,20]

15.4 Allergies or previous adverse drug reactions

15.5 The directions for administration (e.g. timing and frequency ofadministration, route of administration and start and finish dates where appropriate)

15.5.1 **any** ambiguities or concerns regarding the direction for administration of the medicine are raised with the prescriber or a pharmacy professional without delay

15.5.2 **any** calculations needed are double checked where practicable by a second person and uncertainties raised with the prescriber or a pharmacy professional

15.6 The identity of the medicine (or medical gas) and its expiry date (where available)

15.7 That any specific storage requirements have been maintained

15.8 That the dose has not already been administered by someone else (including patient or carers).

16 A risk assessment informs organisational policies/procedures for second signatories, witness requirements, and delegating.

17 Records are kept of all medicines administered or withheld, as well as those declined. (See also the Professional Guidance on the safe and secure handling of medicines.)

17.1 Such records are completed at the time of the administration/refusal or as soon as possible thereafter and are clear, legible and auditable.

17.2 Where a medicine is not administered or refused, details of the reason why (if known) are included in the record and, where appropriate, the prescriber multidisciplinary team is notified in accordance with the organisation policies and procedures. Appropriate action is taken as necessary.

18 Any adverse drug reaction experienced is managed in accordance with the organisation policy/procedures. Where appropriate, details of the reaction are documented and reported nationally (i.e. as a Yellow Card[21]) or through local risk management systems (i.e. into the National Reporting and Learning System[22]).

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11 General Pharmaceutical Council. (2017). In Practice: Guidance on consent.

12 General Medical Council. (2008). Consent: patients and doctors making decisions together.

13 Care Quality Commission. Guidance on the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 11. (accessed online 31/01/18)

14 Nursing and Midwifery Council. (2018). The Code: Professional standards of behaviour for nurses, midwives and nursing associates

15 Mental Capacity Act 2005. (accessed online 31/0/18)

16 Office of the Public Guardian. (2013). Mental Capacity Act Code of Practice.

17 National Data Guardian. (accessed online 31/01/18)

18 Adults with Incapacity (Scotland) Act 2000. (accessed online 31/01/18)

19 Adults with Incapacity (Scotland) Act 2000 - Codes of Practice (accessed online 31/01/18)

20 Royal College of Nursing. (2017). Principles of Consent – guidance for nursing staff.

21 Medicines and Healthcare products Regulatory Agency. Yellow Card Scheme. (Accessed online 18/07/18)

22 NHS Improvement. National Reporting and Learning System (NRLS). (Accessed online 18/07/18)

19 Controlled drugs (CDs) are administered in line with relevant legislation and organisational policies/procedures. (See also the Professional Guidance on the safe and secure handling of medicines.)

20 In exceptional circumstances, where a change or addition to the administration details is required and a delay in administering a medicine (other than a Schedule 2 CD) would compromise patient care, verbal orders are used. The process is underpinned by risk assessments and organisational policy and/or procedures.

20.1 Where appropriate, the prescriber requesting the changes provides a prescription or amends the drug chart or medication administration record containing the new administration details as soon as possible (ideally within 24 hours).

20.2 If the prescriber is unable to issue a new prescription or amend the drug chart or medication administration record, the changes are communicated by an appropriately secure electronic method. The patient's records are updated.

Covert administration

21 Medicines are administered covertly only to people who actively refuse their medication and who are considered to lack mental capacity[23] in accordance with an agreed management plan.

22 Where deemed necessary, covert administration of medicines takes place within the context of existing legal and best practice frameworks (see below).

23 There are organisational policies and procedures in place covering covert administration.

Further guidance on covert administration is available at:

- Adults with Incapacity (Scotland) Act 2000. (accessed online 31/01/18)
- Department of Health and Social Care. Mental capacity act 2005: deprivation of liberty safeguards. (Accessed online 17/10/18)
- Department of Health and Social Care. Mental Health Act 1983: Code of Practice. (Accessed online 29/08/18)
- Mental Welfare Commission for Scotland. (2017). Covert medication.
- National Institute for Health and Care Excellence. (2017). Guideline NG67: Managing medicines for adults receiving social care in the community.
- National Institute for Health and Care Excellence. (2015). Quality Standard QS85: Quality Statement 6: Covert medicines administration.
- National Institute for Health and Care Excellence. (2014). Social care guideline SC1: Managing medicines in care homes.
- PrescQIPP. (2015). Best practice guidance in covert administration of medicines.
- Royal Pharmaceutical Society. (2011). Pharmaceutical issues when crushing, opening or splitting oral dosage forms.
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Transcribing

24 Transcribing can be defined as the act of making an exact copy, usually in writing. **In the context of this guidance**, transcribing is the copying of previously prescribed medicines details to enable their administration in line with legislation (i.e. in accordance with the instructions of a prescriber).

25 Organisational policies and procedures for transcribing are underpinned by risk assessment. Such policies are clear about who can transcribe, when it can be used, and the difference between transcribing and prescribing.

26 Organisations have safeguards in place to ensure that transcribed information is not inadvertently used as a prescription.

27 Since transcribing is the copying of medicines information for the purposes of administration, it cannot be used in place of prescribing to issue or add new medicines or alter/change original prescriptions.

28 Transcribing is used only in the patient's best interests to ensure safe and continuous care: ensuring the medication is administered accurately, without undue delay.

29 Those undertaking transcribing are appropriately trained and assessed as competent to do so.

30 An audit trail exists for all transcribed medicines.

31 Medicines are not transcribed where details are illegible, unclear, ambiguous or incomplete. Particular care is taken in transcribing details of high risk medicines such as insulin, anticoagulants, cytotoxics, or controlled drugs.

32 Organisational policy defines the procedure for dealing with errors in transcribed information.

Glossary

COVERT ADMINISTRATION

The defined process whereby a formal decision has been made between healthcare professionals and carers, for medicines to be administered in a disguised format without the knowledge or consent of the patient who lacks mental capacity.

EXEMPTIONS

Specific medicines that certain healthcare professionals can sell, supply and/or administer in the course of their professional practice as specified by the Human Medicines Regulations 2012 (as amended).

HEALTHCARE SETTINGS

Includes: ambulance services, community health services, dental practices, dispensing doctor practices, GP practices, hospitals (NHS and private), mental health community services, pharmacies, private clinics (including physiotherapy and aesthetic), and secure environments.

PATIENT

The term 'patient' includes adults, children and young adults, service users, clients and in the in the case of maternity services, women. In some cases, it may also apply to parents and or guardians.

PATIENT GROUP DIRECTION

A written direction that allows the supply and/or administration of a specified medicine or medicines, by named authorised health professionals, to a well-defined group of patients requiring treatment of a specific condition.

PATIENT SPECIFIC DIRECTION

An instruction from a doctor, dentist or other independent prescriber for a medicine to be supplied or administered to a named patient after the prescriber has assessed that patient on an individual basis. e.g. written direction in patient's notes or inpatient chart.

Further reading

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National Institute for Health and Care Excellence. (2014). Guideline SC1: Managing medicines in care homes.

National Institute for Health and Care Excellence. (2015). Guideline NG5. Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes.

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Royal College of Radiologists. (2015). Standards for intravascular contrast administration to adult patients.

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