

MEDICINES POLICY



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NB appendices 8-10 have not been formally reviewed or updated as part of this update to the main policy. They will be reviewed and updated by the relevant authors as soon as possible. (See below for updates)

Section	Subject	Change
Throughout		Insignificant updates such as committee names, job titles etc. Change of terminology from 'drug' to 'medicine' in most cases, minor changes in wording as per Aintree policy.
Throughout	Non medical prescribing	Addition/amendment of text to reflect roles of non medical prescribers as well as doctors
3.9	Re-use of patient's own medicines	New paragraph
3.10 (b)	Verbal orders for medicines	Amendment of text as agreed at D&T March 2017
3.13	Trainee nurse associates	Addition of table to clarify roles of trainee nurse associates in medicines administration.
4.1	Medicines storage	Processes must be in place to ensure medicines/cupboards are kept tidy and where applicable monitored appropriately.
4.3	Temperature monitoring of medicines storage areas and fridges	Addition of comments re room temperature monitoring and the need to inform Pharmacy when temperatures outside range.
4.7	Ordering stock medicines	Update to reflect use of the EPMA web portal.
4.8	Medication incidents	Expansion of section including comment on near misses.
4.12	Expiry date checking	New paragraph
5	Controlled drugs	Further comments added about use of EPMA web portal in relation to controlled drugs.
5.7	Storage of controlled drugs	Comment added about stocking flumazenil and naloxone. ³⁴

5.12	Controlled drug destruction	Amendments to table/text detailing disposal/destruction in different circumstances.
Supp guidance/SOP 1	Injectable medicines	Comment added about disposal of sharps. Temporary removal of guidance on flushing lines until fully reviewed.
Supp guidance 7	Critical medicines list	Removal of some medicines from list 2 ('any parenteral drugs, oral chemotherapy, any oral 'stat'), in keeping with Aintree list. Some medicines included in these removals are not urgent/critical, and their removal aids focus on true critical medicines for education/audit purposes.
Supp guidance 11	Covert administration of medicines	New guidance document
SOP	Controlled Drugs	Addition of comments regarding use of electronic web portal to manage controlled drugs. Addition of comment about actions if keys are found to be missing.
Appendix 2	New medicine application	Update of form as per Pan Mersey form.
Appendices	Intrathecal contrast in the X-ray dept and Intrathecal Injections policy	Removal of these appendices as these have been replaced by newer separate documents which include the relevant information.
Appendices	Cytotoxic Drugs Policy and Procedure	To be maintained as a separate document and not an appendix of this policy.

September 2018: Minor changes to controlled drugs section and SOPs: addition of references between main policy section and SOPs, further clarification of processes for destruction, clarification regarding transfer of single doses of controlled drugs only between wards/depts outside of Pharmacy opening hours, addition of requirement to submit an incident form in certain circumstances and addition of issues for consideration when assessing discrepancies in liquid balances. Approved at Drugs & Therapeutics Committee.

November 2018: Addition of comment in self-administration policy that elective patients can self-administer their usual medicines on arrival until they are formally clerked in and their usual medicines prescribed. Agreed at Drugs & Therapeutics Committee April 2018.

July 2020: Update of critical medicines list (supplementary guidance section 7) in line with Liverpool University Hospitals

August 2020: Clarification of registered nurse associates roles in relation to medicines (section 3.13)

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June 2022: Update on the link and contact details for Toxbase ®

October 2022: Pharmacist controlled drug checks updated to 6-monthly interval. Can be done alongside appropriate registered nurse, not limited to ward manager only.

April 2023: Extension until July 2023 agreed. Delay in review (and previous extensions) due to waiting for LUFHT policy merge/update, and time required to then update Walton policy accordingly. Section 5: Addition of link to CD classification list on intranet. Removal of need for witness when adding patients' own controlled drugs to register.

The Walton Centre NHS Foundation Trust

Medicines Policy

Section One

**Table of Contents, Summary, Objectives,
Monitoring and Training**

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1. INTRODUCTION

POLICY APPLICATION

It is essential that the Medicines Policy is read by all individuals who deal with medicines within the Trust. It is the responsibility of ward managers and consultants to ensure that they and all of their staff have a working knowledge of this policy. The policy provides guidance on all aspects of medicines handling and management, including prescribing, ordering, storage and administration and, as such, constitutes an important element of the Trust's risk management strategy.

This Medicines Policy is subject to three yearly revision and may be modified by local protocols, which must be agreed by the Drugs and Therapeutics Committee. Comments and suggestions should be directed to the Assistant Clinical Director of Pharmacy on extension 2218.

This policy should be read in conjunction with the Pan Mersey Formulary, the Trust Guidelines for Antimicrobial Therapy and other relevant local policies and procedures.

OBJECTIVES OF THE POLICY

The objectives of the Medicines Policy are to:

- Ensure that medicines are used safely.
- Ensure that all Trust staff follow standard policies when dealing with medicines.
- Ensure that the following checks are carried out before prescribing, dispensing or administering a medicine:
 - Correct patient – (see Correct Identification of Patients Policy)
 - Correct medicine
 - Correct dose
 - Correct route
 - Correct time
- Provide a standard for the handling of medicines, which can be audited.

All practice involving medicines must be explicitly stated in this policy. Practice not clearly documented in the Medicines Policy is not permitted.

MONITORING ARRANGEMENTS OF POLICY

Adherence to this policy will be monitored as part of the pharmacy service delivery through regular audit reported to the Drugs and Therapeutics Committee. Audits are detailed in the Trust Audit Plan. Pharmacy staff visit wards daily (Monday – Friday) and monitor prescribing and administration of medicines.

MONITORING ARRANGEMENTS

MINIMUM REQUIREMENT TO BE MONITORED	FREQUENCY OF MONITORING	PROCESS FOR MONITORING	RESPONSIBLE INDIVIDUAL	RESPONSIBLE INDIVIDUAL/ GROUP/ COMMITTEE FOR REVIEW OF RESULTS	RESPONSIBLE INDIVIDUAL/ GROUP/ FOR DEVELOPMENT OF ANY ACTION PLANS	RESPONSIBLE INDIVIDUAL/ GROUP/ COMMITTEE FOR MONITORING OF ANY ACTION PLANS AND IMPLEMENTATION	SECTION AND PAGE NUMBER IN POLICY
Process for ensuring the accuracy of all prescription charts	Ongoing	Verification data extracted from the Electronic Prescribing system; reported monthly	Lead Pharmacist, Neurosciences	Divisional Director for Neurology / Quality Committee	Quality Committee	Lead Pharmacist, Neurosciences	Section 2.4
Compliance with controlled drug policy	Quarterly	Audit	Advanced Pharmacist, Governance	Drugs and Therapeutics Committee	Drugs and Therapeutics Committee	Drugs and Therapeutics Committee	Section 5 and SOPs
Process for training staff in line with the training needs analysis	Monthly	Performance report	T+D Department	Business and Performance Committee	Business and Performance Committee	Business and Performance Committee	Section 1

TRAINING

For a full list of staff groups to receive training on medicines management please refer to Appendix 1 of the Trust Corporate Induction and Mandatory Training Policy.

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Section Two Prescribing of Medicines

2. PRESCRIBING

2.1 PRESCRIBING OF MEDICINES (IN-PATIENTS)

All medicines must be prescribed by a medical or dental practitioner or an approved Non-Medical Prescriber. Medical students, physician assistants or nursing staff not registered as Non-Medical Prescribers **ARE NOT** allowed to prescribe medicines.

All in-patient medicines should be prescribed electronically (except critical care and day case patients on Jefferson ward). See supplementary guidance 4 and 5 for further details about electronic or handwritten prescription requirements. Separate (paper) prescription charts are in use for some medicines, such as warfarin, cyclophosphamide, heparin and immunoglobulins. All medicines prescribed on separate paper charts should also be referenced on the Electronic Prescribing and Administration System (EPMA).

All items prescribed electronically should be prescribed using the prescriber's own unique and secure electronic log in. The sharing of log in details is not permitted.

For "regular medicines" (that is, a medicine that is prescribed to be taken on a recurring basis e.g. each day, each week) prescribing times should be in accordance with regular medicine administration rounds wherever possible. A 6am dose should only be ordered if there is a good therapeutic reason, eg 8 hourly IV antibiotics.

For 'as required' medicines the frequency of administration and/or maximum dose in 24 hours should be stated.

Any medicine prescribed as a 'stat' dose must be communicated to the member of staff with responsibility for the administration of medicines to that patient.

Medicines should only be given by injection when the appropriateness of other routes of administration has been excluded. A switch to oral administration should be made as soon as is clinically appropriate.

Where a medicine requires the dose to be calculated based on a patient's weight, the patient must be weighed and their weight in kilograms documented.

2.2 PRESCRIBING BY TELEPHONE / VERBAL ORDER

Prescriptions must not be given or accepted over the telephone or verbally, except in an emergency – see section 3.10.

2.3 VALIDITY OF PRESCRIPTIONS

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Unless the duration of treatment is clearly specified, the prescription will be considered valid until cancelled by the prescriber, except in the case of antibiotics which are issued as per antibiotic formulary, unless the prescriber indicates a specific duration of treatment. This should be done by using the “finish date” box, or by leaving an electronic note stating “PROLONGED TREATMENT”. See the Trust Guide to Antimicrobial Therapy for further information on prescribing antimicrobials.

Prescriptions for ‘when required’ controlled drugs should be reviewed every 3 days.

2.4 PROCESS FOR ENSURING ACCURACY OF PRESCRIBED MEDICINES

Pharmacists visit all acute wards except the day case unit daily Monday – Friday and verify each medicine within the electronic prescribing system (or initial the pharmacy box next to each paper prescription on critical care) to confirm that they have monitored prescribing for clinical efficacy, safety, appropriateness and compliance with the Pan Mersey Formulary and Trust Antimicrobial Guidelines. Prescriptions for patients on rehabilitation wards are reviewed daily and ward visits undertaken regularly.

2.5 ALLERGY STATUS

Any information relating to medicine hypersensitivity reactions should be recorded by the prescriber during the admission process.

In addition, the following healthcare professionals are authorised to complete the allergy section.

Nurses
Pharmacists
Ward Based Pharmacy Technicians

Nursing staff should use caution when administering any medicine recognised as leading to allergic reactions if the hypersensitivity section is not complete e.g. penicillin-related antibiotics, sulphonamides, ACE inhibitors, chemotherapy, diagnostic agents or blood products.

- Medicine allergy status undetermined – should only be used if all reasonable steps have been taken to identify a patient’s allergy status and is only valid for 24 hours.
- NKDA – No Known Drug Allergies should be documented if a patient without cognitive impairment is unaware of any allergies occurring due to medicine treatment or if confirmation of no recorded allergies has been obtained from the GP surgery.

- Actual Allergies – Allergy status should be recorded on the allergy section of the prescription chart or within the electronic prescribing system.

Patients with allergies should be given a red wristband (in addition to the standard patient identification wristband) to signify an alert. Details should be documented on an alert card in the case notes.

The prescribing clinician should transfer details of allergy status to the discharge prescription to ensure appropriate information is provided to the general practitioner.

2.6 MEDICINE PRESCRIBING ON ADMISSION

2.6.1 PRESCRIBER RESPONSIBILITY

The admitting prescriber (doctor or pharmacist independent prescriber), as part of the admission process, should compile a medicine history/list of medicines the patient has been taking prior to admission. This should include:

- Name of medicine
- Dose
- Frequency
- Route

If this information is unavailable or unclear, this should be documented within the admission history.

All patients' regular medicines and any newly initiated medicines should be prescribed on admission to hospital, as clinically appropriate. An omitted dose is defined as a failure to prescribe a medicine in a timely manner. Prescribers should ensure that doses of critical medicines are not omitted or delayed (see supplementary guidance 7).

Details of medication changes should be clearly documented in the medical notes and communicated to the patient and other healthcare professionals, especially at transfers of care (see Discharge policy).

If patients are admitted for administration of a medication (especially any kind of immunomodulatory medicine – for example intravenous steroids, immunoglobulin, alemtuzumab, natalizumab) the prescriber must check the clinical notes carefully before prescribing. The clinical notes and correspondence must be reviewed to ensure that the correct medicine is given. Prescriptions must not be based solely on a verbal request or any other documentation (such as a booking form). If in any doubt about the medicine to be given, senior advice must be requested.

2.6.2 PHARMACIST RESPONSIBILITY

A pharmacist should undertake medicine reconciliation to ensure the medicines prescribed on admission correspond to those the patient was taking before admission; taking into account any appropriate changes made to the patient's prescription. For example, dosage change or medicine omission due to adverse event.

2.7 PAN MERSEY AREA PRESCRIBING COMMITTEE FORMULARY

The approved formulary of medicines available for use at The Walton Centre is contained within the Pan Mersey Area Prescribing Committee Formulary. Medicines that are not listed in the Formulary are not routinely available, except some which are prescribed and administered solely within the Trust, which have been approved by the Trust's Drugs and Therapeutics Committee.

When prescribing medicines, the prescriber should refer to the Pan Mersey Formulary to determine the availability. **Newly prescribed items which are not included in the formulary will need Consultant approval (with reasons for the choice of non-formulary therapy) before they can be ordered.** Some new medicines may require individual financial approval from the respective CCG before use (contact ward pharmacist). New medicines with a one-off or annual cost implication to the Trust of more than £1000 will need prior approval from the Medical or Divisional Director or budget holder before ordering. Forms for this purpose can be found in the appendices 1-4.

If a patient is admitted on a non-formulary preparation which is not stocked by pharmacy, the patient's medication is not being altered, the treatment is appropriate **AND** the patient's own supply is not available (or suitable) for use, the pharmacy department will order a small supply to cover the requirements of that particular patient.

2.8 PURCHASING OF MEDICINES

Medicines are unlike any other items of commerce and for this reason the purchase, storage and distribution must be under the control of a pharmacist. The Trust has a service level agreement with Aintree University Hospital NHS Foundation Trust Pharmacy Department for this service. Medical, nursing, technical and other staff are not permitted to undertake contracting or tendering for, or purchasing of, medicinal products intended for administration to patients within the Trust. The only exception to this is contrast media. **Staff must not accept free samples of any medicine for use within the Trust.**

2.9 MEDICINES AND THE TRANSFER OF CARE

Doctors are responsible for ensuring that sufficient information regarding medication is provided at the transfer of care or discharge from hospital. A discharge prescription should be completed **prior to discharge (ideally 24 hours)**. The prescriber should prescribe every medicine that the patient is taking and not just those that are required for discharge. Alternatively, if the patient has their own supply of their usual medicines, it is acceptable to specify **"NO INTENDED CHANGE TO REGULAR MEDICINES"**.

Each patient will normally receive at least 14 days supply from Pharmacy. (Exceptions include weekly blister packs, nursing home patients, patients with a history of overdose, and patients who have sufficient supplies of their own or do not wish to wait for a further supply.) This should allow sufficient time for the patient to arrange further supplies with their General Practitioner (GP).

Pharmacy does NOT routinely dispense discharge medicines out of hours.

A nurse should never 'dispense' from ward stock for patients going home as this is specifically prohibited within the terms of The Medicines Act 1968. The Trust will accept no responsibility should a medicine related incident occur. Nurses may return patients' own medicines and those medicines specifically dispensed or supplied by pharmacy for this purpose i.e. non-formulary medicines, inhalers and other medicines **labelled for that patient with instructions for use**. Pharmacy will inform nursing staff if medicines have been supplied in this way by annotating the discharge prescription.

2.10 OUT-PATIENT PRESCRIPTIONS

The requirements for out-patient prescriptions are generally as indicated for inpatient prescriptions (supplementary guidance 5) but see also requirements for controlled drugs (section 5 and SOPs).

A maximum of 28 days supply (except antibiotics, short term hypnotics and analgesics, original packs for inhalers and topical preparations) will be dispensed unless circumstances dictate that a different supply is necessary. This includes:

1. Hospital only medicines (those classified as red on the red-amber-green (RAG) list. These cannot be prescribed by General Practitioners and should be prescribed on an ongoing basis by the Trust. Accompanying medicines such as folic acid with methotrexate should also be supplied in full.
2. Certain medicines classified as amber on the RAG list, where there is specific agreement that the Trust should prescribe them for an initial stabilisation period. After this period, the GP should be asked to prescribe.
3. Clinical trial medicines.
4. Pulsed / cyclical treatment.
5. Reducing doses of medicines e.g. steroids.
6. Medicines for tuberculosis treatment.
7. Medicines to ensure continuous supply over public / bank holidays.

Green FP10 (HP) prescription forms should **never** be used by medical staff / Non-Medical Prescribers to prescribe for themselves or their families. These are only for use for **registered out-patients** to take to outside pharmacies **only when the hospital pharmacy is closed**. Green FP10 (HP)s must not be used to order food or toilet articles and other prescriptions which are not medicines or appliances other than those specified in the Drug Tariff. They should not be used for unlicensed creams / ointments / liquid formulations as

substantial extra charges are imposed on the Trust. The use of these forms is routinely audited. The full cost of an FP10 (HP) prescription is charged back to the hospital and in most cases is significantly more than using the hospital pharmacy department. **Invoices will be raised and disciplinary proceedings considered if any unauthorised use is detected.** **FP10 prescriptions/pads should be treated as secure stationary and not left accessible to unauthorised staff or patients.**

2.11 PRESCRIBING BY STAFF FOR THEMSELVES AND THEIR FAMILIES

It has been agreed that within The Walton Centre NHS Foundation Trust:

- a) Medical staff / Non-Medical Prescribers may **not** prescribe for themselves or their families, in line with current General Medical Council (GMC) recommendations.
- b) Medical staff / Non-Medical Prescribers may not prescribe for any other staff members unless they have been referred to the Trust for treatment as a registered patient and they are **formally** registered as an outpatient, inpatient, AED patient or daycase.
- c) In emergencies, staff should attend existing facilities in Aintree University Hospital Accident & Emergency Department or Occupational Health, where a senior doctor will prescribe according to the formulary as necessary. The current prescription charge will be payable. Medical staff must be registered patients of the Trust to be eligible for treatment.
- d) Consultant medical staff **only** may purchase medicines by furnishing a signed order form (available from pharmacy). Medicines will be charged at cost price including VAT, plus a 25% on-cost charge. The on-cost is a minimum of a standard NHS prescription charge and a maximum of £25. Please note that large quantities of medicines or non-formulary items may not be immediately available and may have to be ordered from the manufacturers. **Also note that the GMC recommendations on self prescribing and prescribing for family members apply.**

Consultants may not use the system described in point (d) above to obtain a medicine from the following groups under any circumstances:

- Controlled Drugs
- Hypnotics
- Anxiolytics
- Anti-depressants
- Sedatives
- Anti-psychotics

2.12 HOMECARE

Homecare is defined as a service that regularly delivers medicine supplies and associated care, directly to a patient's choice of location, usually the patient's home. Any plans for new homecare services must be discussed with the Assistant Clinical Director(s) of Pharmacy to ensure a full clinical

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economic and risk assessment has been undertaken. Direct involvement will be delegated to an appropriate specialist pharmacist to support the introduction of new services.

The viability of a homecare service in a clinical area will be assessed against the following criteria:

- Is there an improvement of patient care;
- Are there potential cost savings for the clinical division, Trust or commissioners; and
- Is there a reduction in workload for the Trust to attain improved service provision e.g. improvements in patient flow.

Each new homecare arrangement will require a Service Level Agreement (SLA) to be in place before care delivery is transferred.

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Section Three

Administration of Medicines

3. ADMINISTRATION

3.1 BEFORE ADMINISTRATION

Before administration of any medicine, the following checks should be completed:

- **Correct patient** – Check the patient's identification in line with Trust policy to confirm the patients identification
- **Check allergy status**
- **Correct medicine** – Check labeled medicine (and tablet strip where appropriate) with prescription
- **Correct dose** – Identify the correct dosage of medicine.
- **Correct route** – Identify the correct route for administration.
- **Correct time** – Take appropriate steps to administer medicines at the prescribed time (see section 3.3)
- **Correct documentation** (see section 3.11)

3.2 ADMINISTRATION OF MEDICINES

No medicine should be administered to a patient if there is any doubt about appropriateness, safety, dose, interpretation or medicine quality. Medicines may ONLY be administered to a formally registered patient of the Trust by a member of staff that is employed by The Walton Centre. Staff may NOT self administer or administer medicines to other staff members.

Nurses **must not** re-label containers, or amend / add to labels at ward level, for example, for patients who are to be discharged.

Medicines **must not** be swapped from one storage container into another on the ward.

Except for subcutaneous heparin / low molecular weight heparin injections, all injections must be administered separately from the routine oral medicine round.

If **ONE** dose of a critical medicine or **TWO** consecutive doses of other medicines are not given, the doctor responsible for the patient **MUST BE INFORMED**.

3.3 CRITICAL MEDICINES AND MISSED DOSES

Medicines should be administered at the prescribed time and for most this can be considered as plus or minus two hours of the time prescribed on the inpatient prescription.

- An **omitted dose** is a failure to **administer** a dose before the next scheduled dose is due
- A **delayed dose** is administration of a medicine **2 hours or more** after the time the dose is prescribed.

However, for some critical or life-threatening medicines omission or delay can lead to significant patient harm or death. (See Approved lists of Life-threatening and Critical medicines – supplementary guidance 7).

It is the responsibility of the administering nurse to ensure the medicine is obtained at the earliest opportunity. The option of 'Medicine not available' **must not** be used if:

- The pharmacy is open.
- The medicine is kept in the pharmacy emergency night store. Check the pharmacy intranet site for a list of medicines available in the night store.
- A suitable alternative treatment is available (on recommendation of the on-call pharmacist).

Where medicines are not available on the ward it may be necessary to:

- Use the EPMA web portal to find out if the medicine has been supplied already, where it might be, and if out of hours, where in either Walton or Aintree Trusts the medicine is available.
- Contact the ward pharmacist via the internal bleep system or the pharmacy department directly.
- Use the patients' own medicines after inspection by the pharmacist, doctor or nurse.
- Use the pharmacy emergency night store (**ONLY** outside pharmacy opening hours). A full list of the night store contents is available on the intranet. From the homepage select "Departments" and then select Pharmacy, then 'How to obtain medicines'.
- Borrow the medicine from another ward (**ONLY** outside pharmacy opening hours).
- Contact the 'on-call' pharmacist for supplies or advice.

3.4 SINGLE NURSE ADMINISTRATION

Single nurse administration may be carried out by a first level trained, registered nurse / midwife.

Single nurse administration does **not** apply to:

- Controlled Drugs (See section 5)
- Where the dose has to be calculated (i.e. a liquid dosage form without pharmacy annotation/medicine charting note).
- Where the dose is weight related.
- Any area of injectable therapy, except pre-filled syringes of sodium chloride 0.9% IV flushes, or subcutaneous low molecular weight heparins where a standard pre-filled syringe is used and no dose calculation is required.
- Any time a rate controlling device is used on an injectable medicine.

In these cases, the **administering nurse** must ensure that the second member of staff is competent to undertake the task required. A check is required for the preparation of the medicine and any calculations required. This may be carried out by a second registered nurse/midwife/pharmacist (or Operating Department Practitioner in Theatres) with appropriate approval (i.e. completion of IV course)

3.5 STUDENT NURSE/TRAINEE NURSE ASSOCIATE ADMINISTRATION

A student nurse or trainee nurse associate may only prepare or administer medicines under the direct supervision of a trained and approved registered nurse.

3.6 ADMINISTRATION OF MEDICINES BY TRAINEE THEATRE PRACTITIONERS

Trainee Operating Department Practitioners undergo a period of practical training in preparation and administration of a range of medicines **within agreed protocols** to fulfil one part of the Certificate of Higher Education NVQ Operative Department Practice Level 3. This practical training is taught and supervised by qualified practitioners and each member of staff has their own approved scope of practice. See the Registered Operating Department Practitioner Scope of Practice 2003 (Association of Operating Department Practitioners).

3.7 ADMINISTRATION OF LIQUID MEDICINES VIA ORAL AND OTHER ENTERAL ROUTES.

All liquid medicines must be administered using a 5ml spoon or an appropriate size purple oral/enteral syringe. It is the responsibility of the ward manager to ensure that appropriate stocks of oral syringes are available in clinical areas and that all staff administering oral medicines use the appropriate oral/enteral syringe.

3.8 SELF ADMINISTRATION

To ensure patients receive the highest possible care the routine use of self administration schemes is not recommended, with the exception of the complex rehabilitation unit and neurology patients on Chavasse ward (see supplementary guidance section 9). On other wards, selected patients are permitted to self administer their own inhalers, eye drops, GTN sprays, and topical creams or ointments. Patients may also administer their own insulin under (direct) supervision and all normal checks and documentation must be completed. In all cases, a formal assessment form should be completed before allowing self-administration. If a patient specifically requests to self-administer other medicines, a risk assessment should be carried out, and both the nurse and the patient's consultant should agree to this (see supplementary guidance on self administration).

3.9 RE-USE OF PATIENTS OWN MEDICINES

Patients should be encouraged to bring their own medicines into hospital. Any medicines brought into hospital should be assessed for suitability using assessment before being administered to a patient (see supplementary guidance section).

3.10 ADMINISTRATION BEFORE OR WITHOUT A PRESCRIPTION

No medication should be administered to a patient in the absence of a valid prescription. There are currently some exceptions:

- a) An approved member of staff may administer medicines without prescription when following an approved Patient Group Direction or Nurse Administration Protocol.
- b) Verbal orders: Where feasible, verbal orders should be avoided by means of prescribing the medicines on the electronic prescribing system instead (which may be done remotely if considered urgent and appropriate). In an emergency, a drug may be given based on a verbal instruction from the prescriber to a registered nurse, provided that the name, dose, and route of the drug are recorded in the nursing care plan by the nurse, and the prescriber updates the electronic prescribing record within six hours. A second person (a second nurse if possible) should hear and confirm the verbal order details. This does not apply to controlled drugs.
- c) Medical staff may administer medicines without a written prescription, but should ensure this is recorded as soon as possible afterwards.

3.11 RECORDING OF MEDICINE ADMINISTRATION

After a medicine has been administered, the person(s) administering the medicine must sign the appropriate box on the prescription chart or make an appropriate entry on the Electronic Prescribing and Medicines Administration System (EPMA).

3.12 PATIENT GROUP DIRECTIONS

Patient group directions (PGDs) are a complex area and all requests should be discussed with the Trust NMP/PGD subcommittee, via the Lead Pharmacist for Neurosciences or the Deputy Director of Nursing. All PGDs developed must follow HSC 2000/026 which applies to all Prescription Only Medicines. It is good practice to apply the principles of PGD legislation to GSL and P medicines where possible in the form of a Standard Operating Procedure or administration protocol.

3.13 MEDICATION ADMINISTRATION FOR TRAINEE NURSING ASSOCIATES (TNAs) AND REGISTERED NURSING ASSOCIATES (RNAs)

Medication administration for TNAs must be under direct supervision of Registered Nurse/Practitioner who is physically present with the student from the commencement of the procedure to its completion.

Route / Class / Activity	TNAs	RNAs
Oral excluding Controlled Drugs requiring storage in a Controlled Drug cupboard & warfarin	Observe and practice	Administer
Warfarin	Observe and practice	Administer with 2nd check
Transdermal patches excluding opioid based	Observe and practice	Administer
Controlled Drugs requiring storage in a Controlled Drug cupboard	Observe only	Observe only
Oramorph® liquid	Observe and practice	Administer (no 2 nd check required)
Subcutaneous (SC) excluding syringe drivers	Observe and practice	Administer Obtain/perform 2 nd check for insulin
Intramuscular (IM) medication	Observe and practice	Administer with 2nd check
Intravenous (IV) medication	Observe only	Observe only IV administration (PosiFlush only)
Intravenous (IV) fluids	Observe only	Observe only
Per Rectum (PR)	Observe and practice	Administer
Inhaled therapy including Oxygen and inhalers	Observe only	Administer
Topical Medication e.g. emollients and moisturisers	Observe and practice	Administer
Topical Medication e.g. medicated creams, dressings, eye drops	Observe and practice	Administer
Via Nasogastric (NGT) tubes or Percutaneous Endoscopic Gastrostomy (PEG)	Observe and practice	Administer
Blood Products	Observe only Blood collection only	Observe only Blood collection only
Patient Controlled Analgesia (PCA) & Epidurals	Observe only	Observe only
Medication delivered via Syringe drivers	Observe only	Observe only

- Connection and commencement of any IV medications, IV Therapy / GKI or blood products is NOT permitted.
- Registered Nursing Associates can disconnect and PosiFlush cannulae after completion of IV fluids / IV infusions e.g. antibiotics.
- Registered Nursing Associates can act as **second check** for:
 - Stock/TTO Controlled Drugs received from Pharmacy
 - TTOs being issued to patients on discharge
 - Daily CD cupboard stock check via portal
 - Weekly CD fluid balance check
- Following completion of CD Competency Registered Nursing Associates can act as **second check** for controlled drugs brought in by patients and added to the portal and CD cupboard.
- Trainee nurse associates/nurse associates cannot:
 - Order controlled drugs kept in the controlled drug cupboard
 - Sign as a witness for the removal of controlled drugs (other than Oramorph®) from the controlled drug cupboard
 - Sign as a witness for the administration of controlled drugs on JAC

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Section Four Storage, Delivery, Quality and Disposal of Medicines

4. STORAGE, DELIVERY, QUALITY & DISPOSAL OF MEDICINES

4.1 RESPONSIBILITIES

The Ward / Department Manager is responsible for ensuring that **all** medicines are stored securely in appropriate locations, that access is restricted to authorised staff, and keys are held only by authorised staff. Processes must be in place to ensure medicines/cupboards are kept tidy and where applicable monitored appropriately. **These locations should only be used for the storage of medicines and for no other purpose.**

4.2 PATIENT'S OWN MEDICINES / BEDSIDE LOCKERS AND PATIENT TRANSFER

All patients' own medicine or medicines dispensed for discharge must be placed in the lockable bedside medication drawer/cupboard. Patients may on occasion bring in individual strips of tablets which are permitted for use to avoid a missed dose, provided that there is sufficient information on the strip to identify the correct dosage. A labeled supply of medicines should be ordered from pharmacy at the earliest opportunity. Medicines not currently prescribed should always be removed from the locker as soon as practical.

All patient's own medicines or medicines dispensed for discharge for that patient must be supplied to that patient at discharge in accordance with the discharge prescription. These medicines and any other medicines dispensed for that patient **MUST** also be transferred to the new ward if a patient is transferred during an inpatient stay.

Part of the discharge or transfer procedure **MUST** include checking that the patient's medicines have been removed from the locker / trolley / Controlled Drug cupboard and are with the patient. When a new patient is admitted, a check that the locker is empty must be performed.

4.3 TEMPERATURE MONITORING

4.3.1 Medicines marked 'Store in Refrigerator' should be stored between 2 and 8°C in a locked fridge. The fridge should be defrosted regularly (at least annually) to minimise frost build up, kept locked and reported for repair if the temperature dial indicates a fault. Each fridge should be monitored with a minimum and maximum temperature device. This should be checked and recorded at least daily using **Appendix 7 Fridge Monitoring Form**. Temperatures outside of the required range should be reported to a pharmacist to check whether the medicines are still safe to use.

4.3.2 All medicines must be stored away from direct heat sources and at or below the stated temperature on the packaging. Room temperature should be monitored regularly by ward staff, and any issues arising discussed with Pharmacy and/or Estates as appropriate.

4.4 INSULIN

Opened insulin vials, cartridges and pens should be stored securely at room temperature in the patient's lockable medicine cabinet.

Multi-dose insulin vials are for use in **one patient only**. They should be labelled with the date of opening and patient name/unit number. **An exception is applied to Human Actrapid® used in the preparation of insulin infusions.**

Human Actrapid Insulin vials used solely for the preparation of insulin infusion regimes should be annotated with 'infusion' or 'GKI' to distinguish from direct patient use and labelled with the date of opening.

4.5 EMERGENCY CPR BOXES

The number of emergency boxes available on each ward is at the discretion of the Ward Manager by prior agreement with Pharmacy. When opened or out of date, emergency boxes must be returned to Pharmacy as soon as possible, and a replacement obtained. Out of hours, replacements are available from the pharmacy night store.

4.6 DELIVERY OF MEDICINES

Pharmacy porters will deliver medicines to wards and departments at specified times throughout the day in a sealed bag or box. A signature will be required at each stage of the transfer. The nurse receiving these supplies should ensure the bags are emptied and stored securely **on receipt**.

See Section 5 for the receipt and handling of Controlled Drugs.

Staff should ensure bags and boxes are returned to Pharmacy for re-use.

4.7 WARD STOCK MEDICINES

The ward pharmacist and ward manager will agree the list of medicines held as stock on a given ward. The stock list should be based on the use of medicines on the ward and reviewed as necessary.

Wards may re-order stock medicines using the EPMA web portal.

4.8 MEDICATION INCIDENTS

The NPSA definition of a medication incident is 'any unintended or unexpected incident which could have or did lead to harm for one or more patients'. Included in this statement are actual medication errors

and near misses. A near miss is an incident which did not cause any harm at the time but may have had the potential to cause harm.

All **actual** medication errors must be recorded as they occur using the online DATIX incident form. In addition an entry should be made in the case notes and the following people verbally informed:

- The Ward Manager or Nurse in charge of the ward or department.
- The Medical Team responsible for the patient (to include the consultant or registrar if the error has the potential to lead to patient harm) .
- The patient involved, if inappropriate administration / omission of a medicine has occurred. This information and discussion should also be documented in the patient's case notes.
- The ward pharmacist or on-call pharmacist, if the incident involves loss of a controlled drug or advice / guidance is required.
- Others as detailed in the Trust How to Report an Incident Policy.

See Appendix 6 for classification of medication incidents and further guidance on reporting.

Near miss events must be recorded using the online DATIX form if they had the potential to have caused significant patient harm if allowed to go unchecked. Serious near miss events should also be reported back to the appropriate professional group for prevention/educational purposes.

Notifications of medication incidents reported are routinely sent to the Lead Pharmacist for Neurosciences, as well as to all relevant managers or risk leads.

All medication incidents are reviewed at the multidisciplinary Safer Medication Group, which considers what further action may be appropriate to reduce the risk of similar incidents occurring. This is in addition to the standard procedures for all incidents which are also followed for medication incidents, as detailed in the Trust's How to Report an Incident Policy.

4.9 MEDICINE DEFECT REPORTING PROCEDURE

Health Service Guidelines HSG (93) 13 requires Chief Executives to ensure prompt reporting of adverse incidents and reactions and defective products relating to medical products. This requires an efficient system for the dissemination of hazard / recall notice issued by the Medicines and Healthcare Products Regulatory Agency (MHRA) together with a procedure for assessment of defects arising in hospitals and notification of major defects to the MHRA.

All medicine defects should be reported, as soon as practicable, to the Pharmacy Department. Outside working hours the on call pharmacist must be contacted.

4.10 ADVERSE DRUG REACTION (ADR) REPORTING AND MANAGEMENT

An Adverse Drug Reaction is an unwanted or harmful reaction experienced following the administration of a medicine or combination of medicines **under normal conditions of use** and suspected to be related to the medicine.

If you suspect that a patient's symptoms may be related to the medicine they are taking, please consider submitting a Yellow Card report. You do not have to be certain about causality; if in doubt, please report.

- Report all suspected adverse reactions to new medicines and vaccines (denoted by ▼ in the BNF)
- Report all serious suspected adverse reactions to established medicines and vaccines.

Please include as much information as possible on the report. However, do not delay reporting just because some details are not known.

The ward pharmacist or Medicines Information **MUST** be informed of any suspected adverse drug reaction that meets the reporting criteria and can provide essential advice in the management of any ADR. The on call pharmacist is available for advice outside normal pharmacy hours.

Yellow cards can be found in the back of the BNF.

4.11 DISPOSAL OF MEDICINES

There are 3 categories of medicinal waste

- General medicine waste
- Cytotoxic contaminated waste
- Controlled drugs

1. General Medicine waste

General medicine waste such as unwanted patients' own medicines, expired medicines or part used medicines must be disposed of in the designated blue sharps bins for this purpose in wards/departments.

Used medicine waste should be disposed of as clinical waste following the **Trust Policy on Disposal of Clinical Waste**.

2. Cytotoxic contaminated waste

Cytotoxic waste must be disposed of by using the designated collection point specified in the **Trust Policy on Disposal of Clinical Waste**.

3. Controlled Drugs

Controlled drugs must be returned to pharmacy following the procedure detailed within this policy (section 5)

4.12 WARD CLOSURES AND TRANSFERS

For short term closures less than 7 days, contact pharmacy to assess the risk of leaving medicines in the area versus likelihood of the ward re-opening. Controlled Drugs should never be left in an unoccupied clinical area. For longer term ward closures or opening of new ward areas, contact Pharmacy to agree a plan.

4.13 EXPIRY DATE CHECKING

It is the responsibility of all staff to check that medicines are in date at the point of use (eg dispensing and administration). Pharmacy assistants as part of the ward top up will review expiry dates on a rolling 8 week programme.

Medicines Policy

Section Five Controlled Drugs

5. CONTROLLED DRUGS

Controlled Drugs are those drugs covered by the Misuse of Drugs Act 1971 and associated Regulations including the Safer Management of Controlled Drugs – A Guide to Good Practice in Secondary Care October 2007. Medicines classed as controlled drugs can be found in the current Misuse of Drugs Regulations at www.homeoffice.gov.uk or in the current issue of the BNF.

From time to time the Trust may decide that specified other drugs should be treated in the same way as controlled drugs with respect to some or all of the requirements detailed in these SOPs. This may apply across the Trust or only in specified areas. Information will be provided to the relevant areas where this applies, and a summary table can be found on the intranet at



RESPONSIBILITY

Under the Health Act 2006, the Trust has appointed an Accountable Officer for the safe and effective use of controlled drugs. This Accountable Officer is the Clinical Director of Pharmacy. Controlled drugs will be audited at regular intervals and the results reported to the Trust Board. Medical, Pharmacy, Nursing and other staff retain their own professional and legal responsibilities around the use of controlled drugs.

Any incident involving a controlled drug must be reported to the Accountable Officer as soon as is practical.

ACCOUNTABILITY

The senior registered nurse in charge of a ward is responsible for the safe and secure storage and the use of controlled drugs within their own areas.

5.1 PRESCRIBING OF CONTROLLED DRUGS

All medical staff (NOT students and unregistered locums) may prescribe controlled drugs for inpatients, including discharge prescriptions. For outpatients, only doctors that have achieved full registration with the General Medical Council are permitted to prescribe i.e. not F1 House Officers.

Medical staff are not permitted to prescribe diamorphine or cocaine **for the treatment of addiction** unless licensed by the Home Office to do so. Prescribing of diamorphine for **pain control** (including for addicts, if clinically appropriate) is permitted under Home Office guidelines.

Methadone should **NOT** be prescribed for registered or unregistered addicts at discharge. If it is not possible to make arrangements for a registered addict, the minimum possible quantity should be provided and an **absolute maximum of 2 days** prescribed (exception bank holiday weekends). (See supplementary guidance 1 – Methadone Use.)

Non medical prescribers may prescribe controlled drugs according to the current regulations and their approved personal formulary only. The Trust leads on NMP (Deputy Director of Nursing / Lead Pharmacist, Neurosciences) are available for further advice and guidance. All controlled drug prescriptions must meet the prescribing requirements as specified in the Medicines Act.

Controlled drug prescriptions for out-patients or discharge patients must by law have the:

- a) Full name and address of the patient (unless a barcoded label is used). If using a barcoded label the prescriber must sign the prescription starting on the label and finishing on the paper.
- b) Full name of the controlled drug.
- c) Form of the drug e.g. tablets.
- d) Strength of the preparation.
- e) Dose.
- f) Total quantity of the preparation, or the total number of dose units, in both words and figures.
- g) Hospital Number or patient's NHS Number.

and, in addition,

- h) The prescription must be signed and dated by the doctor.
- i) Controlled Drug Prescriptions are only valid for 28 days.
- j) The quantity of Schedule 2, 3, and 4 CDs to be supplied at any one time must not exceed 30 days.

Prescribers **MUST NOT** prescribe or administer CDs to themselves, family or friends.

When prescribing opioids, prescribers must:

- Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient. This may be done for example through discussion with the patient, or their representative (although not in the case of treatment for addiction), the prescriber, or through medication records.

- Ensure where a dose increase is intended, that the calculated dose is safe for the patient (e.g. for oral morphine or oxycodone in adult patients, not normally more than a 50% increase on the previous dose).
- Ensure they are familiar with the following characteristics of that medicine and formulation: usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects.

5.2 CONTROLLED DRUG STATIONERY

Controlled drug stationery includes the following

- CD order book
- CD register
- CD stock check and patients own register
- Electronic CD records

All controlled drug stationery must be securely stored at all times to prevent unauthorised access i.e. **in a locked drawer or cupboard.**

New order books and registers can be ordered from pharmacy in one of three ways. In all options a check must be made to ensure that a new book is not being ordered because the original book has been lost. Loss of controlled drug stationery should be reported to the Accountable Officer (Chief Pharmacist) as soon as is practical.

1. The pharmacy technician preparing ward controlled drugs may supply a new order book as the last order is made.
2. Requests may be made to the ward pharmacist. The ward pharmacist should confirm that the existing stationery is full and kept on the ward.
3. Members of ward staff wearing a trust identity badge may order stationery in person from pharmacy after presenting the existing stationery for inspection.

All controlled drug records must be retained securely for two years after the date of last entry. Electronic records must be permanently retained. See controlled drugs SOP 1.

5.3 ORDERING CONTROLLED DRUGS FOR INPATIENTS

The standard controlled drug order book or the EPMA web portal must be used for ordering controlled drugs. It is essential to provide full information regarding name of medicine, form, strength, ampoule size (for injections where more than one size exists) and quantity required.

Controlled drugs can only be ordered by qualified nurses or an Operating Department Practitioner (ODP) who have been authorised to do this by

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their Ward or Department Manager. The name of the nurse requesting the CDs should be printed underneath the signature. Requisition books should be sent to Pharmacy before 11am on weekdays and should not be routinely requested at weekends.

Each ward/department should have an agreed stock list of controlled drugs including maximum quantities. This list should be agreed between the ward pharmacist and a senior practitioner from the given area. Excess stock should be returned to pharmacy.

The top copy of the requisition should not leave pharmacy.

The EPMA web portal can be used for ordering controlled drugs against a pre-populated order list, Approval for ordering is granted if the registered user is listed within the JAC prescribing system as a registered nurse and a pre-existing account holder authorises the account. Other controlled drugs can only be ordered electronically if they are electronically prescribed for a particular patient. See controlled drugs SOP 1.

5.4 OBTAINING CONTROLLED DRUGS IN AN EMERGENCY OUT-OF-HOURS

In an emergency **out of hours**, the Accountable Officer has authorised the transfer of CDs between wards as follows. The CD register of the ward supplying the controlled drug should be signed by the nurses in charge of both the supplying and receiving ward. The supplying nurse **MUST** observe the controlled drug being entered into the register of the receiving ward. The name of the patient for whom it is intended should be noted in both registers. Only **single doses** can be transferred. **The law prevents greater quantities being transferred.** In cases of difficulty, the on-call pharmacist can be contacted for advice.

5.5 COLLECTION/DELIVERY OF CONTROLLED DRUGS

At each point where a controlled drug moves from the authorised possession of one person to another, a signature (or electronic stamp) for receipt should be obtained by the person handing over the drug and the person receiving it. This includes:

- Collection by ward staff from pharmacy.
- Collection by porters from pharmacy.
- Delivery by pharmacy staff to wards, departments, theatres.
- Collection by patient or representative, for outpatient items only.
- Delivery by Trust porter/driver
- Delivery by commercial courier (for example, taxi out-of-hours)

The procedure for delivery of controlled drugs will depend on local circumstances but will always be within the following guidelines:

The person who conveys the CD acts as a 'Messenger' delivering a sealed bag. The messenger must be wearing an appropriate ID badge and sign the "accepted for delivery" section of the signature log OR sealed bag. The messenger must ensure that they are clear about the destination of the CD and confirm the identity of the person receiving the CD by only handing to an authorised person wearing an ID badge.

For patient-specific prescriptions (outpatient / discharge prescription or inpatient supply) the pharmacist must ascertain whether the person collecting a Schedule 2 or 3 CD is the patient, the patient's representative or a member of staff.

The following information must be recorded in the CD register for Schedule 2 CDs supplied on prescription:

- Whether the person who collects the drug is the patient, the patient's representative or a healthcare professional acting on behalf of the patient.
- If the person who collected the drug was a health care professional acting on behalf of the patient, that person's name and address.
- If the person who collected the drug was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the dispenser did not ask may be included but this is not mandatory), and whether evidence of identity was provided by the person collecting the drug.

See controlled drugs SOP 2.

5.6 RECEIPT OF CONTROLLED DRUGS ON WARD

Controlled drugs must be received on the ward by a registered nurse and signed for on the delivery sheet, **in the presence of the messenger**. A check should be made to ensure the quantity ordered corresponds to the quantity received. If this is correct then the duplicate sheet in the controlled drug requisition book should be signed in the "received by" section or for electronic orders, receipt acknowledged on the web portal. The appropriate entry should be made in the ward controlled drugs register by the person who received the controlled drugs and witnessed by a second registered nurse. The balance should be checked against the stock level. The drugs should be locked in the controlled drugs cupboard **immediately**. See controlled drugs SOP 3 and 4.

5.7 STORAGE OF CONTROLLED DRUGS

The Misuse of Drugs (Safe Custody) Regulations 1973 (SI 1973 No 798) cover the safe custody of controlled drugs in certain specified premises. The Regulations also set out standards for safes and cabinets used to store controlled drugs.

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Ward CD cupboards should conform to the British Standard reference BS2881 or be otherwise approved by the pharmacy department. This is a minimum security standard and may not be sufficient for areas where there are large amounts of drugs in stock at a given time, and/or there is not a 24-hour staff presence, or easy control of access. In this case a security cabinet that has been evaluated against the SOLD SECURE standard SS304 should be used.

All controlled drugs must be stored in a locked cupboard which can only be opened by a person who can lawfully be in possession of the keys, such as a pharmacist or the registered nurse, midwife or ODP in charge, or a person working under their authority e.g. a pharmacy technician.

General measures for the storage of CDs include the following:

- Cupboards must be kept locked when not in use.
- The lock must not be common to any other lock in the hospital.
- Keys must only be available to authorised members.
- The cupboard should be dedicated to the storage of CDs.
- No other medicines or items should normally be stored in the CD cupboard unless discussed and authorised by the Accountable Officer.

NB all areas stocking controlled drugs must maintain an in date supply of naloxone and flumazenil injection.
See controlled drugs SOP 6.

5.8 AUDIT OF CONTROLLED DRUGS

The ward / department manager or designated deputy is responsible for a **DAILY** check of controlled drugs, **which must be recorded**. This record may be in the CD Register or in the CD Stock Check and Patients Own Register or the EPMA web portal.

Discrepancies should be reported immediately to the Ward/Area Matron or designated deputy and as soon as practical the Ward Pharmacist, who will inform the Accountable Officer.

The pharmacist, along with a registered nurse, will check the balance of controlled drugs at six-monthly intervals.

5.9 ADMINISTRATION OF CONTROLLED DRUGS

Unless administered by a doctor, controlled drugs must be administered by two registered nurses (or ODPs in theatre). The witness should have sufficient knowledge and training to intervene should an error occur. Both the administering nurse/ODP and the witness should check the prescription, observe preparation **and administration** of the dose,

reconcile the stocks remaining and sign the register. Administration must also be recorded within the electronic prescribing system or paper prescription chart. (All other administration policies, including those for parenteral administration still apply).

If part of a vial/ampoule is administered to a patient, the registered nurse, or professional, should record the amount given and the amount wasted e.g. if the patient is prescribed 2.5 mg diamorphine and only a 5mg preparation is available, the record should show, "2.5mg given and 2.5mg wasted".

See controlled drugs SOP 4.

5.10 PATIENTS' OWN CONTROLLED DRUGS

As with other types of medicines, these remain the patients' own property, and should preferably be given back to the patient or relatives at discharge providing that the patient is still prescribed the CD.

Upon receipt of a patient's own controlled drug, it should be placed in the patient's own section of the ward controlled drug cupboard, and an entry made on the EPMA web portal or designated CD Stock Check and Patients Own Register. This entry should include the patient's name and the medicine name, strength, quantity and formulation. When the drugs are issued to the patient or a relative or transferred to another ward with the patient, the entry must be signed by the nurse and **countersigned by a witness**.

If the patient's own controlled drugs are required to be used as part of their inpatient stay, an entry should be made on the EPMA web portal or patient's own register to record the supply. Doses are then given in the usual way and the balance checked each time. **Patient's own CDs should NOT be given to any other patient. They must also NOT be added to ward stock.**

See controlled drugs SOPs 5 and 7.

5.11 METHADONE PRESCRIBING FOR ADDICTS AND ILLICIT SUBSTANCES

See supplementary guidance 1 and 2.

5.12 RETURN OF CONTROLLED DRUGS TO PHARMACY

Unwanted CDs may ONLY be returned to pharmacy via the ward pharmacist. The exception would be areas that do not have a regular ward pharmacy service e.g. theatres, outpatient department, radiology department etc. For these areas, by appointment only, a pharmacist may be requested to visit and remove any unwanted controlled drugs (this would be classed as non urgent activity and normally arranged sometime over the next 7 to 14 days). Alternatively the person designated as responsible for controlled drugs in a given clinical area may return the

unwanted stock to pharmacy in person, where an entry will be made in their CD register to record the return. This is to be countersigned by the returning person.

Patient's own controlled drugs should be returned to the patient or relatives at discharge. If the dose has changed and the pack is not suitable for use, a single line must be drawn through the label and the pack annotated with "dose changed – do not use". The ward pharmacist is available for advice. Expired, excess stock or patient's own controlled drugs should be returned to pharmacy by the ward pharmacist and the senior practitioner.

An entry should be made in the CD register signed by both pharmacist and senior practitioner. In addition a separate page of the CD order book should be used for each returned drug to include the following details:

- Date.
- Name, form, strength and quantity of drug being returned.
- Reason for return.
- Name and signature of the registered nurse, midwife or operating department practitioner.

The top copy of the requisition form should be torn out and returned with the CD.

Alternatively the web portal may be used to record return or destruction of both patients' own or ward stock controlled drugs.

Once in pharmacy, medicines will be assessed for suitability of re-use. If assessed as suitable, the drugs are returned to stock and the top copy of the requisition form retained for 2 years. If expired, not supplied by the Trust pharmacy or unsuitable in any way, the drug must be individually entered into the pharmacy destruction register and destroyed as follows.

Type of medicine	Where destruction should take place	Person who should destroy medicine + method	Person who should witness	Register or record book entry	Notes
Patient's own – unsuitable for use (sent from ward)	In the pharmacy	Pharmacist or registered technician	Pharmacist or registered technician	CD destruction Record Book/Ward Pts own CD book	
Patient's own – unsuitable for use or no longer prescribed (handed in directly to Pharmacy by patient (e.g. Outpatients))	In the pharmacy	Pharmacist or registered technician	Pharmacist or registered technician	Pharmacy CD destruction Record Book	
Type of medicine	Where destruction	Person who should destroy	Person who should witness	Register or record book entry	Notes

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	should take place	medicine + method			
Ward stock – unfit for use	In the pharmacy	Pharmacist or registered technician	Pharmacist or registered technician	Ward CD Record Book + Pharmacy CD destruction register	
Wastage from part doses drawn up in theatre/wards for individual patient, e.g. when giving 5mg dose from 10mg ampoule	In theatre/wards	Registered nurse, midwife or registered ODP Empty into sharps bin or denaturing kit	Registered nurse, midwife, doctor or pharmacist	Theatre/ward CD Record Book	Theatre/ward record book should show name of patient and details of dose/wastage e.g. 5mg given/5mg wasted, signature of person carrying out disposal and witness.
Dose drawn up on ward for individual patient but not given	On the ward	Registered nurse or midwife Empty into sharps bin or denaturing kit	Registered nurse, midwife, doctor or pharmacist	Ward CD Record Book	Ward record book should show name of patient and reason for non-administration, signature of person carrying out disposal and witness.
Wastage from discontinued parenteral dose in infusion bag or syringe In the pharmacy or on ward, or in theatre	On the ward	Denaturing kit	Registered nurse, midwife, doctor or pharmacist	Ward CD Record Book	Details of amount administered and amount discarded, signature of person carrying out disposal and witness should be recorded in either medical record, prescription record, or CD record book.
Dose drawn up in theatre for individual patient but not given	In theatre	Registered nurse, midwife, ODP or anaesthetist Empty into sharps bin or denaturing kit	Registered nurse, midwife, ODP doctor or pharmacist	Theatre CD Record Book	Theatre record book should show name of patient and reason for non-administration, signature of person carrying out disposal and witness.
Pharmacy stock unfit for use (schedule 1 and 2 only)	In the Pharmacy	Pharmacist, pre-registration pharmacist or registered technician	Authorised witness**	Pharmacy CD Register	
Part doses drawn up in Pharmacy during e.g. extemporaneous dispensing for an individual patient	In the Pharmacy	Pharmacist or Member of Pharmacy Staff dispensing the preparation Empty into sharps bin	Pharmacist or registered technician	Pharmacy extemp prep worksheet	Register entry annotated with details of amount issued, BN of extemp. prep. Name of pt

**The destruction of controlled drugs in Pharmacy is documented on the Home Office license as follows:

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Destruction by:

- Registered Pharmacy Technician or Pharmacist.

Witness

- Deputy Clinical Director of Pharmacy

See controlled drugs SOPs 8 and 9.

5.13. PRIVATE PRESCRIPTIONS FOR CONTROLLED DRUGS

Standardised private prescription forms (FP10 PCD) will be required for private prescriptions for all Schedule 2 and 3 CDs to be dispensed in a community pharmacy. These are available through the local Primary Care Trust. Prescribers will need to obtain a prescriber identification number from the PCT should they wish to issue private prescriptions for controlled drugs. This requirement is not applicable to private prescriptions dispensed in hospital pharmacy departments.

5.14 UNPLANNED EVENTS

Any unplanned incident involving a controlled drug must be recorded in the appropriate ward / department controlled drug register and reported to the nurse in charge of the ward, ward manager and ward pharmacist, who will inform the Accountable Officer. An incident form should also be completed.

An unplanned incident could include any of the following (or other as deemed appropriate by healthcare professional):

- Theft
- Balance discrepancy
- Spillage

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Section Six Unlicensed Medicines

6. UNLICENSED MEDICINES

6.1 PRODUCT LICENCES AND THE LICENSING SYSTEM

On its introduction in 1968, the Medicines Act laid down regulations to control the manufacture, sale and use of medicinal products. Medicines are required to have a Marketing Authorisation (MA) (previously a Product Licence), issued by the Medicines and Healthcare Products Regulatory Agency (MHRA), after consideration of data relating to the product. Such data will include validation and justification of the manufacture, storage and shelf life of the product together with its therapeutic indications. The Marketing Authorisation defines the therapeutic or diagnostic purposes and the clinical indications for which a product may be sold or supplied.

In the UK, no medicine may be marketed without a Marketing Authorisation. The Authorisation defines what the medicine may be used for and how it should be used. Should the medicine be defective there is a potential liability under the provision of the Consumer Protection Act 1987 which imposes an obligation on the part of the **supplier** (i.e. the Trust) of a product to compensate a person injured by the same even if there has been no fault on the part of the manufacturer or supplier. The supplier is able to claim an indemnity from the person who has supplied him and through a chain of responsibility the **ultimate liability is that of the manufacturer**.

Such indemnity would not be available for an unlicensed medicine or one used for an unlicensed indication. In these cases, **“liability to compensate the patient for any injury resulting would rest with the prescriber or the pharmacist, for whose actions the Trust would be legally liable through vicarious responsibility for the action of its employees”**.

6.2 TYPES OF UNLICENSED MEDICINES

There are three broad categories of unlicensed medicine:

1. Products made from licensed medicines, for example,
 - Low-dose formulations for children.
 - Some liquid formulations
 - Some sterile products e.g. eye-drops, injections.

These products are made in a ‘specials’ manufacturing unit approved by the MHRA either commercially or within a hospital pharmacy, or prepared in a hospital pharmacy under a Medicines Act exemption Section 10.

2. Products for which a licence has yet to be granted in the United Kingdom; a licence may exist elsewhere.
3. Products that no longer have a licence, or have never had a licence, because they have been abandoned, suspended, revoked

or not renewed or it is not commercially viable to apply for licensing.

6.3 UNLICENSED USE OF LICENSED MEDICINES

The provisions of the Marketing Authorisation are usually summarised in a medicine **data sheet / summary of product characteristics (SPC)**. These are not always published (e.g. generic medicines) and are not usually used at the time prescribing takes place. Even if the contents of the data sheet are known, there are occasions when non-adherence is justified. For example:

- Where the licensed indications do not reflect current knowledge.
- Where the licensed indications do not include well proven uses.
- Where the licensed indications are overly restrictive.

Such anomalies may arise if the manufacturer does not wish to alter the products market niche or to fund the trials necessary to support an application for a change to the original licence.

6.4 RESPONSIBILITIES

The Trust will accept liability for the use of medicines for indications not included in the Marketing Authorisation provided such use would command peer group support.

6.4.1 PRESCRIBER

The responsibility for prescribing any medicine falls to the doctor, who must act responsibly and with reasonable care and skill. Clinical circumstances may make the use of an unlicensed product for a particular patient imperative. It is expected that unlicensed medicines should only be prescribed by a consultant or experienced clinical specialist or staff grade clinician. In certain circumstances, Non-Medical Prescribers may be authorised to prescribe unlicensed medicines or to prescribe medicines for use in an unlicensed manner; this is considered on an individual basis.

When prescribing unlicensed medicines or licensed medicines for unlicensed uses, the prescriber's responsibilities include:

- To recognise that unlicensed medicines are not readily available and have to be sourced from other countries or specials manufacturers. This can lead to a delivery time of greater than 4 weeks in some circumstances. In addition there can be no guarantee that supplies will continue to meet demand and clinicians should build in contingencies to deal with possible supply problems for all unlicensed medicines.
- To prescribe such medicines knowingly and only after very careful consideration.

- To be familiar with the product or be acting on the direct advice of a colleague or be following published precedent.
- To recognise the responsibility that such prescribing entails when obtaining consent to treatment. Where possible, the patient should be informed of the licence status and that for an unlicensed medicine its effects may be less well understood than those of a licensed product.
- To obtain patient consent as appropriate, as when prescribing licensed medicines. In addition, the Drugs and Therapeutics Committee considers it good practice to obtain written consent for elective use of unlicensed medicines. Written consent is obligatory if the procedure/prescribing is not within the terms of a specific ratified WCFT guideline or monograph.
- Provide healthcare professionals responsible for the patient with sufficient information to administer the medicine as safely as possible e.g. patient information leaflet, administration guideline or monograph etc.
- Ensure that where responsibility for ongoing care is to be transferred to the patient's general practitioner, that the general practitioner is informed of the unlicensed status of the medicine and that he or she is willing to accept clinical and legal responsibility for prescribing.

6.4.2 PHARMACISTS

- The Deputy Chief Pharmacist at UHAFT (under a service level agreement) is designated as having overall responsibility for the procurement, supply and audit of unlicensed medicines, the "Designated Pharmacist". However, it is not unusual for several pharmacists to be involved in the decision making process from the Ward / Clinical Pharmacist who receives the request through to the person who signs the order or authorises the invoice.
- When an unlicensed medicine is to be ordered for the first time there needs to be critical, evidence-based evaluation for its use. The Designated Pharmacist is responsible for assessing the evidence and challenging use. The pharmacist must also ensure that all the controls specified within this policy are applied including the maintenance of appropriate records of use.
- To obtain unlicensed medicines **only** on the written authority of a **consultant**.
- To assist the requesting consultant in providing information regarding the practical implications of using an unlicensed medicine or medicines for unlicensed uses.
- To inform prescribers of unlicensed uses of medicines when such uses can be identified from prescribing documents and other sources.
- To compile specifications for all unlicensed medicines purchased by the hospital pharmacy and to seek Pharmacy Regional Quality Control approval before such products are used.
- To keep an approved list of specials suppliers.
- To keep records of all "specials" purchases.

6.4.3 NURSE

To question the doctor or pharmacist if an instruction to administer a medicine is thought to be outside the terms of a product licence or SPC with regard to dose, route of administration, or other aspect of use.

Nurses may refuse to administer medicines being used outside the terms of their product licence or SPC if that is judged to be in the best interests of the patient. **Refusal to administer should not occur solely because a medicine is unlicensed and must be discussed with the prescribing consultant.**

6.4.4 DRUG AND THERAPEUTICS COMMITTEE

The Drug and Therapeutics Committee is responsible for the monitoring of unlicensed medicines and for the approval for use of new unlicensed medicines in the Trust as with any other new medicine. However, in the case of urgent clinical need, the Consultant and Designated Pharmacist may authorise use subject to formal ratification at the next meeting.

For a new unlicensed medicine, the requesting prescriber should complete the relevant new medicine application form Appendix 1 or 2 and in addition the unlicensed medicine risk assessment form in Appendix 3 with a specialist pharmacist for neurosciences and the Designated Pharmacist.

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Section Seven Duties and Responsibilities

7. KEY STAFF AND STAFF GROUPS INVOLVED IN MEDICINES MANAGEMENT

All staff have a personal and professional responsibility to act within their own scope of practice / professional standards / training with respect to the handling, distribution, prescription, storage and administration of medicines.

Staff include:

- **Pharmacy Staff**
- **Medical Staff**
- **Nursing Staff**
- **Other professional groups (AHPs, ODPs)**
- **All Other Staff (Transport, Security, Management)**

In addition to paragraph 5.14 any serious concerns regarding any aspect of medicine handling (including prescribing, preparation, storage, administration) should be reported to the Clinical Director of Pharmacy or designated deputy immediately.

7.1 THE CLINICAL DIRECTOR OF PHARMACY

- **Responsible for the provision, management and development of all pharmacy services throughout the trust.**
- Holds statutory responsibility for ensuring safe systems are in operation for the prescribing, dispensing and administration of medicines.
- Holds corporate responsibility for Medicines Management within the Trust.
- Provides strategic leadership in Medicines Management both within the Trust and across the Health Economy to promote safe, clinically effective and cost-effective use of medicines and control of medicine expenditure.
- Responsible person under the Medicines Act for Aintree University Hospitals NHS Foundation Trust wholesaler dealer's licence and specials manufacturing licence.
- Accountable Officer for the safe management of controlled drugs throughout the Trust.
- Co-ordinates and implements research and development activity in Medicines Management.

7.2 THE TRUST DRUG AND THERAPEUTICS COMMITTEE.

- Reports to the Clinical Effectiveness Service Group and ultimately to the Quality Committee.
- Includes representation from senior medical, nursing and pharmacy staff.
- Considers applications for additions to the Formulary and the purchase / supply of new medicines. Where new medicines / indications have any impact on primary care, submits these to the Pan Mersey New Medicines Subgroup using the agreed processes and documentation, for recommendation by the Area Prescribing Committee to Commissioners. Subsequently implements commissioning decisions within the Trust.

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- Considers all aspects of medicines management, which includes ordering, supply, storage, distribution, prescribing, preparation, dispensing and administration with the overall objective of promoting continued improvement of these systems and reducing associated clinical risks in the Trust.
- Approves medicines-related guidelines and policies.
- Monitors and advises on medicine incidents and near misses.

7.3 PAN MERSEY AREA PRESCRIBING COMMITTEE.

- Forecasts developments in healthcare which involve the use of medicines and provides effective advice on the local implications of such developments and their management.
- Reaches a consensus, based on the available evidence, regarding the place in treatment locally of relevant new medicines and formulations, or of existing medicines with new indications, and works to ensure that such advice is disseminated to all stakeholder organisations. Makes recommendations to Commissioners on whether these developments should be commissioned.
- Responds promptly to local, regional and national changes to NHS policy that will affect prescribing and medicines management locally, including NICE guidance and NSFs.
- Membership from local primary and secondary care Trusts

7.4 THE TRUST CLINICAL GOVERNANCE DEPARTMENT (reporting to the Clinical Effectiveness Service Group).

- Ensures that the Clinical Audit program supports the aims of the quality agenda
- Monitors CQC standards relevant to the Committee ensuring that there is suitable and reliable evidence applicable to the standard
- Reviews and approves the annual Trust clinical audit forward plan before it is presented to the appropriate Committee(s).
- Receives and review quarterly and annual clinical audit activity status reports
- Receives exception reports, monitors progress on the implementation of NICE guidance and NICE Quality Standards
- Facilitates dissemination of information from clinical audit, research outcomes and national guidance

7.5 COMMERCIALY SPONSORED POSTS

Anyone working within the Trust in a commercially sponsored post (where salary is wholly or partly paid by a commercial organisation) should have no role in prescribing decision making or advice, and should not direct patients to a source of medicines supply.

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Supplementary Guidance Section 1

Guidelines for the Use of Methadone

GUIDELINES FOR PRESCRIBING METHADONE FOR PATIENTS ADMITTED FOR AN UNRELATED MEDICAL / SURGICAL REASON

1. INTRODUCTION

Opioid withdrawal symptoms are unpleasant but not life threatening. In contrast, methadone overdose, or its administration to the opioid naive, can be fatal. Opioid withdrawal is not a medical emergency, so methadone does not need to be prescribed in the Accident and Emergency Department.

In pregnancy, opioid or benzodiazepine withdrawal can precipitate serious foetal problems. Rapid stabilisation of symptoms is essential. For pregnant patients, liaise urgently with Liverpool Women's Hospital.

2. WHO CAN PRESCRIBE METHADONE?

Doctors do not need a special licence to prescribe methadone in the management of drug addiction. Only doctors with a special licence issued by the Home Secretary may prescribe, administer or supply diamorphine, dipipanone or cocaine in the treatment of drug addiction. Doctors may still prescribe diamorphine, dipipanone or cocaine for patients, including addicts, for relief of pain due to organic disease or injury, without a special licence.

Oral methadone

This should be prescribed as Methadone Oral Solution 1mg in ml.

Parenteral methadone

Parenteral methadone dosage is equivalent mg for mg to oral but should **not** routinely be prescribed. If the parenteral route is unavoidable, methadone should be given intramuscularly, not intravenously. The injection is only licensed for intramuscular use. Patients must not self-inject whilst in hospital.

3. CAUTION: WHEN NOT TO GIVE METHADONE

The nurse must monitor the patient every time a dose is administered. **METHADONE must NOT be given** to a patient who is drowsy, sedated, ataxic, with slurred speech or asleep. Never wake a patient up to give methadone. If any of these applies, the nurse must ask for a medical review. Do not give methadone if the patient has been absent from the ward and appears drowsy or intoxicated.

4. TAKING THE MEDICINE HISTORY

In addition to taking a full medicine history, the doctor must find out whether the patient is:

- (a) Established on a methadone programme with the Drug

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Services or a GP.

Or

(b) Using “street” drugs or on an unconfirmed dose of methadone.

Then choose the appropriate situation from the guidance below.

5.1 MANAGING PATIENTS ESTABLISHED ON A METHADONE PROGRAMME

The doctor should confirm the dose with the clinic or GP, who should liaise with the community pharmacy where the patient is registered, to cancel outstanding prescriptions.

Take a urine sample and send to biochemistry for “opiates and methadone”.

Establish the total daily dose from clinic. This can be prescribed as a single daily dose or in divided doses. e.g. if the total daily dose is confirmed as methadone 60mg daily, prescribe 30mg twice daily. Do not alter the established dose without relevant Community Drug Team advice.

Methadone should be prescribed in milligrams, not by volume alone. Use Methadone Oral Solution 1mg in ml.

Do not give methadone if the patient is difficult to wake or displaying signs of toxicity such as drowsiness, ataxia or has slurred speech.

The nurse must monitor the patient, observing the Cautions in point 3 above.

If the patient brings in their own prescribed medication, they must give permission for its use or destruction. Ward staff must record receipt in the Controlled Drugs Register, store it in the CD cupboard, and arrange for a pharmacist to transfer back to pharmacy for destruction.

5.2 MANAGING PATIENTS ON “STREET” HEROIN OR UNCONFIRMED PRESCRIBED METHADONE DOSE

Take a urine sample and send to biochemistry for “opiates and methadone”.

Do not start methadone unless there is objective evidence of withdrawal symptoms (point 6)

Prescribe a single dose of methadone 10mg (This should be prescribed as a stat dose on the electronic prescribing system or the front of the prescription chart). Further stat doses of methadone 10mg may be given up to a maximum dose of 40mg in 24hrs. Assess methadone requirement after 24hours and prescribe an appropriate twice daily dosage. These doses must not be exceeded without relevant Community Drug Team advice. Do not prescribe on a “when required” basis.

Do not give methadone if patient is drowsy, sedated, ataxic, has slurred speech or is difficult to rouse.

The nurse must monitor the patient every time, observing the Cautions in point 3 above.

5.3 **MANAGING PATIENTS ON METHADONE WHO ARE ALSO USING STREET OPIATES**

There are those patients who are established on methadone or have been established on it since admission (points 5.1 & 5.2 above), who continue to use street opiates. In these situations, seek advice from the relevant Community Drug Team.

6. **WITHDRAWAL SIGNS AND SYMPTOMS**

Withdrawal symptoms occur when an opioid-dependent individual is without their usual source of opioid for a period of time.

SEVERITY

Is variable and depends on:

1. The amount of opioid usually taken.
2. Route of administration - usually made more severe in intravenous users.
3. Psychological factors, e.g. coping strategies/anxiety.

TIME OF ONSET

Depends on the opioid used.

Short-acting opioids: 6 - 8 hours after last use e.g. Heroin, morphine, dihydrocodeine.

Long-acting opioids: 16-24 hours after last use e.g. Methadone.

SIGNS AND SYMPTOMS

Subjective

- Craving for opioids
- Anxiety symptoms
- Pains and cramps in muscles, particularly stomach, back and legs
- Unable to sleep
- Feeling hot and cold

Objective

- Cold, sweating, clammy and goose flesh
- Dilated pupils
- Yawning
- Nausea, vomiting and diarrhoea
- Restlessness and insomnia
- Tremor
- Lacrimation and rhinorrhea
- BP↑ and tachycardia

NB:

1. These symptoms may occur in other medical conditions or co-exist with other conditions.

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2. Seizures or fits do not occur in pure opioid withdrawal.
3. Drowsiness, sedation, disorientation or confusional states do not occur in pure opioid withdrawal.
4. Pyrexia is not a symptom of opioid withdrawal.
5. Opioid withdrawal may be masked or attenuated by other medicines or substances, e.g. benzodiazepines, barbiturates, alcohol, phenothiazines.

7. URINE ANALYSIS

Urine analysis is always advisable. However, it is a guide and must be interpreted with other clinical findings. The urine test is needed for clinical and medicolegal reasons.

Request urinalysis for opiates and methadone, to confirm the presence or absence of heroin or methadone.

The absence of methadone or opiates in an individual claiming to be a regular user must arouse the greatest suspicion. No opioid should be prescribed until further clinical assessment takes place. Conversely, the presence of methadone or opiates does not necessarily mean that the individual will require methadone therapy.

Note: The opiate test can be positive if the patient is on codeine, pholcodine or dihydrocodeine. This test will not detect other opioids. Contact the lab for advice.

The screening service is available seven days a week, 8.00 a.m. - 10.00 p.m. Screen results should be available within one hour. Any positive finding will be confirmed subsequently, but not in time to affect clinical decision making. Indicate known medication on the request form.

Should there ever be an occasion when "chain of custody" procedures are required for urine samples, this must be discussed with the lab prior to any action.

8. RESPONDING TO REQUESTS FOR ABUSABLE MEDICINES

Analgesics

Patients in hospital may require treatment for painful conditions. Their usual daily dose of methadone may not control additional pain, so they may require pain relief as in any other patient. Non-steroidal anti-inflammatory medicines may be used as appropriate. Opioids may be necessary, but should be dictated by clinical need for analgesia.

Benzodiazepines

Where possible, these should be avoided. If night sedation is required, do not initiate temazepam.

Cyclizine

Avoid cyclizine because of its abuse potential.

Others

Medicines commonly abused are tramadol, gabapentin and pregabalin.

The BNF lists other medicines with abuse potential (see under Misuse of Drugs Act). If in doubt, check with a pharmacist.

9. DISCHARGE PRESCRIBING

The patient should obtain supplies from their usual prescriber. Methadone is only allowed on discharge if there are exceptional circumstances, with a maximum supply of two days.

Refer other patients to the appropriate Community Drug Team, who work to defined catchment areas. Patients must be advised that in-patient methadone is prescribed to cover their hospital medical/surgical treatment. It is not the start of a programme, and a programme cannot be guaranteed to be available immediately on discharge.

10. SOURCES OF ADVICE

SEFTON			
Name	Address	Phone number	Fax number
South Sefton Integrated Recovery Team (CRI)	██████████ ██████████ ██████████	██████ ██████████	
South Sefton Neighbourhood Centre CMHT	██████████ ██████████ ██████████	██████ ██████████	
North Sefton Integrated Recovery Team (Lifeline)	██████████ ██████████ ██████████	██████ ██████████	██████ ██████████
LIVERPOOL			
Drug Dependency Unit (Merseycare)	██████████ ██████████ ██████████	██████████ ██████	██████████ ██████
North Liverpool Community Drug Team (Merseycare)	██████████ ██████████ ██████████ ██████████	██████ ██████	██████████ ██████
Primary Care & Enhanced Shared Care Team (includes patients seen at Croxteth and Hope Street projects) (Addaction)	██████████ ██████████ ██████████ ██████	██████ ██████	██████████ ██████
Liverpool ROB/DIP (Addaction)	██████████ ██████████ ██████████	██████████ ██████	██████████ ██████
ALOT Team (Addaction)	██████████ ██████████ ██████████	██████████ ██████	

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Liverpool DRR (Merseycare)	[REDACTED] [REDACTED] [REDACTED]	[REDACTED] [REDACTED]	[REDACTED] [REDACTED]
KIRKBY			
Community Drug Team (Addaction)	[REDACTED] [REDACTED] [REDACTED]	[REDACTED] [REDACTED]	[REDACTED] [REDACTED]
KNOWSLEY AND HUYTON			
Addaction Drug Addiction Treatment Centre	[REDACTED] [REDACTED]	[REDACTED] [REDACTED]	[REDACTED] [REDACTED]
Addaction Drug Addiction Treatment Centre	[REDACTED] [REDACTED] [REDACTED] [REDACTED]	[REDACTED] [REDACTED]	
ST HELENS			
St Helens Integrated Recovery	[REDACTED] [REDACTED] [REDACTED]		
Primary Care Mental Health			
Primary Care Mental Health	[REDACTED] [REDACTED]	[REDACTED] [REDACTED]	[REDACTED] [REDACTED]

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Supplementary Guidance Section 2

Guidelines for the Handling of Illicit Substances

DEALING WITH UNAUTHORISED DRUGS OR OTHER SUSPICIOUS SUBSTANCES FOUND ON THE WALTON CENTRE NHS FOUNDATION TRUST PREMISES

Introduction

There is a risk of illicit substances being used on Trust premises so all staff are expected to be vigilant and act accordingly should any illicit substance be located or they are suspicious of substances being brought into the Trust by visitors or patients.

When a member of staff takes possession of the substance, he or she is placed in a vulnerable position unless it can be demonstrated that the substance was taken for the purpose of delivering it into the safe custody of a person lawfully entitled to possess or destroy it. It is therefore important that all actions relating to the taking into safe custody or destruction of suspected substances are fully and correctly documented and witnessed and the procedures below followed. The senior nurse in charge and the senior doctor on duty must be consulted. If the senior doctor is not a consultant, he/she should discuss it with the duty consultant. Unless large quantities of drugs are involved, the main aim is to ensure that the drugs are handled and destroyed in a safe and legal manner.

Where large quantities of unauthorised drugs or other substances are found on a patient's person, the police should always be informed and fully assisted in their enquiries. An officer will attend the ward / department and initiate enquiries. The legal position is that the public interest overrides that of confidentiality.

The discovery of quantities of unauthorised drugs consistent with the patient's own personal use rarely leads to a successful prosecution. Furthermore, a heavy handed response can compromise patient care and cause considerable disruption of ward routines and the waste of much time and effort. The police are aware of this and do not wish to compromise patient care. Consequently, following discussions with Merseyside Police, it is recommended that the decision to contact the police or dispose lawfully of the substance should be taken jointly by the ward manager in conjunction with the consultant with clinical responsibility for the patient.

Under no circumstances can a Schedule 1 (Class A, B or C) drug (includes cannabis and lysergide which are not used medicinally) be handed back to a patient at discharge, as the person doing so could be guilty of an offence of unlawful supply of a Controlled Drug.

When a patient is found to be in possession of unauthorised drugs or other suspicious substances:

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1. The member of staff finding the substance should immediately inform the nurse in managerial charge of the ward or department.
2. The ward or department nurse manager should place the substance in a suitable secure container with a label identifying the source (patient's initials and hospital number) and a brief description of the contents ("brownish powder" or "brown resinous material" NOT what the contents are believed to be). The label should be over the seal and signed by the nurse in charge and a witness.
3. The container should then be placed in a locked controlled drugs cupboard.
4. The ward or department nurse manager should contact the consultant in charge of the patient.
5. The ward manager should complete Part A of the **"Form for removal and destruction of unauthorised drugs or other suspicious substances"** (appendix 5). An entry should also be made in the back of the controlled drug register.
6. Where the ward manager and the patient's consultant agree that the quantity of the substance found is consistent with the patient's own personal use, then the ward pharmacist should be contacted to remove the substance for destruction. In this case, Parts B and C should be completed as indicated, by the ward manager, the consultant and the pharmacist. One copy of the form should be filed in the patient's medical record and one copy retained by the pharmacy department. If the patient objects to this course of action, contact the Incident Management Unit (see below).
7. Where either the ward manager or the consultant in charge, or both, consider that the quantity of the substance found is greater than is consistent with the patient's own personal use, Part B must be completed. The ward manager / consultant should then contact the **Incident Management Unit at Lower Lane Police Station, [REDACTED]**
8. If the police officer attends, the ward staff should co-operate fully with the officer. In some cases, the officer may not need to know the identity of the source patient. However, if he or she does, this should be provided by the doctor. In the investigation of an alleged criminal offence, confidentiality is unlikely to be a sufficient defense in law against disclosure.
9. Each case will be treated on its own merits and it is therefore not possible to indicate the precise action the police will take. However, the patient will never be questioned or removed from the ward or department if it is

considered by the consultant in charge to be inappropriate on clinical grounds.

10. Following his enquiries, the police officer will remove the suspicious substance from the ward. Part D should be signed by the police officer and the nurse witnessing the transfer. One copy should be given to the police officer, and one copy filed in the patient's medical record.

Medicines Policy

Supplementary Guidance Section 3

Pharmacy Services

1. PHARMACY SERVICES: GENERAL

1.1 PHARMACY MISSION STATEMENT

The aim of Aintree University Hospitals' Pharmacy Service is:

TO PROVIDE A COMPREHENSIVE, HIGH QUALITY AND COST-EFFECTIVE PHARMACY SERVICE, ENSURING THAT ALL PATIENTS RECEIVE THE CORRECT DRUG, AT THE CORRECT DOSE, AT THE CORRECT TIME.

1.2 PHARMACY SERVICE

Department	Extension
University Hospital Aintree: Dispensary Dispensary Manager (and at weekends) Inpatient Enquiries Discharges (TTOs) Out Patient Enquiries Fax Medicines Information Aseptic Unit Ward Stock	 <div style="background-color: black; width: 20px; height: 10px; margin: 0 auto;"></div> <div style="background-color: black; width: 20px; height: 10px; margin: 0 auto;"></div> <div style="background-color: black; width: 20px; height: 10px; margin: 0 auto;"></div> <div style="background-color: black; width: 20px; height: 10px; margin: 0 auto;"></div>
Out of pharmacy hours contact the on call pharmacist via switchboard	

The dispensary at University Hospital Aintree is open from 8.30am to 5.00pm on weekdays. A morning service is provided on Saturdays between 9.00am and 4.00pm and between 10.00am and 12noon on Bank Holidays. A Sunday service is available between 2.00pm and 3.00pm **for emergency items and urgent discharges only**. The on call pharmacist can be contacted on extension [REDACTED] during weekend / Bank Holiday opening hours and via switchboard at all other out of hours times.

Advice on any aspect of pharmacy services, medicine policy, or medicine use, can be obtained during working hours from ward pharmacists. In addition, all staff can contact the Medicines Information Unit directly.

1.3 GRADES OF PHARMACY STAFF WORKING ON WARDS

All pharmacy staff receive an in-depth induction on pharmacy and Trust policies. All levels of responsibility are approved by senior staff and competency is regularly assessed.

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Pharmacists complete a four year Masters Degree, plus a one year period of pre-registration experience, before they qualify and register as Members of the General Pharmaceutical Council (GPC). In addition, most of our pharmacists have, or are studying towards, further qualifications such as a Clinical Pharmacy Diploma or MSc.

Pharmacy Technicians complete a two year BTEC plus NVQ III course to qualify and register with the GPC. After two years, technicians are eligible to complete an accredited checking course which allows them to undertake the final accuracy check of prescriptions. Technicians also counsel patients on medicines, confirm medicine histories and check / supervise other staff.

Pharmacy Assistants complete NVQ II training and carry out top-up of stock items, assembly of orders, and other duties both within the department and at ward level. They also dispense medicines under the supervision of pharmacists and pharmacy technicians.

2 DISPENSARY SERVICES

The Dispensary Manager can be contacted on extension [REDACTED] for advice or comments regarding the dispensary services.

3 CLINICAL SERVICES

Pharmacists visit all wards every week day. They monitor prescriptions for safety, appropriateness and compliance with formulary policy. Pharmacists will provide information if needed and will advise on all aspects of medicine use, supply and storage on the wards. Pharmacists will also prepare discharge medicines in certain areas and will assess patient medication histories and patient understanding of their medicines.

Within the Walton Centre, some specialist neurosciences pharmacists are registered as pharmacist independent prescribers. They work as part of the clinical multidisciplinary teams, taking part in daily ward rounds, and prescribe for inpatients as part of their day to day roles.

4 MEDICINES INFORMATION

The Medicines Information Unit has access to a wide range of information sources including CD-ROM and on-line databases. Any healthcare professional may use this service.

5 POISONING

The Medicines Information Unit does not deal with poisoning queries. The online poisons database should be accessed (**TOXBASE**) at <https://www.toxbase.org/> in all cases of poisoning as the primary source of advice and information on the treatment and management of the majority of cases. For complex cases not covered by TOXBASE, information should be obtained from the National Poisons Information

Service on [REDACTED]. This national number will connect to the local Centre (Newcastle for Mersey and the North West).

Access to TOXBASE is by password, which **must be applied for in advance**. Accident and Emergency departments have this facility.

6 ADVERSE DRUG REACTION MONITORING

Advice on all aspects of adverse drug reaction monitoring is provided by the Medicines Information Unit and ward pharmacists. Nurses, doctors, or pharmacists who believe that a patient may have suffered an adverse event while taking a medicine should complete a yellow card found in the back of the BNF or on the website (<http://yellowcard.mhra.gov.uk/>) and return it to their ward pharmacist or to the Medicine Information Unit. Reactions and suspected or possible reactions to newer drugs, marked with a black triangle (▼) in the BNF and data sheets **MUST** be reported.

A separate on line system is available, but must be used in conjunction with the ward pharmacist.

7 SAFELINE ANONYMOUS MEDICATION ERROR REPORTING SCHEME

This scheme, which is co-ordinated by the Medicines Information Unit in the Pharmacy Department (extension [REDACTED]), is not a substitute for formal medicine incident reporting. Callers may ring anonymously and in confidence giving details of medication errors. The information is used to build up a picture of medicine incidents and as a basis for targeting education and policies on safe use of medicines. We do not require the identity of the caller, patient or ward, we only need details of the error itself, including “near misses” i.e. those recognised in time to prevent them. Details will **NOT** be passed back to managers even if the voice is recognised. An answerphone is available out-of-hours.

8 ALTERNATIVE DOSAGE FORMS

If a patient cannot swallow tablets or capsules, or tolerate oral medication, ward pharmacists are able to advise on different formulations or alternative products. These might be available commercially or made as (unlicensed) ‘specials’ for individual patients (see Section on Unlicensed Medicines)

9 ASEPTIC PRODUCTION

A range of products can be specially prepared in the Aseptic Unit. These include eye drops, bladder instillations and solutions for nebulisation as well as parenteral nutrition regimes, cytotoxics and some intravenous antibiotics.

10 CYTOTOXIC MEDICINES

10.1 Cytotoxic medicines may present a hazard to the person handling them. Guidelines for the safe handling of cytotoxic medicines are

located in the COSHH file in the pharmacy department and on the intranet. Ward pharmacists can give advice on COSHH.

- 10.2 Intravenous (IV) cytotoxic medicines are prepared in the Pharmacy Aseptic Unit within a specialist isolator in a **controlled environment**. Preparation is a specialist operation requiring extensive staff training and monitoring with extensive records of drugs prepared and the staff involved in preparation.
- 10.3 When a patient is prescribed an IV cytotoxic drug, the Pharmacy Aseptic Unit must be contacted on ext. [REDACTED] and details of the patient provided, including weight, height, haematology and biochemistry results where appropriate. The preliminary or confirmed diagnosis and treatment protocol required should also be provided for new patients. This information allows a further check in the calculation of the cytotoxic dose and reduces the possibility of error in the prescription. A copy of the prescription should be sent or faxed to pharmacy.
- 10.4 Cytotoxic treatment is nearly always elective and adequate notice should be given to ensure that the drug will be available at the required time. Where the actual dose is dependent on blood counts, renal function or hydration status, it may not always be possible to write the prescription until these are available, but notification that treatment is possible is required by pharmacy.
- 10.5 Cytotoxic treatment is unlikely to be considered an emergency treatment and therefore ready made doses will not be supplied out of hours.

11 PARENTERAL NUTRITION

In WCFT, in conjunction with Aintree Hospitals Pharmacy, Total Parenteral Nutrition (TPN) is tailored to individual patient needs and supplied in a ready made 'all-in-one' bag. The nutrition team will design the most appropriate regimen for each patient. Regular U+Es, LFTs, fluid balance, weight and other measurements will be needed. Requests must be made by 11.00am weekdays. Further details about indications, contra-indications and risks of parenteral nutrition can be found from ward pharmacists. Parenteral Nutrition MAY NOT be commenced outside normal pharmacy hours or at weekends.

12 THERAPEUTIC DRUG LEVEL MONITORING (TDM)

If help is needed with anti-convulsant, theophylline, digoxin, gentamicin, vancomycin or other drug level interpretation or dose adjustment then the ward pharmacists will be happy to assist.

Ward pharmacists must be informed of any patient commencing gentamicin or vancomycin. They will give advice on dosage adjustment

and the requirement to monitor medicine plasma levels. This service is available outside normal pharmacy hours by contacting the on-call pharmacist via switchboard.

13 PATIENT COUNSELLING / EDUCATION

Patients' understanding of the medicines they are given should be checked prior to discharge. Pharmacists are prepared, on request, to counsel patients prior to discharge. This will highlight any potential problems and has been shown to increase compliance. If patients have poor memory of their regimen, pharmacists can supply a variety of devices and charts to help. Often, a determined attempt to simplify the regimen, by stopping some items and using long-acting preparations, can make medicine administration much easier for the patient.

14 IDENTIFICATION OF MEDICINES

Pharmacists are available to help identify medicines brought into hospital by patients if there is any doubt as to their composition. This is especially important in cases where these may have to be administered to patients.

15 FORMULARY MANAGEMENT

Pharmacy is responsible to The Walton Centre NHS Foundation Trust Drugs and Therapeutics Committee for ensuring that prescribing is within Formulary guidelines.

16 TRAINING SUPPORT

Pharmacists undertake teaching sessions for various groups of staff within Aintree University Hospital, The Walton Centre, the School of Health Studies and local universities. If you feel that they could assist in your department's training, contact your ward pharmacist or the Pharmacy Department.

17 SPECIALIST PHARMACY SERVICES

WCFT has several named specialist pharmacists with whom to liaise regarding medicines management.

18 MEDICINE HOTLINE FOR PATIENTS

Patients taking medicines home on discharge receive a leaflet with the medicines information direct line telephone number. They can contact this service for help with any query relating to medicines obtained from the Trust.

19 CLINICAL AUDIT

Pharmacists have involvement in clinical audit programmes throughout the Trust. Data on drug usage held on the pharmacy computer system may be of value to clinicians undertaking various therapeutic audits within their specialities. Contact a specialist neurosciences pharmacist to discuss available reports.

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Supplementary Guidance Section 4

Electronic Prescribing

1. ELECTRONIC PRESCRIBING

From April 2014 the majority of inpatient areas use an Electronic Prescribing and Medicine Administration (EPMA) system to hold medicine records. The documentation supporting the use of this system is comprised of Standard Operating Procedures and detailed user guides.

The EPMA system ensures that the majority of the legal requirements pertaining to the prescribing and administration of medicines are automatically completed via an interface with the Patient Administration System (PAS) and mandatory fields. However, the use of EPMA does not absolve responsibility for prescribing or administration and the principles of the Medicines Policy are still applicable.

The use of EPMA has led to a change in the risk profile of prescribing/administration and extreme care must be taken at all stages of the management of medicines.

Below is a detailed list of the available documents supporting the use of EPMA.

Procedure number	Procedure name
JAC/001	JAC Back-up procedure
Stores/Ap1	New drug request form
JAC/002	Procedure for entering a new drug on JAC
JAC/003	Procedure for prescribing an unknown drug
JAC/004	Procedure for prescribing a drug by an unassigned route
JAC/005	Procedure for resetting passwords
JAC/006	Procedure for issuing emergency usernames and passwords
JAC/007	Procedure for PMAINT
JAC/008	Procedure for service desk
JAC/009	Procedure for creating a user account
JAC/010	Procedure for dealing with patient locks
JAC/011	Performing session resets
JAC/012	SOP for pharmacist amendments of prescriptions
JAC/013	Procedure for limited prescribers
JAC/014	Business Continuity Plan - TBC
JAC/015	Setting witness permissions
JAC/016	Pharmacy and Medicines Reconciliation
JAC/017	Procedure for adding a device to JAC

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User Guides

UJAC/01	Prescriber + quick guide
UJAC/02	Administrator + quick guide
UJAC/03	Admin staff and AHP + quick guide
UJAC/04	Locum Doctor
UJAC/05	Agency Nurse
UJAC/06	Alternative Route of Administration
UJAC/07	Transferring Patients Between Clinical Areas
UJAC/08	Recording Weight and Height
UJAC/09	Using Free Form Frequency

Miscellaneous

RJAC/01	EPMA Risk Document
RJAC/02	EPMA Monitoring

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Supplementary Guidance Section 5

Handwritten Prescriptions

MEDICINE NAME

The **NAME OF THE MEDICINE** should be written in black ink **LEGIBLY USING APPROVED NAMES**. Proprietary names (i.e. brand names) must not be used (exceptions to this rule are multi-ingredient preparations with no approved names or products whose proprietary names define a specific formulation).

1. The **DATE** on which treatment is to commence must be entered on the prescription sheet. Dates where treatment is not intended must be crossed out on the chart (eg treatment to start the next day or to be omitted peri-operatively)

2. DOSE

The **DOSE** must be expressed in **Standard International (SI) Units**. Quantities less than 1 gram must be written as milligrams. Decimal points should be avoided, for example 500mg **not** 0.5g to avoid confusion. Whenever a decimal point is necessary e.g. for some digoxin doses, great care must be exercised by both the prescriber and the nurse administering the drug. The terms **MICROGRAM** and **NANOGRAM** must not be abbreviated but must be printed in full and used for quantities less than one milligram. When prescribing drugs expressed as Units, the full word must be used and **NOT** abbreviated to “U” or “IU”. Only the following abbreviations are acceptable, all other dose units must be written in full:-

Quantity	Approved Abbreviation
Milligram	mg
Gram	g
Kilogram	kg
Litre	L
Millilitre	ml
Millimole	mmol

The dose required must not be expressed in terms of the dosage form for single ingredient preparations e.g. “ATENOLOL 2 tablets” is not acceptable. It should be written as e.g. “**ATENOLOL 100mg**”.

3. ROUTE OF ADMINISTRATION

Only the following abbreviations are acceptable:

Route	Approved Abbreviation
Intramuscular	IM
Inhalation	INH

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Intravenous	IV
Nebulised	NEB
Oral	PO
Rectal	PR
Vaginal	PV
Subcutaneous	SC
Sublingual	SL
Topical	TOP
Nasogastric	NG
Percutaneous Endoscopic Gastrostomy	PEG

ALL OTHER ROUTES MUST BE WRITTEN IN FULL.

4. PRESCRIBER'S SIGNATURE

All items on the prescription sheet must be signed by the prescriber. The prescriber should also print their name, bleep number and GMC registration number clearly on their first prescription on each chart.

For controlled drugs, the prescriber's full signature is always necessary.

5. DISCONTINUING MEDICINES

A diagonal line should be drawn through the prescription so that its cancellation is obvious, but the prescription should not be obliterated. The entry must be initialed by the prescriber discontinuing the medicine. A vertical line should be used to indicate the time at which the prescription is to stop.

6. REWRITING OF PRESCRIPTIONS

Where a change in dose, frequency or route of administration is required, the whole prescription (for the medicine affected) must be rewritten and the original entry discontinued. Prescription charts must also be rewritten if they become unclear or untidy eg due to multiple changes in medicine regimens or spillage. When rewriting prescriptions, the prescriber must ensure that the date entered relates to the date when therapy commenced, not the date of rewriting.

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Supplementary Guidance Section 6 Medicines Safety and NPSA

1. Methotrexate

- Oral methotrexate, for the treatment of non-malignant conditions, must always be prescribed and administered as a **once weekly dose using 2.5mg strength tablets**.
- The **dose** and **frequency** must clearly be stated on the prescription. The use of the instruction 'as directed' is not permitted.

2. Insulin

- All regular and single insulin (bolus) doses must be measured and administered using an **insulin syringe or commercial pen device** with pen needle.

3. Low Molecular Weight Heparins (LMWH)

- Therapeutic doses of LMWH should be based on the **indication** for treatment, **patient's weight** and **renal function**.
 - o The first dose should not be delayed pending renal function test results. However subsequent doses should take renal function into account.
- Essential information (dose, weight, renal function, indication, duration of treatment and monitoring arrangements) must be communicated at transfers of care, including on discharge.
- See also anticoagulation guidelines on the intranet.

4. Opioids

- Prior to the prescription of an opioid medicine, the prescriber should ensure that they are familiar with the following characteristics of that medicine and formulation:
 - o Usual starting dose
 - o Frequency of administration
 - o Standard dosing increments
 - o Symptoms of overdose
 - o Common side effects
- It is the responsibility of the prescriber to confirm any recent opioid use including, dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient (although this may not be possible in an acute emergency).

Supplementary Guidance section 7 - Omitted and Delayed Doses

List of Life-Threatening & Critical Medicines

All medicines must be prescribed and administered in accordance with the standards set in the Trust Medicines Policy.

Medicines should be **administered at the prescribed time** and for most this can be considered as **plus or minus two hours** from the time scheduled on the inpatient prescription.

However, for **critical medicines or medicines being used in life-threatening clinical conditions** omission or delay can lead to significant patient harm or death ^[1,2]. In these circumstances the **first dose (usually parenteral, but may be via an alternative route)** is considered **'life-threatening if omitted'** and must be administered **within 1 hour of the scheduled prescription time**. It is essential that there is clear communication between the prescriber and staff responsible for administering the medicine to communicate the urgent need for administration. Use of the stat dose function/section on the electronic prescribing system and/or paper prescription chart may need to be used.

For patients who are prescribed or usually taking a critical medicine(s) and are unable to receive this by their usual route, an alternative formulation and/or route of administration or alternative medicine must be considered as a matter of urgency; senior advice and pharmacist input should be requested as required.

- An **omitted dose** is a failure to:
 - **administer** a dose before the next scheduled dose is due, or
 - **prescribe** a medicine in a timely manner leading to an omitted dose.
- A **delayed dose** is administration of a medicine **2 hours or more** after the time scheduled on the inpatient prescription.
Or **more than 1 hour** for the **first dose of a medicine on the 'life-threatening if omitted' list**

Life-threatening if omitted medicine list **[administer within 1 hour]**

First parenteral dose of:

- Anti-infectives (antibiotics, antifungals, antivirals)
- Anticoagulants and thrombolytics
- Vasopressors and inotropes
- Anti-arrhythmics
- Antihypertensive in hypertensive crises (e.g. malignant hypertension, post-stroke)
- Resuscitation / anaphylaxis medicines (including colloid or crystalloid IV fluids)
- Hydrocortisone for Addisonian crisis
- Antidotes and reversal agents
- Electrolyte replacement (in a metabolic emergency)
- Anti-epileptics (including buccal and rectal benzodiazepines)
- Insulin

Critical medicine list **[administer within 2 hours]**

- Anti-infectives
- Anticoagulants
- Anti-epileptics
- Insulin (in relation to timing of meal/feed)
- Medicines for Parkinson's disease
- Anti-rejection medicines post-transplant
- Long term* and replacement corticosteroids, including hydrocortisone for Addison's disease
- Desmopressin (in Diabetes Insipidus)
- Nimodipine (post SAH**)
- Medicines for Myasthenia Gravis (MG) (e.g. pyridostigmine)

**The definition of long term steroid use is variable however as a guide can be considered to be a regular dose of prednisolone (or alternative corticosteroid) for > 3 weeks or any patient taking replacement steroids (e.g. hydrocortisone with or without fludrocortisone) for adrenal insufficiency*

***SAH – Sub Arachnoid Haemorrhage*

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References: 1. [NPSA alert: Reducing harm from omitted and delayed medicines. 2010.](#)
2. [Specialist Pharmacy Service. Reducing harm from missed or omitted and delayed medicines in hospital. Nov 2018.](#)

Supplementary Guidance Section 8 – Medication Loading Doses – Approved list of medicines

A **loading dose** is an initial large dose of a medicine used to ensure a quick therapeutic response.

- It is usually given for a short period of time (often one or two doses only, depending on the drug), before therapy continues with a **lower maintenance dose**.
- There is often a requirement for **ongoing monitoring** to ensure safety and clinical efficacy (including drug levels for some drugs).

The use of loading doses can be complex and error prone. Incorrect prescribing, supply and administration of loading doses or subsequent maintenance regimens may lead to severe harm or death.

To ensure **patient safety**, it is important that:

- **Dosing checks** are performed by **all staff** prior to **prescribing, dispensing or administration** to ensure that loading and maintenance doses are correct.
- Decisions to commence a loading dose and subsequent maintenance dose (if applicable) should be clearly **documented in the medical notes** by the prescriber.
- There is **clear and effective communication** regarding any prescribed and administered loading doses, especially at transfers of care (including between wards and on discharge from hospital).

All medicines should be prescribed and administered in accordance with the standards set in the Trust Medicines Policy.

- **Warfarin***
- **Amiodarone**
- **Digoxin**
- **Phenytoin**
- **Aminophylline**
- **Heparin***

* Drug-specific paper prescription charts in use for selected drugs.

- The prescription chart should also be referenced on the prescription chart or EPMA as ‘_relevant drug_ - see additional chart’
e.g. ‘HEPARIN infusion – see additional chart’.
- All completed prescription charts should be filed in the medical notes once complete.

Sources of information to assist with **dosing checks**:

- **Prescription charts (warfarin, heparin, aminophylline)** (available on wards).
- **Trust guidance** (via intranet).

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- **IV Drug monograph guide** (via pharmacy page of intranet)
- **Pharmacy Medicines Information department (ext [REDACTED]) or on-call pharmacist** (via switchboard) **if out-of-hours.**
- **BNF online:** www.bnf.org.uk

Supplementary Guidance Section 9

Re-use of Patients Own Medicines

ON ADMISSION

- Patients are expected to bring in all of their own medicines together with any relevant documentation. Patients presenting without their own medicines should be asked to contact a relative or carer to have them sent in as soon as possible.
- On admission all medicines brought in by the patient should be locked in the bedside locker (except controlled drugs which should be stored in the controlled drugs cupboard – see section 5). First check that the cupboard has been emptied of any previous patient's own medicines. These drugs **MUST** be transferred with the patient should they change wards.

THE USE OF PATIENTS OWN MEDICINES

In some circumstances the patient's own medication (PODs; patient's own drugs) may not be suitable for use and a new supply should be obtained from pharmacy. (see algorithm)

The pharmacy team will assess medicines brought into hospital by the patient, but a nurse will need to take responsibility until the pharmacy team attends the ward.

Do not use if:

- The expiry date has been exceeded. (If not indicated, do not use if it is more than six months from the date of dispensing).
- The physical condition of the drugs is unsatisfactory.
- The medicine is not suitably packaged or labelled.
- The label and contents do not correspond, check for:
 - Medicine name
 - Strength.
 - Patient name (excluding other family members).
 - Typewritten dispensing labels.
 - More than one medicine mixed in one container.
 - Incorrect or confusing instructions. (Staff should not alter directions on labels on the ward).

Patient's own medicines that are no longer required should be removed from the bedside locker and disposed of as clinical waste in a sharps bin (see waste policy).

Note - Patient's own medicines cannot be destroyed without the permission of the patient. If a patient insists on keeping any discontinued or changed medicines, the label should have a single line drawn through it and annotated "dose changed (OR "treatment stopped") – do not use". These medicines should be removed from the patients locker and sent home with a carer or relative.

When a patient leaves a ward, a final check must be made to ensure that all drugs are removed from the cabinet before a new patient is admitted. This is to reduce the risk of medicine administration errors.

Algorithm for the use of patients' own medicines (PODs) on the ward

1. Prescribed by a doctor or bought over-the-counter?

Yes —————> No —————> **Do not use**

2. The label is legible and bears the correct name and details (not hand written), drug name and strength, and suppliers name and address. The product is in the original dispensed container and matches the label description.

Note: products with no dosage instructions are acceptable, as are those with no pharmacy label but which are in manufacturers original pack containing blister strips of tablets or capsules on which the drug name, strength and expiry date are clearly visible. The pharmacist should consider relabelling such medicines with appropriate instructions at the earliest opportunity

Yes —————> No —————> **Do not use**

3. Dispensed with the last six months if not marked with a manufacturers expiry date?

Yes —————> No —————> **Do not use**

4. Mixed, dirty or broken tablets or capsules present?

No —————> Yes —————> **Do not use**

5. If there are loose tablets or capsules in a bottle, are they easily identifiable by colour or markings? (contact medicines information ext 3208 if in any doubt for a formal tablet identification)

Yes —————> No —————> **Do not use**

6. If the product is a liquid, inhaler, injection, cream, suppository or pessary, is it in a manufacturers original pack with a clearly visible expiry date?

Yes —————> No —————> **Refer to Pharmacist**

7. If the product is an eye drop or ointment, has it been dispensed within the last month?

(These must be re-supplied within one week)

Yes —————> No —————> **Do not use**

8. Does the product require cold storage?

No —————> Yes —————> **Do not use**

No

Yes Are you satisfied that the cold storage requirements have been met

9. Are there any "Dosette/Venalink/Blisterpack" type boxes

No —————> Yes —————> **Refer to Pharmacist**

If you are satisfied with the general condition, packaging and labelling, the product is safe to use

Supplementary Guidance Section 10

Self Administration of Medicines by Patients

Introduction

Self-administration of medicines is encouraged where appropriate within the Complex Rehabilitation Unit and for neurology patients on Chavasse ward to reflect the requirements of the NSF for Older People, best practice and the NMC Guidelines for administration of medicines. Self administration for other inpatients is currently limited to inhalers, insulin, glyceryl trinitrate (GTN) sprays, eye drops and topical creams/ointments only. Insulin must always be locked away, never kept in an unlocked cupboard or drawer, even for patients who are self administering. For other inpatients who strongly feel that self-administering their oral medication is in their best interests, and who are assessed as suitable by the nurse, self-administration at level 2 or 3 is permitted providing their consultant is in agreement and this is documented in the case notes.

The advantages to be gained using patient self administration include:

- Reduction of waste with corresponding savings in medicines expenditure.
- Improvement in patient-education and concordance.
- Better communication between professionals and reduction in prescribing errors.
- Increased patient empowerment.
- Better use of time in the ward environment by both nursing and pharmacy staff.
- Improved awareness of the patients' ability to cope with medication while they are on the ward and their needs after discharge.

The process consists of a number of basic components:

- Patient request to self administer (where patient self-administers at home)
- Use of patient's own medicines (PODs) (see supplementary guidance 9)
- Assessment of patient's ability to safely self administer
- Bedside storage of the patient's medication.
- Self administration by the patient.

All of these must be in place for a ward to be effective even if very few patients are expected to achieve full self-administration status. This is a flexible system and there will always be scope to modify the system to meet the specific needs of each clinical area, providing that such changes can be justified. Any changes to the procedures in this document must be approved by senior nurse managers and by pharmacy.

Note that when elective patients first arrive on a ward and have not yet been clerked in, so that their usual medicines are not yet prescribed, they may continue to self-administer their usual medicines until they have been seen by the prescriber, provided the ward nurse has no concerns about this.

Storage

The majority of medication must be stored in the lockable bedside cabinet. Exceptions to this include inhalers, glyceryl trinitrate spray, eye drops, or topical creams/ointments prescribed for when required use. **Patient's own insulin must always be locked away, even for patients self-administering insulin.**

Each cabinet is supplied with its own key, which must be kept locked inside the cabinet unless the patient is self-administering at level 3. Staff will only access the cabinet using the master key, kept in the control of a senior nurse. If a key is lost or a lock is broken it must be replaced immediately by ordering a replacement from the manufacturers, ensuring that the replacement is from the same suite as the rest of the ward. All the lockers on a ward should have one master key where possible.

Patients, including those not self-administering, must be instructed that they **MUST NOT** share medicines with anybody else.

Assessment of patients

All patients on CRU should be assessed on admission. If not, then the patient must be assigned level "0" until a **documented** assessment can be done. For neurology patients on Chavasse ward, self-administration of oral medicines is only permitted if the consultant has documented this is acceptable in the notes **and** the ward nurse has completed an assessment and is satisfied this is appropriate. The consultant approval will usually occur in clinic before admission, but occasionally may be agreed after admission. For all other inpatients, only patients on inhalers, insulin, GTN spray, eye drops or topical creams/ointments who wish to self-administer need to be routinely assessed.

Levels of self administration

Level 0	Full nurse administration.
Level 1	Full supervision.
Level 2	Close supervision.
Level 3	Full self administration. (CRU or Chavasse neurology patients only)

Full supervision A nurse must teach the patient how to administer medicines and explain their purpose at each administration.

Close Supervision The patient must ask nursing staff for the key to the locker. The patient checks the medication with the nurse before taking.

Full self administration The patient has the locker key and is allowed to administer their own medicines without

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supervision. This is not routinely permitted on acute wards except for neurology patients on Chavasse.

Points to note with reference to the assessment algorithm:

- 1 If the patient is not going to be self-administering after discharge, staff retain a responsibility to ensure the carer is able to administer to ensure concordance and optimisation of outcomes.
- 2 + 3 Further documented assessments should be made as part of an agreed plan. Both confused and physically ill patients may be able to move to level 3 as their condition improves.
- 4 Patients may not feel confident, especially after admission. Their wishes must be respected but they should be encouraged to self-administer when assessed as competent to do so.
- 5 There are dangers associated with allowing a patient with a history of drug abuse, alcoholism or suicidal tendencies full self administration. Exclusion must be considered, but it may not be in the patient's best interest to refuse the opportunity to take responsibility for their own medicines and each patient must be assessed individually. High-risk patients will still assume control of their medication after discharge. It **may** be appropriate to put the patient at level 3 but only supply suitable amounts of medication e.g. seven days
- 6 + 7 Problems identified with self medication can be addressed by pharmacy prior to discharge
- 8 To achieve Level 3, a patient must have a working appreciation of the medication being taken, what it is for, and potential side effects / dangers. Staff undertaking the assessment must be confident that the patient has sufficient understanding for each medicine.
- 9 Physical and mental states may change, so regular reassessment may be indicated.

Patients should be allowed to manage their medication in a way that reflects

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the way they will cope after discharge. Any problems can then be identified and resolved prior to discharge or support mechanisms arranged post discharge.

Patient information

A leaflet to send to patients pre-admission is shown within this guidance. While patients are self administering it is essential that any changes in prescription are communicated to the patient.

Medicines Information

Pharmacy supply information leaflets (PILs) for all medicines dispensed for a patient. Pharmacy will supplement the leaflets with verbal information when requested. Pharmacy will supply other information e.g. steroid cards or anticoagulant books.

Prescribing

All patients will require an inpatient prescription chart to be completed in the usual way with all medication prescribed according to Trust policies.

Supply

Wards keep a range of stock medicines and pharmacy can supply other medicines during normal opening hours. Urgent medication is available in the pharmacy nightstore.

Records

The risk assessment on eP2 must be completed by the nurse. For patients fully self-administering, a consultant or registrar should also document their agreement in the case notes (except on CRU when agreed and documented at the multidisciplinary team meeting). The electronic prescribing system allows recording of self-administration. Nurses MUST confirm with the patient that the medicine has been self administered before recording that the dose has been taken. Where medication has been temporarily stopped for surgery or some other reason this must be clearly documented to ensure that the medication is restarted on or before discharge.

Self-administration of "as required" medication must be recorded. The nurse must check with the patient and must initial all entries.

If changes are made to the prescription of a patient who is self-administering, prescribers must ensure they inform the patient immediately, to ensure this change can be implemented.

The discharge process

A pharmacist should check the discharge prescription for clinical accuracy and the need to make further supplies before the patient is discharged.

If a member of pharmacy staff has checked the medication while on the ward and there is sufficient quantity the medicines need not be sent to pharmacy and can be issued to the patient from the bedside cabinet.

If there is insufficient quantity, or any new drugs prescribed the TTO should be given to the ward pharmacy team to process.

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Controlled Drugs

Due to legal and storage requirements, controlled drugs are not included in this self medication scheme.

Pharmacy services to wards

A pharmacist / clinical technician will carry out regular visits and will:

- Check new patients' own medicines for quality and authorise continued use.
- Check each patient's prescription for accuracy and anomalies.
- Resolve any prescribing discrepancies or queries.
- Ensure that adequate stocks are ordered for new patients, and on request from nursing staff for existing patients.
- In liaison with nursing staff, ensure that for patients self administering at level 2 or 3, all medicines are fully labeled with the patient's name and directions.
- Discuss with the patient ongoing medication needs including ability to cope at home after discharge.
- Review the patient's competence for self administration and the current level based on ward assessment documentation.
- Discuss the patient's assessment with nursing staff or amend the assessment sheet if necessary.
- Establish expected discharge date and check the discharge prescription for accuracy and the need for further supplies of take home medication.
- Discuss medication with the patient to establish understanding particularly where changes in medication have been made.
- Liaise with the GP and community pharmacist as necessary to ensure continuity of care.
- Ensure that interventions are suitably recorded in the notes.

Monitoring of the Policy

The Trust quality assures compliance with completion of Inpatient risk assessments for medicine administration. This is done via the electronic eP2 system and ward dashboards to display compliance.

The Walton Centre NHS Foundation Trust
Patient Information About Self Administration of Medicines

What is Self Administration of Medicines?

This is a system to improve your knowledge and understanding of your medicines. This will help you cope with your medicines when you get home.

If you self administer your medicines while you are in hospital you will be able to take your medicines either on your own or with the help of the nursing staff. The nurses and pharmacy staff will give you the information you need, but, if you prefer, the nursing staff can look after your medicines for you.

Why use this system?

When you look after your own medicines, this helps you to understand why you take your medicines, how to take your medicines safely and understand more about your own health.

Who can I talk to about Self Administration?

Before you start looking after your own medicines, you can talk to your nurse or the pharmacy staff who visit the ward every day. They can answer any questions you may have about your medicines.

Do I have to Self Administer?

No – you do not have to look after your own medicines. The nurses will look after your medicines for you if you wish.

What will happen if I want to look after my medicines?

If you want to look after your own medicines when you are in hospital a nurse or pharmacist will explain self administration more, and assess whether it is appropriate or not for you to self administer medicines at the present time. In some cases they may judge that it is more appropriate for them to administer your medicines, and if so they will explain the reasons for this. If they agree it is appropriate for you to self administer, they will go through your medicines with you, explaining the dose and any other important information. There are different levels of administration, depending on how much supervision the nurse feels is appropriate, and the nurse will explain these to you. The assessment will be repeated regularly and the decision about level of self-administration may

be changed as appropriate.

You will use your own medicines from home if you are happy to, and if the nurses or pharmacy staff are satisfied that this is appropriate. We will supply any other medicines you need.

To make this work, you will need to:

- Keep your medicines in the locker by your bed and keep the key safe.
- Ask the nurses or pharmacy staff if you are unsure about anything.
- Only take medicines prescribed for you
- Ask the nurses for any medicines you do not have, or any medicine which is not fully labelled with correct directions.
- Tell the nurse or pharmacy staff if you are running out of a medicine.

You MUST keep your locker locked and the key safe at all times. If anyone tries to take medicines from your locker or open your locker you MUST tell a member of staff straight away.

The only people who should look in your locker are you, the nurses or the pharmacy staff.

What will happen when I go home?

A prescription will be written with the medicines you need to take home. This prescription will be checked against the medicines in your locker. These medicines will be given back to you if they are still OK to use. If more medicines are needed or your medicines need to be changed, the pharmacy staff will look after this.

**PLEASE REMEMBER TO GIVE THE LOCKER KEY BACK TO THE
NURSES BEFORE YOU LEAVE THE WARD**

The Walton Centre NHS Foundation Trust

Self Administration of Medicines Assessment Record

Patient Label	
----------------------	--

Ward					
Admission Date					
Initial Assessment Level		Assessed by		Date	

Date	Level Assessed	Assessed by
Weekend leave	Name of carer who has been assessed:	

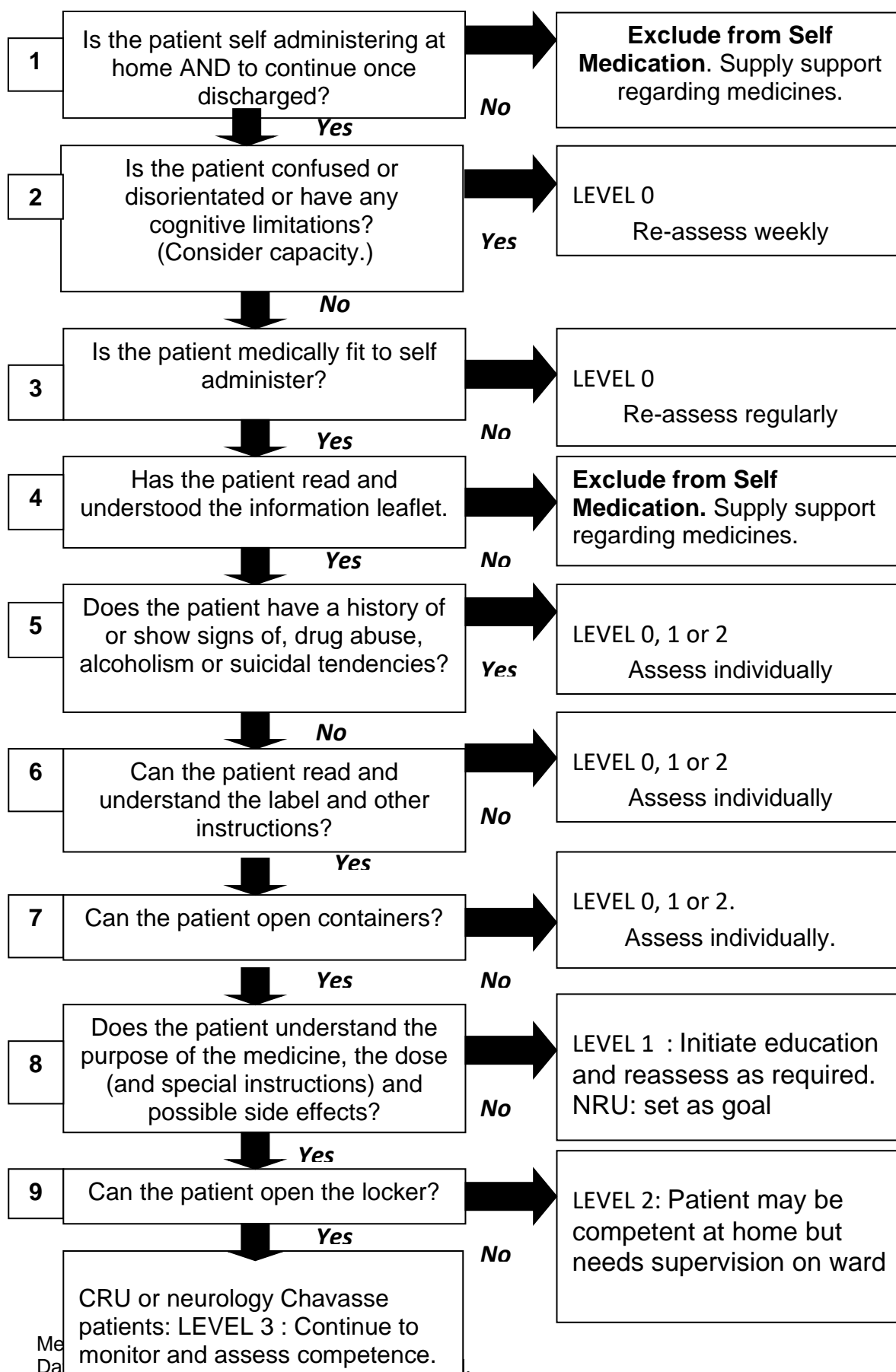
Level 0	Full Nurse Administration
Level 1	Full Supervision
Level 2	Close Supervision (Patient self-administers once nurse has opened locker)
Level 3	Full Self-administration (NRU patients only)

Self-administration on the acute wards (except Chavasse neurology patients) is currently limited to the below list. Please tick which applies to your patient.		
	Tick which applies	Date stopped
Eye drops/ Ointment		
Inhalers		
GTN Spray		
Topical creams		

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Nystatin		
Insulin		
Oral meds (NRU / Chavasse neurology patients only)		
Other: List (NRU / Chavasse neurology patients only)		

The Walton Centre: Self Administration of Medicines Algorithm



Contact ward pharmacy team for advice / support

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Date to be Reviewed: November 2023

Medicines Policy Supplementary Guidance

Supplementary Guidance Section 11

Covert Administration of Medicines

DISGUIISING MEDICINES IN FOOD AND DRINK

COVERT ADMINISTRATION IS SPECIFIC TO THE CARE OF OLDER PEOPLE WITH AN ORGANIC MENTAL ILLNESS, LEARNING DISABILITY SERVICES AND PATIENTS WITH NEUROLOGICAL CONDITIONS WHO LACK CAPACITY.

IF COVERT MEDICATION IS THOUGHT NECESSARY IN OTHER PATIENT GROUPS, LEGAL ADVICE MUST BE SOUGHT AND AGREEMENT OBTAINED AND CLEARLY DOCUMENTED BY THE PATIENT'S CONSULTANT BEFORE COVERT ADMINISTRATION OCCURS.

RATIONALE

The following description seeks to deliver guidance on the covert administration of medicine and the deceptive nature of this practice. This should not be confused with the administration of medicines against someone's will.

Disguising medication in the absence of informed consent may be regarded as deception. However, a clear distinction must always be made between those patients who have the capacity to refuse medication and whose refusal must be respected, and those who lack this capacity. Among those who lack this capacity, a further distinction should be made between those for whom no disguising is necessary because they are unaware that they are receiving medication and others who would be aware if they were not deceived into thinking otherwise.

As a general principle, by disguising medication in food or drink the patient is being led to believe that they are not receiving medication, when in fact they are. The Registered Nurse will need to be sure that what they are doing is in the best interests of the patient, and is accountable for this decision.

CONSENT (NMC POSITION STATEMENT)

"Every adult must be presumed to have the mental capacity to consent or refuse treatment, including medication, unless he or she:

- Is unable to take in and retain the information about it provided by the treating staff, particularly as to the likely consequences of refusal.
- Or is unable to understand that information.
- Or is unable to weigh up the information as part of the process of arriving at a decision.

The assessment of capacity is primarily a matter for the treating clinicians, but practitioners retain a responsibility to participate in discussions in this assessment. Nobody, not even a spouse can consent for someone else,

although the views of family and close friends maybe helpful in clarifying a patient's wishes and establishing his/her best interests.”

NMC's position statement on the covert administration of medicines;

“The NMC recognises that this is a complex issue that has provoked widespread concern. It involves the fundamental principles of patient and client autonomy and consent to treatment, which are set out in common law and statute and underpinned by the Human Rights Act, 1998. The NMC recognises that there may be certain exceptional circumstances in which covert administration may be considered to prevent a patient (who lacks the capacity to give informed consent) from missing out on essential treatment.

GENERAL PRINCIPLES

The best interests of the patient are paramount. The interests of the practitioner, team or organisation should not determine any decision to administer medicines.

Every registered practitioner involved in this practice must reflect on the treatment aims of disguising medication. Such treatment must be necessary in order to save life or to prevent deterioration or ensure an improvement in the patient's or client's physical or mental health. The administration of medicines in this way must be in the best interest of the patient or client.

Those involved in the practice of administering medicines covertly must be fully aware of the aims, intent and the implications of such treatment. Disguising medication in order to save life, prevent deterioration or ensure an improvement in the patient's physical or mental health cannot be taken in isolation from the recognition of the rights of the person to give consent. It may therefore, in such situations be necessary to administer medicines covertly. This must not preclude consideration of an application to the courts for permission to carry this out.

Where adult patients or clients are capable of giving or withholding consent to treatment, no medication is to be given without their agreement. For that agreement to be effective, the patient or client must have been given adequate information about the nature, purpose and associated risks and alternatives to the proposed medication. A competent adult has the legal right to refuse treatment, even if the refusal will adversely affect his or her health or shorten his or her life. Staff must respect a competent adult's refusal as much as they would his or her consent. Failure to do so may amount not only to a breach of their human rights but also attract criminal or civil proceedings. The obvious exception to this principle concerns treatment authorised under the relevant mental health legislation.

For patients or clients detained under the relevant mental health act, the principles of consent continue to apply to any medication for conditions not related to the mental disorder for which they have been detained. The assessment of their capacity to consent to or refuse such medication therefore remains important.

COVERT ADMINISTRATION OF MEDICINES

Covert administration of medicines is only likely to be necessary or appropriate in the case of patients or clients who actively refuse medication but who are judged not to have the capacity to understand the consequence of their refusal.

In such circumstances, and in the absence of informed consent, the following conditions should apply:

- The best interests of the patient or client must be considered at all times.
- The decision of a patient's ability or inability to consent to treatment and capacity is the responsibility of the Consultant. The decision must be documented in the patients' health record, which will form the basis for further discussion.
- The covert administration of medicines is only likely to be necessary or appropriate in the case of patients who actively refuse medication and who are judged not to have the capacity to understand the consequences of their refusal.
- In such exceptional circumstances and in the absence of informed consent - to prevent a patient from missing out on essential treatment, the following considerations may apply:
 - The best interests of the patient must be considered at all times
 - The medication must be considered essential for the patient's health and well being, or for the safety of others.
 - The decision to administer a medication covertly must not be considered routine and must be a contingency measure only. Any decision to do so must be reached after assessing the care needs of the patient individually. It must be patient-specific, in order to avoid the ritualised administration of medication in this way.
- The multi-professional team must agree that this approach is necessary in the exceptional circumstance. The team must include the carers, relatives, advocates and pharmacist led by the Consultant. Family involvement in the care process should be positively encouraged.
- The decision and action taken - including the names of all parties concerned - must be documented in the patient's health record and reviewed on a regular basis.

- Regular attempt should be made to encourage the patient or client to take their medication. This might be best achieved by giving regular information, explanation and encouragement, preferably by the team member who has best rapport with the individual.
- This policy must be used in conjunction with the NMC's Guidelines for the Administration of Medicines – Disguising Medicine in food and drink and the Mental Health Act 1983.

It is mandatory that documentation must be recorded in the patient's notes of all discussion, decisions and reviews with regard to the above points. In addition the form below should be used to assess the patient.

ADDITIONAL ADVICE FOR NURSING STAFF INVOLVED IN THE COVERT ADMINISTRATION OF MEDICINES

The NMC Code of Professional Conduct requires each registered nurse, midwife and health visitor to act at all times in such a manner as to justify public trust and confidence. Registered practitioners are personally accountable for their practice and, in the exercise of professional accountability, must work in an open and co-operative manner with patients, clients and their families, foster their independence and recognise their involvement in the planning and delivery of care.

As a general principle, nurses must be aware that by disguising medication in food or drink, the patient or client is being led to believe that they are not receiving medication, when in fact they are. The registered nurse will need to be sure that what they are doing is in the best interest of the patient or client and be accountable for their part in this decision.

It is unacceptable for the nurse, midwife or health visitor to make a decision to administer medicines in a covert manner in isolation.

For nurses it is important that good record keeping should support their actions even after the completion of risk assessments and the following of appropriate guidelines.

The Walton Centre NHS Foundation Trust
COVERT ADMINISTRATION OF MEDICINES

This form is to be completed by nursing staff and signed by a consultant.

<p>Use addressograph label</p> <p>Patients Name.....</p> <p>Hospital Number.....</p> <p>Date of Birth.....</p>	<p>Date.....</p> <p>Ward.....</p>
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Covert administration is the provision of any medical treatment in disguised form. This usually involves disguising a medicine by administering it in food or a drink. As a result, the person is unknowingly taking a particular medicine. This is likely to be due to a refusal to take a medicine when it is offered, but where treatment is considered necessary for the person's physical or mental health.

In The Walton Centre NHS Foundation Trust the covert administration policy refers specifically to the care of **older people with an organic mental illness, learning disability services and patients with neurological conditions who lack capacity** and is not applicable for any other patient group.

Step 1

The following criteria must be met before a medicine is prescribed covertly for a patient:

Criteria	Date when completed
Alternatives to covert administration have previously been considered eg. Trying different times of administration, different formulations.	
The patient must be deemed to lack capacity to refuse a medicine by a Consultant or Consultant Psychiatrist. This decision must be documented in the patients' health record.	
The multi-professional team must agree that this approach is necessary. The multiprofessional team must include the consultant, nursing staff and ward pharmacist. Ideally, the patient's representative eg. carer, relative or advocate must also be consulted.	

Document the names of all parties involved in the decision in the patient's health record.	
--	--

Step 2- Are the medicines essential?

Review patients' prescribed medicines. Only those which are considered **essential** for the patient's health and well being, or for the safety of others, should be given covertly.

Discuss the medicines required to be administered with the ward pharmacist on a medicine by medicine basis. The ward pharmacist will document within the electronic prescribing system specific instructions for each medicine using a "note to appear when charting". This note will then be displayed each time a medicine is due for administration.

Decision to administer medicines disguised in food or drink taken by:

<i>Name</i>	<i>Signature</i>	<i>Designation</i>	<i>Date</i>
		Consultant	

This decision must be reviewed each time medicines are administered and formally at each consultant review, usually weekly. This must be documented in the medical record.

Form expires:..... (maximum of 3 months)

This document must be retained in the medical record.

Medicines Policy

Supplementary Guidance and Standard Operating Procedure for the Administration of Injectable Medicines

1. COMPETENCY REQUIREMENTS

Registered Nurses or Operating Department Practitioners who administer intravenous medicines must have completed the approved Trust IV training day prior to any involvement in IV therapy. This includes acting as the second check. This is followed by a probationary period during which time the nurse/ODP practices under close supervision and is assessed by a registered nurse colleague with a minimum of 12 months experience.

Junior medical staff appointed to the Trust must complete the aseptic technique and injectable medicines assessments at Trust induction.

1.1 RESOURCES

Intravenous therapy is both complex and hazardous. It is essential that practitioners practice safely. The following information sources can be accessed for information regarding IV therapy.

- Medusa – Injectable Medicine Guide (available from the intranet)
- Ward Pharmacist
- Medicines Information
- On-call Pharmacist

1.2 ADMINISTRATION OF INJECTIONS – GENERAL

NB: Drugs given by intravenous intermittent or continuous infusion should be administered using a rate controlled device.

1.2.1 BEFORE ADMINISTRATION

- Check infusions. They should be free of haziness, particles and discolouration.
- Use aseptic (non-touch) technique at all times.
- Attach administration sets to infusion containers carefully, on a flat surface and using the technique appropriate to the type of container.
- Prime the access device immediately before starting an infusion.

1.2.2 AFTER ADMINISTRATION

- Flush the access device
- Ask the patient to report promptly any soreness at the injection site or discomfort of any sort.
- Record administration.

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- Discard the empty ampoules/vials from which the injection was prepared and any unused medicine.
- Ampoules or vials should never be used to prepare more than one injection unless specifically labelled by the manufacturer for 'multi-dose' use or unless this is specifically authorised within the Trust for that product.
- Re-check the administration site for signs of leakage, infection or inflammation and continue to monitor the patient, contents of the infusion container and the rate of infusion according to local policy.
- Check that arrangements for monitoring fluid balance or clinical parameters have been made. Ensure that relevant documentation is made available for subsequent regular monitoring to take place.

1.3 HAZARDS OF INTRAVENOUS THERAPY

1.3.1 INFECTION

Line infection must be referred to the infection control team and the microbiology department for advice on treatment. Infection can occur through several routes:

- At the time of insertion.

Due to inadequate skin disinfection of the patient or from the operator resulting in contamination of the distal tip of the cannula.

- Between the catheter and the skin

Due to manipulation of the site, inadequate skin disinfection or insufficient anchorage of the cannula.

- Intra-lumenally via any connection in the system.

Due to contamination from the operator's hands or contamination of the component parts.

- Intrinsically

From contaminated solutions, non-sterile equipment, air inlets etc.

- Haematogenous spread

From other sites e.g. pressure sore, wound etc.

1.3.2 OTHER LINE AND SITE RELATED PROBLEMS

This includes the correct identification of lines, the necessity for aseptic technique at all times when using lines and leakage into the lines causing contamination and the possibility of potentially fatal air embolism. Site related

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problems include the choice of site and the factors taken into account when making that choice, the size of the cannula used, possible perforation during cannulation, infiltration or extravasation, phlebitis and haematoma. The site should be inspected regularly to ensure none of the above cause difficulties.

1.3.3 PATIENT RELATED PROBLEMS

These include:

- Circulatory shock, causing collapse of the peripheral vessels.
- Age / Mental State – The very young, confused or violent may disconnect or remove intravenous lines.
- Immunosuppressed – This patient group is at particular risk of line related infection.
- Anaphylaxis

1.4 INCOMPATIBILITIES

Many drugs are not compatible with each other in solution, or during administration using the same line. This could be due to chemical, physical or pharmacological interactions. If incompatible drugs are mixed together several consequences, possibly invisible to the operator, are possible:

- Blockage of the line due to chemical or physical precipitation.
- Vein damage due to chemical or physical precipitation.
- Inactivation of one or more of the co-administered drugs, leading to therapeutic failure.
- Emboli formation due to chemical or physical precipitation.

Medicines should **never** be added to blood products, amino acid solutions (e.g. TPN products), mannitol infusions or sodium bicarbonate infusions. This is due to the likelihood of interactions with these products. Drugs should never be mixed or administered down the same line unless they are known to be compatible.

1.5 STABILITY

Some medicines are stable for a short time period and the stability can be adversely affected by exposure to excessive heat or light. The stability of all infusions and injections should be checked if administration is prolonged.

Following preparation all medicines prepared in a clinical area for injection

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should be used immediately and unless otherwise advised have a 24 hour expiry from the start of infusion.

1.6 TYPES OF INTRAVENOUS ADMINISTRATION

1.6.1 CONTINUOUS INFUSION

- Infusion of large volume hydration fluid or plasma expander
- Addition of a drug to a large volume infusion bag for slow infusion
- Addition of a drug to a small volume syringe for slow infusion via a rate control device.

1.6.2 INTERMITTENT INFUSION

- Addition of a drug usually to a small volume (50ml or 100ml) infusion bag (minibag) connected to the main drip line set, or to a secondary administration set connected to a junction in the main drip line.
- Addition of a drug to a small volume syringe for slow infusion via a rate control device.

1.6.3 INJECTION

- Injection of the drug solution from a syringe into the injection port in the drip line or directly into an indwelling catheter. This resembles direct injection into the vein.
- If administered over 2 to 5 minutes, this is referred to as a slow intravenous injection
- If the injection is to be administered more quickly into the vein, this is referred to as a rapid intravenous injection (sometimes referred to as an intravenous push or direct injection).
- As a general rule, the injection port of the drip-line should be used in preference to the hub of the indwelling cannula.

1.7 COMPARISON OF INTRAVENOUS INFUSION AND INJECTION

1.7.1 CIRCUMSTANCES IN WHICH INTRAVENOUS INFUSION IS NECESSARY:

- When direct injection would cause toxic levels of the drug e.g. potassium chloride
- When direct injection would cause venous irritation. Dilution of the drug

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in a large volume minimises this e.g. high dose benzylpenicillin and certain cytotoxic drugs.

- When the drug is quickly metabolised or excreted or is very short acting and direct injections would need to be given very frequently e.g. heparin and dopamine.
- When the drug has a narrow therapeutic index e.g. aminophylline.

1.7..2 CIRCUMSTANCES IN WHICH INJECTION IS PREFERABLE TO INFUSION:

- When optimum blood levels are required rapidly e.g. in antibiotic therapy.
- When the drug is incompatible with or unstable in infusion fluids.

1.8 DISPOSAL OF SHARPS

- Sharps must be disposed of safely as per Trust policy.

STANDARD OPERATING PROCEDURE FOR THE PREPARATION OF AN INJECTABLE MEDICINE

- A. Preparation must not proceed if the prescription is unclear or incomplete
- B. Ensure that the area in which the medicine is to be prepared is clean, uncluttered and free from interruption and distraction.
- C. Assemble all materials and equipment: sharps bin for waste disposal, medicine ampoule(s)/vial(s), diluent, syringe(s), needle(s), alcohol wipes, disposable protective gloves, clean re-usable plastic tray.
- D. Check the following:
 - (1) Expiry dates;
 - (2) Damage to containers, vials or packaging;
 - (3) That medicines have been stored as recommended, e.g. in the refrigerator.
- E. Check that:
 - (1) The formulation, dose, diluent, infusion fluid and rate of administration correspond to the prescription and product information;
 - (2) The patient has no known allergy to the medicine
 - (3) You understand the method of preparation.
 - (4) Calculate the volume of medicine solution needed to give the prescribed dose. Write the calculation down and obtain an independent check by another qualified and appropriately trained healthcare professional.
 - (5) Prepare the label for the prepared medicine with the following details (Flag labelling technique should be used to ensure graduations are not obstructed on small volume syringes).
 - (i) Name of the medicine
 - (ii) Strength
 - (iii) Route of administration
 - (iv) Diluent and final volume
 - (v) Patient's name and Hospital Number
 - (vi) Prepared date and time
 - (vii) Name of the practitioner preparing the medicine
- F. Clean your hands according Trust Hand Hygiene Guidelines.
- G. Put on a pair of disposable protective gloves.
- H. Use a 70% alcohol wipe or spray to disinfect the surface of the sterile trolley.

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- I. Assemble the syringe(s) and needle(s). Peel open wrappers carefully and arrange all ampoules/vials, syringes and needles neatly onto the trolley.
- J. Use a 'non-touch' technique, i.e. avoid touching areas where bacterial contamination may be introduced, e.g. syringe-tips, needles, vial tops. Never put down a syringe attached to an unsheathed needle.
- K. Prepare the injection by following the manufacturer's product information or Trust guidelines.
- L. No further additions should be made to a bag once an infusion has started.
- M. No additions should be made if the fluid is blood (or blood products including immunoglobulin), plasma, mannitol, sodium bicarbonate or nutrition solutions.
- N. The Minibag Plus system (or equivalent with Ecoflac bottles) should be used whenever possible.

WITHDRAWING SOLUTION FROM AN AMPOULE (GLASS OR PLASTIC) INTO A SYRINGE

- A. Tap the ampoule gently to dislodge any medicine in the neck.
- B. Snap open the neck of glass ampoules, using an ampoule snapper if required.
- C. Attach a needle to a syringe and draw the required volume of solution into the syringe. Tilt the ampoule if necessary.
- D. Invert the syringe and tap lightly to aggregate the air bubbles at the needle end. Expel the air carefully.
- E. Remove the needle from the syringe and fit a new needle or sterile blind hub.
- F. Label the syringe (see above).
- G. Keep the ampoule and any unused medicine until administration to the patient is complete to enable further checking procedures to be undertaken.
- H. If the ampoule contains a suspension rather than solution, it should be gently swirled to mix the contents immediately before they are drawn into the syringe.
- I. The neck of some plastic ampoules is designed to connect directly a syringe without the use of a needle, after the top of the ampoule has been twisted off.

WITHDRAWING A SOLUTION OR SUSPENSION FROM A VIAL INTO A SYRINGE

- A. Remove the tamper-evident seal from the vial and wipe the rubber septum with an alcohol wipe. Allow to dry for at least 30 seconds.
- B. With the needle sheathed, draw into the syringe a volume of air equivalent to the required volume of solution to be drawn up.
- C. Remove the needle cover and insert the needle into the vial through the rubber septum.
- D. Invert the vial. Keep the needle in the solution and slowly depress the plunger to push air into the vial.
- E. Release the plunger so that solution flows back into the syringe.
- F. If a large volume of solution is to be withdrawn, use a push-pull technique.
- G. Repeatedly inject small volumes of air and draw up an equal volume of solution until the required total is reached. This 'equilibrium method' helps to minimise the build-up of pressure in the vial.
- H. Alternatively, the rubber septum may be pierced with a second needle to let air into the vial as solution is withdrawn. The tip of the vent needle must always be kept above the solution to prevent leakage.
- I. With the vial still attached, invert the syringe. With the needle and vial uppermost, tap the syringe lightly to aggregate the air bubbles at the needle end. Push the air back into the vial.
- J. Fill the syringe with the required volume of solution then draw in a small volume of air. Withdraw the needle from the vial.
- K. Expel excess air from the syringe. Remove the needle and exchange it for a new needle or a sterile blind hub.
- L. The vial(s) and any unused medicine should be kept until administration to the patient is complete.
- M. If the vial contains a suspension rather than solution, it should be gently swirled to mix the contents, immediately before they are drawn into the syringe.

RECONSTITUTING POWDER IN A VIAL AND DRAWING THE RESULTING SOLUTION OR SUSPENSION INTO A SYRINGE

- A. Remove the tamper-evident seal from the vial and wipe the rubber

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septum with an alcohol wipe. Allow to dry for at least 30 seconds.

B. Use the procedure in above to withdraw the required volume of diluent (e.g. water for injections or sodium chloride 0.9%) from ampoule(s) into the syringe.

C. Inject the diluent into the vial. Keeping the tip of the needle above the level of the solution in the vial, release the plunger. The syringe will fill with the air which has been displaced by the solution (if the contents of the vial were packed under a vacuum, solution will be drawn into the vial and no air will be displaced). If a large volume of diluent is to be added, use a push-pull technique (see above).

D. With the syringe and needle still in place, gently swirl the vial(s) to dissolve all the powder, unless otherwise indicated by the product information. This may take several minutes.

E. Follow the relevant steps as above to withdraw the required volume of solution from the vial into the syringe.

F. Alternatively, the rubber septum may be pierced with a second needle to let air into the vial as solution is withdrawn. The tip of the vent needle must always be kept above the solution to prevent leakage.

G. If a purpose-designed reconstitution device is used, the manufacturer's instructions should be read carefully and followed closely.

ADDING A MEDICINE TO AN INFUSION

A. Prepare the medicine in a syringe using one of the methods described above.

B. Check the outer wrapper of the infusion container is undamaged.

C. Remove the wrapper and check the infusion container itself in good light. It should be intact and free of cracks, punctures/leaks.

D. Check the infusion solution, which should be free of haziness, particles and discolouration.

E. Where necessary, remove the tamper-evident seal on the additive port according to the manufacturer's instructions or wipe the rubber septum on the infusion container with an alcohol wipe and allow to dry for at least 30 seconds.

F. If the volume of medicine solution to be added is more than 10% of the initial contents of the infusion container (more than 50ml to a 500ml or 100ml to a 1litre infusion), an equivalent volume must first be removed with a syringe and needle.

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G. Inject the medicine into the infusion container through the centre of the injection port, taking care to keep the tip of the needle away from the side of the infusion container. Withdraw the needle and invert the container at least five times to ensure thorough mixing before starting the infusion.

H. Do not add anything to any infusion container other than a burette when it is hanging on the infusion stand since this makes adequate mixing impossible.

I. Before adding a medicine to a hanging burette, administration must be stopped. After the addition has been made and before administration is re-started, the contents of the burette must be carefully swirled to ensure complete mixing of the contents.

J. Check the appearance of the final infusion for absence of particles, cloudiness or discolouration.

K. Label the infusion (see above).

DILUTING A MEDICINE IN A SYRINGE FOR USE IN A PUMP OR SYRINGE-DRIVER

A. Prepare the medicine in a syringe using one of the methods described above.

B. Draw the diluent into the syringe to be used for administration by the pump or syringe-driver. Draw in some air (slightly more than the volume of medicine needed) and remove the needle.

C. Stand the diluent syringe upright. Insert the needle of the syringe containing the medicine into the tip of the diluent (administration) syringe and add the medicine to it. Alternatively, a disposable sterile connector may be used to connect two syringes together directly.

D. Check the following:

i. The total volume of injection solution in the syringe is as specified in the prescription and that the infusion can be delivered at the prescribed rate by the administration device chosen;

ii. The rate of administration is set correctly on the administration device and according to the manufacturer's instructions.

E. Fit a blind hub to the administration syringe and invert several times to mix the contents.

F. Remove the blind hub. Tap the syringe lightly to aggregate the air bubbles at the needle end. Expel the air and refit the blind hub.

G. Carefully check the syringe for cracks and leaks and then label it (see

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standard above), especially noting the requirements specific to syringe drivers.
H. Check that the rate of administration is set correctly on the device before fitting the syringe, priming the administration set and starting the infusion device.

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Standard Operating Procedures for the Safer Management of Controlled Drugs

Title	No
Ordering of Controlled Drugs for Ward Stocks	1
Collection of Controlled drugs from Pharmacy	2
Receipt of Controlled Drugs on Wards	3
Entry of Controlled Drugs into the Ward Register	4
Administration of Controlled Drugs to Patients	
Checking Controlled Drugs	6
Handover of Controlled Drug Keys	7
Handling Patients Own Controlled Drugs	8
Returning Controlled Drugs to Pharmacy	9
Destruction of Controlled Drugs on Wards	10
Dealing with Staff who are Suspected of Controlled Drug Abuse	11
Dealing with Illicit Drugs Found on Patients	12

1. Ordering of Controlled Drugs for Ward Department or Theatre Stocks

Wards are encouraged to use the electronic web portal to order controlled drugs. This has significant safety advantages over the paper based system. The web portal divides controlled drug ordering in to two separate processes.

- 1 Wards can order against an approved stocklist up to the specified maximum. Upon submission, this order will be directed straight to the controlled drug team for dispensing.
- 2 Non stock controlled drugs are ordered per patient and are verified by a clinical pharmacist for assessment before being directed to the controlled drug team for dispensing.

Where electronic ordering is not possible, the controlled order book specified for the ward, theatre or department may be used for the ordering of controlled drugs using a separate page for each item. An authorised registered nurse or ODP can generate an order for the required controlled drugs.

1. Place the carbon paper in between the top and lower page with the carbon placed down.
2. Orders must contain the following details :-
 - Trust name
 - Ward theatre or department name (specify which cabinet if more than one)
 - Name, form strength, volume, quantity of the controlled drug to be ordered. (Only agreed abbreviations can be used.)
 - Signature of person ordering
 - Person ordering must print name also
 - Date of the order.
3. Send the order book down to pharmacy.

NOTES

- Ward stocks must not be issued to patients by ward staff for the purpose of taking home on discharge.
- Controlled drugs must be ordered either electronically via the web portal or in the controlled drug order book specific to that ward, theatre or department.
- Should an area have more than one controlled drug cabinet then each cabinet must have an order book and register, specific to that cabinet.
- Controlled drugs order book, like all controlled stationary, must be kept in a secure place. Should an order book go missing, the most senior nurse in charge must inform the Directorate Manager and pharmacy. An incident report form must be completed.

- In the event of an emergency, where the web portal or CD order book cannot be accessed, emergency orders can be placed in an “ad hoc order book” which is held by pharmacy.
- Order books from other areas cannot be used.
- Controlled Drugs must be ordered directly from pharmacy and cannot be obtained from other controlled drug cabinets on the ward or anywhere else in the Trust.

2. Procedure for the Collection of Stock Controlled Drugs from Pharmacy

1. When a controlled drugs order is ready in pharmacy and ready for collection by the ward, pharmacy will ring the ward to arrange collection.
2. The ward sends down an approved member of staff (who must be able to present a Walton identification badge), known as the messenger, to collect the controlled drugs.
3. The messenger, with a member of the pharmacy staff, checks the controlled drugs for that area. This may be by checking the seal on a sealed bag containing the controlled drugs and order book, or an actual check of the drugs dispensed against the order in the requisition book. This check would include:-
 - The correct drug
 - The correct form
 - The correct presentation size, (eg 1ml or 10ml ampoules)
 - The correct strength
 - The drug is in date
 - The correct quantity (this would include opening packages which are unsealed and counting the contents)
4. If all items are correct, the messenger signs and dates each page ordered or signs the collection sheet.
5. The ordered stock is transferred up to the ward by the messenger in a sealed container.
6. The messenger must go directly to the ward with the supply and hand it directly and in person to the registered nurse in charge of the ward for receipt, or if they are unavailable, a matron or senior nurse on call.

NOTES

- Both qualified and non-qualified staff who the ward manager considers competent, can undertake collection of controlled drugs for ward stock. The member of staff however must be an official Trust employee and possess the full permanent Trust identity badge. This must be on full display when receiving the controlled drugs from pharmacy.
- When collection is made by non qualified staff, they are acting in the capacity as a “messenger”.

3. Procedure for the Receipt of Controlled Drugs on Wards

1. On arrival at the ward, department or theatre a non-qualified messenger must hand the goods to an authorised receiver (who must be easily identifiable) who must inspect each individual item and either:

Check there is the correct quantity and sign the receipt section on the pink copy of each order sheet in the presence of the messenger.

or

Check the delivery section of the web portal for controlled drugs and acknowledge receipt.

2. The authorised person receiving the controlled drugs, must enter each item in the controlled drugs register on their allocated pages and the final balance checked and countersigned.

Entry must include at least

the date

quantity received

signature of receiver

new stock level

signature and countersignature of the witness

confirming correct balance in register

4. Entry of Controlled Drugs into the Ward Register

- Each controlled drugs cabinet must have a controlled drugs register specific to that cabinet (or cabinets if these cabinets are in close proximity).

NOTE

- Once the controlled drugs have reached the ward or department they become the ultimate responsibility of the nurse or ODP who at that time is in charge of the ward or department.
- Any discrepancies must be reported to pharmacy immediately.
- A separate part of the register must be used for different preparations and presentations of controlled drug with the drug identification being written at the top of each page including the strength.
- No cancellation, obliteration or alteration of any entry may be made.
- Corrections must be made by way of marginal notes or footnotes which must be dated.
- Errors in the register are to be bracketed and endorsed "error", signed and as good practice countersigned by a witness.
- Every entry and correction must be in ink or be otherwise indelible.

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- All records must be stored for two years from the date of the last entry in the register.

It is good practice for the ordering and receiving of controlled drugs not to be done by the same person where possible.

5. Procedure for the Administration of Controlled drugs to Patients

1. When authorised prescribers prescribe controlled drugs for patients, an entry must be made in the controlled drugs register against the item each time the dose is administered. This books out the dose.
2. The entry must include :-
 - the date
 - the time
 - patient name
 - amount given
 - signature of staff member administering
 - signature of witness to the administration
 - balance (must be countersigned as correct)

NOTES

- Controlled drugs ordered for ward stock can only be administered to patients on that ward, department or theatre and cannot be transferred to patients on another ward, department or theatre.
- In the event of an emergency outside normal hours when pharmacy is not open, the Trust policy as authorised by the Accountable Officer must be followed (*see Medicines policy section 5.4*)
- Controlled drugs ordered for ward stock can only be administered to patients on that ward, department or theatre against an inpatient prescription written by an authorised prescriber employed by the Trust or acting as a locum for the Trust.
- The Administration of Medicines Policy must be adhered to.
- Administration to patients requires that a second authorised member of staff (registered nurse or operating department practitioner (ODP)) checks the prescription, preparation and all other aspects of the administration and countersigns the register and administration chart as per Trust policy, EXCEPT for anaesthetists (in Theatres and the Post Operative Care Unit). For nurses/ODPs on the POCU administering IV morphine incrementally, a second nurse/ODP should check the prescription and preparation of the dose. A single nurse/ODP may then administer the dose incrementally.
- Should a dose be wasted (e.g. a liquid dose measured and then refused by the patient) then the dose must be destroyed by emptying into a sharps bin or a denaturing kit. An authorised member of the ward department or theatre staff must witness the destruction. The destruction of the wasted dose must be documented in the controlled drugs register and the entry countersigned by the witness.

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- If the dose prescribed is made up of two presentations then two entries are required in the CD Register, each entry giving the quantity /dose booked out for that item.
- Liquid doses of less than 5ml must be measured out using an appropriate oral syringe.

6. Procedure for Checking Controlled Drug Stock Balance

1. Each controlled drug must be checked against the balance in the register by the nurse in charge or an ODP and another authorised nurse acting as a witness.
2. An entry either on the electronic portal or in the green daily drug count register must be made stating that the balance has been checked.
3. Each balance check entry must be signed/date/time by both the person checking and the authorised witness.

Balance checks should include a check of patients' own controlled drugs in the cabinet against the electronic patients' own controlled drug register.

NOTES

- The reconciliation of the stock balance is to be carried out by two qualified nurses or ODPs one of whom must be the assigned nurse or ODP in charge and the check countersigned by both nurses/ODPs.
- The balance of controlled drugs are to be checked at least every 24 hours by ODPs or nursing staff.
- A balance check must be made each time there is stock movement of a controlled drug.
- Any discrepancies* must be fully investigated.
- On discovering a discrepancy, action should include:
 - Recounting balance again and by another individual authorised to do so.
 - Rechecking all entries have been made
 - Rechecking the balance has been calculated correctly
 - Checking stock has not been separated and stored in another area of the controlled drugs cabinet
 - * a 10% or less differential is generally considered acceptable in the case of liquids. However any other recent discrepancies and the number of doses given since the last balance check must be taken into account when judging whether the discrepancy is reasonably explained as wastage during measuring
- If the discrepancy remains, the nurse, midwife or ODP in charge of the ward, or theatre must be informed. If the discrepancy cannot be resolved the ward department or theatre manager must be informed and pharmacy involved. An incident form must be completed.
- In the event of discrepancies or apparent loss, the nurse, midwife or ODP in charge of a ward, theatre or department is responsible for ensuring that pharmacy is informed and an incident report form completed.

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Major incidents are to be reported to the Senior Nursing Manager for that area and the Clinical Director of Pharmacy.

7. Procedure for the Storage of Controlled Drug Keys at Handover

1. The controlled drug keys must be in the possession of an authorised staff member at all times.
2. At Handover, the keys must be returned to the shift leader of that shift who in turn will pass them over to the shift leader taking over.
3. It is good practice to do a balance check of all controlled drugs at Handover. This must be done by the two shift leaders since they hold the responsibility for the controlled drugs during their respective shifts. This may be a good point for the official handover of the keys.
4. If a check is not possible at each handover the CD balance check must be undertaken at least once every day.
5. Loss of keys must be reported to the Senior Nursing Manager for that area and the Clinical Director of Pharmacy, and an incident form completed

8. Procedure for the Handling of Patients Own Controlled drugs

1. Patients own medicines must be placed in the controlled drug cupboard and an entry made on the EPMA web portal or the designated CD Stock Check and Patients Own Register.
2. At discharge either
 - a. If still prescribed the medicine must be given back to the patient and an entry made on the EPMA web portal or the designated CD Stock Check and Patients Own Register countersigned by a witness.

OR

 - b. If the medicine is not prescribed the medicine should be returned to pharmacy for destruction (contact ward pharmacist). The medicine still belongs to the patient and where possible permission should be obtained from the patient before destruction. If the patient refuses to allow the controlled drug to be destroyed please contact your ward pharmacist for advice.

NOTES

- Controlled drugs belonging to patients should, as with other patient own medicines, be treated as patient's own property.
- There may be instances, as with other patient own medicines, when patient own controlled drugs may require to be administered during

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admission. In these circumstances the following procedure on using patient own controlled drugs must be followed.

The medicines must be checked for suitability according to the local procedure for assessing patient own medicines (POD's) (supplementary guidance 09) and not administered to any other patient. An entry must be made on the EPMA web portal or the designated CD Stock Check and Patients Own Register countersigned by a witness

- Controlled drugs belonging to patients may only be used when the presentation is identifiable and in a tamper proof packaging or presentation.
- Ward stock should be ordered at the next available opportunity unless the patient is only in for a short stay and it would not be feasible to obtain hospital stock.
- If a patient dies, controlled drugs belonging to that patient cannot be legitimately handed back to a relative and are to be disposed of via pharmacy according to Trust policy.

9. Procedure for Returning Controlled drugs Back to Pharmacy

1. When a controlled drug is no longer required by a ward, theatre or department the staff must give notice to pharmacy for its removal.
2. The item is booked out of the controlled drug register and the new balance written against the entry.
3. Removal of all controlled drugs - whether they are ward stock or patient's own must be counted and / or measured in the presence of the nurse or ODP making the entry and the pharmacist returning the medicines.
4. The balance entry must be countersigned both by the nurse or ODP making the entry and the pharmacist removing the medicine.

NOTES

- All ward stock of controlled drugs no longer required on the ward / department must be returned to pharmacy for destruction or for reissue if appropriate.
- Before a patient's own medicine is sent to pharmacy, including controlled drugs, the permission of the patient or their guardian must be granted. The procedure for sending patient's own medicines to pharmacy/destruction on the ward must be followed.
- If controlled drugs belonging to the patients are to be sent to pharmacy/destroyed an entry must be made against the record of the storage, and the removal countersigned/dated by the pharmacist and authorised witness.

10. Procedure for the Destruction of Controlled drugs at Ward Level

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All out of date ward stocks of controlled drugs are to be returned to pharmacy for destruction (see section 5.12 of Medicines Policy)

1. Controlled drugs for destruction at ward level are to be destroyed in the presence of a witness who could include another authorised nurse / pharmacist or doctor.
2. An entry of the destruction is to be made in the register and countersigned by both parties witnessing the destruction.
3. Controlled drugs should be destroyed by emptying into a Controlled Drug DOOP (destruction of old pharmaceuticals) bin.

NOTES

*Controlled drugs which are to be destroyed at ward level include.

- Individual doses that are prepared and not administered (the reason why not administered must be recorded in the CD register.)
- The remains of partly used vials or PCA devices.
- The remains of part doses (eg 25mg from a 50mg ampoule).

IV morphine injection wasted in theatre recovery will be documented and countersigned in the controlled drugs record book.

Part used syringes of controlled drugs wasted in Horsley ITU or HDU will be documented and countersigned on the infusion record chart.

11. Procedure for Dealing with Suspected Abuse of Controlled drugs Amongst Staff Members

1. If staff suspect any another member of staff, including prescribing staff, of abusing controlled drugs, then they must confide their suspicions with a more senior staff member. If the suspecting staff member would rather, then they can make contact with the senior pharmacy manager to discuss their suspicions with him/ her.
2. All actions concerning this will be dealt with in a confidential way and will follow the agreed Corporate Trust procedure relating to this issue.

12. Procedure for Dealing with Illicit Medicines Found on Patients

Schedule 1 Products (CD Lic) and other illicit medicines

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Schedule 1 products include such substances as LSD, cannabis and ecstasy. Production, possession and supply of such substances are limited for the purpose of research and authorised personnel must be granted a licence from the Home Office for them to handle such substances. Under normal circumstances pharmacists, doctors, nurses and midwives do not hold such a licence. Other illicit medicines may include other schedules such as Schedule 2, e.g. diamorphine

Such medicines are considered illicit if a patient or staff member is in possession of the medicine without a bona-fide authorised supply i.e. If the patient has had no prescription from an authorised practitioner. If a palliative patient has in their possession diamorphine prescribed for their pain by a doctor – such a patient would be in legal possession of the product.

There may be circumstances when illicit/unknown substances are found on the hospital premises or on patients on admission. (see Medicines Policy - supplementary section 2)

1. In these circumstances a pharmacist can take possession of the substance for the purpose of destruction or for handing it over to the police.
2. Where such a substance is found on a patient the ward pharmacist must be informed. The patient's confidentiality must be maintained
3. In circumstances where extreme quantities are found, the pharmacy manager and senior hospital managers, legal team and clinicians must be informed. In these circumstances it may be acceptable practice to identify the source.
4. When illicit/unknown substances are found on a patient it is not acceptable practice to hand them back on discharge since this may result in the person doing so, guilty of an offence of unlawful supply of a Controlled drug.
5. If a patient does not give authority for the removal and destruction of the medicine, the hospital may be required to call in the police.

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Appendix 1 Named Patient Request for Non-formulary / Non- Stock Drug

Named Patient Request for Non-formulary / Non-Stock Medicine (including unlicensed medicines)

This form should be used in the following instances

1. If a patient is admitted to the Trust on a non-formulary / non-stock medicine one of the following courses of action should be taken:-
 - a. Change patient to a formulary product
 - b. Use patients own supply (after check by pharmacist)
 - c. If a and b are not possible a small supply will be purchased on the request of the ward pharmacist.
2. If it is necessary to initiate treatment with a new or non-formulary drug for an individual patient, a small supply will be purchased at the request of a CONSULTANT. If more than one patient requires treatment a formal request should be submitted to the Drug and Therapeutics Committee (see new drug application form).

In either case the smallest container size will be purchased and its total cost will be charged to the consultant within the directorate concerned. To allow time for ordering there may be at least a 24 hour delay in obtaining the drug.

Please supply the following details

Patients Name Hosp No.....

Ward Name or Outpatient.....

Drug..... Strength.....Form.....

Dose, Frequency and Duration.....

Indication.....

Reason for request.....

Cost (contact pharmacy if unsure).....

Signature Consultant..... Date.....

(For unlicensed medicines- I understand that this medicine does not have a U.K. product license/is not licensed for this purpose and that I take full responsibility for its use in this patient.)*

Approval by Clinical/Medical Director (if annual cost >£1000).....

Is the above medicine rechargeable to a commissioner? YES/NO

Authorising Pharmacist.....

I wish to authorise specific medical officers in my team to prescribe this medicine for this patient in future.

DOCTOR SIGNATURE.....DATE

DOCTOR SIGNATURE.....DATE

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Appendix 2

New Medicine Application Form



Application and Case for Introduction of New Medicine Service Developments

Application for: _____
(please add drug name & indication)

Purpose of this form: for providers to apply to commissioners for in-year funding of any new drug or extended use of an existing drug (e.g. new indication, new patient group) that will impact on prescribing costs to the commissioner. This includes where the prescribing will be passed on to primary care prescribers or where the drug is prescribed in hospital but generates additional PBR costs or is excluded from the Payment by Results Tariff and drug costs are passed on to commissioners. The annual horizon scanning process should be used as the preferred route to identify the majority of new developments, and any in-year funding applications will be subject to a prioritisation process to establish whether it is a local priority to review within the current financial year. Applicants are advised that prioritisation for review does not guarantee a positive commissioning recommendation outcome.

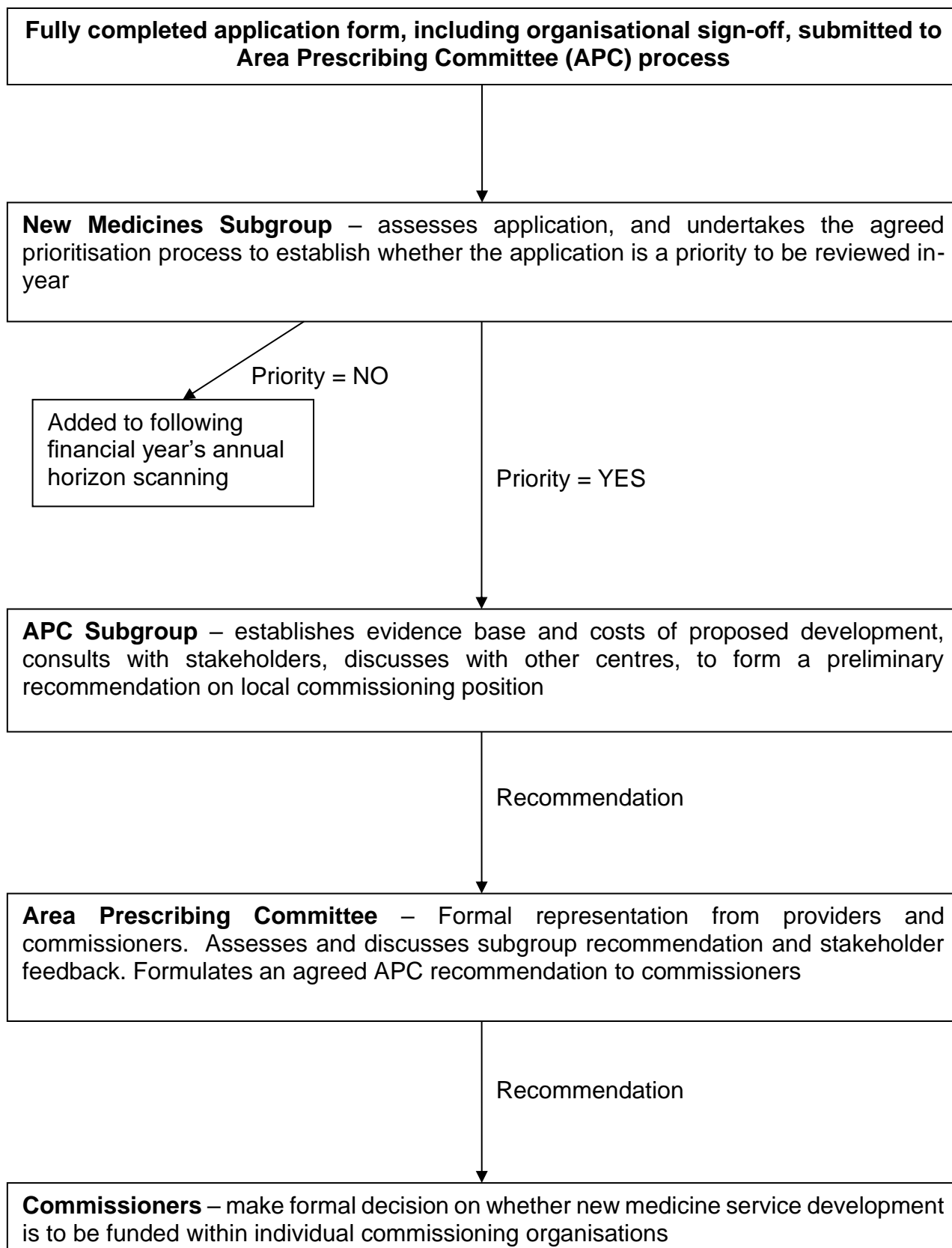
For minor formulary changes please use the [Request for amendment to existing formulary choice or a medicine](#) switch form.

This form is not to be used for Individual Funding Requests (IFR). These are considered where the individual or treatment is exceptional; i.e. where the treatment can be described as exceptional by virtue of the rarity of the condition or the difference of the individual from the generality of similar patients. Separate IFR documentation is available. Sometimes new, innovative treatment options are presented as exceptional: in this case every effort is made to direct the clinical team to the commissioning decision route, via this service development application, although the first few requests via the exceptional treatment route may be considered so as to offer benefit to patients where this is likely.

Please complete this form as fully as possible. Please complete all relevant sections legibly. Any missing or illegible information will delay the application. Applications completed by pharmaceutical companies are not acceptable.

NB New medicines must first be approved by the Walton Centre Drug and Therapeutics and Committee, then submitted to the Pan Mersey New Drugs Subgroup. The form below may be used for both. In the first instance please send an electronic copy and a signed hard copy of the completed form to the Lead Pharmacist, Neurosciences, and the Chair of the Walton Drug and Therapeutics Committee.

Process:



Section 1 Clinical information

Name of medicine (generic and brand name):	
Strength(s) and form(s) of preparation: Dose & schedule of administration:	
Licensed indication(s):	
Proposed Indication (if different from or in addition to the above):	
Is this treatment instead of or in addition to any current treatment? Please give details:	
Reason for proposed change If replacing current treatment please state how it compares regarding efficacy and safety / tolerability	
Proposed place in therapy relative to other therapies (include protocol for use if available)	
Predicted clinical impact on Primary Care e.g. will it be initiated in hospital only but then prescribed in primary care, or may it be initiated in primary care? Will it require shared care? Please describe:	
Monitoring requirements (e.g. for efficiency, side-effects) – if any? Do these differ from current situation?	

<p>Brief summary of evidence in support of requested medicine / additional use Meta-analyses, systematic reviews, double-blind randomised controlled trials in peer-reviewed journals. Ensure that evidence to support advantages / benefits of the new medicine over existing treatments is included where appropriate. Include any relevant morbidity, mortality, health economic and quality of life benefits.</p>	
<p>References Please list and include copies or internet links with the application</p>	

Section 2 Financial information

<p>Costs: (excluding VAT) Cost per patient per year of medicine:</p> <p>Number of patients per year to be treated for the whole organisation: <i>Where possible / applicable, include assessment of patient numbers across Pan Mersey area.</i></p> <p>Additional costs e.g. day case tariff, tests per patient per year:</p> <p>Any impact on PBR activity? Please give details:</p> <p>Overall financial impact:</p>	
--	--

<p>Current treatment(s) usually used (if any):</p> <p>Cost per patient per year currently treated (excluding VAT):</p> <p>Number of patients per year currently treated:</p> <p>Current additional costs e.g. day case tariff, tests per patient per year:</p>	
<p>Predicted financial impact on Primary Care e.g. Is the medicine hospital only but PBR excluded, will it be initiated in hospital only but then prescribed in primary care, or may it be initiated in primary care? Please describe:</p>	

Section 3 Conflicts of Interest

<p>Please state any potential conflicts of interest e.g. funding of research, equipment, consulting or speaking fees, other personal or non-personal or family interest etc. in relation to this request:</p>	
---	--

Name of Applicant:

Role:

Organisation name:

Signature of Applicant:.....

Date.....

Name of Clinical Director:.....

Signature Clinical Director:.....

NB New medicines must firstly be approved by the Walton Centre Drug and Therapeutics Committee, then submitted to the Mersey New Drugs Subgroup. This form is used for both. In the first instance please sign above and submit the completed form to the Lead Pharmacist, Neurosciences, and the Chair of the Walton Drug and Therapeutics and Medicines Management Committee.

After discussion at D&TC, the section below should be completed to indicate approval of this application by The Walton Centre.

Name of Chief Pharmacist or nominated deputy: :.....

Signature of Chief Pharmacist or nominated deputy:.....

Name of Chair of Walton D&TMM committee:.....

Signature of Chair of D&TMM committee.....

Date:.....

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Appendix 3

New Medicine Application Form – Additional Unlicensed Medicines

New Drug Application additional– Unlicensed Medicine

The following page should be included in a new drug application for an unlicensed medicine.

Why is an unlicensed medicine being considered (Delete as appropriate)

1. Equivalent licensed product unavailable because:

2. Other - give details:

A local administration guideline is included with this application to enable the safe administration of this medicine. If this has not been included please state the reason.

An English or English translation of the patient information leaflet is available and will be provided to all patients. If this is not the case please state the reason.

I understand that this medicine does not have a U.K. product license/is not licensed for this purpose* and that I take full responsibility for its use in this patient group.

CONSULTANT

SIGNATURE

DATE

I wish to authorise specific medical officers in my team to prescribe this medicine for this patient group in future. (can be omitted if already signed single request form.)

DOCTOR SIGNATURE.....DATE

DOCTOR SIGNATURE.....DATE

DOCTOR SIGNATURE.....DATE

*Delete where appropriate

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Appendix 4 Unlicensed Medicines – Procurement Form

**Unlicensed Medicine – Procurement Details
To be completed by Specialist Pharmacist**

	Is the medicine to be obtained from:	Circle
1	An NHS specials unit	Y / N
	If yes, specify.....and go to 6.	
A	A commercial specials manufacturer	Y / N
B	A licensed importer	Y / N
C	A company which already has licensed products of the same active ingredient	Y / N
D	A licensed pharmaceutical wholesaler	Y / N
2	Is a specification available?	Y / N
	<i>If yes, attach a copy.</i>	
	<i>If no, then a full product specification will need to be drawn up in conjunction with Quality Control North West</i>	
3	Is the product available “off the shelf” ?	Y / N
	Manufacturer.....	
4	Is the manufacturer on the Manufacturer List given in the Quality Control North West Guidance Document GD 109?	Y / N
5	Is the manufacturer in the UK?	Y / N
A	<i>If no, complete questions A to N below:</i>	
B	Which country?:.....	
C	Is this country within the EU?	Y / N
D	If no, does this country have a mutual recognition agreement with the UK for the manufacture of medicinal products?	Y / N
E	Importer.....	
F	Does the importer have a Wholesale Dealer Import Licence?	Y / N
G	What is the quoted importation time?.....	
H	What quantity is to be imported?.....	
I	What language is used on the label?.....	
J	If not in English, is a translation available?	Y / N
K	Who will provide the translation?.....	
L	Is an English Translation of the Patient Information Leaflet available?	Y / N
M	Who will provide the translation?.....	
N	Are the English Translations Certified?	Y / N
	If yes, by whom.....	
6	Are there any problems associated with continuity of supply?	Y / N
7	What are the costs involved in obtaining this drug?	
8	Issues raised by Quality Control North West	Y / N

Procurement page completed byDate

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Appendix 5 Form for the removal of Illicit substances

Form for the removal or destruction of unauthorised drugs or other suspicious substances

PART A: Description of substance removed from patient and placed in controlled drug cupboard.		
To be completed by the member of staff finding the drug and by the ward or departmental manager.		
Form:	Colour:	Quantity:
Removed from: Patient Initials		
Hospital No		
Ward/Dept:	Date:	Time:
Name of Finder:	Title:	
Signed:		
Ward Manager:	Title:	
Signed:	Date:	Time:

PART B Action by ward manager and consultant in charge of the patient.

We.....(ward manager) and..... (consultant in charge of patient)

(1) **are in agreement*** (2) **are not in agreement*** that the unauthorised substances found on the person or property of the above patient are of a quantity consistent with his or her own personal use.

ACTION (1) We have authorised the transfer of the substance to pharmacy.

ACTION (2) We have contacted the Incident Management Unit at Lower Lane Police Station.

Signed: (ward manager) Date: Time:

Signed:(consultant) Date:..... Time:

*Delete item (1) or item (2) as appropriate.

PART C Collection and removal to pharmacy for destruction according to procedure

Sealed container received by:.....(pharmacist) Date: Time:

Witnessed by: Date: Time:

OR PART D Collection by police (when required)

Sealed container collected by:

Officer's Name:**Signed:**

Witnessed by Name:**Signed:** **Date:** **Time:**

NB: One copy to be filed in patient's medical record.
One copy to be retained by pharmacy department.
One copy to be given to the police (if appropriate).

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Appendix Six Classifications of Medication Incidents

INTRODUCTION AND BACKGROUND

All medication incidents or near misses are classed as clinical incidents and must be reported using the usual incident reporting procedure (see Trust How to Report an Incident policy).

The Trust classifies a medication incident using four different details and then further classifying depending on adverse event. The table below shows the classification system.

Detail	Adverse event
Administration	Wrong dose
	Wrong medicine
	Past expiry date
	Extra dose given
	Wrong formulation
	Wrong frequency
	Card not signed
	Dose missed or delayed
	Wrong date
	Wrong route
	Wrong time
	Wrong patient
	Equipment problem
Dispensing	Wrong patient
	Wrong dose
	Wrong medicine
	Past expiry date
	Wrong formulation
	Wrong frequency
	Wrong route
	Community pharmacy error
	Wrong date
Miscellaneous medication incident	Inappropriate discharge medication
	Wrong storage of medicine
	Missing prescriptions
	Monitoring/follow up of medicine use
	Stock discrepancy
	Inappropriate transport/storage of medicine
Prescribing	Wrong medicine
	Prescription not available – GP having to sign
	Wrong date
	Wrong formulation
	Wrong frequency
	Wrong patient
	Wrong route
	Required medicines not prescribed
	Unclear or illegible prescription
	Inappropriate medicine for patient

The Trust considers certain types of medication incidents as particularly high priority for reporting; any error or incident involving medicines where:

- A patient came to harm
- An error reached a patient eg got wrong drug/dose/dilution/rate, drug continued too long, even if the patient suffered no apparent harm as a result.
- One or more doses are missed
- One or more doses of a critical medicine are delayed
- Administration box is not signed so unclear whether dose given or not
- Potentially serious errors noticed and corrected in time to prevent harm (near miss)
- A dispensing error leaves pharmacy
- A significant adverse drug reaction occurs, or any reactions to patent blue dye
- A high risk drug is involved eg opioids, cytotoxics, IVs, insulin, anticoagulants
- Failure of medical device is involved
- Controlled drugs are involved (including stock discrepancies)
- Discharge medicines are involved
- A significant breach in policy has occurred
- The reporter considers the incident significant or feels the organisation could learn from it.

Monthly Check	Completed
Remove items no longer required and expired stock	Yes / No
Does the fridge require defrosting	Yes / No
Completed By	Date/...../.....