**Lincolnshire Partnership NHS Foundation Trust (LPFT)**

**Medicines Management & Medical Devices Policy**

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1. **Introduction**

1.1 This policy outlines the Trust’s responsibility to ensure that the organisation handles medicines safely and securely, in accordance with legislative requirements and best practice. This includes:

- The Medicine Act 1968, as amended which regulates the manufacture, distribution, import, export and supply of medicinal products.
- The Misuse of Drugs Act 1971, which controls the availability of drugs liable for misuse.
- The Misuse of Drugs Regulations 2001 which enables specified health care professionals to possess, supply, prescribe and/or administer controlled drugs in the sphere of their practice.
- The Controlled Drugs (Supervision and Management of Use) Regulations 2013.

1.2 It is the responsibility of the Trust to recognise the risks associated with medicines management, taking action to fully resource the training and development of all clinical staff to fulfil their duty to safely administer medicines to patients. This will be achieved by:

- Raising the profile of Medicine Management within the Trust.
- Recognising that all clinical staff need to be appropriately trained in the administration of medicines.
- Acknowledging the need of service users to consent to treatment.
- Providing information about medicines to service users.
- Supporting multi-disciplinary collaboration and communication, forums and other networks to monitor the effectiveness of the service.
- Complying with all legal, statutory and local requirements to meet the standards of medicine management.
- Implementing a programme of clinical audit to determine compliance to relevant standards and procedures.
- Ensuring all clinical staff have access to up to date guidance and research relating to the safe and secure handling of medicines and that all procedures support evidence based best practice.

2. **Purpose and Scope**

2.1 This policy aims to ensure that:

- All relevant staff are aware of the requirements for the ordering, dispensing, distribution, safe storage, prescribing and administration of medicines.
- Service Users receive correct medication in a safe and timely manner.
- A system is in place to effectively monitor the standards of medicines management.

2.2 In some situations staff may also need to refer to additional local policies. LPFT staff working in other NHS Trusts, including ULHT, should follow the Medicines policy and guidance of these other trusts which may differ from LPFT.

2.3 The core policies and procedures outlined within this document apply to all employees of the Trust.

Those persons employed by other Authorities or Trusts who are contracted to work within the premises of this Trust will observe the policies and procedures. Managers who contract for services must make it explicit within the written contract that these staff must follow the policy, procedures and associated standards.

2.4 All those with delegated responsibilities under the Trust’s policy for medicine management and these guidelines must in addition act in accordance with current statutory legislation, Department of Health and professional guidelines.

2.3 All employees are reminded that breaches of rules, including breaches of these guidelines, will be dealt with under the provisions of the Trust’s disciplinary procedure.
2.4 All employees with responsibilities relating to these guidelines must apply the provisions relating to the Health and Safety at Work Act and COSHH regulations when handling medicinal products. Particular attention is drawn to the hazards of cytotoxic drugs.

2.5 This policy should be read in association with other Trust Policies and other legal, statutory and professional guidance.

3. Duties

3.1 It is a requirement of the revision of the Duthie Report – “The Safe and Secure Handling of Medicines: A Team Approach” (Royal Pharmaceutical Society March 2005) that the senior management board designate a senior pharmacist be responsible for medicines management system. The Chief Pharmacist has Board designated responsibility for organising, monitoring, reporting and to maintain an effective and economical system by which medicines are managed safely and securely to meet the service user’s clinical needs. Those in charge of wards, departments or teams will ensure that this policy and associated procedures are carried out correctly and are considerate of the needs of patients, consent to treatment, relevant legislation including the Mental Health Act (2007) and Care Quality Commission assurance standards / NHSLA standards.

3.2 The role of the pharmacy is to:

- Advise on and monitor the safe, effective and economic use of medicines.
- Procure medicines
- Supply and/or dispense ready to administer medicines.
- Review medication history of service users
- Guide the prescribing for service users through advice and recommendations
- Provide medicines for discharge and leave
- Advise service users on their use of medicines
- To prescribe for service users in agreed circumstances

Medicines will be procured supplied and dispensed in accordance with the relevant legislation, professional standards, NHS recommended practice and controls assurance guidance.

Pharmacists will monitor all prescriptions for service users in their care and place special emphasis on complex and potentially toxic medicines that require higher levels of monitoring.

When a request for a medicine has been made the pharmacist must check the prescription and other related service user records to ensure the safe, effective and economic use of medicines. Attention must be given to each step of the medicine use process. This includes the need for the medicine, the medicine formulation and the route of administration. In addition pharmacists must monitor for medicine interactions/adverse reactions and whether the therapy is achieving the desired therapeutic end points.

Authorised Pharmacy Staff may annotate the prescription in photocopiable ink. This annotation should ensure the approved name; dose, route and precautions are included on the prescription, to guide practitioners when they administer the medicine. All annotations must be initialled.

Where a pharmacist wishes to make a recommendation to change or modify a service user’s therapy, the pharmacist must record the recommendation in the service user’s notes. It is essential to sign and date the recommendation and provide some background details. These written records must be made, in addition to any verbal communication, with the prescriber.

Service User’s should be advised about their medicines by Authorised Pharmacy Staff during their admission stay or period of admission. This should be a part of an agreed programme for each ward.
3.3 **The Appointed Practitioner in Charge** should agree with the pharmacist and consultant the arrangements for advising service users about their medicines.

Alternative arrangements for advising service users about their medicine may be provided if:

- The nature of the hospital stay is less than one week
- There is a need for a rapid discharge
- The nature of the discussion is considered inappropriate by the consultant
- There is insufficient availability of suitably trained pharmacists

Such alternative arrangements must identify the person responsible for the provision of information and the nature of the information to be provided.

Routine supplies of newly prescribed medicines are made when the pharmacy department is open. Out of hours the on-call pharmacist will determine the clinical urgency of the items and arrange for the supply as appropriate. ([Appendix D](#))

Authorised Pharmacy Staff must be involved in advising on security and medicine storage conditions on the ward/unit or department.

The pharmacy must provide a medicine information service for other healthcare staff and patients.

Pharmacists may undertake responsibility for prescribing for service users as a supplementary prescriber if suitably trained.

3.4 **Registered Nurse**

The following may order, have custody of and or administer medicines:

- Registered General Nurse (RGN)
- Registered Mental Nurse (RMN)
- Registered Nurse in Learning Disability (RNLD)

3.5 **Ward Manager/Team Co-ordinators**

The Appointed Practitioner in Charge with 24 hour responsibility

3.6 **The Medicines Management Committee**

NHS Trusts are required to convene a committee to oversee all aspects of treatment with medicines for which the Trust is responsible. For Lincolnshire Partnership NHS Foundation Trust this is the Medicines Management Committee. This committee

- Has both strategic remit and oversees the operational issues associated with medicines.
- Reports directly to the Service Governance Committee

The Medicines Management Committee (MMC) is recognised by the Trust as the body through which all policy decisions relating to the management of medicines are focussed, monitored, approved, and coordinated across the Trust.

MMC provides a strategic framework to enable and support a safe and cost effective way of providing pharmacological treatment for people with mental health problems.

MMC supports effective medicines management across the Trust and wider local health economy

MMC supports clinical governance in the Trust through effective policies and guidelines which assure best practice in prescribing, supply, administration and monitoring of medicines.
MMC advises on prescribing contract arrangements; promotion of education and research relating to medicines use.

MMC supports and advises on implementation of national guidelines. E.g. NICE and NPSA

MMC reviews the reported trends of medicine related incidents and advises on action plans to further reduce risk to each service through the modern matron and receives back updates on progress.

3.7 Chief Executive

Is responsible for ensuring that a Medicines Management Policy is in place and that all staff working in the Trust are aware of, and operate within the policy.

3.8 The Chief Pharmacist

Has overall responsibility for Medicines Management within the Trust and for ensuring that all pharmaceutical staff are aware of and operate within the policy and medicine management guidelines.

Is responsible in partnership with managers, for instituting an effective monitoring system as required by Controls Assurance / Care Quality Commission Standards and NHSLA.

The Chief Pharmacist is responsible for all aspects of the safe and secure management of controlled drugs within the Trust. This includes ensuring that safe systems are in place for the management and use of controlled drugs, monitoring and auditing the management systems and investigations of concerns and incidents relating to controlled drugs.

The Chief Pharmacist for Lincolnshire Partnership NHS Foundation Trust (LPFT) has overall responsibility for the management of medicines within the Trust including the safe and secure handling of medicines and other associated products. In liaison with clinical teams and pharmaceutical staff implement the controls assurance Care Quality Commission standards (medicine management) and local procedures and guidance relating to the management of medicines.

3.9 The Medical Director

The Medical Director is the Executive Director responsible for informing the Trust Board about medicine related issues.

Is responsible for ensuring that all medical staff are aware of and operate within the policy.

3.10 The Director of Nursing and Quality

Is responsible for ensuring mechanisms are put in place to ensure nursing and allied health professionals within all Services are aware of and comply with the requirements of the medicine management policy.

3.11 The Director of Workforce Development

Is responsible for ensuring that specimen signatures of all those prescribing or ordering medicines are provided to the relevant pharmacy departments.

3.12 Service Managers

Are responsible for ensuring that all managed staff are aware of and operate the medicine management policy.

3.13 Modern Matrons

Modern Matrons have the responsibility for monitoring the adherence to the Medicines Management Policy within their service and for picking up any medicine management issues within the service on a day to day basis.
They have the responsibility of ensuring that any appropriate training associated with medicines management within the Trust is undertaken by nursing staff within their service.

3.14 **Heads of departments & Allied Health Professionals (AHP’s)**

They are responsible for ensuring that all managed staff are aware of, and operate within the Medicines Management Policy.

3.15 **Clinical and Support Staff**

Staff who handle or use medicinal products have a duty to be aware of and work within the confines of the medicine management policy.

All staff who register with a professional body must also ensure that they maintain their professional registration and any associated stipulations or conditions of registration i.e. Continual Professional Development criteria.

4. **Definitions**

Throughout this policy, certain specialist titles describe healthcare staff who have defined responsibilities regarding the management of medicines. Only staff with contracts (or honorary contracts) of employment to work in Lincolnshire Partnership NHS Foundation Trust (LPFT) are recognised as having any involvement with medicines.

4.1 **Medical Practitioner**

A doctor of medicine, excluding medical students.

4.2 **Practitioner**

A healthcare professional who is a member of a recognised registered organisation

4.3 **Appointed Practitioner in Charge**

The senior practitioner appointed in charge of a ward, unit or team.

In situations where the person in charge is NOT from a health care professional background appropriate to take such responsibility (e.g. a community team co-ordinator with a social work background) a nurse practitioner member of the team must undertake the role of Appointed Practitioner in Charge.

4.4 **Assigned Practitioner in Charge**

The practitioner on duty for the ward or community team who has been rostered as the health care professional in charge for that shift.

4.5 **Designated Practitioner**

Any practitioner identified by the Appointed Practitioner in Charge as competent and appropriate to perform a specific function. The designation as such has been communicated to and accepted by the Designated Practitioner. If the practitioner is based in the community they are referred to as ‘Designated Community Practitioner.’

4.6 **Pharmacist**

A registered member of the General Pharmaceutical Council (GPhC).
4.7 **Authorised Pharmacy staff**

Pharmacy staff who have been authorised by the Chief Pharmacist as competent and appropriate to perform a specific function.

4.8 **Authorised Employee**

A member of staff who has following training, assessment and demonstration of competence has been authorised by LPFT to undertake specific duties in relation to medicines.

4.9 **Medicine**

Within the text the term “medicine” is used not only to include substances controlled by the Medicines Act 1968 and the Misuse of Drugs Act 1971, but also those other substances where similar control is necessary e.g. disinfectants, reagents, dressings etc.

4.10 **Self Administration/Patients Own Drugs (SAM/POD)**

A local procedure, approved by Mental Health Pharmacy Services, which enables the use of patient’s own drugs brought into a ward or unit and the ability of the service users to administer their own medicines whilst in hospital.

5. **Ordering of medicines**

5.1 **Controlled Drugs**

The ordering, recording, administration and security of Controlled Drugs (CD’s) are described in the Trust's Standard Operating Procedure for Controlled Drugs Management (Appendix M).

5.2 **Unit stock (Inpatient and Community)**

Ordering of stock medication varies from site to site and ward to ward, but is achieved by one of the following methods:

- Top-up service provided by the pharmacy to an agreed stock list agreed by the Appointed Practitioner in Charge of the ward and pharmacy staff.
- A sequentially numbered requisition form signed by the Designated Practitioner of the ward. A faxed copy is acceptable but the original must follow as soon as possible.

5.3 **Individually Dispensed Medicines**

These medicines are supplied for an individual service user against a doctor’s prescription. In normal circumstances a 14 - 28 day supply of medicines will be dispensed, unless clinical risk assessment dictates smaller supply in line with clinical needs and the National Suicide Prevention Strategy.

5.3.1 It is important that the service user receives adequate information about their medicines PRIOR to discharge. The service user should know the purpose of the medicine, how to take it and for how long it is to be taken.

5.3.2 This is a shared responsibility of the Medic, Designated Practitioner and Authorised Pharmacy staff. It is the responsibility of the Designated Practitioner who discharges the service user to ensure that the service user has received adequate information about their medicines.

5.3.3 Wherever possible a manufacturer’s ‘patient information leaflet’ should be supplied with the medicines along with any other relevant literature referring to the medicines being taken.
5.4 **Controlled Stationery**

All stationery used for ordering medicines is potentially liable to misuse and is designated as “controlled stationery”. It includes pharmacy requisition books, controlled drug order books and registers and FP10 prescription forms. All controlled stationery must be sequentially numbered and kept under secure conditions. Issued in accordance to procedure and issues recorded.

5.4.1 **Prescription charts:**
- ALL prescription charts are held in a centralised storage point.
- Blank prescription charts must be kept under secure conditions and only be accessed by qualified nursing, medical or pharmacy staff at the point of need.
- Prescription charts in use must be stored in a clinic room when not being used to administer or review medication.
- The completion and use of the prescription chart must be in line with the prescription writing standard guidelines.

5.4.2 **FP10HP’s:**
- ALL FP10HP’s are supplied to prescribers via the Mental Health Pharmacy Services.

5.4.3 **White A5 Prescriptions:**

White A5 prescriptions will be stored in a plastic wallet inside of the front cover of the ward stock CD register along with a record sheet.

A maximum of 10 prescriptions will be kept in the CD register at any time.

Pharmacy staff will check serial numbers against record sheets on a daily basis to ensure a secure audit trail is maintained.

Loss or theft of white A5 prescriptions – refer to Appendix M section 4.6.

5.5 **Retention Requirements for Records** *(Standing Financial Instructions 2013)*

Completed CD registers and CD requisition books must be stored by the ward, unit or team for at least TWO YEARS following the date of the last entry. In the event of a ward closure the CD records should be held by the LPFT Pharmacy department.
- All prescription charts must be retained in the patient's medical notes.
- Outpatient prescriptions must be retained in Pharmacy for 2 years.

5.6 **Obtaining Medicines when the Pharmacy is closed.**

If any medication is required out of hours then these methods of obtaining medication should be followed.

5.6.1 **Emergency Medicine Cupboards**

Emergency medicine cupboards are available at both dispensing pharmacy sites, Lincoln and Boston, and on Brant ward, Witham Court and Saxon ward, Carholme Court.

Emergency medicine cupboards are available, via the duty senior nurse and the emergency cupboard access procedure, and contain an agreed list of medicines. Access to these medicine cupboards is restricted. The cupboards are to be used when medicines are required in urgent situations. If any medicine is taken, the complete container should be removed and the record completed.

5.6.2 **Prepacks**

The emergency cupboards may contain pre-packs of medication that can be used out of hours for individuals either on the ward or for use as leave medication. The use of these pre-packs will require a Designated Practitioner or Medical Practitioner to insert some information onto the pre-printed label. The pre-packs are intended for emergency use only and supplied against a written prescription.
5.6.3 FP10HP - Refer to section 6.3

5.6.4 On call pharmacist -
All the above emergency arrangement procedures should be exhausted before contacting the on-call pharmacist.
If the medicine required is not available, and its use is considered an emergency, the on-call pharmacist may be contacted by the doctor or the senior duty nurse through the relevant hospital switchboard.
The on call pharmacist is ONLY available outside of the normal pharmacy opening times (8.45am – 5.15pm Mon-Fri, 9.30am -11.30am Sat)
The on call pharmacist will only respond to urgent inpatient requests that are unobtainable via other out of hour procedures. They will give advice but are not there to handle routine items that should have been dealt with during the normal working hours of the pharmacy department and they will NOT dispense any leave or discharge medication.
Details of relevant pharmacies on call arrangements will be available in all clinical areas. See Appendix D for the on call pathway for access to pharmacy services.

5.6.5 Borrowing -
Borrowing is strongly discouraged but in some circumstances this may be necessary to avoid detriment to the service user. If the above steps have been followed and there is still no available source of medication then borrowing from another LPFT ward/unit may be considered. The borrowing procedure is site specific but the following guidelines must be adhered to:

- Medicines must NOT be borrowed during normal working hours unless a supply cannot be obtained from the pharmacy department and they advise an alternative supplier.
- Controlled Drugs cannot be transferred from one service to another. Single doses only may be provided from stock to a patient from another ward/service. The necessary records must be made in the Controlled Drug Register of the ward supplying the drugs.
- For other medicines, the complete container should be transferred. Medicines should never be decanted from one container to another.
- Only ward stock items may be borrowed NOT individually labelled medicines (patient-named medicines).
- Details of any borrowing must be recorded in the ward/unit borrowing book in line with Trust guidance on borrowing.

5.6.6 Nurse dispensing -
The guidance to nurses (NMC 2006) advice sheet on Medicines Management states that:

"Dispensing medication is the 'labelling' of medication from a stock supply, which is then administered to an individual patient. Where a stock supply of medication has been labelled and dispensed by a pharmacist and is then supplied by a registrant in an 'out-of-hours' or family planning situation this is not dispensing but supplying. Registrants are advised to ensure they have indemnity insurance to cover their dispensing practice. If they are unable to get indemnity cover they must inform the patient/client of this and its implications.

There is no legal barrier to dispensing under exceptional circumstances. However, this must be in the course of the business of an NHS Trust, GP surgery, or independent hospital, and in accordance with medical/nurse prescribers’ written instructions.

Dispensing includes checking the validity of the prescription, the appropriateness of the medicine for an individual patient, assembly and labelling of the medication from stock, in accordance with the Medicines Labelling Regulations (1976), and providing information leaflets for the patient/client. Dispensing should not be confused with supply and administration of medication. This is medication that has been previously labelled in a healthcare setting, e.g. Family Planning Clinics, and supplied and administered to patients against a PSD or PGD.

A nurse prescriber working in a dispensing doctor’s practice may NOT prescribe and dispense the same prescription. The prescription must be checked by an independent dispenser and then dispensed by that independent dispenser. Both the prescriber and the dispenser should record the details of their practice in
the patient’s/client’s records and any other documents required under local clinical governance arrangements. There should be a visible audit trail of all prescribing and dispensing activity.

Any registrant engaging in dispensing must be aware that this represents an extension to their professional practice and that they must adhere to the principles set out in the Professional Code of conduct NMC 2004. The patient/client has the legal right to expect that any registrant dispensing will do so with the same reasonable skill and care expected from a pharmacist.”

The Trust expects Practitioner dispensing to be an exception and done only if all other avenues of dispensing have been considered, tried and are unsuccessful.

Leave medication must only be dispensed by nursing staff outside of pharmacy opening hours and NO MORE than 3 days supply can be dispensed at any one period of time.

5.6.6.1 Instructions for dispensing medication –

The following instructions are relevant to all professionals authorised to request leaves and dispense medication:

- Emergency medication will be dispensed and checked by TWO authorised members of staff, one designated as the dispenser and the other as the checker, against a valid prescription.
- The dispenser MUST complete the label attached to the medication with the following information
  - Name, strength and form of medication.
  - Directions for the service user – dose (in number of tablets/capsules) and frequency.
  - Service users name.
  - Date of supply
  - Ward/unit
- Recommended safe practice is to complete the labelling of each medication before beginning to dispense another.
- The checker must examine each container and verify that the correct medication has been selected and the correct details entered onto the label in accordance with the prescription.
- An emergency supply record should be completed and signed by both parties involved in the dispensing and checking. The record MUST include:
  - Name of service user
  - Ward/unit and consultant
  - Date and time of dispensing
  - Name, strength and form of medication dispensed.
  - Quantity supplied
  - Directions

5.6.6.2 Access to the items required for dispensing are through the emergency cupboards.

5.6.6.3 Any person undertaking any dispensing and checking in dispensing circumstances must have received training and a competency assessment BEFORE undertaking any dispensing related activity.

5.6.6.4 All records of the dispensing, checking and issuing will form part of the mechanisms for audit and checking the appropriate use of the system.

6. Dispensing

6.1 Methods of Dispensing

Service Users may be in possession of medication by one of the following methods:

- Their own personal medication identified and accepted as suitable for continued use. (see section 11.7 Patient’s Own Drugs)
• Using pre-packed medication. Maximum use should be made of available pre-packs. Nurses may issue, any pre-packs stored on the ward or in the emergency cupboards for in-patient use. Pre-packs may be issued for “Take Out” prescriptions, if the item has been in use on the ward, or the prescription has been discussed with a Pharmacist.

To meet legal requirements the pre-pack must be supplied against a legally written prescription and be marked with the name of the service user, the directions for use (including an information leaflet), a batch number and expiry date and a time and date of supply.

The supply must be recorded on the prescription form and be signed by the authorised Practitioner and an authorised and competent witness.

• Dispensed by Pharmacy upon receipt of a prescription according to their Dispensing Policies and Procedures.

6.2 Dispensing Without a Prescription

Supplying pharmacies will not dispense medicines for individual service users without a prescription except in a critical emergency. An example of a critical emergency situation would be:

• A MAJAX (A Major Accident or disaster)
• A prescriber cannot leave a patient.
• No other prescriber is available to write a prescription and the clinical condition requires this.
• Wherever possible, full use should be made of facsimile machines to communicate prescribers’ intentions (except for controlled drugs). Verbal orders are discouraged and are not accepted as good practice (NMC standards for medicines management 2007 section 3).

Inconvenience to a prescriber would never constitute a critical emergency. Prescribing of the drug must be confirmed in writing as soon as possible (immediately after the emergency), with a clear indication that it is a retrospective order.

6.3 Outpatient prescribing and use of FP10HP prescriptions.

Prescribers of the Lincolnshire Partnership Trust (LPT) may need from time to time to prescribe medicines for a person who is not resident on a hospital ward and treated in community where hospital pharmacy supply is not appropriate. For such situations prescribers will be issued with FP10 prescription pads to facilitate direct provision of medicines from a community pharmacy.

6.3.1 When LPFT prescribers should use their FP10 prescription pads

Secondary care prescribers should initiate prescribing using their prescription pads:

• Where the need for the mental health medicine is urgent.
• Where there are complicated psychiatric or social problems that would either benefit from close control of prescribed medicines by the psychiatrist or concordance is likely to be jeopardised or access to a GP is problematic.
• The level of medical risk indicates that prescribing responsibility should be initiated and retained by the consultant.
• Where management is under shared care guidelines that have been agreed (using appropriate consultation) for that particular medicine.

6.3.2 When LPFT prescribers should not use their FP10 prescription pads

Secondary care prescribers should refer back to the service user’s GP for prescribing:

• Following most routine consultations.
• Where there is no immediate urgency for medication to be initiated.
• For prescription of commonly used medicines and where no unusual circumstances exist
• Following initiation by consultant after the service user is considered to have either adequately stabilised or the medical social or psychiatric problems requiring the initial prescription have been overcome or there is no particular convenience to the service user.
6.3.3 The length of time a LPFT prescriber should continue to prescribe for a patient using an FP10

- For urgent use the prescription should be only for 1 to 4 weeks to allow arrangements to be made with the service user’s GP.
- For longer term use the prescriber should only issue a prescription for one month’s supply at a time.
- For the minority of service users who require secondary care prescribing, it would be very rare to continue to prescribe for longer than six months.
- For most medicines with shared care agreements the expectation is for the secondary care prescriber to refer the service user back to his or her GP after 3 months.

6.3.4 Standards of communication

It is proposed that the following standards should apply:

- In all cases the letter to the GP should be sent out to the GP in sufficient time to ensure continuation of supply.
- Where the patient’s GP is asked to prescribe, the non-urgent nature of routine prescriptions should be explained to the service user.
- The letter should specifically state if new medicine is to replace a current medicine or be added on to current treatment.
- GP letters will be audited to ensure compliance with the standard.

6.3.5 Choice of Medicine

- Prescribers should prescribe using FP10s in line with appropriate LPT Guidance and PCT / ULHT Formulary. This is to be monitored and the Trust to take action where this standard is not met.
- Any fraudulent use of prescriptions e.g. for self-prescribing or anyone who is not a registered patient of the Trust will be subject to the Trust disciplinary policy.

6.3.6 Shared Care

For some medicines there is the expectation that the secondary care prescriber will initiate and stabilise treatment prior to referral to the GP. The secondary care prescriber and the GP will agree to share the responsibility for treatment and The Shared Care Guidelines will be drawn up after consultation across primary and secondary care.

6.3.7 Security

It is the responsibility of the consultant/prescriber to ensure that the FP10HP pad allocated to them is kept in a locked and secure environment at all times when not in use.

In the event of an FP10HP pad going missing or being stolen –

- Contact the chief pharmacist LPFT and the relevant line manager to inform them of the incident, include all the missing or stolen pads 11 digit unique identifier number, consultant, service speciality, and last known whereabouts of pad.
- An incident report form MUST be completed using the Trusts incident reporting system.
- The mental health pharmacy team will then contact the PCT pharmacy prescribing team for the information to be disseminated out to ALL local retail pharmacies.
- If the pad is stolen or suspected as being stolen this will be reported to the local police as a theft for investigation.
- The prescriber and/or team prescribing with a new pad MUST write ALL prescriptions in an agreed colour (e.g. red or green) for a period of 30 days from notification of pads missing. Any prescriptions presented during that time not written in the agreed colour will be queried with the prescriber and treated as potential fraud, by the dispensing pharmacy.
7. Distribution

7.1 Security in Transit

All medicines will be transported in sealed containers using a variety of systems which are site specific. All such consignments from Pharmacies Should contain a delivery note describing the contents wherever possible. Medicines must be checked against this note upon receipt and any discrepancy reported to the relevant Pharmacy at once. Once checked, the medicines should be locked in the medicine cupboards without delay.

Managers of staff approved to transport medicines must train their staff to ensure understanding of the need for security, and the arrangements made must be approved by the Chief Pharmacist. A clear audit trail must exist between Pharmacies and their users. In particular, the following must apply:

- The responsibility for the maintenance of security during transportation rests with the individual carrying out the task.
- Transit containers must be locked or sealed and supervised at all times unless being temporarily stored in a secure area away from public access. At no time should they be left unattended in corridors or departments.
- Containers must be collected from and delivered to authorised points or personnel only.
- The person transporting the medicines must record and sign for all transit containers before leaving the Pharmacy.
- The person transporting the medicines must ensure that the assigned Practitioner in Charge at each delivery point signs for receipt of the transit container.
- Any suspicion of damage or discrepancy must be reported immediately to the relevant Pharmacy.

7.2 Extra restrictions applied to Controlled Drugs.

7.2.1 Units with an on-site Pharmacy.

The medicine will be transported in a sealed container directly to the ward, department or clinical area by one of the following:

- Pharmacy staff
- Hospital porter
- A nominated deputy at the discretion of the Assigned Practitioner in Charge.

7.2.2 Units without an on-site Pharmacy.

Delivery will be carried out by:

- Pharmacy staff
- Hospital transport in a locked container
- Prescribers
- Authorised taxi firms

7.2.3 Receipt.

Controlled drugs must be given personally by the person transporting the medicine to a member of staff authorised to hold the appropriate Controlled Drug key. On receipt, they should be checked and signed for on the official requisition. If a box/bottle is sealed, either by the manufacturer or the pharmacy the contents need not be checked until the time comes to use that container. An entry must be made in the Controlled Drugs Register and checked by a second person at the time of receipt to account for the stock received.

7.3 Security between Unit/team base and Pharmacy

The same arrangements as in 7.1 apply in reverse.
8. Storage and Security of Medicines

8.1 Responsibility

The Appointed Practitioner in Charge is responsible at all times for all medicines stored in the ward. Accountability remains with the Assigned Practitioner in Charge even if they decide to delegate the responsibility.

8.2 Containers

All medicines must be stored in their original containers. They should not be transferred from one container to another. Loose blister strips of tablets do NOT represent an original container.

8.3 Storage Locations

Storage accommodation should be sited in a locked room or in a position to allow surveillance and maximum security against unauthorised entry. All medicines, with the exception of medicines for emergency use, large volume sterile fluids and wound care products, must be stored in wards and departments within lockable cupboards which comply with the current British Standards for medicines storage (BS2881), at a temperature not exceeding 25°C. For Controlled drugs, The Misuse of Drugs (Safe Custody) Regulations 2007 apply. The table below details the storage facilities required by each ward or unit.

<table>
<thead>
<tr>
<th>TYPE OF STORAGE</th>
<th>PURPOSE</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controlled Drugs Cupboard</td>
<td>Schedule 2 and 3 Controlled Drugs and other specified medicines</td>
<td>Specification complies with the Misuse of Drugs (Safe Custody) Regulations 2007</td>
</tr>
<tr>
<td>Medicine Cupboard for Internal Medicines</td>
<td>All other medicines except those with specific storage requirements</td>
<td>Specification complies with British Standard BS2881</td>
</tr>
<tr>
<td>Medicine Trolley</td>
<td>Medicines in current use</td>
<td>When not in use it must be locked and secured to a fixed anchor point</td>
</tr>
<tr>
<td>Cupboard for External Medicines</td>
<td>Creams, ointments, lotions and related products, blood glucose monitoring reagents</td>
<td>Lockable cupboard</td>
</tr>
<tr>
<td>Medicines Refrigerator</td>
<td>For all medicines requiring storage at temperature range of 2°-8°C</td>
<td>Lockable. Temperature monitored and recorded daily and fridge defrosted monthly. Not to be used for storage of food or pathological specimens. In event of failure seek Pharmacy advice before using any products.</td>
</tr>
<tr>
<td>Bedside Lockable Medicine Cabinets</td>
<td>POD’s and individual dispensed internal and external medicines in current use including Controlled Drugs</td>
<td>See local SAM/POD procedures. Insulin may be stored and used for up to one month in the cabinets. Remember to put ‘Do not use after date’, from when first put into bedside locker.</td>
</tr>
<tr>
<td>Large volume Sterile Fluids</td>
<td>Large volume intravenous and topical fluids</td>
<td>Need not be stored in a locked area, depending on local circumstances</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>---------------------------------------------</td>
<td>------------------------------------------------------------------</td>
</tr>
<tr>
<td>Cupboard for Flammable Products</td>
<td>Significant quantities of flammable products</td>
<td>Purpose built metal fire retardant cupboard</td>
</tr>
<tr>
<td>Resuscitation Trolley</td>
<td>Agreed range of drugs for clinical emergencies consistent with local guidelines</td>
<td>Sealed with a tamper evident seal and labelled with an expiry date of the product with the earliest expiry</td>
</tr>
</tbody>
</table>

8.4 **Custody and Safe Keeping of Medicine Keys (Inpatient areas)**

Keys should be kept on the person of the Assigned Practitioner in Charge of the ward, or Designated Practitioner nominated by them. Nurses accepting accountability for the medicine keys must sign the appropriate key card acknowledging their responsibility.

8.4.1 Custody and safe keeping of medicine keys in community teams.

The responsibility for the security, audit trail, development and implementation of local Standard Operating Procedures for the medicine keys lies with the team leader (if this is a registered nurse) or the senior registered nurse on duty within the team.

Medicine keys should be kept locked in a separate key box which is attached to a permanent fixture in a safe location within the team base. Access to the key box is to be restricted to registered nurses only. The key box can be locked with either a key/lock system or a combination locking device as long as the combination lock is an integral part of the key cupboard and the combination is changed on a regular basis and a record kept of the person changing the number for maintaining confidentiality and audit trail. The key box should contain a tracer card to show when and who has taken the medicine keys out for use, and a list of nurse signatories showing who has been allocated a key to access the medicine keys.

The person responsible for the security of the medicine keys should check periodically that the security of the keys is not compromised in any way.

8.4.2 Duplicate sets of medicine keys.

A spare set of ALL medicine cupboard keys will be kept in a secure key cabinet accessed only by the senior nurse on duty at the following sites in case of duplicate being required by a ward/unit/community team.

Key cabinets to be kept on Ward 12 Pilgrim hospital for those units in the Boston area. Sycamore Assessment unit for those wards/units in the Grantham/Stamford area and PHC for those wards/units in the Lincoln, except Carholme court who hold their own key cabinet for duplicate keys.

A key tracer card must be completed as to which sets of keys have been borrowed, when and by whom, and the date returned, and signed by the borrowing nurse and senior duty nurse.

Duplicate sets of keys MUST be authorized only by the Chief Pharmacist LPT and a record of all duplicate sets of keys kept by appropriate unit manager or team leader.

Each area must develop their own Standard Operating Procedures (SOP's) for key security.
8.5  Procedure if Drug Keys are Lost

Every effort must be made to find the keys or retrieve them from off duty staff as a matter of urgency. If unsuccessful, the appropriate Manager during normal office hours or Senior Manager ‘on-call’ at all other times and the Pharmacy Manager (as defined in section 3.3) must be informed. It will be the responsibility of the ward manager or team co-ordinator to apply the provisions of the Trust’s policy for reporting Untoward Incidents, Accidents and Near Misses.

8.6  Access to Medicine Cupboards

The Assigned Practitioner in Charge is responsible for controlling access to the medicine storage facilities. They may temporarily delegate access to one of the following groups of people, e.g. other qualified nurses and Pharmacy staff, to enable them to carry out their duties, but overall responsibility still remains with the nurse-in-charge. No lockable storage must be left unattended whilst unlocked.

8.7  Stock Balances

8.7.1  Controlled Drugs

The stock balance of all controlled drugs entered in the register must be checked and recorded at least once a week by two authorised members of staff, one of whom must be a qualified nurse authorised to hold the drug keys. The check must validate the stock balance held. Refer to the Trust’s Standard Operating Procedures for Controlled Drugs Management. Pharmacy will in addition carry out a 3 monthly audit check of the registers and stocks.

8.7.2  All Other Drugs

For wards and services on a “top-up” system, stocks will be checked on a regular basis by a member of the pharmacy department. For all other areas stocks will be reviewed as part of a 3-monthly review cycle carried out by LPT pharmacy staff.

8.7.3  Losses and Discrepancies

Where there is evidence of discrepancies, the Appointed Practitioner in Charge must carry out an immediate investigation. It is the ward manager or team co-ordinators responsibility to inform the Ward Pharmacist and initiate a further investigation. If there is no resolution, the Team leader during normal office hours or the Senior Manager ‘on call’ during all other times and the chief pharmacist must be informed of any loss or unexplained discrepancy.

The provisions of the Trust’s policy relating to untoward incidents, accidents and near misses apply. During the investigation it may necessitate the police being informed during or towards the end of any investigation.

8.8  Return of Medicines No Longer Required

Any medication no longer required, expired, change in regime, over supply, Patient’s Own, etc can be returned to the local acute hospital pharmacy department using the approved return method and paperwork.

Staff should also be aware of & reference to the Trust Waste Management Policy (HS14)

8.8.1  Controlled Drugs:

Refer to the Controlled Drug Standard Operating Procedure (OPR47) for details on how to return a Controlled Drug.

Unwanted controlled drugs may be removed from the ward or team by a Pharmacist or Pharmacy technician with the agreement of the Assigned Practitioner in Charge, in accordance with the Trust's
Standard Operating Procedure for Controlled Drugs Management and the Trust’s policy for dealing with Illicit Substances.

8.8.2 Other Medicines:

The Designated Practitioner may return unwanted stock medicines or individually dispensed medicines to pharmacy via site specific secure systems. (NOT CD’s)

Unwanted stock may also be removed from the ward or team by Pharmacy staff.

In each case a returns note or the relevant documentation must be produced by whoever initiates the return and sent with the returned medication.

8.8.3 Patient’s Own Medication:

Refer to the Patient’s Own Drugs Standard Operating Procedure for the disposal of Patient’s Own Drugs (POD’s)

Disposal of unwanted Patient’s Own Drugs (POD’s) may be done if permission is obtained from the individual who is prescribed the medication.

The appropriate confirmation documentation (PAT/RET) forms need completing ensuring a full list of medication and destination of that medication (use, returned to service user, destroyed) is noted and the service users signature.

If permission is NOT given the drugs must be stored separately and removed from the site to the service user’s residence at the earliest opportunity.

8.9 Ward and Service Closures

8.9.1 Temporary Closure (7 days or less i.e. bank holidays and weekends)

Medicines including controlled drugs may be left in the locked controlled drug cupboard but only if security is to the satisfaction of the nurse-in-charge and the Pharmacist.

8.9.2 Long-term Inpatient or Community Closure (over 7 days)

All medicines must be returned to Pharmacy. The ward pharmacist or pharmacy technician or LPFT Pharmacy Services should be contacted to arrange secure transit of medicines to the Pharmacy.

The controlled drugs must be checked out of the relevant Controlled Drug cupboard, and an inventory made, in accordance with the Trust’s Standard Operating Procedure for Controlled Drugs Management.
9. Prescribing

9.1 Authority to Prescribe

Normally, only a registered medical practitioner has the authority to complete a written prescription and to prescribe medication for Service Users except where the Trust has agreed to allow non-medical prescribing (independent or extended prescribing) and/or supplementary prescribing by non-medical healthcare professionals. (e.g. nurse or pharmacist) Such agreement will be subject to the Medicines Management Committee satisfying them that the appropriate training and supportive guidance is in place for staff involved in such activities.

Only medicines that are licensed in the UK may be prescribed, and only at doses listed in the British National Formulary (BNF) Occasionally a consultant may wish to use a medicine at a dose not listed in the BNF, or for an indication not covered by the terms of its UK licence, or use a medicine with no UK licence. In such cases the consultant MUST first complete an unlicensed medicine request form (Appendix A) by completing this form the consultant accepts responsibility for all outcomes resulting from this use of the medicine.

Pharmacy will NOT supply an unlicensed medicine, or a medicine being used outside the terms of its UK licence, or a medicine outside of BNF dosing recommendations unless the unlicensed medicines request form has first been completed.

Where prescribing occurs outside of a UK licence of BNF dose limits, this will be highlighted to the relevant consultant. (Appendix B)

There must be a system in place whereby the supplying Pharmacy has access to specimen signatures of all prescribers to be able to verify the authenticity of prescriptions.

A doctor holding limited or provisional registration must not prescribe for any persons, except for those service users they are responsible for in the course of employment in relation to which limited registration is granted. They may prescribe drugs on forms FP10(HP) and FP10(FP[ad]) only when specifically required to do so by their employing authority in the course of the employment in relation to which limited registration is granted. (GMC Limited Registration of Sponsored Doctors for Pre-arranged Employment Para 18).

Medical students are not permitted to prescribe.

The use of Non-medical prescribers within the Trust has been authorised subject to stipulated criteria as laid out in the Non-Medical Prescribers policy (Appendix S).

9.2 Prescribing Procedure - Initial Prescription(s)

The prescriber MUST make sure that he/she is aware of the service users full clinical and medication history. This would normally require access to:

- All of the service users prescription charts
- Service users own medicines
- Information supplied from other sources about the service users medication history

9.3 Prescribing Process

Refer to the 'Prescription Writing Standards' for details.

The prescriber must ensure that each prescription chart bears the correct identification details for the service user. This should wherever possible, be by attachment of an addressograph generated from the relevant information system but otherwise the details must be entered by hand, using capital letters and includes the following details:

- Service User name
- Address
- Hospital Number/ NHS number
- Date of birth
- Ward / unit
- Consultant
- Age and weight for children under 12, or whenever there is a dose to be calculated.

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEGIBLE</td>
<td>The prescription must be written clearly and legibly.</td>
</tr>
<tr>
<td>BLACK INDELIBLE INK</td>
<td>To enable photocopying</td>
</tr>
<tr>
<td>CHOOSE APPROPRIATE PRESCRIPTION</td>
<td>e.g. In-patient chart, outpatient prescription or Warfarin chart</td>
</tr>
<tr>
<td>USE APPROPRIATE SECTION OF THE PRESCRIPTION SHEET</td>
<td>e.g. The ‘once only’, ‘prn’ or ‘regular’ section of the treatment chart</td>
</tr>
<tr>
<td>MULTIPLE PRESCRIPTION FORMS</td>
<td>Where space is insufficient on one sheet annotate e.g. 1 of 2 and 2 of 2</td>
</tr>
<tr>
<td>IN ENGLISH</td>
<td>See approved abbreviations (Appendix C)</td>
</tr>
<tr>
<td>GENERIC NAMES –recommended International Non- Proprietary Name ( r INN )</td>
<td>Should be used except for medicines with specific pharmacokinetic properties e.g. modified release preparations, where a brand name should be used. Compound medicines without an approved generic name Should be prescribed by brand name.</td>
</tr>
<tr>
<td>FORM OF MEDICINE</td>
<td>A medicine Should normally only be prescribed within the terms of its product licence. Unlicensed use or the prescribing of unlicensed medication carry addition risks and the appropriate forms must be completed.</td>
</tr>
<tr>
<td>DOSE</td>
<td>See approved abbreviations (Appendix C). Compound medicines Should be prescribed by dose units or volume.</td>
</tr>
<tr>
<td>ROUTE</td>
<td>See approved abbreviations (Appendix C). N.B. there must be a separate prescription for each route.</td>
</tr>
<tr>
<td>TIMES OF ADMINISTRATION</td>
<td>Use tick or ring the specified time at which the drug is to be administered</td>
</tr>
</tbody>
</table>
9.4 **Drug sensitivities/allergies box.**

These must include any known drug/food/chemical/dressing hypersensitivity, and any information which may affect medicine selection or dosage e.g. previous gastro-intestinal bleed with no steroidal anti-inflammatory drugs. This must clearly be recorded on the service user medical record.

The prescriber MUST sign and date the drug sensitivities/allergies box. Any authorised health care professional may add to this if an allergy or sensitivity is subsequently encountered. Each entry must be signed and dated.

**The dispensing pharmacy may refuse to dispense any medication unless this section is completed or a ‘none known’ indication is made.**

9.5 **Prescribing Controlled Drugs**

A service user may need a supply of a Controlled Drug in one of the following circumstances:

- On admission to hospital
- On discharge or leave from hospital
- As an outpatient or day patient

In any of these situations the prescription **MUST** comply with the legal requirements and the guidance in the Trust’s Standard Operating Procedure for Controlled Drugs Management. (Appendix M)

9.6 **Subsequent Prescriptions**

Additional Items - Follow the process detailed in 9.3

9.7 **Prescription Changes**

9.7.1 **Deletion of One Item**

Draw a DIAGONAL LINE through both the PRESCRIBING and RECORDING sections DATE and SIGN the STOP DATE section

If the prescribing section is NOT deleted, administration may incorrectly continue.

9.7.2 **Permanent Alteration of One Item (i.e. Dose or Route of Administration)**

DELETE item as above
REWRITE amended prescription in new section

9.7.3 **Incremental Adjustment of Treatment**

For **frequency** score a line through the boxes where the dose is not to be given.
For **dose**, use the variable dosage section of the prescription chart if available. An alternative method for frequent dosage variation e.g. daily, then the daily dose may be entered in a “spare” administration box under the correct date.

### 9.7.4 Full Prescription Sheet

If a prescription sheet is full the whole sheet must be cancelled by the medical practitioner and re-prescribed on a new sheet.

A diagonal line should be drawn through the old prescription sheet, signed and dated by the prescriber.

It is important to transfer the starting date of treatment to the new chart.

When it is essential to have more than one prescription sheet in use at the same time the prescriber must:

- Annotate the charts as e.g. 1 of 2 charts
- Permanently attach all the charts together
- Return to the use of a single chart as soon as possible

### 9.8 Verbal Orders – Emergency Use ONLY.

Instruction by telephone to administer a previously unprescribed medicine will not be accepted. In exceptional circumstances however, where the medication has been previously prescribed and the prescriber is unable to issue a new prescription, but where changes to the dose are considered necessary a verbal order may be accepted by the nurse in-charge of the ward. He/she must be satisfied that the doctor’s presence is unnecessary or their absence is unavoidable and the verbal message is essential. If possible the use of information technology (such as fax or e-mail) is the preferred method to make amendments to the prescription chart. The following procedure must always be carried out when accepting a verbal order:

- Write the prescription in capital letters in the “once only” section of the treatment chart.
- The verbal order details must contain the name of the service user, the name and form of the medicine, the dose, the route of administration, the date and time of the order and the name of the prescriber and the reason for the dose change (the medicine must have been previously prescribed).
- Repeat the verbal order to the prescriber to confirm that it is correct, if in any doubt spell the name of the medicine and ask the prescriber to confirm.
- Where possible have the instruction repeated by the doctor to a second Practitioner.
- Sign the verbal order (nurse) and annotate “verbal order”.
- Require the prescriber to sign the verbal prescription as soon as possible, preferably within twenty-four hours.
- Verbal orders CANNOT be given for Controlled Drugs or Temazepam.

‘Nurses have the right to refuse to act on a verbal order made by a medical officer’
(Ref: NMC standards for medicines management 2007)
10. **Community Psychiatric Nurses (CPNs)**

10.1 **Personnel.**

Each Community Psychiatric Nurse must carry an official Trust identity card and authorisation to carry medications. They must also be aware of the security and safety issues surrounding the transportation and administration of medicines as staff on inpatient wards.

10.2 **Lead Responsibility**

The Chief Executive authorises possession, carriage and conveyance of drugs as required by CPN's. Each CPN should notify his/her relevant insurance company that drugs may be carried in their vehicle in connection with their work for business purposes.

10.3 **Security**

- CPN's should ensure that medicines are carried in a locked case and when left in their vehicle should be stored away from view in the security of the car boot. Medicines should not be kept in a vehicle overnight.
- The locked case may take the form of a briefcase, satchel or similar item. It must conform to the following requirements:
  - Be of substantial (not soft) leather or rigid construction
  - Have a handle and/or a Shoulder-strap
  - Be lockable with a key either with an integral lock or a padlock
  - Be of sufficient size to contain all medicines and associated paraphernalia required for administration
  - Offer sufficient protection to prevent damage to items in transit
- Any drugs or injecting equipment which is lost or stolen must be reported to the relevant manager and Trust Chief Pharmacist as soon as possible for investigation, and/or reporting to the police if necessary. An incident report completed via the Trust’s incident reporting system.
- If drugs or keys have been stolen all locks and keys associated with the locks MUST be changed immediately.
- A running balance record for all drugs, including depots stored and administered should be kept.
- For reasons of safety, single dose ampoules must be used in preference to multi-dose. Where multi-dose containers are considered essential, approval must be sought from LPT Mental Health Pharmacy Services.
- Medicines should not be administered unless a prescription for an individual patient has been written and signed by an authorised prescriber.
- Any drugs administered must be recorded in the service users’ notes and prescription card, and signed by the administering CPN.
- In the case of an error in the administration of any drug, the appropriate medical practitioner must be contacted immediately and any necessary action taken to ensure the safety of the service user. The incident must be reported to the Team leader during normal office hours or the Senior Manager ‘on call’ at any other time as soon as possible. The provisions of the Trust’s policy relating to untoward incidents, accident or near misses apply.
- Patient Group Directions (Appendix T) must be in place before medicines are administered to service users without a written prescription from a GP or Consultant Psychiatrist.
11. **Administration**

11.1 **Responsibility**

The Appointed Practitioner in Charge in accordance with these guidelines will set the standards for medicine administration in their service.

11.2 **Authority to Administer**

Medicines may only be administered by:

- A medical practitioner
- Designated practitioner
- Authorised pharmacy staff
- A practitioner in training but only under the direct supervision of a designated practitioner. The designated practitioner remains responsible for ensuring that the correct procedure takes place.
- An HCA can give the dispensed medicines under delegation by a registered nurse
- Other authorised employees.

*Registered Nurses can delegate these clinical activities to HCAs on the following basis:*

- You must establish that anyone you delegate to is able to carry out your instructions
- You must confirm that the outcome of any delegated task meets required standards
- You must make sure that everyone you are responsible for is supervised and supported

*Appropriate delegation means:*

- The task is necessary and delegation is in the patient’s best interest
- The HCA/support worker understands the task and how it is to be performed
- The HCA/support worker has the skills and abilities to perform the task competently
- The HCA/support worker accepts the responsibility to perform the task competently
- The Registered Nurse accepts the responsibility for the delegation

No member of staff must dispense a medicine, check or witness the administration of a medicine, take part in the process of administering a medicine, unless they have a documented and demonstratable level of competence for the task. Assessments of competence will be regularly reviewed by the Appointed Practitioner in charge.

All clinical areas will be provided with a current copy of the British National Formulary and the current BNF for children where appropriate, by the Trust Pharmacy Service.

11.2.1 **Children**

A medical practitioner or registered nurse must always accept responsibility for the administration of medicines to children. All aspects of administration must be checked by two practitioners, though it is not necessary to witness the application of topical medicines.

11.2.2 **Adults**

In most situations administration may be undertaken by one qualified practitioner. Some medicine administrations can require complex calculations to ensure the correct volume or quantity of medication is given. To minimise the risk of error, the following situations require a qualified practitioner and an authorised competent witness to check all aspects of administration:

- Calculation and administration of a weight related dose, where the dose is actually prescribed as e.g. mg/kg body weight or mg/m² body surface area.
- Where administration involves an unusual dose needing written calculation e.g. giving 6.7 ml of a 30mg/5ml mixture for a 40mg dose. The calculation method must be recorded near the prescription on the prescription chart and be signed by the two persons involved.
administering subsequent doses should also check the calculation as a matter of course although the administration may be carried out by one person.

- All Controlled Drugs

Medicines dispensed as ward stock or for individual patients MUST NOT be used to treat staff.

11.3 Practical Procedure

11.3.1 The Assigned Practitioner in Charge is responsible for ensuring that ALL prescribed medicines are administered within 60 minutes either side of the prescribed time.

11.3.2 Before administration of any medicine:

- Read the prescription carefully. If there is any doubt that it is correct, the authorised prescriber or the pharmacist should be contacted for advice.
- Check authorisation of administration (forms T2 / T3) if the service user is detained under the Mental Health Act 2007.
- Ascertain that the prescribed dose has not already been administered.
- Check that the service user is NOT allergic or sensitive to the medication prescribed
  - medicines Should not be administered or dispensed if the drug sensitivity / allergy box is left blank or
  - If the service user is reported to be allergic or sensitive to the prescribed medication.
- Select the medication required, from the original container, and check any label against the written prescription.
- BEFORE administration check the identification of the service user by visual recognition and verbal questioning. E.g. request date of birth and check against details on prescription chart. Take extreme care to ensure the correct individual is given correct medication.

The following steps should be performed and checked against the prescription:

- Selection of medicine
- Check that the medicine is ‘in date’
- Calculation of dose, if required
- Measurement of dose
- Check of the patient’s identity

Medicines dispensed for an individual service user must be administered ONLY to that individual (supplies labelled for individuals must NOT be shared).

The practitioner who administered or supervised the administration of the medicine MUST immediately following administration sign with initials in the appropriate column of the prescription chart or indicate with the correct variant code supervised administration / omitted medication.

**Service users must be observed to ensure they have taken their medicines. Prepared medicines must NOT be left unsupervised unless the self administration procedures are being followed.**

If a medicine is omitted the following variant codes must be entered onto the prescription chart and an entry made in the clinical notes as to why the variance occurred;

\[ \text{A} - \text{Absent} \quad \text{L} - \text{On Leave} \quad \text{O/S} - \text{None in stock} \quad \text{O} - \text{Omit} \]

\[ \text{R} - \text{Refused} \quad \text{S} - \text{Self Med} \]

If the service user is absent from the ward, or has missed a dose for some other reason, the delayed dose can be administered at a later time **provided** a prescriber confirms that it is appropriate to do so. The actual time of administration MUST be clearly recorded and an appropriate entry into the service user’s notes is made.
It is good practice that wherever possible ALL medicines be prepared and administered in the presence of another practitioner.

When one Designated Practitioner administers, the Designated Practitioner shall follow full recognised checking procedures and shall ensure that administration does not involve calculation of dose; administration to children under 12 years of age; weight related doses; withdrawals from multi-dose vials or Controlled Drugs. In these instances, a second authorised and competent witness shall check all aspects of administration.

Once selected, medicines Should NOT be left unattended prior to administration to the service user.

Take the measured dose and the prescription to the service user, re-check the identity of the service user against the prescription card and administer to the service user. A person acting as witness for a Controlled Drug must actually see the medicine being given. Enter details in appropriate records if required and on the service users’ prescription card. The reasons for any omitted dose must be noted on the prescription card.

**Side effect monitoring**

All healthcare professionals with responsibility for the prescribing, monitoring or administration of medicines must be aware of the adverse reactions (side effects) of the medicines being used. (See Appendix I)

11.3.3 Any medicine may produce unwanted or unexpected adverse reactions. Detection and recording of these is of great importance.

11.3.4 Practitioners must observe and note any suspected adverse side effects of medicines, record the noted side effects in the appropriate medical notes, and inform the responsible medical staff at the earliest opportunity.

11.3.5 The nursing staff should omit any further doses of the medication implicated in producing the adverse reaction until seen and advised as to the appropriate course of action by the RMO

11.3.6 The RMO should act on the report and note options for dealing with the reported adverse side effect in the medical notes and adjust the prescription chart as necessary.

11.3.7 Service users should be regularly prompted to report or discuss any adverse effects they believe they may be experiencing as a result of their medication.

11.3.8 The monitoring of the service user for reported medicines-related adverse effects should be included in the care plan for any service user who is prescribed medication.

11.3.9 Newly licensed medicines are monitored intensively by the Medicines and Healthcare products Regulatory Agency (MHRA) and are identified by a black triangle symbol in the British National Formulary (BNF).

11.3.10 Where an adverse reaction to a medicine results in an in-patient admission, prolongs an in-patient admission OR involves a “black triangle” medicine, it must be reported to the MHRA. Post pre-paid yellow cards are available at the back of the BNF, or reporting can be completed on-line using the website [www.yellowcard.mhra.org.uk](http://www.yellowcard.mhra.org.uk)

11.3.11 Pharmacists will support any healthcare professional in the reporting of suspected adverse reactions to the MHRA

11.3.12 Leave or discharge:

Any medication that has been dispensed for leave or discharge MUST be checked by a Designated Practitioner against the prescription chart BEFORE giving the medication to the service user, to ensure that there have been no dispensing errors or that the medication has not been changed. Any discrepancy must be identified and the dispensing pharmacy contacted immediately to obtain a new supply.

If a dispensing error is identified, once the dispensing pharmacy has been notified and a new supply ordered, the Trust incident reporting procedure MUST be completed.
11.4 **Liquid Medicines**

Liquid medicines should be administered using an appropriate measuring device e.g. calibrated dropper, oral syringe, 5 mL spoon or graduated plastic cup. Doses of less than 5ml must be administered using an oral syringe or dropper.

11.5 **Recording of Administration**

11.5.1 Controlled Drugs

Each administration of a Controlled Drug must be recorded in the Controlled Drugs Register as described in the Trust’s Standard Operating procedures for Controlled Drugs Management (Appendix M)

11.5.2 Recordable Medicines

Recording for security purposes may be implemented locally for medicines on consultation with the Director of Nursing and Quality and the Chief Pharmacist.

Such recording may operate at one of two levels appropriate to the situation i.e.

- Full register recording - as for Controlled Drugs
- A daily running balance check

No alteration, obliteration or amendment to any record is permitted

11.5.3 Errors or Discrepancies in Record Keeping

Where there is evidence of alteration, obliteration or amendment to records, this must be investigated in the same way as Section 8.7 (Losses and Discrepancies).

11.6 **Self Medication**

Self medication is available to patients subject to approval by the Multidisciplinary Team following a risk assessment, and following approved Trust policy and procedures (refer to self administration of medicines policy, procedure and guidance). The service user must be assessed for suitability for self-administration - this assessment will be ongoing for the duration of the service users stay.

11.7 **Use of Patient’s own drugs (POD’s)** –

Patient’s Own Drugs (POD’s) may be used under strict conditions once they have been assessed for use by a suitably qualified person (i.e. pharmacist, pharmacy technician, authorised senior nurse who has undergone additional training and competency assessment) and assuming that the medical practitioner authorises and prescribes the continued use of them.

All service users who are admitted should be encouraged to bring their medicines into the ward/unit. If a service user fails to or is unable to bring in their own medication either relatives or a carer should be asked to bring them in at the earliest opportunity.

The advantages of having access to POD’s are:-

- The exact nature of the prescription can be clarified.
- Compliance can be assessed.
- If the medicines are changed during admission obsolete medicines do not remain in the service user’s home.
- The medicines can be used whilst the service user is on the ward.

All medicines brought in to the ward/unit by the service user, relative or carer remain the property of the service user. Therefore they should NOT be used or destroyed without the consent of the service user. (See appendix G for consent form)
Service users have the right to consent/refuse permission to use their own medicines. The decision made by the service user for or against using their POD’s must be recorded in the patient’s notes.

A list of ALL medicines brought into the ward/unit must be recorded and the designation of each medicine recorded i.e. POD in use, destroyed, returned to pharmacy. This is recorded on the consent form.

If a service user refuses the use of the medication it should be stored on the ward/unit and returned to the service user’s home as soon as possible, or returned to the individual on discharge from the ward/unit.

Service users MUST be informed if the continued possession of any medication is inadvisable or unsuitable for use and the reasons why.

All medicines brought in for the service user MUST be clinically reviewed by the admitting medical practitioner who may or may not prescribe them.

Medicines brought into the unit, including Controlled Drugs, MUST be checked for appropriateness, suitability and safety by either a pharmacist, pharmacy technician or an authorised senior nurse.

Before any patient’s own drugs are used the following criteria must have been satisfied by the Assigned Practitioner:

- Service user’s permission has been obtained and documented.
- The medicines have been prescribed on an Trust prescription chart.
- The medicine is clearly identifiable.
- The medicine bottle/box contains the correct drug as described on the label.
- The medicine brought in is labelled with the service user’s name; drug name and strength; directions for use; date dispensed (do NOT use medicines if dispensed more than 6 months ago. For ophthalmic preparations they must have a date opened and have been opened for less than 4 weeks or as advised on the dispensing label); Name and address of the supplier.
- Loose medication must NOT be used unless the person undertaking the initial medication assessment is satisfied that the medication in the container is what is on the label; that there contains no mixed brands or types i.e. capsule & tablet; they are free from any contamination or degradation and that they are only used for the shortest possible length of time with an alternative supply being obtained from the pharmacy department as soon as possible.
- Any appropriate storage conditions have been met i.e. fridge items stored correctly.
- The overall appearance of the container, label, and medicine must be acceptable.
- The medicine in the container is ALL of the same type; the appearance of the medication is uniform with no visible contamination.

Medicines that have been brought in with NO dispensing label MUST NOT be used.

Any item that has been brought in must meet the appropriate expiry date criteria shown below:

- Tablets/Capsules - Manufacturer’s expiry.
- Inhalers - Manufacturer’s expiry.
- Creams - 3 months after opening.
- Eye drops - As advised on the dispensing label (between one and four weeks).
- Ear drops - 4 weeks.
- Insulin - 3 months (NOT refrigerated 1 month).
- Glyceryl Trinitrate (GTN) Spray – Manufacturer’s expiry.
- Tablets – 6 weeks.

As soon as is practicable, confirmation of the medication, dosages, and directions MUST be obtained from the service user’s GP. This information should be obtained within 72 hours.

Controlled Drugs MUST be stored in the CD cupboard and recorded as per the CD procedures (Section 5.1).
Any POD’s that are in a compliance aid of any kind should NOT be used. The compliance aid remains the property of the individual and should be stored safely until a decision is made about the compliance aid and its contents.

If the POD’s meet the above criteria they can be used until an alternative supply is available or until they have been assessed by authorised pharmacy personnel for continued use.

If the unit has agreed to the use of POD’s in their area the POD’s MUST be stored in an individual section of the medicine trolley or drug cupboard and be clearly identified to the individual.

Where the POD’s are stored in the medicine trolley, drug cupboard, or individual locker, it is the responsibility of the Assigned Practitioner in Charge to ensure that if an individual moves to a new location, their medication is transferred or returned to the pharmacy.

At the point of discharge the nurse or pharmacy personnel MUST check the service user’s dispensed medication and/or POD’s, against the discharge prescription before returning the medication to the service user or carer.

If the items are found to be no longer required, appropriate advice the service user should be encouraged not to take them home (applicable to any POD’s left on the ward/unit for the individual).

If the service user insists on the return of any POD medication that is their property and they are no longer prescribed it or the doses have changed the medication can still be returned to them. However the service user and/or carer must be advised as to the reasons why the medication is not safe to use, and this documented in the service user’s notes.

The Assigned Practitioner in Charge, after consultation with the prescriber, may assume responsibility for the decision to refuse to return any POD medication to the individual, if in their professional opinion it would be detrimental and unsafe to allow the individual to take the medication away with them. This decision process MUST be clearly documented in the service user’s notes.

If there has been any change in medication, a discharge request MUST be written by the prescriber and sent to the pharmacy. Upon receipt of the discharge medication it MUST be re-checked against the prescription chart for accuracy BEFORE finally giving the medication to the service user or carer.

11.8 Administration by Parents and Carers

In certain circumstances parents or carers may be allowed to administer medicines (subject to service user consent) as part of the agreed treatment and care plan and following appropriate education and training provided by nursing staff. This will be at the discretion of the Assigned Practitioner in Charge. The nurse is still responsible for exercising adequate supervision to ensure that medicines are administered and stored as described in these guidelines.

11.8.1 Administration by health care assistants/support workers

A healthcare support worker/support worker is able to administer medicines as part of an agreed treatment and care plan and following appropriate education and training provided by nursing staff. This practice is at the discretion of the registered nurse who delegates the function to the HCA. The responsibility for the delegation remains with the registered nurse and the HCA is responsible for their acceptance of the competence to complete the task.

11.9 Compliance Aids

Non-compliance with medicines is a major cause of relapse and admission to hospital. There are many factors which can lead to non-compliance with medicines. These include:

- A poor understanding of the need for the medicines.
- A poor understanding of how to take the medicines.
- Forgetfulness.
- Inability to open the containers provided.
- Poor eye sight.
- A complicated regime of medicines.

For some people a compliance aid may assist a person to continue self-administering and remain out of hospital. However providing medicines in a compliance aid may not resolve the non-compliance problems.

Compliance aids may be used in a ward setting to assist the self-administration of medicines as part of a formal assessment of ability or establishment of a correct medicine taking routine prior to discharge.

Compliance aids may be used in a community setting to assist service users to administer their own medicines and/or facilitate compliance monitoring.

11.9.1 BEFORE there is any agreement to provide medicines in a compliance aid, a full assessment of the reason for non-compliance should take place. It may be that the provision of a compliance aid may not be of benefit and some medicines are not suitable for compliance aids due to their stability.

11.9.2 Compliance aids vary but most require to be replenished on a weekly basis. Before compliance aids are issued and the service user trained to use them arrangements must be made for their regular replenishment whilst under Trust care and on discharge through community pharmacies.

11.9.3 The act of filling a compliance aid involves re-dispensing. Only authorised pharmacy personnel and other authorised practitioners who have successfully completed pharmacy approved training and assessments are allowed to fill a compliance aid.

Other practitioners may only:

- Assist service users to fill their own compliance aids
- Train service users to use a compliance aid as part of a ward based training scheme.

12. Administration by ‘patient group directions’ (PGDs)

12.1 The Crown Report (HSC 1998/051) and (HSC 2000/026) allows for the supply and administration of medicines to groups of service users who may not be individually identified before presentation for treatment.

A Patient Group Direction is a specific written instruction for the supply or administration of named medicines in an identified clinical situation where this offers an advantage for individual care, without compromising safety. It will be drawn up locally by doctors, pharmacists and other appropriate professionals, and approved by the Trust. We retain the term 'Patient Group Direction' for such instructions for the supply of medication to service users.

Patient Group Directions allow medicines to be supplied or administered in the absence of a prescription written by a doctor for a specific service user.

The majority of clinical care however, will continue to be provided on an individual service user specific basis.

Any PGD proposed by a practitioner must be approved by the Director of Nursing & Quality, Medical Director & Chief Pharmacist and then ratified by the Medicines Management Committee (MMC) The contents of the PGD MUST comply with the outlines in the Crown report 1998 and include the following information;

- Details of the condition or situation to which the PGD applies.
- Characteristics of the staff authorised to take responsibility for the supply or administration of medicines under the PGD
- A description of the treatment available under the PGD

For details on drawing up and implementing a PGD, refer to the Trust ‘Guidance for development of Patient Group Directions’ documentation.

12.2 The management and monitoring of the PGD

12.2.1 It is the responsibility of the Appointed Practitioner in Charge of each area to ensure that if medicines are administered without a prescription A VALID AND CURRENT Patient Group Direction is available to guide practitioners in their area and that the person administering the medicine has received training and been assessed as competent to use the relevant PGDs.

12.2.2 Copies of the approved PGDs MUST be available in each area and must reflect accurately the practice in that area.

12.2.3 A record of this type of administration must be entered in the ‘Patient Group Direction’ section of the prescription chart and signed by the designated practitioner. A designated practitioner can only administer a medicine initiated by themselves and not by another practitioner.

13. Untoward incidents, accidents, near misses involving medicines and drug alerts

13.1 Incident Reporting

It is the responsibility of the Trust Board to determine the mechanisms and procedures for reporting incidents relating to medicines. Any incident in relation to the prescribing, dispensing and administration of medicines must be reported via the policy relating to Untoward Incidents, Accident and Near Misses.

13.2 Prescribing Errors

Minor errors i.e. those related to legibility including failure to use capital letters, legibility of signature, etc., Should be pointed out to prescriber and corrections made. Repetitive errors of this kind noted by pharmacy or nursing staff should be reported to the Patients Consultant with the knowledge of the prescriber and an incident completed in the Trust’s reporting system.

Serious errors must be reported in accordance with Trust Policy with the knowledge of the prescriber.

13.3 Dispensing Errors

As soon as it is realised in Pharmacy that there has been a dispensing error the following procedure should be undertaken:

- Urgent steps should be taken to recover the wrongly dispensed medicine to ensure the safety of the service user.
- The correct medication should be dispensed and supplied to the service user immediately.
- A Datix form must be completed without delay and report the incident to the Pharmacy manager of the relevant pharmacy. Completion of this form should include supporting statements and proposed improvements in practice and outcome.
- The completed form Should be forwarded to the relevant personnel as outlined in the Trust’s policy relating to Untoward Incident’s Accidents and Near Misses.
- The incident should be reported by the Assigned Practitioner in Charge to the authorised prescriber and the pharmacy for advice, or another prescriber if this is not practical, if the medicine has been administered.
- Inform the service user, carer, relative or advocate.
13.4 **Administration Errors**

As soon as it is realised that there has been an error of medicine administration the following action must be taken:

- The appropriate prescriber should be contacted and when necessary, remedial action taken to ensure the safety of the service user.
- A Datix form must be completed. Supporting statements may be required from all staff concerned, these are essential if there is any possibility of serious injury to the service user or of litigation. The dispensing pharmacy department must be informed if it is an error in supply and LPT pharmacy must be informed for all medication related incidents.
- The incident should immediately be reported to and investigated by the appropriate ward manager, team co-ordinator, or person delegated to act on their behalf initially and team leaders involved if necessary at a later stage of investigation.
- Inform the service user, carer, relative or advocate.

If a student nurse is involved in a medicine error, the Appointed Practitioner in Charge must inform the student’s supervising tutor from tertiary education, College of Nursing and Midwifery. The error will be investigated by the designated Team Manager and a member of the College of Nursing and Midwifery appointed by the Principal. Errors in administration of medicines by practitioners should be dealt with in the same way as prescribing errors.

13.5 **Unexplained Loss of Stock**

Follow the procedure detailed in Section 8.7.

13.6 **Defective Medicinal Products**

If any member of staff discovers a suspected defect or accident with a medicinal product it must be reported to the Team/Service Manager. The Pharmacist on site or the “on-call” pharmacist out-of-hours must be informed and they will insure that the appropriate action is taken in accordance with the Pharmacy Policy Section 4 – “Reporting of Defective Medicinal Products”

This may mean cross working with the LPT medical devices group and with the NPSA.

13.7 **Drug Alerts**

Follow the procedure detailed in Drug Alert Cascading Pathway (Appendix H)

14. **Medical Gases**

ALL medical gases used in the Trust are Licensed Medicines and as such are subject to the Medicines Act and must be treated in the same way as any other medicine.

14.1 **BEFORE** a medical gas is administered to a service user, written authority from a prescriber MUST be obtained. This authority must include the name and concentration of the medical gas (where appropriate) the method of administration and the rate of flow. This can be achieved by:

- An inpatient prescription for an individual service user, normally written on the inpatient prescription chart.
- A Patient Group Direction (PGD) authorising the administration of a medical gas in an emergency.
- In cases of emergency the use of a verbal order as per section 9.8 of this policy could be used to initiate use of a medical gas.
14.2 A designated practitioner administering any medical gas to a service user MUST make a written record that treatment with the particular medical gas prescribed has been initiated on the relevant inpatient prescription chart.

14.3 Procurement, storage, supply of medical gases and other associated issues with medical gases is to be undertaken according to current Health & Safety legislation and locally agreed protocols.

15. Alternative & complimentary medications

Complimentary Therapies are therapies that may be used in conjunction with orthodox medical, nursing, and paramedical treatments to enhance the well-being, quality of life or symptomatic relief of the service user.

15.1 BEFORE any new alternative or complimentary medication therapy can be recognised by the Trust it must be approved by the Medicines Management Committee. Once agreed the therapy must be used within the guidance of this policy.

15.2 If a service user wishes to administer to themselves, or requests administration of, complimentary or alternative medicines they must discuss this with the doctor responsible for their care. This discussion should normally include a pharmacist and nurse looking after the service user.

This discussion should also include the mental capacity of the individual to understand any implications of using an alternative therapy opposed to conventional treatments.

15.3 If the use of alternative or complimentary medication is agreed, this should be recorded on the prescription chart.

15.4 The service user must be informed that any alternative or complimentary medication brought in by them and not supplied through the hospital pharmacy must be brought to the attention of the doctor responsible for their care.

15.5 The service user must be made aware that the Trust cannot accept responsibility for the quality or efficacy of these medications unless approved using the set process (see section 15.1 above) and this must be recorded in the medical notes.

15.6 Qualifications

A designated complimentary therapist MUST have obtained an appropriate qualification. Having obtained the qualification they must then ensure that the practice of the alternative or complimentary medicine is in line with the scope of the professional practice and code of conduct of the accreditation body for that therapy.

15.7 Competence

The interests and welfare of the service user are paramount and the designated complimentary therapist has a duty of care to ensure that their skills and knowledge are updated and that they remain competent to practice the therapy.

15.8 Consent

The service user MUST give informed consent for the practice of a specific alternative or complimentary medication therapy. The therapist must consult the multidisciplinary team involved in the service user’s care before any treatment is undertaken.

15.9 Documentation
The designated complimentary therapist must document within the service user’s care plan the alternative or complimentary medication therapy practiced, maintain the care plan notes of treatments given, dates and evaluations of the outcomes of treatment.

All documentation should be in line with the standards of the Trust on record keeping and the relevant accreditation body of the complimentary therapist.

16 Consultation, Approval and Ratification Process

Consultation and communication with stakeholders will be in accordance with policy ‘Corporate Documents and Policies Procedure’.

The feedback from consultation will be maintained and any amendments made to the policy before it is submitted for approval.

The policy will be approved and ratified in accordance with ‘Corporate Documents and Policies Procedure’.

17. Review and Revision Arrangements including Version Control

17.1 Review of these guidelines will be carried out by the Medicines Management Committee on a biannual basis or on an "as-and-when" basis should there be significant changes to the legal and statutory requirements.

17.2 Amendments

Any proposed amendments should be notified in writing to the Chief Pharmacist who will process any change requests through the Medicines Management Committee.

Changes considered by the Medicines Management Committee will be sent for approval by the Quality Committee.

Once approved amendments will be issued in accordance with the Trust’s Policy.

Corporate & Legal Services will maintain a version control log in accordance with ‘Corporate Documents and Policies Procedure’.

18. Dissemination and Implementation of a Policy

18.1 This policy will be disseminated in accordance with ‘Corporate Documents and Policies Procedure’.

18.2 The policy will be implemented through medical induction training and local area / ward induction training. The Medicines Management Workbook for Nurses available on the Trust intranet cross references this policy and the policy is an integral part of the Nurse Competence Framework.

18.3 Training

The prescribing, supply and administration of medicines to service users is an important aspect of professional practice for clinicians. Professional bodies provide their own guidance/standards expected of all clinicians registered with them and the Trust expects these relevant codes of professional practice relating to the administration of medicines to be implemented in accordance with the advice provided.

All clinical staff will recognise their personal professional accountability for their actions. Dependent on their particular form of registration (i.e. doctor, nurse, pharmacist, dentist etc.) and their area of practice they have an individual responsibility to take steps to continuously develop their professional knowledge and competence.

All clinical staff have a duty to understand and be aware of this policy, relevant guidance, standards and competency requirements that need to be met to undertake any specified task. It will be the responsibility of the Trust to ensure all newly recruited clinical staff are introduced to this policy at their formal induction.
In addition all clinical staff will need to sign to the effect that they have read and understood the policy before the practical administration of part or all of the medicine management arrangements relating to the treatment and care of patients.

In keeping with good practice all clinical staff will as part of their professional supervision, raise any matter in relation to this policy, matters affecting their duty to safely supply and administer medicines to service users as part of their on-going professional development. In addition matters of personal development will need to be addressed with their line manager and incorporated within their personal development plan. It will be the responsibility of the clinical line manager to ensure that where a staff member is deemed not required to undertake the competency assessments, due to meeting the desired requirements through experience, that there is evidence of that decision as part of the annual appraisal for the individual, or a plan to attain the given competence is prepared.

In the event that amendments occur to this policy and the associated guidance the Trust via Medicines Management Committee will circulate as required up to date information about the management of medicines for implementation by all clinical teams. All staff involved in the handling of medicines should be appropriately trained and demonstrate competence with regard to safety and security of medicines and with regard to safeguarding themselves and those under their supervision from any risks posed by drug products. To ensure that staff are appropriately supported to meet this, a series of competence assessments have been drawn up that cover the main areas of medicines management responsibility.

LPFT Mental Health Pharmacy, in conjunction with the training department, offers a basic training programme to support the policy. This includes educating all staff involved with handling medicines on the need for risk management in relation to drug products and procedures as well as defining lines of responsibility and secure methods of handling both medicines and controlled stationery. This basic training is available on the intranet and all staff will need to refresh their knowledge on this aspect of medicines management every TWO years.

Medicine Management training is mandatory training. The organization will provide sufficient and appropriate training for each of the main staff groups as outlined within the Trust Mandatory Training Matrix (Mandatory Training/Corporate Induction in the Human Resources and Workforce Development Policy handbook).

Medics –
- Junior doctor induction programme
- Medics handbook
- Medicines teaching session on doctor training programme each term (3 per year)
- BMJ training package on anticoagulants
- Rapid tranquilisation training package on Trust intranet

Nursing staff –
- Medicines management training workbook on intranet
- Patient Group Direction training package on intranet
- Rapid Tranquilisation training package on intranet

19. **Policy Control including Archiving Arrangements**

Corporate and Legal Services will maintain a copy of this policy for a minimum of 10 years in line with the recommendations contained within ‘Records management NHS Code of practice’ (2006). This ensures that where compliance with the Policy is claimed over a period of time during which different editions of the policy were in operation the processes can be checked against the relevant standards at the time...
20. Monitoring Compliance with and Effectiveness of Policies and Procedures

<table>
<thead>
<tr>
<th>Systems</th>
<th>Monitoring and/or Audit</th>
<th>Measurables</th>
<th>Lead Officer/Group</th>
<th>Frequency</th>
<th>Reporting to</th>
<th>Action Plan/Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systems in place to monitor the prescribing of all staff</td>
<td>No. of pharmacist interventions No of reported prescribing incidents</td>
<td>Clinical pharmacists Modern Matrons</td>
<td>Six monthly reports Quarterly reports</td>
<td>Medicines Management Committee</td>
<td>Medicines Management Committee (for monitoring)</td>
<td></td>
</tr>
<tr>
<td>Systems in place to monitor the arrangements for administration of medication</td>
<td>Safe &amp; Secure Handling of Medicines audit No. of reported administration incidents</td>
<td>Modern Matrons</td>
<td>Annual report</td>
<td>Medicines Management Committee</td>
<td>Medicines Management Committee (for action plans)</td>
<td></td>
</tr>
<tr>
<td>Systems in place for the monitoring of self-administration scheme</td>
<td>No. of service users offered &amp; using the self-administration programme</td>
<td>Modern Matrons/Pharmacy Technicians</td>
<td>Six monthly reports</td>
<td>Medicines Management Committee</td>
<td>Modern Matrons (for monitoring)</td>
<td></td>
</tr>
<tr>
<td>Systems in place for monitoring the safe disposal of controlled drugs</td>
<td>Safe &amp; Secure Handling of Medicines audit No. of reported incidents.</td>
<td>Pharmacy Technicians/Modern Matrons</td>
<td>Six monthly reports</td>
<td>Medicines Management Committee</td>
<td>Trust Accountable Officer (for monitoring)</td>
<td></td>
</tr>
<tr>
<td>Systems in place to monitor the uptake of medicines management training</td>
<td>Staff groups (inpatient, community) No. of staff taking training packages.</td>
<td>Modern Matrons Training Department</td>
<td>Annual report Quarterly training reports</td>
<td>Medicines Management Committee</td>
<td>Modern Matrons (for action plan) Medicines Management Committee (for monitoring)</td>
<td></td>
</tr>
</tbody>
</table>

This policy and the associated guidance form part of the Trusts risk management and quality controls strategy. The risk manager in association with the Medicines Management Committee will develop an annual programme of clinical audit to determine compliance to the relevant medicine management standards.

In addition a quarterly report of adverse incidents involving the management of medicines to the Medicines Management Committee. Any learning points will be identified and appropriate guidance circulated throughout the Trust to improve services.

All incidents or near misses, as defined within the Trust's Serious Untoward Incident Policy, and which relate to this policy must be reported using the Trust’s incident reporting system. In the event that there has been a suspected breach of conduct such matters will require investigation and may lead to the implementation of the Disciplinary Procedure.
21. References

Misuse of Drugs Act (1971)

Misuse of Drugs Regulations 1973 (IS 1973 No.797)

Misuse of Drugs (Amendment) Regulations 1974 (IS 1974 No. 402)

Misuse of Drugs (Safe Custody) Regulations 2007

N.B. Summary of Guidance of the above in (HC(77)16


The Misuse of Drugs Regulations 1985 (IS 1985 No. 2066)

The Misuse of Drugs (Safe Custody) (Amendment) Regulations 1985 (IS 1985 No. 2067)

Security of Drugs Liable to Misuse HM(71)21

Dangerous Drugs. (1973) Misuse of Drugs (Safe Custody) Regulations 1973

Mettrification: Introduction into the Health Service of the International System of Units (HSC(IS)198)

Addition of Drugs to Intravenous Infusion Fluids HC(76)9

Medicines (Prescription Only) Order 1980


Reporting Accidents with and Serious Defects in Medicinal Products, Building and Plant, Equipment and other Supplies whether Medical or Non-Medical HN(83)21

Prescription Only Medicines Order (1985)

Misuse of Drugs Regulations

The Safe and Secure Handling of Medicines : a Team Approach (revised Duthrie Report) March 2005

Cupboards for the Storage of Medicines in Health Care Premises BS2881


Standards for Pharmaceutical Services in Health Authorities, Units and Trusts in England RphO's Special Interest Group December 1991

Standards for the Administration of Medicines UKCC 1992

Guidelines for the Administration of Medicines UKCC 2000


Guidance on Reporting Accidents with, and Defects in Medicinal Products HSG(93)13. Medicines Control Agency

Misuse of Drugs (Amendment)(No. 2) Regulations 1995/SI 1995 No. 3244 (Temazepam)


Security of Prescription Forms HSC 1998/062

Mental Health Act 2007

Nurse Prescribing HSC 1998/232


Patient Group Directions HSC 2000/026

Controlled Drugs (Supervision of Management and Use) Regulations 2013

NMC Standards for medicines management 2007

Standing Financial Instructions 2013

22. Associated Documentation

APPENDIX A  Unlicensed use of Licensed medicines
APPENDIX B  Request for supplies of Unlicensed medicine
APPENDIX C  Abbreviations
APPENDIX D  Pharmacy On Call Pathway
APPENDIX E  CRHT visit / consult with patient pathway
APPENDIX F  Record of emergency leave supply
APPENDIX G  Patient Consent form (POD’s)
APPENDIX H  Drug Alert Cascading Pathway
APPENDIX I  Side Effect Overview
APPENDIX J  Covert Administration Guidelines
APPENDIX K  Medicines Reconciliation Guidelines
APPENDIX L  Medical Devices Guidelines
APPENDIX M  Controlled Drug Management Policy OPR47
APPENDIX N  Rapid Tranquilisation Policy OPR61
APPENDIX O  Substitute Opiate Prescribing Protocol
APPENDIX P  Dexamfetamine Prescribing Protocol
APPENDIX Q  Pharmaceutical Waste SOP
APPENDIX R  Procedure for Management of Illicit Drug Misuse
APPENDIX S  Non-Medical Prescribing Policy
APPENDIX T  Patient Group Direction Policy OPR59
APPENDIX U  Self-Administration of Medicines Policy
APPENDIX V  Inpatient Prescription Chart Guidelines
APPENDIX W  Community Prescription Chart Guidelines
APPENDIX X  Restricted Drug Stock SOP
APPENDIX Y  Royal Pharmaceutical Society Professional standards for Hospital Pharmacy Services
APPENDIX Z  Out of Area Pathways
APPENDIX AA  Urgent Treatment Policy
APPENDIX BB  Medicines Procedure Guidance for Occupational Therapists
APPENDIX CC  Fridge Monitoring Sheet
LINCOLNSHIRE PARTNERSHIP NHS FOUNDATION TRUST

To: Lead Pharmacist

RE: UNLICENSED USE OF LICENSED MEDICINES

I understand that the following medicine does not hold a UK Product Licence for the indication prescribed or to cover the circumstances in which it has been prescribed.

DRUG: __________________________________________

INDICATION: ___________________________________

CIRCUMSTANCES: ___________________________________

I am willing to authorise its purchase and subsequent supply for the treatment of:

Any patient
The following named patients under my care:

Patient name(s) ___________________________________

_________________________________

The prescription of this drug for the above indication:

Should be restricted to my signature only
May be prescribed by Junior Doctors involved in this treatment

Signed: _______________________________ Date: ________________________

Name (Capitals) ____________________________

Consultant: _____________________________

Delete as appropriate
Dear ……………………………

Re: REQUEST FOR SUPPLIES OF UNLICENSED DRUGS

The medicine you have prescribed is not covered by a UK Product Licence. In order that we may obtain supplies of unlicensed ………………………………………… for your patient could you please complete the form below and return to the Pharmacy Department as soon as possible.

Patient’s Name:  __________________________________________________________

Hospital Number:  ________________________________________________________

Indication/Reason for use

..................................................................................................................
..................................................................................................................
..................................................................................................................

I understand that ………………………………………………… is a medicine which is not covered by a UK Product Licence and confirm that the patient has been informed of the position.

Signed:  ____________________________________________  Date:  ________________

Name (Capitals)  __________________________________________

Consultant:  ____________________________________________
## Accepted Standard Abbreviations

### Routes of Administration

<table>
<thead>
<tr>
<th>Routes of Administration</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subcutaneous</td>
<td>s.c.</td>
</tr>
<tr>
<td>Intramuscular</td>
<td>i.m.</td>
</tr>
<tr>
<td>Intravenous</td>
<td>i.v.</td>
</tr>
<tr>
<td>Sublingual</td>
<td>Subling</td>
</tr>
<tr>
<td>Oral</td>
<td>o or po</td>
</tr>
<tr>
<td>Rectal</td>
<td>p.r.</td>
</tr>
<tr>
<td>Vaginal</td>
<td>p.v.</td>
</tr>
<tr>
<td>Nasogastric</td>
<td>NG</td>
</tr>
</tbody>
</table>

All other routes should be expressed in full.

### Frequency and other directions

<table>
<thead>
<tr>
<th>Directions</th>
<th>Abbreviations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Once a day</td>
<td>o.d. (omni die)</td>
</tr>
<tr>
<td>Twice a day</td>
<td>b.d. (bis die)</td>
</tr>
<tr>
<td>Three times a day</td>
<td>t.d.s (ter die sumendus)</td>
</tr>
<tr>
<td>Four times a day</td>
<td>q.d.s (quarter die sumendus)</td>
</tr>
<tr>
<td>At bedtime</td>
<td>o.n. (omni nocte)</td>
</tr>
<tr>
<td>In the morning</td>
<td>o.m. (omni mane)</td>
</tr>
<tr>
<td>Alternate days</td>
<td>alt.die. (alter die)</td>
</tr>
<tr>
<td>Immediately</td>
<td>stat (statim)</td>
</tr>
<tr>
<td>Before food</td>
<td>a.c. (ante cibum)</td>
</tr>
<tr>
<td>After food</td>
<td>p.c. (post cibum)</td>
</tr>
<tr>
<td>When required</td>
<td>p.r.n The minimum dose interval, maximum daily dose where appropriate and the indication must be specified.</td>
</tr>
</tbody>
</table>
### Weights and Measures

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Abbreviation</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kilogram</td>
<td>kg</td>
<td></td>
</tr>
<tr>
<td>Gram</td>
<td>g</td>
<td></td>
</tr>
<tr>
<td>Milligram</td>
<td>mg</td>
<td></td>
</tr>
<tr>
<td>Microgram</td>
<td>Microgram</td>
<td>No abbreviation</td>
</tr>
<tr>
<td>Nanogram</td>
<td>Nanogram</td>
<td>No abbreviation</td>
</tr>
<tr>
<td>Unit</td>
<td>Unit</td>
<td>No abbreviation as “u” frequently be confused with “O”</td>
</tr>
<tr>
<td>Litre</td>
<td>L</td>
<td></td>
</tr>
<tr>
<td>Millilitre</td>
<td>ml or mL</td>
<td></td>
</tr>
<tr>
<td>Millimole</td>
<td>mmol</td>
<td></td>
</tr>
<tr>
<td>Kilocalorie</td>
<td>Kcal</td>
<td></td>
</tr>
</tbody>
</table>

All weights must be expressed in units greater than one e.g. 750mg **NOT** 0.75g

Commas must not be used to divide numbers into groups of three; instead a space must be left after every third digit

e.g. 1 000 000 **NOT** 1,000,000

If a value is less than one a zero Should precede the decimal sign
e.g. 0.123 456 **NOT** .123 456
### Glossary of terms and List of abbreviations:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>LPFT</td>
<td>Lincolnshire Partnership NHS Foundation Trust</td>
</tr>
<tr>
<td>ULHT</td>
<td>United Lincolnshire Hospitals NHS Trust</td>
</tr>
<tr>
<td>POD’s</td>
<td>Patients Own Drugs</td>
</tr>
<tr>
<td>SAM/POD</td>
<td>Self Administration of Medicines – Use of Patients Own Drugs</td>
</tr>
<tr>
<td>PGD</td>
<td>Patient Group Directions</td>
</tr>
<tr>
<td>PSD</td>
<td>Patient Specific Directions</td>
</tr>
<tr>
<td>CRHT</td>
<td>Crisis Resolution Home Treatment</td>
</tr>
<tr>
<td>CD</td>
<td>Controlled Drug</td>
</tr>
<tr>
<td>NMC</td>
<td>Nurse and Midwifery Council</td>
</tr>
<tr>
<td>MAJAX</td>
<td>Major Accident or disaster</td>
</tr>
<tr>
<td>PCT</td>
<td>Primary Care Trust</td>
</tr>
<tr>
<td>BNF</td>
<td>British National Formulary</td>
</tr>
<tr>
<td>GMC</td>
<td>General Medical Council</td>
</tr>
<tr>
<td>rINN</td>
<td>recommended International Non-proprietary Name</td>
</tr>
<tr>
<td>CPN</td>
<td>Community Psychiatric Nurse</td>
</tr>
<tr>
<td>CPA</td>
<td>Care Programme Approach</td>
</tr>
<tr>
<td>MMP</td>
<td>Medicine Management Policy</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Clinical Excellence</td>
</tr>
<tr>
<td>NHSLA</td>
<td>National Health Service Litigation Authority</td>
</tr>
<tr>
<td>NPSA</td>
<td>National Patient Safety Agency</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
</tr>
</tbody>
</table>

**FP10 / FP10(HP)**  
A prescription that can be written by a prescriber and dispensed at a community pharmacy.
Crisis Team (CRHT) access to medication.

Discuss with/contact prescriber. Will patient’s own drugs suffice?

No

Ascertain the day of the week and time of day

Weekend or Bank Holiday?

Is it Saturday before 11.30am?

Yes

Prescriber to write medication on Inpatient card or Outpatient prescription and obtain from pharmacy department

Between 9am and 4pm

Between 4pm and 9am

Is medication required?

Yes

Obtain medication from the emergency store via nurse dispensing procedures

No

Can prescriber use FP10(HP)?

No

Is required medication obtainable in pre-pack?

Yes

Prescribe to write FP10(HP)
Photocopy prescription twice put 1 in patient notes send the other to Mental Health Pharmacy services and the original to the service user for taking to retail chemist.

Yes

Prescriber writes a prescription and nursing staff obtain pre-pack from Crisis drug cupboard or emergency store

Endorse prescription with date and 2 nurse’s signatures. Adjust balance list of pre-packs left in cupboard. Complete appropriate paperwork and leave prescription in cupboard.
Guidelines for obtaining leave medication.

Emergency Leave (out of pharmacy hours) record form.

<table>
<thead>
<tr>
<th>Name of Service user</th>
<th>Ward:</th>
<th>Consultant</th>
<th>Date:</th>
<th>Time:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Medicines dispensed –

<table>
<thead>
<tr>
<th>Name of Medicine</th>
<th>Form</th>
<th>Strength</th>
<th>Directions</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

Name of Nurse Dispenser: (Registered Nurse) Block Capitals

Signature:

Name of Nurse Checker: (Registered Nurse) Block Capitals

Signature:

When completed file in the LPFT Emergency File a copy will be made by pharmacy and placed in the service user's notes.
Service User Agreement Consent form.

When Patient’s Own Drugs (POD’s) are to be used on the ward/unit permission MUST be obtained from the individual before they can be used or destroyed.

Complete the following if any medication is brought into the ward/unit by a service user, relative or carer for the individual.

I ………………………………………………… have brought medication onto the ward. It has been explained that there may be a need to use this medication once it has been assessed for suitability and its use agreed to by the doctor.

I agree / disagree* (* delete as appropriate) for my own medication to be given to me during my admission.

If the service user disagrees to the use of their medication then indicate the reason why:

Please list the medication brought in and what has happened to it. (Attach another sheet if necessary)

Signature of service user:_________________________________________________________
Date:......................

Name and Signature of nurse:_____________________________________________________
Date:......................
Appendix H

Drug Alert Cascading Pathway

SAB (MHRA, NPSA & DoH), SHA or Regional D&T Centre

Chief Pharmacist

With Instructions

Medicines Management Support Officer

Action Required

Relevant Prescribers and/or Unit Contacts and Secretaries
with this voting button at top of email

ACTIONED

Relevant Prescribers and/or Unit Contacts and Secretaries
with ‘Read Receipt’

Medicines Management Support Officer

NON RESPONDERS
within Specified Time (one week)

EMAIL

TELEPHONE
# Antipsychotic Side Effect Overview

<table>
<thead>
<tr>
<th>Problem</th>
<th>What can it feel like?</th>
<th>Is it serious?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Movement problems</strong></td>
<td>- Muscle spasms.</td>
<td>Movement problems are not usually serious.</td>
</tr>
<tr>
<td></td>
<td>- Slowness, or difficulty moving.</td>
<td>In some cases, they can make it difficult to carry out daily tasks, e.g. shaving, making a cup of tea.</td>
</tr>
<tr>
<td></td>
<td>- Stiffness.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Trembling or shaking muscles.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Feeling restless, as if you can't stay still.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Body movements you can't control, (e.g. sticking your tongue out, looking as if you're rolling something between your fingers).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Eyes rolling upwards.</td>
<td></td>
</tr>
<tr>
<td><strong>Putting on weight</strong></td>
<td>- Feeling more hungry or thirstier than usual.</td>
<td>If you become overweight or obese, you increase your risk of developing physical health problems, such as diabetes, heart disease and high blood pressure.</td>
</tr>
<tr>
<td></td>
<td>- No longer feeling full after eating.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Feeling sleepy, so you use less energy (calories).</td>
<td></td>
</tr>
<tr>
<td><strong>Daytime sleepiness.</strong></td>
<td>- Feeling &quot;like a zombie&quot;.</td>
<td>Not serious from a health point of view, but can reduce your quality of life by stopping you from working or socialising.</td>
</tr>
<tr>
<td></td>
<td>- Needing to sleep for long periods during the day.</td>
<td></td>
</tr>
<tr>
<td><strong>Dizziness</strong></td>
<td>- Feeling faint when you get up out of a chair or out of bed.</td>
<td>Dizziness can cause falls.</td>
</tr>
<tr>
<td></td>
<td>- Falling over because you feel dizzy.</td>
<td></td>
</tr>
<tr>
<td><strong>Dry mouth</strong></td>
<td>- Feeling thirsty all the time.</td>
<td>Not usually, but can feel uncomfortable and contribute to tooth decay.</td>
</tr>
<tr>
<td></td>
<td>- Lack of saliva.</td>
<td></td>
</tr>
<tr>
<td><strong>Blurred vision</strong></td>
<td>- Difficulty reading.</td>
<td>Blurred vision could cause you to fall over or have an accident. This problem can usually be dealt with and is not permanent.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Problem</th>
<th>What can it feel like?</th>
<th>Is it serious?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Problems going to toilet</strong></td>
<td>- Feeling constipated (unable to &quot;poo&quot;).</td>
<td>Not usually, but can lead to other health problems if not dealt with.</td>
</tr>
<tr>
<td></td>
<td>- Finding it difficult to go for a wee.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Feeling like you need to go for a wee more often than usual.</td>
<td></td>
</tr>
<tr>
<td><strong>Changes in emotions</strong></td>
<td>- Feeling agitated or restless, as if you can't stay still.</td>
<td>Can make you feel low and unhappy. May stop you from getting out of the house and cause you to feel isolated.</td>
</tr>
<tr>
<td></td>
<td>- Feeling &quot;emotionally numb&quot;.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Feeling as if you no longer enjoy the things you used to.</td>
<td></td>
</tr>
<tr>
<td><strong>“Thinking” problems</strong></td>
<td>- Finding it hard to concentrate on reading a newspaper or watching TV.</td>
<td>Can interfere with your quality of life, or ability to live safely (e.g., remembering to turn off the oven after cooking). May also be caused by getting older, feeling depressed or psychotic symptoms.</td>
</tr>
<tr>
<td></td>
<td>- Forgetting things more than usual.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Feeling &quot;mentally slow&quot;.</td>
<td></td>
</tr>
<tr>
<td><strong>Sexual problems</strong></td>
<td>- Loss of interest in sex.</td>
<td>Rarely serious, but can cause loss of self-esteem and relationship difficulties.</td>
</tr>
<tr>
<td></td>
<td>- No longer feeling as if sex is enjoyable.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Men: no longer able to get or maintain an erection (&quot;hard on&quot;).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Women: loss of vaginal lubrication.</td>
<td></td>
</tr>
<tr>
<td><strong>Sore nipples, or discharge from nipples (men and women)</strong></td>
<td>- Nipples feel tender, sore or swollen.</td>
<td>Not serious, but can be distressing and uncomfortable. A small reduction in dose or a change of medication can usually help the problem.</td>
</tr>
<tr>
<td></td>
<td>- White discharge from nipples. (can affect men as well as women).</td>
<td></td>
</tr>
<tr>
<td><strong>Women only: Loss of or change in periods</strong></td>
<td>- Periods are no longer regular.</td>
<td>Not usually, but if your periods stop altogether, this could make your bones weaker as you get older. It may also stop you from getting pregnant if you want to try for a baby.</td>
</tr>
<tr>
<td></td>
<td>- Periods have stopped completely.</td>
<td></td>
</tr>
</tbody>
</table>
Anticholinergic Side Effects

Anticholinergic, (pronounced “an-ti-kol-in-er-jic”), side effects are a group of problems that affect some people who take certain types of medication. These include some types of antipsychotic medication (e.g. clozapine) and some medicines for movement problems (e.g. procyclidine).

These problems do not affect everybody who takes these medicines, and sometimes they disappear after a few weeks.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Is it serious?</th>
<th>What can be done about it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constipation</td>
<td>It is healthy to go to toilet (&quot;poo&quot;) roughly every 36 hours.</td>
<td>• Eating a healthy diet can stop you becoming constipated. Fruit and veg should make up a third of what you eat each day. Starchy foods, like wholemeal bread, pasta, brown rice and cereal, should make up another third.</td>
</tr>
<tr>
<td></td>
<td>Constipation can be very uncomfortable and make going to toilet painful.</td>
<td>• Make sure you drink plenty as well. Water is best.</td>
</tr>
<tr>
<td></td>
<td>If you don’t go to toilet regularly, your back passage may become blocked, which can be serious.</td>
<td>• If changing your diet doesn’t help, or you are in pain, your Doctor may be able to prescribe you a medication (e.g. lactulose, Fibogel) to help you to go to toilet regularly.</td>
</tr>
<tr>
<td>Unable to wee</td>
<td>Can be serious if nothing is done about it.</td>
<td>• If you are a man and you are getting older, your Doctor will need to check whether you have got prostate problems that may be stopping you weeing.</td>
</tr>
<tr>
<td></td>
<td>The problem is more common in men.</td>
<td>• If the problem is mild, your Doctor might talk to you about reducing the dose of your medication.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• If you take a medication to prevent movement problems (e.g. procyclidine), reducing the dose, or seeing if you can manage without it, might help.</td>
</tr>
</tbody>
</table>

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For further information contact liparied@rcpsych.ac.uk

Problem: Dry mouth

No, but it can feel uncomfortable and make you want to drink more than normal.

Drinking too many sugary drinks (e.g. fruit juices, fizzy drinks) can cause teeth to rot.

A dry mouth can make wearing dentures uncomfortable.

What can be done about it?

• Avoid drinking too many sugary drinks. Try to sip water regularly if your mouth feels dry.

• Arrange to have your teeth checked regularly by a dentist.

• Using an artificial saliva spray (e.g. Glandosane spray) might help.

• Some people find that sucking sugar-free sweets or chewing sugar-free gum helps.

Problem: Blurred vision (finding it difficult to see things clearly, bumping into things).

This problem can be stopped.

Blurred vision can be serious if it causes you to fall over, or have an accident.

What can be done about it?

• If you have a close relative with the eyesight problem called “glaucoma”, make sure you let your Doctor know.

• If the problem is caused by taking a medication for movement problems (e.g. procyclidine), it might be possible for you to cut down the amount you take.

• If blurred vision is a serious problem for you, your Doctor may talk to you about trying a different type of medication.

Problem: Problems thinking or concentrating.

You may find:

• It’s difficult to follow a TV programme or read a newspaper.

• Your mind feels as if it’s been slowed down.

• You forget things a lot more than you used to.

These problems are not usually serious, but they can be frustrating and make life difficult for you.

People sometimes find it harder to concentrate and remember things as they get older.

If you are depressed, or your medication is not controlling your illness well, this may also make it difficult for you to think clearly.

What can be done about it?

• Tell your Care Co-ordinator, CPN or Doctor:

  • when you first noticed the problem.
  • whether it affects you all the time, or only at certain times of the day.
  • how the problem is affecting your life.
  • Try to keep a diary of the sort of problems you’re having for a week. If you live with a carer, relative or partner, ask if they can help you with this.
  • If your medication is causing the problem, it might be possible to reduce the dose you receive, or to try a different drug.
  • If the problem is linked to your illness, a higher dose or different
## Antipsychotic Medication and Movement Problems

<table>
<thead>
<tr>
<th>Problem</th>
<th>What does it feel like?</th>
<th>Is it serious?</th>
<th>What can be done about this?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncontrollable, unusual movements</td>
<td>You may develop odd movements. You may not notice them, but they can look strange to others. Examples are:</td>
<td>It can be, but this is very rare.</td>
<td>* It may be possible to reduce the dose of your medication, or change to another antipsychotic. Sometimes reducing the dose can make the problem worse in the short-run, but better in the long term.</td>
</tr>
<tr>
<td>* tardive dyskinesia*</td>
<td>• Smacking your lips together.</td>
<td></td>
<td>* Trying a medicine such as tetrabenazine can help, but this medication can cause some people to become depressed.</td>
</tr>
<tr>
<td></td>
<td>• Chewing when there's nothing in your mouth.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Sticking your tongue out.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Moving your fingers and hands so that it looks as if you're rolling something between your finger tips or playing the piano.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extreme muscle stiffness</td>
<td>Your muscles may go into spasm, or become very tight and feel as if they are out of your control. Examples include:</td>
<td>Dystonia can range from being mild and easy to ignore, to severe, painful and frightening.</td>
<td>In the short term: * an anticholinergic medicine, such as procyclidine, will help.</td>
</tr>
<tr>
<td>* dystonia*</td>
<td>• eyes rolling upwards.</td>
<td></td>
<td>In the medium term: * Procyclidine can continue.</td>
</tr>
<tr>
<td></td>
<td>• head and neck twisting to one side.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Depending on the muscles affected, you may:</td>
<td></td>
<td>* Consider discussing with the doctor whether a small reduction in antipsychotic dose or switch to another drug may help.</td>
</tr>
<tr>
<td></td>
<td>• find it difficult to speak clearly or swallow food.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• feel as if you are having a fit or choking.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• have difficulty breathing.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Some types of antipsychotic medication can cause movement problems. Some of these problems appear quite quickly after people have started drug treatment, others may develop after people have been on the same type of medication for a long time. This information sheet explains what these problems are and what can be done about them.

<table>
<thead>
<tr>
<th>Problem</th>
<th>What does it feel like?</th>
<th>Is it serious?</th>
<th>What can be done about this?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shaking, or slow movements</td>
<td>You may:</td>
<td>No, but if you are shaking a lot you may find it difficult to do things, like shave or pour a cup of tea.</td>
<td>In the short term: * an anticholinergic medicine, such as procyclidine, will help.</td>
</tr>
<tr>
<td>* parkinsonism*</td>
<td>• feel shaky,</td>
<td></td>
<td>In the medium term: * Procyclidine can continue.</td>
</tr>
<tr>
<td></td>
<td>• feel stiff,</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• find you move more slowly,</td>
<td></td>
<td>* Consider discussing with the doctor whether a small reduction in antipsychotic dose or switch to another drug might help.</td>
</tr>
<tr>
<td></td>
<td>• show less sign of emotion on your face,</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• have more dribble or spit in your mouth,</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• feel as if your mind is working more slowly.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Restlessness</td>
<td>You may feel restless and uncomfortable, both mentally and physically. Relaxing is difficult, so you may feel irritable or act impulsively. You may feel unable to sit still, so you may find yourself:</td>
<td>Not usually. If you feel irritable all the time, or act impulsively, this could make life difficult for you and the people close to you.</td>
<td>Consider discussing with your doctor whether a small * reduction in dose* or switch to another antipsychotic might help.</td>
</tr>
<tr>
<td>* akathisia*</td>
<td>* crossing and uncrossing your legs,</td>
<td></td>
<td>If you can't reduce the dose or switch, discuss with the doctor whether it would be worth trying propranolol (30-80mg/day) - not if you have asthma - cypromethadine (8-16mg/day) or clonazepam (can cause sleepiness).</td>
</tr>
<tr>
<td></td>
<td>* rocking from foot to foot,</td>
<td></td>
<td>* Procyclidine generally doesn't help.</td>
</tr>
<tr>
<td></td>
<td>* pacing up and down to keep on the go.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Leaflet Guide:** This table shows which leaflets are likely to be most appropriate for people prescribed different types of antipsychotic medication. If a leaflet is not indicated for a particular drug, that does not mean that it is totally free of the side effect in question. Bear in mind that even though some side effects are less common with particular types of antipsychotic drug, all antipsychotics may cause any of the problems listed below in patients who are vulnerable to them.

<table>
<thead>
<tr>
<th>Type of antipsychotic</th>
<th>General side effects leaflet</th>
<th>Anticholinergic side effects</th>
<th>Movement disorders</th>
<th>Sexual health &amp; period problems</th>
<th>Weight gain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aminopropyl (Solian®)</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Aripiprazole (Abilify®)</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chlorpromazine</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Clozapine (Cospin®; Deszepine®; Zaponex®)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Fluoxetine (Dapoxol®)</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raphepharmacine (Modoten®; Modecate®)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Haloperidol/Dozolin®; Halodil®; Serenace®</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Olanzapine (Zyprexa®)</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Quetiapine (Seroque®)</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risperidone (oral &amp; long-acting formulations) (Risperdal®)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Sulpiride (Dolmatil®; Substil®; Subpor®)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Trifluoperazine (Stelazine®)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Zuclopenthixol (Clopocid Acuphas®)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Please contact your LPFT pharmacy team for any further information or to request any of these leaflets.
Covert Administration Guidelines

Introduction
It is important to respect the autonomy of individuals who receive treatment. There may be times, however, when a person lacks capacity to either consent to, or to refuse treatment. In such circumstances treatment should be given to the person if it accords with the Mental Capacity Act 2005 (MCA) and if such treatment would be accepted as proper by a responsible body of relevant practitioners. In exceptional circumstances this might require that medicines are administered covertly.

The disguising of medication in food or drink is not to be encouraged. Efforts must be made to obtain the person/carer’s consent to receive prescribed medicines in the normal way. In some cases it is recognised however that covert administration may be in the best interests of the person. When medication is given covertly it is vital that the decision has been properly considered, thorough consultations have been made and that the practice is transparent and open to scrutiny and audit.

On occasions where a person has difficulty in swallowing medication or they find it unpalatable, the medication may be given in food and drink as a last resort following advice from a pharmacist. In this case, the food or drink is aiding administration and occurs with the person's consent. This is not covert administration.

Professional Conduct
As a general principle covert administration leads a person to think they are not receiving medication when they, in fact, are. Registered practitioners will need to be sure that what they are doing is lawful under Mental Capacity legislation and they are accountable for their own decisions and practice.

Registered practitioners should reflect on the treatment aims of disguising medicines. The treatment must be necessary in order to save lives, prevent deterioration or ensure improvement in the person's physical or mental health. Registered nurses involved in the covert administration of medication must be fully aware of the aims, intent and implications of such treatment.

Capacity to Consent
Adults
Every adult is presumed to have capacity to consent to or refuse treatment, including medication unless he or she is unable:

- To understand the information relevant to the decision
- To retain that information
- To use or weigh that information as part of the process of making the decision
- To communicate his/her decision by any means

Assessing capacity in the case of medicines use is primarily the responsibility of the prescriber, but all multidisciplinary healthcare professionals have a responsibility to participate in discussions. It is important to note that a mental disorder might cause temporary or fluctuating capacity and regular re-assessment is required.

The assessment of a person’s capacity must be recorded in his/her medical notes.

Where a person does not have capacity to make a decision about medical treatment, there must be consultation with all relevant people, including the members of the multi-disciplinary team, relatives, carers and advocates (IMCA) to reach agreement that covert administration is in the best interests of the person. All discussion must be documented in the care record. It may also be that consent can be given by an
Attorney under a Lasting Power of Attorney that the person executed while capable, or by a Deputy appointed by the Courts of Protection.

Where a person who lacks capacity is also detained under the Mental Health Act, a Second Opinion Approved Doctor (SOAD) should be consulted before proceeding with covert administration. Teams may wish to maintain the principle of second opinion for informal mental health patients as this would be a sound endorsement of good practice and make actions easier to defend.

Children
It should not be assumed that a child is unable to give consent.

Young people aged 16 to 17 are presumed to have the competence to give consent for themselves

Younger children who understand fully what is involved in the proposed treatment can also give consent, although their parents will ideally be involved. A child with sufficient understanding may consent to treatment on his/her own behalf. Such children are commonly referred to as being “Gillick competent”. In other cases, someone with parental responsibility must give consent on the child’s behalf unless they cannot be reached in an emergency. If a competent child consents to treatment, a parent cannot override that consent.

Legally a parent can consent if a competent child refuses, but it is likely that the taking of such a serious step will be rare.

Refused consent
People who have capacity are entitled to refuse treatment even when it would clearly benefit their health. The only exception to this rule is where the treatment is for a mental disorder and the person is detained under the Mental Health Act 1983 (MHA). When detained, the principles of consent continue to apply to any medication not related to the mental disorder for which the person has been detained. Medication for the mental disorder can be given against a person’s wishes during the first three months of a treatment order or afterwards if sanctioned by a Second Opinion Approved Doctor (SOAD). The MHA Code of Practice reminds us that compulsory administration of treatment which would otherwise require consent is an infringement of the European Convention on Human Rights, however it may be justified where it is accordance with the MHA and proportionate to the legitimate aim of reducing risk and improving health.

With respect to the above, covert administration is not specifically mentioned in the MHA and it is therefore not clearly legal to use the MHA as justification for this practice in a person who has not been assessed and found to lack capacity to make a decision about their medication. Such situations are beyond the scope of this document and an opinion on the individual case should be sought from the Trust’s Legal Department.

Medication Considerations
If it is decided that medication should be given in food or drink then, except in an emergency, a Pharmacist must be consulted about what type of preparation should be used to ensure appropriate delivery of treatment. Ideally the advice and recommendations of the Pharmacist should be received in writing to be added to the person’s medical notes or should be entered directly into the notes by the Pharmacist.

Wherever possible, a suitable licensed liquid, soluble or orodispersible (“melt”) preparation should be used. Crushing tablets or opening capsules should be regarded as a last resort as this is likely to alter the bioavailability of the medication. Dose adjustment may be necessary. Particular risk is possible if slow-release or enteric-coated tablets are crushed as this will change the way the medication is absorbed into the body.

Any medical, cultural or religious dietary requirements should be complied with.

Where necessary medicines should be mixed with a small amount of food or liquid rather than in a whole drink or portion of food. People receiving medication administered in food or drink should not be left by the nursing staff administering the medication until the medication has been consumed.
Any method of administration which is outside the product license of that medication is unlicensed and can only be authorised by an approved prescriber who may be liable if harm ensues. The prescriber must document any authorisation to administer a medication by an unlicensed method, having first considered the safety of the person being treated, the requirement for that particular medication and alternative treatment or means of administration.

Any instructions regarding how to administer the medicines should be clearly annotated on the person’s medication chart to aid nurse administration and the instructions conveyed verbally to the relevant nurse. In addition the recommendations should be documented in the notes.

The medical prescriber and a pharmacist must always agree to any alterations to standard medication administration practice.

**Extreme Situations**

In extreme situations such as putting self and/or others at risk due to their behaviour, a person without capacity who does not consent to treatment may have need for a specifically prescribed medication to be administered covertly. When circumstances prevent an impromptu MDT meeting the nurse may, after discussions with the immediate team, administer the initial dose under Common Law (DOH 1999) where the person is incapable of consenting.

If the person is detained under the MHA then the nurse should further ensure that any administration of medication for a mental disorder is covered by appropriate certification where necessary, or that Section 62 paperwork is completed.

**Treatment Plans**

The proposed treatment plan, including the provision for medication to be administered covertly, will be discussed by all relevant practitioners and with those who the MCA requires to be consulted about the person’s best interests. The extent of any discussions will depend upon individual circumstances and the time available and in an emergency discussion may be more limited.

Where a person is living at home with family or carers there should be discussion between the carers, the person’s General Practitioner (GP) and the community mental health team (CMHT) or learning disability community partnership (LDCP)

A record will be made of any discussions that take place including the views of carers who have been consulted.

The treatment plan must be countersigned by the senior health professionals involved. This would normally involve a Consultant Psychiatrist, a Senior Registered Nurse and a Pharmacist.

The treatment plan should normally be subject to weekly review initially and if the requirement of covert administration persists then full reviews may occur at less frequent intervals. Ongoing efforts should be made to obtain the person’s consent to allow open administration of medication.

**Risk Management**

Any medicines-related incident which occurs as a result of the covert administration of medicines must be reported in accordance with the Trust’s Incident Reporting System, following Trust policy.

**Appeal**

If a member of staff; a relative, carer, friend or representative of the person or an Independent Mental Capacity Advocate (IMCA) wishes to raise concerns about the use of covert administration of medication to an individual, or about the process by which it was decided to use such means, they can be referred to the Medical Director or Chief Pharmacist.
Person refusing prescribed medication

Is the medication necessary to:
- Save life
- Prevent deterioration
- Ensure improvement in physical or mental health

YES

Does the person have capacity relating to treatment on offer
- Understands information
- Retains information
- Able to use & weigh information
- Able to communicate decision

YES

YES

Is person detained under MHA?

YES

NO

NO

Does team/relatives/careers/advocate agree that covert administration is in the person’s best interests?
Consult with SOAD if person is detained under the MHA or if otherwise considered best practice

NO

YES

Does pharmaceutical advice indicate that covert administration is practical?

NO

YES

Document a treatment plan, signed by senior health professionals
Annotate medicine chart with administration instructions

Review treatment plan on a weekly basis initially. Reduce frequency or review if agreed in cases where the need for covert administration persists

Administer medication in accordance with the treatment plan and professional responsibility and accountability

Cannot proceed with covert administration

Medication may be administered against the person’s wishes but covert administration may be unlawful. Seek advice from Trust legal department.
Medicines Reconciliation Guidelines

Introduction

The aim of medicines reconciliation is to ensure that medicines prescribed at any stage of the service user’s journey through the healthcare system correspond to those taken at the previous stage. Medicines reconciliation can be defined as:

- Collecting information on medication using the most recent and accurate sources of information to create a full and current list of medicines, and
- Checking or verifying this list against the current prescription, ensuring any discrepancies are accounted for and appropriate action is taken, and
- Communicating through appropriate documentation, any changes, omissions and discrepancies.

Medicines reconciliation can occur when service users are admitted to hospital, transferred to other units or to other teams within the Trust or when service users are discharged. The principal areas of concern are admission to inpatient units and transfer between inpatient units.

Roles and responsibilities

Prescribers

A prescriber who writes a service user’s prescription chart (inpatient or community) must utilise appropriate sources of information to determine the medication being taken by the service user. This prescription must be accurately transcribed onto the prescription chart(s) including information about the service user’s allergies or sensitivities. Appropriate records should be made in the clinical record of sources used and information collated.

A prescriber who re-writes a prescription chart must accurately transcribe all information about the service user, allergies/sensitivities and current prescription from the old to the new chart(s).

There will be occasions when the prescriber involved in an admission is unable to obtain appropriate sources of information about the medication being taken by the service user. This may typically be overnight when on-call at a time when GP surgeries are closed and so cannot be contacted for information. In such cases prescribing should be completed as fully as possible and suitable communication should occur with the team who will be providing the service user’s ongoing care to ensure that the process is fully completed within 24 hours of admission or transfer.

Where the prescription is intentionally changed, this must be fully documented in the care record.

When a service user is transferred between two LPFT inpatient units it is not necessary for a new prescription chart to be written by the receiving unit, unless it proves necessary for some other reason.

Pharmacy Staff

Pharmacy staff will review the prescriptions of newly admitted service users in the clinical areas to which they are assigned, within 72 hours of admission. Prescriptions will be cross-referenced with the reconciliation information already obtained and additional information will be sourced if thought necessary.

Re-written prescription charts will be cross-referenced with the previous chart.

Any discrepancies in the prescription will be identified, documented and reported appropriately to nursing or medical staff.

Pharmacy staff will make a record of reconciliation activity following admission/transfer on the appropriate form (see below) if not already completed and this will be filed in the service user’s care record.
Nursing Staff

Nursing staff will support the reconciliation process as decided locally. A Standard Operating Procedure should be written to define these activities in each clinical area.

Sources of information

It is strongly recommended that on admission at least two sources of information are used, in addition to the service user, when determining the medication being taken.

The following are potential sources of information about a service user’s medication. This is not an exhaustive list and they are listed in no specific order of preference as reliability can vary according to the situation:

- The service user
- The service user’s “Patient’s Own Drugs” (PODs) including compliance aids
- Relatives or carers
- Repeat prescription documentation
- Referral letters
- Records from the GP surgery (typically faxed information from an electronic system)
- Community Pharmacist
- Medication reminder charts/lists
- Hospital discharge summary, if recent
- Residential or Nursing Home records
<table>
<thead>
<tr>
<th>Systems</th>
<th>Monitoring and/or audit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria</td>
<td>Measurables</td>
</tr>
<tr>
<td>For inpatients, medications taken prior to admission should be documented in the service user medical record within 24 hours of admission, together with source(s) used to obtain the information</td>
<td>Information from clinical record</td>
</tr>
<tr>
<td>For inpatients, intentional changes to medicines are documented in the service user medical record together with reasons for the change</td>
<td>Information from clinical record</td>
</tr>
<tr>
<td>The prescription charts of newly-admitted inpatients should be reviewed by pharmacy staff within 72 hours of admission.</td>
<td>Information from prescription charts</td>
</tr>
<tr>
<td>For inpatients, unintentional changes to medication are reported via the Trust incident reporting system and this information is recorded in the service user’s clinical record</td>
<td>Information from Trust incident reporting system Information from the clinical record</td>
</tr>
<tr>
<td>Reconciliation to be discussed during induction for doctors joining the Trust and working in inpatient areas</td>
<td>Content of induction training Attendance list from induction training</td>
</tr>
<tr>
<td>Standards</td>
<td></td>
</tr>
<tr>
<td>-----------</td>
<td></td>
</tr>
<tr>
<td><strong>TARGET/STANDARDS</strong></td>
<td></td>
</tr>
</tbody>
</table>
| For inpatients, medications taken prior to admission should be documented in the service user medical record within 24 hours of admission, together with source(s) used to obtain the information.  
**Standard: 100%** |
| For inpatients, intentional changes to medicines are documented in the service user medical record together with reasons for the change.  
**Standard 100%** |
| The prescription charts of newly-admitted inpatients should be reviewed by pharmacy staff within 72 hours of admission.  
**Standard 100%** |
| For inpatients, unintentional changes to medication are reported via the Trust incident reporting system and this information is recorded in the service user’s clinical record.  
**Standard 100%** |
| All doctors joining the Trust to work in inpatient areas should attend induction training that includes an introduction to medicines reconciliation.  
**Standard 100%** |
# Medical Devices Management Policy

## Document Version Control

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<th>Medical Devices Management Policy</th>
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<td>April 2007</td>
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<td>July 2015</td>
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<td>Implementation Date:</td>
<td>October 2015</td>
</tr>
<tr>
<td>Author:</td>
<td>Medical Devices Group</td>
</tr>
<tr>
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<td>Board of Directors</td>
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<td>Approval Date:</td>
<td>29th October 2015</td>
</tr>
<tr>
<td>Ratifying Body:</td>
<td>Quality Committee</td>
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1. **Introduction**

1.1 This policy was compiled by a multi-disciplinary county-wide group, comprising members from ULHT Clinical Engineering, ULHT Procurement, LPIT Clinical, Estates and Facilities Services.

2. **Purpose**

2.1 Medical devices and equipment are used every day by most health care professionals to support the care and treatment of patients. The objective of this policy is to provide a framework for the management of medical devices and minimise hazards related to the use of medical devices, to ensure that staff are properly trained and competent in the use of medical devices, that devices are maintained in a safe and reliable condition and recorded on a central database/inventory.

2.2 Risk assessments should be undertaken to identify any hazards associated with medical devices and steps taken to eliminate these risks. Where they cannot be eliminated they must be reduced to a minimum and appropriate control measures identified.

2.3 The policy will promote the requirement for procedures which will instil a safer, more efficient, and high quality management of all medical devices.

Good management will involve assessment of medical devices from the justification of the need, through service life, training and use, until the ultimate disposal of the device.

2.4 This policy should be read in conjunction with:

- Safety, Health, Environment & Fire Policy
- Reporting and Management of Incidents, Complaints & Claims Policy
- Infection Control Policies
- Medicines Management, Medical Devices and Non-Medical Prescribing Policy
- Read in conjunction with: Standards for Better Health, NHSLA (National Health Service Litigation Authority) Standards, Medicines and Healthcare Products Regulatory Agency (MHRA) guidance, including DB2006(05). The role of the MHRA is to protect and promote public health and patient safety by ensuring that the manufacture and use of medical devices meet appropriate standards of safety, quality, performance and effectiveness.

3. **Definitions**

The term "medical device" covers a wide range of products used every day in primary care settings. Devices include items such as needles, syringes, infusion pumps, endoscopes, examination gloves, dressings, walking sticks, and blood glucose meters. In other words, any instrument, apparatus, appliance, material or health care product, excluding drugs, used for, or by, a patient or service user for:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, or alleviation of, or compensation for, an injury or impairment.
- Investigation, replacement, or modification of the anatomy or of a physiological process.
- Control of conception.

A further list of some of the products covered by the definition of medical device and prepared by the Medical Devices Agency is attached at Appendix A.

4. Duties

The following reporting structure shows lines of accountability throughout the organisation.

**Reporting Structure:**

```
Quality Committee

Health & Safety Committee

Medical Devices Group

Physical Healthcare Steering Group

Local practice and procedure
```

4.1 Medical Director

The Medical Director is the Board-level director with the lead for Quality Committee and has overall responsibility for the management of medical devices within LPT.

4.2 Medical Devices Group

For constitution and Terms of Reference see Appendix B.

The Medical Devices group will advise Clinical Governance on policy and procedures relating to the management of medical devices. Any residual risks will be escalated to Operations and Governance Committee.
4.3 **Operations and Governance Committee**

The Governance Committee oversees risks within the organisation and will incorporate any issues relating to medical devices management in its annual report to the Board.

4.4 **Equipment Controllers - Ward Managers/Team Coordinators**

Ward Managers and Team Coordinators will be responsible for the local management of medical devices. This will include identifying all equipment, authorised users and training needs within their area. They are responsible for:

- Ensuring that a local list of equipment and records of training are maintained for their clinical area
- Ensuring purchasing of new equipment is in line with the guidelines within this Policy (see section 5).
- Ensure receipt and commissioning of all new equipment
- Ensure all new equipment is entered onto the LPFT database
- Ensure appropriate servicing and maintenance of medical devices and maintain accurate records are available for inspection upon request
- Recommend replacement of medical devices as appropriate in line with this policy
- Ensure appropriate disposal and decontamination of equipment
- Notify any problem with a medical device to the Risk Department and complete a report form.
- Ensure the device is taken out of use and that all staff under their control are made aware that the equipment must not be used. (See section 13).

4.5 **All staff**

All staff have responsibility with regard to adverse incident reporting and should follow the Reporting and Management of Incidents, Complaints & Claims Policy in respect of medical devices.

Staff must take reasonable care for their own health and safety and also of other people who may be affected by their acts or omissions. They should report any problems relating to use, maintenance, servicing or decontamination as contained in this policy. Any incident involving equipment related to medicines should also be reported to the Pharmacy Department.

5. **Procurement**

5.1 For all queries and actions in relation to procurement of medical devices we have an overarching procurement policy in conjunction with ULHT. This covers all aspects of procurement including:

- The Decision Making Process
- Identification of Need
- Prescription of Devices
To refurbish or replace?
Evaluation and Selection of Equipment
The case for standardisation and variety reduction
Acquisition methods
Purchasing
Leasing
Devices on Loan to the Trust
Indemnity Forms
Donations to the NHS
Pre-Purchase Questionnaires (PPQs)
Suppliers responses
Approval of PPQs
Contract documentation
Retention
Summary
Acceptance of Medical Devices
Acceptance testing
Checking and/or modifying instructions

Please use the following link for all enquiries regarding procurement of medical devices:
Purchaseorders2@ulht.nhs.uk

6. Storage

6.1 All medical devices must be stored in accordance with manufacturing guidance and/or in line with Appendix J.

6.2 Equipment powered by re-chargeable batteries must be stored plugged in to electrical outlet socket to ensure it is available for immediate use.

6.3 Where devices may be stored for some time their shelf life must be monitored with a stock rotation system in place.

6.4 The physical condition of the storage area also requires consideration i.e. wet, inappropriate temperatures will impact on device performance.

6.5 It is important that equipment requiring decontamination or awaiting repair are stored separately and clearly labelled.
7. Training

7.1 It is the responsibility of each individual member of staff to ensure that they are conversant with the content of this policy and are appropriately trained and competent to use the medical devices which they are required to use as part of their duties.

7.2 It is the responsibility of line managers to ensure their supervisees are conversant with the policy content and are appropriately trained and competent to use medical devices which they are required to use as part of their duties. This will be implemented at local induction and subsequently monitored at supervisee annual appraisal for ongoing assurance.

7.3 Managers should ensure that all personnel assigned responsibilities and tasks within the management system are competent to use any equipment necessary.

7.4 All staff need training in the safe use of equipment, in the case of equipment for lifting and handling, the organisation has a duty of care and this training is organized by the Moving and Handling Department.

7.5 Mandatory training for resuscitation and rapid tranquillisation will be monitored by the training Department. Training for other devices will be monitored by the individual ward/team managers.

7.6 An outline of staff authorized to use medical devices and the training required is included in Appendix K (Training Needs Analysis).

7.7 Interactive training on the general principles of using medical devices safely is available on the MHRA website.

7.8 Managers are responsible for maintaining local training records for medical equipment. The Learning and Development Centre will maintain records of staff trained in Moving and Handling and Life Support Equipment.

7.9 Training for Professional Staff

The Manager is responsible for ensuring that staff training is received by the appropriate staff, and documented, including any student on placement. Refresher training must also be provided where appropriate. Managers are responsible for maintaining local training records for medical equipment. The Learning and Development Centre will maintain records of staff trained in Moving and Handling and Life Support Equipment.

7.10 Training for Technical Staff (see 10.2)

All technical staff should be, where appropriate, trained on a variety of general Medical Devices in order to know:

- How the equipment is clinically used.
- What safety precautions, both clinically and technically, need to be adhered to.
- How to approach the equipment in a professional manner, in order to instil confidence in the users.
7.11 **Training for Service Users**

Professional staff should be aware that a failure to pass on to the service user the manufacturer’s original instructions on how to use a device may not only comprise the service user’s ability to use the device safely, but Instructions on the use of a device should be suitable for both service users and their carers. Where necessary these may need to be explained or adapted. Service users with particular disabilities or medical conditions will need special instructions and training from their prescriber.

7.12 **New Devices**

When new models of Medical Devices are delivered into the Trust, all technicians, where appropriate, should have the opportunity to familiarise themselves with the fundamental operation of the device.

7.13 **User Manuals and Training**

The original user manuals should be supplied along with the device, in order to ensure clear and safe use. Recommendations on any other necessary training should be given. The original manufacturer should be able to provide this information, along with any updates which may have been issued since manufacture. Full details on how to maintain or service the device should also be supplied.

*NB: If manuals and training information are not available, the medical device may have been rendered unsuitable for passing onto a new user.*

8. **Decontamination**

8.1 Reference should be made to the Decontamination Policy contained within the Infection Control Policy accessed on the Trust intranet accessible via the following hyperlink:

   http://www.lpft.nhs.uk/assets/files/Accessing%20our%20information/Policies%20and%20Procedures/7g-Decontamination.pdf

8.2 It is the responsibility of the Trust to ensure that all medical devices do not carry a biological or chemical hazard. The Trust has a duty to ensure that decontamination of any device is applied before re-use, submission to maintenance, or repair and before being transported to another location.

8.3 All equipment should be decontaminated as per the suppliers/manufacturer’s instructions. Items subject to inspection, service or repair must be decontaminated appropriately prior to these activities. Any loaned items being returned to a manufacturer/supplier must also be decontaminated.

8.4 After decontamination the items should be labelled with a declaration certificate to identify their status. A copy is included as Appendix M.

8.5 Where decontamination/cleaning would destroy vital evidence, the item should be placed in protective containment, labelled and placed in quarantine. MDA and the manufacturer/supplier should be contacted for advice prior to any further action being taken.
9. **Cleaning**

9.1 All medical devices will fall into specific categories on how to clean and disinfect the particular device. The cleaning agent will be dependent upon the category to which the device belongs.

10. **Medical Device/Equipment Maintenance**

10.1 **User Checks**

Professional users and service users are responsible for pre-use checks, regular cleaning and preparation for use.

10.2 **Service and Repair**

Where medical devices are required to be repaired or serviced various options are available dependent on the device. The Trust has contracts or Service Level Agreements (SLA’s) with the:

I. Manufacturer/distributor/external provider

II. Clinical Engineering (ULHT) – Pay as you go basis

Keeping medical devices safe and effective needs both routine maintenance procedures supervised by professional users, and planned maintenance and repair carried out by suitability trained technicians.

Planned maintenance should follow manufacturer’s guidance on procedures and staff training. Devices which need maintenance work must be cleaned, and where relevant, decontaminated before release.

Maintenance and repair will be fulfilled by the organisations listed above, as part of a contract/Service Level Agreement or on a pay as you go basis. It is currently the responsibility of the individual ward/dept. to arrange for servicing of medical equipment. The equipment will have a sticker on with the date of the last service if it has already been serviced. If new the service will have to be arranged by the ward/dept. A central record will be kept electronically of which equipment needs servicing, how often and when it was last serviced and next due. This is currently held by Estates.

Moving & Handling equipment is processed by the Moving & Handling department and a separate servicing agreement made.

Copies of the Medical Equipment Maintenance Request Form and Category List are available on request by email to clinical.engineering@ulh.nhs.uk

Copies of the Medical Equipment Request form and Category Action list are available on the internet and should be used when submitting equipment to Clinical Engineering at ULHT, for service. (www.ulh.nhs.uk/departments/clinicalengineering/)
10.3 **Register/Database**

Capital assets are recorded on the trust’s financial asset register. This includes medical devices. However the data can often be very general in its description. Best practice is to record all medical devices on a separate medical equipment inventory that lists Make, Model, Date of Installation, order number, cost centre, asset number etc., so that the asset register and the medical equipment inventory can be linked. This allows the requirements of medical equipment management to dovetail into the requirements of the Standing Financial Instructions (SFIs).

The SFIs can be accessed via:

http://www.lpft.nhs.uk/assets/files/Accessing%20our%20information/Corporate%20Governance/LPFT%20SFIs%20August%202013-%20reviewed%20June%202014-%20clean%20copy.pdf

11. **Disposal**

11.1 Medical devices can be disposed of by one of three methods:

I. Transfer of ownership
II. Decommissioning
III. Disposal

11.2 Risk Management is an essential tool to aid with the decision making process for disposing of a used device in the most appropriate and safe method. Staff should consult Clinical Engineering ULHT for queries in relation to disposal of medical devices where unclear using the flowing link: clinical.engineering@ulh.nhs.uk

The manufacturer should provide information on safe methods of disposal.

11.3 Transfer of ownership is subject to national legislation to ensure the equipment is safe for use. There should be documented evidence of legal liability, and legal advice may be required.

11.4 Decommissioning aims to make equipment safe and unusable, while minimizing damage to the environment. It should include decontamination.

11.5 Whichever method of disposal is chosen an inventory form needs to be completed with details of transfer or disposal and sent to LSS inventory department. Any instructions and safety information etc. must be provided on transfer of ownership. The disposal of electrical/electronic equipment is subject to specific regulations (WEEE Regulations – Waste of Electrical Electronic Equipment), which means that there is a separate process for disposal of such equipment. There will be a lockable container at each of the main sites (Carholme Court, Peter Hodgkinson Centre, Beaconfield and Pilgrim Hospital) into which electrical/electronic equipment is placed and logged prior to disposal.
12. **Re-Use/Re-Issue**

12.1 Devices designated for single use must not be re-used under any circumstances.

13. **Adverse Incidents**

13.1 An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of the patients, users or other persons. Reference should be made to the Reporting and Management of Incidents, Complaints & Claims Policy.

13.2 There is a Safety Alert system in place to ensure that every ward/dept. is notified of any hazard notices. This includes any notices in relation to the safety of medical devices.

13.3 **Defective items**

Defective items should be removed from use and reported for repair or disposal.

An investigation should be carried out as per the Reporting and Management of Incidents, Complaints & Claims Policy.

13.4 **Evidence**

All material evidence should be labelled and kept secure. This includes the products themselves and, where appropriate, packaging material or other means of batch identification. The evidence should not be interfered with in any way except for safety reasons or to prevent its loss. If necessary, a record should be made of all readings, settings and positions of switches, valves, dials, gauges and indicators, together with any photographic evidence and eyewitness reports.

If a patient dies unexpectedly, any medical device implicated in the death must not be interfered with in any way, unless necessary for safety reasons or to prevent loss of samples. The procedure for reporting serious adverse incidents is then followed.

The manufacturer should be informed but not allowed to inspect the equipment or remove any part of it without the express consent of the coroner.

The Department of Health has agreed with the Coroners’ Society that, with the consent of the coroner, an officer from the MHRA can examine suspect products so as not to delay remedial action designed to protect others.

14. **Medical Devices on loan to Patients**

14.1 Units issuing patients with devices for use both within the Trust and outside should ensure that:

- Training is given to the patient on the safe use of the medical device.
• Written and approved manufacturer’s instructions are provided where appropriate.
• Contact details are given to the patient in the event of any necessary support being required.
• When on loan for an extended period all medical devices requiring regular maintenance (M.D.A. directive) should be on a programme for planned preventative maintenance.
• Arrangements must be made to recover the device when no longer in use by the patient.

15. Development of Policies and Procedures

15.1 This policy was compiled by a multi-disciplinary county-wide group, comprising members from ULHT Clinical Engineering, ULHT Procurement, LPIT Clinical, Estates and Facilities Services and adapted for use by LPT.

15.2 A stage 1 Initial Equality Impact Assessment was undertaken at the time of review in July 2015.

16. Consultation, Approval and Ratification Process

16.1 This policy will be consulted upon in line with Corporate Documents and Policies Procedure

16.2 Feedback from consultation will be maintained by the policy author in line with Corporate Documents and Policies Procedure and any necessary amendments made before submission for approval.

17. Review and Revision Arrangements including Version Control

17.1 The policy will be reviewed by the Medical Devices Group on an Annual basis.

17.2 Corporate and Legal Services will maintain a version control sheet, as per Corporate Documents and Policies Procedure

18. Dissemination and Implementation of a Policy

18.1 The policy will be disseminated as per Corporate Documents and Policies Procedure

18.2 Training will ensure trust-wide implementation, as detailed in section 7 above

19. Policy Control including Archiving Arrangements

19.1 Corporate and Legal Services will retain a copy of each policy for a minimum of 10 year in line with the recommendations contained within ‘Records Management NHS Code of Practice’ (2006)
## 20. Monitoring Compliance with and Effectiveness of Policies and Procedures

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<tr>
<th>Systems</th>
<th>Monitoring and/or Audit</th>
<th>Criteria</th>
<th>Measurables</th>
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<th>Frequency</th>
<th>Reporting to</th>
<th>Action Plan/Monitoring</th>
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<td>Systems in place to maintain the approved product list.</td>
<td>Systems in place to maintain the approved product list.</td>
<td>Asset register corresponds with the approved product list.</td>
<td>Medical Devices Group</td>
<td>Annual review.</td>
<td>Operations and Governance</td>
<td>Asset register monitored by LPFT electronic method</td>
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<td>Systems in place to monitor the number of adverse incidents/near misses involving medical devices</td>
<td>Systems in place to monitor the number of adverse incidents/near misses involving medical devices</td>
<td>Number of reported incidents</td>
<td>Medical Devices Group</td>
<td>Quarterly</td>
<td>Operations and Governance</td>
<td>MDG to review the number and type of reported incidents.</td>
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<td>Systems in place to monitor the impact of Medical Alerts.</td>
<td>Systems in place to monitor the impact of Medical Alerts.</td>
<td>Responsible Managers disseminate information to teams and complete action returns from.</td>
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<td>Monthly</td>
<td>Health &amp; Safety Committee</td>
<td>Monthly compliance report</td>
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### 20.2 Standards/Key Performance Indicators

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<th>KEY PERFORMANCE INDICATOR</th>
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<tr>
<td>Department of Health – Standards for Better Health C4 Health care organisations keep patients, staff and visitors safe by having systems to ensure that: All risks associated with the acquisition and use of medical devices are minimised.</td>
<td>Availability of an approved product list. The number of patient safety incidents involving medical devices.</td>
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<tr>
<td>Department of Health – Standards for Better Health C4 Health care organisations keep patients, staff and visitors safe by having systems to ensure that: All reusable medical devices are properly decontaminated prior to use and that the risks associated with decontamination facilities and processes are well managed.</td>
<td>The number of patient safety incidents involving medical devices.</td>
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</table>
21. References and related Policies

The former NHS Litigation Authority (2008) NHSLA Risk Management Standards for MH and LD Trusts
www.nhsla.com

22. Associated Documentation

Appendix A - Common categories of medical devices
Appendix B - Medical Devices Group Terms of Reference
Appendix C - Refurbish or Replace
Appendix D - Total Costs checklist
Appendix E - Purchasing
Appendix F - Examples
Appendix G - NHS Form Indemnity A&B
Appendix H - Acceptance Checklist
Appendix I - New Device Checklist
Appendix J - Storage
Appendix K - Training Needs Analysis
Appendix L - Training Record Form
Appendix M - Decontamination label
Appendix A

COMMON CATEGORIES OF MEDICAL DEVICE

This list is not exhaustive. It provides examples of medical devices. Equipment used in the diagnosis or treatment of disease, or monitoring of patients, such as:

- Chiropody and podiatry equipment
- Dental instruments, equipment and materials.
- Dressings
- Endoscopes
- ECT
- Examination gloves
- Gastrostomy tubes
- Intravenous (IV) administration sets and pumps
- Nebulisers
- Ophthalmic equipment
- Peak flow meters
- Surgical instruments
- Suction equipment
- Syringes and needles
- Sphygmomanometers
- Thermometers
- Ultrasound Doppler
- Urinary catheters

Equipment used in life support such as:
- Defibrillators
- Domiciliary oxygen therapy systems
- Insulin injectors
- Pulse oximeters
- Ventilators used in the home

In vitro diagnostic medical devices and their accessories, such as:
- Blood glucose measuring devices
- Cholesterol test kits
- Pregnancy test kits
- Specimen collection tubes
- Urine test strips

Equipment used in care, such as:
- Adjustable beds
- Lifting poles
- Patient hoists
- Pressure relief equipment
- Stoma care equipment

Equipment used by people with disabilities, such as:
- Bathing equipment
- Commodes
- External prostheses and orthoses
- Hearing aids
- Prescribable footwear
- Standing frames
- Urine drainage systems
- Walking aids
- Wheelchairs and special support seating

Other examples include:
- Condoms
- Contact lenses and care products
- Intra-uterine devices (IUDs)
- Drug and Alcohol screening equipment
MEDICAL DEVICES GROUP

Terms of Reference

Structures and Relationships

- The Medical Devices Group reports to the Health and Safety Committee, which will escalate issues as required to Quality Committee.
- The Medical Devices Group works closely with other Trust Committees and Groups, reporting issues, concerns, feedback and information as required.

Specific Objectives for the Medical Devices Group

1. Ensure the Trust has appropriate and effective governance systems and processes in place to monitor and manage medical devices across the Trust.
2. Ensure the planning, monitoring and implementation of continuous improvement in the management of medical devices, including the procurement and maintenance of medical devices. Ensure this is achieved through Point 1 (above) and through implementation of relevant national and local policy and guidance.
3. Provide both clinical and non-clinical leadership and expertise to support medical devices developments across the Trust, identified through Points 1 and 2 above. This includes identifying the support required for staff to achieve and maintain high levels of medical devices management as appropriate to their job roles and responsibilities.
4. Receive feedback from staff and partners, to inform development requirements, to problem-solve, and to identify lessons for learning.
5. Coordinate clear communication in respect of medical devices across the Trust and with key related partners, to support consistently high standards of related practice.
6. Receive Central Alerting System (CAS) Alert updates, including any related system or process issues.
7. Receive procurement reports, including updates on any concerns related to maintaining an up-to-date database of the approved medical devices product lists.
8. Receive Clinical Engineering reports, including updates on any concerns related to the maintenance of the Trust's medical devices.
9. Receive medical devices related contracting updates and concerns as required.
10. Provide updates bi-annually to the Health and Safety Committee, escalating between times as required in line with the Trust's Board Assurance and Escalation Framework.
11. Monitor the successful management of the Trust's medical devices assets, including holding to account the clinical Divisions in respect of their assurance of the maintenance of robust and up-to-date medical devices asset registers across the Trust.
12. Ensure prompt escalation and resolution of medical devices related concerns to ensure patient and staff safety is not compromised.
13. Ensure learning from adverse incidents involving medical devices.
14. Ensure the Trust's Medical Devices section of the Medicines and Medical Devices Policy is up-to-date and reviewed at the required frequency.

15. Provide feedback, and where required instruction, to Trust staff in respect of medical devices, to ensure compliance with local and statutory requirements.
16. Monitor and review any medical devices serious incidents and medical devices related Datix incidents that arise.
17. Ensure medical devices risk issues identified are escalated as required in line with the Trust's Board Assurance and Escalation Framework.

Members are required to attend all meetings or to send deputies where absence is unavoidable.

Matron Specialist Services Division (Chair)
Matron General Adult Services Division (Deputy Chair)
Associate Director of Facilities and Estates
Head of Clinical Engineering (ULHT)
Deputy Operational Purchasing Manager/Capital Buyer (ULHT)
Patient Safety Lead
Specialist Services Division Representative
General Adult Services Representative
Associate Matron and Infection Prevention and Control Lead

Other staff will be required to attend to support specific case or subject discussion including the following:

Head of Workforce and Development
Head of Contracting (or delegated deputy)
Medical Representative
Clinical Systems Team Coordinator
Chief Pharmacist
Physical Healthcare Nurses
Trust AHP Lead
Head of Informatics

**Frequency of Meetings**
Quarterly

**Quorum:** A quorum must include at least five of the required membership.

**Approval Date:** March 2015

**Review Date:** March 2016
## Refurbish or Replace

<table>
<thead>
<tr>
<th>Factor</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Life cycle/replacement</td>
<td>For many items, especially disability equipment, the price is linked to solidity of construction and quality of materials; hence to the useful life of the device.</td>
</tr>
<tr>
<td>Fitness for intended application</td>
<td>The device chosen must meet the user organisation’s performance specification, but unnecessary features may be a disadvantage – complicated devices tend to break down more frequently and are harder to use.</td>
</tr>
<tr>
<td>Guarantee/warranty</td>
<td>Comparison of terms needs to be undertaken as part of the process.</td>
</tr>
<tr>
<td>Safety</td>
<td>Check compliance with safety and performance standards. Which have been used? Do MDA publications reveal persistent problems? Can professionals identify safety problems?</td>
</tr>
<tr>
<td>Reliability</td>
<td>Take into consideration whether other users have experience problems and failures.</td>
</tr>
<tr>
<td>Service support</td>
<td>Check that spares are readily available and that service support is guaranteed. Also if a response time is guaranteed.</td>
</tr>
<tr>
<td>Maintenance requirements</td>
<td>Check the intervals between service, frequency and complexity of checks and calibrations needed during operation.</td>
</tr>
<tr>
<td>Technical advice</td>
<td>Is there free access to technical advice from the manufacturer for professional users and technical staff? Is there a 24-hour helpline?</td>
</tr>
<tr>
<td>Diversity</td>
<td>Assess whether choosing another device will increase the number of types in use. Will this introduce risks in terms of staff requiring training using unfamiliar equipment?</td>
</tr>
</tbody>
</table>
## Total costs checklist

<table>
<thead>
<tr>
<th>Cost</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Price</strong></td>
<td>In some cases, manufacturers will seek to offset low purchase prices with expensive contracts for consumables or servicing</td>
</tr>
<tr>
<td><strong>Tendering</strong></td>
<td>The resources needed to manage and participate in the tendering process.</td>
</tr>
<tr>
<td><strong>Risk assessment</strong></td>
<td>Is the device CE-marked?</td>
</tr>
<tr>
<td></td>
<td>Any previous concerns raised?</td>
</tr>
<tr>
<td></td>
<td>Any MHRA publications related to this device?</td>
</tr>
<tr>
<td><strong>Installation</strong></td>
<td>Any special services required that may not currently be available (e.g. power, water, gas, electricity) plus any minor building works. Costs in terms of environmental and safety.</td>
</tr>
<tr>
<td><strong>Professional user costs</strong></td>
<td>Local production of procedure manuals, if needed. Cost of training sessions for all relevant staff. Updating any 'local' catalogues. NB:</td>
</tr>
<tr>
<td></td>
<td>Complex devices may also require additional staff.</td>
</tr>
<tr>
<td><strong>Consumables/accessories</strong></td>
<td>Are third party and upgrade consumables or accessories cheaper than those produced by the device manufacturer? Are they fully compatible?</td>
</tr>
<tr>
<td></td>
<td>Are they acceptable to use (e.g. invalidation of any guarantees/warranties from the device manufacturer?) Are hardware or software upgrades planned? Would there be any additional costs in 'retro-fitting' later?</td>
</tr>
<tr>
<td><strong>Overheads</strong></td>
<td>Any additional personal protective equipment needed, e.g. masks, goggles? Are there any additional costs in terms of environmental or health monitoring.</td>
</tr>
<tr>
<td><strong>Utilities</strong></td>
<td>Operational costs to be considered, including electricity, water, laundering and cleaning.</td>
</tr>
<tr>
<td><strong>Maintenance</strong></td>
<td>Maintenance contracts and costs of spares</td>
</tr>
<tr>
<td>Repair</td>
<td>Call-out charges and the need for back-up devices in case of failure</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>---------------------------------------------------------------------</td>
</tr>
<tr>
<td>Disposal</td>
<td>Indemnity insurance may be required</td>
</tr>
<tr>
<td></td>
<td>Some types of device are required to be disposed of in such a manner that attracts additional costs (e.g. radioactive isotopes)</td>
</tr>
</tbody>
</table>
### Appendix E

#### Purchasing

<table>
<thead>
<tr>
<th>Topic</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device details</td>
<td>Type number, software version, power supply details, professional user chosen options, standards complied with – as agreed and where relevant.</td>
</tr>
<tr>
<td>Manuals</td>
<td>Professional user manuals, end-user manuals, other technical literature (parts list, circuit diagrams, cleaning instructions)</td>
</tr>
<tr>
<td>Warranty</td>
<td>Specify agreed terms</td>
</tr>
<tr>
<td>Ancillaries</td>
<td>Leads and connectors probes and sensors, calibration equipment</td>
</tr>
<tr>
<td>Consumables</td>
<td></td>
</tr>
<tr>
<td>Installation/Commissioning</td>
<td>Any work which the manufacturer or supplier is to do</td>
</tr>
<tr>
<td>Training</td>
<td>For users of servicing personnel, including initial training on delivery, and on-going training needs during operation Details of your acceptance procedure (see paragraph 5.4)</td>
</tr>
<tr>
<td>Quantity, price, terms, discount</td>
<td></td>
</tr>
<tr>
<td>Maintenance agreement</td>
<td>Intervals and response times – level of service required and agreed cost</td>
</tr>
<tr>
<td>Any other conditions of supply</td>
<td>For example a ceiling on future prices for consumables and spare parts</td>
</tr>
<tr>
<td>Delivery Date</td>
<td></td>
</tr>
<tr>
<td>---------------</td>
<td>--</td>
</tr>
<tr>
<td>Delivery point</td>
<td>All deliveries should be addressed to a single named department, so devices do not get put into service without acceptance checks (see paragraph 5).</td>
</tr>
</tbody>
</table>
Appendix F

Example

1. A clinical engineering manager was called out to repair an electrically operated operating table after a breakdown. The table provided to be on a loan from a manufacturer, the loan having being negotiated by surgical staff without reference to the clinical engineering department. Concerns included the lack of electrical safety checks, the non-availability of manuals, possible effects on purchasing decisions, and liability in the event of an adverse incident.

2. Works department were asked to examine an electric bed that had stopped working. It was on loan from the company to the ward, with the intention of purchasing the model should it meet their needs.

The agreement had been reached between the unit manager and the company representative without consultation with works department of procurement.

Concerns were expressed about the lack of consultation with
- procurement to check product quality and fitness for purpose;
- works department to ensure that safety/electrical checks were carried out prior to usage
- liability for the organisation should there be an accident to either a patient of staff member when the bed was being used.

3. A blood pressure recording machine was sent to the works department as ward staff were concerned that correct readings were not being achieved.

The machine had been purchased through a high street store by staff without consulting the procurement department.

Concerns were expressed about the lack of consultation with
- procurement to check product quality and fitness for purpose.

4. Unit staff contacted works department regarding a nebuliser that had stopped working.

The machine had been donated to ward staff by a grateful relative 6 months before.

Concern was expressed that the nebuliser
- had not had a safety/electrical check by the works department before use
- advice was not sought regarding decontamination after patient usage
Appendix G

NHS Form Indemnity A & B

NHS form of Indemnity A (“Form A”) is to be used for equipment on loan from a supplier to a trust. Only one form A needs to be executed by a supplier.

NHS form of Indemnity B (“Form B”) is to be used for goods in which the legal rights of ownership are to be transferred by the supplier to the Trust (namely, when the Trust is the beneficiary of a gift from a supplier). Only one Form B needs to be executed by a supplier.

Before executing Form A or B, it is advisable that proof of the Suppliers indemnity insurance is seen. On expiry of the insurance, proof of renewal should be obtained from the supplier.

Some suppliers and manufacturers have signed a Master Indemnity Agreement with the NHS Purchasing and Supply agency. A list of these can be found on the Agency’s website at http://nww.pasa.nhs.uk/purchasing/shared/mia/ (NHS net users only). If a supplier’s indemnity form(s) is shown as having expired in the list provided, a check should be made with the agency as to whether a new indemnity form is in the process of being processed BEFORE continuing with a trial or loan.

NB. The use of an Indemnity Form does not remove the need for manufacturer's quality control inspection, or for acceptance tests conducted by the borrower.
### Acceptance Checklist

<table>
<thead>
<tr>
<th>Timescale</th>
<th>Possible Checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediately on delivery</td>
<td>☐☐ Check packaging for damage</td>
</tr>
<tr>
<td></td>
<td>☐☐ Check goods against order – leads accessories, manuals, consumables</td>
</tr>
<tr>
<td></td>
<td>☐☐ Check any identification labels against invoice – model numbers, mains voltage</td>
</tr>
<tr>
<td></td>
<td>☐☐ Check device for obvious defect or damage</td>
</tr>
<tr>
<td></td>
<td>☐☐ Check usage and maintenance instructions are included and any other documents required</td>
</tr>
<tr>
<td></td>
<td>☐☐ Record who does the acceptance checking</td>
</tr>
<tr>
<td>During functional and safety tests</td>
<td>☐☐ Follow manufacturer’s instructions for setting up and testing device</td>
</tr>
<tr>
<td></td>
<td>☐☐ Check the device performs within original specification*</td>
</tr>
<tr>
<td></td>
<td>☐☐ Unless manufacturer’s instructions specifically advise against perform relevant safety tests*#</td>
</tr>
<tr>
<td></td>
<td>☐☐ Update training records for relevant staff</td>
</tr>
<tr>
<td></td>
<td>☐☐ Update maintenance requirements through LSS before first use</td>
</tr>
<tr>
<td></td>
<td>☐☐ Perform the same checks used when a device is returned to use after maintenance*</td>
</tr>
<tr>
<td></td>
<td>☐☐ Recheck suitability of device for intended application*</td>
</tr>
</tbody>
</table>

* checks needing technical or clinical training

# For example, hoist load tests needed for insurance purposes, and electrical safety tests
## Appendix I

### New Device Checklist

<table>
<thead>
<tr>
<th>Topic</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical conditions</td>
<td>Advise Tony Allen at LSS Facilities for inclusion in the Asset Register. Attach label with inventory number.</td>
</tr>
<tr>
<td>Storage</td>
<td>☐ Organise appropriate training for users</td>
</tr>
<tr>
<td></td>
<td>☐ For new models of a familiar device: professional users need to know how the operators manual is organised, how any controls and adjustments work, and to be aware of potential errors arising from misleading similarities to existing devices</td>
</tr>
<tr>
<td></td>
<td>☐ For complex or novel devices, formal training sessions, possibly run by the manufacturer are needed;</td>
</tr>
<tr>
<td></td>
<td>☐ Any necessary training for technical and maintenance staff</td>
</tr>
<tr>
<td></td>
<td>☐ Update training records</td>
</tr>
<tr>
<td>Planned and preventative maintenance</td>
<td>☐ Inform users about day to day checks and operations</td>
</tr>
<tr>
<td></td>
<td>☐ Note which servicing organisation is to be used</td>
</tr>
<tr>
<td></td>
<td>☐ Work out date for first service, enter in record keeping system</td>
</tr>
<tr>
<td></td>
<td>☐ File maintenance manuals</td>
</tr>
<tr>
<td>Labels and documentation</td>
<td>Attach appropriate labels, possibly:</td>
</tr>
<tr>
<td></td>
<td>☐ Warning professional users that this is a new device, and they should monitor treatment carefully</td>
</tr>
<tr>
<td></td>
<td>☐ Warning end users to wait until they</td>
</tr>
</tbody>
</table>
- have been trained
- Giving date when preventative maintenance will be needed
- Giving basic instructions

Make sure copies of manuals are supplied to users with devices (e.g. place on ward/department reference shelves).

For large items, open a log book (to remain with the device) – enter acceptance test results, who to contact in case of problems.
# Appendix J

## Storage

<table>
<thead>
<tr>
<th>Topic</th>
<th>Problems</th>
</tr>
</thead>
</table>
| Physical conditions                                        | - Dirty or wet conditions  
- Inappropriate temperature or humidity  
(labels on packaging should indicate appropriate storage conditions) |
| Storage system                                             | - Stacks too high  
- Fragile equipment stored too far off the ground, likely to be damaged by falling from shelves.                                      |
| Separation of equipment needing decontamination and repair from equipment ready to issue | - Inadequate space for demarcated areas for quarantine, etc.  
- Inadequate labelling of zones  
- Inadequate packaging and refurbished equipment.                       |
| Shelf life and stock rotation                              | - No stock handling procedures, so earliest deliveries are not issued first.  
- Inventory system does not identify out–of–date stock.  
- Excessive storage times cause rubber components to set in position (ventilators), lubricants to migrate (motor-driven devices) and wood to dry out and shrink (crutches)  
- Shelf life of batteries and sterile produces is exceeded.  
- Rechargeable batteries may be damaged if not subjected to regular charge/discharge cycles. |
Appendix K

Training Needs Analysis

NB: If non nursing/medical staff (e.g. Occupational Therapist, Social Worker) is required to use any medical device they will follow the requirements identified for registered or non registered nursing staff depending on what the device is and whether registered.

REGISTERED NURSING STAFF

<table>
<thead>
<tr>
<th>Devices</th>
<th>Frequency of Training</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP Monitor</td>
<td>one off</td>
<td>Formal Training Pre reg.</td>
</tr>
<tr>
<td>Blood Glucose Monitor</td>
<td>yearly</td>
<td>Training dept.</td>
</tr>
<tr>
<td>Alcometer</td>
<td>yearly</td>
<td>Supplier/instruction info</td>
</tr>
<tr>
<td>Thermometer</td>
<td>one off</td>
<td>Formal Training Pre reg.</td>
</tr>
<tr>
<td>Nebuliser</td>
<td>one off</td>
<td>Supplier/instruction info</td>
</tr>
<tr>
<td>Peak Flow Meter</td>
<td>one off</td>
<td>Formal Training Pre reg.</td>
</tr>
<tr>
<td>Resus Equipment</td>
<td>yearly</td>
<td>ULHT SLA</td>
</tr>
<tr>
<td>Suction Equipment</td>
<td>one off</td>
<td>Formal Training Pre reg.</td>
</tr>
<tr>
<td>Syringe/ Needles</td>
<td>one off</td>
<td>Formal Training Pre reg.</td>
</tr>
<tr>
<td>Urinary Catheters</td>
<td>one off</td>
<td>Formal Training Pre reg.</td>
</tr>
<tr>
<td>Oxygen</td>
<td>one off</td>
<td>Formal Training Pre reg.</td>
</tr>
<tr>
<td>Insulin Syringes</td>
<td>one off</td>
<td>Formal Training Pre reg.</td>
</tr>
<tr>
<td>Urine Test Strips</td>
<td>one off</td>
<td>Formal Training Pre reg.</td>
</tr>
<tr>
<td>Moving &amp; Handling Equipment</td>
<td>two yearly</td>
<td>M&amp;H Dept.</td>
</tr>
<tr>
<td>Drug Screening Equipment</td>
<td>one off</td>
<td>Supplier/instruction info</td>
</tr>
<tr>
<td>Epilepsy Seizure Alarms</td>
<td>one off</td>
<td>Supplier/instruction info</td>
</tr>
</tbody>
</table>

UNREGISTERED NURSING STAFF

<table>
<thead>
<tr>
<th>Devices</th>
<th>Frequency of Training</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP Monitor</td>
<td>one off</td>
<td>In-House</td>
</tr>
<tr>
<td>Thermometer</td>
<td>one off</td>
<td>In-House</td>
</tr>
<tr>
<td>Urine Test Strips</td>
<td>one off</td>
<td>In-House</td>
</tr>
<tr>
<td>Moving &amp; Handling Equipment</td>
<td>two yearly</td>
<td>M&amp;H Dept.</td>
</tr>
<tr>
<td>Devices</td>
<td>Frequency of Training</td>
<td>Method</td>
</tr>
<tr>
<td>----------------------</td>
<td>-----------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>BP Monitor</td>
<td>one off</td>
<td>Basic Training</td>
</tr>
<tr>
<td>Blood Glucose Monitor</td>
<td>yearly</td>
<td>Basic Training</td>
</tr>
<tr>
<td>Alcometer</td>
<td>yearly</td>
<td>Supplier/instruction info</td>
</tr>
<tr>
<td>Peak Flow Meter</td>
<td>one off</td>
<td>Basic Training</td>
</tr>
<tr>
<td>Resus Equipment</td>
<td>yearly</td>
<td>ULHT SLA</td>
</tr>
<tr>
<td>Suction Equipment</td>
<td>yearly</td>
<td>Basic Training</td>
</tr>
<tr>
<td>Syringe/ Needles</td>
<td>one off</td>
<td>Basic Training</td>
</tr>
<tr>
<td>Insulin Syringes</td>
<td>one off</td>
<td>Basic Training</td>
</tr>
<tr>
<td>ECT Equipment</td>
<td>one off</td>
<td>In-House</td>
</tr>
<tr>
<td>IV Equipment</td>
<td>one off</td>
<td>Supplier/instruction info</td>
</tr>
</tbody>
</table>
Appendix L

LINCOLNSHIRE PARTNERSHIP NHS FOUNDATION TRUST
MEDICAL DEVICES GROUP
The Policy/ Procedure for: Medical Devices

<table>
<thead>
<tr>
<th>Issue:</th>
<th>03</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status:</td>
<td>Approved</td>
</tr>
<tr>
<td>Author Name &amp; Title:</td>
<td>Matron for Specialist Services</td>
</tr>
<tr>
<td>Issue Date:</td>
<td>September 2015</td>
</tr>
<tr>
<td>Review Date:</td>
<td>September 2018</td>
</tr>
<tr>
<td>Approved by:</td>
<td>Quality Committee</td>
</tr>
<tr>
<td>Distribution/ Access:</td>
<td>Normal</td>
</tr>
</tbody>
</table>

TRAINING RECORD FOR: ……………………. *(INSERT DEVICE NAME)*………

REQUIRED FREQUENCY OF TRAINING: ……………………………………………

<table>
<thead>
<tr>
<th>WARD/UNIT</th>
<th>Name of staff requiring</th>
<th>Designation</th>
<th>Date of training</th>
<th>Signature</th>
<th>Date Next Due</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
## LINCOLNSHIRE PARTNERSHIP NHS FOUNDATION TRUST
### DECONTAMINATION CERTIFICATE

<table>
<thead>
<tr>
<th>DECONTAMINATION CERTIFICATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>For issue prior to inspection, service or repair of any medical or laboratory equipment</td>
</tr>
</tbody>
</table>

To

…………………………………………………………………………………………………………………………

From ………………………………….. Date

………………………………………………..

Item of equipment ……………………….Serial/ Inventory No

……………………………………

Fault/ Repair

…………………………………………………………………………………………………………………………

Job Reference No

…………………………………………………………………………………………………………………………

Tick box A if applicable, otherwise you must complete sections B and C overleaf

A . This equipment has not been in contact with blood, body fluids, respired or pathological specimens and is not visibly contaminated.

Declaration

I declare that I have taken all reasonable steps to ensure the accuracy of the above information

Signature …………………………………….. Print name

………………………………………………

Position

………………………………………………………………………………………………………………………..
**Contaminated Equipment**

B. Has this equipment been exposed to hazardous materials?

Blood, body fluids, respired gases, pathological specimens  YES/NO please circle

Chemicals or substances hazardous to health  YES/NO please circle

Other hazards  YES/NO please circle

**Details of contamination**

C. Has the equipment been cleaned and decontaminated?  YES/NO please circle

If Yes, state method .................................................................

(Please check manufacturer’s guidelines or your local infection control policy)

If No, state why .................................................................

Please note: Equipment that has not been decontaminated must not be returned/presented without prior agreement with the appropriate Technical Department

**Declaration**

I declare that I have taken all reasonable steps to ensure the accuracy of the above information

Signature ........................................ Print Name

........................................................................

Position

........................................................................
## Controlled Drugs Policy

### DOCUMENT VERSION CONTROL

<table>
<thead>
<tr>
<th>Document Type and Title:</th>
<th>Standard Operating Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorised Document Folder:</td>
<td>Operational</td>
</tr>
<tr>
<td>New or Replacing:</td>
<td>Replacing</td>
</tr>
<tr>
<td>Version No:</td>
<td>5</td>
</tr>
<tr>
<td>Date Policy First Written:</td>
<td>December 2006</td>
</tr>
<tr>
<td>Date Policy First implemented:</td>
<td>December 2006</td>
</tr>
<tr>
<td>Date Policy Last Reviewed and Updated:</td>
<td>August 2014</td>
</tr>
<tr>
<td>Implementation Date:</td>
<td>November 2014</td>
</tr>
<tr>
<td>Author:</td>
<td>Chief Pharmacist</td>
</tr>
<tr>
<td>Approving Body:</td>
<td>Medicines Management Committee Quality Committee</td>
</tr>
<tr>
<td>Approval Date:</td>
<td>24th September 2014</td>
</tr>
<tr>
<td>Ratifying Body:</td>
<td>Quality Committee</td>
</tr>
<tr>
<td>Ratified Date:</td>
<td></td>
</tr>
<tr>
<td>Committee, Group or Individual Monitoring the Document</td>
<td>Medicines Management Committee</td>
</tr>
<tr>
<td>Review Date:</td>
<td>August 2016</td>
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</tbody>
</table>
Controlled Drugs Policy

Standard Operating Procedure for Trust Employees
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1. Introduction 4
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3. Definitions 7
4. Controlled Drug stationery 8
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1 Introduction

1.1 The core pieces of legislation applicable to controlled drugs (CDs) are:


1.1.2 The Misuse of Drugs Act (MDA) 1971.

1.1.3 The Misuse of Drugs Regulations (MDRs) 2001 as amended.

1.1.4 The Misuse of Drugs (Safe Custody) Regulations 1973 as amended.

The Advisory Council on the Misuse of Drugs keeps under review ‘dangerous or otherwise harmful drugs’ which are designated as CDs. It provides advice on measures to be taken for preventing the misuse of such drugs or dealing with social problems connected with their misuse, and in particular on measures which ought to be taken. The possession, storage and destruction of CDs are governed by the MDA 1971 and MDRs 2001 as amended.

1.2 In this policy the expression “controlled drug” means any substance or product for the time being specified in part I, II or III of schedule 2, or, schedule 3, 4 and 5 to the Misuse of Drugs Act 1971 or the expression “Class A”, “Class B”, “Class C” Drug. CDs are classified into five different schedules according to the different levels of control attributed to each. Schedule I is the most tightly controlled and schedule V is the least tightly controlled. The five schedules are summarised in Appendix G.

1.3 Controlled drugs are legally defined and subject to specific requirements affecting how and by whom they can be ordered, stored, administered and destroyed. Records must also be kept to the required standard.

1.4 Restrictions to any aspect of controlled drugs and any associated stationery must comply with any conditions attached to it.

1.5 In addition to these legal requirements, the Trust requires certain additional safeguards not specified by law. Trust employees are expected to adhere to these requirements in addition to their legally defined responsibilities.

1.5.1 Within the Trust, Temazepam, Tramadol and Morphine Oral Solution 10mg/2ml are to be treated as a schedule 2 Controlled Drug. It is subject to Trust regulations regarding ordering, storage, administration, destruction and record keeping.

1.5.2 From 01st January 2008 midazolam is now a schedule 3 CD. A CD requisition order is required to supply. Midazolam should be treated in the same way as Temazepam for safe custody and storage but no record in the CD register is required.

1.6 Any illicit or illegally obtained drugs must be recorded in the CD register for the purposes of record keeping only. The disposal/ handling or recording of illicit or illegal substance found or brought onto a unit is laid out in policy OPR/3 ‘Procedure for management of drug and alcohol misuse’.
1.7 The NPSA Rapid Response Report 05, July 2008, states all staff members involved with any aspect of controlled drugs MUST ensure they are familiar with the following characteristics of that medication:

(a) Usual starting dose
(b) Frequency of administration
(c) Standard dosing increments
(d) Symptoms of overdose
(e) Common side effects.

1.8 Particular attention MUST be made when dealing with injectable morphine or diamorphine preparations.

1.8.1 The NPSA document “Ensuring safer practice with high dose ampoules of diamorphine & morphine” (NPSA May 2006) states that good practice must ensure different strengths of these injections are stored separately and not together on the same shelf of the CD cupboard.

1.8.2 It is an offence to contravene any directions given under the Misuse of Drugs Act 1971, any associated legislation concerning controlled drugs or this policy.

2 Duties & Responsibilities

2.1 The Trust’s Accountable Officer for Controlled Drugs is responsible for ensuring compliance with The Misuse of Drugs legislation, framework and all aspects of the safe and secure handling of CDs within the Trust. This includes ensuring that safe systems are in place for the governance, management and use of CDs, monitoring and auditing the management systems and investigation of concerns and incidents relating to CDs. This accountability also includes all controlled drug activities defined in local Standard Operating Procedures, SOPs. The Accountable Officer for the Trust is the Chief Pharmacist and the deputy to cover in the absence of the Accountable Officer is the Security Management Specialist.

2.2 The Accountable officer is a formal member of the Lincolnshire Local Intelligence Network, LLIN, led by the NHS England Accountable Officer. This network includes representatives of NHS and independent healthcare providers, along with regulatory bodies and agencies. The regulations allow information to be shared among responsible bodies. Any information request as part of the CD intelligence network will be dealt with using the existing process in the Trust for information requests, with the Chief Pharmacist as Accountable officer being notified.

2.3 The Accountable Officer will report occurrence and non-occurrence of CD incidents quarterly to the LLIN. The purpose of LLIN is to provide a network for sharing of information regarding the management, use and potential abuse of CDs in the Lincolnshire
area, in accordance with regulation 18, The Controlled Drugs (Supervision of Management and Use) Regulations 2006.

2.4 The appointed nurse in charge of a ward, unit or team is responsible for the safe and appropriate management of CDs in that area. The appointed nurse is in control of keys and can delegate control of access (i.e. key holding) to the CD cupboard to another authorised professional, such as another qualified nurse, member of the pharmacy team or a doctor, however legal responsibility remains with the appointed nurse in charge. The task may be delegated but the responsibility may not.

2.5 The appointed nurse in charge of a ward, unit or team is responsible for ensuring that staffs working under their direction are aware of local SOPs.

2.6 The Accountable officer in the event of suspicion of misuse of CD medications covered in schedules 3 to 5 (e.g. Benzodiazepines) may instigate special recording and storage procedures for specific drugs. See Appendix E.

2.7 Any member of staff who has concerns over possible misuse of medications on their ward should speak in the first place to the appointed practitioner in charge or should contact the Accountable Officer or their deputy.

2.8 Prescribers are responsible for prescribing controlled drugs appropriately, responsibly and legally. They are responsible for correcting any problems with CD prescriptions that prevent legal supply occurring.

2.9 NO member of staff is allowed to administer or dispense a controlled drug unless all the information required by law is given on the prescription and the directions are correct.

2.9.1 In the case of a prescription for a controlled drug in Schedule 2 or 3, a pharmacist CAN amend the prescription if it specifies the total quantity only in words or in figures or if it contains minor typographical errors, provided that such amendments are indelible and clearly attributable to the pharmacist.

2.9.2 Staff should not normally transport CDs. If a member of staff is transporting a CD or CD stationery i.e. prescriptions, then the local SOP must reflect this activity and a risk assessment completed first.

2.9.3 Local SOPs should contain a list of CDs to be held as stock items.

2.9.4 The level of stock should be agreed between the pharmacy team and ward manager or appointed nurse in charge, e.g. medicine link nurse. The stock level should be reviewed regularly and as a minimum every quarter.

3 Definitions

3.1 Authorised Witness: Any member of healthcare staff are permitted to witness specific tasks that they are familiar with and sign to confirm that the task has been performed accurately and correctly. For the purposes of witnessing Controlled Drug tasks the following are authorised witnesses:
- Registered nurses
- Doctors
- Pharmacists
- Pharmacy Technicians
- Any authorised employee of the Trust who has undergone a documented process of competence assessment by the appointed practitioner in charge to undertake the given activity.

3.2 The term stock refers to CDs that have not been issued to, or, dispensed to a service user.

3.3 BNF: The British National Formulary

3.4 Controlled Drug (CD): A medical preparation subject to prescription and security requirements under the Misuse of Drugs Regulations 1985 and the Misuse of Drugs Act 1971.

3.4.1 They are divided into five schedules each specifying the requirements for such activities as import, export, production, supply, possession, prescribing, storage and record keeping.

3.4.2 For further information please refer to the “Controlled Drugs and Drug Dependence” section of the current edition of the BNF.

3.4.3 Please note Trust procedures for Temazepam and Morphine Sulphate Solution 10mg/5ml is in addition to the CD regulations.

3.5 CD Requisition Book: A book containing pre-printed pages, each suitable for the ordering of a single controlled drug preparation and the generation of a carbon copy.

3.6 CD Register: A bound register suitable for the recording of all controlled drug transactions for a specific ward, unit or team.

3.7 FP10: An NHS prescription form that can be dispensed by a registered community pharmacy. Those used by General Practitioners are termed FP10 and those used by prescribers in secondary care are termed FP10 (HP). Those used by specialist drug misuse centres in secondary care are FP10MDASS.

3.8 HMSO: Her Majesty’s Stationery Office.

3.9 LPFT: Lincolnshire Partnership NHS Foundation Trust.

3.10 POD: Patient’s Own Drugs, medicines which are the property of an individual service user whether purchased by, or prescribed for, them by a GP or a Trust prescriber.
4 Controlled Drug Stationery

4.1 CD Registers

4.1.1 Each ward, unit or team that holds stocks of CDs or holds CDs on behalf of service users must keep a record of CDs received, administered or supplied to service users in an appropriate CD register.

4.1.2 A CD register is a bound book suitable for the purpose of recording controlled drug transactions for a ward, unit or team. Within the Trust the only approved form of register is that printed by HMSO (Her Majesty’s Stationery Office) for the purpose. Registers are available from the dispensing pharmacy and should be ordered using the stock order book (see 4.5).

4.1.3 The appointed nurse in charge of the ward, unit or team together with the local pharmacy team are responsible for keeping the CD register up to date and in good order.

4.1.4 CD’s for both stock and named patient use received onto the ward from the dispensing pharmacy should be signed for and the receipts returned to the dispensing pharmacy.

4.1.5 All receipt, administration or supply of CDs by the ward, unit or team must be recorded in the CD register.

4.1.6 All removal of CDs from the ward, by any means, must be recorded in the CD register.

4.1.7 All entries must be signed by a designated practitioner and witnessed by another authorised person, who may be one of the following:

- Registered nurse
- Doctor
- Pharmacist
- Pharmacy Technician
- Any authorised employee of the Trust who has undergone a documented process of competence assessment by the appointed practitioner in charge to undertake the given activity.

4.1.8 These requirements, within the Trust, apply to controlled drugs in both schedule 2 and schedule 3, including temazepam, and morphine sulphate liquid. Other medicines may be added at various times.

4.1.9 Each preparation used as inpatient stock, and therefore available for administration to any service user against an appropriate prescription, must be recorded on a separate page of the CD register. The index page at the front of the register must be kept up-to-date to allow staff to identify the appropriate page to use for a particular CD preparation.
- On reaching the end of such a page in the CD register, the balance must be transferred to a fresh page in the register. The new page number must be added to the bottom of the finished page and the index updated.

- The transfer of balances and page numbers must be witnessed.

4.1.10 Each preparation received as “Patient’s Own Drugs”, whether brought in by the service user or dispensed by the pharmacy must be recorded on a separate page of the CD register specific to that preparation and that service user. The index page at the front of the register must be updated to allow the correct page to be identified for future recording of administration, supply or return of this preparation for this service user.

- On reaching the end of such a page in the CD register, the balance must be transferred to a fresh page in the register. The new page number must be added to the bottom of the finished page and the index updated.

- The transfer of balances and page numbers must be witnessed.

4.1.11 When a stock balance reaches zero it must be recorded as “nil” in words and not as “0”.

4.1.12 Any spillage of medication should also be recorded and witnessed

4.1.13 Any wasted medication doses should also be recorded in the register. The wasted items should be disposed of as per Trust policy (section 13)

4.1.14 Any medication wasted by spillage or refusal by service user, should (if at all possible) be put into an appropriate sized plastic bag and labelled with date, problem i.e. refused, initials of professional bagging item and quarantined in a separate section of the CD cupboard. LPFT pharmacy services should then be informed and asked to come to locally destroy the item at the earliest opportunity.

4.1.14.1 An entry on the correct page in the CD register MUST be made indicating the wastage of that dose.

4.2 Correcting errors in a CD register

4.2.1 To correct an error in the CD register the following procedure must be followed:

- Under no circumstances should entries be crossed out

- Bracket the error in such a way that the original entry is still legible. This must be signed, dated and witnessed in the same way as any other entry.

- If the correction affects the running stock balance of the CD then follow the procedure in section 5 to reconcile the register value with the physical stock held of that CD.
- Alterations should be clear and unambiguous. Asterix, initial and date the bracketed error, then write the correct information on the next line. At the bottom of the same page cross-reference the asterix and write an explanation.
- The witness must also sign the correction.
4.2.2 When starting a new CD register, the balance of CDs in stock must immediately be written into the new register by ward staff. The transfers must each be signed by a designated practitioner and witnessed as specified above. The old register must be archived as described in section 4.7.

4.3 CD Requisition Books

4.3.1 The only approved CD requisition book used by the Trust is that printed by HMSO for the purpose.

4.3.2 Only one CD requisition book per ward, unit or team is to be in use at any one time.
4.3.3 See section 7 for the procedure for requisitioning CDs

4.4 Secure Storage of CD Stationery

4.4.1 CD stationery must be stored by the ward, unit or team in a locked cupboard or receptacle, i.e. approved safe. It should not be kept in the CD cupboard. Access should be restricted to the nurse in charge or a person authorised by them.

4.5 Supply of CD Stationery

4.5.1 CD stationery will be issued to the ward, unit or team from the pharmacy against a written requisition signed by a designated practitioner using the stock order book or Trust-headed paper.

4.6 Loss or Theft of CD Stationery

4.6.1 Loss or theft of any CD stationery that may be used to order CDs must be reported as soon as possible to the Accountable Officer (Chief Pharmacist) or Security Resilience Specialist.

4.6.2 Any such incident must be reported using the Trust’s incident reporting system in the same way as a missing Controlled Drug.

4.7 Archiving

4.7.1 Completed CD registers, delivery notes and CD requisition books must be stored by the ward, unit or team for at least TWO YEARS following the date of the last entry. In the event of a ward closure the CD records should be held by the LPFT Pharmacy department.

4.7.2 When a book is to be archived it must have the date of the last entry written on the front cover, as well as the earliest date for destruction, e.g.:

- LAST ENTRY: DD/MM/YYYY
- DO NOT DESTROY BEFORE DD/MM/YYYY

5 Possession of CDs

5.1.1 Unlawful possession of any CD constitutes a criminal offence.

5.1.2 A member of staff is allowed to possess a CD, who in the course of their duties, engages as a carrier, when at work.

5.1.3 A member of staff is allowed to possess a CD, which has been removed from someone else to stop them offending and is immediately taking it to a
person who may lawfully possess it or to an LPFT premises with the appropriate storage facilities.

6 Reconciliation of CD Stocks

6.1.1 Any controlled drugs held by a ward, unit or team MUST be reconciled against the CD register on a daily basis.

6.1.2 The running balance of CDs remaining should be reconciled after each transaction and balances checked with the physical amount of stock.

6.1.3 The accountability for maintaining running balances and dealing with any discrepancies lies with the staff member in charge and not with the person to whom the task is delegated, e.g. preceptor or assistant.

6.1.4 Where possible two members of staff should check all entries for CDs received or issued and both individuals should initial the entry.

6.1.5 Reconciliation must occur at least once a day UNLESS the ward, unit or team performs a risk assessment and satisfies the Chief Pharmacist that a reduced frequency will still ensure that discrepancies will be identified in a timely way.

6.1.6 Reconciliation will also be performed by the Accountable Officer and their deputy at least once every year and a report provided for the ward, unit or team manager. This check will also involve the following:

- A check of a sample of CD requisition copies to ensure they have been entered correctly in the CD register
- A review of the security and quality of record keeping
- Checking for exceptional use of CDs
- Checking the physical security of CDs, CD cupboards, clinic rooms, CD stationery and key-holding logs
- Checking “Patient’s Own Drug” CDs held on the ward at the time

6.1.7 Reconciliation must involve TWO authorised members of staff as described in section 3.1. Where possible, the staff undertaking this check must be rotated periodically. The check must take account of the following:

- Reconciliation involves the checking of the balances in the CD register against the CD cupboard contents, not the other way around, to ensure that all balances are checked.
• It is not necessary to open packs with tamper-evident seals. Any tamper-evident seals on packs of CDs should be left intact when reconciling balances. This will simplify and speed up routine balance checks, as sealed containers can be assumed to contain the full amount as stated on the pack.

• Stock balances of liquid medicines can be checked by nurses daily, by visual inspection, but, must be checked by pharmacy using the appropriate measure. The balance must be confirmed to be correct upon completion of a bottle.

• Excess volume of stock liquids highlighted due to manufacturer’s overage in the bottle should be reported to the ward pharmacist who will amend the records at the next visit. If there is no regular pharmacist visit then contact the LPFT pharmacy department and one of the following will be arranged:

(a) A pharmacist will visit the ward or unit within one week to amend the records

(b) A pharmacist will authorise a designated practitioner to amend the records and make an incident report

(c) The Accountable officer will authorise a member of staff to carry out the correction.

• All checks and balances reconciled by the pharmacy team must be completed with an approved witness.

• All such amendments must be counter-signed in the Controlled Drug register by an authorised witness.

6.1.8 A record indicating that this reconciliation has been carried out and has confirmed that the stock is correct must be made in the appropriate CD register on each page whose balance is checked. The record must state the date and time of reconciliation, the wording “balance checked” or “check of stock level” and the signature of the designated practitioner and authorised witness.

6.1.9 Any discrepancy found between a register and stock held must be immediately investigated by the appointed practitioner in charge or team co-ordinator or a delegated senior member of staff.

6.1.10 Local SOPs should clearly define the action to be taken if a discrepancy arises that cannot be resolved.
• The ward manager or senior most members of staff on duty should be informed.

• The Accountable Officer and their deputy should be informed immediately.

• An incident form should be completed. The description should contain what action was taken and evidence secured.

6.1.11 If the reason for discrepancy cannot be identified and corrected (such as an arithmetic error in the running balance) then the Trust Accountable Officer (Chief Pharmacist) or Deputy Accountable Officer (Security Resilience Specialist) must be informed and an incident reported on the Trust's incident reporting system.

6.1.12 Alterations should be clear and ambiguous with no crossings out. Asterix, initial and date the bracketed error, then write the correct information on the next line. At the bottom of the same page cross-reference the asterix and write an explanation.

6.1.13 There is a requirement for stock balances to be checked and signed for at shift hand-over. Where this is not possible a risk assessment should be completed.

6.1.14 If reconciliation reveals that a stocked CD is not being used then the reasons for keeping the CD must be reviewed by ward and pharmacy staff and if appropriate the CD returned to the dispensary in accordance with the
standard operating procedure (section 10). This must be done at the next pharmacy visit.

6.1.15 When controlled drug medicines are prescribed, dispensed, supplied or administered every member of staff concerned should confirm the:

(a) Dose prescribed, or, where an increase is intended, ensures that the dose is correct and safe.

(b) Any recent dose changes

(c) Formulation

(d) Frequency of administration

(e) Any co-prescribed medicines e.g. analgesics

6.1.16 Pharmacy staff will reconcile the balance of CDs at least once weekly as part of their stock top-up process. If CDs are actively being used the balance will be reconciled at each pharmacy visit.

6.1.17 The aim of maintaining running balances is to ensure irregularities are identified as quickly as possible.

7 Record of Transfer

7.1 If a service user is transferred with a CD from another LPFT ward the balance must be transferred out of the CD register of the discharging ward and written as ‘nil’ and transferred into the CD register of the admitting ward. The CD must be transferred in a sealed bag with a PATRET form completed as an audit trail.

8 Controlled Drug Cupboards and Keys

8.1 The Misuse of Drugs (Safe Custody) Regulations 1973 covers the safe custody of controlled drugs in certain specified premises. The Regulations also set out standards for safes and cabinets used to store CDs.

8.2 CD cupboards used by wards, units or teams must conform to the British Standard reference BS2881 or be otherwise approved by the Pharmacy Services department. This is a minimum safety standard and may not be sufficient for areas where large amounts of CDs are stocked or where there is not a 24-hour staff presence. In these cases, a security cabinet that has been evaluated against the SOLD SECURE standard SS304 must be used (see www.soldsecure.com). If a cupboard on a unit is not of the approved...
type then the ward or unit should seek advice from the LPFT pharmacy department before arranging to purchase an approved cupboard.

8.3 All controlled drugs must be stored in a locked receptacle that can only be opened by a person who can lawfully be in possession, such as a pharmacist or the assigned practitioner in charge of an area or an authorised person working under their authority.

8.4 CDs must be stored in the CD cupboard and locked away when not in use.

8.5 CD cupboards must be kept locked when not in use. Keys must only be available to authorised members of staff and at any time, the key-holder must be readily identifiable.

8.6 In certain circumstances, CDs supplied as leave or discharge medication may be stored in the ward, unit or team’s CD cupboard. These medicines must be segregated from CD stocks and must be recorded in the CD register.

8.7 Where permissible due to size of the cupboard different strengths of the same CD should be segregated, e.g. separate shelves.

8.8 CDs cannot be stored in the out of hour’s cupboard.

8.9 No other medicines or items must be stored in the CD cupboard unless specified by a local or Trust policy.

8.10 Stocks of naloxone 400mg in 1mL injection kept for the purpose of reversing respiratory depression caused by the parenteral administration of opiate drugs should be stored with the other emergency drugs on the ward and NOT in the CD cupboard.

8.11 On occasions, for the purposes of stock audit, the keys may be handed to an authorised member of pharmacy staff.

8.12 There must be a local policy for keeping the keys secure. This is particularly important in areas that are not operational at all times.

8.12.1 The keys required for access must be kept with a qualified member of staff only and any hand over of keys recorded on the log sheet. At any time, key holders must be readily identifiable.

8.12.2 The keys must never be made accessible to an unauthorised member of staff.

8.12.3 A duplicate second set of keys should be kept in a secure location on the premises with a key log to readily identify possession. If CD keys cannot be
located or are lost the Chief Pharmacist and Security Management Specialist must be informed immediately.

8.13 **Missing Keys**

8.13.1 If the keys cannot be found then urgent efforts must be made to retrieve them as quickly as possible, e.g. by contacting staff who have just gone off duty or left the ward, unit or team base.

8.13.2 If the keys cannot be retrieved then the following must be informed as soon as possible

- Appointed Practitioner in Charge
- Accountable Officer (Chief Pharmacist)

8.13.3 If the Accountable Officer is unavailable then the Deputy Accountable Officer must be informed of the missing keys.

8.13.4 The Accountable Officer or the Deputy Accountable Officer will decide whether to call the police.

8.13.5 The loss of keys must not impede service user care. In such cases any necessary staff must be informed to arrange a supply of medication.

9 **Requisitioning Controlled Drugs as a Stock Supply**

9.1 Controlled drugs for administration to inpatients must be requisitioned using a CD Requisition Book

9.2 For the legal supply of a controlled drug from one Trust to another Trust a registered medic MUST either sign or countersign a nurse signature when a request is made for ANY controlled drug using the CD order book.

9.2.1 A copy of the prescription chart can be sent with the order as a measure of good practice enabling the dispensing pharmacy to double check the appropriateness of the CD order.

9.3 A separate requisition must be made for each CD preparation required. Multiple CDs cannot be supplied against a single requisition.

9.4 The requisition must specify the following:

- Name of the hospital or site
- Ward, unit or team
- Name of the drug (e.g. Morphine Sulphate)
- Form of the drug (e.g. tablets, MR tablets, injection)
- Strength of the required preparation (e.g. 10mg)
- Ampoule size if more than one is available
- Quantity of the preparation required (e.g. 20 tablets, 10 ampoules)

9.5 The details of the requisition should be double checked against the relevant prescription chart and the requisition must be signed by a medic who must also print their name next to their signature.

9.6 Midazolam preparations must now also be ordered using the CD order book.

9.7 It is the responsibility of the appointed practitioner in charge to ensure that the dispensary and the Trust pharmacy department have a copy of all authorised signatures for the ward or unit and that the list is kept up-to-date when staff leave or join the team. The dispensary retains the right to refuse supply to an unrecognised signatory. See appendix B for authorised signature paperwork. This list should be updated annually and any deletions or additions forwarded to the pharmacy departments as needed.

9.8 The completed requisition book must then be sent to the dispensing pharmacy.

9.9 Controlled drugs cannot be supplied against a faxed requisition

9.10 The CD order **MUST NOT** be for any more than a maximum of 30 days’ supply.
9.11 If ordering injectable opiates such as morphine, diamorphine or oxycodone, the ward or unit must have ready access to naloxone injection (400 micrograms in 1ml) to reverse respiratory depression should it occur. If naloxone is not available as a ward stock then it must be ordered from pharmacy at the same time as the opiate.

9.11.1 Stock levels should be kept to a minimum but enough to meet clinical need.

9.11.2 The level of stock should be reviewed at an appropriate basis to reflect patterns of use, i.e. either when a person is discharged or at least on a quarterly basis.

9.11.3 All requisitions for CDs must have the doctors’ signature and named printed.

10 Receiving Controlled Drugs

10.1 Delivery and Receipt

10.1.1 Controlled drugs supplied by the dispensary will be delivered to the ward or unit in a secure container such as a sealed transport bag or a locked box.

10.1.2 The person delivering the controlled drugs must have signed for receipt either on the duplicate requisition or in a separate book kept for the purpose by the dispensing pharmacy.

10.1.3 On delivery, the container must be handed personally to a designated practitioner. The container must not be left unattended and must be opened and the contents checked as soon as possible, preferably immediately against both the delivery note and the CD requisition book.

10.1.4 If it is not possible to open and check the contents of the bag immediately, it should be placed safely in the clinic room with the tamper-evident seals still intact. The tamper-evident seals must only be removed in the presence of another member of staff.

10.1.5 The pharmacy delivery receipt should be completed by two people, the qualified person receiving the controlled drugs and one competent other.

10.1.6 The appropriate records should be made in the CD register, the running balance updated, and the CDs placed in the CD cupboard. The second competent witness should countersign the CD register and delivery note.

10.1.7 The serial number in the CD requisition book must be entered in the CD register on the same line the receipt is entered. This should be cross-
referenced with the delivery note and running balance to ensure they all tally.

10.1.8 The delivery note should then be filed on the ward and kept for a minimum period of two years.

10.1.9 As a matter of good practice, the person receiving the controlled drugs must not be the same person who ordered them unless this is unavoidable.

10.2 Receiving CDs supplied by requisition

10.2.1 The ward or unit’s CD requisition book will be returned with the controlled drugs supplied against a requisition. Each such CD received must be checked and, if correct, have its carbon copy page signed by the authorised professional receiving the controlled drugs.

10.2.2 Any packs of medicines received with tamper-evident seals should be left intact when reconciling balances.

10.2.3 If, when the tamper-evident seal is broken, or when any discrepancy between items ordered and items received do not match, it must be reported immediately to the pharmacy team, dispensary, if open, or the on-call pharmacist if not. Appropriate records must be made in the CD register and all necessary action taken to resolve the discrepancy. If appropriate an incident report should be completed. (See section 5.16, 5.17)

10.2.4 Wherever possible the pack should be kept as evidence and the CD dispensed from an alternative pack. Where this is not possible because care will be compromised, the member of staff should assure themselves that the contents are suitable to administer.

10.2.5 Each order received must be entered into the ward or unit’s CD register on the page specified for the preparation. If the preparation received does not already have a page, then a new page must be used and the index at the front of the register updated to reflect this.

10.2.6 The record of receipt must include the date and time of receipt, the identity of the supplying dispensary, the amount of preparation received & the CD order book page number for the order received, the current stock balance of the preparation and the signatures of a registered nurse and an authorised witness. As the CD register has no specific area to sign for receipt of CDs, staff should utilise the “Given by” and “Witnessed by” areas of the appropriate line on the appropriate page of the CD register.

- Staff recording receipt of a controlled drug MUST confirm that the item ordered and received conforms to the relevant inpatient prescription chart.
10.2.7 Place the CDs in the appropriate CD cupboard and check that the running balance of the preparation tallies with the quantity that is physically present. Any discrepancy must be reported as described in section 5.16, 5.17 above.

10.3 Receiving Patient's Own Drugs, including leave and discharge medication

10.3.1 Controlled drugs labelled for a specific service user must be recorded in the CD Register. Each preparation must be recorded on a page specific to both the preparation and the service user.

10.3.2 The record must include the date and time of receipt, the name of the service user, the drug name, form, strength and quantity of each preparation received and the signatures of two authorised professionals. The page header must specify the name of the preparation and the name and date of birth of the service user for whom they were dispensed.

10.3.3 “Patient's Own Drug” CDs that are not suitable to be used must not routinely be stored and arrangements must be made to either have them returned to the dispensary with the service user's consent for them to be destroyed, or for them to be returned to the service user's home via an identified adult.

- Where such drugs are stored in the CD cupboard, they must be clearly segregated from CD stock and must be clearly marked. They must still be entered in the CD register on a separate page with service user name, drug name, form, date and time and signed by two authorised professionals. The entry should be marked as “stored prior to disposal”.

- If such items are returned to service users or appropriate adult to take home then the person collecting the POD medication should sign the register for receipt of the preparation along with two authorised professionals. The balance in the register should be recorded as “zero” in words or “nil” and lines drawn through the remaining space on the page to prevent further entries being made.

- For non-identifiable preparations refer to the Trust policy on illicit drugs for advice on how to handle such items. Under no circumstances should unidentifiable medications be returned to a service user.

10.4 Storage

10.4.1 All CD cupboards conform to British Standard reference BS2881 or are otherwise approved by the Security Management Specialist and Chief Pharmacist.
10.4.2 Ideally, the CD cupboard should be within a medicines cupboard. Where standalone CD cupboards are approved the clinic room must be lockable and not accessible to patients.

10.4.3 The keys required for access must be kept with a qualified member of staff only and any hand over of keys recorded on the log sheet. At any time, key holders must be readily identifiable. The keys must never be made accessible to an unauthorised member of staff.

10.4.4 A duplicate second set of keys should be kept in a secure location on the premises with a key log to readily identify possession. If CD keys cannot be located or are lost the Chief Pharmacist and Security Management Specialist must be informed immediately.

10.4.5 TTOs or leave medicines containing CDs once recorded, should be stored in the CD cupboard but kept segregated from the ward CD stock.

10.4.6 Any controlled drugs received, once recorded in the CD register must immediately be placed in the ward, unit or team’s CD cupboard and the cupboard locked.

10.4.7 The CD cupboard must be kept locked when not in use.

10.4.8 No other medicines or items should be stored in the CD cupboard except a minimum of two CD DOOP kits.

10.4.9 Particular attention MUST be made when dealing with injectable morphine or diamorphine preparations.

10.4.10 The NPSA document ‘Ensuring safer practice with high dose ampoules of diamorphine & morphine’ (NPSA May 2006) states that good practice must ensure different strengths of these injections are stored separately and not together on the same shelf of the CD cupboard.

10.5 Naloxone

10.5.1 If receiving or storing injectable opiates, the pharmacy team to ensure that the ward, unit or team has a supply of naloxone injection 400 micrograms in 1ml, an antidote to opiate-induced respiratory depression, if it occurs.

10.5.2 Naloxone should be stored in the designated emergency drug section in the ward/unit/team drug cupboard.

11 Administration of controlled drugs

11.1 A seal should only be broken when the pack is required for administration.
11.2 Controlled drugs may be administered to a service user from either:

- ward stock
- named patient supply
- “Patients Own Drug” supply

11.3 In these cases, the service user’s medication card will indicate when a dose is due, either as part of a regular regime or on an “as required” or “once-only” basis.

11.4 When a dose is due, a designated practitioner or prescriber must select the dose from the controlled drug cupboard and check it against the medication chart.

11.5 If administering a schedule 5 CD from a PGD, only those staff specified in the PGD and signed as competent to do so, can do so.

11.6 In accordance with NPSA guidance ‘Reducing dosing errors with opioid medication’ (NPSA/2008/RRR05) Before administering opioid medicines to service users, other than in an acute emergency, the authorised nurse and authorised witness should:

- Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the service user. This may be done, for example, through discussion with the service user 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 service user (e.g. for oral morphine or oxycodone in adult service users, not normally more than 50% higher than 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.

11.7 The administration must be recorded in the CD register when the dose is removed, using the appropriate page for the preparation used and taking care that a preparation may be used from either a stock supply or “Patient’s Own Drugs” and these will be recorded on different pages.

11.8 The record must include the date and time of administration, the name of the service user, the signature of the designated practitioner or prescriber.
administering the dose, the signature of an authorised witness, the amount administered and the revised stock balance

- If administration involves the finishing of a bottle of an oral liquid CD, then the stock balance in the register must be reconciled with any remaining stock as described in section 5

- The authorised witness must be familiar with the process of drug administration. For this reason it may not be appropriate for pharmacy staff to act in the capacity of authorised witness for this specific task

11.9 If only part of a vial or ampoule is administered to a service user, the record must indicate the amount given and the amount wasted

11.10 Any calculations performed in preparing the dose must be checked as per the Trust's Medicines Management Policy.

11.11 Before administering any injectable opiates, first ensure that a supply of naloxone 400 micrograms in 1ml injection is available to reverse respiratory depression if it occurs. Naloxone should be stored in the designated emergency drug section in the ward/unit/team drug cupboard.

11.12 The dose must be checked by an authorised witness and the dose administered to the correct service user in accordance with Trust procedures and professional practice. Both authorised professionals must witness the administration and the administration must be recorded on the service user’s medication chart.

11.13 Any controlled drug dose that is prepared but not used, or only partly used must be destroyed by an authorised nurse in the presence of an authorised witness and a record made in the appropriate CD register, signed by both parties.

11.13.1 The partial dose remaining must be rendered in accessible by placing it in the secure sharps bin.

11.13.2 Any quantities in excess of one prescribed dose of a CD must NOT be destroyed by the ward or unit. It must be quarantined in a separate section of the CD cupboard clearly marked by placing it in an appropriate receptacle (plastic bag or bottle), labelled with the name and strength of medication, quantity, date of quarantine, and initials of the person carrying out the task and it must either be returned to the dispensary using the appropriate paperwork (see section 10) or locally destroyed by the authorised staff (see section 13).
11.14 If an opiate patch is applied, the date of application must be written on the patch.

12 Returning Controlled Drugs

12.1 When a controlled drug is no longer required by the ward, unit or team if it is still in date & could possibly be re-used it must be returned to the dispensary, using the approved method and paperwork.

12.1.1 If the CD no longer required is to be destroyed the Accountable officer or their Deputy can appoint authorised trained named personnel to provide destruction services on the unit using approved destruction kits. See Appendix F and section 10.5.

12.2 If the controlled drug has passed its expiry date then local destruction of the Controlled Drug should be arranged.

12.3 Medication awaiting destruction or removal should be stored in the CD cupboard segregated from any other drugs currently in use. The medication should (if at all possible) be put into an appropriate sized plastic bag and labelled with date, problem i.e. refused, initials of professional bagging item and quarantined in a separate section of the CD cupboard and the CD returns register.

12.3.1 LPFT pharmacy services should then be informed and asked to come to locally destroy the item at the earliest opportunity.

12.4 “Patient’s Own Drug” controlled drugs brought in by the service user may be returned to the service user instead of being returned to the dispensary, however it is often safer and more appropriate to arrange for these to be destroyed on the ward or returned to the dispensary for destruction, with the service user’s written permission using Trust approved paper work.

12.5 If a CD is to be removed from the ward/unit/team for return to the dispensary the following procedure must be followed:

12.5.1 Remove the correct CD preparation from the CD cupboard

12.5.2 Ensure that the CD is not required any longer

12.5.3 If the CD is a “Patient’s Own Drug” then seek written permission from the service user before it is sent to the dispensary. Use the PATRET form if necessary.
12.5.4 An entry must be made in the CD register on the appropriate page for the preparation (and service user if “Patient’s Own”) including the following details:

- Date of return
- Name and address of the dispensary to which the CD is being returned.
- Quantity being removed
- Reason for return
- Amended stock balance
- Signature of designated practitioner, pharmacist or pharmacy technician
- Signature of an authorised witness

12.5.5 If removal leaves a running balance of more than nil, then the balance in the CD register must be reconciled with the remaining physical stock of the CD.

12.5.6 Complete appropriate returns stationery

- If pharmacy staff are returning the CD then nursing and pharmacy staff must complete a “Return of Controlled Drugs” form (see Appendix A) and/or the pharmacy returns book.
- If nursing staff are returning the CD then the pharmacy returns book sheet must list each item and then for each item returned complete a page in the CD order book as for CD order, with the following amendments:
  
  (a) Write in RED ink
  
  (b) Write “RETURN” in block capitals at the top of the page
  
  (c) Delete “ordered by” and insert “returned by”

12.5.7 Secure the controlled drug(s) in a sealed pharmacy bag or box with a copy of the pharmacy returns sheet and patient consent form for medication disposal and arrange delivery to the dispensary or hand to a member of Pharmacy staff.

12.6 Authorised pharmacy staff approved by the Accountable officer may dispose of medication on site following the Trust SOP on Controlled Drug destruction and using the ward supply of DOOP bins. The recording and paper work should be completed as above section 10.2 to 10.4.3 inclusive.
12.6.1 The Authorised person should complete the register with the following information:

(a) Date of destruction

(b) ONSITE AUTHORISED DESTRUCTION written in RED BY [print name of person]

(c) Quantity and item to be destroyed

(d) Reason for destruction

(e) Amended balance

(f) Signature of authorised person

(g) Signature of witness.

12.7 Any illicit or illegal substance found on the ward must NOT be disposed of or destroyed. Staff also must not transport it away from the unit for storage, disposal or destruction. All items should be reported to the police who will arrange for legal removal. See policy OPR 3 ‘Procedure for management of drug and alcohol misuse’.

13 Prescribing Controlled Drugs

CD prescriptions are only valid if signed by a prescriber with the appropriate registration.

13.1 When prescribing opioid medicines to service users, other than in an acute emergency, the prescriber or their clinical supervisor should:

11.1.1.1 Confirm any recent opioid dose and administration of any other analgesic preparations.

11.1.1.2 Ensure where a dose increase is intended, that the calculated dose is safe for the service user (e.g. for oral morphine or oxycodone in adult service users, not normally more than 50% higher than the previous dose)

11.1.1.3 Ensure they are familiar with the medication, formulation, usual starting dose, standard increment doses, symptoms of overdose & common side effects

11.1.1.4 Ensure that they follow the guidance in the latest copy of the BNF section on ‘Controlled Drugs and Drug Dependence.’
13.1.1 The Misuse of Drugs (Supply to Addicts) Regulations 1997 require that only medical practitioners who hold a special licence issued by the Home Secretary may prescribe, administer, or supply diamorphine, cocaine & dipipanone in the treatment of addiction.

13.1.2 A prescriber cannot prescribe for themselves or anyone they have a close personal or emotional relationship with.

13.1.3 Prescribers must comply with all legal requirements.

13.2 Prescribing for inpatient use

13.2.1 For inpatients, CDs can be prescribed on the inpatient medication chart in line with relevant Trust policies and guidelines.

13.2.2 The writing requirements for these controlled drug prescriptions are the same as for other medicines.

13.3 Prescribing for leave or discharge

13.3.1 Prescriptions for CDs for service users who are going home must be completed on the appropriate Trust prescription paperwork. These prescriptions must be on either INTERNAL LPFT outpatient prescriptions for dispensing at a hospital pharmacy or FP10 for dispensing at a community pharmacy. Controlled drugs can be ordered on the prescription chart. The ‘Any other medication for leave or discharge’ section on the back of the inpatient chart can be used to write a CD leave. These inpatient prescriptions must conform to all requirements of the Misuse of Drugs Regulations for a CD prescription (see appendix D). i.e. prescriber’s own hand writing, quantities in words and figures.

13.3.2 Up to a maximum of 7 days leave or discharge supply must normally be prescribed as a matter of good practice within the Trust. Where the prescriber believes that it is the clinical interest of the service user to prescribe more than 7 days and would not pose an unacceptable risk to service user or public safety, the prescriber may prescribe accordingly but must document the reasons in the service user’s notes.

13.3.3 The quantity prescribed should be appropriate to the clinical need of the service user.

13.4 Prescribing for outpatients

13.4.1 Prescriptions for CDs for outpatients must be written in accordance with the requirements of the Misuse of Drugs Regulations. The prescription document can either be a Trust outpatient prescription form (for dispensing by United Lincolnshire Hospitals NHS Trust) or a hospital FP10 (for dispensing by a community pharmacy).
13.4.2 A prescription for schedule 2 and 3 CDs (including temazepam, midazolam or morphine sulphate liquid within the Trust) must contain the following details, written so as to be indelible:

- Service user name, address and where appropriate, age.
- Name and form of the drug
- The strength of the preparation required where appropriate
- The dose to be taken
- The frequency or equivalent directions for “as required” doses. It is not appropriate to use the direction “as directed”
- The total quantity of the preparation, or the number of dose units, to be supplied in both WORDS and FIGURES
- If a medication is to be supplied in daily or single dose packs this should be clearly written on the prescription. E.g. Seven by 1 days rather than 7 days supply. Similarly if for a liquid preparation for example methadone then 30ml (thirty mL) in single daily supplies for 3 days not 90mls. The TOTAL quantity to be supplied is still required in words and figures.

13.4.3 It is good practice to include the service user’s NHS number on the prescription.

13.4.4 The prescription must be signed by the prescriber with his/her usual signature, in his/her own handwriting. i.e. not electronically generated.

13.4.5 The prescription must be dated by the prescriber. This does not have to be handwritten.

13.4.6 If the prescription is prepared by someone other than the prescriber, then that person must be a registered healthcare professional.

13.4.7 If pre-printed addressograph labels are used on a CD outpatient prescription then they must be signed by the prescriber. This ensures that the addressograph is not tampered with, or another addressograph placed on top.

13.4.8 Up to a maximum of 30 days should be prescribed for out-patients as a matter of good practice. Prescribers are advised to limit prescribed quantities of CDs.

13.4.9 To minimise the misuse of outpatient prescriptions the prescriber should draw a diagonal line across the blank part of the prescription to indicate that no more medication was intended to be prescribed.

13.5 Supplementary Prescribers
13.5.1 Regulations were amended in 2005 to permit a supplementary prescriber to prescribe any CD included in an individual care management plan (CMP).

13.6 **Nurse Independent Prescribers**

13.6.1 From 1st May 2006 the Nurse Prescribers’ Extended Formulary was discontinued. Qualified Nurse Independent Prescribers are now able to prescribe any licensed medicine for any medical condition within their competence, including CDs for specific conditions.

13.6.2 At the time of writing the only specified drugs and conditions relevant to mental health are:

- Chlordiazepoxide for the oral treatment of initial or acute alcohol withdrawal symptoms in service users habituated to alcohol
- Diazepam for the parenteral treatment of tonic-clonic seizures
- Lorazepam for the parenteral treatment of tonic-clonic seizures
- Midazolam for the parenteral or buccal treatment of tonic-clonic seizures

13.7 **Pharmacists**

13.7.1 At the time of writing, Pharmacist Independent Prescribers are not permitted to prescribe CDs.

13.7.2 In the case of a prescription for a controlled drug in Schedule 2 or 3, a pharmacist **CAN** amend the prescription if it specifies the total quantity only in words or in figures or if it contains minor typographical errors, provided that such amendments are indelible and clearly attributable to the pharmacist.

14 **Supplying Controlled Drugs**

14.1 This section covers the supplying of CDs to service users to take as in-patients or into the community. This may involve the supplying of a whole dispensed prescription, or the supplying of smaller, individually dispensed quantities such as daily supplies for community teams to deliver.

14.2 This includes the following

- In-patient administration
- Leave medication
- Discharge medication
• Outpatient medication

• “Patients Own Drugs” being returned

14.2.1 Staff must only supply medication in original dispensing containers. It must not be transferred to alternative containers such as compliance aids or envelopes.

14.2.2 The appointed practitioner in charge of the ward, unit or team remains responsible for ensuring that CDs are given to the correct service user or an appropriate adult representative. The task of supplying the CD may be delegated to an authorised nurse.

14.2.3 Medication prescribed for an individual service user must be administered or supplied to, and used by, them only.

14.2.4 If prescriptions are left for collection, they should be left in a safe place to minimise the stealing and misuse of prescription forms.

14.3 Controlled drugs may be collected by the following:

• Service user

• Service User’s Representative known to and approved by staff and service user.

  11.1.1..1 If a person collects or accepts the CD on behalf of the recipient service user, a statement in writing must first be obtained to the effect “I am empowered by the recipient to receive this medication on their behalf”.

  11.1.1..2 The member of staff must be reasonably satisfied the document is genuine.

• Member of LPFT Staff

14.4 The person collecting the CD must be known to the person supplying it, or must provide identification such as an identity badge for staff or a passport/driving license for service users or representatives.

14.5 The CD must be signed out of the CD register from the page appropriate to the specific preparation and service user. The record must include the following:

• Date and time of issue

• Amount issued
• Signature of designated practitioner issuing the CD

• Signature and printed name of the person collecting the CD

• Signature of an authorised witness if the person collecting the CD is not a registered healthcare professional employed by LPFT

• Revised stock balance

• For FP10 prescriptions the dispensing pharmacy will require a signature from the person collecting the prescription along with appropriate identification

• An emergency supply of a schedule 2 or 3 controlled drug is not permitted either at the request of a service or a practitioner. A requisition must be obtained for the supply of an in-patient, out-patient, and patients own supply of a controlled drug on site, or, for any leave or discharge medication.

• The only exception to the emergency rule is the supply of phenobarbital for the treatment of epilepsy.

• For CDs supplied for leave or discharge the service user must countersign the ‘issued by’ box in the leave section of the in-patient prescription chart.

• For out-patient supply of CDs the service user as well as the qualified nurse must sign the ‘supplied by’ box on the chart.

• For self-administration:

  Stage 1 – Only the two qualified nurses administering the CD needs to sign the prescription chart

  Stage 2 – Only the two qualified nurses handing the service user the CD to self-administer, under staff supervision, need to sign the prescription chart.

  Stage 3 – Both the service user and two qualified nurses must sign the compliance record each time, i.e. weekly; the CD is issued to the service user.

15 Controlled Drug Destruction

15.1 An amendment to the Misuse of Drugs Regulations (2001) came into effect on 16th August 2007 allowing Accountable Officers to authorise people or groups of people to witness the destruction of controlled drugs, a role
previously undertaken by Royal Pharmaceutical Society Inspectors or Police Officers.

15.2 Only a person listed on the authorised destruction sheet for that particular unit can destroy or cause a CD to be destroyed.

15.3 A person authorised to witness destruction of Controlled Drugs must ensure that the method of destruction renders the drug irretrievable prior to safe disposal.

15.4 The method of destruction will depend on the nature and quantity of the controlled drug to be destroyed.

15.5 Half doses of schedule 4 part 1 CDs can be destroyed using cat litter.

15.6 The Accountable Officer or Deputy may approve authorised, named, senior staff or pharmacy staff to dispose of stock or named patient controlled drugs on a ward, using DOOP destruction kits. Non-approved staff may not dispose of CD’s.

15.6.1 Approved staff for the localised destruction of CDs under delegated authority from the Trust Accountable officer include – LPFT Chief Pharmacy Technician & LPFT Senior Pharmacy Technician (Adult services); Pharmacists.

15.7 Each ward shall have a minimum of two 250ML DOOP destruction kits available at all times. These can be obtained from the RDC catalogue see appendix C for more details.

15.8 CDs should be destroyed in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or re-used. Where denaturing is carried out on the wards, the methods used should be those currently recommended by the RPSGB [Guidance for pharmacists on the safe destruction of CDs]. Once the destruction is all completed and water has been added to the DOOP kit, replace the lid and seal with sellotape to ensure its tamper evident.

15.9 If no DOOP kits are available on the unit then the authorised person will not be able to destroy the controlled drug(s).

15.10 Destruction of CDs must be recorded in the CD register and witnessed in the same manner as any other CD transaction.

15.10.1 These records MUST be kept for at least 7 years after last entry in the CD register.

15.10.2 The record of destruction must include:
- the name of the CD
- Form
- Strength
- Quantity
- The date it was destroyed.
- The signature and signatory of the person destroying the CD
- The signature and signatory of the person witnessing the destruction, i.e. two signatures.

15.10.3 CDs stored for destruction must be segregated and clearly marked for destruction in a clear plastic bag.

15.10.4 For patient’s own CDs requiring destruction a PATRET form should be completed and signed by the service user to obtain consent to destroy the CD. Where it is not possible to obtain consent i.e. due to lack of capacity, this should be documented in the patient’s notes and the CD destroyed.

15.10.5 A separate CD register should be maintained for the destruction of CDs.

16 Ward and Service Closures

16.1 Temporary Closure (7 days or less)

16.1.1 For closures of no more than 7 days it is permissible to allow CDs to remain locked in the CD cupboard.

16.1.2 The security of the ward and its CD cupboard must be satisfactory to both the appointed practitioner in charge of the ward, unit or team and to the Trust Chief Pharmacy Technician.

16.1.3 If there is any doubt about security then follow the guidance for long-term closures

16.2 Long-term Closure (more than 7 days)

16.2.1 All controlled drugs recorded in the CD registers must be reconciled with the actual stock held, following the procedure outlined in section 5 of this document

16.2.2 All controlled drugs must be returned to the pharmacy dispensary in accordance with the procedure outlined in section 10 of this document

16.2.3 All registers and order books both current and archived should be sent securely to LPFT Pharmacy Department for storage.
17 Audit and Quality Control Measures

17.1 The following will be assessed at least once a year for each ward, unit or team who handle controlled drugs

17.1.1 The use of paperwork to order and record controlled drugs follows this standard operating procedure with a full audit trail

17.1.2 There is a current list of authorised signatures

17.1.3 Register entries and current stock balances are correct

17.1.4 The register has a separate page for each controlled drug preparation in use and a complete index of these pages

17.1.5 Patients’ own drugs are recorded and stored correctly

17.1.6 The disposal and/or return of controlled drugs is conducted in-line with this standard operating procedure and a full audit trail is available

17.1.7 Two DOOP kits are available for the safe destruction of controlled drugs

17.1.8 The ward has a current copy of this document

17.2 Any discrepancies will be reported to the manager of the ward, unit or team and to the Accountable Officer/Chief Pharmacist
18 References

Controlled Drugs Change guidance (RPSGB).

Safer management of controlled drugs. (Department of Health October 2006)

The safe and secure handling of medicines: a Team approach (RPSGB March 2005)

Medicines, Ethics & Practice Guide (RPSGB July 2007)

Ensuring safer practice with high-dose ampoules of diamorphine and morphine, (NPSA May 2006)

Guidance on the destruction of controlled drugs - new role for Accountable Officers - Authorising people to witness the destruction of controlled drugs (Department of Health August 2007)

Misuse of Drugs Act 1971

Misuse of Drugs Regulations 2001

Medicines Act 1968

Reducing Dosing Errors with Opioid Medication (NPSA/2008/RRR05)

British National Formulary www.bnf.org
## Return of Controlled Drugs by Pharmacy Staff

**Ward:**

**Date:**

<table>
<thead>
<tr>
<th>Service user name/STOCK</th>
<th>Drug</th>
<th>Form</th>
<th>Strength</th>
<th>Quantity</th>
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**Authorised Nurse**

**Pharmacy Staff**

**Sign**

**Print**

**Returned to**: pharmacy department

**Returned via:**

- [ ] LPFT Pharmacy staff
- [ ] ULHT Pharmacy staff
- [ ] Transport (specify which transport): __________

**Accepted by pharmacy department**

**Sign:**

**Date:**

**Print:**

Original to be retained by LPFT Pharmacy Services, Gervas House, Long Leys Road, Lincoln. This can be copied by the receiving pharmacy if required.
Appendix B

Authorisation and Destruction Signatory List

**Controlled Drug Authorisation and Destruction Sheet.**

Approved list of staff on …………………………… who are qualified and authorised to order or destroy Controlled Drugs in adherence to LPFT Policies.

The list of people nominated to authorise or destroy CDs must be kept up to date within 6 months.

<table>
<thead>
<tr>
<th>NAME</th>
<th>SIGNATURE</th>
<th>POSITION</th>
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</table>

I, Unit / Ward Manager confirm that the above people are authorised to order, administer and record any controlled drugs used on …………………………… in accordance with LPFT Policies.

Signed ………………………..  Print Name……………………..  Date ………………..
(Ward Manager)

Signed ………………………..  Print Name……………………..  Date ………………..
(Chief Pharmacist)

Expiry Date ………………....
Appendix C

Details of DOOP kits

**DOOP CD DESTRUCTION KITS INFORMATION**

A safe and reliable solution for the destruction of controlled drugs

**Size:** 250 ml.

The PHS Waste management Controlled Drugs disposal kit is a highly convenient and cost-effective solution for denaturing controlled drugs, thereby rendering them harmless and without value. These kits are recommended by the PSNC (Pharmaceutical Services Negotiating Committee) as an effective and appropriate means of destroying drugs.

These kits are available from the RDC catalogue.

All wards or units who potentially could order or store controlled drugs should ensure that at any time two DOOP kits are available for Authorized personnel to use for the destruction of Controlled Drugs.

Please order using the ward or units ordering scheme for RDC products.
### Sample Controlled Drug Prescription

<table>
<thead>
<tr>
<th>Surname</th>
<th>Smith</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forename</td>
<td>John</td>
</tr>
<tr>
<td>Address</td>
<td>123 High Street Anytown Lincs</td>
</tr>
<tr>
<td>Consultant</td>
<td>Dr Freud</td>
</tr>
<tr>
<td>Drug/Form</td>
<td>Methadone 1mg in 1mL Solution</td>
</tr>
<tr>
<td>Dose/Dir</td>
<td>30ml each morning</td>
</tr>
<tr>
<td>Sensitivities/Allergies</td>
<td>Penicillin</td>
</tr>
<tr>
<td>Pharmacy Use Only</td>
<td></td>
</tr>
<tr>
<td>Print Name</td>
<td>Dr E MEDIC</td>
</tr>
<tr>
<td>Signature of Prescriber:</td>
<td></td>
</tr>
</tbody>
</table>

**E Medic**

This prescription can ONLY be dispensed at the Hospital Pharmacy.
Appendix E

**Special Procedure Records**

In the event of suspected misuse of any drug, it may be necessary for temporary measures to be taken to ensure the legal, safe and appropriate handling of the drug. This may not be limited to Controlled Drugs within schedules 3-5.

Examples of medications that could be subject to temporary restrictions are:

- Alprazolam
- Chlordiazepoxide
- Codeine Phosphate
- Co-Codamol 30/500
- Diazepam
- Dihydrocodeine
- Flurazepam
- Loprazolam
- Lorazepam
- Lormetazepam
- Nitrazepam
- Oxazepam
- Tramadol
- Zaleplon
- Zolpidem
- Zopiclone
The Chief Pharmacist may instigate the following actions in the event of suspected misuse of any drug. These actions may be instigated Trust-wide or limited to defined areas as specified by the Chief Pharmacist/Accountable Officer

Record Keeping:

1. Instigate the use of a separate register to record the receipt, administration and destruction of specific medications. If named patient medications then individual page records must be kept for each service user.

2. When receiving and administering medicines a registered nurse plus one other approved witness shall document the details including date, patient, dose and running balance.

3. Two registered nurses shall check the balance tallies and record checked and correct in the register a minimum of once daily.

Storage:

1. Packs of medication must be stored in the CD cupboard, in a designated area or a separate box within the CD cupboard. The exception being Lorazepam injections or any other medication with specific refrigeration storage requirements which can remain in the fridge.

2. Opened containers may at the Accountable Officers discretion be kept in the medicines trolley during medication rounds to facilitate easy access.
Appendix F

Local Destruction Approved by Accountable Officer LPFT

Under the Misuse of Drugs Regulations 2001, regulation 27, those required to maintain a Controlled Drugs Register are not allowed to destroy schedule 1 – 4 controlled drugs which are surplus or out of date stock without the destruction being witnessed by an authorised person. The Trust Accountable Officer is empowered to nominate individuals who are authorised to witness the destruction of these controlled drugs.

All staff approved by the Trust Accountable Officer for the localised destruction of CDs must

- Be directly accountable to the Accountable Officer
- Must NOT destroy CDs in any area that that person has regular clinical activity
- Must be independent to the ordering, supply & administration processes in that area
- Be competent and familiar with the task to be undertaken.

The authorised person must be familiar with

- Current CD SOP OPR/47
- Current legislation requirements around the storage, handling & destruction of CDs
- Familiar with the process for destroying various formulations - solid dose; liquids; patches; parenteral; & aerosol CD preparations.
- Must have read the DoH document ‘Safer Management of Controlled Drugs – a guide to good practice in secondary care’ (October 2007)

Authorisation by Accountable Officer

**Name of Accountable Officer:** ………………………………………………………………

I , the Accountable Officer for Lincolnshire Partnership Foundation Trust, authorise the following individuals to witness the destruction of controlled drugs in accordance with the amendment to The Misuse of Drugs Regulation 2001

The individuals ( printed name and signature) are :

This authorisation to be reviewed after two years.

Signed ……………………………………………………………….. Date ……………………

Name ………………………………………………………………. 
### Appendix G

#### Schedule of CDs

<table>
<thead>
<tr>
<th>Schedules</th>
<th>Definition</th>
<th>Examples of Drugs included</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schedule 1 (CD Licence)</td>
<td>These drugs have virtually no therapeutic use. Production, possession and supply are only allowed for the purposes of research or other special purposes. A Home Office License is required.</td>
<td>Hallucinogenic drugs (e.g. LSD), ecstasy-type substances, cannabis etc.</td>
</tr>
<tr>
<td>Schedule 2 (CD POM)</td>
<td>These drugs are used medicinally, but prescribing, dispensing, administration and disposal are all tightly controlled. Enhanced prescription requirements are in place as are safe custody requirements (except secobarbital (quinalbarbitone)), record keeping requirements and tight controls on disposal. Prescriptions are valid for 28 days.</td>
<td>Cocaine, dexamfetamine, di morphine, dipianone, fentanyl, hydromorphine, methadone, methylphenidate, morphine, nabilone, oxycodone, pethidine, secobarbital (quinalbarbitone), tapentadol etc.</td>
</tr>
<tr>
<td>Schedule 3 (CD No Register)</td>
<td>These drugs are used medicinally and are liable to abuse. Controls are less rigorous than with Schedule 2. Special record keeping requirements apply in LPFT except for midazolam. Prescriptions are valid for 28 days.</td>
<td>Barbiturates (e.g. amobarbital, butobarbital, phenobarbital), buprenorphine, diethylpropion, flunitrazepam, meprobamate, midazolam, pentazocine, phentermine, temazepam, etc</td>
</tr>
<tr>
<td>Schedule 4 Part I (CD Benzodiazepines)</td>
<td>This schedule has a lower level of control than those described above. Possession of a drug from this schedule is an offence without the authority of a prescription. Possession by practitioners or pharmacists acting in their professional capacity is authorized. Remainder half doses or tablets should be denatured.</td>
<td>Benzodiazepines (except flunitrazepam midazolam and temazepam), zolpidem and ketamine (e.g. chlordiazepoxide, clonazepam, diazepam, lorazepam, alprazolam, lorazepam, lormetazepam, nitrazepam, oxazepam etc).</td>
</tr>
<tr>
<td>Schedule 4 Part II (CD Anabolic Steroids)</td>
<td>There is no restriction on the possession of a drug from this Schedule when it is part of a medicinal product. There are no special prescription requirements, nor is there a requirement for special record keeping. Prescriptions are valid for 28 days.</td>
<td>Anabolic and androgenic steroids and growth hormones e.g. testosterone, mesterolone, nandrolone (Deca-Durabolin), chorionic gonadotrophin and somatropin.</td>
</tr>
<tr>
<td>Schedule 5 (CD Invoice: CD Inv P or CD Inv POM)</td>
<td>Schedule 5 contains preparations of certain CDs which are exempt from full control because they are present in these formulations in such low strength that their risk of misuse is reduced.</td>
<td>Co-codamol, co-codaprin, codeine linctus BP, codeine phosphate tablets, co-dyramol, co-phenotrope, dihydrocodeine tablets, Gee’s Linctus BPC, kaolin and morphine mixture, Oramorph™ oral solution 10mg in 5ml.</td>
</tr>
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</table>
## Appendix H

### LPFT Guide for Requirements for CD Schedule I-V

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Schedule 2</th>
<th>Schedule 3</th>
<th>Schedule 4 Part 1</th>
<th>Schedule 4 Part 2</th>
<th>Schedule 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Examples</td>
<td>Cocaine</td>
<td>Diamorphine</td>
<td>Buprenorphine</td>
<td>Chlordiazepoxide</td>
<td>Testosterone Growth hormones</td>
</tr>
<tr>
<td></td>
<td>Diamorphine</td>
<td>Morphine</td>
<td>Midazolam,</td>
<td>Diazepam</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Methadone</td>
<td>Amphetamines</td>
<td>Flunitrazepam</td>
<td>Lorazepam</td>
<td></td>
</tr>
<tr>
<td>Safe custody in CD cupboard</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td>x</td>
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<tr>
<td>Prescription requirements for leave, OP and discharge.</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
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<tr>
<td>Requisition Necessary</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Records to be kept in CD register</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Emergency supplies allowed</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

- Midazolam does not need to be recorded in the CD register
- An emergency supply is allowed for phenobarbitone to treat epilepsy
### Appendix I

**CD Denaturing Requirements**

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Schedule 2</th>
<th>Schedule 3</th>
<th>Schedule 4 Part 1</th>
<th>Schedule 4 Part 2</th>
<th>Schedule 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Examples</td>
<td>Cocaine Diamorphine Morphine Methadone Amphetamines Fentanyl</td>
<td>Temazepam Buprenorphine Midazolam, Flunitrazepam</td>
<td>Chlordiazepoxide Diazepam Lorazepam</td>
<td>Testosterone Growth hormones</td>
<td>Co-codamol Codeine Dihydrocodeine Oramorph</td>
</tr>
<tr>
<td>Unused/unwanted tablet (prepared dose)</td>
<td>Denature by halving (if possible), adding to a DOOP kit and then adding water and place in green bin</td>
<td>Denature by adding tablet to hot soapy water, allowing to disperse and then add enough cat litter to soak up liquid and place in green bin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All loose tablets/half doses must be denatured</td>
<td>Denature by adding to a DOOP kit and then adding water and place in green bin</td>
<td>Denature by adding to hot soapy water and then add enough cat litter to soak up liquid and place in green bin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unwanted liquid</td>
<td>Denature by depositing liquid into DOOP kit and then add water. Place in green bin. Sharps must be placed in sharps bin (yellow lidded)</td>
<td>Denature by depositing liquid into hot soapy water and then add enough cat litter to soak up liquid and place in green bin. Sharps must be placed in sharps bin (yellow lidded)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unused prepared injections</td>
<td>Place in green bin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Empty blister pack/empty tablet bottle</td>
<td>Denature by adding hot soapy water and then depositing liquid into plastic cup containing cat litter. Place bottle and plastic cup in green bin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Empty liquid bottle</td>
<td>Denature by drawing up hot soapy water into syringe and then depositing liquid into plastic cup containing cat litter. Place both syringe and cup in green bin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Used oral syringe</td>
<td>Fold patch in half (sticky side inwards) and place in green bin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Used/ unwanted patch</td>
<td>Place needle and syringe in sharps bin (yellow lidded)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Empty used syringe (e.g. Midazolam)</td>
<td>Place in a sharps bin (yellow lidded)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Used rectal preparations</td>
<td></td>
<td></td>
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<td></td>
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## Rapid Tranquillisation Policy

### DOCUMENT VERSION CONTROL

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<tr>
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<td>September 2008</td>
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<tr>
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<td>September 2009</td>
</tr>
<tr>
<td>Implementation date:</td>
<td>October 2009</td>
</tr>
<tr>
<td>Authors:</td>
<td>Chief Pharmacist / Medicines Safe Practice Group</td>
</tr>
<tr>
<td>Approving body:</td>
<td>Quality Committee</td>
</tr>
<tr>
<td>Approval date:</td>
<td>October 2009</td>
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<td>Ratifying body:</td>
<td>Audit &amp; Assurance Committee</td>
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<td>Quality Committee</td>
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<tr>
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13. Zuclopenthixol Acetate (Clopixol Acuphase)
14. Legality issues
15. Capacity to consent
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Appendix: Clinical Guidelines.
1. Purpose

The Trust recognises that it is sometimes necessary to use pharmacological interventions to maintain the safety and physical health of some service users who are acutely unwell. It is hoped that this Policy and continued collaboration with service users, will ensure that Rapid Tranquillisation is undertaken only when necessary, and always with utmost respect and sensitivity for the individual.

The use of Rapid Tranquillisation is a high-risk practice which has to be well managed to avoid unnecessary harm, so Rapid Tranquillisation, along with de-escalation and physical interventions, should be seen as a management strategy and is not regarded as a primary treatment technique.

The aim of this document is to ensure that rapid tranquillisation is used safely and effectively within Lincolnshire Partnership NHS Foundation Trust (the Trust). It establishes a framework for:

- Ensuring the decision to use rapid tranquillisation is made with due consideration.
- Ensuring rapid tranquillisation is used safely, effectively and appropriately.
- Ensuring the use of rapid tranquillisation is reflected on and learnt from by staff and service users.

The Trust acknowledges that the medications described in this policy will be needed for the treatment of service users that are not exhibiting symptoms of aggression. However, where medication, including PRN, is used specifically to promote a reduction in agitation and aggressive behaviour, the guidance outlined within this policy, particularly in relation to the physical aftercare of the service user, should be followed.

All staff should be aware of the clinical implications and monitoring requirements when prescribing, dispensing or administering any medication.

This policy should be read in conjunction with other Trust policies, procedures and programmes of work including:

- Medicines Management Policy (OPR17)
- Seclusion Policy (OPR13)
- Identification, Treatment & Management of Challenging Behaviour and Violence Policy (OPR29)
- Policy for the Safe and Supportive Observation of Patients (OPR05)
- Mental Capacity Act Policy (MEN65)
- Induction and Mandatory Training Policy (PER/25)
2. Background

During an acute episode of illness some service users can become behaviourally disturbed and may need help to calm down. The engagement of skilled health care staff who can listen and respond to the needs and anxieties of service users will help to alleviate personal distress. Occasionally however when a service user has become violent or aggressive, the use of quick acting drugs may assist in this process.

National guidelines for the use of rapid tranquillisation form part of the clinical guideline for the short-term management of violence (CG25, NICE, 2005) as well as being covered in the clinical guideline for the treatment of schizophrenia (CG82, NICE, 2009)

Rapid tranquillisation is defined as:

“The use of medication to calm/lightly sedate the service user, reduce the risk to self and/or others and achieve an optimal reduction in agitation and aggression, thereby allowing a thorough psychiatric evaluation to take place and allowing comprehension and response to spoken messages throughout the intervention. Although not an overt intention, it is recognised that in attempting to calm/lightly sedate the service user, rapid tranquillisation may lead to deep sedation/anaesthesia.”

Where possible, the advice and recommendations from these documents has been incorporated into this policy. These documents can be viewed on-line:

www.nice.org.uk/CG25
www.nice.org.uk/CG82

Rapid Tranquillisation (RT) should only be considered once de-escalation techniques have failed to calm the service user. The RT intervention (along with de-escalation, physical intervention and seclusion) should be considered a management strategy and is not to be regarded as a primary management technique. When determining which intervention to employ clinical need, the safety of service users and others, and where possible any advance statements should be taken into account. It must also be noted that the intervention used must be reasonable and proportionate to the risk posed by the service user at that particular time.

The aim of rapid tranquillisation is to achieve a state of calm sufficient to minimise the risk posed to the service user or others. An optimal response would be a reduction in agitation or aggression without sedation, enabling the service user to participate in further assessment and treatment. Ideally the drug should have a rapid onset of action, low level side effects, and be have a short duration of action.

This policy has been reviewed and finalised by the Trust’s Medicines Safe Practice Group and the Medicines Management Committee.

3. Scope of this policy

This policy is one component of the Trust’s Strategy for Clinical Risk Management. It is therefore essential that the Policy is viewed within this wider context, and implemented in conjunction with all other relevant Trust policies.

Rapid Tranquillisation must only be undertaken on hospital premises where there is emergency defibrillation equipment, and there are staff trained to use them within the clinical area 24 hours a day.

This policy applies to:

Adult in-patients, including people in learning disability adult services (see Appendix for prescribing guidelines).

All in-patients in older people services (See Appendix for prescribing guidelines).
All in-patients in Children and Family Services (CAFS) aged 12 - 18 yrs (see Appendix for prescribing guidelines).

The policy will be amended to reflect any subsequent briefs or direction from the Department of Health or the National Institute for Clinical Excellence (NICE).

4. Duties and responsibilities

4.1 The Chief Executive

Is responsible for the implementation of this policy

4.2 The Medical Director

Is responsible for ensuring that all medical staff are aware of and operate within the policy, including training requirements

4.3 The Director of Nursing and Strategy

Is responsible for ensuring mechanisms exist to ensure nursing and allied health professionals within all services are aware of and comply with the requirements of the rapid tranquillisation policy including training requirements and performance measures

4.4 Service Managers

Are responsible for ensuring that all managed staff with involvement in RT are aware of and comply with the requirements of the policy, including training requirements and performance measures

4.5 Chief Pharmacist

Is responsible for being the lead author for the RT policy, including its associated prescribing and monitoring guidelines, and ensuring that the document is reviewed with appropriate frequency

Is responsible for identifying any risks posed to the Trust by the use of RT or the failure to adequately implement the policy

4.6 Medicines Management Committee is required to

Provide advice on the content of the policy, including associated prescribing and monitoring guidelines, to the Chief Pharmacist to ensure it meets standards of good practice for medical and nursing care

Review reported trends of clinical incidents associated with RT and advice on actions to reduce risk to each service and to the Trust as a whole

4.7 Pharmacy Department

Clinical Pharmacists will monitor prescribing as per policy and guideline, assess the clinical appropriateness of any deviations and provide feedback to multidisciplinary teams

Pharmacy staff will support the Learning and Development Centre in devising and revising suitable training materials.

Pharmacy staff will review this Policy as deemed necessary

Pharmacy staff will support the audit of rapid tranquillisation practice and the reporting of audit results as detailed in section 17 of this policy
4.8 **The Unit/Ward Manager is required to**

Ensure that all staff are aware of this policy.

Ensure that staff have access to training to enable them to safely implement these guidelines.

Inform Senior Management if the guidelines are not being used appropriately.

4.9 **The Nurse in Charge is required to**

Be fully aware of the contents of this policy and supporting policies and guidance before an incident arises.

Assess risk and implement the policy when they feel appropriate.

Ensure that non-pharmacological methods are tried first.

Ensure that the incident is fully recorded, including the physical monitoring and aftercare of the service user.

Ensure the correct monitoring of the service user is carried out by competently trained staff in the use of physical observations.

Ensure that any untoward signs/symptoms or any other cause for concern are reported promptly.

Continue to use de-escalation techniques throughout if appropriate.

4.10 **The Prescriber is required to**

Be familiar with the policy.

Be quickly available when alerted by nursing staff to support the team in the clinical management of the service user, when rapid tranquillisation, physical intervention and/or seclusion are implemented.

Assess the service user and take a drug history where possible, including allergies and adverse drug reactions.

Carry out a mental state examination, where practical before prescribing and administering any medication.

Consider any advanced statements before prescribing.

Follow the guidance of the Mental Health Act 1983 and the Code of Practice (2008) in relation to the use of rapid tranquillisation.

Complete all relevant documentation, highlighting any omissions/deviation from the policy.

Discuss with the nurse in charge in respect to any decisions regarding the administration of regular medication.

Ensure that the service users’ medication chart is amended to reflect the administration of ‘Rapid Tranquillisation.’

4.11 **Learning and Development Centre**

Will provide suitable training material and keep records of training.
Will provide reports on RT training numbers to relevant managers as detailed in section 17 of this policy

5. Equipment

Resuscitation equipment should be available within 3 minutes in healthcare settings where rapid tranquillisation is going to be used.

All equipment must be maintained and checked weekly and a recorded log kept of this.

6. Decision to utilise rapid tranquillisation

When a service user is distressed, appropriate non-drug measures should be taken to de-escalate the distress.

“PRN” medication

If a service user shows early, mild signs of agitation, then the clinical team may consider the use of a single, oral dose of an “as required” (PRN) medication if appropriate, as part of a de-escalation strategy. Such prescriptions should be pre-written as part of a management plan for a service user with a known history of agitation or aggression, taking due account of the service user’s history, physical health, any advance decision/statements and prescribing guidance provided in this Policy. The plan should also specify any post-administration monitoring of the service user that the prescriber considers necessary.

This administration of medication to relieve agitation as part of a de-escalation strategy must be recorded as such in the service user’s notes on each occasion.

If oral PRN medication is not prescribed, unavailable, considered unsuitable for the service user or proves insufficiently effective then the duty doctor should be called by the nurse in charge of the clinical area. Further use of medication for the control of agitation or aggression should be considered Rapid Tranquillisation.

The doctor should:

- Check whether any advance decision to refuse treatment or advance statement is in place that may affect the choice of medication
- Check if there is any management plan in place for the use of RT in the specific service user
- Review the service users’ notes with regard to his/her general medical history and consider the possibility of a physical examination
- Check recent ECG, blood and urine drug screen results; check for a previous history of severe extra-pyramidal effects, previous response to Rapid Tranquillisation or other methods of managing imminent violence.
- Review current prescribed medication and recently administered medication, taking note of administration of PRN medication
- If prescribing rapid tranquillisation, do so in the appropriate sections of the prescription chart so that nurses can clearly identify when they are administering medicines for rapid tranquillisation, and undertake appropriate monitoring
- Take care to ensure that high doses do not accidentally occur through the use of PRN medication given in combination with regular medication
- Ensure that oral and intramuscular medications are prescribed separately

Extra care should be taken when implementing rapid tranquillisation in the following circumstances:
Where there is a known presence of congenital cardiac conductive abnormalities.

Where there is a known presence of certain disorders that may affect metabolism (e.g. hypothermia, hyperthermia, extreme physical exertion)

Where there is co-prescription of medications that can directly or indirectly lengthen the QTc interval

Where antipsychotic drugs are prescribed for an antipsychotic naïve service user

Where an intramuscular injection is to be administered to a service user who is struggling or highly aroused; increased blood flow will increase the rate of absorption of the administered dose and a lower dose may need to be prescribed

When the duty doctor has established that it is safe and appropriate to utilise rapid tranquillisation a suitable drug, preparation and dose should be prescribed. Oral preparations should be used where possible.

7. Administering rapid tranquillisation

If an intramuscular injection is to be used, the service user should receive an explanation of the medication, its effects and why the intramuscular route may be considered necessary for rapid tranquillisation.

If intramuscular benzodiazepines are to be administered then staff must ensure that a supply of flumazenil is available in the clinical area.

If both olanzapine and a benzodiazepine are prescribed for intramuscular use, they must not be administered within 1 hour of each other.

If rapid tranquillisation is administered out of hours, then the on call doctor must be alerted.

When administering rapid tranquillisation, steps must be taken to try to ensure that such administration has the least impact on privacy and dignity as possible and particular attention should be made in respect of gender issues.

Following the administration of RT, appropriate recording must occur on the prescription chart and in the service user’s notes. Current in-patient prescription charts include specific tick-boxes for PRN (as required) and STAT (once only) prescriptions to indicate when administration of a medicine has been for the purpose of RT.

8. Physical care of the service user during and after rapid tranquillisation

The purpose of monitoring vital signs and side effects is to ensure early detection and intervention if adverse effects occur. Any deviation from normal values or evidence of adverse effects should be reported to the Team or Duty Doctor. The frequency of monitoring should be agreed between the nursing staff and doctor and should normally follow the current monitoring guidelines (see Appendix).

The doctor should remain on, or be contactable by and available to, the ward after intramuscular rapid tranquillisation has been administered until it is clinically and medically safe to leave the service user in the sole care of nursing staff.

The doctor should agree a care plan with the nurse in charge of the ward detailing any actions that must be taken in the case of any change to the service users’ clinical stability. The doctor should make an entry into the clinical notes to this affect.

If any abnormalities are identified by the nurse in-charge following the doctor leaving the ward/clinical area they should refer to the care plan and inform the duty doctor immediately.
Physiological observations should be monitored as per guidelines or as agreed with the prescriber and the frequency should be increased if abnormal physiology is detected.

9. Service users unable to be monitored

The requirement to physically monitor a service user as described in the RT Clinical Guideline may on occasions be counter-therapeutic, add to the individuals’ distress or pose significant risks. The critical point is that the practitioner concerned will need to record and be very clear as to why the deviation from the guideline has occurred and what steps they have taken to ensure the service user remains physically well.

10. Post rapid tranquillisation

Risk assessment and treatment plans must be reviewed following rapid tranquillisation including the use of oral PRN medication to manage agitation unresponsive to de-escalation.

Review causes of violence, diagnosis and consider ongoing management. This is likely to require a review of continuing pharmacological treatment. RT provides a short-term strategy for managing a high risk of imminent violence.

Medium and longer-term measures should be considered at an early stage with the aim of avoiding repeated RT. The diagnosis and its relationship to violence should be considered. Regular treatment should be reviewed.

The service user's care plan should be reassessed and the service user helped to reintegrate in to the ward.

Where this intervention is applied, there must be a Mental Health Act assessment carried out as soon as possible.

11. Rapid tranquillisation and seclusion

The use of seclusion, for patients receiving rapid tranquillisation should be avoided wherever possible.

However if seclusion following rapid tranquillisation is judged necessary to manage the serious risk of violence, the service user must be placed under constant observation.

The following advice should be carefully considered and followed in conjunction with the service users management care plan:

If the Service User is secluded, the potential complications of rapid tranquillisation should be taken particularly seriously

The service user should be monitored within ‘eye sight’ observation by a suitably trained individual as agreed by nurse in charge of the ward/unit.

Once Rapid tranquillisation has taken affect, seclusion should be terminated as soon as reasonably possible.
12. Debriefing and reporting following the use of rapid tranquillisation

After the use of rapid tranquillisation, physical interventions or seclusion, the service user’s care plan should be reassessed and the service user should be helped to reintegrate into the ward environment at the earliest safe opportunity.

Following the use of rapid tranquillisation the nurse in charge should ensure that the service user is offered debriefing as soon as is practicable. This should include an explanation of the decision to use rapid tranquillisation.

The service user should be given the opportunity to write their experiences in their care plan. This may necessitate the assistance of advocates and relatives. The written account will be filed in the service users care record. Service users will be engaged in discussion with staff to learn and share lessons.

A post incident Review should take place as soon as possible and at least within 72 hours of the incident ending. Wherever possible a person not directly involved in the incident should lead the review which should address:

- What happened during the incident?
- Any trigger factors
- Each person’s role in the incident
- Their feelings at the time of the incident, at the review and how they may feel in the near future
- What can be done to address their concerns?

13. Zuclopenthixol Acetate (Clopixol Acuphase)

The use of zuclopenthixol acetate does not constitute RT due to the slow onset and prolonged action of this drug.

The use of zuclopenthixol acetate may be considered in a management plan for services users with psychotic or manic illness who fail to respond to repeated RT or have a history of successful response to the drug. It should only be prescribed on the instructions of a consultant.

If zuclopenthixol acetate is considered appropriate, the BNF and the Summary of Product Characteristics (available from www.medicines.org.uk) should be consulted for dosing instructions.

Zuclopenthixol acetate must only be prescribed in the “once-only” section of the prescription chart.

A full MDT review should be conducted as a consequence of the administration of zuclopenthixol acetate.

Care must be taken not to confuse zuclopenthixol acetate with zuclopenthixol decanoate as the latter is a long-acting depot preparation.
14. Legality issues

Rapid tranquilisation is undertaken by health care professionals as a clinical necessity. Health professionals must remain aware of their legal responsibilities and the need to be able to justify their actions.

The National Institute of Clinical Excellence recommended that staff be familiar with in particular:

- The relevant sections of the Mental Health Act 1983 (as amended by the Mental Health Act 2007) and the Mental Health Act Code of Practice (2008)
- Mental Capacity Act 2005 (MCA 2005)
- The requirements of the relevant articles of the European Convention on Human Rights

In the case where by an informal service user requires medication to assist them to manage their levels of distress, a dynamic risk assessment must take place as to the need for this intervention, whether the intervention meets the tenets of justifiability (reasonable, proportionate and necessity) and as to whether the service user is medically fit for this intervention to be carried out.

15. Capacity to consent

The principles of the Mental Capacity Act 2005 (MCA 2005) must be followed in relation to consent to treatment.

Before the act is done, or the decision is made, regard must be had to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person’s rights and freedom of action.

The assessment of the individual’s ‘capacity to consent’ should be taken by the staff team who carry out the intervention required to manage the situation and clearly documented.

Whether the person has the capacity to consent is incident specific and time specific, this means there may be parts of treatment a person may have capacity to consent to; and at times they may have capacity to consent. An assessment may draw upon the expertise of other healthcare professionals, family, carers and advocates who are close to that person.

The assessment should follow the 2 stage test as outlined in the MCA 2005.

16. Consultation, Approval and Ratification Process

This policy will be consulted upon in line with ‘Corporate Documents and Policies Procedure’. The policy will be approved and ratified as outlined in ‘Corporate Documents and Policies Procedure’.
17. Review and Revision Arrangements including Version Control

This policy will be reviewed every 3 years or more frequently as required. Corporate & Legal Services will maintain a version control log, in accordance with ‘Corporate Documents and Policies Procedure’.

18. Dissemination Training and Implementation

This policy will be disseminated in line with ‘Corporate Documents and Policies Procedure’.

It will be implemented by staff through supervisory arrangements with their line manager.

The LPFT pharmacy services will ensure that the document and training package are available on the LPFT medicines management pages of the intranet. Pharmacy services will also inform staff through the Medicines Matters newsletter and Trust weekly word.

Staff involved in the prescribing and administration of rapid tranquillisation are expected to demonstrate a competency with regard to safeguarding themselves and those under their supervision from the risks posed by rapid tranquillisation.

To ensure that staff are appropriately supported to meet this, LPFT Learning and Development Centre in conjunction with the Pharmacy Department, offers a training programme to support this policy.

This training is available to all qualified staff and should be refreshed EVERY TWO YEARS.

The organisation will provide sufficient and appropriate training for each of the main staff groups as outlined within the Trust Mandatory Training Matrix (Induction and Mandatory Training Policy PER/25)

In line with NICE CG25, all staff involved in the prescribing, administration and management of rapid tranquillisation should be competent to a minimum standard of Immediate Life Support (ILS – Resuscitation Council UK) (covers airway, cardio-pulmonary resuscitation [CPR] and use of defibrillators). Staff involved in rapid tranquillisation should have training in the use of pulse oximeters.

Staff responsible for carrying out physical observations of patients, under the supervision of a registered nurse must have up to date knowledge in Basic Life Support (BLS)

Staff must be trained in how to assess and manage potential and actual violence, using de-escalation techniques, restraint, seclusion and rapid tranquillisation. This is available through the Trust’s Learning and Development Centre.

All staff involved in rapid tranquillisation need to be aware of the legal framework that authorises this intervention.

Additional clinical pharmacy advice and support is available from the Trust’s pharmacy department.

19. Policy Control including Archiving Arrangements

Corporate & Legal Services will retain a copy of this policy for a minimum of 10 years in line with the recommendations contained within ‘Records Management: NHS Code of Practice’ (2006).
## 20. Monitoring compliance and effectiveness

<table>
<thead>
<tr>
<th>Systems in place to monitor RT training</th>
<th>Measurables</th>
<th>Lead Officer</th>
<th>Frequency</th>
<th>Reporting to</th>
<th>Action Plan/ Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of nursing/medical staff with/without evidence of RT training in previous 2 years</td>
<td>Learning and Development Centre</td>
<td>Quarterly</td>
<td>Service Managers, Chief Pharmacist, Medicines Management Committee, Clinical Governance</td>
<td>Monitoring/Action Plan</td>
<td></td>
</tr>
<tr>
<td>Systems in place to ensure appropriate use of RT in practice</td>
<td>Number of reported clinical incidents involving RT</td>
<td>Chief Pharmacist</td>
<td>Quarterly</td>
<td>Clinical Governance</td>
<td>Monitoring/Action Plan</td>
</tr>
</tbody>
</table>
| Audit of prescription charts and notes for evidence of adherence to policy:  
  • Use of appropriate drugs and doses  
  • Appropriate recording of RT on prescription charts & in notes  
  • Evidence of appropriate physical health monitoring following RT | Chief Pharmacist | Annually | Clinical Governance | Monitoring/Action Plan |
Appendix: Clinical Guidelines.

These guidelines reflect current opinion on the most appropriate drugs and doses to be used in rapid tranquilisation as well as the current consensus view of the appropriate level of monitoring of the service user during and after rapid tranquilisation. A further guideline is provided to advice on the appropriate action to be taken to manage serious side-effects of RT medication.
**Guidelines for use of Rapid Tranquillisation in Adults (18-65 years)**

(for frail service users or those with a learning disability, the algorithm for older adults may be appropriate)

**Nurse-in-charge**

Ensure clinical team have tried appropriate de-escalation techniques but if service user remains distressed then contact duty doctor

**Duty Doctor**

- Agree appropriateness of rapid tranquillisation
- Agree suitable therapeutic goal (e.g. level of sedation/control) with team
- Ensure case notes have been checked for advanced decisions and complicating factors.
- Ensure service user has not been using alcohol or opiates.
- Ensure appropriate mental capacity act documentation completed and lessons shared with staff.

**If unsuccessful or declined use I/M route. Caution if using restraint.**

- I/M Lorazepam 1-2mg up to 4mg/day
  (dilute before administration)

**Psychotic context:**

Use antipsychotics with caution if medication history unknown or antipsychotic naïve or cardiac disease present:

- Lorazepam 2mg and/or
- Haloperidol 5-10mg up to 30mg/day
- Risperidone 2mg up to 8mg/day
- Olanzapine 5-10mg up to 20mg/day

(If haloperidol is used, consider an anticholinergic).

**Nurse-in-charge**

Check blood pressure, pulse and respiratory rate according to team decisions based on guidelines for monitoring (1:1 observations if sleeping) Allow sufficient time for clinical response between doses. Monitor and record vital signs.

**Abnormalities**

- Contact duty doctor

**Continued distress**

- Continue to use appropriate de-escalation techniques and continue checks as above. If de-escalation techniques fail to reduce distress contact duty doctor

**Distress reduced**

- Transfer to oral route at earliest opportunity.
- Debrief service user when alert (include opportunity to include written account of their experience in case notes)
- Discuss at MDT meeting to ensure appropriate Mental Capacity Act documentation completed and lessons shared with staff

**Duty Doctor**

- Administer I/V flumazenil if respiratory rate <10 (See Appendix 1)
- Agree any other action with consultant or senior doctor on-call
- Dial 999 if uncontrollable

- Consider additional dose of medication. If maximum dose already given contact consultant (on-call) to determine safest course of action. Allow sufficient time for clinical response between doses.
- Give explanation of medication and why necessary
- Ensure BNF maximum dose not exceeded
- Ensure checks continue as above

**In exceptional circumstances intravenous route may be considered.**

- It is strongly recommended that use of the intravenous route is agreed with Consultant/Senior Doctor on-call
- Ensure appropriate resuscitation equipment is available
- Use minimum effective dose of lorazepam, or haloperidol (also consider an anticholinergic)

- Oral Procyclidine 2.5-5mg up to 3 times or parenteral 5-10mg Procyclidine for acute dystonia.
- For IM Haloperidol, SPC request record of ECG,
- Oral combination of an antipsychotic and benzodiazepines may reduce need for injection.
- Do not repeat IM Olanzapine within 2 hours

Aripiprazole should only be used in service users not already taking antipsychotics. Only the intramuscular preparation is licensed for control of agitation of disturbed behaviour (in schizophrenia).
### Guidelines for use of Rapid Tranquilisation in Older Adults (65+ years)

(These guidelines may also be clinically appropriate for physically frail younger adults or those with a learning disability)

#### Nurse-in-charge

Ensure clinical team have tried appropriate de-escalation techniques but if service user remains distressed then contact duty doctor or refer to care plan.

#### Duty Doctor

- Agree appropriateness of rapid tranquilisation
- Agree suitable therapeutic goal (e.g. level of sedation/control) with team
- Ensure case notes have been checked for advanced decisions and complicating factors.
- Ensure service user has not been using alcohol or opiates.
- Ensure service user given an explanation of the medication and why it is necessary.

<table>
<thead>
<tr>
<th>Offer oral preparation. Allow sufficient time for clinical response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lorazepam 0.5 - 1mg up to 4mg/day, Allow at least 30-60 minutes to assess clinical effect</td>
</tr>
</tbody>
</table>

**Psychotic context:**

Exclude Dementia with Lewy Bodies (DLB)

Use antipsychotics with caution if medication history unknown or antipsychotic naive or cardiac disease present:

- Lorazepam 0.5 - 1mg up to 4mg/day
- Haloperidol 0.5 - 2mg up to 15mg/day
- Risperidone 0.5 - 1mg up to 2mg/day
- Olanzapine 2.5 - 5mg up to 10mg/day

(If haloperidol is used, consider an anticholinergic).

<table>
<thead>
<tr>
<th>If unsuccessful or declined consider I/M route only in cases of extreme emergency. Consultant approval required. Caution if using restraint.</th>
</tr>
</thead>
<tbody>
<tr>
<td>I/M Lorazepam 0.5 - 2mg up to 4mg/day (dilute before administration) (IM Midazolam considered in some cases of Learning Disability)</td>
</tr>
</tbody>
</table>

**In exceptional circumstances intravenous route may be considered:**

- It is strongly recommended that use of the intravenous route is agreed with Consultant/Consultant-on-call
- Ensure appropriate resuscitation equipment is available
- Use minimum effective dose of lorazepam, or haloperidol (also consider an anticholinergic)

- Oral Procyclidine 2.5mg up to 3 times or parenteral 2.5-5mg Procyclidine for acute dystonia.
- For IM Haloperidol, SPC request record of ECG
- Oral combination of an antipsychotic and benzodiazepines may reduce need for injection.
- Do not repeat IM Olanzapine within 2 hours

<table>
<thead>
<tr>
<th>Aripiprazole should only be used in service users not already taking antipsychotics. Only the intramuscular preparation is licensed for control of agitation of disturbed behaviour (in schizophrenia). Experience in the elderly is limited and low doses are recommended</th>
</tr>
</thead>
</table>

#### Nurse-in-charge

Check blood pressure, pulse and respiratory rate according to team decisions based on guidelines for monitoring (1:1 observations if sleeping) Allow sufficient time for clinical response between doses. Monitor and record vital signs.

<table>
<thead>
<tr>
<th>Abnormalities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact duty doctor</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Continued distress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continue to use appropriate de-escalation techniques and continue checks as above. If de-escalation techniques fail to reduce distress contact duty doctor</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Distress reduced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfer to oral route at earliest opportunity. Debrief service user when alert (include opportunity to include written account of their experience in case notes)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Duty Doctor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administer I/V flumazenil if respiratory rate &lt;10 (See Appendix 1)</td>
</tr>
<tr>
<td>Agree any other action with consultant or senior doctor on-call</td>
</tr>
<tr>
<td>Dial 999 if uncontrollable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Duty Doctor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consider additional dose of medication. If maximum dose already given contact consultant (on-call) to determine safest course of action. Allow sufficient time for clinical response between doses. Give explanation of medication and why necessary Ensure BNF maximum dose not exceeded Ensure checks continue as above</td>
</tr>
</tbody>
</table>

Debrief service user when alert (include opportunity to include written account of their experience in case notes)

Discuss at MDT meeting to ensure appropriate Mental Capacity Act documentation completed and lessons shared with staff

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Guidelines for the monitoring of service users undergoing Rapid Tranquillisation

### Vital signs to measure

- Pulse
- Blood Pressure
- Respiration
- Level of consciousness
- Oxygen saturation level
- Body temperature

It is recommended that vital signs be recorded using a “Track & Trigger” chart to aid the identification of results that are beyond “normal” values

### Recommended frequency of measurement

<table>
<thead>
<tr>
<th>Time</th>
<th>Measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td>On admission</td>
<td>Obtain measurements of all vital signs</td>
</tr>
<tr>
<td>Before RT</td>
<td>Check all vital signs</td>
</tr>
<tr>
<td>0-1 hours after RT</td>
<td>Check all vital signs every 15 minutes</td>
</tr>
<tr>
<td>1-4 hours after RT</td>
<td>Check all vital signs every 60 minutes</td>
</tr>
<tr>
<td>4-12 hours after RT</td>
<td>Check all vital signs every 4 hours</td>
</tr>
</tbody>
</table>

### Notes

- Fluid balance should be monitored as clinically indicated
- ECG monitoring is recommended whenever intramuscular antipsychotics have been given beyond BNF limits and may be advised for some antipsychotics at lower doses
- Service users should be monitored for extra-pyramidal side-effects (EPSEs) following administration of antipsychotics
- If the service user is unrouseable, call ambulance and doctor
Guidelines for use of Rapid Tranquillisation in Adolescents (12-18 years)

**Nurse-in-charge**

Ensure clinical team have tried appropriate de-escalation techniques but if service user remains distressed then contact duty doctor or refer to care plan.

**Duty Doctor**

- Agree appropriateness of rapid tranquillisation
- Agree suitable therapeutic goal (e.g., level of sedation/control) with team
- Ensure case notes have been checked for advanced decisions and complicating factors.
- Ensure service user has not been using alcohol or opiates.
- Ensure service user given an explanation of the medication and why it is necessary.

If resuscitation equipment not available, advance decisions are outside normal clinical practice or alcohol/opiate use suspected contact Consultant/Senior Doctor on-call to determine safest course of action.

- Oral Procyclidine 2.5mg up to 3 times or parenteral 5mg Procyclidine for acute dystonia.
- For IM Haloperidol, SPC request record of ECG.
- Do not repeat IM Olanzapine within 2 hours.

**Psychotic context:**

Use antipsychotics with caution if medication history unknown or antipsychotic naïve or cardiac disease present.

- Lorazepam 1-2mg every 4 hours up to 4mg/day
- or one of the following
  - Haloperidol 1-5mg up to 15mg/day
  - Risperidone 0.5-1mg up to 4mg/day
  - Olanzapine 5mg once in 24 hours
  (If Haloperidol is used, consider an anticholinergic).

**Offer oral preparation. Allow sufficient time for clinical response**

Lorazepam 0.5 - 2mg up to 4mg/day. Allow at least 30-60 minutes to assess clinical effect.

**Check blood pressure, pulse and respiratory rate according to team decisions based on guidelines for monitoring (1:1 observations if sleeping) Allow sufficient time for clinical response between doses. Monitor and record vital signs.**

- Abnormalities
  - Contact duty doctor

- **Duty Doctor**
  - Administer I/V flumazenil if respiratory rate <10 (See Appendix 1)
  - Agree any other action with consultant or senior doctor on-call
  - Dial 999 if uncontrollable

- **Duty Doctor**
  - Consider additional dose of medication. If maximum dose already given contact consultant (on-call) to determine safest course of action. Allow sufficient time for clinical response between doses.
  - Give explanation of medication and why necessary
  - Ensure BNF maximum dose not exceeded
  - Ensure checks continue as above

- **Distress reduced**
  - Transfer to oral route at earliest opportunity.
  - Debrief service user when alert (include opportunity to include written account of their experience in case notes)
  - Discuss at MDT meeting to ensure appropriate Mental Capacity Act documentation completed and lessons shared with staff.

- **Continued distress**
  - Continue to use appropriate de-escalation techniques and continue checks as above. If de-escalation techniques fail to reduce distress contact duty doctor

- **If unsuccessful or declined use I/M route. Caution if using restraint.**
  - I/M Lorazepam 1-2mg up to 4mg/day (dilute before administration)
  - I/M Lorazepam 1-2mg up to 4mg/day, (dilute before administration) and/or
  - I/M Haloperidol 1-5mg up to 10mg/day
  - I/M Olanzapine 5mg up to 20mg/day (not to be given within 1 hour of I/M benzodiazepines)
### Guidelines for the management of serious side-effects of Rapid Tranquillisation

<table>
<thead>
<tr>
<th>Complication</th>
<th>Symptoms/signs</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute dystonia</td>
<td>Severe painful muscular stiffness</td>
<td>Procyclidine 5-10 mgs i/m</td>
</tr>
<tr>
<td>Hypotension</td>
<td>Fall in blood pressure (orthostatic or &lt;50mmHg diastolic)</td>
<td>Lie service user flat and raise legs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Monitor closely</td>
</tr>
<tr>
<td>Neuroleptic malignant syndrome</td>
<td>Increasing temperature, fluctuating blood pressure, muscular rigidity, confusion/ altered consciousness</td>
<td>Withhold antipsychotics</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Monitor closely, consider CPK level</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Liaise with general medical team immediately</td>
</tr>
<tr>
<td>Arrhythmias</td>
<td>Slow (&lt;50/minute) or irregular pulse</td>
<td>Monitor closely and liaise with general medical team immediately</td>
</tr>
</tbody>
</table>
| Respiratory depression                | Reducing respiratory rate, reducing consciousness   | If respiratory rate drops below 10/minute in a service user who has received benzodiazepines, give flumazenil (caution in epilepsy):

1. 200 microgram i/v over 15 seconds
2. if consciousness not resumed within 60 seconds give 100 microgram over 10 seconds
3. repeat at 60 second intervals. Maximum dose 1mg in 24 hours

N.B Elderly doses are the same.

Liaise with general medical team.

Continue to monitor after respiratory rate returns to normal. Flumazenil has a shorter duration of action than many benzodiazepines therefore there is a risk that patients may become re-sedated. Further doses of Flumazenil may be required. Patients may become agitated or anxious on wakening.
### Substitute Opiate Prescribing Protocol

<table>
<thead>
<tr>
<th>DOCUMENT VERSION CONTROL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Document Type and Title:</strong> Substitute Opiate Prescribing Protocol</td>
</tr>
<tr>
<td><strong>Authorised Document Folder:</strong> Medicines Management</td>
</tr>
<tr>
<td><strong>New or Replacing:</strong> Replacing February 2015 version 1.</td>
</tr>
<tr>
<td><strong>Version No:</strong> 2.</td>
</tr>
<tr>
<td><strong>Date Policy First Written:</strong> August 2013</td>
</tr>
<tr>
<td><strong>Date Policy First Implemented:</strong> 29th January 2014</td>
</tr>
<tr>
<td><strong>Date Policy Last Reviewed and Updated:</strong> September 2015</td>
</tr>
<tr>
<td><strong>Implementation Date:</strong> 29th January 2014</td>
</tr>
<tr>
<td><strong>Author:</strong> Dr Neil Wright, Consultant in Addiction Psychiatry, Drug and Alcohol Recovery Team, Lincolnshire Partnership NHS Foundation Trust</td>
</tr>
<tr>
<td><strong>Approving Body:</strong> Medicines Management Committee, Lincolnshire Partnership NHS Foundation Trust</td>
</tr>
<tr>
<td><strong>Approval Date:</strong> November 2015</td>
</tr>
<tr>
<td><strong>Committee, Group or Individual Monitoring the Document:</strong> Dr Neil Wright, Consultant in Addiction Psychiatry, Drug and Alcohol Recovery Team, Lincolnshire Partnership NHS Foundation Trust</td>
</tr>
<tr>
<td><strong>Review Date:</strong> September 2017</td>
</tr>
</tbody>
</table>
SUBSTITUTE OPIATE PRESCRIBING PROTOCOL

Author: Dr Neil Wright
Consultant in Addiction Psychiatry
Drug and Alcohol Recovery Team
Lincolnshire Partnership NHS Foundation Trust

Revised September 2015
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» THE PURPOSE OF THIS DOCUMENT
» OBJECTIVES OF PRESCRIBING SUBSTITUTE DRUGS TO PROBLEMATIC DRUG TAKERS
» BASIC PRINCIPLES AND CORE PRACTICE OF SUBSTITUTE PRESCRIBING
» REFERRAL TO PRESCRIBING INTERVENTIONS
» RESTRICTIONS TO NON-MEDICAL PRESCRIBING
» MENU OF PRESCRIBING BY NON-MEDICAL PRESCRIBERS
» MENU OF PRESCRIBING BY DART MEDICAL PRESCRIBERS
» MENU OF PRESCRIBING BY SHARED CARE PRESCRIBERS
» PRESCRIBING ‘SYMPTOMATIC DETOXIFICATION’
» INITIATION AND INITIAL INCREASES OF METHADONE AND BUPRENORPHINE DOSAGE BY NON-MEDICAL PRESCRIBERS
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» STABILISING METHADONE AND BUPRENORPHINE PRESCRIPTIONS
» CLINICAL PATHWAY FROM MEDICAL PRESCRIBING TO NON-MEDICAL PRESCRIBING
» CLINICAL PATHWAY FROM NON MEDICAL PRESCRIBING TO MEDICAL PRESCRIBING
» PRESCRIBING BY THE MEDICAL LEAD
» REVIEW PROCESS
» WORKING WITH HEROIN USE ON TOP OF A METHADONE/BUPRENORPHINE PRESCRIPTION
» WORKING WITH METHADONE USE ON TOP OF A METHADONE PRESCRIPTION
» WORKING WITH BENZODIAZEPINE USE AND HEAVY DRINKING ON TOP OF A METHADONE/BUPRENORPHINE PRESCRIPTION
» FAILURE TO ATTEND APPOINTMENTS
» FAILURE TO ATTEND PHARMACY FOR SUPERVISED CONSUMPTION OR TO PICK UP MEDICATION
» SUBSTITUTE PRESCRIBING FOR SERVICE USERS WITH MENTAL HEALTH PROBLEMS OF A NATURE OR SEVERITY THAT IMPACTS ON THEIR ABILITY TO ENGAGE WITH DART
» HOLIDAY PRESCRIPTIONS
» PRISON RELEASES
» SUBSTITUTE PRESCRIBING FOR PREGNANT SERVICE USERS
» SUPERVISION

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» RECOVERY NURSE
» MEDICAL AND NON-MEDICAL PRESCRIBERS
» ADMINISTRATOR

APPENDIX 2: GUIDANCE ON DRUG TESTING FOR OPIATE USERS
» WHY/WHEN
» TESTING METHOD

REFERENCES
OVERVIEW

In line with the 2010 Drug Strategy, and with guidance from the National Treatment Agency and Department of Health (2007), this Lincolnshire Partnership NHS Foundation Trust (LPFT) prescribing protocol is based on holistic drug treatment which focuses on physical and psychological health and on all components of social functioning. This approach includes emphasis on ensuring community prescribing by the Drug and Alcohol Recovery Team (DART), or by prescribers commissioned by LPFT, does not take place in isolation; it is a component of a whole treatment package, not a treatment on its own. Prescribing drugs as substitutes for other drugs that have become problematic is not treatment unless accompanied by help for service users to access appropriate interventions for all co-existing medical problems; by psychological therapies matched to service users’ needs and by help for service users to resolve their social problems. This approach aims to promote recovery from all types of drug related problems through on-going abstinence from all illicit substances, but it recognises that goals based on harm reduction principles are appropriate for some service users.

THE PURPOSE OF THIS DOCUMENT

This protocol provides guidance for all medical and non-medical prescribers who work for the DART under the clinical supervision of the medical lead (Consultant in the Psychiatry of Substance Misuse), and for medical prescribers commissioned by LPFT to provide treatment, including substitute prescribing (the latter is referred to hereafter as shared care). This protocol describes the roles of prescribers and interactions between prescribers and the DART, which are consistent with latest guidance from the Royal College of Psychiatrists (2012). This protocol enables all DART prescribers and shared care prescribers to formulate prescribing interventions consistent with best practice. Within the DART and the DART commissioned shared care, only the medical lead substitute prescribes for problems related to use of non-opiate drugs, and this document does not encompass alcohol treatment, hence, this document focuses on substitute prescribing for DART service users who have problems related to taking opiates.

OBJECTIVES OF PRESCRIBING SUBSTITUTE DRUGS TO PROBLEMATIC DRUG TAKERS

- To alleviate withdrawal symptoms.
- To reduce or eliminate illicit drug taking.
- To reduce the risks and harms associated with drug taking, in the following areas: physical health, mental health, relationships, childcare, criminality, employment, finances, and accommodation.
- To minimise diversion of prescribed substitute drugs.
- To engage and retain service users in treatment and gradually withdraw or detoxify them from prescribed substitute medication when this is mutually agreed and in their best interests.
- To enable service users to exit from the DART abstinent from illicit drugs and to continue to lead non-drug orientated lifestyles.

BASIC PRINCIPLES AND CORE PRACTICE OF SUBSTITUTE PRESCRIBING

The following is a list of principles and practice of substitute prescribing for medical and non-medical prescribers working for the DART, and for medical prescribers commissioned by LPFT in a shared care arrangement. Any deviation from these principles or modes of practice should first be sanctioned by the medical lead, who may keep the chief pharmacist informed of such matters.

- DART medical and non-medical prescribers and doctors in shared care should recognise their prescribing and other professional limitations and act to ensure they are not working outside of these limitations. They should discuss any concerns on such matters with their clinical supervisor.
DART medical and non-medical prescribers and shared care prescribers will prioritise new referrals such that they are offered a prescribing clinic appointment within the current target timescale set by Public Health England.

DART medical and non-medical prescribers and shared care prescribers must be satisfied that a comprehensive assessment and a recovery plan have been completed before any new prescription is started. The comprehensive assessment must include all physical, psychological, and social problems and needs, and at least one drug screen. Only if a comprehensive assessment indicates that the expected benefits of a substitute prescription outweigh its potential risks, will a substitute prescription be issued; this being consistent with achieving harm reduction, however, any number of consecutive positive screens for opiates and an account of daily opiate use need not equate to sufficient evidence that the balance of benefits and risks is in favour of substitute prescribing.

Expectations over reducing or stopping opiate use are always accompanied by a wide variety of other goals, and by consequences for success or failure in achieving these goals. Such goals may pertain to any aspect of presentation that influences progress in drug treatment. The prescriber should be familiar with each individual recovery plan and discuss each one with the recovery worker prior to initiating a prescription and before all follow-up appointments.

Before every new substitute prescription is commenced, the prescriber should be satisfied that each service user is aware of service policy regarding missed appointments and non-collection of prescription. (See ‘Failure To Attend Appointments’, page 17 and ‘Failure To Attend Pharmacy For Supervised Consumption Or To Pick Up Medication’ pages 17-18.)

DART medical and non-medical prescribers and shared care prescribers verify that service users are informed about the driving regulations and if they should contact the Driving and Vehicle Licensing Agency.

See ‘Initiation and initial increases of Methadone and Buprenorphine dosage by non-medical prescribers’ (page 10-11) and ‘Initiation and initial increases of Methadone and Buprenorphine dosage by DART medical prescribers and shared care prescribers’ (page 11) for initial doses and rates of increase.

On commencing each substitute opiate prescription, the prescriber completes a prescribing information form which records start date, dosage, and pick-up arrangements; this is sent to each service user’s general practitioner. (This is relevant to new clients to shared care only when the prescriber is not the service user’s own general practitioner).

On commencing each substitute opiate prescription, shared care prescribers also send a copy of the prescribing information form to the DART, either by Fax or by email: Fax number:- Lincoln:- 01522 577390, Lincoln email:- lincoln.dart@nhs.net, Grantham Fax number:- 01476 591739, Grantham email:- grantham.dart@nhs.net, Boston Fax number: 01205 314437, Boston email:- boston.dart@nhs.net. This should facilitate appropriate payment.

New substitute prescriptions are daily supervised, except if this is impractical because of travel distance to the pharmacy, or because of service users’ work commitments.

Relaxation of daily supervision to less than daily supervision, to daily pick-up, or less than daily pick-up, occurs only if a service user provides at least one urine screen negative for opiates and presents with evidence that taking home the medication will not create significant risks (associated with deviation from the prescribed dose; consumption of other intoxicants; or leakage of the prescribed medication into the drug taking community). Such evidence accrues gradually, hence, prescribers should be most cautious about relaxing daily supervision arrangements within 3 months of the start of a substitute prescription.
Prescribers are aware of the regularity and the results of drug screens and breath alcohol tests and advise on changes to timing, frequency, or context of testing and book higher frequency appointments with those whose tests cause concern.

Accurate, contemporaneous records must be kept of all prescriptions, including date issued, dates to start, drugs prescribed, and dosage.

An electrocardiogram must be performed and the QTc interval measured in the normal range on all service users before being increased to a Methadone dose of 100 mg daily, or more.

See 'Holiday Prescriptions', (Page 18), for actions to be taken when service users want to temporarily reside outside of the DART catchment area.

Green FP10 prescriptions should be used only when they are absolutely necessary to facilitate a pick-up arrangement for Methadone, Buprenorphine or Diazepam, not possible with a blue FP10. Green FP10 prescriptions should be reverted to blue FP10 prescriptions as soon as this is practical.

Liaison between community pharmacies and recovery workers is fundamental to good drug treatment, as the pharmacist is usually the health care professional who has most regular (potentially daily) contact with a service user. Prescribers should discuss all pharmacy issues with recovery workers and with service users, including the acceptability of any third party collecting medication.

See ‘Review Process’ (page 14-15) for timing and frequency of reviews by medical and non-medical prescribers.

An administrator sends a medication change form to a client’s general practitioner whenever a DART medical or non-medical prescriber changes the dose of a substitute prescription.

Shared care prescribers send a medication change form to DART whenever a change is made to the dose of a substitute prescription. Such changes can be conveyed by fax or email.

All decisions to suspend/discontinue a prescription, ideally, should be made with the agreement of the service user’s recovery worker. All such decisions and their rationales should be documented.

Prescribers should consider reverting service users to daily supervised consumption whenever a service user who takes medication home provides consecutive positive tests for opiates and when a service user presents with significant and especially with escalating drug related problems. However, if diversion (leakage) of medication is suspected and the service user is on 50 ml of Methadone daily, or more, the prescriber must consider the risk that daily supervision could cause overdose and in these cases the prescriber should consider abruptly discontinuing the prescription (ideally, but not necessarily following a clinic appointment with the service user). When a prescription is stopped in these circumstances, the recovery worker attempts to formulate a new recovery plan with the service user, and if this is achieved and the recovery plan is also acceptable to the prescriber, a further prescribing clinic appointment follows.

REFERRAL TO PRESCRIBING INTERVENTIONS

In some cases, the extent, nature and severity of drug problems identified by the comprehensive assessment will not reach the defined thresholds for considering a prescription (see Operational Protocol). These cases are not discussed with a prescriber.

Each potential prescribing intervention by a DART medical or non-medical prescriber is facilitated by presentation of the compressive assessment, by a recovery worker to the prescriber. This is followed by an individual appointment for the service user with the prescriber, at which the recovery worker usually remains present. In shared care the recovery worker will not always be at surgery to present new assessments, or for reviews.
If comprehensive assessment raises questions about the indication for substitute prescribing, these should be discussed by the assessor and/or recovery worker in weekly case management meetings, in clinical supervision and/or with a medical or non-medical prescriber outside of prescribing clinic. These service users are not offered a prescribing clinic appointment until the assessor and/or recovery work is/are satisfied with the quality of the assessment and of the possibility that a substitute prescription could be indicated.

The decision to present to a prescriber, with a view to commencing a prescription, may be taken at the initial assessment, or may follow more extensive, even prolonged, preparatory work. Likewise, the medical prescriber may conclude from discussion with the assessor and/or recovery worker, or from interviewing the service user in the prescribing clinic, that a prescription could be of overall benefit, but necessary circumstances/conditions do not yet prevail, hence, further preparatory work is needed before the service user can receive a substitute prescription.

Ultimately, eligibility for a prescription to compliment a treatment package for opiate-related problems is a matter of clinical judgement, based on evaluation of the balance of predicted benefits and risks.

RESTRICTIONS TO NON-MEDICAL PRESCRIBING

Non-medical prescribers may have restrictions placed on the extent of their independent prescribing practice. This is particularly likely for newly qualified non-medical prescribers, and those who have cumulated little prescribing experience. For instance, initiation of substitute prescribing may not be approved by the Trust, hence, prescribing practice may be restricted to continuation of stable service users who have been initiated by another prescriber. The extent of clinical prescribing practice for each individual non-medical prescriber is agreed within clinical supervision with the medical lead, and recorded within the supervision notes. The parameters for prescribing are then agreed with the head of service who keeps a record of these parameters within the DART approved prescribers file; this information is also sent to the Trust’s chief pharmacist.

MENU OF PRESCRIBING BY NON-MEDICAL PRESCRIBERS

Non-medical prescribers with no individualised restrictions to their prescribing options with regard to drug type and dosage, will prescribe only the following medications up to the stated maximum doses, unless case discussion with, or review by the medical lead concludes that a higher dose is indicated. The rationale for a higher dose is recorded in prescribing notes or electronically and the non-medical prescriber continues to liaise with the medical lead over the dose, as long as it remains above the usual maximum.

- Methadone mixture (1mg/1ml) – up to 90 mgs daily
- Buprenorphine – up to 24 mgs daily
- Zopiclone – up to 7.5 mgs nightly, or Zolpidem 10 mg nightly for up to 2 weeks, repeated only after a break of at least 4 weeks.

MENU OF PRESCRIBING BY DART MEDICAL PRESCRIBERS

DART shared care prescribers might prescribe any medications (except those requiring a Home Office licence), however, medications other than Methadone, Buprenorphine, Zopiclone and Zolpidem will be prescribed very rarely and generally, these are psychotropic medications, such as benzodiazepines, or opiates, taken over from non-DART prescribers who have continued the prescription despite the rationale having ceased to exist, or despite problems sufficient to undermine the rationale.

The planning that should accompany Methadone and Buprenorphine reducing regimes makes the prescription of α adrenergic agonists, anxiolytics or other daytime sedatives, muscle relaxants, antiemetics and anti-motility medications, unnecessary and inappropriate, even toward or at the end of such regimes. However, initiating these medications instead of Methadone or Buprenorphine may be occasionally indicated. (See ‘Prescribing Symptomatic Detoxification’ page 10).
MENU OF PRESCRIBING BY SHARED CARE PRESCRIBERS

Shared care prescribing is limited to: Methadone, 1mg/1ml oral mixture. Methadone tablets might be prescribed to be taken during service users’ holidays. (See ‘Holiday Prescriptions’, page 18). Buprenorphine, Zopiclone, and Zolpidem, within British National Formulary guidance and limits. Any other medications prescribed by shared care doctors will not be deemed to constitute a part of shared care drug treatment.

The planning that should accompany Methadone and Buprenorphine reducing regimes makes the prescription of α adrenergic agonists, anxiolytics or other daytime sedatives, muscle relaxants, antiemetics and anti-motility medications, unnecessary and inappropriate, even toward or at the end of such regimes. However, initiating these medications instead of Methadone or Buprenorphine may be occasionally indicated. (See ‘Prescribing Symptomatic Detoxification’ below), but prescription of such medications, without need for opioid substitutes does not amount to shared care prescribing.

PRESCRIBING ‘SYMPTOMATIC’ DETOXIFICATION

A tailored ‘Symptomatic Detoxification’ using a combination of non-opiate medications (α adrenergic antagonist, anxiolytic, other daytime sedative, muscle relaxant, antiemetic, anti-motility) may be more appropriate than a Methadone or Buprenorphine prescription for clients Taking only over the counter opiates daily, or taking illicit opiates daily in small quantities (maximum 0.2g illicit Heroin daily) over a short time (less than 6 months).

INITIATION AND INITIAL INCREASES OF METHADONE AND BUPRENORPHINE DOSAGE BY NON-MEDICAL PRESCRIBERS

Non-medical prescribers may have individualised restrictions placed on the doses at which they can initiate Methadone and/or Buprenorphine and/or on the size or rate of any subsequent increases to such prescriptions.

Non-medical prescribers should liaise with a medical prescriber over initiation of a substitute opiate prescription to service users with any of the following presenting features:

- Binge drinking amounting to a risk to well-being
- Positive breath tests for alcohol; or identified as drinking at predictably harmful levels (men above 50 units per week, and women above 35 units per week)
- Unstable, severe, or enduring mental illness
- Pregnancy
- Significantly problematic use of non-opiate psychotropics
- Severe physical problems
- Any other presenting feature that causes the non-medical prescriber to question if she/he should commence prescribing.

Non-medical prescribers with no individualised restrictions on their practice can initiate Methadone at a dose in the range of 20-40 mgs, with subsequent increases of no more than 10 mgs daily and a maximum increase of 30 mgs in the first week, to an anticipated stable dose.
Non-medical prescribers with no individualised restrictions on their practice can initiate Buprenorphine at a dose in the range of 2-8 mgs, with subsequent increases of no more than 4 mgs daily to an anticipated stable dose.

INITIATION AND INITIAL INCREASES OF METHADONE AND BUPRENORPHINE DOSAGE BY DART MEDICAL PRESCRIBERS AND SHARED CARE PRESCRIBERS

DART medical prescribers and shared care prescribers will usually initiate Methadone at a dose in the range of 20-40 mgs and subsequent increases of no more than 10 mgs daily, and a maximum increase of 30 mgs in the first week and they will usually initiate Buprenorphine prescriptions at a dose in the range 2-8 mgs with subsequent increases of no more than 4 mgs daily.

Higher initial doses of Methadone or Buprenorphine may be safe and appropriate for service users who are well known from previous, especially recent, episodes of treatment, but higher initial doses should be considered by DART medical prescribers and shared care prescribers only if they feel their experience and a thorough assessment makes this a reasonable risk. They should consider discussing high initial doses with the medical lead.

DART medical prescribers and shared care prescribers can increase Methadone and Buprenorphine prescriptions by any amounts; although they should consider discussing single increases of more than 20 mg Methadone or more than 6 mg Buprenorphine with the medical lead.

STABILISING METHADONE AND BUPRENORPHINE PRESCRIPTIONS

The likely stable dose of Methadone or Buprenorphine is estimated in each case on the basis of the full clinical assessment and in conjunction with service user preference. A first medical review of dosage (and of all other relevant aspects of presentations) should occur, at most, one week after initiation of Methadone or Buprenorphine. If a service user complains of significant withdrawal phenomena and attributes on-going illicit drug use to these experiences, or if a service user anticipates taking illicit opiates for this reason, an increase to more than the originally anticipated stable dose should be considered.

CLINICAL PATHWAY FROM MEDICAL PRESCRIBING TO NON-MEDICAL PRESCRIBING

This section relates to DART medical and non-medical prescribing; not to shared care.

Service users can be transferred from their medical prescriber to a non-medical prescriber only when opiate substitute prescriptions are in the range for non-medical prescribing, or if an exception is made on the basis of the individual features of the case. Further, service users will be transferred when their presentations are consistent with clinical prescribing practice identified for their non-medical prescriber. Transfer to a newly qualified non-medical prescriber, and to those who have cumulated little prescribing experience, should only be considered for service users who are ‘stable’; as indicated by all of the following:-

- Regular attendance for appointments with a recovery worker and with the medical prescriber.
- No increase to Methadone or Buprenorphine dosage within the previous 4 weeks.
- No evidence of a pattern of problematic use of prescription drugs or illicit drugs, other than Heroin
- No evidence of heavy or problematic drinking
- No current major mental health disorder
No severe or deteriorating physical problems that complicate drug treatment

Transfer to an experienced non-medical prescriber, who has no individualised restrictions to practice should be considered in all cases except when:

- The medical prescriber is providing DART prescriptions other than oral Methadone, 1mg/1ml, Buprenorphine, or Z drugs
- The dose of Methadone, Buprenorphine or Z drug is above the maximum set for non-medical prescribing (see menu of prescribing by non-medical prescribers, page 9) and no special care exception is made.
- The medical and non-medical prescribers both agree the service user is unsuitable for non-medical prescribing (any non-medical prescriber can refuse to take responsibility for prescribing to any service user. Usually this will be on grounds of complexity and/or risks).

**CLINICAL PATHWAY FROM NON-MEDICAL PRESCRIBING TO MEDICAL PRESCRIBING**

This section relates to DART medical and non-medical prescribing; not to shared care prescribers.

The following presenting features should trigger a discussion between a non-medical prescriber and a medical prescriber about a return of prescribing to the latter:

- Pregnant client asking for, or agreeable to decreased/increased dose
- Deteriorating physical or mental health
- Drug screens consistently positive for opiates
- Evidence of heavy or problematic use of other substances, including alcohol
- Recurrent failure to collect prescription
- Failure to attend most appointments
- When considering an increase of more than 10 mgs Methadone or 4 mgs Buprenorphine, or to a dose above the maximum set for non-medical prescribing.
- Representation after a break from substitute medication of 3 or more days. If the non-medical prescriber does not have Trust approval to initiate prescriptions, this situation will result in transfer to a non-medical prescriber who does, or to a medical prescriber.
- Any other presenting feature that causes the non-medical prescriber to feel concerned about lack of progress or level of risks.

It is not intended that service users repeatedly oscillate between non-medical and medical prescribers. Most discussions between a non-medical prescriber and a medical prescriber (including the clinical lead) about ‘unstable’ service users will result in advice only, but some discussions will result in the medical prescriber providing a single assessment appointment, and in these situations, the service user remains prescribed by the non-medical prescriber. When one or more of the above criteria is/are clearly met, and unlikely to resolve quickly, discussion between a non-medical prescriber and a medical prescriber (including the clinical lead) may result in a transfer of the prescription to the medical prescriber. These service users will remain prescribed by a medical prescriber until their presentations are consistent with the criteria for being prescribed by a non-medical prescriber; (see 'Clinical Pathway From Medical Prescribing To Non-Medical Prescribing' page 12) hence, there is no minimum or maximum time for service users to stay with a medical prescriber.
PREScribing BY THE MEDICAL LEAD

In the absence of another DART medical prescriber, the medical lead may prescribe to all service users who are unsuitable to be prescribed by a non-medical prescriber, and have chosen treatment by DART rather than shared care. Further, in a geographical area without a DART medical prescriber and without a non-medical prescriber who is able to initiate substitute prescriptions, the clinical lead will see all new cases assessed as candidates for substitute prescribing, who have chosen treatment by DART rather than shared care.

The medical lead will hold a caseload of service users from geographical areas where there are DART medical prescribers, and also, some service users who are registered with doctors who provide shared care. These service users present with the most complex problems. If these service users achieve a greater stability and their substitute prescription is consistent with the ‘Menu of Prescribing Options’, for DART medical prescribers and shared care prescribers, the medical lead may liaise with the appropriate other prescriber with a view to transferring the responsibility for substitute prescribing.

The medical lead may have a caseload of service users who for reason of their identity are not seen by DART medical, or non-medical prescribers, or in shared care.

The medical lead assesses service users for the following types of prescription:

- Injectable opiates or opioids
- Methadose
- Long term prescribing of Methadone tablets
- Dexamphetamine
- Benzodiazepines
- Any other medication not on ‘Menu of Prescribing Options’

When the medical lead initiates a prescription that is outside of the prescribing practice detailed in ‘Menu of Prescribing Options,’ or advocates other non-conventional elements of treatment, these service users will remain on the medical lead’s caseload until the prescription is consistent with the ‘Menu of Prescribing Options’, or until exit from treatment with the DART.

REVIEW PROCESS

DART Medical and non-medical prescribers and shared care prescribers should have frequent, often informal, discussions with, and feedback from, recovery workers about the service users to whom they prescribe.

Formal reviews involve structured feedback and discussion between recovery workers/nurses and prescribers, followed by a face-to-face meeting between the service user and prescriber, at which the recovery worker/nurse should also be present, whenever this is possible. The prescriber should make legible written or electronic notes. The total time for a review, including preparatory discussion, face-to-face meeting and making a written record, should not normally exceed 30 minutes.

Non-medical prescribers should routinely offer service users a review appointment at a minimum frequency of every 6 weeks; DART medical prescribers and shared care prescribers should review service users every 12 weeks, but all prescribers must review at a higher frequency if there is significant change to a prescription, or any indications of significant or worsening problems.

Some Methadone and Buprenorphine maintenance prescriptions are issued by DART non-medical prescribers to service users who are relatively unchanging in presentation over long periods. Non-medical
prescribers can discuss such service users with the medical lead, with a view to agreeing that reviews can be at a frequency of every 12 weeks. This resonates with practice standard 19 in the Standards For Proficiency For Nurse and Midwife Prescribers (2006): ‘A review must take place following a maximum of 6 prescriptions’, which equates to 12 weeks of prescribing by DART. Such service user specific agreements on lower frequency reviews are followed by at least yearly non-medical prescriber presentation of each of these service users to the clinical lead at supervision. Any changes in a service user’s presentation, but especially any changes that indicate maintenance prescribing might not continue to be the best prescribing option, are most likely to cause the medical lead to end an agreement on reviewing every 12 weeks.

Failure to attend a review with any DART or shared care prescriber should usually result in giving another appointment as soon as possible.

Case discussions between the medical lead and DART medical or non-medical prescribers or shared care doctors may result in the medical lead giving verbal advice, or in rare cases, the medical lead will take over the prescribing role.

WORKING WITH HEROIN USE ON TOP OF A METHADONE OR BUPRENORPHINE PRESCRIPTION

If a service user has continued to take Heroin on a daily, or near daily basis since the initiation of a substitute prescription, consideration should be given to increasing the dosage of the substitute prescription. Also, in these circumstances, if Buprenorphine has been prescribed, consideration should be given to changing from Buprenorphine to Methadone.

Sporadic Heroin taking on top of a substitute prescription should be addressed through taking a detailed drug history, with particular emphasis on temporal, cognitive, and environmental associations with the pattern of Heroin taking. This may be assisted by asking the client to keep a drug diary, of the timing and accompanying thoughts/urges and contexts of the Heroin use.

If a service user is taking Heroin regularly, or daily, whilst on a substitute prescription at a dosage which earlier in the same treatment episode was associated with abstinence from Heroin, generally, this too should be addressed with cognitive behavioural strategies, as set out above. In these circumstances increasing the dosage of the substitute prescription sets a precedence for doing exactly the same in the future, hence, this risks a series of increases in response to on-going Heroin use. This also risks a deteriorated rapport with the service user, when this repeat cycle is finally ended by (illogical) refusal to perpetuate it further. However, in some cases, most notably when large amounts of Heroin are being taken on top of a low or moderate Methadone prescription, it may be reasonable to provide an increase of more than 10 mgs of Methadone daily, on the understanding that within a defined period of the increased dosage, further Heroin use will result in either a return to the original dosage, or a cessation of prescribing, re-assessment, and renegotiation of a new recovery plan.

WORKING WITH METHADONE USE ON TOP OF A METHADONE PRESCRIPTION

If a service user presents as a new referral with an account of taking illicit Methadone, but no Heroin, the prescriber should consider advocating a self-reduction of illicit Methadone with a view to providing a Buprenorphine substitute prescription. If this is not feasible or acceptable, the ramifications of being prescribed substitute Methadone, but continuing to take illicit Methadone must be discussed at length. The need for openness about taking illicit Methadone on top of prescribed Methadone should be emphasised, and the service user should understand that under these circumstances, the clinical choice is between advocating self-reduction of illicit Methadone, whilst the prescription continues and cognitive behavioural therapy is provided by a recovery worker; or a single increase to the prescribed substitute dosage accompanied by an agreement that illicit use of Methadone will cease, and a plan for the prescribed Methadone dosage to reduce incrementally back to the original dosage. If the latter strategy is tried and it fails, because the service user still continues to take illicit Methadone, the first strategy should be pursued.
and the service user reminded that increasing the prescribed Methadone dosage in response to illicit use of
Methadone was mutually agreed as a one off.

If a service user begins to take illicit Methadone in addition to a Methadone prescription at some point
during a treatment episode, having previously taken only the prescribed dose and no other opiate; whether
this is during a phase of maintenance prescribing, or during mutually agreed gradual reduction or
detoxification, in general, this should not result in an increase to the prescribed dosage. This history raises
concerns about the service user’s appetite for Methadone itself, and prescribing more Methadone is contra-
indicated. Essentially, this situation is akin to prescribing to non-opiate drug takers, as prescribing
Methadone is now no longer a substitute medication (just as prescribing a benzodiazepine to a taker of
illicit benzodiazepines is not substitute prescribing). Changing to Buprenorphine as a new substitute is
unlikely to be feasible/effective for reasons of the Methadone dosage and the service user’s appetite for
opioid effects, however, if a service user takes illicit Buprenorphine on top of a Buprenorphine prescription;
a change to Methadone should be considered.

If a service user discloses considerable use of Methadone in addition to a Methadone prescription, to the
extent that the total dosage and/or its day to day variation and/or added risks of other drug use, (particularly
other sedatives; benzodiazepines or alcohol) raise concerns about overdose, the Methadone prescription
should be stopped, immediately.

WORKING WITH BENZODIAZEPINE USE AND HEAVY DRINKING ON TOP OF A
METHADONE OR BUPRENORPHINE PRESCRIPTION

Service users who take benzodiazepines and/or drink heavily on top of their substitute prescription are at
high risk of death by aspiration of vomit or respiratory failure. Service users who also continue to take
Heroin add still further to these risks. Use of prescription and illicit benzodiazepines and level/pattern of
alcohol consumption should all be covered in the DART comprehensive assessment, and when relevant,
incorporated into recovery plans. Service users who are prescribed benzodiazepines by their general
practitioner are informed before they are started on an opiate substitute prescription that DART will advise
their general practitioner about reducing and stopping the benzodiazepines if the original rationale for
prescribing no longer exists, or if the original rationale was to replace an illicit supply, or if there are any
concerns about deviation from the prescribed daily dose. DART medical and non-medical prescribers and
shared care prescribers will initiate and continue substitute opiate prescriptions for service users who are
taking benzodiazepines or drinking heavily/problematically, only if the potential and/or objective benefits
outweigh the harms/risks. Service users who take benzodiazepines and/or drink heavily/problematically
will be prescribed substitute opiates by DART medical and non-medical prescribers and shared care
prescribers at the minimum dosage consistent with achieving harm reduction and are highly likely to be on
daily supervised consumption.

Prescribing benzodiazepines is not part of the LPFT DART shared care arrangement. Shared care
prescribers should generally not prescribe benzodiazepines as substitutes for illicit benzodiazepines as
testing cannot then show if the illicit source is still being taken and hence, the prescription may simply
become a second, additional source.

FAILURE TO ATTEND APPOINTMENTS

The DART recognises that different service users have different abilities to keep appointments, and they
face different obstacles to keeping appointments, but they also create different concerns when they fail to
keep appointments. However, if attendance for appointments is so poor that the balance of risks and
benefits ensuing from substitute prescribing cannot be known and there is no reason to expect future
attendance will improve sufficiently to rectify this situation; the substitute prescription should be stopped
abruptly.

FAILURE TO ATTEND PHARMACY FOR SUPERVISED CONSUMPTION OR TO
PICK UP MEDICATION
Any failure to pick up prescriptions raises questions about other aspects of compliance, but failures that result in a service user missing 3 or more days of medication always trigger suspension of the prescription and re-assessment of the service user. The prescriber should question the recovery worker on the service user's drug seeking and taking during the period he or she was without a prescription. Any use of a personal 'stock' of medication should alert the prescriber to previous under-use of the prescription and therefore, to the potential to re-initiate the prescription at a lower dose. It also establishes a rationale to restart with daily supervision. Non-medical prescribers must meet with service users before restarting them on prescription. DART medical prescribers and shared care prescribers also base their decisions about restarting prescriptions on face to face assessment of the service user except if the reason for failure to continue the prescription is straightforward and raises no suspicion, and the period off prescription is short and the service users account of drug taking whilst off prescription creates minimised risks for restarting the prescription.

SUBSTITUTE PRESCRIBING FOR SERVICE USERS WITH MENTAL HEALTH PROBLEMS OF A NATURE OR SEVERITY THAT IMPACT ON THEIR ABILITY TO ENGAGE WITH DART

Service users of DART who suffer mental health problems of a nature or severity likely to impact on their ability to engage in drug treatment will have a recovery worker with a high level of experience and skills in drug work and whenever possible, in psychiatry, too. Before a substitute prescription is commenced, a prescriber should be satisfied that the comprehensive assessment includes adequate focus on mental health needs and their current management, and their likely impact on the service user's ability to engage in, and benefit from drug treatment, including a substitute prescription and it has also, adequately defined risks to the service user and to others associated with the mental health problem. The comprehensive assessment must include liaison with the professionals involved in the treatment of the mental health problems, and clarity on the pharmacological and psychosocial elements of the psychiatric care plan and an agreement to share all relevant information on the service user's physical and mental health, social circumstances, upcoming reviews, and any changes to the pharmacological or non-pharmacological elements of each service's recovery plan.

HOLIDAY PRESCRIPTIONS

Service users on daily supervision are not provided with holiday prescriptions unless daily supervision can be arranged for the entire holiday. This is part of The Lincolnshire Pharmacy Based Supervised Administration Program Contract.

Recovery workers should try to make arrangements with pharmacies that facilitate the continuation of pick-up arrangements during holidays in Britain.

Changes to prescriptions to facilitate foreign holidays are considered only after service users have shown their recovery workers documentation that details their travel arrangements. Hence, service users are advised by recovery workers to discuss the prospects of having a holiday prescription prior to making any foreign travel arrangements. Service users planning to travel outside of the European Union are advised by their recovery worker to contact the appropriate embassy to verify if taking prescribed opiate medications to their country will create any problems. Service users planning to leave Britain for more than 3 months should be advised that they must apply for a Home Office certificate to accompany their medication; alternatively, recovery workers will attempt to liaise with treatment services in the foreign country with a view to transferring care on an agreed date early in a long holiday.

Convenience of transport and storage may make it more appropriate to prescribe Methadone tablets, instead of Methadone mixture, for the duration of longer holidays, particularly, for service users who are on relatively high doses of Methadone. Non-medical prescribers cannot prescribe Methadone tablets for this purpose.

PRISON RELEASES
DART medical prescribers and shared care prescribers will provide prescriptions of Methadone or Buprenorphine to prisoners on their release. Very often this will require a prescription is signed in advance of the release. This cannot be done by a non-medical prescriber. Prescriptions are signed in anticipation of release only if the prison has provided documented evidence (usually a faxed copy of the prison medicine card) of the medication, and its dosage. The prescriber should verify that a comprehensive assessment is scheduled for the new service user and ensure the new service user has the next available prescribing clinic appointment. If DART is requested to continue medications not consistent with the 'Menu Of Prescribing Options’, this should be discussed with the medical lead.

SUBSTITUTE PRESCRIBING FOR PREGNANT SERVICE USERS

Substitute prescribing of Methadone or Buprenorphine can occur at any time in pregnancy, and if service users take the medication as prescribed and changes to Methadone and Buprenorphine dosages are incremental, this is associated with considerably lower risks to service user and to the unborn than is continued illicit drug use. However, the evidence base for prescribing Methadone in pregnancy is considerably greater than that for prescribing Buprenorphine in pregnancy. Hence, unless a pregnant client has a very strong preference for Buprenorphine, and/or is taking relatively small amounts of Heroin; Methadone is the substitute medication of choice. Service users who become pregnant whilst on Buprenorphine as a substitute medication should remain on Buprenorphine if this is effective and unless circumstances change due to the pregnancy.

The prescription of Methadone and Buprenorphine in pregnancy follows the same general principles as prescribing in other circumstances, however, there is likely to be a greater focus on achieving reductions, so that the service user is down to a minimal amount of substitute medication at the time she gives birth. Hence, the prescriber should focus on providing a substitute prescription at a dose which is the minimum likely to be associated with a discontinuation of Heroin use, and assess the potential to make small, frequent reductions in the second trimester (concern about miscarriage in the first trimester or premature labour in the third trimester make the second trimester the preferred time to make dose reductions).

Many non-opiate drugs are considerably more damaging to the foetus than are opiates; hence, there should be a strong focus on motivating the pregnant service user to stop taking other drugs, particularly stimulants and benzodiazepines, and to drink only minimal amounts of alcohol.

Prescribing clinic appointments with pregnant service users should also focus on wider health and social needs and the prescriber should liaise as closely as is necessary with obstetric services, and other professionals involved with the client.

The clinical lead should be involved in any decision to prescribe to pregnant service users outside of the ‘Menu of Prescribing Options’.

SUPERVISION

The medical lead provides individual clinical supervision to all DART medical and non-medical prescribers. Supervision sessions involve a 1 hour meeting and occur at a frequency of once a month for non-medical prescribers and at a frequency of between once a month, and once every 3 months for medical prescribers, according to individual need. The clinical lead makes a written record of the following:-

- Topics raised in advance by supervisor
- Topics raised in advance by supervisee
- Topics discussed
- Outcome actions for supervisor
Outcome actions for supervisee

Date of next supervision

Once the content of the written record is agreed by clinical lead and supervisee, it is signed by both.

The medical lead will provide shared care prescribers with support and advice on request, and sometimes this will involve a meeting with an individual shared care prescriber. The medical lead will also provide supervision for shared care prescribers who are new to the field of substitute prescribing. The medical lead will also hold 6 monthly group meetings with all shared care prescribers; at which prescribing practice will be discussed and the clinical lead will present on topics chosen in advance by the shared care prescribers.

APPENDIX 1: ROLES AND RESPONSIBILITIES OF STAFF WORKING IN AND SUPPORTING DART SPECIALIST PRESCRIBING CLINICS

RECOVERY NURSE

- Attend the specialist prescribing clinic and represent the specialist prescribing modality, providing detailed information relating either to service users for whom nurse has care coordination responsibilities or to all service users attending for prescribing initiation or for review. Prescribers and nurses liaise on which of these two models works best in the different clinic localities.

- Coordinate the clinic; ensuring all necessary equipment and paperwork is present, prevent over booking and ensure a timely schedule is adhered to, including the management of late attendees and missed appointments.

- Manage and negotiate crisis and other ad hoc appointments relating to the clinic where necessary.

- Provide all relevant, accurate and up to date information relating to the service users attending the clinic.

- Provide clinical support to specialist prescribing medical officer's/non-medical prescribers.

- Set up and coordinate pharmacy contracts.

- Monitor prescription changes and provide list of changes to an administrator to enable alterations to Bomic and general practitioners letters to be compiled.

- Enter established review dates into specialist prescribing clinic diary, ensuring adherence to established frequency and appointment duration and liaise with an administrator for diary management.

- Provide relevant feedback to individual care coordinators.

- Provide relevant feedback to wrap around services involved with individual service users, where necessary and through appropriate mode, involving admin where necessary.

- Ensure adherence to the Substitute Opiate Prescribing Protocol and to the prescription issuing procedures at all times.

MEDICAL AND NON-MEDICAL PRESCRIBERS

- Undertake assessment of service users engaging in new treatment episodes.

- Undertake individual service user reviews at appropriately timed intervals.
➢ Write/sign prescriptions.

➢ Advise the attending nurse/practitioner of any additional drug testing requirements and required documentation.

➢ Contribute to individual service user recovery plans as required.

➢ Ensure adherence to the Substitute Opiate Prescribing Protocol and prescription issuing procedures at all times.

ADMINISTRATOR

➢ Send timely appointment letters to individual service users as required from the specialist prescribing clinic diary.

➢ Order new (blank) prescriptions when necessary, ensuring adequate float is maintained within each prescribing area.

➢ Print all necessary prescriptions and place within individual service user’s prescribing wallet.

➢ Provide all required prescriptions to the attending nurse prior to commencement of the specialist prescribing clinic for all attendees and make available to the attending non-medical /medical prescriber for the start of each clinic.

➢ Make timely amendments to Bomic following receipt of prescription change forms from nursing staff and/or practitioners.

➢ Make timely amendments to Bomic relating to service user details to ensure Bomic accuracy.

➢ Compile change of prescribing letters to general practitioners following receipt of prescribing change information from nursing staff and ensure these are PP’d and faxed within 24 hours.

➢ Draw up pharmacy contracts in a timely fashion to facilitate effective prescription management, using information provided by nursing staff.

➢ Ensure adherence to prescription issuing procedures at all times.

APPENDIX 2: GUIDANCE ON DRUG TESTING FOR OPIATE USERS

WHY

➢ For SAFETY pre and post prescribing interventions so we can assess overdose potential especially use of alcohol, benzodiazepines and additional/other opiates.

➢ Confirming treatment COMPLIANCE especially for those on unsupervised prescriptions.

➢ As a MOTIVATIONAL TOOL for some service users.

WHEN

➢ At initial assessment we should be testing for alcohol, opiates, methadone, Subutex, cocaine, amphetamines and benzodiazepines as a minimum with additional drugs tested as per clinical judgement.
Fortnightly testing thereafter for at least the first three months (or until stable). Testing should take place even if the service user has disclosed opiate use and should include alcohol, opiates (recently there has been no opiate in some of the substance sold as heroin) & benzodiazepines with additional drugs tested as per clinical judgement.

Monthly testing of stable service users on daily supervised consumption with testing for alcohol, opiates & benzodiazepines and random testing of other drugs as per clinical judgement.

Bi-monthly or Quarterly testing of service users on unsupervised consumption who are stable and whose behaviour and presentation are within the expected norms. Testing for the prescribed medication, alcohol, opiates & benzodiazepines and random testing of other drugs as per clinical judgement.

Ad hoc testing of service users where presentation/behaviour is a change from the norm for that person or when life circumstances raise concern over stability. Testing for prescribed medication, alcohol, opiates & benzodiazepines and other drugs as per clinical judgement.

As requested by a Probation Order.

As requested by a service user (to aid motivation or for proof of abstinence for social services).

TESTING METHOD

Urine testing should be undertaken as a first line choice because it provides test results at the time of contact with the service user. However, in some instances, oral mouth swabbing may be indicated as first line; particularly if the service user is taking a prescribed, or over the counter opiate, that is indistinguishable from Heroin on instant urine testing, or if the service user claims infrequent Heroin use, but always tests opiate positive on urine screening. Also, oral swabbing should be used, when there is suspicion that an ingenuine urine sample has been provided.

Please note that all future testing events should include alcohol testing and must be done on a quarterly basis as a minimum as per Orange Guidelines. All testing and DISCLOSED substances must be added to the BOMIC record as promptly as possible after the event.

REFERENCES


Lincolnshire Partnership NHS Foundation Trust, (March 2012) Drug and Alcohol Recovery Team Operational Protocol


REVIEW DATE: APRIL 2017
DEXAMFETAMINE PRESCRIBING PROTOCOL

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PRESCRIBING DEXAMFETAMINE AS PART OF A TREATMENT PACKAGE

Like any drug takers who present to Lincolnshire Partnership Foundation Trust (LPFT) Drug and Alcohol Recovery Team (DART), service users with significant problems caused by taking illicit amphetamine require full assessment and a treatment response, which as far as possible, matches their needs. This may include: advice, education and psychotherapeutic interventions for the amphetamine user; family members may also require advice, education and support. In certain circumstances there is also a rationale for substitution therapy, with prescribed dexamfetamine sulfate as part of a package of treatment. However, the evidence for the effectiveness of prescribed amphetamine is limited to a few uncontrolled studies. Whilst the thin evidence base makes it appropriate to have a high threshold for prescribing dexamfetamine, it is also true that sparsity of evidence reflects a lack of enthusiasm to research substitute amphetamine prescribing, based on the misconception that stimulant drugs, including amphetamine, cause a lesser ‘addiction’ than do depressant drugs. It is important that the limited evidence for effectiveness is not invariably aligned to an expectation of perfect compliance with substitute dexamfetamine i.e. no use of illicit amphetamine. This may preclude discussion of such ongoing use and thereby, may hinder concurrent psychological approaches to help service users to desist from illicit use.

FEATURES THAT SUGGEST SUBSTITUTE PRESCRIBING MAY BE APPROPRIATE

Prescription of dexamfetamine may be appropriate if the service user’s history includes all of the following features:

- Considerable problems directly, or indirectly caused by amphetamine. (These may be in the realms of physical or psychological health, relationships, childcare, employment, finances, criminality or accommodation. Injecting amphetamine directly contributes to problems, but also is a reflection on appetite for amphetamine and its prioritisation over other activities and over responsibilities which leads to indirectly amphetamine-related problems. A level of amphetamine problems indicative of dexamfetamine prescribing will usually include problems at least part attributable to injecting).

- Illicit amphetamine is taken regularly, but not necessarily daily. (Occasional days without illicit amphetamine need not undermine the rationale for a daily dexamfetamine prescription, particularly if such breaks occur only because of factors such as loss of supply, lack of money, incarceration etc. Predictable, intermittent illicit amphetamine use e.g. problematic weekend use, might very occasionally provide a rationale for an intermittent, usually weekend, substitute dexamfetamine prescription).

- Long history; usually the service user has taken amphetamine daily, or near daily, for at least the last 2 years.

- Lack of success at ceasing to take amphetamine for significant periods of time.

- Strong evidence that the service user has fully engaged in psychosocial interventions and these have not been significantly beneficial

- There is evidence of good motivation and likely compliance.
Heavy or escalating use, tolerance and craving are features that in themselves should not influence the decision to prescribe. However, they are likely to be positively associated with the level of amphetamine related problems and hence, will be common features of service users for whom dexamfetamine prescriptions are provided.

**CONTRAINDICATIONS TO PRESCRIBING**

- History of severe mental illness
- Significant, concurrent alcohol or other drug-related problems (Being prescribed an opioid substitute is not a contraindication, but use of other opiates/opioids on top of such a prescription is a contraindication to prescribing dexamfetamine).
- Hypertension/blood pressure controlled by anti-hypertensives
- Cardiovascular illness
- Pregnancy (A short term reducing prescription to assist rapid attainment of abstinence, may be appropriate as an in-patient, but maintenance prescribing in any part of pregnancy is not advised because of the risks to the foetus).
- An erratic, stop-start pattern of illicit amphetamine use, with breaks in use, despite ongoing availability
- Pattern of dangerous, reckless or violent behaviour whilst intoxicated with amphetamine

**TREATMENT GOALS**

- To reduce / stop the use of ‘street’ amphetamine
- To reduce / stop injecting
- To encourage a more stable way of life (stabilisation indicators as for substitute opiate prescribing)

**TREATMENT PATHWAY TO DEXAMFETAMINE PRESCRIBING**

Any service user of DART, who appears to fulfil criteria for a dexamfetamine prescription, should be discussed with the DART medical lead. If the medical lead considers a dexamfetamine prescription may be indicated, a full assessment by the medical lead is arranged. The medical lead will set up the treatment contract and will initiate the prescription and provide follow-up appointments. The medical lead will receive feedback from the recovery nurse at a frequency determined by the complexity of the case, but at least every 3 months and will fully reassess the service user if discussions at feedback suggest a need for this.
PRESCRIBING: SUITABLE PREPARATIONS, INITIATION, DOSAGE AND SUPERVISION

The dose should be the minimum sufficient to attain the treatment goals. It should be sufficient to minimise desire to take illicit amphetamine and in many cases it will be sufficient to induce intoxicating effects.

Dexamfetamine Sulfate is prescribed as a liquid elixir or as a suspension (1mg/1ml).

The starting dose is usually the anticipated therapeutic dose (no ‘titration’), particularly if the first dose can be observed by the prescriber. There is no strict maximum dose; generosity is facilitated by evidence that deaths related to dexamfetamine or to ‘street’ amphetamine are extremely rare. However, if consumption is not supervised, doses in excess of 100mg daily should rarely be prescribed.

Reported level of previous illicit use is only a rough guide to the level of substitute prescribing because of different treatment goals (a detoxification may start from a lower dose than the estimated average street use), and individualised treatment contracts (more generous prescribing may be associated with higher frequency of contact and a strict contract), and because of the inherent uncertainty about purity and variations in day to day illicit use. These factors make it necessary to have a high frequency of early follow up appointments between the service user and the medical lead (prescriber) and this applies not only in rare cases initiated with a formal plan to titrate the dosage, but in all cases.

Doses are usually prescribed for once daily consumption, but service users who do not have supervised consumption may split their daily dose. If this is associated with attainment of treatment goals it need not be discouraged.

DISPENSING

Daily dispensing will only be relaxed if it is a clear impediment to other activities, particularly employment. Supervised consumption may be indicated, particularly at higher daily doses, or if there are difficulties in monitoring frequently through mouth swab or urine testing. However, supervised consumption may undermine compliance because the pleasure derived from taking amphetamine is usually very context dependant.

REGIMES: SHORT TERM REDUCTION AND LONGER TERM PRESCRIBING

The aim of longer term prescribing is to help reduce, ideally eliminate, amphetamine related problems and, eventually, to taper the dose to achieve abstinence. The rate of reduction should be negotiated according to individual characteristics.

It is reasonable to stop a dexamfetamine prescription abruptly, particularly from a low (<30mg daily) dose, if the service user is judged sufficiently motivated and supported to endure the effects of sudden withdrawal without restarting illicit amphetamine use, or substituting to other psychoactive substances, however, this is a very uncommon clinical scenario.

A dexamfetamine prescription should be stopped abruptly if treatment goals are not achieved. Ideally, cessation of the prescription should be preceded by discussion on this issue between service user, recovery nurse and medical lead (prescriber).

Given the indications for prescribing, most prescriptions will be long term. However, because of the considerable uncertainty over the benefits of prescribing, the plan/contract with each service user should tie the continuation of the prescription not only to unequivocal evidence of ongoing benefits attributable to the
prescribing, but also to evidence that these benefits would be lost if the service user was weaned from the prescription.

**MONITORING AND EVALUATION**

Service users should be seen at least once a fortnight by their recovery nurse and evaluation should include the following:

- Injection behaviour
- Mental state
- Blood pressure
- Weight and diet
- Sporadic testing, which can distinguish between prescribed dexamfetamine and ‘street’ amphetamine (I to d isomer ratio)
- Lifestyle: stability of relationships, involvement in non-drug related interests, training, education and work, parenting, criminality.

**TESTING**

Conventional dipstick and laboratory tests do not differentiate between prescribed and illegally manufactured amphetamine. Given the sparsity of evidence for the efficacy of substitute dexamfetamine prescribing, it is vital to very closely monitor progress to justify the continuation of a dexamfetamine prescription.

Isomer testing can differentiate legally and illegally manufactured amphetamine. This testing is available at the clinical chemistry laboratory at Queens Medical Centre (QMC). Each resource centre has bottles, labels and packaging for postage of urine samples to QMC.

Amphetamine Sulphate contains l, (laevo) and d, (dex) isomers. The d isomer is about twice as potent as the l isomer. Prescribed dexamfetamine, as its name suggests, almost entirely consists of the d isomer. The potency of illegally manufactured amphetamine varies with its purity (usually in the range 2-10%) and with the proportions of the l and d isomer (often it contains about equal amounts of l and d isomer).

The markedly different proportions of l and d isomer in legally and illegally manufactured amphetamine allows isomer testing to be helpful in establishing if a ‘street’ supply has been taken in addition to a dexamfetamine prescription.

The QMC laboratory reports the relative quantities of the isomers as a decimal. A report of 0.5 indicates 50 parts l to 100 parts d; which is the same as an l to d ratio of 1:2, or a d content of 67%. The laboratory states that a result higher than 0.3 indicates illicit use. Given that the maximum proportion of l isomer in prescription dexamfetamine is not quoted, it is not possible to form an opinion on how ‘generous’ is 0.3 as a threshold for suspicion of illicit use. However, a ‘ratio’ of less than 0.1 is sometimes reported, hence, unless there is at least a threefold variation in isomer content between batches of dexamfetamine, the cut off is ‘generous’ and a reported ‘ratio’ just below 0.3 should raise suspicions about illicit use, especially if the result is for a service user on a high dose prescription (the higher the prescribed dose, the less is the influence of a given amount of illicit amphetamine on the ‘ratio’).
Illicit use will be less influential on the isomer test result and hence, becomes more difficult to detect if:

- The service user is on a large prescription
- The service user takes small amounts/low percentage purity illicit amphetamine
- The service user takes high quality (low l to d ratio) illicit amphetamine
- The timing of prescribed and illicit use results in mostly prescribed dexamfetamine in circulation over the period during which the urine was produced. This is almost always a consequence of prescription dexamphetamine having been taken since last illicit use.

**CONCURRENT PRESCRIBING**

Concurrent prescribing is a matter for the medical management of each individual case. Many people who take amphetamine also take benzodiazepines and other tranquillisers or hypnotics to help them sleep, or to otherwise cope with a 'come down', although most of the service users who meet the LPFT DART criteria for a dexamfetamine prescription will have sufficiently adapted to the effects of dexamfetamine for 'come downs' and sleep problems to no longer be issues. Nevertheless, it is worth emphasising that, Illicit supplies of these drugs cannot be differentiated from an on-going prescribed supply by any form of testing. Therefore, prescribing tranquillisers to amphetamine users with known illicit supplies of tranquillisers results in dual supplies, potential for heavier use, no benefit and no test results on which to base sanctions.

SSRI antidepressants may enhance dexamfetamine intoxication, including the experience of psychotic symptomatology and confusion. Hence, SSRIs should be avoided.

On commencing a dexamfetamine prescription, the DART medical lead will inform the service user's general practitioner of this, and may request to take over the prescriptions for any other psychotropic medications.

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Standard Operating Procedure

Disposal of Pharmaceutical Products and Containers Contaminated with Pharmaceutical Products
1. Introduction:

Purpose of the procedure

1.1 The purpose of this procedure is to ensure that all Lincolnshire Partnership NHS Foundation Trust (LPFT) employees are aware of and compliant with the appropriate pharmaceutical waste regulations set out in the Department of Health Guidance “Safe Management of Healthcare Waste version 2” and the Trust’s “Medicines Management and Medical Devices” policy.

Relevant staff

1.2 Pharmacy staff who have clinical responsibilities.

1.3 Nursing staff and other allied health professionals who handle and need to dispose of unwanted pharmaceutical products or containers contaminated with pharmaceutical products.

1.4 Support staff (e.g. ward clerks) who will be involved with the pharmaceutical waste contract and contractor.

Responsibilities

1.5 The Medicines Management Link Nurse and Unit Manager have joint overall responsibility for ensuring that all unit staff are aware of and adhere to the current pharmaceutical waste regulations within their clinical setting.

1.6 All ward staff who handle medicines must dispose of pharmaceutical waste appropriately.

1.7 The nominated Pharmacy Technician has overall responsibility for ensuring that their designated area(s) are compliant with the current pharmaceutical waste regulations. They also have overall responsibility for ensuring that all pharmaceutical products are destroyed or returned correctly.

1.8 The nominated Pharmacy Assistant is responsible for ensuring that all pharmaceutical products are destroyed or returned correctly (see section “Procedure for LPFT pharmacy staff” for exemptions) for all areas that they cover.

1.9 The nominated Pharmacist will support the Pharmacy Technician and Pharmacy Assistant with all aspects of pharmaceutical waste.

Definitions

1.10 Any pharmaceutical product that cannot be reused or a container that is contaminated with a pharmaceutical product is classed in the current guidelines as pharmaceutical waste.

1.11.1 A “container” referred to in this procedure means a container contaminated with pharmaceutical waste including, but not limited to, the following:

- Empty blister packs/strips
- Empty inhaler cartridges/capsules
- Empty liquid bottles
- Empty tablet bottles
- Empty tubes/pots that are contaminated with an external product
- Enema container
- Pessary applicator
- Suppository packaging
• Used ampoules/vials
• Used eye/ear/nose drop bottles
• Used injection syringes
• Used liquid measuring pots
• Used minims
• Used oral syringes
• Used patches
• Used enema tube

1.11.2 A “pharmaceutical product” or “medication” mentioned in this procedure includes the following, but is not limited to, the following forms:
  • Aerosols
  • Capsules
  • Creams/ointments/topical solutions
  • Enemas
  • Eye/ear/nose drops/sprays
  • Inhalers (cartridges/capsules)
  • Injections
  • Liquids
  • Minims
  • Patches
  • Pessaries
  • Suppositories
  • Tablets

1.11.3 Dietetic products (e.g. Fresubin, Fortisip and Ensure Plus) are not classified as pharmaceutical products and therefore should not be disposed of as pharmaceutical products and are not included in this document.

1.12 A “unit” or “ward” mentioned in this procedure refers to an inpatient ward or a community team.

1.13 An LPFT team that is located within a premise that is attached to or adjacent to a ULHT (United Lincolnshire Hospitals Trust) site is termed within this procedure as being a ULHT site. This does not apply to teams attached to or adjacent to the Grantham hospital site, as the ULHT pharmacy does not provide a service to LPFT teams in this area.

1.14 An LPFT team that is located within a premise that is not attached or adjacent to a ULHT site is termed within this procedure as being a non-ULHT site.

2. Types of bin

2.1 There are three types of pharmaceutical waste bins that are to be used by LPFT for the disposal of pharmaceutical waste and also unwanted pharmaceutical products.

2.2.1 30 and 50 litre green plastic bins (green bins): are to be used for the majority of pharmacy waste. All pharmaceutical products and containers contaminated with a pharmaceutical product that are not: a sharp, contaminated with a bodily fluid or cytotoxic/cytostatic will go in the green bin.
2.2.2. 2.5 litre yellow bins with purple lid (purple lidded bins) are for all products (including sharps/contaminated with bodily fluids) that are either cytotoxic or cytostatic.

2.2.3 Yellow bins with yellow lids (yellow lidded bins) are for all pharmaceutical products (with the exception of cytotoxic/cytostatic products) that are classed as a sharp or have been contaminated with bodily fluids.

### 3. Procedure – ward/ community team staff

Please read the appropriate section(s) when disposing of a pharmaceutical product or container contaminated with a pharmaceutical product.

#### 3.1 Empty containers

All empty containers that have been contaminated with a pharmaceutical product must be disposed of by placing them in the most appropriate pharmaceutical waste bin. Under no circumstances should liquid bottles be rinsed prior to placing them in the appropriate bin.

#### 3.2 Part used pharmaceutical products

All pharmaceutical products that are no longer required should be removed from the medication trolley/medication locker and placed in the pharmacy returns cupboard for pharmacy staff to dispose of.

##### 3.3.1 Full boxes (excluding Patient’s own medication)

All pharmaceutical products that are no longer required but have not been opened should be removed from the medication trolley/medication locker/medication cupboard and placed in the pharmacy returns cupboard for pharmacy staff to return to ULHT pharmacy for credit.

##### 3.3.2 Flu vaccines which are no longer required or out of date should be disposed of via the yellow lidded yellow medicinally contaminated sharps bin.

#### 3.4 Patients’ own medication

4.1 All patients’ own medication that has been brought into an LPFT premise should be documented on the approved LPFT patients’ own medication return form (PATRET) and consent for using or disposing of the medication should ideally be sought by the patient or carer. Suitability of patients own medication must be approved for use by nursing or pharmacy staff prior to being used.

4.2 All patients’ own medication that has been approved for use but is no longer prescribed should be removed from the medication trolley/medication locker/medication cupboard and placed in the pharmacy returns cupboard for pharmacy staff to dispose of. Prior to being disposed of the medication must be documented on a PATRET form (see 3.4.1).

4.3 All patients’ own medication that has not been approved for use or is not required (e.g. out of date, not in original container) should be placed in the pharmacy returns cupboard for pharmacy staff to dispose of. Prior to being disposed of the medication must be documented on a PATRET form (see 3.4.1).

#### 3.5 Refused/rejected pharmaceutical products prepared for administration

5.1 All pharmaceutical products that have been prepared for administration and subsequently have either been refused or rejected (e.g. spat out) must be disposed of by placing them in the most appropriate pharmaceutical waste bin.

5.2 All pharmaceutical products that have been prepared but not given should be transported to the appropriate pharmaceutical waste bin for disposal. This applies if the medicine trolley is not being used in the clinical room setting or the medication is not being given in a location near the pharmaceutical waste bin. The container with the unwanted medication should remain supervised at all times e.g. kept in a locked trolley and not be in easy reach of patients.

5.2.1 Solid pharmaceutical products (e.g. tablets/capsules) should be transported in a measuring pot to the appropriate pharmaceutical waste bin for disposal.

5.2.2 Liquid pharmaceutical products (e.g. lactulose) should be put in a measure and cat litter added to absorb all liquid before being disposed of in the appropriate pharmaceutical waste bin.

#### 3.6 Schedule 2 and 3 controlled drugs – prepared doses

Schedule 2 and 3 controlled drugs (CDs) that have been prepared but subsequently not given should be disposed of as per the CD policy. The CD should be denatured by a qualified nurse by placing the CD in hot soapy water, allowing the CD to dissolve (if appropriate), then adding cat litter and placed in the appropriate pharmaceutical waste bin. This process should be witnessed by an authorised person (e.g. an assessed nursing auxiliary). Any CDs prepared but not given should be documented in the CD register, as per CD policy.

#### 3.7 Schedule 2 and 3 controlled drugs – no longer required

Pharmacy staff should be made aware of any schedule 2 and 3 CDs that are no longer required. These can include patients own and stock CDs. Pharmacy staff will either return the CDs to a ULHT pharmacy or denature them on the ward, as per CD policy.

**Under no circumstances should any other staff denature or return CDs.**

#### 3.8 Schedule 2 and 3 controlled drugs – contaminated containers

All empty containers that have a residue of a CD (e.g. patch/liquid container) should have the residue denatured (see section 3.6) prior to being placed in the appropriate pharmaceutical waste bin, as per CD policy.
3.9 **Schedule 4 and 5 controlled drugs – prepared doses**

Schedule 4 and 5 CDs that have been prepared but subsequently not given should be disposed of as per the CD policy. The CD should be denatured by a qualified nurse by placing the CD in hot soapy water, allowing the CD to dissolve (if appropriate), adding cat litter and placed in the appropriate pharmaceutical waste bin. This process should be witnessed by an authorised person (e.g. an assessed nursing auxiliary).

If the ward has documentation for the recording of schedule 4 and 5 CDs, this must be completed appropriately.

3.10 **Schedule 4 and 5 controlled drugs – no longer required**

Schedule 4 and 5 CDs that are no longer required should be placed in the returns cupboard for pharmacy to dispose of.

3.11 **Schedule 4 and 5 controlled drugs – contaminated containers**

All empty containers that have a residue of a CD (e.g. patch/liquid container) should have the residue denatured prior to being placed in the appropriate pharmaceutical waste bin, as per CD policy.

For all sites, Schedule 4 and 5 CDs – contaminated containers should be disposed of in the most appropriate pharmaceutical waste bin (once denatured) on the unit.

### 4. Procedure - LPFT pharmacy staff

Please read the appropriate section(s) when disposing of a pharmaceutical product or container contaminated with a pharmaceutical product

4.1 **Documentation**

All pharmaceutical products (excluding empty containers) that are returned to ULHT pharmacy (for disposal or credit) or disposed of on an LPFT premise must be documented in the approved pharmacy return book, as per pharmacy returns procedure.

All patients own medication must also have a PATRET form completed.

4.2 **Empty containers**

All empty containers that have been contaminated with a pharmaceutical product must be disposed of by placing them in the most appropriate pharmaceutical waste bin. Under no circumstances should liquid bottles be rinsed prior to placing in the appropriate bin.

4.3 **Part used pharmaceutical products**

All pharmaceutical products that are no longer required should be removed from the medication trolley/medication locker and placed in the pharmacy returns cupboard.

4.3.1 **ULHT sites:**

Pharmacy staff should document all medication returned, place in an approved pharmacy bag, seal and deliver personally to ULHT pharmacy. The original copy of the returns paperwork should be sent to ULHT pharmacy with the medication.

4.3.2 **Non-ULHT sites:**

Pharmacy staff should document all medication for disposal and then dispose of in the appropriate pharmacy waste bin. Both copies of the return paperwork stay with the team. Under no circumstances should the medication be taken out of the original container. “Destroyed on ward” must be stated in the returns paperwork.

4.4 **Full boxes (excluding patients’ own medication)**

All pharmaceutical products that are no longer required but have not been opened should be removed from the medication trolley/medication locker/medication cupboard and placed in the pharmacy returns cupboard.

4.4.1 **ULHT sites:**

Pharmacy staff should document all medication returned, place in an approved pharmacy bag, seal and deliver personally to ULHT pharmacy. The original copy of the returns paperwork form should be sent to ULHT pharmacy with the medication. Please ensure that “For Credit” is clearly documented on the returns paperwork.

4.4.2 **Non ULHT sites:**

Pharmacy staff should document all medication returned, place in an approved pharmacy bag/box, seal and leave in a safe and secure place for a driver/porter to take back to ULHT pharmacy. Under no circumstances should pharmacy staff transport in their own vehicle unless they have motor insurance that covers transportation of pharmaceutical products. The original copy of the returns paperwork should be sent to ULHT pharmacy with the medication. Please ensure that “For Credit” is clearly documented on the returns paperwork.

4.4.3 Flu vaccines which are no longer required or out of date should be disposed of via the yellow lidded yellow medicinally contaminated sharps bin.

4.5 **Patients’ own medication.**

4.5.1 All patients’ own medication that has been brought into an LPFT premise should be documented on the approved LPFT PATRET form and consent for using or disposing of the medication should ideally be sought
by the patient or carer. Suitability of patients own medication must be approved for use by nursing or pharmacy staff prior to being used.

4.5.2 All patients’ own medication that has been approved for use but is no longer prescribed should be removed from the medication trolley/medication locker and placed in the pharmacy returns cupboard. Prior to being disposed of the medication must be documented on a PATRET form (see 3.4.1).

4.5.3 All patients’ own medication that has not been approved for use or is not required (e.g. out of date, not in original container) should be placed in the pharmacy returns cupboard. Prior to being disposed of the medication must be documented on a PATRET form (see 3.4.1).

4.5.4 ULHT sites:
Pharmacy staff should document all patients’ own medication returned, place in an approved pharmacy bag, seal and deliver personally to ULHT pharmacy. The original copy of the returns paperwork and the original copy of the PATRET form should be sent to ULHT pharmacy with the medication.

4.5.5 Non ULHT sites:
Pharmacy staff should document all patients’ own medication and dispose of in the appropriate pharmaceutical waste bin. Both copies of the return paperwork and PATRET form stay with the team. “Destroyed on ward” must be stated in the returns paperwork.

4.6 Refused/rejected pharmaceutical products prepared for administration
4.6.1 All pharmaceutical products that have been prepared for administration and subsequently have either been refused or rejected (e.g. spat out) must be disposed of by placing them in the most appropriate pharmaceutical waste bin.

4.6.2 All pharmaceutical products that have been prepared but not given should be transported to the appropriate pharmaceutical waste bin for disposal. This applies if the medicine trolley is not being used in the clinical room setting or the medication is not being given in a location near the pharmaceutical waste bin. The container with the unwanted medication should remain supervised at all times e.g. kept in a locked trolley and not be in easy reach of patients.

4.6.2.1 Solid pharmaceutical products (e.g. tablets/capsules) should be transported in a measuring pot to the appropriate pharmaceutical waste bin for disposal.

4.6.2.2 Liquid pharmaceutical products (e.g. lactulose) should be put in a measure and cat litter added to absorb all liquid before being disposed of in the appropriate pharmaceutical waste bin.

4.6.3 For all sites, refused or rejected pharmaceutical products should be disposed of in the most appropriate pharmaceutical waste bin on the unit.

4.7 Schedule 2 and 3 controlled drugs – prepared doses
Schedule 2 and 3 CDs that have been prepared but subsequently not given should be disposed of as per the CD policy. The CD should be denatured by a qualified nurse by placing the CD in hot soapy water, allowing the CD to dissolve (if appropriate), then adding cat litter and placed in the appropriate pharmaceutical waste bin. This process should be witnessed by an authorised person (e.g. an assessed nursing auxiliary). Any CDs prepared but not given should be documented in the CD register, as per CD policy.

4.7.1 For all sites, prepared doses of schedule 2 and 3 CDs should be denatured as per CD policy on the unit.

4.8 Schedule 2 and 3 controlled drugs – no longer required
Pharmacy staff should be made aware of any schedule 2 and 3 CDs that are no longer required. These can include patients own and stock CDs.

4.8.1 ULHT sites:
All schedule 2 and 3 CDs that are no longer required should be returned to ULHT pharmacy by either a pharmacy technician or a pharmacist. The CDs should be signed out of the CD register as per the CD policy. The following paperwork should be completed: returns paperwork (original copy should go to ULHT pharmacy), PATRET form (if patients’ own medication) and CD disposal receipt form (ULHT can have a copy but original should be sent to LPFT Chief Pharmacy Technician).

4.8.2 Non ULHT sites:
Wherever possible all schedule 2 and 3 CDs that are no longer required should be returned to a ULHT pharmacy. ULHT have given approval for all CDs from all LPFT sites to be returned to a ULHT pharmacy. All schedule 2 and 3 CDs that are no longer required should be returned to ULHT pharmacy by either a Pharmacy Technician or a Pharmacist. The CDs should be signed out of the CD register as per the CD policy. The following paperwork should be completed: returns paperwork (original copy should go to ULHT pharmacy), PATRET form (if patients’ own medication) and CD disposal receipt form (ULHT can have a copy but original should be sent to LPFT Chief Pharmacy Technician).

If the CDs cannot be returned to a ULHT pharmacy, the CDs should be denatured by either a pharmacy technician or a pharmacist on the unit using a DOOP kit or cat litter, as per policy. The denatured CD should then be placed in the appropriate pharmaceutical waste bin. “Destroyed on ward” must be stated in the returns paperwork.

Denaturing on the ward should only be done in extreme circumstances.

Under no circumstances should any other staff denature or return CDs.

4.9 Schedule 2 and 3 controlled drugs – contaminated containers
All empty containers that have a residue of a CD (e.g. patch/liquid container) should have the residue denatured prior to being placed in the appropriate pharmaceutical waste bin, as per CD policy.
For all sites, Schedule 2 and 3 CDs – contaminated containers should be disposed of in the most appropriate pharmaceutical waste bin (once denatured) on the unit.

4.10 Schedule 4 and 5 controlled drugs – prepared doses
Schedule 4 and 5 CDs that have been prepared but subsequently not given should be disposed of as per the CD policy. The CD should be denatured by a qualified nurse by placing the CD in hot soapy water, allowing the CD to dissolve (if appropriate), adding cat litter and placed in the appropriate pharmaceutical waste bin. This process should be witnessed by an authorised person (e.g. an assessed nursing auxiliary).
If the ward has documentation for the recording of schedule 4 and 5 CDs, this must be completed appropriately.
For all sites, Schedule 4 and 5 CDs should be disposed of in the most appropriate pharmaceutical waste bin (once denatured) on the unit.

4.11 Schedule 4 and 5 controlled drugs – no longer required
Schedule 4 and 5 CDs that are no longer required should be placed in the returns cupboard for pharmacy staff to dispose of.

4.11.1 ULHT sites
Pharmacy staff should document all medication returned, place in an approved pharmacy bag, seal and deliver personally to ULHT pharmacy. The original copy of the returns paperwork should be sent to ULHT pharmacy with the medication.

4.11.2 Non ULHT sites
Pharmacy staff should document all medication and then schedule 4 and 5 CDs should be denatured by using cat litter or in a DOOP kit (if appropriate). Once denatured, dispose of in the appropriate pharmacy waste bin. “Destroyed on ward” must be stated in the returns paperwork.

4.12 Schedule 4 and 5 controlled drugs – contaminated containers
All empty containers that have a residue of a CD (e.g. patch/liquid container) should have the residue denatured prior to being placed in the appropriate pharmaceutical waste bin, as per CD policy.
For all sites, Schedule 4 and 5 CDs – contaminated containers should be disposed of in the most appropriate pharmaceutical waste bin (once denatured) on the unit.

4.13 Deviation from procedure
If there is any deviation from this procedure remedial action (e.g. place incorrectly segregated empty container in correct pharmaceutical waste bin) should be taken to ensure compliance if safe to do so.

The following steps should be taken:

<table>
<thead>
<tr>
<th>First deviation from procedure</th>
<th>Team manager or Medicine Management Link Nurse informed and correct procedure communicated to unit staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Second deviation from procedure</td>
<td>Contact pharmacy lead for waste (Gary Jacobs)</td>
</tr>
<tr>
<td>Third deviation from procedure</td>
<td>Bespoke local training should be given</td>
</tr>
<tr>
<td>Fourth deviation from procedure</td>
<td>Datix report should be completed</td>
</tr>
</tbody>
</table>

Any deviation from procedure must be reported to the medicine management link nurse or team manager.

5. Pharmaceutical waste bins – 30/50 litre green bin and green metal outer bin

5.1 Green metal outer bin
5.1.1 All ward teams with the exception of Long Ley Court Bungalows, Francis Willis Unit and Ash Villa will have a green metal outer bin (outer bin) to house the 50 litre green plastic bins (green bin).
5.1.2 All outer bins must be kept locked at all times. One key must be kept with the medication keys and the spare key(s) should Ideally be kept with the spare medication keys.
5.1.3 All green metal outer bins must be kept in the clinic room with no unsupervised patient access.
5.1.4 Whilst using the outer bin, the lid to the green bin must be placed within the outer bin.
5.1.5 When ready for collection, the lid should be placed securely on the green bin.

5.2 30/50 litre green bins
5.2.1 The waste contractor will provide all green bins and under no circumstances should the units order their own green bins. If additional bins are required, these should be ordered via the pharmacy department.
5.2.2 To assemble the green bin, the lid must be securely fastened on top of the bin so that it cannot be removed. Ensure that the porthole lid is always kept in the temporary closed position when not in use. Under no circumstances should it be removed from the bin on a permanent basis.
5.2.3 All 30 or 50 litre bins that are in use must be kept in a locked area with no unsupervised patient access such as the clinic room.
5.2.4 Where units have more than one green bin, any full bins must be sealed, the porthole lid depressed and locked in place and stored in a locked area with no patient access such as the clinic or sluice room. Ensure that the location of full green bins is known to and collected by the waste contractor.
5.2.5 Do not over-fill a green bin. If a bin is full before the next collection is due and there is no spare bin, contact pharmacy to arrange delivery of further green bins.


6.1 The waste contractor will provide all yellow bins with purple lids and under no circumstances should the units order their own bins. If additional bins are required, these should be ordered via the pharmacy department.

6.2.1 To assemble the bin, the lid must be securely fastened on top of the bin so that it cannot be removed.

6.2.2 Immediately upon assembly, the assembler must complete the “Assembled by”, the “Hospital”, “Area/Dept/Ward” and “Date” sections on the bin label.

6.2.3 The lid opening should remain in the temporary closed position except whilst in use.

6.3.1 The lid opening should only be in the permanent closed position when full or being collected by the waste contractor.

6.3.2 Immediately upon permanent closure, the member of staff who closed the bin must complete the “Closed/Disposed by” and “Date” sections on the bin label.

6.4 All purple lidded yellow bins that are in use must be kept in a locked area with no unsupervised patient access such as the clinic room.

6.5 Where units use more than one yellow bin with purple lid, any full bins must be sealed and stored in a locked area with no patient access such as the clinic or sluice room. Ensure that the location of full bins is known to and collected by the waste contractor.

6.6 Do not over-fill a yellow bin with purple lid. If a bin is full before the next collection is due and there is no spare bin, contact pharmacy to arrange delivery of further yellow bins with purple lids.

6.7 To be compliant with current guidelines and best practice yellow bins with purple lids will be collected once a year by the waste contractor.

6.8 To be compliant with current guidelines every time a yellow bin with purple lid is collected, a hazardous waste consignment note has to be completed. This is completed by the waste contractor.

7. Yellow bins with yellow lids

7.1 Yellow bins with yellow lids are not included in the pharmaceutical waste contract and are part of the clinical waste contract. Please see the clinical waste policy for all operational aspects pertaining to these bins.

8. Collection of pharmaceutical waste

8.1 The healthcare waste contractor will visit each premise on the designated day within normal working hours.

8.2 Any alteration to the collection frequency or the supply of bins to any unit must only be done by the designated people (Gary Jacobs, Richard Brooks or Shiraz Haider).

8.3 The waste contractor will always carry photographic identification. If this is not provided, entry to the unit should be refused.

8.4 The driver will permanently close the porthole lid, if not already done so, before removal of the bin from LPFT premises.

8.5 The driver will collect bins from the designated storage area only.

8.6 The driver should present the collection paperwork to any qualified nurse or any of the designated unit staff members (Unit Manager, Unit Medicines Management Link Nurse and Ward Clerk) for signature.

8.7 The paperwork must not be altered by the driver. Any alterations can be made by the designated staff members only.

9. Paperwork and posters

9.1 Waste contractors are obliged by law under section 34 of the Environmental Protection Act 1990, to produce paperwork when collecting clinical and pharmaceutical waste from a waste producer.

9.2.1 Under the regulations, a Controlled Waste Transfer Note (CWTN) must be produced and handed to the waste producer upon collection of a green bin containing pharmaceutical waste.

9.2.2 CWTNs must be stored safely, in date order and for two years from the date of issue as the Environment Agency can impose fines if CWTNs are missing.

9.3.1 Under the regulations, a Hazardous Waste Consignment note must be produced and handed to the waste producer upon collection of a purple lidded yellow cytotoxic/cytostatic bin.

9.3.2 HWGCNs must be stored safely, in date order and for three years from the date of issue as the Environment Agency can impose fines if HWGCNs are missing.

9.4.1 All teams that use a green pharmaceutical waste and purple lidded cytotoxic/cytostatic waste bin must display the appropriate “Pharmaceutical Waste” and “Pharmaceutical Waste Bins” posters and a poster detailing that plastic drinks cups should not be placed in the pharmaceutical waste bin, near to the bin.
9.4.2 All teams must have the “Information for Pharmacy Staff” document stored in the pharmacy returns cupboard or in the clinic pharmacy folder.

10. Audit procedure

10.1 A pharmacy waste audit will be carried out by a designated member of the pharmacy team on a 3 monthly basis to ensure that standards are being met.

10.2 The audit tool (Appendix A) will be used to assess the current standards against the agreed standards in the SOP.

10.3 The audit will be carried out by LPFT band 5 Pharmacy Technicians or persons designated by the LPFT band 6 Pharmacy Technician responsible for pharmaceutical waste.

10.4 An audit report will be issued to each team upon completion of the audit detailing areas of non-compliance and a plan with a defined time frame to ensure compliance is achieved.
Pharmaceutical Waste Audit Tool
Complete one form for each ward/team.

<table>
<thead>
<tr>
<th>Question Number</th>
<th>SOP Reference</th>
<th>Criteria</th>
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<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>4.3, 4.5, 4.8, 4.11</td>
<td>Is all unwanted medication returned to ULHT pharmacy for disposal (as per policy)?</td>
<td>☐ Please go to Q1d</td>
<td>☐ Please go to Q1b</td>
<td></td>
</tr>
<tr>
<td>1b</td>
<td></td>
<td>Is all unwanted medication destroyed on site?</td>
<td>☐ Please go to Q1e</td>
<td>☐ Please go to Q1f</td>
<td></td>
</tr>
<tr>
<td>1c</td>
<td></td>
<td>What happens to unwanted medication? Please state:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1d</td>
<td>4.3, 4.5, 4.8, 4.11</td>
<td>Is this task done by LPFT pharmacy staff</td>
<td>☐ Please go to Q1f</td>
<td>☐ Please go to Q1e</td>
<td></td>
</tr>
<tr>
<td>1e</td>
<td></td>
<td>Is this task done by ward/team staff?</td>
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<td>☐</td>
<td></td>
</tr>
<tr>
<td>1f</td>
<td>3.2, 3.3, 3.4, 3.10</td>
<td>Is all unwanted medication placed in the returns cupboard?</td>
<td>☐ Please go to Q1g</td>
<td>☐ Please go to Q1h</td>
<td></td>
</tr>
<tr>
<td>1g</td>
<td></td>
<td>Is the returns cupboard locked at all times?</td>
<td>☐ Please go to Q1i</td>
<td>☐ Please go to Q1i</td>
<td></td>
</tr>
<tr>
<td>1h</td>
<td></td>
<td>Where is the unwanted medication stored? Please state:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1i</td>
<td>4.4</td>
<td>Is all suitable medication returned to ULHT pharmacy for credit?</td>
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<td>☐</td>
<td></td>
</tr>
<tr>
<td>1j</td>
<td>4.1</td>
<td>Does the team have an approved pharmacy returns book?</td>
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<td>☐</td>
<td></td>
</tr>
<tr>
<td>1k</td>
<td>4.1</td>
<td>Is the approved pharmacy returns book completed in accordance with the SOP?</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
</tbody>
</table>

LPFT teams based on ULHT sites, please start at question 1.
LPFT Teams not based on ULHT sites, please start at question 2.
<table>
<thead>
<tr>
<th>Question Number</th>
<th>SOP Reference</th>
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<td>Is there evidence that schedule 4 and 5 CDs are being denatured in accordance with the SOP?</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>1m</td>
<td></td>
<td>Is it documented on the approved pharmacy returns book that schedule 4 and 5 CDs have been denatured?</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>1n</td>
<td>4.5</td>
<td>Is a PATRET form completed for all patients’ own medication?</td>
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<td></td>
</tr>
<tr>
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<td></td>
<td><strong>Please go to Question 3</strong></td>
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### 2 Non-ULHT Site Specific Requirements

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<tr>
<th>2a</th>
<th>4.3, 4.5, 4.8, 4.11</th>
<th>Is all unwanted medication destroyed on the ward (as per policy)?</th>
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<th>Please go to Q2b</th>
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</thead>
<tbody>
<tr>
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<td>Is all unwanted medication returned to ULHT pharmacy for disposal?</td>
<td>Please go to Q2d</td>
<td>Please go to Q2b</td>
</tr>
<tr>
<td>2c</td>
<td></td>
<td>What happens to unwanted medication? Please state:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2d</td>
<td>4.3, 4.5, 4.8, 4.11</td>
<td>Is this task done by LPFT pharmacy staff?</td>
<td>Please go to Q2e</td>
<td>Please go to Q2e</td>
</tr>
<tr>
<td>2e</td>
<td></td>
<td>Is this task done by ward/team staff?</td>
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<tr>
<td>2f</td>
<td>3.2, 3.3, 3.4, 3.10</td>
<td>Is all waste medication placed in the returns cupboard?</td>
<td>Please go to Q2i</td>
<td>Please go to Q2i</td>
</tr>
<tr>
<td>2g</td>
<td></td>
<td>Is the returns cupboard locked at all times?</td>
<td>Please go to Q2i</td>
<td>Please go to Q2i</td>
</tr>
<tr>
<td>2h</td>
<td></td>
<td>Where is the unwanted medication stored? Please state:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2i</td>
<td>4.4</td>
<td>Is all suitable medication returned to ULHT pharmacy for credit?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2j</td>
<td>4.1</td>
<td>Does the team have an approved pharmacy returns book?</td>
<td></td>
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<tr>
<td>2k</td>
<td>4.3, 4.1</td>
<td>For medication destroyed on the unit, does it state this on the approved pharmacy returns book?</td>
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<td></td>
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<tr>
<td>Question Number</td>
<td>SOP Reference</td>
<td>Criteria</td>
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</tr>
<tr>
<td>2l</td>
<td>4.1</td>
<td>Is the approved pharmacy returns book completed in accordance with the SOP?</td>
<td></td>
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</tr>
<tr>
<td>2m</td>
<td>4.9, 4.10,4.11</td>
<td>Is there evidence that schedule 4 and 5 CDs are denatured in accordance with the SOP?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2n</td>
<td>4.11</td>
<td>Is it documented on the approved pharmacy returns book that schedule 4 and 5 CDs have been denatured?</td>
<td></td>
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<tr>
<td>2o</td>
<td>4.5</td>
<td>Is a PATRET form completed for all patients’ own medication?</td>
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<tr>
<td>3</td>
<td></td>
<td><strong>Bin Compliment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3a</td>
<td>5.1</td>
<td>Does the unit have a 50 or 30 litre bin?</td>
<td></td>
<td></td>
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<tr>
<td>3b</td>
<td>5.1</td>
<td>Does the unit have a green metal outer bin?</td>
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<tr>
<td>4</td>
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<td><strong>Bin Compliment – Green Metal Outer Bin</strong></td>
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<tr>
<td>4a</td>
<td>5.1.2</td>
<td>Is the bin kept locked at all times?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4b</td>
<td>5.2.3</td>
<td>Is the bin located in the clinic room?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4c</td>
<td></td>
<td>If not kept in the clinic room then, where is the bin located? Please specify:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4d</td>
<td></td>
<td>Does the unit have a key for the green metal outer bin?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4e</td>
<td></td>
<td>Is the bin kept clean and tidy?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4f</td>
<td></td>
<td>Does the green metal outer bin bear the correct PHS label</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- “Nominal Capacity 50 Litres”</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- “Suitable for liquid pharmaceuticals in original packaging up to 500ml.”</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- “All waste must be in original packaging, e.g. blister packs and bottles except for prepared doses”</td>
<td></td>
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</tr>
<tr>
<td>4g</td>
<td></td>
<td>Does the green metal outer bin bear the sticker “FOR MEDICATION AND CONTAINERS CONTAMINATED WITH MEDICATION”?</td>
<td></td>
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<tr>
<td>4h</td>
<td>5.1.1</td>
<td>Is there a 50 litre green plastic bin situated within the metal outer bin?</td>
<td></td>
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<td>4i</td>
<td>2.1.3</td>
<td>Is the black lid placed within the green metal outer bin?</td>
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<tr>
<td>Question Number</td>
<td>SOP Reference</td>
<td>Criteria</td>
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<tr>
<td>-----------------</td>
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<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>4j</td>
<td></td>
<td>Does the bin <em>only</em> contain unwanted pharmaceuticals and contaminated containers compliant with the SOP?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4k</td>
<td></td>
<td><strong>Does the green bin contain the following?</strong></td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Plastic/paper drinking cups</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Outer packaging (cardboard, plastic, plastic film)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Paper towel waste</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td></td>
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<td>Dietetic products</td>
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<td>☐</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Waxed tablet pots</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Needles</td>
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<tr>
<td></td>
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<td>Objects contaminated with bodily fluids</td>
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<td></td>
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<td>Objects contaminated with Cytotoxic/cytostatic medication</td>
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<td></td>
<td></td>
<td>Other</td>
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**Please go to Question 7**

### 5

*Bin Compliment – 50 Litre Green Plastic Bin*

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<th>SOP Reference</th>
<th>Criteria</th>
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<tr>
<td>5a</td>
<td></td>
<td>Is the bin kept in a locked room at all times?</td>
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<tr>
<td>5b</td>
<td></td>
<td>Is the bin located in the clinic room?</td>
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<tr>
<td>5c</td>
<td></td>
<td>If the bin is not kept in the clinic room, where is the bin located? Please specify:</td>
<td>Please go to Q5c</td>
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<td>☐</td>
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<tr>
<td>5d</td>
<td>5.2.2</td>
<td>Has the bin been assembled correctly?</td>
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<td>5e</td>
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<td>Is the porthole lid in place?</td>
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<td>Is the bin kept clean and tidy?</td>
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<td>5g</td>
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<td>Does the bin <em>only</em> contain unwanted pharmaceuticals and contaminated containers compliant with the SOP?</td>
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<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5h</td>
<td></td>
<td><strong>Does the green bin contain the following?</strong></td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5h i</td>
<td></td>
<td>Plastic/paper drinking cups</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5h ii</td>
<td></td>
<td>Outer packaging (cardboard, plastic, plastic film)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5h iii</td>
<td></td>
<td>Paper towel waste</td>
<td>☐</td>
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<td>☐</td>
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<td>5h iv</td>
<td></td>
<td>Dietetic products</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Question Number</td>
<td>SOP Reference</td>
<td>Criteria</td>
<td>Yes</td>
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<tr>
<td>5h v</td>
<td></td>
<td>Waxed tablet pots</td>
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<tr>
<td>5h vi</td>
<td></td>
<td>Needles</td>
<td></td>
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<tr>
<td>5h vii</td>
<td></td>
<td>Objects contaminated with bodily fluids</td>
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<tr>
<td>5h viii</td>
<td></td>
<td>Objects contaminated with Cytotoxic/cytostatic medication</td>
<td></td>
<td></td>
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<td>5h ix</td>
<td></td>
<td>Other</td>
<td></td>
<td></td>
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<tr>
<td>5i</td>
<td></td>
<td>Does the plastic green 50 litre bin bear the correct PHS label</td>
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<tr>
<td></td>
<td></td>
<td>“Nominal Capacity 50 Litres”</td>
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<td></td>
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<tr>
<td></td>
<td></td>
<td>“Suitable for liquid pharmaceuticals in original packaging up to 500ml.”</td>
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<td></td>
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<tr>
<td></td>
<td></td>
<td>“All waste must be in original packaging, e.g. blister packs and bottles except for prepared doses”</td>
<td></td>
<td></td>
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<tr>
<td>5j</td>
<td></td>
<td>Does the green metal outer bin bear the sticker “FOR MEDICATION AND CONTAINERS CONTAMINATED WITH MEDICATION”?</td>
<td></td>
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</tbody>
</table>

Go to question 7

6

**Bin Compliment – 30 Litre Green Plastic Bin**

| 6a              |               | Is the bin kept in a locked room at all times?                           |     |    |     |
| 6b              |               | Is the bin located in the clinic room?                                   |     |    |     |
| 6c              |               | If not kept in the clinic room, where is the bin located? Please specify: |     |    |     |
| 6d              | 5.2.2          | Has the bin been assembled correctly?                                   |     |    |     |
| 6e              | 5.2.2          | Is the porthole lid in place?                                           |     |    |     |
| 6f              |               | Is the bin kept clean and tidy?                                         |     |    |     |
| 6g              |               | Does the bin only contain unwanted pharmaceuticals and contaminated containers compliant with the SOP? |     |    |     |

6h

**Does the green bin contain the following?**

<p>| 6h i            |               | Plastic/paper drinking cups                                             |     |    |     |
| 6h ii           |               | Outer packaging (cardboard, plastic, plastic film)                      |     |    |     |
| 6h iii          |               | Paper towel waste                                                        |     |    |     |
| 6h iv           |               | Dietetic products                                                        |     |    |     |
| 6h v            |               | Waxed tablet pots                                                        |     |    |     |
| 6h vi           |               | Needles                                                                   |     |    |     |</p>
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<td></td>
<td>Objects contaminated with bodily fluids</td>
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<tr>
<td>6h viii</td>
<td></td>
<td>Objects contaminated with Cytotoxic/cytostatic medication</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>6h ix</td>
<td></td>
<td>Other</td>
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<td>Please specify:</td>
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<td>Does the plastic green 30 litre bin bear the correct PHS label</td>
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<td></td>
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<td>• &quot;Nominal Capacity 30 Litres&quot;</td>
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<td></td>
<td></td>
<td>• “Suitable for liquid pharmaceuticals in original packaging up to 500ml.”</td>
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<td>• “All waste must be in original packaging, e.g. blister packs and bottles except for prepared doses”</td>
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<td>6j</td>
<td>5.2.3</td>
<td>Does the green metal outer bin bear the sticker “FOR MEDICATION AND CONTAINERS CONTAMINATED WITH MEDICATION”?</td>
<td></td>
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<td>7</td>
<td>Purple Lidded Yellow Cytotoxic/Cytostatic Bins</td>
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<tr>
<td>7a</td>
<td></td>
<td>Is the bin a 2.5 litre purple lidded yellow bin?</td>
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<tr>
<td>7b</td>
<td></td>
<td>Is the bin kept in a locked room at all times?</td>
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<tr>
<td>7c</td>
<td></td>
<td>Is the bin located in the clinic room?</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Please go to Q7c</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7d</td>
<td></td>
<td>If not kept in the clinic room, where is the bin located?</td>
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<td></td>
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<td>Please specify:</td>
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<tr>
<td>7e</td>
<td>6.2.1</td>
<td>Has the bin been assembled correctly?</td>
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<td>7f</td>
<td>6.1.2</td>
<td>Has the information required on the bin label been completed?</td>
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<tr>
<td>7g</td>
<td>6.3</td>
<td>Is the lid opening in the temporarily closed position?</td>
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<tr>
<td>7h</td>
<td></td>
<td>Is the bin kept clean and tidy?</td>
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<td></td>
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<tr>
<td>7i</td>
<td></td>
<td>Does the bin only contain unwanted pharmaceuticals and contaminated containers compliant with the SOP?</td>
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<td></td>
<td></td>
<td>Please go to Q7k</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7j</td>
<td></td>
<td>Does the purple lidded yellow bin contain the following?</td>
<td></td>
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<tr>
<td>7j i</td>
<td></td>
<td>Outer packaging (cardboard, plastic, plastic film)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7j ii</td>
<td></td>
<td>Waxed tablet pots</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7j iii</td>
<td></td>
<td>Needles</td>
<td></td>
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<td>7j iv</td>
<td></td>
<td>Objects contaminated with bodily fluids</td>
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<tr>
<td>7j v</td>
<td></td>
<td>Objects contaminated with Cytotoxic/cytostatic medication</td>
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<td>7j vi</td>
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<td>Other</td>
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<td></td>
<td>Please specify:</td>
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<td>SOP Reference</td>
<td>Criteria</td>
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<tr>
<td>7k</td>
<td></td>
<td>Does the purple lidded bin bear the &quot;For Cytotoxic/Cytostatic Waste Medication Only No Sharps&quot; label?</td>
<td></td>
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<tr>
<td>8</td>
<td></td>
<td><strong>Spare bins</strong></td>
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<td>8a</td>
<td>5.2.3</td>
<td>Does the unit have more than one 50 litre green plastic bin?</td>
<td></td>
<td></td>
<td>Please go to Q8b</td>
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<td>8b</td>
<td>5.2.3</td>
<td>Are all green plastic pharmaceutical waste bins permanently closed (as per SOP)?</td>
<td></td>
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<td>Please go to Q9a</td>
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<tr>
<td>8c</td>
<td>5.2.3</td>
<td>Are full bins stored in a locked area with no patient access?</td>
<td></td>
<td></td>
<td>Please go to Q8d</td>
</tr>
<tr>
<td>8d</td>
<td></td>
<td>Where is the full bin stored?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>9</td>
<td></td>
<td><strong>Paperwork</strong></td>
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<td>9a</td>
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<td>Does the unit retain all the collection notes (CWTNs)</td>
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</tr>
<tr>
<td>9b</td>
<td></td>
<td>As an approximate percentage (to nearest 5%) how many notes have they retained from the last two years?</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>..................%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9c</td>
<td>9.2.2</td>
<td>Are CWTNs retained for two years?</td>
<td></td>
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<tr>
<td>9d</td>
<td>9.3.1</td>
<td>Does the unit retains all the hazardous collection notes (HWCNs)</td>
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<tr>
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<td>As an approximate percentage (to nearest 5%) how many notes have they retained from the last two years?</td>
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<td></td>
<td></td>
<td>..................%</td>
<td></td>
<td></td>
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<td>9f</td>
<td>9.3.2</td>
<td>Are HWCNs retained for three years?</td>
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<td>9g</td>
<td>9.2.2, 9.3.2</td>
<td>Does the unit have suitable storage for all waste paperwork?</td>
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<td><strong>Where is the paperwork stored?</strong></td>
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<td></td>
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<tr>
<td>9h i</td>
<td></td>
<td>Clinic Room</td>
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<td>9h ii</td>
<td></td>
<td>Admin Office</td>
<td></td>
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<td>9h iii</td>
<td></td>
<td>Manager's Office</td>
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<tr>
<td>9h iv</td>
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<td>Housekeeping Supervisor's Office</td>
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<td>Question Number</td>
<td>SOP Reference</td>
<td>Criteria</td>
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<td>9h v</td>
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<td>Please specify:</td>
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<tr>
<td>9i</td>
<td></td>
<td>Does the unit have a copy of the Standard operating procedure for disposal of pharmaceutical products and containers contaminated with pharmaceutical products or does the</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
</tr>
</tbody>
</table>

### 10 Poster

| 10a             | 9.4.1         | Does the team have the appropriate “Pharmaceutical Waste” poster displayed clearly near to the pharmaceutical waste bin? | ✔️ | ✔️ |     |
| 10b             | 9.4.1         | Does the team have the appropriate “Pharmaceutical Waste Bins” poster displayed clearly near to the pharmaceutical waste bin? | ✔️ | ✔️ |     |
| 10c             | 9.4.2         | Does the team have the “Information for Pharmacy Staff” poster placed within the pharmacy returns cupboard or the pharmacy folder? | ✔️ | ✔️ |     |
| 10d             | 9.4.1         | Does the team have the poster detailing that plastic cups should not be placed in the pharmaceutical waste bin? | ✔️ | ✔️ |     |

### 12 Other comments

Continue overleaf if necessary
Introduction:

1.1 The Trust recognises that it is an offence for any of these activities to take place on its sites, this is not an exhaustive list:

1.1.1 Producing or attempting to produce a controlled drug
1.1.2 Supplying, attempting to supply, or offering to supply a controlled drug to another person
1.1.3 Smoking cannabis, cannabis resin or prepared opium
1.1.4 Supplying, attempting to supply, or offering to supply any legally recognised illicit substance.

Notes to consider:

1.2 Implicit to this procedure is that staff will use information gained from their knowledge of the service user through the therapeutic relationship and the general circumstances of the situation to facilitate a therapeutic risk assessment and risk management plan.

1.3 Staff should balance this relationship with the duty of care to the wider public and if in doubt seek legal advice from LPfT as to how to proceed.

1.4 Staff should be aware that there is a legal obligation to inform the police of illicit drug use and any actual or intent to supply a controlled drug.

Legal guidance:

1.5 A Home Office licence would be required to possess schedule 1 controlled drugs (with the exception of Sativex). However some pharmacists, particularly those working within a hospital, may be asked to deal with substances removed from patients on admission, which may be schedule 1 products (e.g. cannabis). A pharmacist, under two specific exemptions, can take possession of such controlled drugs.

The first exemption is when possession is taken for the purpose of destruction. The second is for the purpose of handing over to a police officer. The patient’s confidentiality should normally be maintained and the police should be called on the understanding that the source will not be identified. If, however, the quantity is so large that the drug could not be purely for personal use the pharmacist may decide that the greater interests of the public require identification of the source. Such a decision should not be taken without first considering discussing the situation with the other health professionals involved in the patient’s care and taking advice from the pharmacist’s professional indemnity insurer’s legal adviser.

1.6 The patient should give authority for the drug to be removed and destroyed. If the patient refuses, the pharmacist may feel that he or she has no alternative other than to call in the police. Under no circumstances can a suspected illicit drug be handed back to a patient.

Inpatient settings:

2.1 Process if illicit substances are suspected / found on the ward.

2.1.1 An explanation is made to the service user suspected of being in possession or found to be in possession of an illegal or suspected illegal product about the procedure for removing this to a safe, quarantined environment and the ramifications of their actions. E.g. informing the police
2.1.2 If the service user declines to hand the substance to staff a search may be carried out of the individual and/or bed space. Care MUST be taken with this and legal advice should be sought if the service user refuses to be searched.

2.1.3 If a search is to be carried out it MUST follow the current LPfT search procedures.

**Process for any found substance:**

2.2.1 Two members of staff, wearing gloves, will seal the unknown or illicit substance, including any packaging containing the suspected item, in a clear plastic bag and sign the sealed bag. Staff must NOT unwrap any packaging to view contents.

2.2.2. If needles are found then for reasons of safety these are placed directly into the wards contaminated sharps bin.

2.2.3 An entry is made in the Controlled Drug register identifying the item in the plastic bag (if known) or indicating it as ‘an unknown substance’ and the quantity being quarantined. This entry is to be signed by two authorised staff members.

2.2.4 The plastic bag is then quarantined in the Controlled Drug cupboard and locked away.

2.2.5 The pharmacy department is to be notified that an unknown substance is quarantined and awaiting destruction.

2.2.6 Report the issue on the risk management system.

2.2.7 Every incident should be assessed on an individual merit and decisions about the future management of the service user concerned will be made at the discretion of the Multidisciplinary team (MDT)

**Pharmacy support**

2.3 Once pharmacy have been notified that an unknown or suspected illicit product has been found on the ward a member of the pharmacy team, at the earliest possible time, will arrange to visit the site to determine if the police need to be called or whether it can be destroyed on site.

2.3.1 The pharmacy team member will check to see if the item found has been quarantined correctly and an entry made in the Controlled Drug register.

2.3.2 If the item is clearly identified as an illicit substance, or an unidentified white powder the pharmacy member will inform the chief pharmacist and also call the local police for advice.

2.3.3 If the item is ‘unknown’ and not a white powder the pharmacy team member will write out a ‘Patient Return Drug form (PatRet form) identifying the item as unknown and the quantity. Then either the pharmacy team member or a senior member of the nursing staff will ask the service user from whom the item was taken to sign the PatRet form giving us permission to destroy the unknown item.

2.3.3.1 If the service user refuses to sign the PatRet form giving us permission to destroy the unknown item they must be informed that the police will be called to remove the item and that normal judicial processes will follow.

2.3.4 Once the service user has signed the PatRet form the pharmacy team member and an authorised nurse will destroy the unknown substance using due process for destroying the item in the wards DOOP kit and placing in the pharmacy waste. (Crushing and dissolving solid doses in water, emptying capsules into water, folding opiate patches back in on themselves, drawing up the contents of ampoules and adding to the DOOP kit etc.)
2.3.5 If the service user does not have capacity, or is deemed not to have capacity, to consent then the PatRet form will be signed by two members of the clinical team on behalf of the service user and a note made in the service users electronic records.

2.3.6 Once the unknown substance has been destroyed the Controlled rug register will be annotated and signed by the two people involved in the destruction process.

Community settings:

3.1 The trust does not routinely expect its staff to remove illicit substances from a service user in any community setting.

3.1.1 However the trust does expect its staff to be vigilant and report any act that may be a criminal offence.

References:

Reference: Page 60 of MEP 36 contains guidance on the possession of Schedule 1 controlled drugs.

NMC guidelines on medicines management & prescribing - standard 21 disposal & standard 26 controlled drugs (May 2013)
Appendix A

PatRet form

UNITED LINCOLNSHIRE HOSPITALS NHS TRUST

Appendix 1
HOSPITAL COPY

Record of Drugs Brought in by Patient

Date

Patients Name: ____________________________ Ward: ________________ S.A.M. : Y or N

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<th>NAME OR MEDICINE</th>
<th>FORM</th>
<th>STRENGTH</th>
<th>QUANTITY</th>
<th>LOCATION</th>
<th>SIG</th>
<th>DEPOTASHE</th>
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</table>

I hereby certify that the above drugs were brought into hospital and that I agree to their use for my treatment only or to their destruction if it is considered that they should not be re-used.

Signature of Patient: ____________________________ Date: ________________

(or representative)

Signature of Recipient: ____________________________ Date: ________________

(on ward)

KEY TO DISPOSAL/REUSE/LOCATION

| Returned to Patient Unopened | A | Mixed Doses in Packet | P | Stored in Medication Cabinet | F |
| Returned to Patient Interviewed | B | Considered to be Vital for Use | F | Back to Pharmacy | F |
| Returned to Patient Interviewed | F | Not Able to be Identified | G | Sent Home with Patient | F |
| No Longer Prepared | D | Not Prepared by Pharmacy Staff | H | Stored in Ward POD Cooling | F |
|                   | E |                      |     |                         | F |

FOR PHARMACY USE ONLY

Disposal of by: ____________________________ Name in Block Capitals

Signature: ____________________________ Date: ________________

LPFT Medicines Management & Medical Devices Policy V.9 November 2015 211
Lincolnshire Partnership NHS Foundation Trust (LPFT)

Non-Medical Prescribing Policy

<table>
<thead>
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<tr>
<td>Authorised Document Folder:</td>
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| Author: | Michelle Persaud
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| Approving Body: | Board of Directors |
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| Committee, Group or Individual Monitoring the Document | Quality Committee |
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Equality Statement

Lincolnshire Partnership NHS Foundation Trust (LPFT) to its best ability will develop and implement business plans, project initiation documents, service change, service delivery and provision and policies and other corporate documents that meet the needs of the local community. They will take account of the provisions outlined in the Equality Act 2010, to eliminate discrimination, harassment and victimisation, promote equality of opportunity and build on good relations between the diverse communities.

The aim is to ensure no individual receives less favourable treatment on the grounds of age, disability (learning disabilities), sex (gender), race, gender reassignment, sexual orientation, religion and belief, marriage and civil partnership and pregnancy and maternity.

LPFT will have due regard to the different needs of those listed as the ‘protected characteristics’ and those not listed to ensure dignity and respect, leading to a fair and equitable service for all.

1. Introduction

The NHS Plan (2000) emphasised the necessity to organise and deliver services around the needs of service users. As part of this commitment prescribing is one area that has been developed to allow a wider group of health care professionals to undertake prescribing roles. Prescribing can be split into the domains of medical prescribing for Doctors and Dentists and non-medical prescribing for Nurses, Pharmacists and Allied Health Professionals. This Policy focuses on non-medical prescribing (NMP) within Lincolnshire Partnership NHS Foundation Trust.

A full history of non-medical prescribing is available on the Department of Health website. A reference guide and application forms for the Application, Training and Post Registration Process are available as appendixes to the Non-Medical Prescribing Policy.

The key principles identified by the Department of Health (2005) that underpin non-medical prescribing are:

- Allowing service users quicker access to medication
- Providing services more efficiently and effectively
- Increasing service user choice
- Making better use of the skills and knowledge of Nurses, Pharmacists and Allied Health Professionals.

The principles emphasise the importance of communication and involving service users in their care. A service user should be treated as a partner in their care and informed consent sought.

2. Purpose & Scope

This policy is to be used as a framework within which non-medical prescribing (independent and supplementary prescribing) is implemented. It applies to non-medical prescribers employed by Lincolnshire Partnership NHS Foundation Trust, who are authorised to prescribe following successful completion of Independent/Supplementary nonmedical prescribing training, and their subsequent registration with their professional body i.e. NMC./RPSGB.

The purpose of the policy is therefore to:

- Set out the principles on which non-medical prescribing is based
- Identify the appropriate standards and procedures to support safe practice
- Specify an accountability framework
- Reflect the Clinical Strategy, where reference is made to NMP
This policy applies to LPFT staff that have a specific qualification as a NMP and have a role profile or additional addendum to their role profile for them to prescribe pharmaceutical products as a part of their employment within the organisation.

This policy applies to service managers that employ or are looking to develop NMP’s within their services and line mangers of NMPs.

This policy applies to those members of staff looking to access the NMP course.

This policy applies to medical staff and to senior NMPs providing clinical supervision to NMPs.

The policy is not intended for those staff members prescribing medical devices.

3. Duties

Chief Executive

Is responsible for ensuring that a Medicines Management Policy is in place and that all staff working in the Trust are aware of, and operate within the policy.

The Chief Pharmacist

Has overall responsibility for Medicines Management within the Trust and for ensuring that all pharmaceutical staff are aware of and operate within the policy and medicine management guidelines.

Is responsible in partnership with managers, for instituting an effective monitoring system as required by Controls Assurance / Care Quality Commission regulations (2015) and NHSLA.

The Chief Pharmacist is responsible for all aspects of the safe and secure management of controlled drugs within the Trust. This includes ensuring that safe systems are in place for the management and use of controlled drugs, monitoring and auditing the management systems and investigations of concerns and incidents relating to controlled drugs.

The Chief Pharmacist for Lincolnshire Partnership NHS Foundation Trust (LPFT) has overall responsibility for the management of medicines within the Trust including the safe and secure handling of medicines and other associated products. In liaison with clinical teams and pharmaceutical staff implement the controls assurance Care Quality Commission standards (medicine management) and local procedures and guidance relating to the management of medicines.

The Chief Pharmacist is responsible for maintaining a register of all LPFT approved prescribers and ensuring each prescriber is supplied with the most up to date version of the British National Formulary (BNF). Specimen signatures of prescribers are maintained as a part of the register and the signatures of those prescribing are provided to relevant pharmacy departments. FP10 prescription are available when required for each prescriber.

The Medical Director

The Medical Director is the Executive Director responsible for informing the Trust Board about medicine related issues and is responsible for ensuring that all medical staff are aware of and operate within the policy.

The Director of Nursing and Quality

Is responsible for ensuring mechanisms are put in place to ensure nursing and allied health professionals within all Services are aware of and comply with the requirements of the medicine management policy.
The Associate Director of Nursing and Quality

Is the Trust lead for NMP and has the responsibility of ensuring that the NMP policy is reviewed and updated in line with Trust policies.

Medicines Management Committee

Is the committee responsible for approving the policy.

Service Managers

Are responsible for ensuring that, they and all managed NMP staff are aware of and operate within the NMP policy.

They are responsible for establishing and writing a service model that require the function of non-medical prescribing within their services. There should be a clear service model that supports the development of NMP and provides a clear structure and scope of practice following qualification. It is incumbent on the Service Manager to ensure that applicants are selected with the right skills and attributes to undertake the course and subsequent prescribing role.

Heads of departments & Allied Health Professionals (AHPs)

They are responsible for ensuring that, they and all managed NMP staff are aware of, and operate within the NMP Policy.

Learning and Development Department

Have responsibility to ensure that LPFT provides continued professional development (CPD) opportunities for NMP staff to remain up to date in their field of practice.

Non-Medical Prescribing Staff

Staff who handle or use medicinal products have a duty to be aware of and work within the confines of the Medicine Management Policy.

All NMP staff must also ensure that they maintain their professional registration and any associated stipulations or conditions of registration i.e. Continual Professional Development criteria.

NMP staff will work within the duties described within this document and the Medicines Management Policy.

3.1 Job Descriptions- Non-medical prescribing must be reflected in the post holder’s job description, either as a stand-alone post with an appropriate job description/role profile or as an addendum for that individual to their existing role profile. The service model will establish how the individual role will function within the service.

3.2 Under the Human Medicines Regulations 2012 roles approved to undertake training and practice as a non-medical prescriber are:

- Registered Nurse
- Registered Midwife
- Registered Pharmacist
- Registered Chiropodists/Podiatrist
- Registered Physiotherapist
- Registered Radiographer
- Registered Optometrist
3.3 Independent and Supplementary Non-Medical Prescribing

3.3.1 All independent and supplementary non-medical prescribers must only agree to prescribe medication or products they are satisfied fall within their area of clinical competence and experience, and within the remit of their job description/role profile and the service model of the service within which they are employed.

3.3.2 Supplementary prescribers prescribe in partnership with an independent medical prescriber who must be a doctor or a dentist. The independent medical prescriber will determine which service users may benefit from supplementary prescribing and specify the medicines that may be prescribed under a service user-specific Clinical Management Plan (CMP).

3.3.3 The independent medical and supplementary prescriber must determine the extent of the responsibility the supplementary prescriber has under the CMP. They will need to take into account the experience and areas of expertise of the supplementary prescriber.

3.3.4 Supplementary prescribers should prescribe in line with existing Trust prescribing policies and guidelines, preferred prescribing lists or locally agreed formularies.

They may prescribe for the full range of medical conditions, provided they do so under the terms of the CMP. This CMP must be drawn up following diagnosis of the service user by the independent medical prescriber, and following consultation and agreement between the independent medical prescriber(s) and supplementary prescriber(s). The service user must also agree to this approach to managing their ongoing care (Department of Health, 2005).

3.3.5 Independent non-medical prescribers are responsible and accountable for the assessment of service users with undiagnosed or diagnosed conditions and for decisions about the clinical management required, including prescribing. In partnership with the service user, independent prescribing is one element of the clinical management of a service user. It requires an initial patient assessment, interpretation of that assessment, a decision on safe and appropriate therapy and a process for ongoing monitoring. The independent non-medical prescriber is responsible and accountable for at least this element of a service user's care. Normally prescribing would be carried out in the context of practice within multidisciplinary team, either in a hospital or in a community setting and within a single accessible healthcare record (Department of Health, 2006).

3.3.6 From 23rd April 2012 amendments to the Controlled Drug Regulations came into force; enabling nurse and pharmacist independent prescribers to prescribe, administer and give directions for the administration of Schedule 2, 3, 4 and 5 Controlled Drugs. Independent nurse prescribers and pharmacist prescribers are not able to prescribe diamorphine, dipipanone or cocaine for treating addiction but can prescribe these items for treating organic disease or injury. If the NMP is in any doubt as to a patient's request for a Controlled Drug, then good practice dictates that consultation with the Responsible Doctor for the patient must take place.

3.4 Eligibility to Access Non-Medical Prescribing Training

3.4.1 Access to training is via completion of the application form found in Appendix 1, along with guidance for application. Eligibility and access is in accordance with the guidance published by the Department of Health (2005) Supplementary Prescribing by Nurses, Pharmacists, Chiropodists / Podiatrists, Physiotherapists and Radiographers within the NHS in England: a guide for implementation, and Department of Health (2006) Improving Patients Access to Medicines: A guide to Implementing Nurse and Pharmacist Independent Prescribing within the NHS in England, and by Trent Workforce Development Confederation.

3.4.2 All applicants must have had an enhanced DBS check within the previous twelve months prior to commencing the training programme to enable them to register their qualification with the appropriate professional body.

3.5 Preparation for Non-Medical Prescribing
3.5.1 The Trust designated Non-Medical Prescribing Lead who has overall responsibility for approving all applicants for NMP training programmes is the Associate Director of Nursing and Quality.

3.5.2 It is the role of the General Manager in conjunction with medical and service leads to determine service models that require the function of Non-medical prescribing. There should be a clear service model that supports the development of NMP and provides a clear structure and scope of practice following qualification. It is incumbent on the Service Manager to ensure that applicants are selected with the right skills and attributes to undertake the course and subsequent prescribing role.

3.5.3 Nominated Nurses and Midwives must attend an NMC approved education programme which will normally be at a Higher Education Institution within the region.

3.5.4 Nominated Pharmacists must attend a GPhC accredited higher education institution delivered programme.

3.5.5 Nominated Allied Health Professionals must be a registered professional whose name is held on the relevant part of the Health Professions Council Membership Register must attend an approved education programme which will normally be at a Higher Education Institution.

3.6 Qualified Non-Medical Prescribers

3.6.1 A database of all qualified non-medical prescribers will be maintained by the Chief Pharmacist. It is the responsibility of the non-medical prescriber to ensure that they provide the information required for this database and that this information is kept up to date. The Chief Pharmacist will meet with all new proposed entrants onto the database to review them for Trust approval for practice prior to being added to the database.

Scope of prescribing practice for each individual should be reviewed with a medical lead for the service and the service manager and be in line with the strategic direction of the service model. All NMPs must receive clinical supervision from a Consultant (or senior suitably experienced Medical or Non-Medical Prescriber). The scope of prescribing practice is an individual determined progression rate that is agreed via clinical supervision and then agreed by the service manager as a part of the strategic direction.

3.6.2 A register of non-medical prescribers requiring The British National Formulary (BNF) is maintained by the pharmacy department, and updated BNF’s will be distributed twice a year. If a Children’s BNF is also required, the non-medical prescriber will need to inform the Chief Pharmacist to ensure that this is ordered.

3.6.3 When non-medical prescribers require a FP10 prescription they should gain these from the pharmacy department. A local record must be maintained of any destroyed prescriptions. It would be seen as good practice to record the prescription number within clinical records as a part of the record keeping process.

3.6.4 In the event of a medication error the non-medical prescriber must take appropriate immediate actions to ensure the safety of the patient and follow the trust incident reporting of management of risk policy and process. The prescriber must record all prescribing practice including incidents within the clinical records.

3.7 Continuing Professional Development (CPD)

3.7.1 Employers have a responsibility to ensure that prescribers have access to undertake the relevant continuing professional development as identified through their staff appraisal. This must be undertaken in order to maintain registration as competent to prescribe.

3.7.2 It is the NMP’s responsibility to remain up-to-date with knowledge and skills to enable them to prescribe competently and safely.
3.7.3 The NMP must act in accordance with their code of professional conduct, performance and ethics.

3.7.4 As a health professional who is recorded on the register as being a prescriber, the NMP should ensure that their continuing professional development is in line with their role as a prescriber.

3.8 RETURNING TO PRACTICING

3.8.1 A non-medical prescriber returning to practice after any period of not prescribing for more than 6 months or changing work area should undertake an assurance process. This process is set out in Appendix 5 of this policy.

3.8.2 As part of the trusts’ governance process a NMP already qualified, who is subsequently employed by the trust, should undertake an assurance process to evidence their competency within their sphere of practice, before prescribing and undertaking a role as a NMP within the trust.

The time commitment required by the trust to evidence assurance is a minimum of 45 hours of clinical shadowing/supervision with a prescribing supervisor who will provide that assurance.

3.9 GOOD PRACTICE GUIDANCE

3.9.1 Guidance on good prescribing practice is available within the medicines management policy.

3.10 LEGAL AND CLINICAL LIABILITY

3.10.1 When a Nurse, Pharmacist or Allied Health Professional is appropriately trained, qualified and prescribes as part of their professional duties with the consent of their employer, the employer is held vicariously liable for their actions. Where the role is an addition to an existing job role then an addendum will require to be added to that individual’s role profile.

3.10.2 All non-medical prescribers have a responsibility for accepting professional accountability and clinical responsibility for their prescribing practice, working at all times within their clinical competence and with reference to their regulatory body’s professional standards.

3.10.3 It is strongly recommended that all non-medical prescribers ensure that they have professional indemnity insurance, for instance, by means of membership of a professional organisation or trade union.

3.10.4 Any concerns regarding non-medical prescribing should be referred to LPFT’s NMP Lead.

3.12 RELATIONSHIP WITH PHARMACEUTICAL INDUSTRY

It is recognised that pharmaceutical company representatives provide a useful and informative service to health professionals but it is important that the choice of medicinal product is based on clinical evidence and cost effectiveness grounds only. Personal gifts are prohibited and it is an offence to solicit or accept a prohibited gift or inducement. Companies may offer hospitality at a professional meeting although this must be appropriate to the event and the main purpose of the meeting. All non-medical prescribers must be aware of the Trust policy - Commercial sponsorship and hospitality - policy, code of conduct and guidance (COR 23) and maintain their own ‘Register of Interests’ where appropriate.

3.13 PRESCRIBING FOR SELF AND FAMILY

Prescribing for self and family and friends should not take place under any circumstances.

3.14 PRESCRIBING CONTROLLED DRUGS (CDs)
The proposed list of CDs that independent physiotherapists, chiropodists or podiatrist prescribers can currently prescribe is below. The Care Quality Commission (CQC) requires assurances that independent prescribers prescribe these within their competence.

### Table 1 - Physiotherapists

<table>
<thead>
<tr>
<th>Controlled Drug</th>
<th>Route</th>
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<tbody>
<tr>
<td>Temazepam</td>
<td>Oral</td>
</tr>
<tr>
<td>Lorazepam</td>
<td>Oral</td>
</tr>
<tr>
<td>Diazepam</td>
<td>Oral</td>
</tr>
<tr>
<td>Dihydrocodeine</td>
<td>Oral</td>
</tr>
<tr>
<td>Morphine</td>
<td>Oral and Injectable</td>
</tr>
<tr>
<td>Fentanyl Transdermal</td>
<td>Patch</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>Oral</td>
</tr>
</tbody>
</table>

### Table 2 – Chiropodists/Podiatrists

<table>
<thead>
<tr>
<th>Controlled Drug</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temazepam</td>
<td>Oral</td>
</tr>
<tr>
<td>Lorazepam</td>
<td>Oral</td>
</tr>
<tr>
<td>Diazepam</td>
<td>Oral</td>
</tr>
<tr>
<td>Dihydrocodeine</td>
<td>Oral</td>
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</tbody>
</table>

3.15 LEAVING THE TRUST

It is the responsibility of the appropriate Line Manager to inform the Chief Pharmacist when a non-medical prescriber leaves the Trust to enable their details to be removed from the database and prescription pads returned.

3.15.1 It is the responsibility of the non-medical prescriber to make arrangements to return any FP10 prescription pads by hand that are no longer required so that arrangements can be made for their witnessed destruction.

4. Definitions

**Independent Prescribing** - A prescriber who is legally permitted and qualified to prescribe and takes the responsibility for the clinical assessment of the patient or client, establishing a diagnosis and the clinical management required, as well as the responsibility for prescribing, and the appropriateness of any prescribing. (NMC 2010)

**Supplementary Prescribing** - A voluntary partnership between an independent prescriber (doctor or dentist) and a supplementary prescriber, to implement an agreed patient or client-specific clinical management plan with the patient or client’s agreement. (NMC 2010).

**Community Practitioner Nurse Prescribers** - These are registrants who have successfully undertaken a programme of preparation to prescribe from Community Practitioner Nurse Prescribers’ Formulary. They can prescribe the majority of dressings and appliances, and a limited range of prescription only medicines. (NMC 2010)

5. Development of Policies and Procedures

In reviewing this policy, LPFT benchmarked the review against 2 external NHS trust policies along with the national guidance documents: Department of Health (2006) Improving patients access to medicines: A guide to implementing Nurse and Pharmacist Independent Prescribing within the NHS in England.
The good practice and previous learning from the implementation of LPFT's previous NMP policy was utilised in the development of this replacement policy.

This policy is intrinsically allied with LPFT's wider Medicines Management Policy which has been used as a baseline for this document. This policy should be read in conjunction with the wider Medicines Management Policy.

6. Consultation, Approval and Ratification Process

The policy will be consulted upon, approved and ratified in accordance with the Trust's Corporate Documents and Policies Procedure. The relevant Executive Committee is identified in the appendices to that procedure.

7. Review and Revision Arrangements including Version Control

This policy will be reviewed bi-annually by the policy author in accordance with the Corporate Documents and Policies Procedure. Revision may occur earlier if relevant new legislation or guidance is issued.

The Executive Committee monitoring the effectiveness of the policy may also call for an early review on the basis of the reports it receives.

The Trust Secretary’s Office will maintain a version control sheet, as per the Corporate Documents and Policies Procedure.

8. Dissemination and Implementation of a Policy

This policy will be disseminated in accordance with the Corporate Documents and Policies Procedure.

The Policy will be implemented to all potential applicants and qualified non-medical prescribers employed in a substantive post by LPFT who are required to carry out the duties of non-medical prescribing. The Pharmacy department will email the policy to all employed registered NMPs and those who have applied for or currently accessing the NMP training course following committee approval.

The Pharmacy Department will add the policy to the overarching Medicines Management & Medical Devices Policy and the Pharmacy site on the Trust intranet course following committee approval.

9. Policy Control including Archiving Arrangements

Corporate and Legal Services will retain a copy of each policy for a minimum of 10 years in line with the recommendations contained within ‘Records Management NHS Code of Practice’ (2006).

Individuals wishing to obtain previous versions of this policy should contact Corporate & Legal Services.

10. Monitoring Compliance with and Effectiveness of Policies and Procedures

Monitoring compliance is undertaken in accordance with section 20 of the Medicines Management & Medical Devices Policy.
<table>
<thead>
<tr>
<th>Systems</th>
<th>Monitoring and/or Audit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementation complete within designated timescale</td>
<td>As per section 8</td>
</tr>
<tr>
<td>For each service line to have service model to support safe practice in service areas with NMP.</td>
<td>Monitored via NMP steering group</td>
</tr>
</tbody>
</table>

### 11. References


11.5 Department of Health (May 2005) Supplementary prescribing for Nurses, Pharmacists, [www.dh.gov.uk](http://www.dh.gov.uk)

11.6 Chiropodists/Podiatrists, Physiotherapists and Radiographers within the NHS in England: A guide for implementation. [www.dh.gov.uk](http://www.dh.gov.uk)


11.10 National Prescribing Centre (2005) Training non-medical prescribers in practice: guide to help doctors prepare for and carry out the role of designated medical practitioner. [www.npc.co.uk](http://www.npc.co.uk)

11.11 Nursing and Midwifery Council (2006) Standards or Proficiency for Nurse and Midwife Prescribers. [www.nmc-uk.org](http://www.nmc-uk.org)

11.12 Trent Workforce Development Confederation Website - Application process and criteria: [www.trentconfed.nhs.uk/workstreams/non-medical-prescribing](http://www.trentconfed.nhs.uk/workstreams/non-medical-prescribing)


11.14 University of Southampton; Keele University (2010). Evaluation of Nurse and Pharmacist Independent
12. **Associated Documentation**

Medicines Management & Medical Devices Policy

**Appendices:**

Appendix 1 Application for Non-Medical Prescribing Preparation  
Appendix 2 Application Process  
Appendix 3 Entry to the NMP Register  
Appendix 4 Sample Signature  
Appendix 5 Return to practice/change to clinical setting competency assurance for NMP's  
Appendix 6 Clinical Management Plan
APPENDIX 1

APPLICATION FOR NON-MEDICAL PRESCRIBING PREPARATION
NURSE / MIDWIFE APPLICANT GUIDANCE

Applicants must provide evidence that they have met the NMC’s criteria for eligibility to undertake a nurse independent/supplementary prescribing programme. The criteria are:

- You must be a registered first level nurse, midwife and/or specialist community public health nurse

- You must have at least three years’ experience as a practising nurse, midwife or specialist community public health nurse and be deemed competent by your employer to undertake the programme. Of these three years, the year immediately preceding application to the programme must have been in the clinical field in which you intend to prescribe, e.g. neonates, mental health. Part-time workers must have practised for a sufficient period to be deemed competent by their employer

- You must provide evidence of your ability to study at the appropriate level. If you are unable to provide this evidence, you will be requested to comply with the Accreditation of Prior and Experiential Learning (APEL) process in order to consider your application. Further details will be sent to you as necessary on receipt of your application.

In addition, you will need to have written confirmation from:

- Your employer of their support for you to undertake the preparation programme.

- The programme lead about your selection on to the preparation of prescribers education programme. This will be provided to the applicant and employer.

- A designated medical practitioner who meets eligibility criteria for medical supervision of non-medical prescribers and who has agreed to provide the required term of supervised practice.
Responsibilities of Employer

The NMC requires employers to undertake an appraisal of an applicant’s suitability to prescribe before they apply for a training place. Employers must also have the necessary clinical governance infrastructure in place including a Disclosure and Barring Service check (formerly a Criminal Records Bureau check) to enable the registrant to prescribe once they are qualified to do so.

Where the applicant is not undertaking a module to prepare them in diagnosis and physical assessment alongside the nurse/midwife independent/supplementary prescribing programme, then the employer is responsible for confirming that:

- The applicant has been assessed as competent to take a history, undertake a clinical assessment, and diagnose, before being put forward
- There is clinical need within the applicant’s role to justify prescribing
- The applicant has sufficient knowledge to apply prescribing principles taught on the programme of preparation to their own area and field of practice
- The applicant must be able to demonstrate appropriate numeracy skills

Employers should not put applicants forward if they haven’t demonstrated the ability to diagnose in their area of speciality. It should be possible to identify whether an applicant has these skills through Continuing Professional Development (CPD) reviews within the workplace setting.

Applicants must remember they work as a part of a team of prescribers.

The University of Lincoln must be satisfied that any applicant to the programme of preparation has the ability to study at the appropriate level. In addition, the University of Lincoln must support the designated medical practitioner (DMP) with a suitable competence framework to assess learning in practice. They are also responsible for ensuring that the DMP meets the eligibility criteria listed in this document.

Applying to undertake the programme should be a collaborative arrangement between the employer, the University and the applicant, in order to confirm that the applicant is competent to undertake the course, is in a role that enables them to prescribe, and that the necessary infrastructure will be in place to allow them to do so.

The application form will identify whether an applicant has applied and commenced a programme of preparation previously. Where this is the case, the reason for not completing must be stated. This will allow a decision to be made by the employer in collaboration with the University as to whether it is appropriate for them to re-apply.

Prescribing for children and young people

The NMC ‘Standards of proficiency for nurse and midwife prescribers’ were published in May 2006. This
document states that:

‘Only nurses with relevant knowledge, competence, skills and experience in nursing children should prescribe for children. This is particularly important in primary care (e.g. out of hours, walk-in-clinics and general practice settings). Anyone prescribing for a child in these situations must be able to demonstrate competence to prescribe for children and refer to another prescriber when working outside their area of expertise or level of competence’ (NMC. 2006, page 7).

‘It is the responsibility of the employer to ensure that the registrant is able to apply the prescribing principles to their own area of practice’ (NMC.2006, page 6).

All nurse / midwife independent / supplementary prescribing programmes must incorporate an additional learning outcome to ensure that on successful completion of the programme, they can take an appropriate history, undertake a clinical assessment and make an appropriate diagnosis, having considered the legal, cognitive, emotional and physical differences between children and adults.

In addition the assessment must demonstrate the registrant’s ‘recognition of the unique implications and developmental context of the anatomical and physiological differences between neonates, children and young people.’ (NMC. 2006, page 6).

In keeping with the existing standards of proficiency for nurse / midwife prescribers the assessment should take place within the context of their work setting.

If there is any doubt about the ability of the applicant to demonstrate knowledge, skill and competence in the areas described above, further training in relevant aspects of the legal, cognitive, emotional and physical differences between children and adults and in taking an appropriate history, undertaking a clinical assessment and making an appropriate diagnosis for a child, should be undertaken prior to them completing a prescribing course.

A medical practitioner who is experienced and competent in prescribing for children should confirm the demonstration of competence.

If an applicant who is already a prescriber moves into a new role which requires them to prescribe for children for the first time, or after a break in practice, it would be considered good practice for them to have a period of preceptorship and they may require additional education and supervision in relation to assessment, diagnosis and prescribing for children (NMC Circular 22/2007).
PHARMACIST APPLICANT GUIDANCE

The GPhC requires that pharmacists applying to undertake an independent prescribing programme must:

- Be a registered pharmacist with the GPhC or the Pharmaceutical Council of Northern Ireland (PSNI)
- Have at least two years appropriate patient-orientated experience in a UK hospital, community or primary care setting following their pre-registration year

Applicants must have identified an area of clinical practice in which to develop their prescribing skills and have up-to-date clinical, pharmacological and pharmaceutical knowledge relevant to their intended area of prescribing practice. They must also demonstrate how they reflect on their own performance and take responsibility for their own CPD.


ALLIED HEALTH PROFESSION APPLICANT GUIDANCE

The HCPC requires that Radiographers applying to undertake a supplementary prescribing programme and all physiotherapists and podiatrists applying to undertake a supplementary or independent prescribing programme must:

a) Be registered with the HCPC in one of the relevant allied health professions.

b) Be professionally practising in an environment where there is an identified need for the individual to regularly use independent / supplementary prescribing (physiotherapists and podiatrists) or supplementary prescribing (radiographers).

c) Be able to demonstrate support from their employer / sponsor including confirmation that the entrant will have appropriate supervised practice in the clinical area in which they are expected to prescribe.

d) Be able to demonstrate medicines and clinical governance arrangements are in place to support safe and effective supplementary and / or independent prescribing.

e) Have an approved medical practitioner, normally recognised by the employer / commissioning organisation as having:

i) experience in the relevant field of practice
ii) training and experience in the supervision, support and assessment of trainees, and
iii) agreed to:
- Provide the student with opportunities to develop competences in prescribing
- Supervise, support and assess the student during their clinical placement

f) Have normally at least 3 years relevant post-qualification experience in the clinical area in which they will be prescribing.

g) Be working at an advanced practitioner or equivalent level.

h) Be able to demonstrate how they reflect on their own performance and take responsibility for their own Continuing Professional Development (CPD) including development of networks for support, reflection and learning.

i) Provide evidence of a Disclosure and Barring Service (DBS) check within the last 3 months.

ELIGIBILITY GUIDANCE FOR DESIGNATED MEDICAL PRACTITIONERS

The curricula for preparing nurse and pharmacist prescribers include no less than 12 days of learning in practice. The curricula to prepare allied health professionals (initially chiropodists/podiatrists, radiographers and physiotherapists) and optometrists as supplementary prescribers will include similar requirements.

This period of learning in practice is to be directed by a DMP who will also be responsible for assessing whether the learning outcomes have been met and whether the registrant has acquired certain competencies. The outcomes and competencies will be identified by the University of Lincoln.

Eligibility criteria for becoming a DMP

The DMP must be a registered medical practitioner who:

- Has normally had at least three years recent clinical experience in a group of patient/clients in the relevant field of practice

- Is within a GP practice and is either vocationally trained or is in possession of a certificate of equivalent experience from the Joint Committee for Post-graduate Training in General Practice Certificate or is a specialist registrar, clinical assistant or a consultant within a NHS Trust or other NHS employer

- Has the support of the employing organisation or GP practice to act as the DMP who will provide supervision, support and opportunities to develop competence in prescribing practice

- Has some experience or training in teaching and/or supervising in practice

- Normally works with the registrant. If this is not possible (such as in nurse-led services
or community pharmacy), arrangements can be agreed for another doctor to take on the role of the DMP, provided the above criteria are met and the learning in practice relates to the clinical area in which the registrant will ultimately be carrying out their prescribing role.

**Competencies for designated medical practitioners**

Before taking on the role of DMP the doctor, and the organisation, should consider the competencies needed to effectively undertake this role. The West Midlands Deanery has identified the following broad, core competency areas for GP trainers which can be adapted and used as a checklist for potential DMPs:

- the ability to create an environment for learning
- personal characteristics
- teaching knowledge
- teaching skills.

The components which make up the core competencies are available from the GP Trainer website at [www.trainer.org.uk/members/theory/evaluation/competencies_wm.htm](http://www.trainer.org.uk/members/theory/evaluation/competencies_wm.htm)

**What is a designated medical practitioner expected to do?**

The DMP has a crucial role in educating and assessing non-medical prescribers. This involves:

- Establishing a learning contract with the registrant
- Planning a learning programme which will provide the opportunity for the registrant to meet their learning objectives and gain competency in prescribing
- Facilitating learning by encouraging critical thinking and reflection
- Providing dedicated time and opportunities for the registrant to observe how the DMP conducts a consultation/interview with patient/clients and/or parents/carers and the development of a management plan
- Allowing opportunities for the registrant to carry out consultations and suggest clinical management and prescribing options, which are then discussed with the DMP
- Helping to ensure that the registrant integrates theory with practice
- Taking opportunities to allow in-depth discussion and analysis of clinical management using a random case analysis approach, when patient/client care and prescribing behaviour can be examined further
- Assessing and verifying that, by the end of the course, the registrant is competent to assume the prescribing role.
APPENDIX 2

Application Process through to Practice

1. Clearly established and written service model identifying need for non-medical prescribing role and how this role will be utilised including a role profile. Eligible staff nominated to apply for training and submit application form (Trust).

2. Application reviewed by Trust Non-Medical Prescribing Lead and where necessary, face to face review of the application with the applicant and/or line manager arranged.

3. Decision made by Trust Lead to approve the application for access to training or rejected at current time. Decision given to applicant and authorising manager.

4. Following Trust approval, applicant advised to contact University of choice to secure funded training place i.e. Lincoln or Nottingham. Details entered onto NMP training Register.

5. University request for enrolment confirmation with appropriate professional lead for Learning Beyond Registration (LBR). NMP Register checked.

6. Applicant undertakes NMP programme (6 months x 1 day per week)

7. NMP practitioner completes NMP programme, notifies lead for non-medical prescribing and registers qualification with professional body. NMP Register is amended.

8. Applicant interviewed (pre-practice) by Chief Pharmacist, details recorded and prescriptions ordered as required. Chief Pharmacist registered NMP Trust register.

9. NMP practitioner provided with revised Role Profile to cover for practice within the Trust as a NMP

10. Scope of practice agreed between the NMP, clinical supervisor and service lead. Scope of practice should identify an agreed formulary for the newly qualified NMP. As the NMP develops the scope of practice and formulary may be increased to meet the full needs of the service model.

11. Sample signature form completed (appendix 4), a copy is kept by the Pharmacy department and distributed as required.
### APPENDIX 3

**Entry to NMP Register**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FULL NAME</td>
<td>.................................................................</td>
</tr>
<tr>
<td>PROFESSION</td>
<td>.................................................................</td>
</tr>
<tr>
<td>PRESCRIBING QUALIFICATIONS</td>
<td>.................................................................</td>
</tr>
<tr>
<td>DATE OF REGISTRATION</td>
<td>Y........................</td>
</tr>
<tr>
<td>NMC/RPSBG REGISTRATION NUMBER</td>
<td>.................................................................</td>
</tr>
<tr>
<td>CRB CLEARANCE</td>
<td>YES/NO*</td>
</tr>
<tr>
<td>AREA OF PRACTICE</td>
<td>.................................................................</td>
</tr>
<tr>
<td>APPROVED TO PRESCRIBE AS AN INDEPENDENT PRESCRIBER?</td>
<td>YES/NO*</td>
</tr>
<tr>
<td>APPROVED TO PRESCRIBE AS A SUPPLEMENTARY PRESCRIBER?</td>
<td>YES/NO*</td>
</tr>
<tr>
<td>LOCATION/TEAM</td>
<td>.................................................................</td>
</tr>
<tr>
<td>CONSULTANT (other see 3.6.1) SUPERVISOR NAME</td>
<td>.................................................................</td>
</tr>
<tr>
<td>SIGNATURE OF NON MEDICAL PRESCRIBER</td>
<td>Date DD/MM/YY</td>
</tr>
<tr>
<td>TEAM ADDRESS</td>
<td>.................................................................</td>
</tr>
<tr>
<td>TELEPHONE NO</td>
<td>.................................................................</td>
</tr>
<tr>
<td>EMAIL ADDRESS</td>
<td>.................................................................</td>
</tr>
<tr>
<td>CHIEF PHARMACIST Signature</td>
<td>Date DD/MM/YY</td>
</tr>
<tr>
<td>NMP LEAD Signature</td>
<td>Date DD/MM/YY</td>
</tr>
</tbody>
</table>

Copy to Nonmedical prescriber [ ]

Line Manager [ ]

Personal File (Workforce) [ ]

Director of Nursing and Service Design [ ]

Chief Pharmacist [ ]

Pharmacy Department [ ]

*Please delete as appropriate
NMP Sample Signatures
To be completed in BLOCK CAPITALS please

Surname: ..........................................................................................................................

Forenames: ........................................................................................................................

Registration No: ............................................................................................................... 

Position: ...........................................................................................................................

Site / Base: ........................................................................................................................

Date commenced: .................... DD/MM/YYYY ..........................................

Leaving Date (if known): ........... DD/MM/YYYY .............................

NMP Contact telephone Number (office) ............... (mobile) ............... 

I understand that prescriptions, which do not comply with the Trust policy, will be referred back for correction before dispensing or administration to the service user.

Sample of FULL signature x 3
1 .................................................................................................................................

2 ..................................................................................................................................... 

3 .....................................................................................................................................

For Office Use Only. Copies to:

Personal file, Workforce

Chief Pharmacist (LPT)

Chief Pharmacist (ULHT)

Pharmacies (Boston, Lincoln, Grantham) 

Return to: Chief Pharmacist, Gervas House, Long Leys Road, Lincoln LN1 1EJ 01522 577000 ext. 7563
APPENDIX 5

RETURN TO PRACTICE/CHANGE TO CLINICAL SETTING COMPETENCY ASSURANCE FOR NMP’S

As a part of the Trust Governance arrangements for NMP the Trust seeks to maintain high levels of competencies within the NMP workforce. A single competency framework for all prescriber, National Prescribing Centre, May 2012 set out the standards that NMP’s should maintain whilst practicing under this registration. For those who work within the role of NMP’s there is a professional obligation to undertake continued professional development specifically around the prescribing practice they provide. Where prescribing is additional to their role then there will be an expectation that they engage in additional CPD to ensure that they are both up to date within their wider job role and their prescribing practice. However, for those who have a break in practice working as a NMP it can be seen that there is no evidence of current competency for that individual in prescribing. Additional where a NMP changes the field in which they work (e.g. acute inpatient psychiatry to community older adults) the knowledge and skills for the new practice area are likely to be significantly different and as such the competency to prescribe within the new clinical area would need to be evidenced. Whilst it is acknowledge by the Trust that NMP have a clear professional duty only to prescribe and practice where they are clinically competent to do so, the Trust requires assurance and needs to evidence that they have shown due diligence in allowing an individual returning to practice following a break of 6 months or more or changing to a different clinical area/specialism. For these individuals it is a requirement to undertake clinical shadowing/supervision with a prescribing supervisor who will provide the assurance of that individual’s competence. The Trust uses the same competency areas that Lincoln University take from the NPC competency framework as a part of the Lincoln University NMP course.

Time commitment for assurance of suitability to prescribe in clinical area

<table>
<thead>
<tr>
<th>Out of practice for 6 to 12 months</th>
<th>Out of practice 12 months to 5 years</th>
<th>Out of practice over 5 years</th>
<th>New clinical area/specialism with previous in depth clinical experience in area</th>
<th>New clinical area/specialism with no or limited previous working experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>45 hours</td>
<td>90 hours</td>
<td>90 hours + following this 6 to 12 months working only as a supplementary prescriber</td>
<td>45 hours</td>
<td>90 hours + 6 months experience in new work area</td>
</tr>
</tbody>
</table>

The clinical shadowing/supervision should allow the NMP a platform to discuss all aspects of prescribing and undertake diagnosis and prescribing decisions with the assessor or other prescribers within the service. It is important to note that, whilst it is possible for the NMP to undertake both the diagnosis and decision making over prescribing under the supervision of the assessor/prescriber, the NMP must not sign the actual prescription as they are not currently covered by the Trust to do so until after they have completed the assurance process. Whilst it is seen that spending time with different prescribers can broaden the experience at least 50% of the time needs to be spent with the assessor and there should be clear routes of feedback by other prescribers to the assessor.

On successful completion of the assurance process the NMP should discuss this further with the service manager to ensure that they have a job description to prescribe and fully understand how they will be expected to practice within the service delivery model. The NMP and manager should also ensure that the Trust Lead for NMP has approved the individual for prescribing prior to commencing any prescribing practice and that the NMP’s name is placed on the prescribers register held within the pharmacy department.
<table>
<thead>
<tr>
<th>The consultation</th>
<th>How the competency was evidenced</th>
<th>Assurance evidenced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has up to date clinical, pharmacological and pharmaceutical knowledge relevant to own area of practice.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Makes or reviews a diagnosis, generates management options for the patient within the scope of independent (or supplementary) prescribing. Follows up management.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Establishes a relationship based on trust and mutual respect. Recognises patients as partners in the consultation. Applies the principles of concordance and shared decision-making.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Prescribing effectively</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is aware of own limitations. Does not compromise patient safety.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ensures prescribing practice is consistent with scope of practice, organisational, professional and regulatory standards, guidance and codes of conduct.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actively participates in the review and development of prescribing practice to optimise patient outcomes.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Prescribing in context</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Understands and works with local and national policies, processes and systems that impact on prescribing practice. Sees how own practice impacts on the wider healthcare community.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knows how to access relevant information. Can critically appraise and apply information in practice.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Works in partnership with colleagues for the benefit of patients. Is self-aware and confident in own ability as a prescriber.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Prescribing for children and young people</strong> <em>(for NMP prescribing to under 18’s)</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Can take an appropriate history, undertake a clinical assessment and make an appropriate diagnosis having considered the legal, cognitive, emotional and physical differences between children and adults.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Signature of NMP…………………………………………………………………………………………………Date……………………………………

Signature of Prescriber
Supervisor/assessor…………………………………………………………………………………………………Date……………………………………
## Clinical Management Plan

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<thead>
<tr>
<th>Name of Patient:</th>
<th>Patient medication sensitivities/allergies:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient date of birth:</td>
<td>Patient number or NHS Number:</td>
</tr>
<tr>
<td>Date of implementation:</td>
<td></td>
</tr>
<tr>
<td>Current Medication:</td>
<td>Medical History:</td>
</tr>
<tr>
<td>Independent Prescriber(s): Contact details [tel./email/address]</td>
<td>Supplementary prescriber(s): Contact details [tel./email/address]</td>
</tr>
<tr>
<td>Condition(s) to be treated:</td>
<td>Aim of treatment:</td>
</tr>
<tr>
<td>Medicines that may be prescribed by SP:</td>
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</tr>
<tr>
<td>Preparation</td>
<td>Indication</td>
</tr>
<tr>
<td>Guidelines or protocols supporting Clinical Management Plan:</td>
<td></td>
</tr>
<tr>
<td>Frequency of review and monitoring by:</td>
<td></td>
</tr>
<tr>
<td>Supplementary prescriber</td>
<td>Supplementary prescriber and independent prescriber</td>
</tr>
<tr>
<td>Process for reporting ADRs:</td>
<td></td>
</tr>
<tr>
<td>Shared record to be used by IP and SP:</td>
<td></td>
</tr>
<tr>
<td>Agreed by independent prescriber(s): (Signature &amp; Print)</td>
<td>Agreed by supplementary prescriber(s): (Signature &amp; Print)</td>
</tr>
<tr>
<td>Date:</td>
<td>Date:</td>
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</table>
Production and use of Patient Group Directions (PGDs)

<table>
<thead>
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<th>DOCUMENT VERSION CONTROL</th>
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</thead>
<tbody>
<tr>
<td><strong>Document Type and Title:</strong></td>
<td>Production and Use of Patient Group Directions: Policy</td>
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<tr>
<td><strong>New or Replacing:</strong></td>
<td>Replacing</td>
</tr>
<tr>
<td><strong>Version No:</strong></td>
<td>2</td>
</tr>
<tr>
<td><strong>Date document first written:</strong></td>
<td>May 2008</td>
</tr>
<tr>
<td><strong>Date document first implemented:</strong></td>
<td>October 2009</td>
</tr>
<tr>
<td><strong>Date document last reviewed and updated:</strong></td>
<td>September 2015</td>
</tr>
<tr>
<td><strong>Implementation Date:</strong></td>
<td>September 2015</td>
</tr>
<tr>
<td><strong>Author:</strong></td>
<td>Chief Pharmacist</td>
</tr>
<tr>
<td><strong>Approved by:</strong></td>
<td>Board of Directors</td>
</tr>
<tr>
<td><strong>Approval Date:</strong></td>
<td>29th October 2015</td>
</tr>
<tr>
<td><strong>Ratifying Body:</strong></td>
<td>Board of Directors</td>
</tr>
<tr>
<td><strong>Ratified Date:</strong></td>
<td>29th October 2015</td>
</tr>
<tr>
<td><strong>Committee, Group or Individual Monitoring the Document:</strong></td>
<td>Medicines Management Committee</td>
</tr>
<tr>
<td><strong>Review Date:</strong></td>
<td>September 2016</td>
</tr>
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  4.2 Consideration of the PGD
  4.3 Completing a PGD template
  4.4 Approval of a PGD
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1 Introduction

In August 2000, following publication of the 1998 Crown report ‘Review of the Prescribing, Supply and Administration of Medicines’ changes were made to legislation to clarify the role and status of group protocols. These became Patient Group Directions (PGDs). At this time the government issued guidance to help ensure that organisations used and produced PGDs in a consistent and safe way (HSC 2000/026: http://www.dh.gov.uk). The current legislation for PGDs is included in The Human Medicines Regulations 2012. The legislation was amended in 2013 to reflect changes as a result of The Health and Social Care Act 2012.

PGDs provide a framework for health professionals to work more flexibly for the benefit of the patient.

This guidance provides good practice recommendations for LPFT staff involved with PGDs, with the aim of ensuring patients receive safe and appropriate care, and, timely access to medicines, in line with legislation. Clear governance and accountability arrangements must be in place.

2 Purpose

This guidance outlines the procedures to be followed in fulfilling the responsibility of Lincolnshire Partnership NHS Foundation Trust (LPFT) to ensure that the administration of medicines by staff operating under Patient Group Directions is safe, secure and in accordance with Legislative requirements and best professional practice. This policy outlines the approach to be taken by LPFT to the development, approval, and implementation of PGDs. The policy takes into account the NICE Good Practice Guidance (MPG2) published in August 2013.

This guidance ensures a consistent approach within the Trust for the development and use of PGDs. The guidance should be read in conjunction with the following documents:

- LPFT Medicines Management Policy (OPR17)

The purpose of a PGD is to:

- Deliver effective patient care that is appropriate in a pre-defined clinical situation, without compromising safety
- Provide equity in the availability and quality of service when other options for supplying the treatment are not available
- Offer a significant advantage to patient care by improving access to appropriate medicines
- Provide a safe legal framework to protect patients
- Reduce delays in treatments
- Maximise the skills of the health professionals

3 Definitions

3.1 Patient Group Direction (PGD):

A PGD is defined in Health Service Circular (HSC 2000/026) as a written instruction for the supply or administration of a single dose or a short course of a specified medicine in a specified clinical situation by a specified registered healthcare professional. The treatment can be given without the need of a prescription or written instruction. It can be considered for use where this offers an advantage to service user care without compromising safety and is consistent with professional accountability. PGD’s are not
intended as a substitute for individual prescribing where there is an opportunity in the care pathway for a medicine(s) to be prescribed. The majority of clinical care should be provided on a one-2-one basis.

PGDs must be produced by healthcare professionals working in a clinical area where the PGD will be used. Legislation requires a PGD must be approved by at least the medical director and chief pharmacist. A PGD must also be ratified by the Trust’s Medicines Management Committee before final approval for use is given.

3.2 Appointed Practitioner in Charge:

For the purpose of this policy, an appointed practitioner in charge is a registered healthcare professional with overall responsibility for the delivery of care within a ward / unit / area of the Trust, who will have overall responsibility for adherence to PGD policy in this area.

3.3 Nominated Assessor:

An experienced PGD Practitioner nominated by the Appointed Practitioner in Charge to assess the competence of the proposed PGD Practitioner(s).

3.4 PGD Practitioner:

For the purpose of this policy, a PGD Practitioner is a registered healthcare professional who has successfully demonstrated their competence to their Appointed Practitioner in Charge or Nominated Assessor and has been validated by the Appointed Practitioner in Charge to supply or administer specified medicines to service users by PGD.

4 Procedure for Producing a Patient Group Direction

4.1 Proposal for the production of a PGD

PGDs should be reserved for situations where their use offers benefit to care without compromising safety. To ensure legal compliance and a standardised approach when developing a PGD, the following procedure must be followed to satisfy Trust policy and national legislation. Details on current legislation can be found from:

https://www.nice.org.uk/guidance/mpg2/chapter/1-Introduction

The team identifying a need for a new PGD will in conjunction with their locality clinical pharmacist develop rationale using the template in Appendix B. Teams considering the need for a PGD are advised to consult the following documents available from


- ‘So you think you need a PGD’
- ‘To PGD or not to PGD?’ (Appendix A)
- ‘Is a PGD appropriate?’

4.2 Consideration of the PGD

PGD’s must only include medicines with a UK marketing authorisation. Unlicensed medication may not be administered under a PGD. This includes the mixing of two licensed medicines to make one new unlicensed product. Off-label use of a licensed medication can be included in a PGD only when clearly justified by best clinical practice.
Black triangle (▼) medicines are new medicines and vaccines that require additional monitoring. These may be included as a PGD; however it must be clearly justified by current best clinical practise (see section 6 – Adverse Reactions Management).

Certain controlled drugs may only be included in a PGD when legally permitted and clearly justified by best clinical practise. Controlled drugs may not be supplied or administered if required to treat addiction.

Medicines which require frequent dosage adjustments or frequent monitoring such as anticoagulants or insulin are not appropriate to be included as a PGD.

PGD’s which are supplied are applicable to prescription charge rules and exemptions. PGD’s administered to an in-patient do not incur a prescription charge.

4.3 Completing a PGD template

A member of the local multidisciplinary team will complete a PGD template (Appendix C). The PGD must

- Ensure that the medicine is used in a manner consistent with its summary of product characteristics and/or any relevant guidance from the National Institute for Health and Clinical Excellence (NICE). Information on medicines SPC can be found at https://www.medicines.org.uk/emc/
- Ensure all the legally required information is completed on the PGD template (Appendix C)
- Ensure that the medicine issued complies with the European Community Labelling and Leaflet Directive 92/27
- Specify any additional training that a practitioner must undergo and any competence that must be demonstrated before a practitioner can be authorised to work under the PGD.

The completed template and rationale for the PGD (Appendices B and C) are submitted to the Trust Pharmacy Service for consideration by the Medicines Management Committee. The PGD should contain the following information;

- The duration the PGD will be effective
- The medicine the PGD covers
- The clinical situation in which the PGD may be used
- The clinical criteria for treatment
- What inclusion or exclusion restrictions if any, the medicine or approved practitioner may have i.e. administering a vaccine only if recently trained, limiting the supply or quantity of a medicine, etc?
- When further medical advice needs to be sought and what actions will be followed up, and by whom
- The strength, dosage, frequency and route of the product
- Any time intervals or durations between which, or, within which, the medicine should be administered.
- Any interactions, contraindications, warnings or precautions

4.4 Approval of a PGD

Considerations and evidence as to why the PGD would be the most appropriate option must be put forward in the PGD template as set out by NICE guidelines (www.nice.org.uk/guidance/mpg2/chapter/2- Recommendations). If approved, the PGD will be forwarded for authorisation to the Medicines Management Committee co-chair, or Medical Director in their absence to avoid undue delay in authorising PGDs if
necessary, Chief Pharmacist and Trust Clinical Governance / Nursing Lead. PGDs must also be signed on behalf of the authorising body (e.g. CCGs, local authorities, NHS trusts or NHS foundation trusts, the NHS Commissioning Board), as set out in the legislation.

The final version must be made available on the Trust intranet pharmacy homepage.

### 4.5 Use of the PGD

An authorised PGD may be used by practitioners within the local team whose competence to do so has been verified by the Appointed Practitioner in Charge or their Nominated Assessor. The competency must ensure that the health professional has understood the content and context of the PGD and have signed the relevant documentation to state as such.

When supplying and/or administering PGD’s health professionals must ensure

- That the PGD is in date and it is the most recent document available
- That the patient meets the inclusion criteria and that no exclusion criteria apply
- That they are aware of information about the medicine (e.g. how to administer, dosage calculations, how medicine works in the body, potential adverse reactions, drug interactions, precautions and contraindications)
- That they have carried out the relevant clinical checks and have assessed the service user
- That they know how and where to document administration and/or supply. Details must include date, time, how the patient met the criteria, details of medicine being given, and a signed statement that the medicine has been given by using a PGD.

A flow chart of things to consider when administering a PGD can be found in Appendix E of this document. It is intended as a prompt for staff, so they are clear on what they need to be thinking about when administering PGD’s.

### 4.6 Review of a PGD

A PGD may remain in use for two years after authorisation before it requires a review into re-authorisation. PGD’s should be reviewed in advance of the expiry date or sooner if problems are identified. The PGD should be reviewed with the following in mind;

- Is the PGD still the most appropriate option to deliver the service? (e.g. are there additional prescribers available?)
- Any changes in legislation or to NICE guidelines
- New information in drug safety
- Changes in the summary of product characteristics
- Changes to the local formulary
- How often is the PGD being used and does the criteria meet patient need
- The views of health professionals working under the PGD
- Any patient safety incidents

Findings from the safe and secure handling of medicines audit should be linked when reviewing and revising a PGD.

If a PGD is reviewed and re-authorised it is essential that old copies are removed and destroyed and only current copies are in use.
5 Duties and Responsibilities

5.1 Organisational Responsibility

- The Trust has a responsibility to oversee this process and to ensure that PGDs are managed in a safe manner.
- Local teams are responsible for managing their PGD administration.
- The co-chair for the Medicines Management Committee or, Medical Director in their absence, Chief Pharmacist and Director of Nursing of the Trust will sign to authorise the PGD once approved before use by the Medicines Management Committee (MMC).
- The Trust’s Medicines Management Committee will oversee the development and management of all Patient Group Directions.
- The Trust’s Corporate & Legal Services Department will ensure that for each authorised PGD, a master record is kept of:
  - The serial number of the PGD
  - Ward(s), area(s) or team(s) using the PGD
  - Medication to be administered or supplied
  - Clinical indication for administration or supply
  - Authorisation date
  - Review date
- The Trust’s Training Department will manage training materials, and keep copies of PGD Practitioner verification documents.
- The Trust Pharmacy Service will retain copies of all authorised PGDs, including obsolete ones.
- The Trust Pharmacy Service will ensure that PGDs are developed according to the legal and clinical requirements and provide support in the training and management of PGDs.
- Personnel from within the clinical area where the PGD is proposed to be used must be involved in its development. A local doctor and pharmacist and member of the profession to whom it relates, should be involved. The proposed PGD must be signed by a doctor/dentist and pharmacist involved in its writing along with a member of the profession to whom it relates.
- Local teams are responsible for the review and updating of PGDs
- Local teams will re-submit the PGD to the Pharmacy Service before its expiry date, or if any alterations are required before this date, for re-submission to the Medicines Management Committee (MMC). A PGD may not be altered without being ratified by MMC and re-authorised for use.
5.2 Local Management Responsibility

Authorised PGDs may remain in use for a maximum of two years from the date of authorisation. The local team using the PGD retain responsibility for the following:

- Auditing PGD practice. The audit should address the following aspects to ensure the safe and appropriate use of the PGD:
  - The PGDs are in date and approved for use.
  - PGD medicines are only administered by verified PGD practitioners.
  - Written administration / supply records and signatures are recorded.
  - Information about the medicine is given to service users.
  - If pre-packed medicines are used for PGD supply, the Stock Record Book provides a clear audit trail of pre-pack usage.
  - Re-submitting the PGD to the Medicines Management Committee (MMC) via the Trust Pharmacy Service before its expiry date, or if any alterations are required before this date. A PGD may not be altered in any way without being ratified by MMC and re-authorised as outlined in the procedure above.

Ensuring adequate document control of all paperwork relating to the PGD. At any time only the current version of a PGD must be available.

5.3 Appointed Practitioner in Charge or Nominated Assessor

- The Appointed Practitioner in charge of each ward, department or area is responsible for ensuring that proposed PGD Practitioners have had their competence verified and maintain list of names of authorised PGD Practitioners within their area (Included with Appendix C PGD template).

- Competencies are validated by signing the competency statement (Appendix D) to indicate that a PGD Practitioner has achieved this satisfactory standard of competency.

- The Appointed Practitioner in Charge or their Nominated Assessor is responsible for ensuring that a PGD Practitioner is given a copy of any PGD that they are verified to work under. Further copies of the PGD must be available on the ward / area / unit for reference.

- The Appointed Practitioner in Charge must adhere to the requirements of any document control procedures put in place locally or across the Trust

- Re-verifying competence for a PGD practitioner may be necessary after major review of a PGD or as deemed fit by clinical supervision requirements.

- A 'Managers Manual' is available as a guide to assist managers in the day-to-day management of PGDs within their units. A manager can delegate the task of assisting in managing the PGDs and assessing potential practitioners to a nominated person (the Nominated Assessor). Trust Pharmacy staff will provide support to managers and Nominated Assessors where requested.
5.4 **PGD Practitioner Responsibility**

- A practitioner wishing to work under a PGD must demonstrate knowledge and understanding of the legal framework of PGDs to their Appointed Practitioner in Charge or Nominated Assessor. Practitioners must demonstrate knowledge and understanding to evidence their competence to work under a specific PGD.

- Authorisation to be a PGD Practitioner with another organisation does not negate this requirement. PGD study material is available for staff to access on the Medicines Management intranet site.

- PGD Practitioners are responsible for keeping up to date with all medicines that they are administering or supplying under PGD. Practitioners must work within the PGD and their own clinical competence.

Failure to comply with any of the above will result in cancellation of the PGD Practitioner’s verification.

5.5 **Service User Responsibilities**

- Service users may accept or decline to be treated under a PGD protocol.

6 **Adverse Drug Reactions Management**

6.1 In addition to making a record in the service user’s medical notes, suspected adverse drug reactions may also need to be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) via the “Yellow Card” scheme:

6.2 Yellow cards can be found at the back of the British National Formulary, or can be completed online at [http://www.yellowcard.gov.uk](http://www.yellowcard.gov.uk).

6.3 For intensively monitored (black triangle) drugs, all suspected reactions, including those not considered to be serious is expected to be reported. For established drugs and herbal remedies, serious adverse reactions in adults should be reported; all serious and minor reactions in children Under 18 years should be reported.

LPFT Pharmacy Services should be contacted for further advice if necessary.

7 **Training and Competency**

A senior person in each profession should be responsible for ensuring that only fully competent, qualified and trained health professionals use PGDs. The training should cover:

- Understanding of the requirements of PGDs
- Knowledge of the legislative framework that underpins the PGD
- Knowledge of pharmacology of the drug.
- Knowledge of the administration practices.

It is the responsibility of each practitioner to ensure they are competent to deal with each patient under the terms of the PGD.

Supply and/or administration of a medicine must not be delegated to any other person under a PGD.
Professionals should identify gaps in competency and establish an appropriate training programme for all people involved in considering the need for, developing, authorising, using and updating PGDs.

8 Consultation, Approval and Ratification Process

This policy will be consulted upon in line with ‘Corporate Documents and Policies Procedure’. The policy will be approved and ratified according to the processes laid out in ‘Corporate Documents and Policies Procedure’.

9 Review and Revision Arrangements including Version Control

This policy will be reviewed by the appropriate Executive Committee every THREE years or as the need arises due to changes in legislation or guidance.

Corporate and Legal Services will maintain a version control sheet, as per ‘Corporate Documents and Policies Procedure’.

10 Dissemination and Implementation

The policy will be disseminated as per ‘Corporate Documents and Policies Procedure’.

Implementation of the policy will be ensured partly through staff supervision which will involve staff who use PGDs having to give assurance and demonstrate competence to their assessor.

Correct implementation of the policy can also be monitored through medicine management audits.

To ensure the safe and appropriate use of medicines under a PGD the following table indicates the training needs of relevant groups of Trust staff:

<table>
<thead>
<tr>
<th>Staff group</th>
<th>Training need</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Medical Staff</td>
<td>To be aware of this policy and any updates.</td>
</tr>
<tr>
<td>Non-Medical Prescribers</td>
<td>To be aware of this policy and any updates.</td>
</tr>
<tr>
<td>Approved PGD Practitioners</td>
<td>To be aware of this policy and any updates. To demonstrate competence in supply / administration of specific medications within their practice. To demonstrate knowledge and understanding of the legal framework of PGDs.</td>
</tr>
<tr>
<td>Allied Health Care Professionals, who may be authorised to use PGDs</td>
<td>To be aware of this policy and any updates. To demonstrate competence in supply of specific medications within their practice. To demonstrate knowledge and understanding of the legal framework of PGDs.</td>
</tr>
<tr>
<td>LPFT Pharmacy staff</td>
<td>To be aware of this policy and any updates, in order to give adequate support to PGD Practitioners / Assessors.</td>
</tr>
</tbody>
</table>
For practical guidance, see:

- ‘A practical guide and framework of competencies for all professionals using PGDs’

- [http://medicines.mhra.gov.uk/inforesources/publications](http://medicines.mhra.gov.uk/inforesources/publications)

- PGD study material on the Trust Medicines Management intranet site.

- Patient Group Directions. Guidance and information for nurses. Royal College of Nursing 2006

11 Policy Control including Archiving Arrangements

Corporate and Legal Services will retain a copy of each policy for a minimum of 10 years in line with the recommendations contained within 'Records Management NHS Code of Practice' (2006)

12 Monitoring Compliance and Effectiveness

Audit must be used to ensure the safe and appropriate use of PGDs within the Trust.

Local audit of PGD practice should address the following aspects to ensure the safe and appropriate use of the PGD:

- The PGDs are in date and approved for use.

- PGD medicines are only administered by verified PGD practitioners.

- Administration / supply records and signatures are complete.

- Information about the medicine is given to service users.

- If pre-packed medicines are used for PGD supply, the Stock Record Book provides a clear audit trail of pre-pack usage.

Trust audit data will be obtained from:

- The submitted requests for development of a PGD

- The Safe & Secure Handling of Medicines Audit tool

- Training department records of staff authorised as PGD Practitioners.
<table>
<thead>
<tr>
<th>Systems</th>
<th>Monitoring and/or Audit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria</td>
<td>Measurables</td>
</tr>
<tr>
<td>Systems in place to ensure that the policy is being adhered to.</td>
<td>Number of PGDs approved by MMC and dates of approval. Number of PGDs rejected, at what stage and for what reason</td>
</tr>
<tr>
<td>Systems in place to ensure all PGDs are reviewed before their expiry date is reached.</td>
<td>Number of PGDs past expiry date that have not been re-submitted for approval</td>
</tr>
<tr>
<td>Systems in place to ensure departments audit use of the PGD locally</td>
<td>Number of audits received by departments in comparison with PGDs and action taken.</td>
</tr>
<tr>
<td>Staff are verified as being approved practitioners</td>
<td>Number of staff verified as being approved practitioners under one or more PGDs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TARGET/STANDARDS</th>
<th>KEY PERFORMANCE INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>All PGDs submitted and written as per policy &amp; national guidance.</td>
<td>Number of PGDs rejected as incomplete</td>
</tr>
<tr>
<td>All PGDs used are in date</td>
<td>Number of PGDs not reviewed within timescale</td>
</tr>
</tbody>
</table>

13 References


14 **Associated Documentation**

- Appendix A: To PGD or not to PGD
- Appendix B: Proposal for the Production of a PGD
- Appendix C: PGD Template Incorporating Approved Practitioner List
- Appendix D: Competency Testament
TO PGD OR NOT TO PGD? – That is the question.

(A guide to choosing the best option for individual situations)

This guide has been prepared in response to the many queries that are now being raised both locally and nationally about the implementation of HSC 2000/026 (in England), WHC (2000) 116 in Wales, on Patient Group Directions. The co- incidental introduction of nurse prescribing (and its likely extension to new groups of nurses) has confused many practitioners, and there is a danger that inconsistencies may develop as the implementation of both initiatives continues.

Practitioners and their managers who wish to formalise or set up new systems for prescribing by nurses, or alternatively the supply or administration of medicines, are faced with a range of different methods and need to select the most appropriate route in each case. The diagram below takes the practitioner through a logical process that aims to assist decision-making. The majority of clinical care should still be provided on an individual, patient-specific basis.

START

An area of practice that involves prescribing, supply or administration of medicines has been identified. You are asked to consider whether a Patient Group Direction (PGD) would be appropriate.

Yes

Are the products involved all licensed medicines?

No

A PGD is not needed for dressings and other medical devices – the PGD legislation applies only to licensed medicines.

Consider protocol or treatment guidelines.

Yes

Are the practitioners involved accredited with the UKCC as nurse prescribers, and provide activity within a walk-in centre or GP practice? AND Are the medicines involved included in the current nurse prescriber’s formulary (NPF)?

No

Are the medicines involved P(Pharmacy) or GSL (General Sales List) medicines?

Yes

Continued on next page.

No

Does the practitioner want to administer only, and does not need to supply the medicines for patient to take at home?

Yes

P medicines can only be sold or supplied through registered pharmacies, so PGD may be required.

No - supply is required.

GSL medicines There is no problem with GSL medicines.

Yes

PGD may be good practice, but is not legally required. Honestly comply protocols can be arranged without the need for PGDs provided all medicines are P or GSL.

Appendix A
Continued from previous page.

Are the practitioners who will supply or administer medicines included below?
- Nurses
- Midwives
- Health visitors
- Optometrists
- Pharmacists
- Radiographers
- Orthoptists
- Physiotherapists
- Ambulance paramedics
- Chiropodists / podiatrists

No

Is the treatment to be provided by:
- NHS Trust
- Health Authority
- Walk-in Centre
- Primary Care Trust
- GP or dental practice
- NHS funded family planning clinic?

No

Is the activity provided by a private or voluntary sector organisation but funded via an NHS contract?

Yes

Does activity involve any Controlled Drugs?

Yes

PGD may be used.

No

Misuse of Drugs Act does not allow use of PGD for CDs. This may be amended in future.

Yes

This may be addressed most appropriately through supplementary prescribing, when this is introduced. It does not fit the present definition for a PGD.

No

The HSC/WHC states that: *supply or administration of medicines under PGD should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.*

- Does the proposed activity meet these principles?

Yes

A PGD may be the most appropriate route to provide this clinical activity. Follow guidance in HSC/WHC, ‘Crow’ Report and local Trust or HA policy.

No

An alternative method using individual prescriptions will need to be considered e.g. obtaining prescription in advance to be dispensed if needed, standby supply of medication etc.
## Proposal for Production of a Patient Group Direction

<table>
<thead>
<tr>
<th>Ward/ area/ unit or team</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td></td>
</tr>
<tr>
<td>Clinical Indication</td>
<td></td>
</tr>
</tbody>
</table>

**For administration or supply?**

- **What is the current clinical practice in this situation?**

- **What benefits to service user care would this PGD offer?**

- **What risks to service user care would this PGD present?**

---

### Submitted by

<table>
<thead>
<tr>
<th>Signature</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Print name</td>
<td></td>
</tr>
<tr>
<td>Job Title</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td></td>
</tr>
</tbody>
</table>

This proposal must be submitted with Appendix C
Patient Group Direction Template

Incorporating Approved PGD Practitioner List

**PGD Serial Number ……………………**

<table>
<thead>
<tr>
<th><strong>Name of Medication</strong></th>
<th><strong>Legal Classification</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>For service users under the care of …………………….Ward/Unit/Team</td>
<td>(P / PoM)</td>
</tr>
</tbody>
</table>

**Staff authorised to work under this PGD**

*Detail all necessary qualifications, registration details and mandatory training*

*(For example; registered nurse with a valid professional registration who has undertaken appropriate training and Trust validation to administer / supply medicines under PGD).*

The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development.

<table>
<thead>
<tr>
<th><strong>PGD valid from</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PGD review date</strong></td>
<td></td>
</tr>
<tr>
<td><strong>PGD expiry date</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Authorised by Trust**

<table>
<thead>
<tr>
<th><strong>Name</strong></th>
<th><strong>Signature</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Chief Pharmacist</td>
<td></td>
</tr>
<tr>
<td>Medical Director</td>
<td></td>
</tr>
<tr>
<td>Clinical Governance Lead</td>
<td></td>
</tr>
</tbody>
</table>
Patient Group Direction Template

Incorporating Approved PGD Practitioner List

<table>
<thead>
<tr>
<th>Name of Medication</th>
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</tr>
</thead>
<tbody>
<tr>
<td>For service users under the care of …………………….Ward/Unit/Team</td>
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</table>

<table>
<thead>
<tr>
<th>Clinical Condition</th>
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</thead>
<tbody>
<tr>
<td>Indication</td>
</tr>
<tr>
<td>Inclusion Criteria</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
</tr>
<tr>
<td>Cautions/need for further advice</td>
</tr>
<tr>
<td>Action if excluded</td>
</tr>
<tr>
<td>Action if treatment declined</td>
</tr>
</tbody>
</table>
### Patient Group Direction Template

**Incorporating Approved PGD Practitioner List**

PGD Serial Number …………………

<table>
<thead>
<tr>
<th>Name of Medication</th>
<th>Legal Classification (P / PoM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>For service users under the care of …………………….Ward/Unit/Team</td>
<td></td>
</tr>
</tbody>
</table>

#### Details of Medication

<table>
<thead>
<tr>
<th>Details of Medication</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of medicine</td>
<td></td>
</tr>
<tr>
<td>Dose</td>
<td></td>
</tr>
<tr>
<td>Route of administration</td>
<td></td>
</tr>
<tr>
<td>Frequency of administration</td>
<td></td>
</tr>
<tr>
<td>Period of treatment</td>
<td></td>
</tr>
<tr>
<td>Potential side effects</td>
<td></td>
</tr>
<tr>
<td>Follow-up action if required</td>
<td></td>
</tr>
</tbody>
</table>

### Record keeping

Details of records to be made in the service user’s notes:

- Assessment of service user need in relation to the intervention
- Name of the medicine (including brand if relevant)
- Batch number and expiry date of medicine
- Date and time of administration
- Dose given
- Site of injection (if relevant)
- Advice given to the service user
- Signature and printed name in black ink for paper records
- Authentication of practitioner delivering care for computer
<table>
<thead>
<tr>
<th>Black Triangle Drug?</th>
<th>YES / NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment within the terms of the manufacturer’s Summary of Product Characteristics (SPC)?</td>
<td>YES / NO</td>
</tr>
</tbody>
</table>

References
Patient Group Direction Template
Incorporating Approved PGD Practitioner List

PGD Serial Number ……………………

<table>
<thead>
<tr>
<th>Name of Medication</th>
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</tr>
</thead>
<tbody>
<tr>
<td>For service users under the care of …………………….Ward/Unit/Team</td>
<td></td>
</tr>
</tbody>
</table>

Approved PGD Practitioner List

<table>
<thead>
<tr>
<th>Date</th>
<th>Practitioner</th>
<th>Verifying Manager</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Name</td>
<td>Signature</td>
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<td></td>
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</table>

This list is to be kept on the ward with a master copy of the PGD
All staff approved to work under this PGD should be given a copy.
COMPETENCY TESTEMENT

I have undergone PGD competency assessment for the drugs listed below and I agree to act as an approved PGD Practitioner within the terms of the PGDs below.

In return, the Trust accepts vicarious liability for the approved practitioner acting under the terms of the PGD.

Practitioner’s name (print)
Signature
Job title
Professional registration number
Date

I verify the above practitioner has demonstrated their understanding of Patient Group Directions and is competent to work under such Directions within Lincolnshire Partnership NHS Foundation Trust.

Name (print)
Signature
Job title
Date

All registered professionals are personally responsible for their practice and in the exercise of professional accountability, there is a requirement to maintain and improve their professional knowledge and competence. Practitioners should be aware of any changes to the recommendations for the medicine listed.

<table>
<thead>
<tr>
<th>Drug</th>
<th>PGD Serial Number</th>
<th>Approved Practitioner in Charge / Nominated Assessor Signature &amp; Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
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<tr>
<td>2.</td>
<td></td>
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<td>3.</td>
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<tr>
<td>4.</td>
<td></td>
<td></td>
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<tr>
<td>5.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Original to be kept by Approved Practitioner in Charge
Copy to PGD Practitioner
Copy to Learning & Development Department
What to consider when using a PGD - Flowchart

Service user (inpatient) complaining of specific ailment.
Is a prescriber available?

Yes

Do not use PGD; individual prescribing should always be first line treatment

No

Are you happy with what service user is telling you, have you assessed the patient and carried out the relevant clinical checks – are you able to provide patient care under a PGD without compromising patient safety?

No

Do not supply/administer under PDG. Maintaining patient safety is always the priority

Yes

Consider all alternatives before supplying/administering under a PGD

Are there any alternative therapies available at this time?

Yes

No

Unable to supply/administer anything under PGD criteria. If this is a reoccurring issue consider proposing a new PGD

Is there a PGD in place which is applicable to the clinical indication?

No

Yes

Consider all alternatives before supplying/administering under a PGD

Yes

Does the service user fit the clinical inclusion criteria for the specific PGD?

No

PGD may NOT be used

Yes

No

Does the service user suffer from any of the clinical exclusion criteria?

Yes

PGD may NOT be used

No
Have you taken into consideration the service user’s allergy status, medical history, patient consent

Yes

Is the service user prescribed or taking any other medication which may cause an interaction, contraindication or where precautions may arise?

Yes

PGD may NOT be used

No

Are you aware of the summary of product characteristic for the medication?

Yes

 Ensure you are completely familiar with the SPC’s for all of the PGD’s available to you. SPC’s can be found at https://www.medicines.org.uk/emc/

No

Are you aware of the route of administration, the dose and the period of treatment?

Yes

Refer to specific PGD. Ensure you are aware of all the information included in the PGD before supply/administration

No

Do you know where, what to record and how to record the supply/administration of a PGD to a service user?

Yes

Refer to specific PGD. Ensure you are aware of all the information included in the PGD before supply/administration

No

Yes

No

PGD may be supplied/administered.
# DOCUMENT VERSION CONTROL

<table>
<thead>
<tr>
<th>Document Type and Title:</th>
<th>Self-Administration of Medicines Programme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorised Document Folder:</td>
<td>Operational</td>
</tr>
<tr>
<td>New or Replacing:</td>
<td>Replacing</td>
</tr>
<tr>
<td>Document Reference:</td>
<td>Medicines Management and Medical Devices Policy Appendix O</td>
</tr>
<tr>
<td>Version No:</td>
<td>2</td>
</tr>
<tr>
<td>Date Policy First Written:</td>
<td>September 2007</td>
</tr>
<tr>
<td>Date Policy First Implemented:</td>
<td>October 2007</td>
</tr>
<tr>
<td>Date Policy Last Reviewed and Updated:</td>
<td>June 2013</td>
</tr>
<tr>
<td>Implementation Date:</td>
<td></td>
</tr>
</tbody>
</table>
| Author: | Richard Lewis (Chief Pharmacy technician)  
| | Gary Jacobs (Senior Pharmacy technician) |
| Approving Body: | Medicines Management Committee |
| Approval Date: | |
| Ratifying Body: | Quality Committee |
| Ratified Date: | |
| Committee, Group or Individual Monitoring the Document: | Medicines Management Committee |
| Review Date: | Two years from revision approval |
POLICY FOR THE SELF ADMINISTRATION OF MEDICINES PROGRAMME
Contents

1. Introduction
2. Purpose
3. Duties
4. Definitions
6. Consultation, Approval and Ratification Process
7. Review and Revision Arrangements including Version Control
8. Dissemination and Implementation of a Policy
9. Policy Control including Archiving Arrangements
10. Monitoring Compliance with and Effectiveness of Policies and Procedures
11. References
12. Associated Documentation
   1. Appendix 1: SAM Assessment Form
   2. Appendix 2: Patient Consent Form
   3. Appendix 3: Service Users Personal Administration Record
   4. Appendix 4: SAM stage 1 and 2 Form
   5. Appendix 5: SAM stage 3 Form
   6. Appendix 6: Medication Compliance Aid Assessment Form
1. Introduction

The aim of this programme is to allow service users to administer their own medicines. This should be of benefit for the service user's rehabilitation, enhancing understanding of their medicines and reducing re-admission to hospital due to poor medication compliance.

Before a service user commences this programme a number of conditions must be met:

1) The service user is selected by the multidisciplinary team, having been considered a suitable candidate.

2) A risk assessment is carried out to identify the risks associated with the service user keeping supplies of their own medicines in lockable facilities at stage 3 of the programme.

3) The service user's medication knowledge and skills required for correct handling of medication has been assessed (Self Medication Assessment, Appendix 1), and the service user has commenced appropriate training to ensure knowledge of the medication, dose and timing of administration, and whether he/she can manipulate the packaging satisfactorily.

4) A contract is signed by the service user, named nurse, consultant and pharmacy staff before commencing each stage of the programme. (Consent to join form Appendix 2)

This programme comprises of three stages, with varying levels of supervision:

- **Stage 1: Assessment and supervised administration**
- **Stage 2: Self administration with direct supervision**
- **Stage 3 Self administration without direct supervision**

2. Purpose

- The aim of this policy is to outline the Trust's responsibility to ensure that the organisation handles self-administration of medicines safely and securely, in accordance with the Trust's Medicines Management Policy, legislative requirements, NHSLA Standards and best practice.
This guideline has been prepared in line with the National Service Framework 2002 milestone for self-administration of medicines and with reference to the Nursing and Midwifery Council Guidelines for the Self Administration of Medicines. The Healthcare Commission document *Talking about Medicines – the management of medicines in trusts providing mental health services* (2007), highlights that persons wishing to self-administer should be encouraged to do so, or if deemed inappropriate, should be advised as to the reasons why.

This policy applies to service users currently receiving inpatient care supervised by LPFT.

To be able to offer self-administration to service users, we need to ensure there is no unacceptable increase in risk to the service user or others. As such, there must be an assessment of competency to self-administer.

Self-medication allows medication to be taken at the correct time, instead of waiting for a medication round. It provides opportunity to access service user's understanding of their medication and their ability to safely administer their own medication in preparation for regular leave periods, and eventual discharge into the community. The process should lead to a more seamless discharge into the community as the service user has already been assessed and reviewed on their medication administration ability and provided with the necessary information about their medicines.

Self medication should therefore reduce the number of re-admissions to hospital linked to medication problems and will provide increased contact and communication between service users, healthcare staff on the wards and pharmacy staff.

Opportunities during the self-medication assessment process are extended to provide education to the service user regarding the importance of medication in their treatment, and for the service user to discuss any concerns they may have about their medication and possible side effects. Increased knowledge and understanding should increase confidence and compliance.

Ideally, individually named inpatient medication prepared by the pharmacy for self-medication should be used. However, the multidisciplinary team and the service user may agree that use of a compliance aid is beneficial for the process. In this case, a compliance aid assessment form has to be completed (appendix 6) by the LPFT pharmacy team, before supply will be made from the dispensing pharmacy.

Individually named inpatient medication prepared by the pharmacy for self-medication can be used for leave and discharge medication. There is a potential financial saving on re-dispensing and a more efficient leave/discharge process. There needs to be sufficient medication to cover the leave period, if not the leave medication needs to be ordered from pharmacy. This can occur at Stage 2 and 3 of the self-administration of medications.

More intensive supervision and checking of administration is required during the self-medication process to ensure that service users take the correct medicines at the appropriate times (stage 3 only).

Extra documentation other than the signing of the medicine administration record (the prescription chart) is required to ensure that self-administration does not increase risk to the service user or others. This documentation should be available as an integral part of the care plan and readily accessible for MDT review.

During stage 3 service users will require access to secure, lockable medication storage facilities to store limited supplies of their medicines for self-administration.
As the service user progresses through the stages of self-administration, it will be necessary to check that the service user is storing the medicines safely and securely and that the correct amount of medicine is being taken (stage 3).

Ward nursing staff will need to regularly check service users secure medication storage areas for compliance and items to be re-ordered for the self-medication process, although the service user should be encouraged to prompt staff when medicines are running low.

During stages 2 and 3 of the programme, there is a risk of problems arising if service users are not made aware of any changes to their prescription by the medical team. The medication administration chart (the prescription chart) must clearly state that the service user is self-medicating so that any changes can be implemented safely and promptly and medication no longer required can be removed from the service user’s lockable medication storage facility.

This document updates all previous recommendations for the use of Self Medication Programmes within Lincolnshire Partnership NHS Foundation Trust.

3. **Duties**

3.1 It is the duty of the Director of Nursing and Strategy, the Medical Director & Chief Pharmacist to ensure that there are policies, procedures and safe systems in place enabling service users to have opportunity to self-administer their medication.

3.2 It is the duty of service managers to ensure the staffs within their service are aware of the policies, procedures, and safe systems for self-administration of medication and operate within its guidance.

3.3 It is the duty of clinical and support staff to ensure that service users are offered the self-administration scheme (e.g. at ward round), where clinically appropriate, and to ensure that the safe systems in place are adhered to throughout; enabling a service user to become self-reliant and competent to administer their own medication.

4. **Definitions**

4.1 All staff definitions are given in the Medicine Management Policy

4.2 Appointed practitioner in charge – the senior practitioner in charge of a ward, unit and/or team.

4.3 Assigned practitioner in charge – the nurse practitioner on duty for the ward who has been rostered as the health care professional in charge for that shift.

4.4 Designated Practitioner – Any practitioner identified by the appointed practitioner in charge as competent and appropriate to perform a specific function.

4.5 Authorised employee – a member of staff who has following training, assessment and demonstration of competence been authorised by LPFT to undertake specific duties in relation to medicines.

4.6 Pharmacist – a registered member of the General Pharmaceutical Council.

4.7 Pharmacy Technician – a registered member of the General Pharmaceutical Council.

4.8 Named Nurse – nurse specified as the lead practitioner responsible for the care of an individual.

5. **Development of Policies and Procedures**
5.1 **Assessment for suitability to enter the self administration of medicines (SAM) programme:**

The service user must be assessed by their named nurse, consultant (or delegate) and pharmacy team to establish:

<table>
<thead>
<tr>
<th>OBSERVATION</th>
<th>RISK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mental state</td>
<td>Confusion, risk of self-harm, suicidal thoughts disorientation, risk to self or others</td>
</tr>
<tr>
<td>Intellectual capacity</td>
<td>Level of understanding</td>
</tr>
<tr>
<td>Sensory perception</td>
<td>Visual or hearing problems, manual dexterity problems</td>
</tr>
<tr>
<td>Likelihood of stay in hospital being long enough to progress through the programme at a pace suitable to the service user</td>
<td>Imminent discharge may require an element of ‘fast tracking’ the process, which can affect success</td>
</tr>
</tbody>
</table>

Details of the assessment are provided in Appendix 1

Assessment must take place in a quiet, safe environment where the conversation cannot be overheard by others. A chaperone should be available if the assigned practitioner in charge identifies that a one to one session is inappropriate or is requested by the service user.

### 5.1.1 Items Required for the Assessment

The following items must be available during the assessment:

- Medication administration chart (the prescription chart)
- All the service user’s medication including any appropriate PRN (‘as required’) medication
- Approved patient information leaflets for all medicines being taken.
- A self administration of medicines consent to join form – (Appendix 2)

### 5.1.2 Content of the Assessment

The assessment should involve discussion of the following:

- What a self-medication programme involves.
- Why the service user has been considered suitable to undertake the scheme.
• Assessment of the service user’s knowledge and discussion to clarify the medicines they are prescribed, including strengths, doses and timing of doses.

• Assessment of the service user's knowledge and discussion to clarify the reasons for taking each medicine.

• Any side effects experienced and level of concern.

• The possible outcomes of stopping taking medication or not taking as prescribed.

• What to do if a dose is missed.

• The effects of drinking alcohol whilst taking prescribed medication.

• Ability to read a label or whether large print labels are required.

• Ability to open child-resistant containers (‘clic-loc’ caps) or foil packs.

• Counting out tablets and / or measuring liquids.

• Taking medicines with adequate volumes of water (e.g. 100 ml)

• How to dispose of unwanted medicines.

• How to order repeat medicines from the GP service. (if going out into community care)

• Explanation of each stage of the self-medication scheme and the essential monitoring that will be required by both the service user and staff.

5.1.3 Reflection time

• Following the assessment, time must be allowed for service user to absorb the information and ask questions. If the service user is unable to think of any questions, the following prompts may be helpful:

  ➢ Does my medicine have any other names and what are they?
  ➢ Why am I taking it?
  ➢ How much should I take and how often?
  ➢ Is there a best time to take it?
  ➢ Are there potential side effects, and what should I do if they happen?
  ➢ What should I do if I miss a dose?
  ➢ Does this medication interact with my other medications or with any foods?
  ➢ Does this medication replace anything else I have been taking?
  ➢ Where and how should I store it?
  ➢ How soon should I start to feel better?
  ➢ When should I report back to my healthcare professional?
  ➢ Could I become tolerant, dependent or addicted to this medicine? If so, how can I avoid this?
  ➢ Where can I get more information about this medicine?
  ➢ If the directions state I should take the medication every three or four hours, does that mean throughout the night as well as during the day?
  ➢ Is this medication available in a child-resistant container?
  ➢ What is this medication's expiration date?
• Offer Trust-approved patient information leaflets (including any special information e.g. lithium cards) for all medicines the service user is taking.

• Talk through the details of the medication administration chart (the prescription chart).

• If the service user agrees to participate in the scheme, a consent to join form should be completed (Appendix 2) and a record made in the medical notes.

• Service users should be advised they can withdraw from the scheme at any time, and a withdrawal of consent form completed (Appendix 2).

• The multi-disciplinary team may also decide that it is no longer appropriate for a service user to continue on the SAM programme. In these circumstances, it must be clearly documented on SAM assessment form (Appendix 2) and the patient’s medical notes the reasons for discontinuation.

5.2. The Self-Administration of Medicines (SAM) Programme

5.2.1 Supply of Medicines

• Once assessment for suitability for the SAM programme has been undertaken, it is advised that medicines to be used during self-administration should be supplied in 28-day instalments for Stage 1 and Stage 2 and 7-day instalments for Stage 3 by the supplying pharmacy. If appropriate and documented at stage 2, 7 days instalment can be used. Each item should be individually labelled as for an outpatient prescription (only applies for 7 day supplies).

• Any medicines transferred from another LPFT site with the service user will need to be checked against the medication administration chart (the prescription chart) for current use, and correct dosing instructions.

• Service users who have been participating in the programme on their previous ward/unit, should have their SAM records checked to re-confirm their suitability to continue on the programme.

• If a service user is admitted directly from home, ‘patient’s own drugs’ (PODs) that fulfil LPFT Medicines Management Policy criteria may be used. (Clearly identifiable medicines that are currently prescribed, correctly labelled and in date).

• The use of compliance aids must only be considered in exceptional circumstances, if it is felt these would be useful in helping the service user to get greater benefit from their medicines. A compliance aid assessment form is to be completed by LPFT pharmacy staff (appendix 6) before the service user can commence on a compliance aid. Generally they are not considered useful in aiding compliance as once filled; less attention is focused on the medicine being taken from the appropriate time/day slot.

• If the service user is awaiting a supply of their individual medicine and there is a stock supply of the medicine on the ward/unit, doses should be administered from this supply by designated practitioners, until an individual supply is obtained from the supplying pharmacy.

5.2.2 Administration of the Programme

• A risk assessment for inclusion must be successfully completed and signed by the service user and the multidisciplinary team (Appendix 1), a copy should be given to the service user
and the original must be placed in the service user’s medical notes. This documentation should be available as an integral part of the care plan and readily accessible for multidisciplinary team meeting (MDT) review

- The consent to enter the scheme form (Appendix 2) must be completed and signed by the service user and a member of the multidisciplinary team as a witness. A copy should be given to the service user and the original must be placed in the service user’s medical notes.

- Service users should be offered further support from the LPFT mental health pharmacy team at this stage, to discuss any problems, queries or concerns relating to the medicines and their use.

- Withdrawal of consent can take place at any stage, and the consent form (Appendix 2) amended to this effect. Please notify LPFT pharmacy when a patient is no longer on the SAM programme.

- The service user can re-start the programme at the discretion of their MDT, taking into account possible increased risks of failure to comply. A re-assessment of the service user’s suitability for the SAM programme should take place and be documented in their medical notes.

- Weekly administration records must be kept by the service user (Appendix 3). Failure to comply will result in suspension of the programme.

- The MDT should complete assessment of each stage of the programme and record (Appendix 1, page 3), before the service user moves on to the next stage.

5.2.3 Implementation

- Medicines must be prescribed by an authorised LPFT prescriber on an LPFT medicine administration chart (the prescription chart).

- A new chart should be written at commencement of the programme. The suitability of the service user to remain on the SAM program should be assessed at the time of each chart re-write every six weeks. This is to be documented in the patient’s medical notes.

- Medication charts should be clearly marked that the patient is taking part in the Self Administration of Medicines Programme – (tick box on the front of the chart).

- Medicines will be dispensed on an individual, named-patient basis, and labelled with full directions for use (as for an outpatient prescription – stage 2/3 only).

- If required, additional instructions should be provided for the service user (large or bold printed labels). These can be requested from the supplying pharmacy.

- Any changes to dispensed medication requirements must be discussed with the service user by the prescriber, named nurse or pharmacy staff. A list of the patient’s current medications is listed on the Stage 3 Compliance Monitoring Record (Appendix 5), which is to be amended when medications changes occur, and is re-written weekly.

- The service user will be offered an LPFT approved patient information leaflet during the initial assessment. If declined, this should be documented in patient’s notes.

- Service users at Stage 1 or 2 of the programme should record their medication times in a personal administration record (Appendix 3).
- A service user at Stage 3 of the programme is able to take their medicines home when they go on leave; therefore, the need for a leave prescription to be written and dispensed is removed. If the quantity of medicine remaining in the supply is considered too great a risk to take out of the hospital, a leave prescription must be obtained in the usual way. If insufficient medication, leave medication must be ordered to cover the entire leave period.

- Designated staff and/or LPFT visiting pharmacy staff will be responsible for the ordering of on-going medicine supplies.

- Designated practitioners involved in the supervision of service users participating in the programme must be registered nurses.

- Each service user involved in the programme at Stage 3 should be supplied with a secure, lockable medicines ‘container’ for storage of their individual medicines.

- PRN (as required), once only, variable dose medicines, Controlled Drugs and injections will continue to be administered by designated practitioners. However, inhalers, even if prescribed PRN are suitable for the self-administration process.

- If a service user is admitted directly from home, ‘patient’s own drugs’ (PODs) that fulfil LPFT Medicines Management policy criteria may be used. (Correctly labelled, in date and clearly identifiable medicines that are currently prescribed).

5.3 Stages of Self Administration of Medicines (SAM)

Stage 1: Assessment and supervised administration

Stage 2 Self administration with direct supervision

Stage 3 Self administration without direct supervision
Medication is stored in patient’s locked cupboard

Stage 1: Assessment and supervised administration

- Each service user participating in the programme will be supplied by pharmacy with a 28 day, individually labelled supply of medication which will be stored in the ward / unit drug cupboard.

- The service user should approach staff at the appropriate time and request their medication. They should then read their prescription to the designated practitioner, select the appropriate
medication, read the instructions to them, select the correct dose and return the container to
the designated practitioner, who will observe the selection and administration of the correct
medication.

- The designated practitioner will draw attention to any discrepancies noted e.g. incorrect
medication or any not selected, and will administer these in the usual way.

The designated practitioner should initial the drug chart and record any refusals etc. in the usual way, then
complete the monitoring record and note any concerns (Appendix 4).

- It is recommended that this stage lasts for 28 days, unless exceptional circumstances dictate
otherwise and the period of time is extended. Once the 28 day period is completed, an
assessment of the service user’s progress must be undertaken by the multi-disciplinary team
to determine their suitability to move on to Stage 2. The consultant will authorise moving to
Stage 2, if appropriate, by signing the authorisation at the end of the assessment in Appendix
1.

**Stage 2 Self-administration with direct supervision**

- Each service user participating in the programme will be supplied by pharmacy with a 28 day,
individually labelled supply of medication which will be stored in the ward / unit drug
cupboard.

- Service user participating in the programme can be supplied by pharmacy with a 7-day,
individually labelled supply of medication which will usually be stored in the ward/unit drug
cupboard.

- The service user should prompt staff to have access to their medicines at the correct times.

- If self-administration does not happen within an agreed time scale (usually 30 minutes either
side of the administration time), it will be the designated practitioner’s responsibility to prompt
and observe the selection and administration of the correct medication.

- Failure to attend at the correct time should be noted on the monitoring record, along with any
other concerns (Appendix 4).

- The nurse should initial the medicine administration chart (the prescription chart) and record
in the usual way.

- It is recommended that this stage should last for a minimum of 28 days. A further MDT
assessment of the service user’s progress must be undertaken and the consultant will
authorise moving to stage 3, if appropriate, by signing the authorisation at the end of the
assessment in Appendix 1.

**Stage 3 Self-administration without direct supervision**

- The service user will have custody of their locker key and their medicines stored in the locker,
if available. (If not, custody of the medicines must remain in the ward / unit drug cupboard).

- At this stage the service user must have been assessed as capable of self-administering their
correct medication at the correct time with minimum intervention/supervision from nursing
staff, and for their awareness of the security implications for safe storage of their personal medication.

- The supplying pharmacy will dispense the agreed quantity of individually named medication for the service user. The agreed quantity will be dependent on an assessment by nursing, medical and pharmacy staff – usually 7 days but may be more, if considered appropriate.

- Monitoring of the service user’s compliance to the programme should be carried out and the monitoring record (Appendix 5) completed. This must include ad hoc dose counts at least twice a week to ensure the highest level of compliance is taking place, and any discrepancies are identified and recorded. These checks will be carried out by designated practitioners.

- The service user should continue to complete their personal administration record (Appendix 3), but the designated practitioner is not required to sign the medicine chart, or the weekly monitoring form (Appendix 4), unless they have witnessed the administration of the medicine.

- To ensure continuity of medicines in an appropriate format it may be necessary to provide supported self-administration via primary care e.g. GP. This is for service users who continue to need assistance in the supply of appropriate dose systems and quantities. (e.g. compliance aids)

6. Consultation, Approval and Ratification Process

This policy will be consulted upon in line with Corporate Documents and Policies Procedure. The policy will be approved and ratified according to the processes laid out in Corporate Documents and Policies Procedure.

7. Review and Revision Arrangements including version Control

This policy will be reviewed by the Medicines Management Committee every TWO years or as the need arises due to changes in legislation or guidance.

Corporate and legal Services will maintain a version control sheet, as per ‘Corporate Documents and Policies Procedure’.

8. Dissemination and Implementation of a Policy

The policy will be disseminated as per ‘Corporate Documents and Policies Procedure’.

Implementation of the policy will be ensured through regular safe and secure audit measures and through auditing clinical notes to review the appropriate consideration of self-administration for a service user and if deemed applicable implementation of the policy.

Individual staff implementing the policy will be reviewed through regular staff supervision.

9. Policy Control including Archiving Arrangements

Corporate and Legal Services will retain a copy of each policy for a minimum of 10 year in line with the recommendations contained within 'Records Management NHS Code of Practice' (2006)

10. Monitoring Compliance with and Effectiveness of Policies and Procedures
<table>
<thead>
<tr>
<th>Systems</th>
<th>Measurables</th>
<th>Lead Officer</th>
<th>Frequency</th>
<th>Reporting to</th>
<th>Action Plan/Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systems in place to ensure staff know how to monitor the service user on SAM.</td>
<td>Discussion about SAM policy and implementation through supervision notes</td>
<td>Line manager</td>
<td>Yearly</td>
<td>Modern Matron</td>
<td>Line manager for action</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Modern Matron for monitoring</td>
</tr>
<tr>
<td>Systems in place for the monitoring of self-administration scheme uptake</td>
<td>Number of service users offered SAM</td>
<td>Modern Matrons</td>
<td>Yearly</td>
<td>Medicines Management Committee</td>
<td>MDT for action</td>
</tr>
<tr>
<td></td>
<td>Number of services users using SAM</td>
<td></td>
<td></td>
<td></td>
<td>Modern Matron for monitoring</td>
</tr>
</tbody>
</table>

11. References


www.nhsla.com

Nursing and Midwifery Council ‘Medicines Management’ (2006)

National Service Framework for Older People – Standard 7 Mental Health in Older People (2001)


Leeds Mental Health Services Teaching NHS Trust – Self administration/Self-medication Practice guidelines


ULHT NHS Trust – Care of medicines relating to self-administration of medicines and patient’s own drugs.

National Prescribing Centre (NPC) April 2008 - ‘Medicines Management Service Improvement Guide: Self-administration of medicines in Mental Health Trusts’

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### Appendix 1

#### Self-administration of Medicines (SAM) Programme

**Risk Assessment**

<table>
<thead>
<tr>
<th>Service User</th>
<th>Ward</th>
</tr>
</thead>
</table>

**All Current Medications:**
Refer to the patient’s medication administration chart

**Knowledge of Prescribed Medication**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>Does the service user know the names of the medications that they are taking?</td>
</tr>
<tr>
<td>b.</td>
<td>Is the service user familiar with the number of tablets or capsules to take and the frequency?</td>
</tr>
<tr>
<td>c.</td>
<td>Does the service user know what they are taking the medicines for?</td>
</tr>
<tr>
<td>d.</td>
<td>Is the service user able to identify the tablets or capsules correctly?</td>
</tr>
</tbody>
</table>

If any of the above answers are negative then a decision has to be made as to whether the service user is able to self-medicate at this stage, or whether education and a later review is more appropriate.

**Administration Ability**

- Can the service user open the containers, bottle tops, blister packs and cartons?
- Is the service user able to read the labels
- Are inhalers, eye drops, creams or other devices are used
- Can the service user use them correctly? YES/NO

If there are any concerns, then a decision has to be made whether comprehensive administration/compliance aids may need to be considered.

**Other Information**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>Does the service user take any non-prescription medication?</td>
</tr>
<tr>
<td>b.</td>
<td>Does the service user know how to dispose of unwanted medicines?</td>
</tr>
<tr>
<td>c.</td>
<td>Has the service user been told how to obtain further supplies of medicines?</td>
</tr>
</tbody>
</table>
## Risk Assessment

<table>
<thead>
<tr>
<th>Risk</th>
<th>Level of Risk</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service users mental state is currently stable enough to administer their own medicines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Service user understands the importance of taking medicines as prescribed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Service user understands how and when to take their medicines, can read labels and has no obvious visual, hearing or manual dexterity problems</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Service user is likely to conceal medicines they should have taken</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Service user is likely to misappropriate medicines and possibly pass on to other service users</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Service user has a history of non-compliance</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The service user has been assessed as suitable / unsuitable (delete as appropriate) to join the self administration of medicines programme and agrees to take medicines as prescribed, at appropriate times and to store medicines safely in lockable facilities.

Service User’s Signature ____________________________  Date __________
Consultant’s Signature     ____________________________ Date __________
Named Nurse’s signature ____________________________ Date __________
Pharmacy signature     ____________________________ Date___________

**Risk Levels:**
- **HIGH** - Unlikely to succeed with self administration
- **MEDIUM** - Likely to succeed with high levels of support
- **LOW** - Likely to succeed with support.
After MDT review and assessment of service user’s progress, it has been agreed that:

(Name): ______________________________________ should commence:

### Stage One
- Patient signature____________________ Date________
- Print Name_______________________________________
- Doctor’s signature________________ Date________
- Print Name_______________________________________
- Pharmacy signature________________ Date________
- Print Name_______________________________________
- Comments, if applicable

### Stage Two
- Patient signature____________________ Date________
- Print Name_______________________________________
- Doctor’s signature________________ Date________
- Print Name_______________________________________
- Pharmacy signature________________ Date________
- Print Name_______________________________________
- Comments, if applicable

### Stage Three
- Patient signature____________________ Date________
- Print Name_______________________________________
- Doctor’s signature________________ Date________
- Print Name_______________________________________
- Pharmacy signature________________ Date________
- Print Name_______________________________________
- Comments, if applicable

It is advised that each stage should last for a minimum of 28 days
Appendix 2

Self-administration of Medicines (SAM) programme
Consent to administer own medicines

As an essential part of your long term rehabilitation, the multidisciplinary team have determined that you have reached a stage in your treatment when it would be helpful to you to administer your own medicines.

Name: ___________________________        Ward/Unit: __________________

Consent to administer own medicines

The self-administration of medicines programme has been explained to me, and I am willing to take part. I have been made aware that I can withdraw my consent at any time, and return to nurse-administered medicines.

Service user’s signature: ____________________________________________
Date: ____________________________

Witnessed by:
Name: ___________________________________________________________
Designation: ______________________________________________________

Changes to Self Administration of Medication programme

Reasons for change: 
________________________________________________________________

Service user’s signature: ____________________________________________
Date: ____________________________

Discussed with staff member:
Name: ___________________________________________________________
Designation: ______________________________________________________

Assessment is needed before re-commencing on the SAM programme.
Appendix 3

Self-administration of Medicines (SAM) programme

Service user’s Personal Weekly Administration Record

Name: ___________________________      Ward/Unit: ____________________

Week commencing: _________________________

Put a tick or your initials in the correct box each time you have taken your medicines

<table>
<thead>
<tr>
<th></th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
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<tbody>
<tr>
<td>Breakfast Time</td>
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<tr>
<td>Lunch Time</td>
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<tr>
<td>Tea time</td>
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<tr>
<td>Night time</td>
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</tr>
</tbody>
</table>

Comments:
Appendix 4

Self-administration of Medicines (SAM) programme Stage 1 & 2 Monitoring Record

Name: ___________________________  Ward/Unit: ____________________  Week commencing ________________

<table>
<thead>
<tr>
<th></th>
<th>MONDAY</th>
<th>TUESDAY</th>
<th>WEDNESDAY</th>
<th>THURSDAY</th>
<th>FRIDAY</th>
<th>SATURDAY</th>
<th>SUNDAY</th>
</tr>
</thead>
<tbody>
<tr>
<td>* see key below—→</td>
<td>B</td>
<td>L</td>
<td>T</td>
<td>N</td>
<td>B</td>
<td>L</td>
<td>T</td>
</tr>
<tr>
<td>Requests medicines at correct time</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Selects correct medicine(s)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Reads instructions on labels correctly</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Selects correct doses</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Takes medicine(s)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Returns medicine(s) to appropriate container</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Initials

KEY:  I = independently performs tasks  P = needs prompting  N/A = not applicable  B – Breakfast (morning) medication  L – Lunchtime medication  T – Teatime medication  N – Night time medication
Appendix 5

**Self-administration of Medicines (SAM) programme: Stage 3 Compliance Monitoring Record**

Name: ________________________  Ward/Unit: ____________________  Week commencing: ________________

Medication given by: ________________________________________________________________  Date: __________

Medication checked by: _____________________________________________________________

Medication received by (patient receiving): ____________________________________________

Write next Spot check date in the Nurses Diary

<table>
<thead>
<tr>
<th>Name (or letter) of drug, dose and frequency</th>
<th>Number of doses received</th>
<th>Number of doses remaining</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
<th>Sunday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual</td>
<td></td>
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<td></td>
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<td>Expected</td>
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<td></td>
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<tr>
<td>Initials: Staff</td>
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<td>Patient</td>
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<td></td>
</tr>
<tr>
<td>Initials: Staff</td>
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<tr>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Initials: Staff  Patient

Actual  Expected

Initials: Staff  Patient

Actual  Expected

Initials: Staff  Patient

Actual  Expected
**REQUEST FOR MEDICATION COMPLIANCE AID (DOSETTE BOX)**

<table>
<thead>
<tr>
<th>Workbox</th>
<th>Ward__________________________</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Consultant______________________</td>
</tr>
<tr>
<td></td>
<td>Named Nurse______________</td>
</tr>
<tr>
<td></td>
<td>Date of request__________</td>
</tr>
</tbody>
</table>

### Reason for requesting medication compliance aid:

1. Is the patient on a complex drug regime (more than 4 medications)? Yes/No

2. Has a medication review been completed to rationalise medication doses? Yes/No. If yes, specify who and time of review______________________

3. Does the patient have memory problems? Yes/No

4. Have other reminder aids (e.g. Calendars) been tried? Yes/No

5. Does the patient have trouble opening medicines containers? Yes/No

6. Does the patient have difficulty reading labels? Yes/No

7. Other reasons (Please specify)_____________________________________

### Suitability Assessment for Medication Compliance Aid:

1. Does the patient consent to using a compliance aid? Yes/No

2. Will the patient be willing to pay for medication compliance aids if applicable? Yes/No

3. Is the patient administering their medication? Yes/No
   
   If no, please state who will be responsible for medication administration:

<table>
<thead>
<tr>
<th>Physical:</th>
<th>(Delete as appropriate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can patient open compartment? Yes/No</td>
<td></td>
</tr>
<tr>
<td>Can patient remove medication safely? Yes/No</td>
<td></td>
</tr>
</tbody>
</table>

| Cognitive: |
|___________|
| Does the patient understand why a medication compliance aid is needed? Yes/No |
| Is the patient orientated to time and day? Yes/No |

### Refilling Compliance Aid after discharge:

LPFT Medicines Management & Medical Devices Policy V.9 November 2015 282
Hospital Pharmacy (usually only for clozapine)
Community pharmacy (name and telephone number)

**For LPFT Pharmacy to complete:**

<table>
<thead>
<tr>
<th>ALLERGY STATUS:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are medications stable for dispensing into a medication compliance aid (Yes/No)</td>
</tr>
</tbody>
</table>

**List of Current Medications**

|__________________________________________________________________________________|
|__________________________________________________________________________________|
|__________________________________________________________________________________|
|__________________________________________________________________________________|
|__________________________________________________________________________________|
|__________________________________________________________________________________|

**Are Medications obtained from other sources ('not in a compliance aid') Yes/No**

If Yes please specify

|__________________________________________________________________________________|
|__________________________________________________________________________________|

**Who will be responsible for collecting medication compliance aid in the community?**
Please specify

|__________________________________________________________________________________|

Service user signature _____________________________ Date ______

Named nurse _____________________________ Date __________________

Locality Pharmacist/Pharmacy Technician approval _____________________________

Date _____________________________
### DOCUMENT VERSION CONTROL

<table>
<thead>
<tr>
<th>Document Type and Title:</th>
<th>Trust wide guidelines for use of Inpatient charts</th>
</tr>
</thead>
<tbody>
<tr>
<td>New or Replacing:</td>
<td>New</td>
</tr>
<tr>
<td>Version No:</td>
<td>1</td>
</tr>
<tr>
<td>Date document first written:</td>
<td>August 2008</td>
</tr>
<tr>
<td>Date document first implemented:</td>
<td>October 2008</td>
</tr>
<tr>
<td>Date document Last Reviewed and Updated:</td>
<td>December 2012</td>
</tr>
<tr>
<td>Implementation Date:</td>
<td>October 2008</td>
</tr>
<tr>
<td>Author:</td>
<td>Stephen Jones, Clinical pharmacy services manager / Richard Lewis, Chief pharmacy technician</td>
</tr>
<tr>
<td>Approved by:</td>
<td></td>
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<tr>
<td>Approval Date:</td>
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<td>Ratifying Body:</td>
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<td>Ratified Date:</td>
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<tr>
<td>Committee, Group or Individual Monitoring the Document</td>
<td>MMC</td>
</tr>
<tr>
<td>Review Date:</td>
<td>December 2015 (three years)</td>
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An introduction to the in-patient prescription chart
1. **General Points**

1.1. These guidelines should be read in conjunction with the Medicines Management Policy, Records Management Policy and any other relevant Trust or local procedures.

1.2. The duties and responsibilities of all staff that prescribe and/or administer medication are detailed in the Medicines Management Policy (OPR/17) and MUST be adhered to.

1.3. The inpatient prescription chart has been designed for use in clinical areas within the Trust where one or both of the following occur on a daily, or close to daily, basis:
   - Recorded administration of medication by staff
   - Recorded self-administration of medication
   - Recorded delivery of medication to service users by staff

1.4. The chart need not, therefore be limited only to inpatient areas and will be suitable for day ward use and may be preferred by some community teams, depending on their case mix

1.5. The chart will be used
   - By Trust prescribers to prescribe medication
   - By authorised employees to order medication from the dispensing pharmacy
   - To record medication administered, self-administered or supplied to service users by an approved member of Trust staff

1.6. All details should be completed on the chart in accordance with Trust policies for medicines management and clinical record keeping. Entries MUST:
   - Be legible
   - Be written in indelible ink
   - Be written in the correct section of the chart
   - Use approved generic British Approved Name (BAN) or Recommended International Non-Proprietary Name (rINN) of the medication prescribed

1.7. Each page of the prescription chart must contain details of the service user details as specified. This is a requirement of all service user specific documents used by the Trust and is necessary for safe interpretation of faxed prescription charts. As a minimum requirement these sections must be completed with the service user’s name, date of birth and the number of charts in use and at least one must contain the full data requested (address, NHS or hospital number, etc)

1.8. Adverse drug reactions, allergies and sensitivities MUST be documented on the chart. If none are known then the “None Known” box should be ticked. The entry should be signed and dated by the person completing it.

1.9. In cases where the clinical effects of a drug are affected by the brand used, the required brand should ALSO be specified

1.10. The regular administration section of the chart is designed for a maximum of six weeks daily administration. Each prescription on the chart is valid for up to six months from the date of signing, unless a shorter duration is specified. Each item on the prescription chart should be reviewed before the prescription for the item expires, or insufficient space to record administration remains, and rewritten if a continuing supply is required

1.11. When an item is no longer required it should be clearly cancelled with a diagonal line, the canceller’s initials and the stop date. The administration section of the chart should also be clearly marked with a diagonal line.

1.12. Non-medical prescribers who prescribe on the chart should complete their details in the boxes provided on page four of the chart

1.13. The chart forms part of the service user’s clinical record and should be filed in the appropriate section of the service user’s Trust notes

1.14. The chart should be available at any service user review

2. **Prescribing medication and requesting leave medication**

2.1. **As required medication (See Appendix A page 1)**

   2.1.1. As required medication should be prescribed on page one of the chart and must include the indication for which the prescription is intended
2.1.2. Each “as required” medication must include details of the dose to be administered at any one time, the minimum interval that must pass before a further dose can be given and the total dose that can be administered in any continuous 24 hour period.

2.1.3. Each “as required” prescription should be reviewed frequently to ensure it is still appropriate for the service user.

2.2. Regular medication (See Appendix A page 2)

2.2.1. Regular medication should be prescribed on page two of the chart.

2.2.2. The dose required at each time of day should be written next to the indicated time (8, 13, 17 or 22:00 hours).

2.2.3. The timings are deliberately printed in pale green to enable them to be over written as per 2.2.4. However if the chart is to be faxed then these timings MUST be clearly over written to highlight the required timing of medicines for the dispensing pharmacy.

2.2.4. If the medication should be given at a time other than one of these options then over write one of the printed times clearly indicating the desired administration time using the 24-hour format, i.e. 20.00 for 8pm.

2.2.5. If a regular prescription is to start after the commencement date of the chart, then the date on which administration should start should be preceded by a vertical line and an arrow (see example) to avoid administration errors. Remaining administration boxes for cancelled prescriptions should be marked with a diagonal line (see example).

2.2.6. When the six-week duration of the chart is reached, a new chart MUST be written.

2.3. Long acting and depot injections (See Appendix A page 2)

2.3.1. Long-acting and Depot injections should be prescribed in the specific section at the top of page two of the chart.

2.3.2. Each depot prescription has space to allow four administrations to be recorded after which the prescription will need to be reviewed and if still required the current prescription should be cancelled and a new prescription written in the next available space.

2.3.3. Long-acting and depot injections MUST be prescribed using the full generic name (e.g. zuclopenthixol decanoate) to reduce the risk of confusing similar products.

2.4. Once-only prescriptions (See Appendix A page 5)

2.4.1. Once-only prescriptions should be written in the specific section provided at the top of page four of the chart. The date of the prescription relates to the date the medication should be administered. This may differ from the date on which the prescription is written.

2.4.2. Prescriptions made by verbal order may also be entered here, but their status must be indicated by completing the box provided and the prescriber must sign the prescription within 24 hours. Verbal orders are only valid for 24 hours after which they may not be administered. The use of verbal orders should be restricted to emergency situations and practice must conform to the guidance issued by both the General Medical Council (GMC) and the Nursing and Midwifery Council (NMC). Other methods of remote prescribing (fax, email) are preferred. Further guidance on the responsibilities of staff who give or follow verbal orders is included in the Medicines Management Policy (OPR/17)

2.4.3. If the medication is to be used for Rapid Tranquilisation, this must be identified by ticking the appropriate box.

2.5. Leave and discharge (See Appendix A pages 3+4)

2.5.1. Leave medication of no more than 7 days duration may be ordered without requiring an additional prescription, using the columns provided on page three of the chart by staff authorised to do so.

2.5.2. Medication for leave of longer than 7 days, or for discharge must be prescribed by a doctor or authorised non-medical prescriber in the far right-hand column of page three of the chart.

2.5.3. As required medication needed for leave or discharge should be indicated by transcribing the code letter(s) of the prescription(s) on page one onto the appropriate section on page three. If no such medication is required then the box should be cancelled with a cross (see example). The dispensing pharmacy will supply a quantity of any requested “as required” medicine to match the length of the leave indicated by the request for regular medication, up to the maximum dose prescribed and taking into account current frequency of administration recorded, on page one of the chart.
2.5.4. Regular medication needed for leave or discharge should be indicated by entering the number of days supply required for each regular item in the appropriate section on page three. Any regular medication lines for which no medication is required for this leave/discharge should have its “number of days” box cancelled with a cross (see example). Any regular prescriptions for controlled drugs that are required should have the “number of days” box endorsed with “see separate prescription” and they should be prescribed on a white out-patient prescription form.

2.5.5. Requests for leave medication by authorised staff MUST include the date ordered and the initials of the staff member making the request.

2.5.6. If any depot injections, controlled drugs or variable dose regimes are required for discharge or leave of any duration these should be prescribed in full using the section provided on page four of the chart.

2.5.7. Controlled Drug prescriptions CANNOT be dispensed against a faxed prescription; it must be dispensed against the original prescription. So if a CD is required for leave or discharge the original prescription MUST be sent to the dispensing pharmacy.

3. Ordering Medication – (See Appendix A page 3)

3.1. When medication is required the whole chart should be taken or faxed in full to the dispensing pharmacy, unless the ordering is being done by a pharmacy technician pharmacy staff using agreed protocols.

3.1.1. If a service user has multiple charts then all charts in use should be taken or faxed in full to allow pharmacy staff to fully check for interactions and appropriateness of prescribing.

3.2. Each faxed request for medication for a service user must be accompanied with a fax cover sheet indicating the number of charts faxed for the service user and clearly indicating what is required to be dispensed (see Appendix B).

3.3. If ordering ONLY ‘As Required Medication’ then please indicate the number of days required on the fax cover sheet.

3.4. Clozapine, if ordered, will only be supplied if the necessary blood tests have been completed and the results are satisfactory.

4. Receiving Dispensed Medication – (See Appendix A page 4)

4.1. When requested medication is supplied by the dispensing pharmacy for an individual service user, the medication must be checked by a designated practitioner or pharmacy staff to ensure that it is the correct medication, at the correct dose with correct instructions (where appropriate) on the label and that this matches the current prescription chart.

4.2. In the case of medication for leave or discharge, this check must be acknowledged on page 3 of the drug chart in the column for that particular leave or discharge by initialling and dating in the appropriate boxes.

4.3. If any discrepancies are noted then a re-supply must be arranged immediately as soon as possible by contacting the dispensing pharmacy. The incorrect medication quarantined and noted actions taken.

4.3.1. If the discrepancy is due to a dispensing error rather than, for example, a prescriber changing the prescription chart, then an Sentinel incident report must be completed.

5. Issuing leave and discharge medication – (See Appendix A page 4)

5.1. Leave and discharge medication must only be issued to a service user or carer by designated practitioners or pharmacy staff, working within their own professional competence.

5.2. The medication must be checked against the current prescription chart to ensure that the correct medication is taken at the correct dose and frequency by the service user.

5.3. The issuing of leave or discharge medication must be recorded on page three of the prescription chart by the authorised employee initialling and dating the appropriate boxes.

6. Recording Administration of medication

6.1. Important considerations

6.1.1. When recording the administration of any medication using the prescription chart it is the responsibility of the designated practitioner who administers the dose to record administration immediately, as directed in the Medicines Management Policy (OPR/17).
6.1.2. Any prescriptions which require review because of patient response or because the prescription chart needs rewriting, must be highlighted to the prescriber with a further record in the service user's clinical notes record if necessary.

6.2. As required medication (See Appendix A page 1)
   6.2.1. The administration of “as required” medication should be recorded on page one of the prescription chart by recording the date, time, dose administered and the initials of the authorised professional administering the medication.
   6.2.2. If the medication has been administered for the purposes of rapid tranquillisation, then the box provided should be ticked, otherwise the box should be left blank.

6.3. Regular medication (See Appendix A page 2)
   6.3.1. The administration of regular medication should be recorded by placing the initials of the designated practitioner who administers the dose in the box provided for that medication at the time on that date on page two or three of the prescription chart as appropriate.
   6.3.2. If administration is not possible for reasons such as service user refusal, non-attendance due to leave etc or the service user self-administers medication, then enter the appropriate code (as indicated on page one of the chart) in place of the designated practitioner’s initials.
   6.3.3. Omissions or refusals should also be documented in the service user’s clinical notes records.

6.4. Long-acting and depot injections (See Appendix A page 2)
   6.4.1. Administration of long acting and depot injections is recorded in the appropriate section of page two of the prescription chart by recording the date given, the dose administered, the site used (left or right), the initials of the designated practitioner who administers the dose, and the initials of any witness.
   6.4.2. Depending on local policy, the date of the next due injection may be entered on the prescription chart on the next available administration record line.

7. Patient Group Directions (PGD) – (See Appendix A page 5)
   7.1. A PGD is a Trust document authorising appropriate staff to administer or supply a specific medication to a specific individual in a specific situation. An example is the administration of paracetamol to a service user with a headache and no contra-indications to the use of paracetamol. This allows the short-term use of medication without a prescription.
   7.2. Medication administered under a PGD is recorded in the appropriate section on page four of the prescription chart by recording the date, medication, dose, route, initials of the designated practitioner who administers or supplies the medication and the time of administration or supply.

8. Once-only prescriptions – (See Appendix A page 5)
   8.1. The administration of once-only prescriptions is recorded in the appropriate section on page four of the prescription chart. This includes prescriptions made by remote prescribing or “verbal order”.
   8.2. Administration of once-only doses must occur on the date indicated by the prescriber, and in accordance with any other directions the prescriber may have indicated.

9. Filing prescription charts
   9.1. Once a prescription chart is no longer in use it must be scanned into MARACIS and filed for reference in the service user’s clinical notes.
   9.2. To facilitate filing, charts should be hole-punched along their top edge.
Appendix A

A Sample Chart
<table>
<thead>
<tr>
<th>Pharmacy</th>
<th>Drug</th>
<th>Route</th>
<th>Dose</th>
<th>Min interval</th>
<th>Max in 24 hr</th>
<th>Start Date</th>
<th>Stop Date</th>
<th>Date</th>
<th>Time</th>
<th>Dose</th>
<th>Given</th>
<th>For R. Tranq?</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>LORAZEPAM</td>
<td>Po</td>
<td>0.5mg</td>
<td>1 hour</td>
<td>4mg</td>
<td>1/7/08</td>
<td></td>
<td></td>
<td>1/7</td>
<td></td>
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<tr>
<td>B</td>
<td>LORAZEPAM</td>
<td>Po</td>
<td>1mg</td>
<td>1 hour</td>
<td>4mg</td>
<td>1/7/08</td>
<td></td>
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</tr>
</tbody>
</table>

Use of As Required medication for the purposes of Rapid Tranquilisation should be indicated by ticking the appropriate box when recording administration.
<table>
<thead>
<tr>
<th>Pharmacy</th>
<th>Drug</th>
<th>Route</th>
<th>Start Date</th>
<th>Stop Date</th>
<th>Dose</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Risperdone</td>
<td>PO</td>
<td>1/7/08</td>
<td></td>
<td>2mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>FLUCLOXACILLIN</td>
<td>PO</td>
<td>4/7/08-11/7/08</td>
<td></td>
<td>250mg</td>
<td>To be given on an empty stomach</td>
</tr>
</tbody>
</table>

Cancellation of a regular prescription
Request for one day’s leave supply of PRN drug “A” (lorazepam) and regular oral risperidone and flucloxacillin

Leave does not have to be ordered by a prescriber if for 7 days or less

Request for seven day’s discharge supply of PRN drug “A” (lorazepam) and regular oral risperidone

Discharge must be authorised on the chart by a prescriber
Issuing of leave and discharge medication to the service user must be recorded by ward staff.

Receipt of dispensed leave and discharge medication must be recorded by ward staff.
Once-only “STAT” prescriptions are recorded here. The use of medication for Rapid Tranquilisation must be indicated.

While long acting injections are not normally supplied on discharge, there may be occasions when this is necessary.

This part of the chart can also be used to prescribe reducing-dose courses of medication or dose titration, or controlled drugs in some circumstances.

Medication administered under a Patient Group Direction (PGD) is recorded here.
Appendix B

Fax Cover Sheet
<table>
<thead>
<tr>
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</thead>
<tbody>
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<td></td>
</tr>
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<td></td>
<td></td>
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</thead>
<tbody>
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<td></td>
</tr>
<tr>
<td>Medication required by (Date and time)</td>
<td>Urgent ring when ready Y☐ / N☐</td>
</tr>
<tr>
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<td>(Signature &amp; Print)</td>
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</thead>
<tbody>
<tr>
<td></td>
<td>1. Deliver to ward/team</td>
</tr>
<tr>
<td></td>
<td>2. Staff will collect from pharmacy</td>
</tr>
<tr>
<td></td>
<td>3. Service user/carer will collect from pharmacy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medication required:</th>
<th>Delete as appropriate:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1. Leave or discharge medication as indicated on prescription chart</td>
</tr>
<tr>
<td></td>
<td>2. The following medication for inpatient use:</td>
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Please fax all current prescription chart(s) for this service user together with this request form
# Community Chart Guidelines

## DOCUMENT VERSION CONTROL

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<td>Date document first written:</td>
<td>August 2008</td>
</tr>
<tr>
<td>Date document first implemented:</td>
<td>October 2008</td>
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<tr>
<td>Implementation Date:</td>
<td>October 2008</td>
</tr>
<tr>
<td>Author:</td>
<td>Stephen Jones, Clinical pharmacy services manager/ Richard Lewis, Chief pharmacy technician</td>
</tr>
<tr>
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<td></td>
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<tr>
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An introduction to the community prescription chart.
1. **General Points.**

1.1. These guidelines should be read in conjunction with the Medicines Management Policy (OPR/17), Records Management Policy (RM/06) and any relevant Trust wide or local procedures.

1.2. The duties and responsibilities of all staff members that prescribe and/or administer medication are detailed in the Medicines Management Policy (OPR/17) and MUST be adhered to.

1.3. The community chart has been designed for use in specialist community teams within the Trust.

1.4. The chart will be used
   - By Trust prescribers to prescribe medication
   - By authorised professionals to order medication from the dispensing pharmacy
   - To record medication Issued, administered, or supplied to service users by an approved member of Trust staff.

1.5. All details should be completed on the chart in accordance with Trust policies for medicines management and clinical record keeping. Entries MUST:
   - Be legible
   - Be written in indelible ink
   - Be written in the correct section of the chart
   - Use approved generic British Approved Name (BAN) or Recommended International Non-Proprietary Name (rINN) of the medication prescribed

1.6. Each page of the prescription chart must contain details of the service user’s details as specified.

1.6.1. This is a requirement of all service user specific documents used by the Trust and is necessary for safe interpretation of faxed prescription charts.

1.6.2. As a minimum requirement these sections must be completed with the service user’s name, date of birth, NHS number and the number of charts in use and at least one must contain the full data requested including the service user’s address. NB there are two distinct sides to this chart, on four pages.

1.6.3. If side 2 of the chart (long acting and depot injections) is not being used, then it is not necessary to complete the service user details on this side of the chart.

1.6.4. If side 1 of the chart is not being used (i.e. for a service user prescribed a depot injection only) then it is not necessary to complete the service user details on this side of the chart.

1.7. Adverse drug reactions, allergies and sensitivities must be documented on the chart. If none are known then the “None Known” box should be ticked. The entry should be signed and dated by the person completing it.

1.8. In cases where the clinical effects of a drug are affected by the brand used, the required brand should ALSO be specified

1.9. Each prescription on the chart is valid for up to six months from the date of signing, unless a shorter duration is specified. Each item on the prescription chart should be reviewed before the prescription for the item expires and rewritten if a continuing supply is required

1.10. When an item is no longer required it should be clearly cancelled with a diagonal line or lines, the canceller’s signature/initials and the stop date.

1.11. There is a section for completing details about the current General Practitioner (GP) on both sides of the chart. The minimum information of GP name and practice should be provided.

1.11.1. If both sides of the chart are being used only one side needs to be completed with GP information.

1.12. Non-medical prescribers who prescribe on the chart should complete their details in the boxes provided at the bottom of the chart.
1.13. The chart forms part of the service user’s clinical record and should be scanned into the electronic record system and filed in the appropriate section of the service user’s Trust notes. The chart can be hole-punched at either side or top when required for filing.

1.14. The chart should be available at any service user review.

2. Prescribing medication other than long-acting depot injections (side 1)

2.1. The prescription section needs to reflect as accurately as possible all the medication that the service user is taking, whether provided by LPFT, via the GP or regularly as over-the-counter (OTC) medications.

2.1.1. If any particular medicine is only obtained from the GP then the tick box at the end of the prescribing section should be used to indicate this.

2.1.2. This indicates to the team that this medication is not normally to be ordered or dispensed and is only as a record to allow prescribing in the full knowledge of all medication that a service user is taking.

2.1.3. Very occasionally, such medication may need to be ordered in an emergency situation, but the nursing staff ordering the medication should first contact the dispensing pharmacy to make them aware of the situation.

2.2. It is the responsibility of community team leaders to ensure that procedures are in-place and being used, to ensure that the information on the chart is kept up-to-date.

2.3. Maximum supply column – this column is for the prescriber to indicate the maximum number of days that can be requested for supply to a service user at any one time. (NB staff ordering medication do NOT have to order the maximum they can order any amount, or combination of days up to this stated maximum)

2.4. When a medication is reviewed or needs to be re-written, the current prescription must be cancelled and if there is enough space on the chart, re-written on the next available line indicating the date it has been re-written.

3. Prescribing long-acting depot injections (side 2)

3.1. When prescribing long-acting or depot injections, if the service user receives other medication from LPFT, the GP or over-the-counter (OTC) the details of these medicines must be recorded on side 1 of the chart. See section 2 of this document for further information.

3.2. Only long-acting or depot injections should be prescribed on side 2 of the chart. This may include non-psychotropic medication such as contraceptive or vitamin B12 injections. If these are not to be administered by LPFT staff then the “comments” column should be used to record this.

3.3. Long acting or depot injections MUST be prescribed by full generic name (e.g. zuclopenthixol decanoate) to reduce the risk of confusing similar products.

4. Ordering medication.

4.1. When a supply of medication is required for a service user, the order can be made by an appropriate professional member of the LPFT pharmacy team, otherwise the complete chart should be faxed or taken to the appropriate hospital pharmacy

4.2. The person ordering the medication MUST:

4.2.1. Check that the details on the chart are completed correctly; otherwise this may cause a delay in dispensing and supply to the service user.

4.2.2. Complete the next available box in the ‘medication dispensing & issuing’ section, or ‘depot medication ordering, dispensing & administration’ section of the chart.

4.2.3. Indicate by letter which prescribed medication(s) they require for the service user. This may not always include every item on the prescription

4.2.4. Indicate the number of days that they require the medication to be dispensed for, or the combination of days required i.e. 3 days & 4 days, up to any maximum set by the prescriber (see paragraph 2.3)

4.2.5. If combinations of supplies are required (i.e. 3 days & 4 days or 7 x 1 day) then please ensure that each request is in a separate order box. (3 days in one and 4 days in the next one, or 7 separate single daily requests in 7 order boxes) This enables staff to sign for supplying the separate supplies when handing out to the service user.
4.2.6. Sign to say who ordered the medication and indicate the date they requested the medication.

4.3. Note that most depot injections will sometimes be general stock lines for community teams and will not need ordering from pharmacy as an individual named item.

4.4. Please note that the chart will need to be faxed for every supply required. (Weekly, fortnightly or monthly depending on supply requirements) Pharmacy will NOT supply on a repeat standing order. as previously.

5. Receiving dispensed medication

5.1. When requested medication is supplied by the dispensing pharmacy for an individual service user, the medication must be checked by an authorised person to ensure that it is the correct medication, at the correct dose with correct instructions (where appropriate) on the label and that this matches the current prescription chart.

5.2. This check needs to be undertaken as soon as the medication has arrived back with the community team, to enable any discrepancies to be rectified.

5.2.1. If any discrepancies are noted then a re-supply must be arranged immediately as soon as possible by contacting the dispensing pharmacy.

5.2.2. Whilst the correct medication is being obtained, the incorrect current supply of medication MUST be quarantined and it must be noted that there is an inconsistency between this and the prescription. Note of the date and action being undertaken must also be available with the medication.

5.2.3. If the discrepancy is a dispensing error, rather than a change to the prescription made by the prescriber after the request to pharmacy was made, then an Sentinel incident report needs to be submitted.

5.3. If the medication is correct then the person receiving and checking the medication must sign & date the received by section to indicate that the prescription has returned as requested.

5.4. The medication can then be locked away by the receiving person until required to be issued to the service user.

6. Issuing medication.

6.1. Medication must only be issued to a service user or carer by an authorised designated practitioner or as a delegated duty on behalf of the assigned practitioner in charge to an authorised & competent person in accordance with a local standard operating procedure.

6.2. The medication must be checked by the practitioner against the current prescription chart to ensure that the correct medication is taken at the correct dose and frequency by the service user as there is a risk that the prescription may have been amended since the medication was received.

6.3. The issuing person then signs & dates the ‘supplied by’ section of the chart, and if required the service user can initial in that box to say they have received the medication.

6.4. Once medication has been issued, it may be appropriate to order the next supply unless a change is prescription is anticipated.

6.4.1. Local procedures must be in place to ensure that required medication is ordered in time for the next supply to be made to the service user.

7. Administration of depot medication

7.1. If the service user is prescribed a depot injection, the depot side of the chart enables the administering person to record the date administered, the amount given on that date, and the site of administration (left or right).

7.2. Administration should also be recorded in the service user’s clinical record.

7.3. The person administering should, once administration is complete, indicate when the next injection is due.

7.3.1. Local procedures must be in place to ensure that required injections are ordered in time for the next administration, unless stock supplies are being used.

8. Dispensing
8.1. The dispensing pharmacy will dispense according to their local procedures.

8.2. All medication will be dispensed according to the prescriber’s request, as per the repeat interval guidance, and in line with the requested medication.
   - The dispensing pharmacy will not dispense any medication that has the GP box ticked unless previously contacted by the mental health team to arrange supply.

8.3. Clozapine will only be dispensed and released subject to satisfactory blood results, as per clozapine procedures.

8.4. The pharmacy will complete the ‘pharmacy’ section of the chart pertinent to the request, be it faxed or original.

8.5. All dispensed medications will be returned to the community sites as per the current local procedures.

9. **Filing prescription charts.**

9.1. Once a prescription chart is no longer in use, it must be scanned into the electronic record system and filed for reference in the service user’s clinical notes.
## Fax Cover Sheet
### Medication Request by Fax

<table>
<thead>
<tr>
<th>Date of request</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ward/Team</td>
<td></td>
</tr>
<tr>
<td>Contact number</td>
<td></td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Service user initials and date of birth</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of charts faxed with this request</td>
<td></td>
</tr>
<tr>
<td>Medication required by (Date and time)</td>
<td>Urgent ring when ready Y/ N</td>
</tr>
<tr>
<td>Medication Requested by:</td>
<td>(Signature &amp; Print)</td>
</tr>
</tbody>
</table>

### Delivery

Delete as appropriate:
1. Deliver to ward/team
2. Staff will collect from pharmacy
3. Service user/carer will collect from pharmacy

### Medication required:

Delete as appropriate:
1) Medication as indicated on prescription chart
2) Depot medication

---

Please fax all current prescription chart(s) for this service user together with this request form
Appendix A

Sample Charts
**COMMUNITY PRESCRIPTION CHART**

1. MEDICATION (INSTALLMENT) PRESCRIPTION FORM

<table>
<thead>
<tr>
<th>Name: Homer J Simpson</th>
<th>Address: 11 Springfield Road</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOB: 30/4/80</td>
<td>NHS No: 123 456 7890</td>
</tr>
<tr>
<td>Consultant: XYZ</td>
<td>Team: A. Nother</td>
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**Drug Sensitivities / Allergies**

<table>
<thead>
<tr>
<th>None Known</th>
<th>Verified by</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔</td>
<td>Dr Prescriber</td>
<td>12/6/10</td>
</tr>
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</table>

**PRESCRIPTIONS**

Prescriptions are valid for a maximum of 6 months from the date of prescribing.

<table>
<thead>
<tr>
<th>Date</th>
<th>Drug</th>
<th>Dose and Directions</th>
<th>Maximum Supply</th>
<th>Prescriber signature and print name</th>
<th>Stop date</th>
<th>Tick if normally from GP</th>
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<tbody>
<tr>
<td>12/6/10 A</td>
<td>OLANZAPINE</td>
<td>10mg BD</td>
<td>F</td>
<td>A Prescriber</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12/6/10 B</td>
<td>FLUOXETINE</td>
<td>20mg manse</td>
<td>F</td>
<td>A Prescriber</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12/6/10 C</td>
<td>NIFEDIPINE (ADALAT LA20)</td>
<td>1 MANE</td>
<td>F</td>
<td>A Prescriber</td>
<td></td>
<td>✓</td>
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**MEDICATION DISPENSING AND ISSUING RECORD**

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<th>Drug letter(s)</th>
<th>Number of days</th>
<th>Pharmacist check</th>
<th>Dispensing info</th>
<th>Received by</th>
<th>Date received</th>
<th>Supplied by</th>
<th>Date supplied</th>
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</thead>
<tbody>
<tr>
<td>14/6/10</td>
<td>A Nurse</td>
<td>A, B</td>
<td>7</td>
<td>A Pharm</td>
<td></td>
<td>A Nurse</td>
<td>15/6/10</td>
<td>B Nurse</td>
<td>18/6/10</td>
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</table>
## 2. LONG ACTING DEPOT INJECTION (COMMUNITY) PRESCRIPTION FORM

<table>
<thead>
<tr>
<th>Name:</th>
<th>Marge Simpson</th>
<th>Gender:</th>
<th>M / F</th>
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<tbody>
<tr>
<td>Address:</td>
<td>11 Springfield Road</td>
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<td>Lincoln</td>
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<tr>
<td>DOB:</td>
<td>30/4/80</td>
<td>NHS No:</td>
<td>123 456 7899</td>
</tr>
<tr>
<td>Consultant:</td>
<td>XYZ</td>
<td>Care co-ordinator:</td>
<td>A. Nother</td>
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<tr>
<td>DOB:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Team:</td>
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### Drug Sensitivities / Allergies

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<th>Verifed by</th>
<th>Dr Prescriber</th>
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### FOR ORDERING LONG-ACTING INJECTIONS ONLY

<table>
<thead>
<tr>
<th>Date</th>
<th>Drug / Form / Strength</th>
<th>Dose</th>
<th>Frequency</th>
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<th>Stop date</th>
<th>Comments</th>
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<tbody>
<tr>
<td>12/12/09</td>
<td>ZUCLOPENTHIXOL DECANOATE</td>
<td>200mg</td>
<td>1/52</td>
<td>AP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12/06/10</td>
<td>ZUCLOPENTHIXOL DECANOATE</td>
<td>200mg</td>
<td>1/52</td>
<td>AP</td>
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Rewritten after 6 months

Full generic name of the depot
## DOCUMENT VERSION CONTROL

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<td>Date Policy Last Reviewed and Updated:</td>
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</tr>
<tr>
<td>Implementation Date:</td>
<td>Date SOP comes into effect</td>
</tr>
<tr>
<td>Author:</td>
<td>Richard Lewis</td>
</tr>
<tr>
<td>Approved by:</td>
<td>Medicines Management Committee</td>
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<td>Review Date:</td>
<td>May 2016</td>
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Standard operating procedure for the management of Restricted Drugs

This procedure should only be implemented by staff that have been approved as competent and received appropriate training.
Introduction

1.1 To reduce the risk of abuse and diversion of specified medicines, Lincolnshire Partnership NHS Foundation Trust, (LPFT) requires that at least ONCE daily monitoring of these medicines takes place on all in-patient wards and community teams where monitoring occurs e.g. Crisis teams where they are kept. The security, record-keeping and inspection of these items is analogous to that for Controlled Drugs. These medicines will be termed “Restricted Drugs” and this will include, but not exclusively, medicines that are legally classed as Controlled Drugs of schedules 4 and 5.

1.2 It is recognised that the term “Restricted Drug” is a local one and has been introduced to address concerns specific to the Trust. The term has no legal standing and is unlikely to be recognised by external bodies.

2: Purpose of the Procedure

2.1 Account for the use and stock-holding of medicines identified as having a significant potential for abuse, diversion and theft.

2.2 Ensure that any discrepancies are identified and investigated in a timely manner.

2.3 Ensure that discrepancies that cannot be resolved are reported in a timely manner to the appropriate individuals.

2.4 Ensure that the LPFT Medicines & Medical Devices Management Policy is adhered to.

3: Scope

3.1 This procedure encompasses a range of activities including storage, record-keeping, stock reconciliation and reporting.

3.2 This procedure encompasses medication considered, by the Chief Pharmacist, to have a significant risk of diversion, misuse or theft (see Appendix A).

4: Responsibilities

4.1 Trust Board

4.1.1 The Trust Board are responsible for reviewing the ongoing need for this procedure and for the need to maintain the definition of Restricted Drugs within the Trust.

4.2 Chief Pharmacist

4.2.1 The Chief Pharmacist is responsible for the monitoring, updating and dissemination of this procedure throughout the Trust.

4.2.2 The Chief Pharmacist is responsible for ensuring there is evidence that all pharmacy team members involved in managing Restricted Drugs have read and understood this procedure (Appendix C).
4.2.3 The Chief Pharmacist is responsible for informing the relevant General Manager of any significant concerns about the security of Restricted Drugs on an inpatient ward or community team.

4.2.4 The Chief Pharmacist is responsible for providing assurance to the Trust Board that Restricted Drugs are being managed safely and securely.

4.3 Ward Manager/Team Leader

4.3.1 Ward Managers/team leaders are responsible for ensuring there is evidence that all registered nurses working on the ward/community team with responsibility for medication have read and understood this procedure and their responsibilities (Appendix B).

4.3.2 Ward Managers/Team Leaders are accountable for this procedure being implemented and followed on the ward or in the community team.

4.3.3 Ward Managers/Team Leaders are responsible for ensuring that medication keys are kept in the possession of Registered Nursing Staff, Pharmacy Staff or locked cupboard at all times and that evidence of this can be provided.

4.4 Registered Nursing Staff

4.4.1 Registered Nursing Staff are accountable for the accurate recording of doses of Restricted Drugs that they administer to service users. This includes recording the receipt and supply of TTO medicines for leave or discharge.

4.4.2 Registered Nursing Staff are accountable for the security of medication while they are on duty.

4.4.3 Registered Nursing Staff are responsible for conducting a daily reconciliation check of the stock balances of Restricted Drugs on weekdays, when no pharmacy visit occurs, and at weekends (if the community team works weekends).

4.4.4 Registered Nursing Staff are responsible for investigating any discrepancies in the quantities of Restricted Drugs that are discovered in 4.4.3 above.

4.4.5 Registered Nursing Staff are responsible for reporting any discrepancies that cannot be resolved, as described in “Investigating Discrepancies”, below.

4.5 Pharmacy Staff

4.5.1 Pharmacy staffs are responsible for ensuring that the balances of Restricted Drugs are reconciled with the written record on each day that the ward/community team receives a visit from a member of the pharmacy team.

4.5.2 If more than one member of the team visits the ward on a day then only one check needs to be made, the team members should communicate with each other or leave adequate records to assure one another that the necessary checks have been completed.

4.5.3 Pharmacy staff are responsible for investigating any discrepancies discovered when reconciling Restricted Drug quantities as per 4.4.4 above.
4.5.4 Pharmacy staff are responsible for reporting any discrepancies that cannot be resolved as described in “Investigating Discrepancies”, below.

4.5.5 Pharmacy staff must adhere to the ward/community team procedure governing the possession of ward/community team medication keys.

4.5.6 Pharmacy staff are responsible for the review and monitoring of the amounts of Restricted Drugs held as ward/community team stock and must discuss any concerns or intended changes with the Ward Manager/Team Leader or a registered nurse employed to work on the ward. An audit trail must be kept of any changes to the ward/community team stock list.

4.5.7 Pharmacy staff are responsible for reporting to the Ward Manager/Team Leader any concerns about adherence to this procedure and, if concerns remain unresolved, to the Head of Community Services and the Chief Pharmacist.

4.5.8 Pharmacy staff (pharmacist or technician) are responsible for ordering the appropriate amount of each restricted drug, using the approved ordering systems when completing the stock checks.

4.6 Head of Community Services

4.6.1 Head of Community Services is responsible for ensuring that this policy is implemented in full by ward managers/Team Leaders, including the collection of statements of understanding (Appendix B).

4.6.2 Head of community Services is responsible for reporting to the Chief Pharmacist any concerns about the security of Restricted Drugs or the implementation of this procedure.

5: Storage & Record Keeping

5.1 The restricted drugs are to be kept in the locked drugs trolley or drugs cupboard. All restricted drugs are to be kept separately from all other drugs in the drugs cupboard for ease of identifying and counting.

5.1.1 The drug keys are to be held on the person of a qualified nurse or designated person for the duration of fulfilling a delegated task. E.g. pharmacy staff

5.1.2 The drug keys need to be signed for using the key record log (see appendix E) as a daily running check list. The keys will need to be signed for every time the person holding the keys hands them over to another member of staff – even if this is only a temporary period of time. This way there should be an unbroken record of who holds the keys are at all times.

5.2 Any ‘restricted drug’ that is required by the ward will also be on the ASCribe stock sheet but will hold a balance of ZERO.

5.2.1 All stock levels should be kept to a minimum and if no one is currently using that line of medication it must be removed and a balance of zero maintained until needed. (The only exception will be community teams that have an agreed stock level of certain medication e.g. pre-packs.)

5.3 A daily running-record of the quantity kept of each Restricted Drug will be kept by the ward/community team in a format agreed with the Chief Pharmacist.
5.3.1 This can either be a register (bound hard back book) or the daily record sheet (see Appendix D)

5.4 The running-record will include all Restricted Drugs, including:

- Those kept as ward/community team stock
- Those supplied as named-patient medicines for use on the ward/community team, with a separate record for each medicine for each service user.
- Those supplied as TTO medication for leave or discharge, with a separate record for each such medicine container for each service user

5.5 The appropriate section of the running record should be updated in the following instances:

- The receipt of Restricted Drugs, whether as ward/community team stock, named-patient or TTO supplies
- The administration of Restricted Drugs to service users
- The supply of TTO Restricted Drugs to service users
- The removal of Restricted Drugs from the ward/community team, such as for the purposes of re-use or destruction
- The destruction or disposal of individual Restricted Drug doses on the ward/community team, such as in the event of doses being refused by service users
- Each day a new sheet should be completed by nursing staff, after a complete stock check and reconciliation of stock against sheet. (if using daily check sheets this is not necessary if using a register)

5.6 An entry should be made in the running record whenever a quantity is checked as part of the daily reconciliation process. The entry should confirm the following:

- The date and time of the check being made
- The identity of the person making the check
- A record of whether the balance was reconciled or not

5.7 Those restricted drugs that are prescribed for service users on level 3 SAM are exempt from recording with the restricted drugs as they are ordered for a named patient supply each week which is spot checked by staff for compliance during the subsequent week.

5.8 Records of ‘restricted drugs’ should be kept on the locality site for a minimum of 1 year before being destroyed as confidential waste.
6: Investigating Discrepancies

6.1 Any discrepancies arising from the daily check must be investigated to discover if they can be easily resolved, such as those due to an omission in the record-keeping process described above.

6.2 If the discrepancy can be resolved then an appropriate entry should be made in the running record and the matter discussed with the staff-member who was in error.

6.2.1 Concerns about repeated errors or significant numbers of omitted records should be discussed in the first instance with the Ward Manager/Team Leader and if concerns remain then with the Head of community services and Chief Pharmacist for advice on whether to regard these as a reportable incident.

6.3 If the discrepancy cannot be resolved then this must be reported without delay using the Trust’s incident reporting system. The Ward Manager/Team Leader or Chief Pharmacist should be informed of the discrepancy as soon as possible.

7: Controlled Stationary & Drugs (See CD SOP in Medicines Management Policy for details)

7.1 All controlled drugs kept on the ward/community team MUST be entered into a Controlled drug register.

7.1.1 Each type of controlled drug MUST be entered onto its own page and all Patient Own (POD) CDs must be recorded at the back of the CD register

7.2 All controlled drugs will be checked by a member of the pharmacy team at each visit to the site and at least ONCE a week a reconciliation of balance against register will be undertaken.

7.3 All balance checks must be entered onto the appropriate page of the CD register and signed by the pharmacy team.

7.4 All discrepancies will be investigated locally and an incident report form completed.

7.5 White A5 outpatient scripts kept on each inpatient site and in outpatient clinics and FP10’s kept by consultants and delegated junior doctors are all classed as ‘controlled stationary’.

7.6 All outpatient and FP10 scripts should be recorded on the appropriate template log when received and when used, with a running balance total of all scripts left on site.

7.6.1 The pharmacy team will undertake a balance check against all outpatient scripts held on inpatients sites at each visit made to the ward, this check will be done alongside the regular CD checks.

7.6.2 It is best practice for all clinicians using any of these scripts to check at the start of each day that the balance remaining matches the record log, in case some have been used or taken since the last time the scripts were used.
7.7 If there are any discrepancies between the current number of scripts held and the template log the nurse in charge/team leader and chief pharmacist must be immediately informed and a Datix report completed.
Appendix A

Examples of Restricted Drugs (November 2013)

1. **Benzodiazepines for oral administration**, including but not limited to:
   - Diazepam
   - Lorazepam
   - Oxazepam

2. **Anabolic steroids**, including but not limited to:
   - Clostebol
   - Stanozol

3. **Opiate analgesics** not already treated as Schedule 2 Controlled Drugs (see the Trust Policy for Controlled Drugs), including but not limited to:
   - Codeine
   - Dihydrocodeine
   - Co-codamol
   - Co-dydramol

Please note that the Trust treats all Temazepam preparations, Tramadol preparations, all Buprenorphine preparations and Morphine Sulphate oral liquid 10mg in 5mL as Schedule 2 Controlled Drugs, although they are not legally classified as such.

4. **Hypnotics** that are classed as ‘Restricted drugs’ due to the potential for abuse and miss-appropriation include
   - Zopiclone
   - Nitrazepam
   - Lormetazepam
   - Loprazolam
   - Zolpidem

**Items currently exempt from the ‘Restricted Drug’ counts include:**

Lorazepam injection
Diazepam rectal products
Chlordiazepoxide
Pregabalin
Gabapentin
Appendix B

Statement of understanding for nursing staff

This document should be completed by each registered nurse with responsibility for any aspect of Restricted Drug management.

A copy must be retained by the ward manager/team leader.

Statement:

I have read the standard operating procedure for the management of restricted drugs understand my responsibilities and consider myself competent to work within the procedure.

Signature: ________________________________ (Registered Nurse)
Print Name: ________________________________
Date: ________________________________

I acknowledge that the above nurse is aware of their responsibilities and is competent to work within this procedure within the Trust.

Signature: ________________________________ (Ward Manager/team leader)
Print Name: ________________________________
Date: ________________________________
Appendix C

Statement of understanding for pharmacy staff

This document should be completed by each member of pharmacy staff with responsibility for any aspect of Restricted Drug management.

A copy must be retained by the Chief Pharmacist.

Statement:

I have read the standard operating procedure for the management of restricted drugs understand my responsibilities and consider myself competent to work within the procedure.

Signature: ____________________________ (Pharmacy Team Member)
Print Name: ________________________________
Date: ________________________________

I acknowledge that the above member of the pharmacy department is aware of their responsibilities and is competent to work within this procedure within the Trust.

Signature: ____________________________ (Chief Pharmacist)
Print Name: ________________________________
Date: ________________________________
### Daily Record Sheet for restricted stocks

<table>
<thead>
<tr>
<th>Stock Medicine</th>
<th>Date:</th>
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</thead>
<tbody>
<tr>
<td>Lorazepam 1mg</td>
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<tr>
<td>Service User Initials</td>
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<tr>
<td>Staff Initials</td>
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<tr>
<td>Lorazepam 1mg</td>
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<tr>
<td>Service User Initials</td>
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<td>Staff Initials</td>
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<tr>
<td>Diazepam 2mg</td>
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<td>Service User Initials</td>
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<td>Staff Initials</td>
<td></td>
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<tr>
<td>Diazepam 5mg</td>
<td></td>
</tr>
<tr>
<td>Service User Initials</td>
<td></td>
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<tr>
<td>Staff Initials</td>
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<td>Diazepam 10mg</td>
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<td>Service User Initials</td>
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<td>Staff Initials</td>
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<td>Nitrázepam 5mg</td>
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<td>Service User Initials</td>
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<td>Staff Initials</td>
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<tr>
<td>Zopiclone 3.75mg</td>
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<td>Service User Initials</td>
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<td>Staff Initials</td>
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<tr>
<td>Zopiclone 7.5mg</td>
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<td>Service User Initials</td>
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<td>Staff Initials</td>
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<tr>
<td>Clonazepam 500mcg</td>
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<td>Service User Initials</td>
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<td>Staff Initials</td>
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<tr>
<td>Co-codamol 30/500</td>
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<td>Service User Initials</td>
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<td>Staff Initials</td>
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<tr>
<td>Codeine Phosphate 30mg</td>
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<tr>
<td>Service User Initials</td>
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<td>Staff Initials</td>
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<tr>
<td>Codeine Phosphate 15mg</td>
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<td>Service User Initials</td>
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**Dihydrocodeine 30mg**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Service User Initials</th>
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**Additional ‘restricted drugs’ used by the local site:**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Service User Initials</th>
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<th>Date:</th>
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### TTO / Leave or Discharge medication

<table>
<thead>
<tr>
<th>Service user</th>
<th>Drug (including form &amp; strength)</th>
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<th>Initials</th>
<th>Quantity Out</th>
<th>Initials</th>
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### Record of any Patient's Own Restricted drug Medication

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<thead>
<tr>
<th>Service user</th>
<th>Drug (including form &amp; strength)</th>
<th>Quantity in</th>
<th>Initials</th>
<th>Quantity Out</th>
<th>Initials</th>
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Appendix E

Key record log

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<th>Time keys taken</th>
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Royal Pharmaceutical Society Professional standards for Hospital Pharmacy Services

Please click on the image below to view the document.
Appendix Z

Out of Area Pathways

- Appendix A - Out of Area Procedure – Page 310
- Appendix B - Pathway for out of area patients requiring depot medication who are not known to LPFT – Page 311
Appendix A - Out of Area Procedure

The pathway below offers advice on how to proceed if you receive a request to administer a depot to an out of area service user who is a LPFT service user.

Local team to make request giving as much notice as possible

The following information MUST be uploaded on to Silverlink by the requesting team:

- Mental Health Act status
- A copy of the current prescription – ensure original prescription is given to temporary team, to reduce the risk of duplicate administrations.
- Name & strength of depot
- Date due, site & frequency of administration
- Medication history & allergy status
- Length of stay & number of depots required during stay (if known)

Contact LPFT Pharmacy team if the depot required is not stocked by the temporary team. Pharmacy will liaise with the supplying ULHT pharmacy / CO-OP (where necessary) to arrange delivery of medication to the temporary team.

When all required information is uploaded, agree a date care hands over. Ensure the service user has the contact details for the temporary team and knows where to attend for their depot.

When the service user returns to their local team ensure the original prescription also returns to the team for continuity.
Appendix B - Pathway for out of area patients requiring depot medication who are not known to LPFT

If your team receives a request to give a depot injection to an out of area service user the pathway below offers advice on how to proceed. If the service user is subject to the Mental Health Act please contact LPFT Mental Health Act team on 01522 573614.

Service user MUST register with a local GP Practice as a temporary resident.

Is the GP willing to administer the depot medication?

**YES**

No further action

**NO**

GP makes a referral to SPA

SPA refer to local CMHT and their Consultant

The following information is uploaded on to Silverlink

Mental Health Act status, a copy of the current prescription, depot name & strength, date due, site for administration, frequency, medication history, allergy status, length of stay & number of depots required during stay. Risk assessment and location where depot medication will be administered.

When the team is happy they have all the information they require the service user will receive a one off depot or, depending on length of stay, an agreed number of depots.
# Urgent Treatment Policy

## DOCUMENT VERSION CONTROL

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<td>New or Replacing</td>
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<td>Version No</td>
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<td>August 2015</td>
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<td>Date Policy First Implemented</td>
<td>August 2015</td>
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<td>Date Policy Last Reviewed and Updated</td>
<td>August 2015</td>
</tr>
<tr>
<td>Implementation Date</td>
<td>October 2015</td>
</tr>
<tr>
<td>Author</td>
<td>Andrew Coburn – MHA Manager</td>
</tr>
<tr>
<td>Approving Body</td>
<td>Board of Directors</td>
</tr>
<tr>
<td>Approving Date</td>
<td>29th October 2015</td>
</tr>
<tr>
<td>Committee, Group or Individual Monitoring the Document</td>
<td>MHA Monitoring Committee and Medicines Management Committee</td>
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2. Purpose
3. Duties
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5. Urgent treatment - inpatient setting
   5.1 Treatment that can be administered under section 62
   5.2 Treatment when a T2 or T3 ceases to have effect
   5.3 Action to be taken to administer treatment under section 62
   5.4 ECT
   5.5 Advance decisions and treatment under section 62
5. Urgent treatment – community setting
   6.1 Patients with capacity to consent to treatment
   6.2 Patients lacking capacity to consent to treatment
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   Appendix 2 – T3b - Verbal Instruction of administration of urgent treatment under Section 62
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   Appendix 4 – Urgent treatment – inpatient flowchart
   Appendix 5 – Urgent treatment – community patient flowchart
1. Introduction

Part 4 (sections 56-64) of the Mental Health Act 1983 [herein MHA] gives powers for patients detained under certain sections of the Act to be treated either with or without consent. Within sections 56 – 64 MHA it is recognised that there may be circumstances when it is necessary for non-consenting or incapacitated patients to be treated urgently in situations where it is not possible to obtain a Second Opinion Appointed Doctor. It is section 62 MHA that provides the authority to administer certain treatment to a patient who is detained under specific circumstances which are detailed in this policy. Section 64B provides authority in respect of capacitated consenting patients.

Part 4A (sections 64A – 64K), more specifically section 64G, MHA provides for patients under a Community Treatment Order to be treated in an emergency situation where they lack capacity as detailed in this policy. Informal patients and those detained under sections 4, 5[2], 5[4], 38, 135[1], 136 or guardianship are not covered by the powers to treat under section 62. In the event that urgent treatment needs administering to any patients who fall outside the criteria for treatment under section 62, the treatment must be justified under either common law or the Mental Capacity Act 2005.

2. Purpose

The purpose of this guidance is to:

- Provide operational guidance to clinical staff in the provision of urgent treatment to detained patients, in compliance with the MHA 1983;
- Outline the definition of urgent treatment under the MHA 1983;
- Outline which treatment can be administered to detained patients under the powers of section 62 and section 64 MHA 1983.

3. Duties

Hospital Managers

The Hospital Managers are required to monitor the use of the urgent treatment provisions within the Mental Health Act to ensure they are not used inappropriately and excessively. This requirement is delegated to the Mental Health Act Admin office. As such the MHA office should be informed of every use involving the urgent treatment provisions and provided with the appropriate form.

Responsible Clinician / Out of Hours on-call consultant

It is the responsibility of the Responsible Clinician, or exceptionally when they are not available, the Out of Hours on-call consultant to make the decision to administer urgent medical treatment under section 62. The consultant must comply with the requirements laid down in section 62 and be satisfied that the patient is legally detained under an appropriate section of the Mental Health Act. Once authorised, the consultant should complete the appropriate form, where required, in conjunction with the nursing staff, if applicable.

Clinical staff

It is not a requirement under section 64G that an approved consultant makes the decision to administer medication when a community patient lacks capacity. Where treatment is administered under section 64G MHA the person authorising and administering must satisfy themselves that the conditions laid down in section 64G are and complete the appropriate form.

Before administering any treatment which has been prescribed whether that be under section 62 or section 64G, clinical staff must adhere to this guidance and be satisfied that the relevant documentation is in place. Should there be any doubt clinical staff should seek advice from their line manager prior to administering the treatment.

Any breaches should be reported as per Trust policy.

4. Definitions

Urgent Treatment

Urgent treatment is defined under the Act as treatment which is immediately necessary to:-

- save the patient’s life;
- prevent a serious deterioration of the patient’s condition, and the treatment does not have unfavourable physical or psychological consequences which cannot be reversed;
• alleviate serious suffering by the patient, and the treatment does not have unfavourable physical or psychological consequences which cannot be reversed and does not entail significant physical hazard; or
• prevent patients behaving violently or being a danger to themselves or others, and the treatment represents the minimum interference necessary for that purpose, does not have unfavourable physical or psychological consequences which cannot be reversed and does not entail significant physical hazard.

If the treatment is ECT (or medication administered as part of ECT) only the first two categories above apply.

The immediacy of the treatment refers to the need for treatment and not the consequences that would flow if the treatment was not provided.

5. Emergency treatment – inpatient setting

5.1 Treatment that can be given under section 62:-
   • Any other treatment which is felt to be of urgent necessity and which meets the definition as detailed above at paragraph 4; and
   • ECT which is covered in more detail at section 5.4

5.2 Treatment when a T2 or T3 ceases to have effect:-
   When a patient:
   • Has previously consented to treatment [medication after 3 months], [i.e. there is a T2 in place] and then withdraws their consent;
   • Has previously consented to treatment [medication after 3 months] but then ceases to have the capacity to consent;
   • The patient is recalled from their CTO and they have a CTO12 or CTO11 in place [i.e. during the 72 hour window]

Treatment may be continued if the approved clinician in charge of the patient’s care considers that the withdrawal of the treatment would cause serious suffering to the patient. In these circumstances the approved clinician in charge of the patient’s care should complete form T3a

It is also recommended that a second opinion appointed doctor should be sought promptly to authorise continued treatment in the longer term.

5.3 Action to be taken to administer treatment under Section 62
   It is the responsibility of the patient’s Responsible Clinician to make a decision to treat a patient urgently under Section 62 of the MHA 1983. There may be however exceptional circumstances where a decision has to be made by the Approved Clinician/Consultant on call.

Wherever possible, the patient’s Responsible Clinician will discuss the proposed treatment with others involved with the patient’s care and:
• The decision to treat using the powers under section 62 will be recorded in the clinical records, with details of the proposed treatment and why it is to be given under Section 62;
• Completion of the section 62 form [T3a] must be undertaken by the Responsible Clinician or, if out of hours, by the Approved Clinician/Consultant on-call [see appendix 1] or;
• If the decision is taken out of hours by the Approved Clinician/Consultant on-call to treat using the powers under section 62 via a verbal instruction, nursing staff should clearly document the verbal instruction from the Approved Clinician/Consultant on-call on the appropriate form, T3b (see appendix 2)
• Treatment should then be administered to the patient
The section 62 form, T3a (appendix 1) and the verbal instruction form, T3b (appendix 2) can be completed the next working day by the Approved Clinician/Consultant on-call [who gave the verbal instruction]. A copy should be placed on silverlink and in the patient’s medical records and Mental Health Act Admin office informed.

5.4 ECT

ECT can be given under section 62 if is immediately necessary to:-

- Save the patient’s life; or
- Prevent a serious deterioration of the patient’s condition [and the treatment is not irreversible].

Note that a patient who has capacity to consent to ECT but refuses it should not be given ECT.

If a clinician is considering the use of ECT under section 62, it is recommended that discussions take place with the ECT department and the MHA office in relation to the number of treatments that may be given.

If the patient is receiving ECT, the section 62 form, T3a, is to be attached to the clinical records which will accompany the patient to the ECT department:

- If the patient is receiving on-going medication under section 62 a copy of the form is to be attached to the patient’s drug card;
- Once the treatment has been administered, the section 62 form, T3a, is to be placed in the medical records as the SOAD from the CQC will need to review it;
- Once a T3, T4, T5 or T6 form has been completed, a copy needs to be attached to the ECT records or medication prescription chart, and the original sent to the Mental Health Act Office.

5.5 Advance decisions and treatment under Section 62

Where treatment is considered to be immediately necessary and the requirements of paragraph 4 within this policy are met, treatment can be given even if it conflicts with an advance decision, or the decision of someone who has the authority under the MCA to refuse it on behalf of the patient.

However if this is the case:

- The Responsible Clinician must document in the clinical records why the decision has been made to treat irrespective of the patients expressed advance decision. An explanation as to why their advance decision cannot be complied with is to be given to the patient prior to the treatment being administered. If this is not possible for any reason, the explanation is to be given as soon as is clinically indicated following treatment; and
- A record of this discussion is to be made by the Responsible Clinician in the patient’s clinical record.

6. Urgent treatment – Community setting

Note that the guidance below is for patients who have attained the age of 18. For advice in relation to urgent treatment and young persons or children who are detained under the Mental Health Act, please contact the Mental Health Act Admin Office.

6.1 Patients with capacity

Paragraph 24.17 Code of Practice 2015 notes that:

“A patient subject to a Community Treatment Order who has capacity to consent cannot be treated without their consent, even in an emergency. There are no exceptions to this.”

Where a patient has capacity, the provisions of section 64B MHA must be followed. Fundamentally, the patient must have capacity to consent and consent to the treatment. The LPFT staff member certifying that the patient has capacity and the LPFT staff member who administers the treatment, if different, must both document any treatment given in the patient’s notes. This should include a documented capacity assessment by the staff member who certified capacity.
6.2 Patients lacking capacity
Emergency treatment in the community should be reserved for those rare situations where it is in the best interests of the patient to be immediately treated with force in the community rather than be transported to hospital under the recall powers under the MHA for treatment to be provided there. For example, recall is unrealistic or may exacerbate their condition. Situations like this should be exceptional.

Where a patient lacks capacity, the provisions of section 64G MHA must be followed. Unlike under section 62 MHA, the treatment does not have to be given under the direction of an approved clinician. Chapter 24 Code of Practice offers guidance on treatment in the community where a patient is not recalled to hospital. Section 64G(2) – (5) MHA lays down three conditions which are detailed below:

First condition: lack of capacity:
Where treatment is to be provided, those administering the medication must first confirm that the patient lacks capacity to consent to the treatment as treatment can only be given if there is a reasonable belief that the patient lacks the capacity to consent.

Second condition: treatment must be immediately necessary
The treatment is immediately necessary to:

- save the patient’s life, or
- Prevent a serious deterioration of the condition [not being irreversible], or
- Alleviate serious suffering to the patient [not being irreversible or hazardous], or
- Prevents the patient from behaving violently, or being a danger to themselves or others and the treatment represents the minimum interference necessary for that purpose [not being irreversible or hazardous].

Third condition: may be necessary to use force (whether or not the patient objects):
It is necessary to use force against the patient to administer the treatment and the use of the force is proportionate to the likelihood of the patient’s suffering and to the seriousness of the harm.

If treatment is provided to a patient who lacks capacity in the community, the reasons for this with specific reference to the conditions noted above should be written in the patient’s notes and a copy of form CTO11a scanned onto silverlink. MHA office should be informed.

7. Development of Policies and Procedures
On drafting and reviewing this policy and associated procedure, the Author has drawn on the policies of other Mental Health Trusts.

The policy will form an agenda item on the Medicines Management Committee and MHA Committee. The policy should be brought to the attention of medical staff, in particular consultants and registered nurses and CPNs.

8. Consultation, Approval and Ratification Process
The policy will be consulted upon, approved and ratified in accordance with the Trust's Corporate Documents and Policies Procedure. The relevant Executive Committee is identified in the appendices to that procedure.

9. Review and Revision Arrangements including Version Control
This policy will be reviewed bi-annually by the policy author in accordance with the Corporate Documents and Policies Procedure. Revision may occur earlier if relevant new legislation or guidance is issued. The Executive Committee monitoring the effectiveness of the policy may also call for an early review on the basis of the reports it receives.

The Trust Secretary’s Office will maintain a version control sheet, as per the Corporate Documents and Policies Procedure.
10. Dissemination and Implementation of a Policy
This policy will be disseminated in accordance with Corporate Documents and Policies Procedures. The intention is to implement the plan via:-

<table>
<thead>
<tr>
<th>Action</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email sent to all General Managers / Clinical Directors and Heads of Service informing them of the amended policy and requesting dissemination through their staffing structure</td>
<td>Within one week of policy implementation</td>
</tr>
<tr>
<td>Training packages to include new /amended provisions of policy</td>
<td>Immediately</td>
</tr>
<tr>
<td>New / amended forms to be sent to ward managers to replace all other forms on the ward</td>
<td>Within one week of policy implementation</td>
</tr>
<tr>
<td>The appended flowcharts will be provided to all inpatient wards and community teams</td>
<td>Within one week of policy implementation.</td>
</tr>
</tbody>
</table>

11. Policy Control including Archiving Arrangements
Corporate and Legal Services will retain a copy of each policy for a minimum of 10 years in line with the recommendations contained within ‘Records Management NHS Code of Practice’ (2006). Individuals wishing to obtain previous versions of this policy should contact Corporate & Legal Services.

12. Monitoring Compliance with and Effectiveness of Policies and Procedures
The Hospital Managers are required to monitor the use of the urgent treatment provisions within the Mental Health Act to ensure they are not used inappropriately and excessively. The monitoring of compliance with this policy, and the use of the urgent treatment provisions contained in the Mental Health Act will be on an ongoing basis with information fed into the MHA Committee.

13. References
- Mental Health Act Code of Practice 2015
- Mental Health Act 1983
- Mental Health Act 2007
Urgent treatment under Section 62 of the Mental Health Act 1983
Please indicate if the Section 62 for ECT [ ] or Medication [ ]
(tick whichever applies)
I the Responsible Clinician/Approved Clinician
(Full Name and Address of RC/AC)

In my opinion:
(Full name and address of patient)

(delete the statement which does not apply)
(a) is capable of understanding the nature, purpose and likely effects of the treatment outlined below and has refused consent.
OR
(b) is not capable of understanding the nature, purpose and likely effects of the treatment outlined below.

Is Section 62 being used for (tick whichever applies):
A. One-off treatment [ ] (go to point A)
OR
B. Plan of treatment [ ] (got to point B)

A. One-off treatment
(Detail treatment authorised)

In my opinion this treatment is (tick whichever applies):
 a) Immediately necessary to save the patient’s life [ ]
b) Which (not being irreversible) is immediately necessary to prevent a serious deterioration of the patient’s condition [ ]
c) Which (not being irreversible or hazardous) is immediately necessary to prevent serious suffering [ ]
   (not applicable for ECT or medication administered as part of ECT)
d) Which (not being irreversible or hazardous) is immediately necessary and represents the minimum interference necessary to prevent the patient from behaving violently or being a danger to himself or others [ ]
   (not applicable for ECT or medication administered as part of ECT)

B. Plan of treatment
I certify that discontinuation of current treatment and/or a plan of treatment pending compliance with Section 57 would cause serious suffering to the patient.

Has a request been made for a second opinion? YES/NO
Date the request was made ...........................................
Length of time treatment given ......................................
Signed: ........................................... Date: .................
Verbal Instruction for the administration of urgent treatment under Section 62 of the Mental Health Act 1983  
(To be used out of hours)

I the Qualified Mental Health/Learning Disability Nurse:-

(Full Name of Nurse)

Have received a verbal instruction over the telephone from:

(Full name and address of RC/AC)

To allow for the administration of Medication for:

(Full name and address of patient)

Is Section 62 being used for one-off treatment [ ]

(Detail treatment authorised)

In the opinion of the RC/AC this treatment is (tick whichever applies):

a) Immediately necessary to save the patient’s life [ ]
b) Which (not being irreversible) is immediately necessary to prevent a serious deterioration of the patient’s condition [ ]
c) Which (not being irreversible or hazardous) is immediately necessary to prevent serious suffering [ ] (not applicable for ECT or medication administered as part of ECT)
d) Which (not being irreversible or hazardous) is immediately necessary and represents the minimum interference necessary to prevent the patient from behaving violently or being a danger to himself or others [ ] (not applicable for ECT or medication administered as part of ECT)

Signed: _______________________________ Date: ______________
(by Nurse receiving the verbal instruction)

Nurse to agree with the RC/AC when they will come and sign this form i.e. Next Day or Next Working Day
(Please indicate which)

Signed: _______________________________ Date: ______________
(by the RC/AC who approved the verbal instruction, and on the date as agreed above)
Form CTO11a
Mental Health Act 1983 – section 64G Emergency -section 58 treatment required for patient on SCT -patient lacks capacity to consent

(PRINT full name)............................................................................................................................................

(PRINT full name and address of patient)............................................................................................................................................

........................................................................................................................................................................

Patient’s NHS number............................................................................................................................................

I believe that he/she requires the following treatment in an emergency situation, as laid down by section 64G of the Mental Health Act 1983 (as amended by the Mental Health Act 2007) (*give details of the treatment*)

........................................................................................................................................................................................................................................................................

I certify that the patient is:

a) Not capable of understanding the nature, purpose and likely effects of the above treatment

AND

b) In my opinion the treatment is immediately necessary to: (*delete as appropriate*)

- *save the patients life;
- *prevent a serious deterioration of the patient’s condition, and the treatment does not have unfavourable physical or psychological consequences which cannot be reversed;
- *alleviate serious suffering by the patient, and the treatment does not have unfavourable physical or psychological consequences which cannot be reversed and does not entail significant physical hazard; OR
- *prevent patients behaving violently or being a danger to themselves or others, and the treatment represents a minimum interference necessary for that purpose, does not have unfavourable physical or psychological consequences which cannot be reversed and does not entail significant physical hazard.

AND

b) If it is necessary to use force in order to provide this treatment, the force is proportionate to the harm that the treatment is preventing.

Signed ................................................................. Date ..............................
It is the responsibility of the patient’s Responsible Clinician to make a decision to treat a patient urgently under Section 62 of the MHA 1983. There may be however exceptional circumstances where a decision has to be made by the Approved Clinician/Consultant on call.

**One off treatment**

Is the treatment a ‘one-off’ or is it a continuation of a treatment plan?

Contact is made with RC or Out of Hours Consultant who decides that treatment is:-

Immediately necessary to:-
- save the patient’s life, or
- Prevent a serious deterioration of the condition [not being irreversible], or
- Alleviate serious suffering to the patient [not being irreversible or hazardous], or
- Prevents the patient from behaving violently, or being a danger to themselves or others and the treatment represents the minimum interference necessary for that purpose [not being irreversible or hazardous].

If the treatment is ECT (or medication administered as part of ECT) only the first two categories above apply.

**Continuation of treatment plan**

T2 / T3 certificate becomes invalid: e.g. patient ceases to consent, no SOAD certificate, patient is recalled

Discussion is had with MDT and RC makes decision to continue treatment plan pending new certificate (usually T3)

RC completes form T3a.

In all cases form is placed in medical records and medical card and scanned onto silverlink [notifying MHA Admin]

**Out of hours**
- If RC / OOH consultant is on site complete form T3a; or
- If verbal order nurse completes form T3b (verbal order)

**In hours**
- RC completes T3a
Does the patient have capacity to consent to treatment?

Yes - does the patient consent?

Yes – treatment can be given. A full record should be made in the clinical notes of the capacity assessment and treatment.

No – Trust staff member must confirm that the criteria are met before administering treatment:

First condition: lack of capacity:
Where treatment is to be provided, those administering the medication must first confirm that the patient lacks capacity to consent to the treatment as treatment can only be given if there is a reasonable belief that the patient lacks the capacity to consent.

Second condition: treatment must be immediately necessary
The treatment is immediately necessary to [if the treatment is ECT (or medication administered as part of ECT) only the first two categories below apply]:
- Save the patient's life, or
- Prevent a serious deterioration of the condition [not being irreversible], or
- Alleviate serious suffering to the patient [not being irreversible or hazardous], or
- Prevents the patient from behaving violently, or being a danger to themselves or others and the treatment represents the minimum interference necessary for that purpose [not being irreversible or hazardous].

Third condition: may be necessary to use force (whether the patient objects or not):
It is necessary to use force against the patient to administer the treatment and the use of the force is proportionate to the likelihood of the patient's suffering and to the seriousness of the harm.

Conditions met – treatment can be given and form CTO11a is completed, put in med recs, scanned onto Silverlink and MHA office notified

Conditions not met – treatment should not be given. Contact MHA Admin office for further advice.
Introduction

The purpose of this guidance is to clarify the legal and professional standards on the involvement in medication management by occupational therapists and must be used with reference to the Trust's Medicines Management Policy (2013) and the COT Briefing on Safe Management of Medicines for occupational therapists (2011).

This guidance has been developed by the Trust Lead Occupational Therapist in consultation with the Lead Occupational Therapists governance group, as well as the Trust Lead Pharmacist.

The guidance covers occupational therapists working in all clinical areas and services within the Trust including those working as a care coordinator, and can also be used by occupational therapists who are registered with the HCPC but do not hold a specific post titled as an occupational therapist. It has been developed to ensure that occupational therapists are appropriately trained for this role in the administration of medication or in supporting services users taking their own medicines.

Occupational therapists frequently work with individuals with complex needs that entail the therapist synthesising relevant knowledge of biological, medical, human, psychological, social, technological and occupational sciences (COT 2009). It is therefore important that all occupational therapists have a working knowledge of medicines (DH 2008).

All medicines are potentially harmful if misused and care must be taken to ensure that the appropriate storage, administration and control of medicines takes place at all time.

The College of Occupational Therapists (COT) fully support occupational therapists involvement in medicines management as it offers many benefits for patients and carers.

In July 2009 a report was published scoping the role of allied health professionals (AHPs) in prescribing and managing medication stating that occupational therapists should have an understanding of the types of medicines used in acute and long term conditions commonly treated by occupational therapy, their side effects and properties that may affect the occupational therapy intervention (DH 2009).

1.1 National and Local Investigations

This guidance has been produced with reference to recent investigations involving occupational therapists and their roles within medicines management. The following investigations are of note:

- An independent investigation in 2006 commissioned by NHS Yorkshire and Humber highlighted the conflict between guidance provided by the College of Occupational Therapists to its members about medicine management and the role and responsibility of a care coordinator.
  It recommended that the College take a lead role in defining the skills and competencies relating to medicine management that an OT working as a care coordinator would need.
  COT has updated its guidance accordingly in a briefing entitled Mental Health Coordination and Occupational Therapy (2011)

- In October 2010 NHS South East Coast issued an independent investigation into the care and treatment of Mr X. An issue was highlighted in that report about the role of an occupational therapist acting as a care coordinator to a client on clozapine, the recommendation is as below:
We consider it would have been more appropriate if Mr X had been allocated a clozapine-trained community psychiatric nurse as his care coordinator, with Occupational Therapist 1 providing regular focused occupational therapy (OT) input. Alternatively, if Occupational Therapist 1 was the allocated care coordinator, a clozapine trained CPN should have had a formal and regular role in monitoring Mr X.

- In November 2012 Lincolnshire Partnership NHS Foundation Trust commissioned an independent investigation into errors in the prescription, dispensing and administration of Zuclopenthixol. Mrs Y had been in a care home for about 3 weeks. She had been deluded and responding to hallucinations. She had been diagnosed with a urine infection, but her blood tests had normal results. She was initially assessed by an Occupational Therapist OT1 who discussed the case with consultant psychiatrist CP1. On the basis of OT1’s assessment CP1 concluded that a depot antipsychotic injection was the best treatment option and he sent a fax to the GP surgery requesting the prescription of “Clopixol IM 50mg weekly x 3 (to be reviewed)”. The general practitioner wrote a prescription for zuclopenthixol acetate, which was dispensed by the community pharmacist. Mrs Y was subsequently visited by CPN1 to administer the depot injection. It was not given because Clopixol Acuphase had been dispensed.

Finding 1 – The initial assessment was undertaken by an Occupational Therapist, who although dedicated and professional in her approach, did not have the optimal training and experience for performing the assessment regarding medication issues.

Recommendation 1 - That the role of an OT in a community team is clarified and that unless they have had additional training they are not expected to be involved in medication issues’

1.2 Regulatory and Professional Context

The COT and the Health Care Professions Council (HCPC) make it clear that occupational therapists must act within their professional competence at all times, and ensure they have training if they are taking on new roles and responsibilities. The administration and supply of medicines are not basic skills for occupational therapists, falling outside the scope of occupational therapy practice and therefore it is vitally important therefore that the occupational therapist acts safely and appropriately within her/his professional scope of practice.

The Medicines Code defines roles in relation to the handling and administration of medication. Occupational therapists will most usually fall into the category of Authorised Employee – a member of staff who following training has been authorised by the Appointed Practitioner in Charge to undertake specific duties in relation to medication.

1.3 Indemnity and Assurance

The British Association of Occupational Therapists (BAOT) professional indemnity insurance covers members for occupational therapy practice only. The handling of medication is therefore not covered, although under the Medicines Act 1968 there is nothing to prevent an occupational therapist handling medication after it has been dispensed. As such occupational therapists employed by the Trust will be indemnified by the Trust as long as this procedural guidance is adhered to.

All job descriptions for qualified occupational therapists will now contain the following phrase: “Have a basic working knowledge of the medication prescribed for people under your care. This includes information on the usual dosage, common side effects and the need for any special monitoring. Any reported or observed side effects must be brought to the attention of the prescriber.”
2. The Occupational Therapist and their role in medication management

In response to the Trusts investigation, a survey in 2013 was undertaken to identify the current practice of occupational therapists in medication management and the concerns and benefits of occupational therapists undertaking certain aspects of medication management have been considered. This guidance and the medicines management interventions outlined has been informed by the outcomes from the survey.

Two roles for occupational therapists were subsequently identified:

**2.1 Occupational Therapists working in the role of care coordinator.**

Occupational Therapists often act as a care coordinator, coordinating a service user’s care. This will include ensuring that the CPA wellbeing care plan includes arrangements for medication and may include the completion of a medication care plan. Information pertaining to aspects of medication to inform the care plan should be obtained by the occupational therapist from the service user’s psychiatrist or nurse; compiled with them and documented on the electronic care record. The care plan must be agreed and signed by the psychiatrist and/or nurse.

Any non compliance with the medication care plan or where a significant deterioration is noted, must be fed-back to the RMO and/or discussed with a senior nurse and recorded.

As a care coordinator an occupational therapist may prompt a service user to remind them to take their medication as prescribed although this is not viewed as a primary role of an occupational therapist. Where verbal prompts are provided, this must be recorded in the electronic care record.

Where medication compliance and monitoring are the main clinical issues but the service user also has significant occupational needs, they should be care coordinated by a nurse with the occupational therapist providing occupational therapy interventions.

**Special Precautions:**

Where a service user is taking Clozapine and their key worker is an occupational therapist, a nurse must be identified who is responsible for the monitor of medication prescribed.

If a service user on Clozapine has missed more than two days medication, the occupational therapist must seek advice from a psychiatrist or nurse as soon as possible. The service user must be informed that the occupational therapist is seeking advice.

**2.2 Occupational Therapists working in a specialist role**

Occupational Therapists are skilled at assessing areas such as a person’s:-

- attitude to their medication
- identifying people unlikely to adhere to their medication regime
- assisting in identifying possible side-effects particularly noting when there is a negative impact on occupational performance
- identifying other potential non-compliance issues such as confusion

They are also skilled at developing interventions that address lifestyle planning and daily routine which can include strategies to assist service users to incorporate the routine of self medicating into their daily routine. This may include identifying and prescribing assistive technology which can assist in self medication management e.g. an electronic monitored dosage system (MDS) which can be prescribed by the occupational therapist via the Lincolnshire Telecare Service.
Self-administration of medication is viewed as an activity of daily living that requires manual dexterity and coordination to get medicines out of containers, reading and eyesight skills to read labels on containers, an ability to follow written instructions, temporal orientation to understand how often and when to take medicines, memory to remember when to re-order medicines and the ability to use transport if necessary to go and collect medicines.

3. Guidance on specific interventions relating to medicines management

3.1 Conveyance, collection and transporting medication

3.1.1 Occupational therapists working in the community

Occupational therapists will only convey or collect medication currently prescribed for a service user. This includes the collection of medication or a prescription form from a pharmacy or doctor and, in an exceptional circumstance, when a housebound service user has missed a pharmacy delivery.

If the medication is new to the person and it is unclear whether the medication has been explained by the prescriber, then the medication should only be conveyed by a registered nurse so that the medication can be explained and the service user can ask questions.

In all circumstances a service user should be supported to collect their prescription themselves, with the support of the occupational therapist if required.

If the medication is to be dispensed from a medicines cupboard, it must be handed to the occupational therapist by the registered community nurse and it remains the responsibility of the nursing staff to check the contents of the medication to be taken and that this is correctly dispensed and labelled.

All medicines to be transported will be secured in sealed containers using a variety of systems which are site specific. The responsibility for the maintenance of security during transportation rests with the individual carrying out the task. All medicines must be stored in their original containers and occupational therapists must be made aware of security issues if they are to transport schedule 2 and 3 controlled drugs. Medicines must not be stored in cars because of the extreme variation which occur.

The conveyance and transportation of medication by an occupational therapist must be documented by the dispensing nurse in the electronic care record.

3.1.2 Occupational therapists working in acute units

When a service user is going on leave from an acute unit, they should be prompted to collect their own medication from ward nursing staff and carry the medication independently to their own home.

It remains the responsibility of the ward nursing staff to check the contents of the medication to be taken away and that this is correctly dispensed and labelled.

Where a service user has been identified as lacking the functional skills to safely handle their medication containers due to either physical or cognitive deficits, an occupational therapist can act as an agent of the service user and deliver the prescribed medication for service users they are escorting home, who are being taken on a home visit or who may be already on leave. This must be documented on the electronic care record. The medication must be handed to the occupational therapist by the ward nurse. The conveyance and transportation of medication by an occupational therapist must be documented by the dispensing nurse in the electronic care record.

All medicines to be transported will be secured in sealed containers using a variety of systems which are site specific. The responsibility for the maintenance of security during transportation rests with the individual carrying out the task. All medicines must be stored in their original containers and occupational therapists
must be made aware of security issues if they are to transport schedule 2 and 3 controlled drugs. Medicines must not be stored in cars because of the extreme variation which occur.

### 3.2 Administration of medication

Occupational therapists are not allowed to administer or select any form of medication for a service user and should support service users to administer their own medication. They are not allowed to fill dosette boxes or any other type of container.

### 3.3 Prescription of medication

The Department of Health in England has expanded the range of health professionals (including allied health professionals) able to supply and/or administer medicines and train as prescribers with appropriate legal changes to support this (DH 2009). The Medicines Act (1968) and the Misuse of Drugs Act (1971) govern the use of medicines and as such each Act has had many secondary pieces of legislation that have included for example, occupational therapists use of Patient Group Directions.

A recent Department of Health review of occupational therapists’ use of PGDs in England revealed some use in acute care settings such as walk in centres and occasionally in rheumatology to administer corticosteroid injections. However as much of the work of occupational therapists involves management of long term conditions, elderly care and mental health, these clinical pathways can be less suited to PGD use (DH 2009). Occupational therapists are not legally able to be Supplementary or Independent prescribers. **The Trust currently does not support occupational therapists to use PGDs**

### 3.4 Removal of medication

If it is necessary to remove medication from service users home, consent must be gained from the service user or carer (if more appropriate) and the disposal of patients own drugs form completed (form available in the Trusts medicines management policy)

Where a service user is at high risk, or is incapable, following a capacity assessment, of being unable to give informed consent, the occupational therapist can act in the best interests of the service user and independently remove the medication for safekeeping.

Medication should be taken to a pharmacy for disposal or handed to ward staff (if the service user is on leave from an acute unit). This includes the empty containers. The pharmacist should be asked to sign for receipt of the medicines and this should be included in the patient record.

If the storage of unused medication in the service users home presents as low risk, the occupational therapist should request the service user or carer to return it to a pharmacy for disposal.

### 3.5 Monitored Dosage Systems

Decisions on whether or not a monitored dosage system (MDS) or compliance aid are suitable for a particular patient depends upon an assessment of the patient, the type of monitored dosage system and the type medication. It will often be inappropriate for medicines to be stored in an MDS for pharmaceutical stability reasons or clinical reasons and many medicines will need to be kept in their original packaging. Some medicines degrade very quickly when outside of their original packaging, whilst others may have variable doses. Many medicines such as liquids, inhalers and creams are not suited to MDS.

To discuss details of medication suitability using an MDS for an individual, occupational therapists should contact the pharmacist involved.
3.6 Information and advice on medications

An occupational therapist is able to verbally provide general information on the effects of medicines that may be applied to a whole population, but patients should be advised to see a doctor or pharmacist if they have specific concerns or if they wish to change or stop medicines. Occupational therapists are not trained to provide advice about the use or actions of medicines, or to interpret blood test results.

An occupational therapist can provide written information (using agreed information leaflets) on medication to reinforce advice given by a prescriber, or a staff member qualified to give such information. Written information to give to service users, in the form of leaflets, is accessible using the Trust approved website www.choiceandmedication.org Information written in such leaflets can be read out by the occupational therapist to a service user who has poor literacy skills or other language barrier.

A service user should be encouraged to access information using Trust approved websites or information available on their ward.

3.7 Medication Errors

A medication error is defined as ‘any error made in prescribing, dispensing, administering, disposal and recording of any medication or the omission of any of these parts’

All medication errors must be reported on Datix.

If an error occurs, the occupational therapist should contact a ward or community nurse, or Trust pharmacist.

4. Training and Competency

A scope of practice is the area in which an occupational therapist has knowledge, skills and experience to practice lawfully, safely and effectively in a way that meets the HCPC standards, and does not expose any danger to the public or themselves (DH 2009).

An occupational therapist's scope of practice will change over time and the practice of experienced occupational therapists often becomes more focused and specialised than that of newly registered occupational therapists. Competency levels will vary for each individual occupational therapist and will necessitate the use of personal judgement in regards to medicines management.

Different AHPs receive different levels of pharmacology and medicines training at undergraduate level and COT recognise that appropriate medical knowledge is still necessary in order for graduates to work in health care settings where pharmacological interventions may be a crucial to achieving optimum outcomes for a patient (COT 2009).

All Trust occupational therapists involved in specific areas of the medication management process will be appropriately trained and professionally supervised by a more senior occupational therapist.

This ensures that safeguards are in place that promote the safety of, and protect the rights of, service users, regardless of race, disability, gender, gender identity, age, sexual orientation, religion or belief.

Training will include:

- the role of medication
- handling of medication
- high risk medicines
- side effects, titration and concordance
- Trust Medicines Code and associated policy
- storage, security and storing medication
- medication records
Training will be specially designed for Trust occupational therapists and occupational therapists will be required to complete training once a year (either face to face training or via e-learning). Following training occupational therapists will be required to complete a theoretical competency assessment.

Service managers will work with the Trust Lead occupational therapist in identifying practitioners who need additional training to support their role in relation to medication management, for example if they are newly qualified practitioners.

Occupational therapists working as care coordinators will need further training on the following areas:
- an understanding of who prescribes medication
- where it is obtained from
- the instructions for medication administration
- knowledge of medication that is prescribed for physical health conditions
- untoward incidents involving medication

Modernising AHP Careers (DH 2008) presents an online framework on the Skills for Health website of all AHP competencies and is a tool to support career development and assist competence based workforce planning. It is not compulsory and is separate from the HCPCs standards of proficiency.

It contains five competencies related to medicines management.

Occupational therapists are encouraged to look further at the details for each competency:

<table>
<thead>
<tr>
<th>CHS74:</th>
<th>Manage an individual's medication to achieve optimum outcomes;</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHARM10:</td>
<td>Issue a prescribed item (after it has been dispensed);</td>
</tr>
<tr>
<td>CHS2:</td>
<td>Assist in the administration of medication;</td>
</tr>
<tr>
<td>CHS3:</td>
<td>Administer medication to individuals;</td>
</tr>
<tr>
<td>MH36:</td>
<td>Support individuals to administer their own medication.</td>
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</table>

Appendix 1 provides occupational therapists a framework to guide their practice in medicines management by considering the components in the Model of Human Occupation.

5. Monitoring Compliance

Adherence to this guidance will be monitored through:

The Trust Lead occupational therapist who is responsible for the professional governance of occupational therapy staff employed by the Trust.

Divisional specialist occupational therapists who will work with service managers to identify staff training needs and monitor compliance in attending training, as well as using supervision to monitor and ensure competence in this area.

Individual practitioners are accountable and responsible for their own practice. All occupational therapists must practice and abide by the code of ethics and professional conduct as set out by the COT and the HCPC and within the policies, protocols and guidelines laid down by the Trust.

6. References:

BJOT (2011) Cole, Julie: Extending the role of the occupational therapist in the promotion of collaborative medication management to facilitate occupation

COT (2011) Mental Health Care Coordination and Occupational Therapy
COT (2011) Safe Management of Medicines for Occupational Therapists
DH (2009) AHPs prescribing and medicines supply mechanisms scoping project report
LPFT (2013) Medicines Management Policy
LPFT (2013) OT Medicines Management survey
Appendix 1
A framework to aid occupational therapists in the practice of medication management, by considering the components of the Model of Human Occupation (BJOT Nov 2011 74(11)

Volition

<table>
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<tr>
<th>Beliefs about the effectiveness of medication (general or from personal experience), side effects (real or perceived) and perceived ability to cope with these.</th>
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<tr>
<td>Does the person want the effects that the medication purports to give even if they are seen by wider society to be positive?</td>
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<td>Beliefs about meaning behind ‘reliance’ on medication.</td>
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<td>Is medication ‘contraindicated’ by faith or societal beliefs or by lifestyle choices (for example, religious law, vegetarianism, veganism or activism, and strong belief in efficacy of complementary therapies over and above traditional medicine?)</td>
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Habitation

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<tr>
<th>How often and/or when is medication taken?</th>
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<td>Is there a requirement to combine taking medication with another activity?</td>
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<td>Is there a routine around taking the medication (required or developed)?</td>
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<td>Do religious practices affect when medication can be taken (for example, fasting)?</td>
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<td>Does timing of taking medication affect occupational performance (for example, fatigue, concentration, pain levels, ease of movement and response to side effects)?</td>
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<td>Does habitual use of medication change occupational performance over time?</td>
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<td>Does use affect the ability to retain chosen or necessary roles to enforce new ones?</td>
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Performance capacity

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<th>Are there changes in energy levels that could have been caused by medication?</th>
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<td>Do decreased energy levels hinder the ability to take medication?</td>
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<td>Is there difficulty with any of the following: swallowing medication; imbibing medication due to postural constraints; opening packets due to deficits in coordination or strength; understanding the rationale of medication; understanding the instructions for administration; remembering to take medication or remembering that it has been taken; taking medication at recommended times due to fatigue; and using aids supplied to assist with medication management?</td>
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<td>Are there visual problems affecting the ability to read instructions or gauge dosage?</td>
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<tr>
<td>Are there problems with any of the following: retaining information that has been heard about medication; comprehending the reason for taking medication; and sequencing the steps required in the task?</td>
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Environment

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<th>Are there geographical limitations on obtaining sufficient medication (micro or macro)?</th>
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<td>Is there safe storage (access, temperature and use of dosing box)?</td>
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<td>Is there sufficient light to take medication safely?</td>
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<td>Can the person obtain the medication that he or she needs for symptom control (licensing, cost constraints (national and personal) and legality)?</td>
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<td>Are doctor or nurse prescribers’ prescribing habits well matched to the individual’s preferences?</td>
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<td>Who is prepared to or allowed to administer or prompt medication? How often can they do this?</td>
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<tr>
<td>Are other people’s ideas about medication influential?</td>
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<td>Does the method of administration raise problems about privacy and dignity?</td>
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Appendix 2

Glossary - Definitions used in Medicines Legislation

Administration - To administer is to give a medicine either by introduction into the body by direct contact with the body or not (e.g. by injection or orally) or by external application (e.g. application of an impregnated dressing). It could also involve assessing for a patient’s ability to use self-administration, prompting self-administration, supporting administration or full administration.

Dispense - To dispense is to make up or give out a clinically appropriate medicine to a patient for self-administration or administration by another. Dispensing must be in response to a legally valid prescription and the act of dispensing is combined with advice about safe and effective use.

Medicines Management - Although there is no official definition, medicines management can be described as the process of managing the way in which medicines are chosen, bought, delivered, prescribed, dispensed, supplied, administered and reviewed in order to make the most contribution to improving care and interventions for service users.

Prescribe - To prescribe is to authorise in writing the supply of a medicine for a named patient.

Supply - To supply is to provide a medicine to a patient or carer for administration. There is no legal distinction between “dispense” and “supply” although there are considerable differences in practice. In common usage “dispense” is usually reserved for the activity of pharmacists and would include checking the validity of the prescription, the appropriateness of the medicine and assembly of the product and “supply” is used for nurses and other healthcare professionals.
Appendix 3
Guidance for Occupational Therapists working in Older Adults Mental Health Services on Care Coordination and Case Management of Patients Prescribed medication

New Patients
Occupational Therapists will be responsible for assessing new patients. Following assessment if the primary need is with regards to review of medication or initiation and titration of new medications the Occupational Therapist should liaise with the MDT to consider the following options:

a) Where the patient has a need for occupational therapy intervention the OT can arrange for the patient to be seen by a medic who will make the decision to prescribe and/or titrate medication. OT staff can monitor and report back side effects as guided by the medic through the course of their interactions with patient.

b) Where the patient has no need for occupational therapy intervention the OT can arrange for the patient to be seen by a medic and if they decide to initiate a significant review of medication or prescribe a new medication the OT should liaise with the Team Co-ordinator to discuss and record the need for an inter team transfer to a CPN to titrate and monitor medication.

c) Where the patient is on multiple/complex medications that may cause some inter-drug interaction and/or due to co morbidities or the advice is to initiate is antipsychotic or depot medication the OT should always discuss and record the need for transfer the lead professional role or care coordination to a CPN.

Existing Patients
Where an individual's needs have changed in the duration of treatment Occupational Therapists should consider the following:

a) Where the patient has a need for occupational therapy intervention the OT can arrange for the patient to be seen by a medic who will make the decision to prescribe and/or titrate medication. OT staff can monitor and report back side effects as guided by the medic through the course of their interactions with patient, or request CPN involvement to support with medication issues where the OT will retain care coordination for the duration of their therapeutic interventions.

b) Where the patient has completed their occupational therapy interventions and has no further OT needs, the OT can arrange for the patient to be seen by a medic and if they decide to initiate a significant review of medication or prescribe a new medication the OT should liaise with the Team Co-ordinator to discuss and record the need for an inter team transfer to a CPN to titrate and monitor medication.

c) Where the patient is on multiple/complex medications that may cause some inter-drug interaction and/or due to co morbidities or the advice is to initiate is antipsychotic or depot medication the OT should always discuss and record the need for transfer the lead professional role or care coordination to a CPN.
### Fridge Monitoring Sheet

**APPENDIX CC - FRIDGE MONITORING SHEET - WARD ___________ MONTH ___________ YEAR ___________**

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<tr>
<th>Day</th>
<th>TEMPERATURE</th>
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**KEY:**
- Please record Max, Min and Current temp across the range as shown.

- **Do not use stock.** Quarantine products, contact Pharmacy asap for advice. **Report on DATIX**

- Quarantine products, contact Pharmacy asap for advice. Treat Insulin as non-refrigerated; see manufacturer’s advice for shelf life and mark expiry date on boxes. Adjust temp and/or defrost fridge and monitor every 4 hours.

- Continue to monitor temperature DAILY, defrost MONTHLY

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**CLINIC ROOM**
- Monitor Clinic Room temperature daily, and contact Pharmacy asap if temperature exceeds 25°C

**KEY:**
- Please record Max, Min and Current temp across the range as shown.