
# MEDICINE CODE

# SECTION 4
# MEDICINE MANAGEMENT

| Reference Number | Version | Status | Executive Lead(s) Name and Job Title | Author(s) Name and Job Title |
|---|---|---|---|---|
| 89 (section 4) | 5.1 | Draft | David Throssell Medical Director | Nicky Thomas Pharmacy Healthcare Governance Manager |

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| **Approval Body** | TEG | **Date Approved** | |
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| **Date Issued** | | **Review Date** | 01/07/2016 |
| **Contact for Review Name and Job Title** | Nicky Thomas Pharmacy Healthcare Governance Manager | | |

## Associated Documentation:

### Trust Controlled Documents

53 Incident Management Policy
54 Mandatory and Job Specific Training Policy

### Legal framework

Medicine Act 1968 and Medicine Act Orders.
Human Medicines Regulations 2012
Misuse of Drugs Act 1971
Misuse of Drugs Regulations 1985, 2001, 2005, 2006
National Health Service Act 1977
Environmental Protection Act 1990
Hazardous Waste Regulations 2005
Poisons Act 1972
Consumer Protection Act 1987
Control of Substances Hazardous to Health (COSHH) Regulations 1989
Medicinal Products: Prescription by Nurses Act 1992 + Amendments
Health Act 1999 (section 18)
Medicines for Human Use (Clinical Trials) Regulations 2004

### External Documentation

Standards for Medicines Management NMC 2007
Standards of Conduct, Performance and Ethics for Nurses and Midwives 2007
Midwives Rules and Standards 2009
Medicines, Ethics and Practice (A Guide for Pharmacists) RPSGB (Royal Pharmaceutical Society of Great Britain) Edition 36, July 2012
Duthie Report – Guidelines for the safe and secure handling of medicines 1988, 2005
Crown Reports 1989, 1998, 1999
Guidelines issued by GMC (General Medical Council) and BMA (British Medical Association)
Aitken Report 1958 – Control of Dangerous Drugs and Poisons in Hospitals
Building a Safer NHS for Patients: Improving Medication Safety *Dr Jim Smith* 2004 DOH
Shipman Report and Associated Responses
Safer Management of Controlled Drugs – A Guide to Good Practice in Secondary Care (England) October 2007
Standards for Clinical Verification of Prescriptions for Cancer Medicines (BOPA)

### Version history

| Version | Date Issued | Brief Summary of amendments | Owner's Name: |
|---|---|---|---|
| 4 | 07/06/2011 | Advice on unsuitable patient's own drugs if patient not agreed to their disposal. Guidelines for handling medicines belonging to a deceased patient | Nicky Thomas |
| 4.1 | 03/01/2012 | Updated as a result of the switch from enoxaparin to dalteparin | Nicky Thomas |
| 5 | 19/07/2013 | Updated to include Community Services. Alternative outpatient prescriptions. Controlled drugs update. ICE electronic discharge prescriptions. | Nicky Thomas |
| 5.1 | | Sections referring self administration, dispensing for discharge and concentrated potassium amended to be in line with updated policies. Section on security of medicines made more robust. Amendments to the management of controlled drugs in line with changes to legislation. Never event list updated. | Nicky Thomas |

## Document Imprint

# Executive Summary

## MEDICINE CODE – SECTION 4

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|---|---|
| **Document Objectives:** | To describe clarify and standardise practices and procedures for the supply, storage and disposal of medicines across the Trust. |
| **Group/Persons Consulted:** | Clinical Directors, Nurse Directors, Lead Nurses, Clinical Risk Management Group, Matrons, Clinical Management Board, Nurse Directors, Medicine Safety Committee, Medicine Management and Therapeutics Committee. |
| **Monitoring Arrangements and Indicators:** | Key indicators will be monitored by the Clinical Assessment Tool and responses checked by the Medicine Safety Manager. Medicine Safety Committee will receive high level reports from the Clinical Assessment Tool and quarterly reports of medication incidents reported via Datix. |
| **Training Implications:** | All training related to medicine use has been classified as Job Specific Training therefore staff within the organisation will require this training dependant upon their role. The training is specified in the Central Training Needs Analysis |
| **Equality Impact Assessment:** | An Equality Impact Assessment has been completed – no negative impacts identified. A copy of the EIA is posted on the Trust's internet site |
| **Resource implications:** | All resources for training and monitoring are already in place. |
| **Intended Recipients:** | All Healthcare Staff within STH NHS Foundation Trust involved in the use of medicines, this includes prescribing, administration, dispensing, handling and disposal |
| Who should:- | |
| ➢ be **aware** of the document and where to access it | Staff receive basic awareness of this policy through central induction |
| ➢ **understand** the document | Ward/department managers and clinical supervisors |
| ➢ have a **good working knowledge** of the document | STHFT staff involved in the administration, supply, storage and disposal of medicines |

# 4 Medicines Management

Medicines Management encompasses the way that medicines are selected, purchased, stored, dispensed or manipulated, distributed, prescribed, administered and the therapeutic outcome reviewed to ensure optimum patient care. Prescribing and administration are covered in sections 2 and 3 respectively. This section will deal with the other aspects of medicines management. Procedures for clinical pharmacy services in the acute setting are available within the Clinical Pharmacy Standards and Guidelines.

STHFT spends approximately £88M a year on medicines and so in order to obtain the best value for money, medicines are purchased on 'contracts'. These may be at a National level (brokered by the Commercial Medicine Unit – CMU), Regional level (STHFT is in the Yorkshire and Humber NHS Pharmaceutical Purchasing Consortia) or individual Trust level. These processes ensure fair competition for the manufacturers whilst delivering medicines at the best price, thus ensuring value for money.

Within the acute services medicines are purchased through STHFT Pharmacy, either directly from the manufacturer or from a wholesaler. In either case the continuity of supply is of paramount importance and should be considered first, above the cost. The urgency of the medicine may determine the route of supply (e.g. goods from a wholesaler may be obtained in a matter of hours whereas those directly from the manufacturer may take several days). The majority of dressings and appliances are ordered through supplies.

Nursing staff are responsible for ordering supplies of medicines for inpatients to ensure they are available for patients under their care. Before a container is emptied nursing staff should ensure that a further supply is available for subsequent doses.

In Community Services medicines, appliances, dressings and some dietary products are prescribed on FP10 prescriptions and dispensed by community pharmacies or dispensing doctors or as stock from Sheffield Health and Social Care Trust.

In primary care approximately £85M is spent on prescribed items. Each dispensed prescription has a cost code; these are either GP surgeries or budgeted services that have cost centres for medication.

Where appropriate, nursing staff should advise patients that the policy at Boots outlets within STHFT is to not knowingly sell any medicines to inpatients, due to the potential for duplication of dosing and interaction with medicines prescribed on their inpatient prescription chart.

## 4.1 Mechanisms for the Supply of Medicines

### 4.1.1 Stock Medicines

#### General

Within the hospital setting each ward/clinical area has a list of medicines specific to that area, which are kept as stock.

Appropriate pharmacy staff responsible for the ward/clinical area (e.g. medicines management technicians/pharmacists) and the health care professional should agree the list of stock medicines and review it regularly to ensure the appropriateness of medicines on the list and stock levels.

Naloxone injection 400 micrograms in 1ml must be available on all wards/clinical areas where opiates are administered. Flumazenil 100 micrograms in 1ml must be available on all wards/clinical areas where parenteral benzodiazepines are administered.

In every location where anaesthesia is given, emergency medicines including Intralipid®, sugammadex and dantrolene must be available and in date.

If the same medicine runs out regularly, the appointed health care professional should discuss this with the appropriate pharmacy staff (e.g. MMT) to have the levels altered.

A risk assessment of all injectable medicines must be undertaken and reviewed annually by a pharmacist and senior practitioner to determine the safest presentation and location for storage and preparation.

Expired stock must be returned to the appropriate Pharmacy for destruction (see section 4.7).

Stock medicines must never be placed in individual patient medicine cabinets or drawers or given to patients to take home, except topical preparations and inhalers which must be labelled with the patient's name at the earliest opportunity.

The pharmacist/medicines management technician/pharmacy must be notified of any discrepancies in stock orders received. The discrepancy should be dealt with as in section 4.10.

## Community Services

Some Community Health Services also have an agreed list of medicines specific to that area, which are kept as stock. This is obtained from a variety of sources for example Michael Carlisle Centre supplies podiatry orders and adrenaline for district nurses administering flu injections.

## Pharmacy Top-Up System for Acute Services

Most wards/clinical areas have their stock medicines replenished by a Pharmacy 'topping-up' service whereby appropriate pharmacy staff check the cupboards and order stock medicines to the agreed levels. All medicines received on the ward/clinical area should be checked against the order by appropriate ward/department staff or pharmacy staff where appropriate.

The frequency of the 'top-up' depends on the ward/clinical area and site.

Pharmacy staff will check the expiry dates of stock medicines when the top-ups are undertaken.

If a ward/clinical area requires additional stock medicines before the next top-up, it is the responsibility of nursing staff to ensure supplies are ordered. Appropriate mechanisms include via a stock requisition slip or book or contacting the MMT/pharmacist depending on the area.

**Areas without a Top-Up System**

These areas will order stock via an approved mechanism, for example a requisition book. The responsibility for managing stock levels and ordering stock items rests with the ward/department manager/appointed nurse/midwife.

Nursing/department staff are responsible for checking the expiry dates of stock where a top-up service is unavailable.

## 4.1.2 Non-Stock Medicines for Inpatients

A patient specific supply will be made for inpatients prescribed medicines which are not routinely stocked by a ward/clinical area. It is the responsibility of nursing staff to initiate such supplies. When a pharmacist/MMT is available on the ward, they may undertake this task or they may be contacted by nursing staff during normal working hours. A clinical check by a pharmacist MUST be made before patient specific supplies are issued by Pharmacy, and the quantity supplied and date is annotated on the inpatient prescription chart.

It is desirable to ensure that prescription and administration charts remain on the ward/clinical area. Therefore nursing staff are required to make a clinical judgement to determine the clinical significance of prescribed non-stock items. Whenever appropriate, the item should be referred to the MMT/pharmacist on their next visit to the ward/clinical area.

For non-stock medicines requisitioned by nursing staff, all current prescription and administration charts and/or relevant supplementary prescriptions should be sent to Pharmacy where possible with the appropriate requisition in order that the pharmacist can make a clinical check. All clinical checks and supplies will be endorsed on the prescription and administration chart in line with pharmacy procedures.

Supplies of named patient methotrexate will be issued 24 hours before the dose is required. Only one dose will be dispensed at any one time. If the day of the week is not stated on the prescription, this must be clarified before the dose can be dispensed.

Where a FAX machine is in operation, nursing staff must ensure that all appropriate documents are included in the transmission.

During core working hours ward/clinical area staff at RHH, NGH and WPH should access the tracking system if they wish to be updated on the progress of requests.

Prescription and administration charts will be returned to wards/clinical areas as soon as possible after clinical checks have been made to ensure that they are available for medicine rounds/ward rounds. The mechanism for this to be achieved depends on the ward/clinical area and site and includes the pneumatic tube or ‘POD’ system, pharmacy deliveries, and collection by ward/clinical area staff.

Temporary stock will only be supplied in exceptional circumstances and must be authorised by a pharmacist or the Appointed Dispensary Manager.

**TPN**

Total parenteral nutrition infusions are made by the Aseptic Dispensing Unit within Pharmacy according to a patient specific prescription. It is the responsibility of the nursing staff to

ensure that infusions have been requisitioned from Pharmacy. The Nutrition Support Team will undertake this role where available from Monday to Friday. Requests for TPN infusions out of hours should be referred to the on-call pharmacist. Refrigerated emergency neonatal TPN infusion bags are available for out of hours use on NITU in the Jessop Wing.

## Cytotoxics

Supplies of prepared parenteral cytotoxic medicines are made by the Cytotoxic Dispensing Unit within Pharmacy according to a patient specific prescription. Oral cytotoxic medicines are supplied as in 4.1.1 and 4.1.2 above. It is the responsibility of the nursing staff to ensure that cytotoxic medicines have been requisitioned from Pharmacy. The pharmacist/MMT will undertake this role when they are available. The service will operate routinely from 09.00 to 17.00 from Monday to Friday. Routinely there is no service outside these hours with the exception of pre-planned short shelf life preparations, which could otherwise not be supplied. Preparations for the weekend and bank holiday periods will be prepared in advance. For intrathecal cytotoxics, refer to section 3.11.5.

## Aseptically Prepared Additives

Certain syringes and infusions are available in a prepared form from the Aseptic Dispensing Unit within Pharmacy. It is the responsibility of the nursing staff to ensure that syringes and infusions have been requisitioned from Pharmacy. The pharmacist/MMT will undertake this role when they are available. The service will operate routinely during normal working hours from Monday to Friday and with a limited service at the weekend and bank holidays. For guidance on the services, which the on call pharmacist is authorised to provide, see the list available from the lead nurse in each speciality.

## Dietary Products

Supplies are available from the Dietetics Department at WPH, from the Catering Department at RHH and currently from Pharmacy at NGH.

## Controlled Drugs

See section 4.8.

## Non-Formulary Medicines

The Trust Medicines Formulary is operated under the auspices of MM&TC (see section 2.5). It is maintained and developed by the Pharmacoeconomics Pharmacists. Medicines officially approved and stocked by Pharmacy are listed along with preferred prescribing choices and supporting information where appropriate. The Formulary contains supplementary policies and guidelines as approved by MM&TC.

A mechanism exists for dealing with non-formulary medicines, whereby requested items may be obtained on a ‘one-off’ basis if clinically justified. Items ordered in this way are usually obtained on the same day or the following day. There may be occasions where it is deemed appropriate to use a patient’s own medication or switch to a formulary alternative if a patient is admitted on a non-formulary medicine.

### Extemporaneously Prepared Medicines (Extemps)

Certain preparations are not routinely available from normal external suppliers for example because the strength is different to the standard preparation, they are too unstable for commercial viability or they are very specialised preparations and therefore not commercially viable. In these cases it may be possible for Pharmacy to order or prepare the medicines as extemporaneously prepared products.

Data needs to be obtained (for example on storage, stability, diluents etc.) together with raw materials in some cases before a preparation can be prepared for the first time and therefore these preparations will not be immediately available. In some cases it may not be possible to prepare what is requested.

Pharmacy staff will provide patients and wards/departments with realistic lead times for the availability of individual extemporaneously prepared products.

Prescribers should discuss any unusual requests at the first available opportunity with the designated clinical pharmacist for that area or with Medicines Information departments in Pharmacy (Ext. 14371 [NGH] and Ext. 12346 [RHH]).

## 4.1.3 Medicine Supplies in Community Services

Approved Community Health Services have stock medication and prescribe non-stock medications on appropriate FP10 prescription forms. These are dispensed by community pharmacy, and include prescriptions for dressings, appliances and dietary products.

### MAR Charts (Medicine Administration Record)

In Community Health Services MAR charts are routinely produced by community pharmacies. In exceptional circumstances it may be necessary for Community Health Service staff to produce or amend MAR charts, in line with local procedures.

### MDS (Monitored Dosage Systems)

MDS for community patients are produced by community pharmacy. New MDS should only be started when the patient has undergone an assessment by an appropriately qualified person. Agreement must be sought from the patient's GP and nominated community pharmacy.

If an existing MDS needs amending (e.g. if a medication has been stopped by the prescriber), this will routinely be undertaken by the dispensing pharmacy. In exceptional circumstances a MDS may need to be amended by Community Health Services, in line with local procedures.

### Delivery of Medication to Patients

Routinely medication is dispensed at a community pharmacy and collected by the patient, relative or carer or delivered by the community pharmacy delivery service.

For urgent medications it may be necessary for community health care practitioners to take a prescription to a community pharmacy for dispensing and subsequently take the medication to the patient. This should be documented in the patient's notes. Staff may be required to sign for the receipt of medicines including of controlled drugs.

## 4.1.4 Patient Movement

If the patient is transferred to another ward within the Trust (including a different site for example the Intermediate Care Beds), it is the responsibility of the nursing staff to transfer all the patient-specific medication and any individually dispensed items stored in the fridge (including TPN and additives) and PODs with the patient. The nurse responsible should initial the appropriate box on the front of the prescription and administration chart.

Pharmacy will not routinely re-supply medicines if it is documented on the prescription and administration chart that adequate supplies exist.

## 4.1.5 Discharge and Temporary Leave Prescriptions

A discharge summary (sometimes referred to as a 'TTO' – 'to take out' prescription) must be completed for all inpatients and day case patients on leaving hospital. The discharge summary should be completed electronically using the ICE discharge module where available. Otherwise the self-copied multiple paper form, should be completed in black ink on a hard surface to ensure all details are recorded on every page. Refer to section 2.7.3 for further information.

A separate 'Temporary Leave Prescription' is currently under development and should be used when available to obtain medication supplies for patients leaving the hospital but not being discharged, on weekend leave for example. In the meantime a discharge summary document should be used in these circumstances with a clear instruction that the prescription is for temporary leave.

Prescribers must ensure that all medicines to be taken after discharge are prescribed in time to ensure minimal delays to patient discharge. Ideally this should be 24 hours prior to discharge. Except for clinical areas operating the Trust approved 'Dispensing of Pre-Labelled Patient Packs from Clinical Areas' all discharge summaries including out of hours must receive a clinical check from a pharmacist before medicines are given to the patient. Every side of the prescription and administration chart must be checked against the discharge summary when the clinical check is performed.

Schedule 2 controlled drugs should not routinely be written for registered substance misusers. If they are required, only enough medication for one day should be prescribed. In extreme circumstances it may be necessary to prescribe up to three days supply (e.g. to cover bank holidays). Discharge arrangements must be communicated to the patient's usual prescriber and supplying pharmacist. Further information about substance misuse in pregnant patients will be available on the Trust Intranet later in the year.

All discharge summaries and temporary leave prescriptions, including those from out-of-hours must receive a clinical check from a pharmacist before medicines are given to the patient.

Failure to complete the discharge summary accurately may lead to: -

- medicines being duplicated
- changes made in hospital not being implemented
- supplies of medicines not being available
- errors in dosages
- misunderstandings between secondary and primary care

Prescribers are responsible for ensuring that patient details (name, date of birth, hospital number) and ward are completed correctly. Nurses should check these details have been completed before sending paper TTOs to Pharmacy.

TTOs produced using the ICE discharge module are transmitted to Pharmacy electronically by the prescriber. The prescriber is responsible for notifying the ward clerk or nursing staff according to local procedure, that a TTO has been completed.

The ward clerk or nursing staff will ensure that the current prescription and administration charts and supplementary charts are sent to Pharmacy.

When the paper TTO is used, all copies should be given to a member of the pharmacy team if they are available on the ward. If they are not available, it is the responsibility of the nurse to send the TTO to Pharmacy. This must NEVER be by internal post. Where the pneumatic tube or the Dispensing for Discharge system is in operation, the nurse will also send all current prescription and administration charts and supplementary charts to Pharmacy.

Where a second paper discharge summary is written for a patient, all copies of the original discharge summary together with the prescription and administration chart should be sent to Pharmacy for checking and to make sure appropriate action is taken to ensure patient safety.

If the TTO is required urgently, nursing staff must contact the dispensary to discuss the possibility of priority being given to the prescription before sending it down to the Pharmacy. If it is agreed that the ward staff can wait for the prescription, Pharmacy will endeavour to process the TTO straight away. If 'RWR' (ring when ready) is written on the TTO, the ward/department will be telephoned when the TTO is ready but priority will not necessarily be given. The time that the clinical area is telephoned will be recorded on the Pharmacy copy of the prescription together with information regarding the failure of a clinical area to answer the phone in a reasonable timescale if this is pertinent. The standard waiting time for non-priority requests is usually less than two hours from when the request is received in the Pharmacy, provided there are no unforeseen problems.

During core working hours ward/clinical area staff at RHH, NGH and WPH should access the tracking system if they wish to be updated on the progress of TTOs.

Pharmacy staff are responsible for ensuring that all patients are discharged with a minimum of 14 days treatment for long-term medicines.

A MMT or pharmacist should confirm the medication requirements for patients being discharged to a care home.

Original pack dispensing will be used wherever appropriate to ensure the European Directive to issue a patient information leaflet (PIL) is met. Where the Dispensing for Discharge Policy operates, individual patient supplies and patient's own drugs (PODs) will be utilised where appropriate.

Medication Administration Record (MAR) Charts are available for appropriate patients from STHFT Pharmacy from Monday to Friday 9am to 5pm (and at weekends at NGH). Patients discharged to Beech Hill Intermediate Care beds must be given MAR charts. Nurses/midwives must complete the request form in full and send it to Pharmacy together with the patient's discharge prescription and inpatient prescription and administration chart. A period of 24 hours notice is required for all requests.

Monitored Dosage Systems (MDS) are available for appropriate STHFT patients from STHFT Pharmacy from Monday to Friday 9am to 5pm (and at weekends at NGH). Nurses/midwives must complete the MDS request form and send it to Pharmacy together with the patient's discharge prescription, inpatient prescription and administration chart and original MDS (if available). A period of 48 hours notice is required for all requests.

The medical team is responsible for referrals to specialist services (e.g. low molecular weight heparin referral forms) and ensuring that relevant patient held records are updated (e.g. anticoagulant booklet, lithium booklet, methotrexate booklet)

Patients discharged on dalteparin must be issued with a Dalteparin Patient Starter Pack available for ward staff to order free of charge from http://www.medisis.com/medisis/.

Patients starting on oral anticoagulant therapy must be issued with the NPSA Oral Anticoagulant Therapy Patient Information Pack.

Patients initiated on insulin within STHFT must be issued with an Insulin Passport and patient information booklet by the Diabetes Nurse Specialist. For further information contact the Diabetes Centre on Ext. 14445 (NGH) or 13479 (RHH).

Patients initiated on lithium within STHFT should be issued with a lithium information booklet, alert card and record book (NPSA/2009/PSA005).

Patients initiated on methotrexate within STHFT should be issued with a methotrexate booklet.

For patients discharged on amiodarone, the Shared Care Protocol should be followed. Patients should be issued with an amiodarone leaflet and 'advisory notice' labels should be attached to any GP copies of the prescription.

Nurses must not supply ward stocks of medicines to patients on discharge.

All discharge medication must be stored in a locked medicine cupboard (or refrigerator for refrigerated items) until discharge.

It is the responsibility of the nurse discharging the patient to ensure that the patient leaves with all their required medication (except items endorsed 'POD at home'). The use of a taxi to deliver medication to the patient's home after they have been discharged should only be considered in exceptional circumstances, and must be authorised by the Matron.

The nurse must check the discharge medication against both the TTO and the prescription and administration chart (ensuring every side of the prescription and administration chart is checked to avoid omissions). They must:

- Check and confirm that the patient is clear which medicines they are to take and is aware of any changes made
- Involve the patient in medication checks on discharge where appropriate
- Ensure the patient is only given medicines documented on the discharge summary
- Ensure that the possibility of duplicating medication with supplies at home is minimised
- Ensure that all required therapy and necessary sundries (e.g. medicine spoon) are supplied
- Record any advice given to the patient regarding their medication in the notes
- Ensure appropriate sharps bins are provided where required (e.g. patients on dalteparin)

Any discrepancies must be clarified with the medical team or pharmacist.

The nurse responsible for final discharge is responsible for signing off the multidisciplinary check list for completed activities. If any medication is missing or incorrect, the nurse must contact Pharmacy immediately.

The white copy of the TTO is retained in Pharmacy (either as the original or on optical disc) for a minimum of 2 years. The other copies are returned to the ward and it is the responsibility of the ward staff to process them as follows: -

| | |
|---|---|
| GREEN | to GP by post, round robin or via the patient |
| BLUE | to the patient with the medication (where appropriate) |
| YELLOW | to file in the patient's record |

If a patient takes their own discharge and is taking medicines which should be continued after discharge, every effort should be made to persuade them to either wait for their discharge prescription or return to the clinical area (or send a representative) to collect the discharge medication at an agreed time. Ward stock must NOT be issued to the patient.

If the assessed risk to the patient by not taking their discharge medicines is considered significant, the patient's GP must be informed by telephone. All action must be documented in the patient's record. See STHFT Discharge Policy for further information.

## Patient Discharge from Intermediate Care Beds

Discharge planning should start on admission and be discussed at the multidisciplinary team meeting. FP10 prescriptions should be produced in line with local procedures and in Intermediate Care beds the responsible nurse must check the discharge medication as above against the MAR chart and the record of the prescription in the patient's notes.

## Dispensing for Discharge

The Medicines Management Strategy, which is supported by the Trust, is to implement Dispensing for Discharge in all appropriate inpatient areas. For full information, see the STHFT Dispensing for Discharge Policy.

This is a system, which utilises patient's own drugs (PODs) supplemented with hospital supplies when necessary to provide each patient with their own supply of all appropriate medications in discharge format (i.e. with full labelled instructions) for the duration of their hospital stay. The same medicines can then be used for discharge purposes.

Dispensing for Discharge aims to ensure that patients have continuity of supply of medication, reducing the risks associated with duplication. It also aims to reduce the stock holding at ward level and inpatient medicines expenditure by reducing the reissue of medicines. This should reduce dispensing workloads and facilitate a faster discharge process. The system also enables the patient to self-administer their medicines where appropriate during their admission (See STHFT Self-Administration Policy).

PODs remain the property of the patient and consent for their use (after assessment), relabelling or destruction must be obtained. The admitting nurse should seek consent from the patient or their representative.

The Policy can only be implemented in clinical areas receiving a level of Pharmacy services considered appropriate by the Clinical Services Manager. In most cases the minimum service considered appropriate will comprise a medicines management technician (MMT) and a junior pharmacist.

The policy can only be adopted and maintained in a clinical area where an appropriate number of the nursing staff (permanent and temporary) have successfully completed the designated training to ensure that adequate numbers of trained staff are available on each shift.

Dispensing for Discharge will only operate where medicines can be stored in approved individual medicine receptacles.

The Directorate of Pharmacy and Medicines Management maintains a register of areas which have implemented dispensing for discharge.

### 4.1.6 Outpatient Prescriptions

Outpatient prescriptions are usually dispensed within 30 minutes but in exceptional circumstances the wait may be longer than this (e.g. a problem with the prescription, an item which needs aseptic preparation such as eye drops etc.). The patient will be informed of any anticipated delays with a prescription.

In some circumstances it may be appropriate to dispense the prescription in instalments (e.g. methotrexate, fertility treatments, clozapine). The patient will be informed by the Pharmacy of the arrangements necessary to obtain further supplies depending on the medicine involved.

Some outpatient prescriptions (coloured blue) and some Chemocare prescriptions issued from RHH are presented for dispensing at Boots UK in the Royal Hallamshire Hospital. There is the option for the completed prescription to be collected at the patient's local Boots Pharmacy. The blue outpatient prescription must always be presented at Boots Pharmacy within RHH in the first instance.

Clinics/departments must NEVER send outpatient prescriptions to Pharmacy by internal post.

Patients starting on oral anticoagulant therapy should be issued with the NPSA Oral Anticoagulant Therapy Patient Information Pack.

Patients initiated on insulin within STHFT should be issued with an Insulin Passport and patient information booklet by the Diabetes Nurse Specialist. For further information contact the Diabetes Centre on Ext. 14445 (NGH) or 13479 (RHH).

Patients initiated on lithium within STHFT should be issued with a lithium information booklet, alert card and record book (NPSA/2009/PSA005).

Patients initiated on methotrexate within STHFT should be issued with a methotrexate booklet.

Clinics should ensure appropriate sharps bins are provided where required (e.g. patients on dalteparin).

For patients prescribed amiodarone, the Shared Care Protocol should be followed. Patients should be issued with an amiodarone leaflet and 'advisory notice' labels should be attached to any GP copies of the prescription.

## 4.1.7 Other Supply Mechanisms

### Theatres

Non-stock medicines should be obtained from the appropriate Pharmacy either via the clinical area/department prior to the patient going to theatre by the standard method (see section 4.1.2) and sent with the patient to theatre. Or it should be obtained by theatres via a prescription and administration chart (or supplementary medicine chart if appropriate) and a signed requisition.

In certain circumstances, where medicines need preparing (e.g. emergency ophthalmic injections), the theatre staff should also telephone the appropriate department within STHFT Pharmacy to minimise delays.

### Pre-Labelled Patient Packs

Pre-labelled patient packs of medicines with pre-printed standard labels are supplied by STHFT Pharmacy for certain wards/departments/clinical areas and for PGDs (see below). These must be agreed by the Pharmacy Management Board or Operations Board and be in the patient's best interest and not for staff convenience. The health care practitioner issuing the pre-pack is responsible for completing the patient's name, date and dosage instructions, where applicable, on the label. The Trust's SOP Dispensing of Pre-Labelled Patient Packs from Clinical Areas must be followed for clinical areas wanting to adopt this practice.

### PGDs

Supplies of medicines listed in PGDs are made directly from stock held in the clinical area to the patient. There is no involvement of the Pharmacy directly with the patient. For further information refer to the current STHFT Patient Group Directions Protocol

### Supply to External Organisations

Supplies are made by STHFT Pharmacy to certain external organisations or Community Health Services on the presentation of the appropriate signed paperwork for example:-

- GP Collaborative (e.g. pre-packs)
- Community pharmacies
- Other hospitals in an emergency or out-of-hours.

### Blood Products

Plasma derived products (e.g. human albumin, immunoglobulins, anti-D, factor concentrates) must only be administered on the written direction of an approved prescriber or via a PGD.

Due to the small risk of transfer of certain diseases (e.g. vCJD), the following additional requirements apply to medicines derived from blood: -

- Batch numbers of all issues must be recorded in Pharmacy
- DO NOT use dispensed items for another patient
- If kept as stock, record patient details and batch numbers on a dedicated record sheet or book and retain for 30 years (recommendation from transfusion practitioners)
- Record the batch number on the prescription and administration chart (e.g. the sticker from the preparation) or in the patient's notes

Refer to the STHFT Transfusion Policy for guidance or contact the Specialist Practitioners of Transfusion at the Northern Site on Ext. 15246 (pager 07623 858311) or the Central Site on Ext. 12909 (pager 07623 858305).

### Nuclear Medicines

Radioactive compounds (radiopharmaceuticals) are administered to patients in nuclear medicine for the purposes of both diagnosis and treatment.

See the Policy for Administration of non-radioactive Pharmaceuticals given as part of a Nuclear Medicine Study for further information.

To book a nuclear medicine scan, a request card available from the ward or nuclear medicine department must be completed and sent to nuclear medicine.

Further information can be obtained from the Department of Nuclear Medicine (Ext. 14374 [NGH], Ext. 12779 [RHH] and Ext. 65171 [WPH]) or from the Nuclear Medicine Site on the Trust Intranet.

## 4.1.8 Continued Supplies of Medicines by STHFT Pharmacy

It is sometimes necessary for the Trust to continue to supply a patient at home with a particular medicine. Examples where this is appropriate include: -

- Unlicensed medicines not prescribed by the GP (see STHFT Unlicensed Medicines Policy)
- Non-formulary Medicines
- Medicines requiring specific monitoring (e.g. methotrexate, clozapine, thalidomide)

- Home TPN, IV antibiotics and other infusions (e.g. Intrathecal baclofen)
- Extemps

Health care professionals must liaise with a senior clinical pharmacist or the relevant pharmacy section manager (e.g. Dispensary or Aseptic Unit) as soon as it is known that a non-standard dispensing service will be required.

The method for obtaining further supplies will be discussed with the patient or patient's representative by appropriate Pharmacy staff when the prescription is presented for dispensing. It is preferable for the patient or patient's representative to collect further supplies from the Pharmacy if at all possible particularly if stability or storage is a problem with the medicine.

In exceptional circumstances, continuing supplies of medicines can be posted by the Pharmacy, sent by 'Medicar' or taxi depending on the circumstances. All medicines, which are posted, will be sent by special delivery and be insured against loss or damage.

Further supplies of certain medicines may be obtained from an external company (e.g. home TPN).

## 4.1.9 Out of Hours

An out-of-hours service is available from STHFT Pharmacy for emergencies. The out-of-hours pharmacist should be paged/bleeped via switchboard. When the pharmacist has been bleeped, allow 10 minutes for the bleep to be answered before bleeping again as the pharmacist may be engaged on another call.

From the normal closing time of the dispensary at NGH and RHH Pharmacy (19.00 from Monday to Friday and 16.00 on Saturday, Sunday and bank holidays), one pharmacist provides a 'priority only' service, which comprises: -

- Newly prescribed medication if urgent and no alternative available on the ward
- TTOs and prescriptions from A & E and Admissions Units which are prescribed out of hours for the same day and requested before midnight
- Sterile services at the discretion of the pharmacist
- Urgent requests for medicines information

The following items **will not usually be dispensed**: -

- Items forgotten to be ordered during the day
- Nutrition items
- Ward stock and pre-packs
- Doses for the following morning

After midnight until normal opening of the dispensary the pharmacist will only take **urgent calls** and these must be via switchboard. The on-call pharmacist is at home and is only available for **urgent items**, which cannot wait until the next morning. Out of hours dispensing for Jessop Wing, Weston Park and Charles Clifford is provided from RHH Dispensary

## 4.1.10 Fraudulent Prescriptions

Fraudulent prescriptions include:

- prescriptions written or amended by a person who is not a registered prescriber
- prescriptions written on stolen or photocopied stationery and
- prescriptions deliberately written by a registered prescriber that are not required/intended for the patient named on the prescription

The dispensing of a forged prescription for a controlled drug or prescription only medicine can constitute a criminal offence.

Pharmacists must be vigilant and query prescriptions which appear inappropriate or excessive before making the supply

If it is suspected that a staff member has written a fraudulent prescription, the pharmacist must inform the Local Security Management Specialist (Trust Head of Security) and the Chief Pharmacist immediately and the STHFT Anti-Fraud, Bribery and Corruption Policy response plan must be followed.

### Fraudulent Prescriptions written by Patients, Carers and Visitors

If a forgery is suspected, the pharmacist must contact the prescriber using a telephone or bleep number from a valid source (e.g. STHFT switchboard, outpatient reception, bleep list) and not the number given on the prescription.

The pharmacist must confirm the details of the intended prescription with the prescriber and in the outpatient setting confirm that the prescriber still wants the Pharmacy to dispense the items as originally prescribed.

In the outpatient setting, the pharmacist must clearly endorse the prescription with the action taken and the details of the intended prescription. In the inpatient setting the prescriber should re-write the prescription.

The pharmacist should explain the situation to the patient and caution them that the forging of a prescription may constitute a criminal act.

If an addressograph label is not on the prescription, the patient's address must be confirmed from the patient information system and recorded on the prescription.

In the outpatient setting, the prescription must be retained by Pharmacy, even if no items have been dispensed against it.

The incident must be reported to the patient's consultant and the Pharmacy Healthcare Governance Manager (ext. 13007).

If this is the first offence by the patient, the consultant and the Pharmacy Healthcare Governance Manager will consider the clinical situation of the patient and the severity of the forgery, and decide whether a criminal act has been committed, or was intended. If so they will report the incident to the Director of Finance or the designated Local Counter Fraud Specialist (LCFS).

If this is not the first offence, they will report the incident directly to the Director of Finance or the designated Local Counter Fraud Specialist (LCFS).

## 4.2 Borrowing within Acute Services

Wards/departments must not borrow medicines from other clinical areas when Pharmacy is open.

Controlled drugs and concentrated potassium solutions MUST NOT be borrowed at any time from any location.

The on call pharmacist must be contacted if a clinical area requires an urgent supply of the following medicines: weak opioids, benzodiazepines and other medicines subject to abuse (NB this contains all codeine, dihydrocodeine, diazepam and lorazepam)

Pharmacy will only authorise borrowing from other clinical areas if the following conditions are met:

- The medicine is clinically urgent and the supply cannot wait until Pharmacy is next open
- The ward/clinical area have contacted the on call pharmacist and his/her workload does not enable the item(s) to be dispensed.
- The on-call pharmacist has entered the request to borrow the medicines on the on call log. The log will be regularly monitored.
- When borrowing has been authorised, the requester will be directed to a specific ward/clinical area and that area will be contacted by the on-call pharmacist. The nurse/midwife collecting the medicine should take the prescription and administration chart for the patient for which the drug is required.

If borrowing is approved, medicines must not be decanted into secondary containers. The original pack must be taken to the borrowing ward/clinical area for the dose to be appropriately administered following usual procedures and checks and then returned to the lending ward/clinical area. Within Community Services borrowing is not applicable.

## 4.3 Restricted Medicines

Certain medicines are treated by STHFT as ‘restricted’ and processed with increased safety measures in place. This may include treating them as controlled drugs (see section 4.8).

Medicines may be restricted for several reasons including: -

- Patient safety (e.g. concentrated potassium preparations – treated as a controlled drug )
- Abuse potential (e.g. ketamine [now a schedule 4 controlled drug])
- Local problems with supply/storage (e.g. sildenafil, mifepristone)
- Restriction by MHRA (e.g. thalidomide, clozapine)
- Increased data requirements (e.g. albumin, immunoglobulins requiring batch numbers)

Different sites within the Trust have restrictions on different medicines depending on local problems and medical/surgical specialties on those sites. Further information can be obtained from the individual dispensaries (NGH Ext. 15544/15545, RHH Ext. 12424/12275, Jessop Ext. 68220/68216, and WPH Ext. 65102 /65750).

## 4.4 Security of Medicines

The appointed health care professional is responsible for the security of medicines supplied to her/him within a ward/clinical area including those supplied for self-administration.

When a clinical area is being designed or refurbished, consideration must be given to the security of medicines including the location and size of medicine storage systems. The manager or the clinical area will liaise with the Medicine Service Supply Manager and Estates staff to ensure that the facilities are fit for purpose.

Within a ward/clinical area medicine storage must be within an area with controlled access and there should be separate lockable storage for each of the following

- controlled drugs cupboard [that complies with the Misuse of Drugs (Safe Custody) Regulations 1973]
- internal medicines cupboard
- external medicines cupboard
- refrigerator/freezer for medicines
- individual receptacles, such as individual lockable medicine cabinet, or individual drawer in a lockable bay cupboard or trolley in areas where Dispensing for Discharge has been adopted
- cupboard for diagnostic agents
- area for IV fluids and sterile topical fluids
- areas (separate) for flammable fluids (locked flammable cupboard) and gases
- discharge medicines
- medicines for return to pharmacy

All epidural and spinal injections and infusions should be stored separately from other injections and infusions. All potassium containing infusions should be stored separately from other infusions. It is permissible for these products to be in the same cupboard or fridge as other medicines (but not with other injections or infusions), providing they are located on a separate, dedicated and shelf preferably within a labelled open box or container.

All patient's own methotrexate must be stored in the ward CD cupboard and not be used for nurse administration during an inpatient episode. The methotrexate should only be returned to the patient after authorisation by a pharmacist/MMT.

Cupboards which are used for storing medicines must comply with the current British Standard(s) [currently BS2881 (1989)].

Medicine storage facilities (including medicine trolleys and individual medicine cabinets/drawers) should be locked when not in use. Trolleys should also be immobilised when not in use. Individual patient medicine cabinets within bedside lockers do not need to be attached to a wall, providing they are not readily portable.

Storage cupboards within secure rooms which are secured by keys, swipe cards, proximity cards and fob locks do not need to be locked.

All medicines should be returned to the appropriate lockable storage cupboard when not in use.

The appointed health care professional is responsible for controlling access to the medicine cupboards and trolley. This may be delegated if she/he is unavailable but responsibility remains with the appointed health care professional.

To ensure medicines are readily available in theatres, the appointed nurse/midwife may delegate control of access to a qualified deputy or medical practitioner (e.g. anaesthetist) or, if unavailable, to an operating department practitioner (ODP) or an operating department assistant (ODA).

A second set of keys should be kept in an appropriate, secure location within the clinical area or directorate in case of emergency.

Individual medicine receptacles for dispensing for discharge or self-administration, must be purchased as a suite with a dedicated master key which only opens the receptacles in a single clinical area. Each clinical area should have at least one master key held with the main set of medicine keys, and one spare master key, or spare duplicate set of keys, kept in a secure location. Clinical areas may choose to have additional master keys to enable simultaneous medicine rounds by more than one nursing team. Robust local procedures must be in place to account for the allocation of additional master keys, which must not leave Trust premises.

The keys to the CD cupboard in clinical areas/departments must be kept by the appointed/assigned nurse/midwife/ODP/health care professional and must be kept separate from general clinical area/department keys.

For areas with electronic access to medicines, the appointed nurse/midwife/ODP/health care professional is responsible for permitting access to authorised staff. Permitted access depends on the grade of staff and functional role.

Any lost access cards MUST be immediately reported to the senior staff member responsible for electronic cards and Security in order that the card can be deactivated.

Where PIN codes are used, these should be specific to an individual if the system allows. Otherwise PIN numbers must be changes frequently, kept secure and not divulged to unauthorised staff members.

In certain clinical areas where no nursing staff are in attendance, it is permissible for other staff groups to hold the keys (e.g. radiographers). The CD keys though must only remain in the possession of staff groups who are permitted in law to possess and supply CDs.

Containers for medicines are filled and labelled by pharmacy staff. Contents of containers must not be transferred to other containers by any other members of staff or patients.

***Exceptions***

Emergency resus boxes and trays must be available for clinical emergencies (see section 4.10). They should not normally be stored in a locked cupboard but in a suitable place where security is maintained.

Insulins and topical medicines (inhalers, nasal sprays, GTN sprays, eye drops, ear drops and skin preparations) may be stored out of sight at the patient's bedside in line with the Self-Administration Policy.

## 4.4.1 Security Breaches and Stock Discrepancies

All concerns about the security of medicines must be reported to the manager/appointed nurse/midwife or in her/his absence, the designated nurse/healthcare professional.

Significant concerns (e.g. unauthorised access to areas where medicines are stored and evidence of tampering with medicines) must be escalated to the Local Security Management Specialist (Head of Security) and the Chief Pharmacist. They will co-ordinate an investigation and involve the police if appropriate.

Where theft or tampering with medicines is suspected but it is not possible to identify the person responsible, the Head of Security and Chief Pharmacist will advise on the use of appropriate local measures, including the storage of non-controlled drugs in the controlled drugs cupboard, installation of CCTV and marking of medicine packs. They will also notify other ward/department managers if relevant.

All controlled drug discrepancies must be reported to the manager/appointed nurse/midwife or in her/his absence, the designated nurse/health care professional. A thorough investigation must occur to resolve the discrepancy. If this fails to identify the problem, the discrepancy must be reported immediately to the relevant matron/service manager and the Dispensary Manager. The incident must be reported via the Datix system.

For other medicines, if the POD or pharmacy supply section of the prescription and administration chart indicates that a medicine is available, every reasonable effort should be made to locate that supply including contact with the referring ward in the case of patients being transferred.

Where a thorough investigation fails to locate items issued by Pharmacy and there is documentary evidence that it was issued by Pharmacy, the incident must be reported via the Datix system and the incident reported to the appointed nurse/midwife/health care professional. These reports will be reviewed by Pharmacy and trends investigated.

If a supply cannot be located despite a thorough search by nursing staff, the appropriate Pharmacy should be contacted to discuss initiation of further supplies.

If a member of staff is suspected of committing fraud, the STHFT Fraud Policy and Response Plan must be followed.

## 4.5 Storage Temperature for Medicines

The ambient temperature in rooms where medicines are stored should be below 25℃. Routine ambient temperature monitoring is not required, but nursing staff should report concerns about temperature control to the appropriate Estates department.

Pharmaceutical refrigerators must be maintained at 2- 8℃ (optimally 4℃) to store any medicines requiring cold storage. These must be fitted with minimum/maximum thermometers, or other approved monitoring devices, which are checked daily. The current temperature and maximum and minimum temperatures should be recorded and signed by the person performing the monitoring and the thermometer reset.

Refrigerators, which are not running at an optimal temperature, must be reported to the appropriate Estates department.

The action card for failure of a pharmaceutical refrigerator must be displayed on, or near the refrigerator and followed in this event.

The Medicines Information departments in Pharmacy (Ext. 14371 [NGH] and Ext. 12346 [RHH]) or the on-call pharmacist out of hours can be contacted for further information on the suitability of using medicines, which have been stored at a sub-optimal temperature.

Medicines must not be stored in food refrigerators.

## 4.6 Patient Self-Administration

Within inpatient settings patient self-administration (SA) is a system where selected patients maintain or gain a level of independence during their admission. It seeks to identify and resolve any difficulties which patients may be experiencing with their medicines and increase their understanding of them.

This policy can only be adopted by a clinical area where the STHFT Dispensing for Discharge Policy is implemented (see section 4.1.5) as all the requirements for Dispensing for Discharge apply.

The policy can only be adopted and maintained by a clinical area where an appropriate number of nursing staff (permanent and temporary) have successfully completed the designated training to ensure that adequate numbers of trained staff are available on each shift.

Self-administration of medicines is only possible where medicines can be stored in individual lockable cupboards/drawers ideally secured to the wall and all PODs have been assessed and stored in individual containers, labelled with full and current dosage instructions.

Where the patient holds the key to the individual cupboard/drawer, it must only give access to medicines prescribed and dispensed for them. Pharmacy and nursing staff will still have access to these medicines when necessary.

The Directorate of Pharmacy and Medicines Management maintains a register of areas which have implemented self-administration.

For full information, see STHFT Self Administration Policy.

In Community Health Services, patients in their own homes may be independent with medication administration, receive assistance from a relative or carer or receive medicines assistance from a care provider.

Patients who receive assistance with medication administration from carers and want to be independent should be identified for pharmaceutical reablement. Community Health Services that undertake pharmaceutical reablement should do so in line with locally approved procedures.

## 4.7 Disposal of Medicines

### 4.7.1 Spillages

All wards/clinical areas should have COSHH assessments for potentially hazardous materials within their areas together with procedures and control mechanisms in place for dealing with them. This may include specific spillage kits, personal protective equipment and additional reporting mechanisms (see STHFT Policy on Control of Substances Hazardous to Health).

It is important that spillages are contained and dealt with promptly to avoid further potential incidents.

**ISOLATE** the area using cones or hazard tape.

**CONTAIN** using cloths/paper towels to absorb small amounts of liquid or granules to absorb large volumes of liquid. Place all residues in an appropriate clinical waste container for incineration. Make every reasonable effort to find all dose units

**CLEAN** the area using appropriate solution/powder as necessary.

**DISPOSE** of all residues via the normal clinical waste for incineration route (see 4.6.2).

Dropped/spilled solid doses (e.g. tablets, capsules, suppositories) must not be reused but disposed of as clinical waste for incineration (yellow coding).

Care must be taken with broken glass (e.g. from ampoules, bottles). Gloves should be worn and the residues disposed of as sharps via the clinical waste route for incineration.

Any dropped/spilled/broken controlled drugs will additionally need a witnessed entry in the ward/clinical controlled drugs register (see section 4.8).

Any spillage involving a hazardous medicine must be reported via the Datix system.

## Cytotoxics

All wards/clinical areas routinely dealing with cytotoxics must keep a cytotoxic spillage kit within that area. Areas infrequently dealing with cytotoxics must be aware of where to obtain a cytotoxic spillage kit from. Replacements are available from Pharmacy.

All cytotoxic spillages are hazardous and must be dealt with immediately to minimise the risk of contamination to the patient, staff and visitors.

Personal protective equipment must be worn when cleaning up cytotoxic spillages.

Staff involved in cleaning up cytotoxic spillages must be suitably trained and aware of the hazards involved.

The area should be isolated using cones or hazard tape and all personnel (including patients and visitors) removed from the immediate area.

If the spillage is liquid, cloths/paper towels and/or absorbent granules should be used to absorb the liquid (depending on the volume). This should start at the outer edge and be worked to the centre to avoid spreading the spillage.

For powder spillages, a respiratory mask should be worn. The powder should be damped with water on cloths/paper towels to aid removal.

The area should be thoroughly cleaned with copious amounts of water and detergent. Domestic Services should be informed to ensure that a routine clean is performed.

Any contaminated clothes or bed linen should be removed as soon as possible, double bagged in a specific cytotoxic bag (yellow with purple stripe) and disposed of via incineration.

In the highly unlikely event of cytotoxic contact with the eye, it should be immediately flushed with water or saline. Occupational Health should be contacted immediately.

If the spillage involves direct skin contact, the area should be washed thoroughly with soap and water. Occupational Health should be contacted as soon as possible.

All contaminated residues and materials used in containing the spillage should be double bagged and disposed of as hazardous waste with a ‘Cytotoxic Waste’ label on the bag (see section 4.6.2).

The incident should be reported via Datix giving full details of the incident.

Further information can be obtained from STHFT Waste Policy and Procedures, the Trust Waste Manager, (Ext. 15754), Infection Control Guidelines 2006, P3 local procedures, the Management of Skin/Eye Contamination and Cytotoxic Spillages and the Trust Intranet.

## 4.7.2 Medicines for Destruction

Further information can be found in STHFT Waste Policy and Procedures.

Controlled waste generated within the Trust falls into 3 categories: -

- Household (non-clinical/domestic/general)
- Clinical (treatment and incineration)
- Hazardous

To comply with Duty of Care requirements, different types of controlled waste need to be kept separate.

All waste arising from healthcare premises is controlled waste. The Environment Protection Act 1990 imposes a Duty of Care on any person who imports, produces, carries, keeps, treats or disposes of controlled waste.

The European Directive 91/687/EEC – The Hazardous Waste Directive - identifies all medicines as clinical waste and certain medicines to be hazardous and sets out a framework to control the movement of hazardous waste. The directive was transposed into English Law as the Hazardous Waste Regulations 2005.

Matrons/ward managers/heads of department must ensure that all staff in their area of responsibility are adequately trained to deal with waste generated by their activities.

All staff have a legal responsibility to ensure that the waste generated by their activities is disposed of correctly.

Medicines must not be disposed of via the sewerage system.

### Acute Services

**It is the responsibility of nursing staff to remove all unwanted or out-of-date medicines for return to Pharmacy for disposal/processing.** This includes named patient medicines from either the patient's locker or the medicine trolley. This should be undertaken within 24 hours of a patient being discharged, being deceased or the medicine being crossed off. Areas with a top-up service may store such medicines in a designated area within a locked cupboard for collection by pharmacy staff.

Clinical trials medication **MUST NOT** be disposed of on the ward. All clinical trial medication no longer required by the patient, including empty containers/vials **MUST** be returned to the Pharmacy Department. Sharps must be disposed of as per Trust policy and **NOT** returned to Pharmacy. See section 4.12 for further details.

Patients must give consent for their own medicines to be sent to Pharmacy for destruction. This should be documented on the Contact Assessment Form. If consent is not given, the medicines should be stored in a locked medicine cupboard until the patient is discharged or given to a carer/relative to take home. Any medicines belonging to a patient which are left on Trust premises after discharge will be sent to Pharmacy for destruction within 24 hours.

If the pharmacist considers the risk of the patient retaining medicines which are unsuitable for continued use or no longer prescribed to be unacceptable, the patient must be advised of the associated risks of continued use of the medicine. This discussion must be fully documented in the patient record.

When a patient dies in hospital, all items dispensed by the hospital Pharmacy for that patient and all medicines brought in to hospital on admission must be returned to Pharmacy for destruction within 24 hours, regardless of whether consent was given by the patient. Under no circumstances should medicines prescribed for the patient be handed over to the relatives or carers. Consideration must also be given to likelihood of investigation by the Coroner. If this is a possibility, the medical team should be asked to confirm whether any of the medicines are implicated including IV infusions and empty vials/ampoules from prepared doses, and if so they should be retained, sealed and locked, for the investigation and not sent for destruction.

Pharmacy must dispose of unwanted or out-of-date medicines as clinical waste (or exceptionally hazardous waste) according to local SOPs and Trust Waste Policy and Procedures.

Pharmacy will not accept medicines brought in from patients' homes for the sole purpose of destruction. These should be taken to a community pharmacy.

All unwanted controlled drugs must be processed as in 4.7

***Exceptions***

Any unwanted or out-of-date medicines from barrier-nursed patients must not be returned to Pharmacy but disposed of as clinical waste for incineration.

Individual oral doses (e.g. refused doses or dropped doses which have been removed from their blister strips) and residual volumes of liquids may be disposed of as clinical waste for incineration in the clinical area.

Emergency trays used for the treatment of barrier-nursed patients must have all non-absorbent surfaces, inserts and contents wiped with an alcoholic wipe before returning to Pharmacy. Sealed foam inserts, glass and plastic packaging are all considered non-absorbent. Items contained in cardboard packaging may be wiped clean and returned providing the cardboard does not soften and the printed information is not removed. Porous foam insets and items contained in absorbent cardboard packaging must be disposed of as clinical waste for incineration on the ward/clinical area.

Any medicine or container, which has been contaminated with body fluid, must be disposed of as hazardous waste on the ward/clinical area.

## Community Services

In Community Health Services medication should be returned to the dispensing pharmacy where possible for destruction.

Medication in patients' homes is the patient's property. Responsibility for returning expired or discontinued unused medication to the community pharmacy for disposal lies with the patient. There may be occasions when a health care practitioner feels it is necessary to remove medication from the patient's home on the grounds of safety. Consent should be sought from the patient to do this and it should be documented it the patients notes.

## Household Waste

e.g. hand towels, plastics, packaging, cardboard outer containers, empty blister strips,

Waste produced in non-clinical areas is potentially household waste, as is waste from clinical areas that has not been used in direct patient contact is not soiled with body fluids.

Household waste containers are identified using BLACK coding e.g. black plastic bags.

Brown paper sacks (or suitable recycling containers) should be used for unbroken non-medicinal glass and cans.

Bags should not be more than ¾ full or weigh more than 10kg.

## Clinical Waste

e.g. treatment (orange coding) - soiled dressings, stoma bags, saline and glucose bags with no added medicines
incineration (yellow coding) - medicines, sharps, empty vials/ampoules
Further information can be obtained from the Trust Waste Manager (Ext. 15754).

Non-hazardous medicinal waste (except for controlled drugs [see pages 120 - 121]) including oral doses and residual volumes in ampoules, syringes and bags should be placed in a clinical waste for incineration container.

Clinical waste containers for incineration are identified with YELLOW coding.

All containers for clinical waste must be UN 3291 approved. The UN logo is printed on any container conforming to this standard.

The type of containment must be appropriate to the level of risk (e.g. medium or heavy duty sacks, sharps bins, boxes, one trip bins [NB these must NOT be used for sharps disposal]).

Bags/boxes must be replaced daily or when ¾ full. The contents must not be compressed by hand to allow additional filling.

The contents of clinical waste containers must not be transferred from one container to another.

Clinical waste containers (except Sharpsmart containers) must be sealed using a security tag.

Security tags must be attached to the lid or handle of all other clinical waste containers before final disposal.

Waste containers **MUST NOT** be left in public thoroughfares during normal working hours under any circumstances/

## Sharps

A sharp is any item, which has the potential to cut or penetrate the skin.

All sharps must be disposed of in an approved sharps bin conforming to BS 7320.

Clinical waste containers are identified using YELLOW coding for medicinal waste and YELLOW and PURPLE coding for hazardous sharps.

The person using the sharp is responsible for its correct disposal.

Sharps bins must be correctly assembled.

Sharps bins in use must be suitably stored (e.g. out of the reach of children and confused patients/visitors).

Sharps bins must never be filled to greater that 2/3 capacity or past the 'fill line'.

After sealing, Sharpsmart bins must be labelled with the hospital name and ward, the date opened and date closed but not tagged and kept securely stored while awaiting removal. Traditional sharps bins must be labelled with the point of origin, the initials of the person locking the bin and security tagged and kept securely stores while awaiting removal.

See section 3.11 for further information.

## Hazardous Waste

e.g. cytotoxic waste, thalidomide, vaccines, hormones, antiretrovirals (a full list is available in Appendix A at http://www.cdc.gov/niosh/docs/2010-167/pdfs/2010-167.pdf.

A consignment note is required for disposal in addition to Duty of Care requirements. In most areas this is dealt with by the portering staff.

Appropriate UN 3291 approved clinical waste containers (YELLOW and PURPLE) must be used.

## Cytotoxics

Rigid containers with a purple lid should be used for cytotoxic waste disposal,

YELLOW and PURPLE coded heavy duty bags may be used when appropriate and available.

Where appropriate containers are not readily available, (e.g. for contaminated paper waste), additional warning labels detailing 'cytotoxic – contaminated waste for incineration only' must be used (see waste strategy for sample label).the bags must be **heavy-duty** bags and detail 'for incineration only'. They should be sealed with a security tag as clinical waste containers

Waste containers **MUST NOT** be left in public thoroughfares during normal working hours under any circumstances.

### Radioactive Waste

The use and disposal of radioactive substances is very tightly controlled.

Patients receiving nuclear medicines remain radioactive until the radioactive material has decayed and/or has been excreted from the body. Depending on the isotope administered, blood, vomit, urine, faeces, sweat and saliva may be radioactive. The Nuclear Medicine Department will advise the ward/clinical area of the hazards regarding contaminated body fluids and the period for which the hazard will exist.

Collection of body fluids should only be performed if essential whilst the patient remains radioactive and should be clearly labelled as 'Radioactive' and taken directly to the laboratories.

Any waste arising from work processes involving radioactive sources must only be dealt with by staff fully trained in local Radioactive Waste Disposal Procedures.

The use of radioactive substances is restricted to certain areas with the Trust and should not therefore be found in the clinical or household waste streams.

## 4.8 Controlled Drugs

*The following applies to the current legislation but is subject to change following the implementation of the Shipman Enquiry recommendations.*

The 'Accountable Officer' (the Chief Pharmacist) is responsible for ensuring the safe and effective use and management of controlled drugs (CDs) within the Trust.

All incidents and 'near misses' involving CDs MUST be reported via the Trust's Datix system.

The Misuse of Drugs Act 1971 controls "dangerous or otherwise harmful drugs" which are designated as "Controlled Drugs". The primary purpose of the Misuse of Drugs Act is to prevent the misuse of CDs. It does that by imposing a total prohibition on the possession, supply, manufacture, import or export of CDs except as allowed by regulations or by licence from the Secretary of State. The use of CDs is permitted by the Misuse of Drugs Regulations 2001 as amended. Other regulations deal with the safe custody of CDs and with the notification of and supply of drugs to misusers.

The Trust Standard Operating Procedures (SOPs) approved by the Accountable Officer must be adhered to for all CD activity.

Concentrated potassium solutions (parenteral solutions of 0.1mmol/ml and above) as defined by the Trust Concentrated Potassium Policy are processed by pharmacy and clinical areas in the same way as schedule 2 CDs with the exception of the need for Adult Critical Care Units (general, neuro and cardiac) to record administration in the CD register, maintain a running balance or have a second nurse check for potassium chloride 20mmol in 100ml and 40mmol in 100ml when administered in line with Intravenous potassium replacement in Critical Care guidelines.

Controlled Drugs are classified in the Misuse of Drugs Regulations 2001 into five schedules according to different levels of control (e.g. possession, supply, record keeping etc.).

| Schedule | Examples | Comments |
|---|---|---|
| Schedule 1 (CD Lic) | Hallucinogenic drugs (e.g. LSD), ecstasy-type substances, cannabis | Production, possession and supply of drugs in this schedule is limited to research and other special purposes and a licence from the Home Office is required for lawful possession. Safe custody regulations apply. |
| Schedule 2 (CD POM) | Opiates (e.g. diamorphine, morphine, fentanyl, oxycodone, methadone, pethidine), major stimulants (e.g. amfetamine), secobarbital, ketamine from 30/11/2015 | Safe custody applies to all sch 2 drugs except secobarbital. Sativex® treated as sch 2 drug in terms of ordering, documentation, storage and destruction. Ketamine treated as sch 2 drug in terms of ordering, documentation, storage and destruction until November 2015 then officially sch 2 |
| Schedule 3 (CD No Register) | Minor stimulants (e.g. benzfetamine), other drugs not thought so likely to be misused as those in schedule 2 (e.g. temazepam, phenobarbital, midazolam, tramadol) | Safe custody applies to temazepam, buprenorphine and flunitrazepam. At STHFT these drugs are treated as sch 2 drugs in terms of ordering and destruction also. Safe custody DOES NOT apply to tramadol, phenobarbital or midazolam. The use of a register is a local decision but where it is used, requirements are as for sch 2 CDs |
| Schedule 4 Part I (CD Benz) | Most of the benzodiazepines, zaleplon, zolpidem, zopiclone, ketamine (sch 2 from 30/11/2015) Sativex® | Safe custody does not apply. Sativex® and ketamine treated as sch 2 drugs in terms of ordering, documentation, storage and destruction (ketamine officially sch 2 from Nov 2015) |
| Schedule 4 Part II (CD Anab) | Most of the androgenic and anabolic steroids, clenbuterol and growth hormones (5 polypeptide hormones) | Safe custody does not apply. |
| Schedule 5 (CD Inv.) | Includes preparations of certain controlled drugs such as codeine, pholcodine, cocaine and morphine at a sufficiently low strength to be exempt from full control | Safe custody does not apply. Morphine sulfate oral solution 10mg in 5ml and morphine hydrochloride 10mg in 5ml should still be ordered in the CD book (and if returned using a CD Transit Form) but do not require safe custody or documentation in the CD register |

"Controlled Drugs" are also divided into 3 classes according to the Misuse of Drugs Act 1971 according to the 'harmfulness attributable to a drug when it is misused' so are often referred to as:-

**Class A** e.g. diamorphine, cocaine, LSD

**Class B** e.g. oral amfetamines, barbiturates, cannabis, ketamine

**Class C** e.g. most benzodiazepines, anabolic and androgenic steroids

## 4.8.1 Prescriptions for Controlled Drugs

For the purposes of UK customs, it is now sufficient (from 01.01.08) to have a covering letter from the prescriber for a patient to take their own prescribed CDs abroad for up to 3 months. However legislation in the countries to be visited must also be complied with. Further information can be found at https://www.gov.uk/travelling-controlled-drugs, Medicines Information in Pharmacy (Ext. 14371 [NGH] and Ext. 12346 [RHH]) or the Home Office (020 7035 0484).

### Inpatients

Controlled drugs must be prescribed in the same way as any other medicine (see section 2.6).

For registered substance misusers, the current dose must be confirmed with their regular prescriber and/or supplying pharmacy.

### Outpatient, Discharge and FP10 Prescriptions

It is an offence for a prescriber to issue a prescription, which does not comply with the Misuse of Drugs Act. It is an offence for a Pharmacist to dispense such a prescription.

Current legislation states that the following is required on the prescription:-

- Name of patient
- Address of patient
- Age of patient (if under 12 years)
- Name, strength* and form* of the preparation
  (e.g. tablets DEXAMFETAMINE 5mg)
- Dose*
  ('as directed' is not permitted but 'one as directed' is permitted)
- Total quantity in words and figures*
  (e.g. 28 (twenty-eight) tablets)
- The words 'For Dental Treatment Only' if issued by a dentist
- Signature of the prescriber including the prescriber's name, (and bleep number for hospital prescriptions).
- Date (prescriptions are valid for 28 days)

* The prescription requirements for dose, form, strength and total quantity in both words and figures do not apply to controlled drugs in schedules 4 and 5.

The prescription does not need to be in the prescriber's own handwriting (SI 2864 14/11/05) but must be signed by him/her.

When a TTO prescription is generated using the ICE module, all the patient and drug details should be entered electronically but the prescription must be printed, signed by the prescriber and sent to Pharmacy in order to be dispensed.

Addressograph labels are not permitted for schedule 2 and 3 controlled drugs.

Prescriptions should not exceed 30 days treatment. This is not a legal restriction but prescribers should be able to justify the quantity requested (on a clinical basis) if greater than 30 days supply is prescribed.

Any liquid preparation should preferably be prescribed as original packs. Temazepam prescriptions should be dispensed for the exact amount of the prescription.

Schedule 2 controlled drugs should not routinely be written for registered substance misusers. If they are required on discharge, only enough medication for one day should be prescribed. In extreme circumstances it may be necessary to prescribe up to three days supply (e.g. to cover bank holidays or for Jessop Wing patients on their approved management system). Discharge arrangements must be communicated to the patient's usual prescriber and supplying pharmacist. Further information about substance misuse in pregnant patients will be available on the Trust Intranet later in the year.

FP10 prescriptions may be dispensed by the Northern Campus dispensary out-of-hours as part of the GP Collaborative out-of-hours contract.

FP10 prescriptions may be posted to community pharmacy for dispensing by approved carriers e.g. Royal Mail

**Private Prescriptions**

Private prescriptions for controlled drugs must be written on special private prescription forms (FP10PCD) issued by the South Yorkshire & Bassetlaw Local Area Team (LAT) NHS England if they are to be dispensed by a community pharmacist and not written on headed paper. New prescribers within STHFT requiring FP10PCD forms must have the request authorised by the Accountable Officer before requesting their prescriptions from the Accountable Officer of the South Yorkshire & Bassetlaw LAT. Private prescriptions for CDs to be dispensed within STHFT may still be written on headed paper.

Private prescriptions for CDs will only be dispensed at registered STHFT dispensaries for patients being treated at STHFT. These prescriptions should be written on headed notepaper.

## 4.8.2 Controlled Drug Requisitions for Acute Services

A CD requisition book must be used for all requests for CDs from clinical areas/departments.

CD requisition books and registers are supplied as controlled stationery from Pharmacy.

Each request must be on a separate duplicated, numbered page. If the requisition book uses carbon paper to duplicate the order, ensure it is in the correct place before writing out the order.

Ensure that all details are completed including the strength of the preparation.

The order must be signed and dated by the person making the order and additionally have their name printed on the order.

Pharmacists and appropriately trained pharmacy technicians and medicines management technicians may fill in the CD order book but the order must be signed by the appointed/assigned nurse/midwife/ODP.

All staff authorised to order controlled drugs must provide a sample signature which is maintained centrally in Pharmacy in order that Pharmacy can verify their authority to make the request.

The appointed nurse/midwife/ODP must ensure that the list of staff authorised to order CDs is accurate and up-to-date and that all staff signing the list are authorised to do so.

Overall responsibility for CDs remains with the appointed nurse/midwife/ODP for a clinical area/department.

Orders must be made by the registered appointed nurse/midwife/ODP in the clinical area/department or by the registered assigned nurse/midwife/ODP in his/her absence.

The appointed/assigned nurse/midwife/ODP must ensure that adequate CDs are available on the clinical area/department for their patients' anticipated requirements.

The appointed/assigned nurse/midwife/ODP must always order the lowest strength of CD available to fulfil the current prescription of the patients on the clinical area/department.

The appointed nurse/midwife/ODP must ensure that naloxone injection 400 micrograms in 1ml is available in the same clinical storage location where opiates are stored or administered.

For areas other than clinical areas/departments (e.g. laboratories), a designated person must order any CDs required.

## 4.8.3 Dispensing of Controlled Drugs by STHFT Pharmacy Department

CDs are stored in Pharmacy under 'safe custody' before supply to a clinical area/department or to a patient via a prescription.

CDs are dispensed in the Pharmacy by authorised and competent staff according to local Standard Operating Procedures (SOPs).

Requisition books and prescriptions must be signed by the member of pharmacy staff involved in dispensing. All issues must be checked.

All supplies must be entered in the Pharmacy CD register as an issue is made (or at the latest the following day) according to SOPs.

## 4.8.4 Issuing of Controlled Drugs by STHFT Pharmacy Department

### Via Requisition Books

Any appropriate STHFT member of staff may undertake the role of 'messenger' to collect and deliver CDs. They must sign and date the 'accepted for delivery' section in the CD requisition book. The white copy must be retained by the Pharmacy for 2 years. "Messengers" must always wear STHFT identification name badge according to Trust Policy.

The "messenger" must hand over the CDs to a registered nurse/midwife/ODP on a clinical area/department. The registered nurse/midwife/ODP must sign for the package in the presence of the "messenger". The white copy of the order must be returned to Pharmacy by the 'messenger' (NB The white copy will be retained in Pharmacy at the point of the "messenger" signing for the package when CDs are collected). For other departments (e.g. laboratories), the "messenger" must hand over the CDs to the designated person and the above procedure followed.

In some cases the "messenger" and the person accepting delivery may be the same person (e.g. a registered nurse).

Deliveries of CDs must be recorded in the CD register on the receiving clinical area/department by a registered nurse/midwife/ODP or designated person (in the case of laboratories) and this should be witnessed by a second responsible person.

Any discrepancies in the order must be reported immediately to the Pharmacy for investigation by the appointed/assigned nurse/midwife/ODP.

### Via Outpatient Prescriptions/Discharge Notes

The prescription/discharge note for a CD must be signed on the reverse of the Pharmacy copy by the person collecting it.

The address (e.g. clinical area/department) must be included if a health care professional (or member of staff acting as a messenger) is collecting the CDs. An STHFT identification name badge must be shown as identity.

The member of pharmacy staff giving out the CD should ask to see proof of ID and record which form of identity has been seen on the reverse of the Pharmacy copy.

Acceptable forms of identity include: -

- Driving Licence
- Any official photo ID
- Passport
- Cheque guarantee, debit or credit card
- Birth/marriage certificate
- Cheque book
- Utility bills
- Pension or benefit book
- Council tax payment book

- Recent bank or building society statement or book
- Store charge card
- Council rent book
- National savings book
- Household bills

Details must be retrospectively recorded in the Pharmacy CD register according to local Pharmacy SOPs

**Via FP10 Prescriptions**

FP10 prescriptions from GPs working for the GP Collaborative may be dispensed out-of-hours according to standard Pharmacy SOPs.

A copy signature for the GP must be available in the Pharmacy and written proof of identity must be provided by the GP before CDs will be issued.

## 4.8.5 Storage of Controlled Drugs

CDs in clinical areas/departments must be stored in a locked CD cupboard, which can only be accessed by nursing and pharmacy staff routinely and by medical staff in an emergency. CDs in other areas (e.g. laboratories) must be stored in an approved locked receptacle, which can only be opened by a person who can lawfully be in possession of them.

All CDs must be stored in the correct original outer packaging carrying the dispensing label from Pharmacy.

Loose dose units, not stored in the original outer packaging carrying the dispensing label from Pharmacy should be returned to Pharmacy for destruction. Clinical area/department staff must be reminded that this is unacceptable practice.

CDs which require refrigeration must be stored in a locked refrigerator which can only be accessed by nursing and pharmacy staff routinely and by medical staff in an emergency (see section 4.4)

The keys to the CD cupboard in clinical areas/departments must be kept by the appointed/assigned nurse/midwife/ODP and must be kept separate from general clinical area/department keys.

For areas with electronic access, only authorised staff should have access to CD areas.

CD cupboards/receptacles must be kept locked when not in use.

Higher strengths of morphine and diamorphine injectable products (i.e. 30mg and above) should be stored away from the lower strengths to minimise the risk of accidental overdoses.

High strength midazolam (5mg/ml in 2ml and 10ml ampoules and 2mg/ml in 5ml ampoules) must be restricted to general anaesthesia, intensive care, palliative care and areas formally risk assessed and approved by Pharmacy.

The CD cupboard/receptacle must only be used for the storage of CDs and other medicines deemed restricted by Trust Policy (e.g. concentrated potassium solutions – see section 4.4)

CDs dispensed on discharge notes, as TTOs must be stored in the CD cupboard until the patient is discharged. An entry must be made in the 'Patient's Own' section of the CD register or specific CD register if the patient is not for same day discharge.

**Storage of Controlled Drugs in Patient's Homes**

CDs in patients' homes are the property of the patient and will not be stored in a locked CD cupboard. A register is not required.

## 4.8.6 Audit and Monitoring

The stock balance of CDs must be checked daily against the actual stock available by a registered nurse/midwife/ODP and a second responsible person acting as a witness. Liquids should be estimated and unopened containers assumed to contain the nominal volume. This is to decrease the loss of liquid in repeated measuring of volumes and to ensure that excessive handling does not compromise the integrity of the liquid. Preparations and strengths of CDs not required for current patients on the ward/clinical area should be returned to Pharmacy (see section 4.8.12).

The Accountable Officer must authorise deviations from daily balance checks.

All discrepancies must be reported to the appointed/assigned nurse/midwife/ODP. A thorough investigation must occur to resolve the discrepancy. If this fails to identify the problem, the discrepancy must be reported immediately to the Dispensary Manager and ultimately the Accountable Officer. The incident must be reported electronically via Datix.

The security and balance of clinical area/department stock of CDs should be checked every three months by pharmacy staff with a registered nurse/midwife/ODP. Liquids should be measured during this check according to GPhC Guidelines. A report form must be completed and retained by Pharmacy for a minimum of 2 years. This report will also include a check on security, a check on the quantity and range of CDs stocked, a random check on requisition and register details and a review of all current authorised signatures. Preparations and strengths of CDs not required for current patients on the clinical area/department should be returned to Pharmacy (see section 4.8.12).

The Medicine Safety Manager produces a quarterly Trust wide report from Datix of all incidents involving controlled drugs. The Medicine Safety Manager arranges follow up meetings with relevant senior staff from any area identified as reporting 4 or more incidents in one quarter, or 3 or more incidents in two consecutive quarters. At this meeting the actions already taken are reviewed and further actions agreed which are then summarised in a written report. These reports and the quarterly report are sent to the Accountable Officer, the Healthcare Governance Committee and the Local Intelligence Network.

## 4.8.7 Record Keeping

Records must be kept in Pharmacy of all CDs received or issued according to local SOPs.

CD registers must be kept by all clinical areas/departments requisitioning CDs from Pharmacy.

Separate pages within the register must be used for each drug and strength. NB See SOP CLINCD20 for Spinal Pain Management (when available).

The drug, form and strength must be written at the top of each page within the register. Each specific drug of a particular form and strength should only have one set of pages within a register with a cumulative total stock balance.

Entries in the register must be made at the time of receipt or administration of CDs.

CDs dispensed on discharge notes and stored in the CD cupboard should be checked by a registered nurse/midwife and a second responsible person acting as a witness. They should be recorded in the 'Patient's Own Drugs' section of the CD register or specific CD register if not for same day discharge. On discharge, an appropriate annotation should be made in the register when they are given to the patient.

Entries must be in ink.

When a CD is administered to a patient, the following entry should be made in the register: -

- Date and time
- Name of patient
- Dose
- Signature of both practitioners (given by and witnessed by)
- New stock balance

NB The records required for theatres are detailed in the Trust SOP.

According to the Misuse of Drugs Regulations 2001, the appointed/assigned nurse/midwife/ODP may only administer a CD to a patient under their care in accordance with the directions of an authorised prescriber, or return the supply to Pharmacy.

CD requisition books are controlled stationery and must be kept in a locked drawer/cupboard when not in use. Other CD stationery must be stored with suitably restricted access.

CD requisition books must be retained by the clinical area/department for 2 years from the last entry. CD registers must be retained for 2 years from the date of the last entry but for 7 years if there is any record of destruction (Pharmacy CD registers).

Transfer of balances to a new CD register must be carried out by 2 registered nurses/midwives/ODPs, who are authorised to order CDs.

It is good practice to transfer all balances when a new CD register is started in a clinical area/department.

## 4.8.8 Administration of Controlled Drugs

Section 3 (Administration) applies to all CD administration. In addition, the following requirements apply for all CD administrations:

Two practitioners must check the administration of CDs. One practitioner will take the lead and administer the medicine, the other act as a witness to the procedure. The witness, who may be a student nurse, must be present at all stages of the process from obtaining the medicine from the locked cupboard to administering the correct dose to the patient. The witness must independently check to confirm the identity of the CD, the strength, dose and expiry.

In situations where it is impossible for two practitioners to check the administration of a dose (e.g. Community Health Services, midwives administering at home births, palliative care administration in the patient's home), local procedures should be followed and a risk assessment performed and agreed by the Accountable Officer.

The anaesthetist is responsible for administering CDs in theatre.

When opiates are given to opiate-naïve patients, additional observation must be made for the first hour to monitor for respiratory depression.

Naloxone injection 400 micrograms in 1ml must be available on all wards/clinical areas where opiates are administered.

A ward supply of CDs should be used for administration to any registered substance misusers.

## 4.8.9 Patient's Own Controlled Drugs

CDs brought into hospital by patients should be checked by 2 registered nurses/midwives and recorded in the 'Patient's Own Drugs' section of the CD register or the specific 'Patient's Own' CD register. They should not be recorded as 'stock'. The CDs should be placed in a 'Patient's Own' clear CD bag, the bag sealed and the label on the bag completed by both nurses/midwives. The bag should be placed in the CD cupboard.

On clinical areas/departments where 'Dispensing for Discharge' is in place, patient's own CDs may be used, providing they satisfy the assessment criteria. In this case they must be recorded on a separate page of the CD register in the area used for patient's own drugs such that an entry may be made whenever a dose is given.

If it is appropriate, the CDs may be returned to the patient on discharge. An appropriate annotation should be made in the register when they are returned to the patient.

If the CDs are not appropriate for returning to the patient, the patient's/carer's permission must be obtained for sending the CDs to Pharmacy for destruction (see section 4.7.2). The CDs should be signed out of the CD register by appropriate pharmacy staff and a registered nurse/midwife and a transit form completed.

If the CDs are not suitable for returning to the patient and permission is not obtained for destruction, a decision must be made by the pharmacist and doctor as to the fate of the CDs and the course of action documented in the patient's record as well as the CD register. The patient should be given appropriate advice.

It is occasionally necessary to use patient's own CDs while they are in hospital until an appropriate supply can be obtained from Pharmacy. In this case the CDs should be entered as patient's own drugs in the CD register as above, but on a separate page so that doses administered can be recorded in the register.

## 4.8.10 Clinical Trials

See section 4.11 for more information.

Any CDs used in clinical trials must comply with both clinical trials legislation and the Misuse of Drugs regulations.

A separate CDs register in STHFT Pharmacy must be used for CD trial material. A separate page must be used in the ward CD register for CD trial material.

If the trial involves schedule 1 CDs (e.g. cannabinoids) a licence from the Home Office will be required for Pharmacy to receive the CDs into stock. This should be held by the Chief Pharmacist.

## 4.8.11 Prescribing for Addiction

### Community Services

For prescribing drugs listed in Schedule 2 of the Misuse of Drugs Regulations and buprenorphine or diazepam by instalment prescribing for the treatment of addiction, prescribers should use the appropriate FP10MDA (blue) form. This form must not be used for any other purpose, including when the total quantity needs to be dispensed at one time. In this situation a standard FP10 must be used.

The prescribing of diamorphine, dipipanone and cocaine, for the treatment of addiction, requires a special Home Office licence.

Form FP10MDA must specify the following details:

- The instalment amount and the dose specified separately
- The intervals to be observed between instalments; if necessary, instructions for supplies at weekends or bank holidays should be included
- The total quantity of CD that will provide treatment for a period not exceeding 14 days

Prescriptions which contain a direction that specified instalments of the total amount may be dispensed at stated intervals must not be dispensed otherwise than in accordance with the directions **unless** Home Office approved wording is included in the prescription:

> *For supervised consumption*: "Supervised consumption of daily dose on specified days; the remainder of supply to take home. If an instalment prescription covers more than one day and is not collected on the specified day, the total amount prescribed less the amount prescribed for the day(s) missed may be supplied"
>
> *For unsupervised consumption*: "Instalment prescriptions covering more than one day should be collected on the specified day; if this collection is missed the remainder of the instalment (i.e., the instalment less the amount prescribed for the day(s) missed) may be supplied."

### Acute Services

When registered substance misusers are admitted, the prescriber **must** ensure that contact is made with the patient's usual prescriber and supplying pharmacist before prescribing. Schedule 2 controlled drugs should not routinely be prescribed for registered substance misusers. If they are required on discharge, only enough medication for one day should be prescribed. In extreme circumstances it may be necessary to prescribe up to three days supply (e.g. to cover bank holidays or Jessop Wing patients on their approved management system). Discharge arrangements must be communicated to the patient's usual prescriber and supplying pharmacist. Further information about substance misuse in pregnant patients will be available on the Trust Intranet later in the year.

## 4.8.12 Destruction of Controlled Drugs

### Patient's Own Drugs

In acute services patient's own drugs, which are for destruction according to section 4.8.9 above, should be signed out of the ward CD register by a registered nurse/midwife and the pharmacist/MMT/pharmacy technician and returned to Pharmacy. A Pharmacy 'Transit Form' must also be completed. They should be disposed of in Pharmacy according to local SOPs.

In community, patient's own drugs, which are for destruction, must be returned to community pharmacy for destruction. Patient's own reconstituted parenteral CDs may be destroyed at a patient's home by STHFT staff following approved Trust SOPs.

### Expired/Unwanted Stock

Expired or unwanted CDs must be signed out of the clinical area/department CD register by a registered nurse/midwife/ODP and the pharmacist/MMT/pharmacy technician. A 'Transit Form' must also be completed, except for concentrated potassium solutions.

If the stock is unsuitable for reuse, it should be processed in Pharmacy according to local Pharmacy SOPs and stored in the Pharmacy CD room/cupboard for later destruction by an 'authorised witness'. The frequency of destruction will depend on the quantity of material for destruction and the storage area available.

Authorised witnesses for the Trust currently include Alison Redfern (Ext. 69110), Andrew Scott (Ext. 66320), Home Office Inspectors, Inspectors of the GPhC, Police Chemist Liaison Officers and persons nominated by the Accountable Officer.

If the stock is suitable for reuse, it should be returned to Pharmacy stock in the CD cupboard/room and re-entered into Pharmacy CD registers according to local SOPs.

## Permitted Disposal on Wards/Clinical Areas

This may include part doses for individual patients, discontinued infusions, used patches and lozenges, doses drawn up but not given, unused dose units (e.g. dropped tablets) etc.

An 'Authorised Witness' (e.g. Home Office Inspector, Police Chemist Liaison Officer) is not required for CD destruction in clinical areas/departments.

Full details must be recorded in the controlled drugs register by a registered nurse/midwife/ODP and witnessed by a second responsible person.

In theatres, the anaesthetist must destroy any unused CDs, which have been issued to him/her for individual patient administration and have this witnessed by a second responsible person. Details must be entered into the CD register.

Sharpsmart Access bins containing absorbent mats are available in most clinical areas and must be used for CD disposal where available. In areas where they are not provided, standard Sharpsmart bins containing absorbent mats must be used. NB Areas with high cytotoxic activity (e.g.P3, WPH) should use purple hazardous waste containers for destruction.

The unwanted CDs must be destroyed according to the STHFT Waste Policy (and rendered irretrievable before being sent for incineration by using absorbent mats and absorbent granules with water if appropriate) as follows:-

- Medicines must not be disposed of in sinks, toilets or sluices.
- Solid dosage forms (e.g. tablets, capsules, lozenges) should be placed directly in a clinical waste container for incineration
- Patches (e.g. fentanyl) should be folded so the adhesive sides stick to each other and placed directly in a clinical waste container for incineration
- Volumes of less than 10ml should be expelled into a clinical waste container for incineration together with the empty vial/ampoule/syringe
- Larger volumes of liquid should be expelled from their container into a clinical waste container for incineration containing suitably absorbent material (see below).

The absorbent mats in the waste containers will absorb and render irretrievable approximately 100ml of liquid. If greater volumes individually or cumulatively are being disposed of, absorbent granules should be added additionally to the bin to ensure liquid is adequately absorbed and rendered irretrievable. If granules are used, additional water up to a total of 1000ml per sachet should be added to ensure the CDs are rendered irretrievable.

All sharps used in the preparation and administration of controlled drugs MUST be disposed of safely into yellow clinical waste containers (or purple hazardous waste containers) according to STHFT Waste Policy and current Control of Infection Guidelines.

Dropped/broken ampoules/vials must be carefully cleaned up according to ward/clinical area procedures. The action must be witnessed and recorded and witnessed in the CD register by a registered nurse/midwife/ODP and second responsible person acting as a witness.

Liquid preparations (e.g. oxycodone) often contain 'overage' in the bottle such that there will be more than the nominal bottle volume. If the total contents of the bottle have been correctly administered according to the nominal bottle volume and the CD register and there is a volume remaining in the bottle, the CD register should be corrected by 2 registered nurses/midwives/ODPs and a reason for the correction given – stating that the excess is being returned to pharmacy for destruction (providing the deviation is less than ±10%). Deviations of more than 10% must be investigated according to Trust SOPs (see section 4.7.6).

## 4.8.13 Midwives and Controlled Drugs

A registered midwife may possess diamorphine, morphine, pethidine and pentazocine in her own right so far as necessary for the practice of her profession.

Within the Jessop Wing at STHFT, midwives may administer doses of morphine, diamorphine and pethidine during labour according to local guidelines using the midwives exemption. The 'doses administered without prescription' section of the prescription and administration chart must be completed. Ward stock should be used for this administration.

## 4.8.14 Illicit Substances

It is an offence to possess certain CDs as defined by the Misuse of Drugs Act 1971 (Schedule 1 e.g. cannabis, ecstasy-type substances, LSD) and other CDs covered by the Act held without a prescription [i.e. illicit substances].

It is forbidden to use, possess or supply illicit substances within Trust premises.

Any illicit substances found on a clinical area/department must be documented by two registered nurses/midwives/ODPs and Pharmacy informed as soon as possible.

The Trust has a 'Zero Tolerance' approach to violence, so if a member of staff is uncomfortable about approaching the individual (e.g. if they are aggressive or violent), they should seek the assistance of other staff members or security (or in extreme circumstances the Police). See STHFT Policy for the Management of Violence and Aggression at Work and Policy for Withholding Treatment from Violent and Abusive Patients.

If a patient persistently refuses to hand over an illicit substance, the STHFT Policy for the Management of Violence and Aggression at Work and the Policy for Withholding Treatment from Violent and Abusive Patients may need to be considered provided they are appropriate for the circumstances.

UNDER NO CIRCUMSTANCES MUST AN ILLICIT SUBSTANCE BE RETURNED TO THE PATIENT OR THEIR REPRESENTATIVE.

The incident MUST be reported electronically via Datix for any incident involving illicit substances.

Further guidance will be available in the STHFT Policy on the Management of Suspected Illicit Substances (when available)

## 4.9 Reporting Medication Incidents

Refer to the STHFT Incident Management Policy and the STHFT Serious Untoward Incident Policy for further information.

Medication incidents and near misses must be reported in line with the STHFT Incident Management Policy and associated local procedures.

- An 'incident' is *any untoward, unplanned or unwanted event or circumstance that did lead or could have led to harm, loss or damage.*
- A 'serious incident' is an incident which is of such a magnitude that the consequences have a serious impact on individuals or the organisation.
- A 'near miss' is a *situation either in which an event or omission could have caused harm if not corrected at the last minute.* This will include situations where some part of a plan or procedure has not been followed, but the error has been spotted in a final check.

To promote a consistent standard of reporting medication incidents, the trigger list below should be used as a guide. Individual directorates may have incorporated more specific medicine triggers in their lists.

### Trigger List

**Never events (including near misses)**

- Mis-selection of potassium-containing solutions
- Wrong route administration of medication
- Overdose of insulin due to abbreviations or incorrect device (despite electronic prescribing)
- Mis-selection of high strength midazolam during conscious sedation
- Overdose of methotrexate for non-cancer treatment (despite electronic prescribing)

For detailed information about 'Never Events' please refer to http://www.england.nhs.uk/wp-content/uploads/2015/04/never-evnts-pol-framwrk-apr.pdf

**High risk medicines**

Medicines requiring monitoring

e.g. gentamicin, vancomycin, warfarin, heparins, digoxin, anticonvulsants, thalidomide, hypoglycaemic agents

Cytotoxic agents

Including cancer chemotherapy, cyclophosphamide and methotrexate for immunosuppression

Concentrated potassium

Controlled drugs

Clinical Trial agents

Unlicensed medicines

Parenteral agents

Including spinal injections, TPN

**Missing items**

Where there is documented evidence that the item was issued by Pharmacy, but the ward/department did not receive it

**Items dispensed without a clinical check**

Includes self-administration prior to clinical check

**Wrong dose prescribed and administered**

Where potential for clinical risk

**Wrong medicine prescribed or administered**

Includes failure to acknowledge patient allergy.

Excludes therapeutic substitution according to policy and formulary

**Issue of incorrect information**

Includes advice from all departments, inaccurate medication charts (green/yellow cards)

**All dispensing/supply errors, which leave the Pharmacy undetected**

Includes cytotoxics, CIVAs, TPN, extemporaneous products, batch products, stock issues, clinical trials and dispensed items

**All serious or potentially serious incidents**

Includes all critical and major non-compliances with GMP (Technical Services), problems resulting in recall of internally prepared product, staff exposure to high risk medicines (e.g. needle stick injury, cytotoxic spillage) and all extravasations.

**All incidents or potential incidents where there is concern that the patient may make a formal complaint or claim**

Clinical areas will inform their nominated pharmacist of all reported medication errors. Clinical pharmacists should be involved in the initial investigation of all incidents involving medicines, recommending suitable clinical action and ensuring any adverse drug reactions are reported appropriately (see section 3.10). The Pharmacist will assist/advise in the initial investigation of the incident.

Where appropriate, the clinical area may also contact Medicines Information departments in Pharmacy (Ext. 14371 [NGH] and Ext. 12346 [RHH]), or the on-call pharmacist out of hours for advice on managing the immediate clinical situation to ensure patient harm is minimised.

The local governance lead and either the Medicine Safety Manager, Pharmacy Healthcare Governance Manager or a senior pharmacist manager must be notified promptly of all serious untoward incidents, never events and serious near misses involving medicines.

The pharmacist/medicines management technician/appropriate dispensary staff should investigate any reported problems with discrepancies in stock orders received by clinical areas. The correct stock should be reissued and confirmation sought that the medicines have not be inappropriately administered. A Datix entry must be completed.

A Datix entry must be completed for all medication incidents and near misses and submitted to the risk manager/clinical area concerned.

Staff in the clinical area where the incident occurred are responsible for undertaking the investigation and ensuring that the incident is entered on to the Datix system and that the outcome of the investigation are also entered on to the Datix system, ensuring that all details on the medication screen are completed.

The Medicine Safety Manager is responsible for producing quarterly reports to the Medicines Safety Committee of all reported medication incidents and near misses. The Medicines Safety Committee will identify trends and suggest actions to decrease medication incidents.

## 4.9.1 Dispensing Errors

The following errors must be reported by any health care professional detecting them:

- All errors associated with issues or dispensing of medicines made by any section of any Pharmacy department within STHFT
- All dispensing errors originating from community pharmacies or dispensing general practitioners
- All dispensing errors originating from other hospital trusts

### Responsibilities of All Health Care Staff

Any health care practitioner who detects an error associated with the issue of a medicine must report it to the pharmacist or MMT for their clinical area.

Clinical areas, which do not receive a daily pharmacy service, must report the error to the Pharmacy Dispensary or the Manager of the Community Health Service.

Errors involving parenteral cytotoxic agents should be reported directly to the appropriate Pharmacy Cytotoxic Unit.

Wherever possible, the medicine and all associated packaging and labelling should be handed to the member of pharmacy staff dealing with the report.

If the error relates to a medicine brought into hospital by a patient, verbal consent must be obtained from the patient before the medicine is removed.

If the patient has taken doses of the affected medicine, consideration must be given to the potential clinical effect of the error, medical staff informed and the error documented in the patient's record.

In the acute setting and Community Services dispensing errors should be reported via the Datix system.

**Pharmacy Staff**

Appropriate pharmacy staff within STHFT Pharmacy will ensure the following in line with Pharmacy SOPs for reporting dispensing errors: -

- The incident is entered on the Datix system
- The patient is informed
- Replacement supply is made where appropriate
- The community pharmacy and relevant Clinical Governance Lead is informed where appropriate
- STHFT errors are fully investigated and documented

## 4.9.2 Adverse Drug Reactions (ADRs)

Any unexpected reaction to a medicine must be reported immediately to the prescriber and recorded in the patient's record. It must also be reported on the incident report form.

See section 3.10 for further information.

## 4.9.3 Defective Medicinal Products

Any health care staff identifying a defective medicine or prescribed dressing will report it to Medicines Information in Pharmacy via the nominated pharmacist where applicable.

It is recognised that some products licensed as medical devices (identified by the presence of a CE mark) contain medicines (e.g. pre-filled syringes for flushing containing sodium chloride 0.9%). Any health care staff identifying a defective device should complete and submit a medical device adverse incident form and if the device contains a medicine, also notify Medicines Information.

Community Health Services any health care staff identifying a defective medicine or prescribed dressing will report it to the Care Group Risk Lead.

The following are typical examples of defects, which should be reported: -

- Inadequate or unsatisfactory packaging (e.g. containers leaking or difficult to open)
- Indistinct or damaged labelling
- Containers bearing no batch number
- Packs containing significantly more or less than the stated amount
- Ampoules, which do not open satisfactorily
- Formulation deficiencies (e.g. difficulty of re-suspension or reconstitution, cracked emulsion)
- Particulate or microbial contamination
- Dusty or broken tablets or capsules
- Accessories, (e.g. spoons), which are inaccurate or unsuitable for the intended purpose

All defective medicinal products should be reported by the Medicines Information pharmacists or Risk Lead via the NHS Analytical Information Centre (AIC) using the on-line electronic reporting system at http://www.qaeastmidlands.nhs.uk/. More serious defects should be reported directly to the MHRA in addition.

The following information will be required: -

- Product name
- Supplier (from label)
- Manufacturing site
- Product License number
- Legal status (POM, P, GSL, Unlicensed)
- Dosage form and strength
- Container type/size
- Batch/Lot number
- Expiry date (if known)
- Date issued/dispensed by Pharmacy (if known)
- Details of defect and any associated clinical incident

Wherever possible, a sample container should be forwarded with the report. If the medicine belongs to a patient, consent must be obtained and an explanation given to them before removing the container. If clinically appropriate, an alternative supply must be ordered.

The Medicines Information pharmacist should also inform the relevant manufacturer and establish the possibility of product replacement.

***Exceptions***

Other safety issues (e.g. lack of child-resistant closures or identical packaging for different medicines or strengths) with a medicinal product should be reported via the nominated pharmacist where applicable to either the Procurement Pharmacist (Ext. 12362), Medicine Safety Manager (ext. 13251) or the Pharmacy Healthcare Governance Manager (Ext. 13007). If this results in an incident, an incident form or Dispensing Error Report form should be completed, refer to sections 4.9 and 4.9.1.

## 4.9.4 Medicine Alerts and Warnings

Medicine alerts and warnings are issued by the Medicines and Healthcare Products Regulatory Agency (MHRA).

MHRA alerts are received into the Trust from the regional Drug and Therapeutics Centre (RDTC) at Newcastle.

MHRA alerts are classed according to the following prioritisation system: -

| | |
|---|---|
| Class 1 | ACTION NOW (including out of hours) |
| Class 2 | Action within 48 hours |
| Class 3 | Action within 5 days |
| Class 4 | Caution in use |

Alerts and warnings will be managed by Pharmacy according to local Pharmacy SOPs. This may necessitate removal of medicines from wards/clinical areas and sometimes from patients at home. Pharmacy will ensure replacement supplies are arranged where appropriate. Cooperation is required from all health care staff to ensure that alerts and warnings are dealt with in the required time frame.

Other alerts and warnings concerning equipment and devices are formally received into the Trust from MHRA by the Directorate of Legal and Corporate Governance. These are cascaded via the Safety Alert Broadcasting (SAB) system to Trust Directorates for action.

Pharmacy will ensure that medicine alerts and warnings together with actions taken are logged on SABs. It will not usually necessary to cascade these to other Directorates.

## 4.10 Clinical Emergencies

For acute services, emergency resuscitation boxes/trays and anaphylaxis shock packs are available at strategic locations throughout the Trust. The appointed nurse/midwife is responsible for ensuring that the box/tray is kept in a suitable location which all staff are aware of.

The contents of the emergency trays are agreed by the STHFT Resuscitation Committee.

The expiry date must be regularly checked by nursing staff to ensure that the box/tray is always in date.

The appropriate pharmacy is responsible for filling and issuing emergency boxes/trays.

Any expired, used or unsealed boxes/trays (even if unused) must be returned promptly to the appropriate pharmacy for replacement.

Sharps MUST be disposed of according to STHFT Waste Strategy and Policy and Infection Control Guidelines and NOT returned to Pharmacy with the box/tray.

Emergency trays used for the treatment of barrier-nursed patients must have all non-absorbent surfaces, inserts and contents wiped with an alcoholic wipe before returning to Pharmacy. Sealed foam inserts, glass and plastic packaging are all considered non-absorbent. Items contained in cardboard packaging may be wiped clean and returned providing the cardboard does not soften and the printed information is not removed. Porous foam insets and items contained in absorbent cardboard packaging must be disposed of as hazardous waste on the ward/clinical area.

Any medicine or container, which has been contaminated with body fluid, must be disposed of as hazardous waste on the ward/clinical area.

Trays/boxes for other emergencies are available in specialised areas e.g. Pre-eclampsia trays at Jessop Wing.

Staff employed within Community Services should refer to the Community Services Directorate Procedure for Management of Emergency Medication.

## 4.11 Ward/Clinical Area Closures

It is inevitable that wards/clinical areas will need to close from time to time (e.g. for redecoration). The appointed nurse/midwife is responsible for arranging for all medicines issued to the ward/clinical area to be stored safely during the time of the closure.

### Controlled Drugs

Controlled drugs (CDs) will be checked and signed out from the ward/clinical area to the Pharmacy for safe keeping by a registered nurse on the ward/clinical area and the MMT/pharmacist. The CDs will be placed in a sealed container together with the controlled drugs register and requisition book and taken to Pharmacy by the MMT/pharmacist. The staff involved must sign a 'Transit Form for the Removal of controlled drugs to Pharmacy for Storage'.

The controlled drugs will be stored in the Pharmacy controlled drugs room/cupboard.

When the ward/clinical area reopens, the controlled drugs will be checked back by a registered nurse from the ward/clinical area and the MMT/pharmacist. The 'Transit Form' must be completed and retained in Pharmacy for 2 years.

### Other Medicines

If nursing staff will be available in the ward/clinical area staff during closure and are able to take responsibility for the other medicines (non-controlled drugs) stored during closure, then the medicines remain in securely locked cupboards on the ward/clinical area and the cupboard keys are kept securely.

If nursing staff in the ward/clinical area are unable to take responsibility for other medicines (non-controlled drugs) during closure, the medicines will be packed up and stored in Pharmacy for the duration of the closure. The cupboard keys must be stored securely in the clinical area during the closure. The medicines are returned to the ward/clinical area when it is due to reopen.

## 4.12 Clinical Trials

Clinical Trials must comply with EU Clinical Trials Directive 2001/20/EC (Clinical Trials), the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 1031), Research Governance and EU Directive 2005/28/EC (GCP, authorisation of manufacturing or importation).

For the latest guidance on planning and conducting clinical trials, contact the Research Manager, currently Dr. Dipak Patel at the Research Department (Ext. 65941)

Pharmacy contacts are: -

| | |
|---|---|
| RHH | Ext. 13840 |
| NGH | Ext. 15456 |
| WPH | Ext. 65101 |
| JW | Ext. 68216/68220 |

When planning research involving a medicinal product, the Research Department should be contacted and the website visited for further information and guidance. The first step in the process of research authorisation is the completion of the STHFT Research Department registration

All clinical trials involving the use of a medicine as the intervention or control require a Clinical Trial Authorisation (CTA).

Regulatory approval (including Trust Approval) must be obtained for each trial before clinical trial medicines can be released.

All clinical trial medicines must be received and distributed by the Pharmacy Department.

Clinical trial medicine should not be prescribed or dispensed until a pharmacy file has been set up and medication released for use in the trial by the Pharmacy.

Clinical trial medicines may be licensed or unlicensed but should always be labelled as clinical trial supplies.

All prescriptions must clearly indicate that the medicine is trial material. For most outpatient trials this is usually stated on the designated prescription form.

Any discrepancy/problem must be queried before prescribing clinical trial medicines.

Full accountability must be maintained for medication supplied for use in a clinical trial.

Returned clinical trial medicines must be retained in the Pharmacy until authorisation by the company/sponsor for the return or destruction of the medicine.

Written informed consent must be obtained from each patient before they are entered into a clinical trial. This process should be undertaken in line with Research Department SOPs.

Suspected adverse reactions to clinical trial medicines will be reported directly by the health care professionals to the 'Sponsor' and the STHFT Research Department and not via the 'Yellow Card' scheme. SOP (A122) "Reporting, Monitoring and Recording of Adverse Events for Externally Sponsored Studies" and SOP (A123) "Recording, Management and Reporting of Adverse Events for STHFT Sponsored Studies" gives comprehensive guidance on all aspects of pharmacovigilance and the timescales required by the regulatory body under UK law.

Further information is available from the STHFT Research Office.

## 4.12.1 Code Breaking

The SOP (C109) "Code Break Procedure for STHFT Sponsored IMP" must be followed for STHFT sponsored IMP studies. For external studies, the code break procedure will be described in the protocol and the trial specific SOPs and will be reviewed by Pharmacy prior to project authorisation.

It is the responsibility of the sponsor to ensure that a mechanism is in place to permit rapid identification of the product(s) in the case of a medical emergency but does not permit undetectable breaks of the blinding.

It is the responsibility of the investigator(s) to ensure that there is a mechanism on site which will provide a rapid response to a request for a code break 24 hours a day, 7 days a week.

Different mechanisms of code break are available (e.g. sealed envelopes, tear-off labels with scratch panels, fax systems, central 24-hour telephone numbers) depending on the study.

The STHFT Pharmacy Department is the 24-hour contact point for all trials conducted at the Royal Hallamshire Hospital, Jessop Wing and the Northern General Hospital, and for some trials at Weston Park Hospital. However, the code breaking mechanism for most blinded trials at WPH is IVRS (interactive voice recognition system) and is managed by the Cancer Research Centre staff. On all sites, for trials where the code breaks are held in Pharmacy, code breaking is carried out by the either the Clinical Trials Pharmacist, the Pharmacy Clinical Trials Manager or in their absence, a pharmacist.

The reason for breaking the code must be appropriately recorded according to the trial protocol. The sponsor and investigator must be contacted as soon as possible if this was not done prior to the breaking of the code.

A Serious Adverse Event (SAE) must be reported to the sponsor within 24 hours of the investigational team becoming aware of it. In some circumstances an entry via the Datix system will also be necessary.

### 4.12.2 Inpatients

If a patient admitted to hospital is already participating in a clinical trial, the clinical trial medication must be brought in from home. If this is not possible, the Pharmacy should be contacted for advice. Hospitalisation may be a serious adverse event as described by the Medicines for Human Use Regulations. It is vital that if a patient on a clinical trial is admitted to hospital that the contacts described on the research alert page are contacted as soon as possible. This may be the Principle Investigator at the site or a delegated individual. This individual will off immediate advice regarding potential patient safety and follow the process as described in the STHFT Research Department SOP (A122) “Reporting, Monitoring and Recording of Adverse Events for Externally Sponsored Studies” and SOP (A123) “Recording, Management and Reporting of Adverse Events for STHFT Sponsored Studies”.

Staff should be aware that contact details for the study team are listed on the research alert page in the patient case notes, and that an ‘Informed Consent’ form and ‘Patient Information’ sheet will be present in the research section of the notes.

Clinical trial medication must never be shared between patients. Only use clinical trial medication prescribed for each particular patient.

If a patient commences on a clinical trial as an inpatient, all staff involved in that patient’s care should have a level of understanding of the protocol, treatment and documentation commensurate with their involvement in the study.

### 4.12.3 Outpatients

Pre-printed study specific prescriptions should be used where they are available. All sections of the prescription should be completed. All legal requirements for prescribing still apply to clinical trial prescriptions.

Prescription charges may still apply to clinical trials in some circumstances.

## 4.13 Therapeutic Drug Monitoring

Certain medicines given to patients have a narrow therapeutic range for them to be effective and not cause toxicity. It is therefore important that blood levels of these medicines are monitored closely to ensure that dosing is effective.

Medicines which require particularly close monitoring include: -

- Digoxin (oral and IV)
- Gentamicin (IV)
- Tobramycin (IV)
- Lithium (oral)
- Phenytoin (oral and IV)
- Theophylline (oral)
- Aminophylline (IV)
- Vancomycin(IV)

Unless toxicity is suspected, blood levels should not be measured until after 4 – 5 half lives (this does not apply if the patient has received a loading dose or is on an IV infusion or overdose is suspected).

For further information contact Medicines Information in Pharmacy (Ext. 14371 [NGH] and Ext. 12346 [RHH] or the on-call pharmacist out of hours), Clinical Chemistry (Ext. 14716 [NGH] and Ext. 12348 [RHH]) or Microbiology (Ext. 14527 [NGH] and Ext. 13126 [RHH]). Information can also be found on the Trust Intranet.

Levels should be ordered by completing the relevant laboratory request form including the following: -

- Indication for treatment
- Dose regimen
- Duration of treatment
- Time and date of last dose (and next dose where appropriate)
- Time and date blood sample taken)

Certain samples may need to be sent to Sheffield Children's Hospital NHS Trust laboratories for analysis (e.g. some neonatal samples [such as phenytoin, phenobarbitone, digoxin and caffeine] and methotrexate samples).

## 4.14 Company Representatives and Samples

In order that the STHFT Drug Formulary is used properly, the activities of Medical Representatives must be regulated when promoting medicines, wound care products obtained through Pharmacy and diagnostic agents

Medical representatives should make appointments to see Trust staff wherever possible.

Medical staff below consultant grade should only see medical representatives with the full knowledge of their consultant.

Medicines and dressing samples intended for use on patients **MUST NOT** be left in clinical areas or the Pharmacy.

Nursing staff are not encouraged to have contact with medical representatives unless it is pertinent to their immediate area of practice and prior agreement has been obtained from the matron or service manager for the clinical area concerned.

Pharmaceutical company involvement in the new drug application process is strictly limited to the provision (on request) of relevant information to the applicant or committee members.

Junior pharmacy staff are encouraged not to have contact with medical representatives except for the purposes of educational meetings.

### 4.14.1 Introduction of New Products

The Medicine Management and Therapeutics Committee must approve the introduction of any new licensed medicine into routine use within the Trust (see section 2.5).

The Medicines Safety Committee (MSC) must approve unlicensed medicines (see section 2.8).

Diagnostic products can only be introduced through the Near-Patient Testing Committee.

The Sheffield Wound Care Group must approve wound care products obtained through Pharmacy for routine use.

Further information is available from the Trust Policy for the Regulation of the Activities of Medical Representatives on the Trust's Intranet.

## 4.15 Controlled Stationery

### 4.15.1 Acute Services

In order to minimise the risk of medicines being obtained fraudulently, all stationery pertaining to the acquisition or administration of medicines should be controlled.

All new or updated prescriptions or administration documents will be controlled.

All prescriptions for inpatient and outpatient use should be ordered via the STHFT Pharmacy department.

All prescriptions should be numbered and a record made of the date and form numbers issued to particular wards/departments/clinics/prescribers.

All prescriptions issued from Pharmacy should be signed for to assist in any audit trails.

All controlled stationery should be stored out of sight on the ward/department/clinic when staff are in attendance.

Controlled stationery must never be left unattended (e.g. during outpatient clinics).

All controlled stationery must be stored securely on the ward/department/clinic when the ward/department/clinic is closed.

Clinical trials material may be prescribed on pre-printed study specific prescriptions provided by the sponsor.

Electronically generated patient-specific prescriptions may be used in certain circumstances (e.g. Chemocare prescriptions for chemotherapy). A permanent record of the prescription should be kept.

If controlled stationery is unaccounted for, the manager of the ward/clinic/department and Pharmacy should be informed so that a full investigation can be carried out and the risk of fraudulent use minimised. A Trust incident report form should be completed.

## 4.15.2 Community Services

FP10 prescription forms for non-medical prescribers are ordered via local procedures (see STHFT Non-Medical Prescribing Policy). Community prescribing clinics (e.g. PCAS/GP Collaborative/Dental) should order from Yorkshire Primary Care Agency (01302 566620).

In the event of loss or suspected theft of FP10 prescription forms, prescribers must report this immediately to their line manager and the incident reported on the Trust's Datix system immediately.

The prescriber's line manager must report the loss or suspected theft to Sheffield CCG's Contracts Assistant and the Counter Fraud Officer.

If it occurs out of hours, staff must contact the on-call manager who will report the incident to the police.

When a prescriber leaves the Trust, Sheffield CCG must be informed. Any unused prescription forms must be recovered, recorded and securely destroyed by the Service Manager

Prescribers are responsible for the security of FP10 prescription forms once issued to them, and should ensure they are securely locked away when not in use (for example in a locker in the office). Prescription forms should not be left unattended or in cars.

Sheffield CCG, the manager of the Community Health Service and individual prescribers must keep a record of the serial numbers of prescriptions issued. The first and last serial numbers of each pad should be recorded.

Blank prescriptions forms should never be pre-signed.

Patients and visitors should never be left alone with prescription forms.

Prescriptions must not be left unsecured in printers.

## 4.15.3 New/Updated documents

All new or updated documents relating to medicines and destined for filing in the patient record, must comply with Trust design standards and be approved by the New Documents Sub Group (NDSG).

Further information on the requirements for new documents can be found on the New Documents Sub Group pages of the Trust Intranet.

## 4.16 Archiving of Documentation

### 4.16.1 General

All NHS records are public records under the terms of the Public Records Act 1958. Chief Executives and Senior Managers of all NHS bodies are personally accountable for records management within their organisations and have a duty to make arrangements for the safe keeping of these records under the overall supervision of the Chief Executive of the National Archives

The Trust's Record Management System is administered by the devolved individual directorates and departments across the Trust using guidelines set out in Records Management – NHS Code of Practice (supersedes HSC 1999/053), which is the basis for all Trust records management.

The Director of Service Development has executive responsibility for the overall management of the system and procedures.

The Information Governance Department is responsible for keeping the Trust's records management policies and procedures under review and ensuring that these comply with good practice in the NHS and other public sector organisations.

Directorate and Departmental Records Managers are responsible for ensuring that their areas comply with Trust policies and procedures and that local arrangements are in place to this end.

Individual staff members are responsible for any records that they create or use. They have a Common Law Duty of Confidence to patients and to the Trust, which continues after the death of the patient, or after the staff member has left the Trust.

The Caldicott Review recommended that "Guardians" of patient information were created within each NHS Trust. These "Guardians" are responsible for approving and ensuring that national and local guidelines and protocols on the handling and management of confidential personal information are in place. The Caldicott Guardian within STHFT is the Medical director.

In clinical trials, upon completion of the study, the pharmacy files should be archived with the Investigator Site File as the principle of chief investigator is ultimately responsible for the archiving process. The archiving process for research is covered in SOP (A127) "Archiving of Essential Documents Generated during Clinical Research" and further guidance is available from the Research Department.

### 4.16.2 Archiving and Destroying Documents

There are 3 stages to store a physical record: -

- **Immediate** – records recently created or in current use should normally be stored as close to the user as possible.

- **Short Term** – records no longer required for immediate use should be stored where they can be retrieved within 24 hours

- **Long Term** – records no longer required for immediate or short-term use should be destroyed/archived according to the Code of Practice for the Management of Records.

The Trust is working towards a policy of non-destruction of clinical records and steps are already in place with respect to permanent preservation of records. The current year and usually the previous 3 years are kept as paper copies. Previous years, which are not still active, are scanned and stored (e.g. on optical disc or microfilm).

Most NHS documents contain sensitive and/or confidential information and therefore confidentiality **MUST** be safeguarded at every stage. The method of destruction must therefore be carefully considered.

Staff wishing to destroy records of any kind must obtain the permission of their manager.

Further information is available on the Trust's Intranet (Code of Practice for the Management of Records – current version [reviewed each January]).

The following table, which is not exhaustive, lists the minimum document retention periods for documents relating to medicines but there may be circumstances where records could be kept for longer periods for specific purposes.

| Record Type | Retained by | Retention Period | Comments |
|---|---|---|---|
| All Clinical Records including inpatient prescription and administration charts and copies of TTOs | Medical Records | See Records Management – NHC Code of Practice | |
| Pharmacy copy prescriptions | Pharmacy | Minimum of 2 years | |
| Pharmacy requisitions/ward pharmacy sheets | Pharmacy | Minimum of 2 years | |
| Stock requisition books | Ward/Clinical Area | Minimum of 2 years | |
| Unlicensed medicine dispensing records | Pharmacy | Minimum of 5 years | |
| PGDs | Originator | Minimum of 8 years but 25 years for paediatrics | |
| Medicines Information query records | MI in Pharmacy | Minimum of 8 years but minimum of 25 years for paediatric/obstetric forms | |
| Clinical Trials prescriptions and documentation | Pharmacy | Minimum of 15 years depending on the trial protocol | Further information from Research Department |
| Controlled Drug registers, destruction records, record books, forms, order books, order and delivery notes | Wards/Clinical Areas | Minimum of 2 years (from last entry if register/record book) | |
| Controlled Drug registers, destruction registers, record books, forms, order books, order and delivery notes | Pharmacy | Minimum of 2 years (from last entry if register/record book) but 7 years if destruction records | 7 years is recommended by GPhC but this may increase to 11 years following the Shipman Enquiry. Currently The Yorkshire Region is recommending 2 years storage. |
| Transfusion Service – records & lab specimens in donors and recipients | Laboratory | Minimum of 30 years | |


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