MEDICINES POLICY

(Policy on the Purchasing, Prescribing, Supply, Storage, Administration and Control of Medicines)

Department / Service:	Pharmacy
Originator:	Associate Director - Medicines Optimisation and Director of Pharmacy
Accountable Director:	Chief Medical Officer
Approved by:	Medicines Safety Committee
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Target Organisation(s):	Worcestershire Acute Hospitals NHS Trust
Target Departments:	All departments
Target staff categories:	All staff undertaking any medicine related task

Policy Overview
Worcestershire Acute Hospitals NHS Trust is committed to the safe and secure handling of medicines to protect its patients, staff and visitors, and its financial resources. The Medicines Policy describes the Trust's control measures for reducing medicine-related risks (including Handling, Purchasing, Prescribing, Supply, Storage, and Administration of medicines) within a framework provided by legislation and official guidance and must support Clinical Governance within the Trust.

Key amendments to this document		
Date	Amendment	By
Nov 2008	Addition of sections to bring into line with Trust Policy for Policies	Paul Benham, Director of Pharmacy
Aug 2009	Clinical Trials section updated	Paul Benham, Director of Pharmacy
July 2010	Section 5.2.19 updated in line with MSC decision on allergy documentation	Alison Smith, Lead Pharmacist Medicines Safety
Aug 2010	Reformat in line with Trust Policy for Key Documents. Reformat approved by Nick Hubbard, Chairman of Medicines Safety Committee 8/9/10	Paul Benham, Director of Pharmacy
Sep 2010	Review of Training Needs Analysis to be reviewed yearly in line with Trust Policy	Alison Smith, Lead Pharmacist Medicines Safety
May 2012	Recording of one of drugs given in A&E, theatres etc.	MSC

May 2012	Removal of Strong Potassium Chloride section and replaced with MedPolSOP23	MSC
May 2012	Statement that unauthorised taking of Trust medicines is theft.	MSC
May 2012	Change to wording on what to do if a patient found to be in possession of illegal substances.	Charles Ashton, as Accountable Officer
May 2012	Change to formatting of obtaining medicines outside pharmacy opening hours	Nick Hubbard, Director of Pharmacy
May 2012	Change of wording about reporting defective medicines	Nick Hubbard, Director of Pharmacy
May 2012	Change of detail wording to Midwives – Supplementary Policy	Nick Hubbard, Director of Pharmacy and Patti Paine, Divisional Director of Midwifery
June 2015	Update job titles and post holders names throughout 1.3 reference added to Medicines Optimisation 5.1 Reference made to Francis enquiry and inclusion in policy. 5.1.13 The most up to date version of the BNF is available on the Trust intranet 5.2.6 Transcribing – updated to remove NMPs and clarify competency assessment. 5.2.16 Multiple charts containing several cancelled prescriptions should be amalgamated. 5.2.22 PGDs – remove requirement to keep hard copies of PGDs in clinical areas 5.2.24 Prescribing and dispensing (supply) – separation of duties reworded to be consistent with NMP policy and MedPolSOPs 1-3. 5.3.11 e) where a medicine has a 'once opened' expiry date this should be marked on the container 5.4 Reference to Wholesaler Dealer Licence added. 5.4.1 f) A 'stock list' should be agreed with Pharmacy 5.4.3b Amendments to wording re CD requisitions. 5.5.2 a) Where there is concern that the ambient temperature where medicines are stored may be regularly over 25degC, this should be escalated to the Divisional Director of Nursing, who will manage the	Medicines Safety Committee

	situation according to Trust policies and, where necessary, contact the Director of Pharmacy for advice about the medicines. 5.5.2 c) Medicines should be stored in the containers supplied by Pharmacy (i.e. no loose strips of tablets), which should be in good repair and include an expiry date and batch number. 5.5.3 a) CD cupboard keys must be carried on the person of the Appointed or Assigned HCP-in-charge when not in use, separate to other medicines keys. 5.5.3.c) A single set of medicine keys should be in use. 5.5.9 A record of this daily temperature monitoring must be maintained for inspection by pharmacy staff. 5.5.14 Replaced PCT with LAT Removed references to bodies that are no longer legal entities e.g. NPSA	
June 2015	5.5.3d reference to pharmacy key holding	Alan Catterall, Director of Pharmacy
August 2016	Interim review v7.1 Changes throughout • Medicines Safety Committee replaced by Medicines Optimisation Expert Forum • Clinical Director of Pharmacy replaced by Associate Director – Medicines Optimisation • Medicines Management replaced by Medicines Optimisation 4.2 Change of Controlled Drugs Accountable Officer to the Associate Director - Medicines Optimisation and Director of Pharmacy 5.2.22 Move to NMP rather than PGDs strengthened, as per NICE MPG 5.3.7 Inclusion of revised section on the checking of administration, approved June 2016 as part of the updated Injectable Medicines Policy 5.3.11 Link to ID patient/wristband policy 5.4.7 Addition of safe supply of stock penicillins and storage in designated cupboards	Richard Cattell, Associate Director - Medicines Optimisation and Director of Pharmacy

	5.5.3 Update of storage requirements	
June 2017	5.2.8 Update of prescribing requirements to include patient's weight (kg) for adults 5.5.2 Storage of medicines revised wording to better describe a patient-focused, risk based approach	Medicines Optimisation Group
June 2018	Medicines Optimisation Group to be changed to Medicines Safety Committee throughout 5.2.7 The content of standardised (e.g. pre-printed prescriptions, templates, or e-prescribed order sets) must be approved before use by Medicines Safety Committee (or according to a procedure approved by Medicines Safety Committee) 5.3.1 inclusion of time critical medicines 5.3.2 escalation of non-administration of medicines to the medical team 5.3.15 In general, patients have a right to refuse medicine and covert administration must not be used. 5.4.2 enabling policy for electronic ordering of stock medicines 5.5.1 clarity of accountability for storage of medicines 5.5.1 and 5.4.2 inclusion of checking expiry dates in responsibilities 5.5.3 clarity of requirements relating to keys for medicines storage	Medicines Safety Committee
February 2019	Extended unchanged for 3 months to allow review to be completed	Medicines Safety Committee
June 2019	Extended unchanged for 3 months to allow review to be completed	Medicines Safety Committee
September 2019	Document extended until end of march to facilitate the completion of review process	Medicines Safety Committee
March 2020	Document extended until May to allow for approval at MSC and CGG	Tania Carruthers/Mike Hallissey
June 2020	Document extended for 6 months during Covid-19 period	

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Introduction

1.1 Worcestershire Acute Hospitals NHS Trust is committed to the safe and secure handling of medicines to protect its patients, staff and visitors, and its financial resources.

1.2 The Medicines Policy describes the Trust's control measures for reducing medicine-related risks (including Handling, Purchasing, Prescribing, Supply, Storage, and Administration of medicines) within a framework provided by legislation and official guidance and must support Clinical Governance within the Trust.

1. SCOPE OF THIS DOCUMENT

2.1 The Medicines Policy covers the policy and procedures associated with the handling, purchasing, prescribing, administration, supply and storage of medicinal products. It is mandatory for all staff employed by and/or working

within Worcestershire Acute Hospitals NHS Trust. This includes all midwifery and nursing personnel working in the home or visiting general practitioners' premises but excludes those staff seconded to other organisations.

2.2 Medicine Policy Standard Operating Procedures (MedPolSOP) are mandatory, detailed, Trust-wide procedures for implementing aspects of the Medicines Policy and should be read alongside this policy.

2. DEFINITIONS

Medical Product/Medicine

For the purpose of this policy a 'medicinal product' (or a 'Medicine') is defined as a substance or article, or an ingredient of either of these, (not being an instrument, apparatus or appliance) supplied for administration to human beings for a medicinal purpose.

Medicinal Purpose

Means any one or more of the following: treating or preventing disease, diagnosing disease or ascertaining the existence, degree or extent of a physiological condition, contraception, inducing anaesthesia, otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.

Medicinal purpose exclusions:

Disinfectants (being applied to inanimate objects), Reagents, Sterile Water Not for Injection, Un-medicated dressings, ligatures and sutures, Whole blood and products obtainable from the Blood Transfusion Service, Medical Gases except that sections 5.2 and 5.3 of the main policy (i.e. prescribing and administration) apply for Oxygen, Antiseptics used as cleansing agents for the skin and wounds and Barium Contrast media are exempted from the requirements of section 5.2 and 5.3 (i.e. prescribing and administration).

Hospital

Any establishment maintained by the Trust for the prevention and treatment of human ailments.

Controlled Drug

Any medicine included in Schedules 1, 2 3, 4 and 5 of the Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007 and Misuse of Drugs Regulations 2001.

Medical Officer/Doctor

A person registered in the Register of Medical Practitioners maintained in pursuance of the Medical Act 1983.

Dental Officer/Dentist

A person on the Dentists' Register (Dentists Act 1984)

Prescriber
As described in the prescribing section of this policy.

Nurse
Any member of the nursing profession, excluding Health Care Assistants, Health Care Support Workers and Nursery Nurses but including Nurses in training.

Trained Nurse, Qualified Nurse
A Nurse registered on the NMC register and who has a legal right to practice.

Midwife, Practising Midwife
A State Certified Midwife or Registered Midwife who holds a post for which a midwifery qualification is essential and notifies her intention to practice to the local supervising authority.

Appointed Health Care Professional (HCP)-in-Charge
The Senior Sister/Charge Nurse/Midwife or other registered healthcare professional who has continuing responsibility for a ward or department

Assigned Health Care Professional (HCP)-in-Charge
The senior trained nurse/midwife or other registered healthcare professional on duty for the ward or department who has been identified as in charge for that shift.

Health Care Support Workers A person complementary to the Nursing Service who has not received statutory nurse training: Includes Health Care Assistants, Nursing Assistants, Team Assistants and Nursery Nurses.

Operating Department Practitioner (ODP)
A qualified and registered member of the theatre team who has undergone a two year training course to culminate in the attainment of:-

- The Diploma of Higher Education in Operating Department Practice.
- City and Guilds 752/NVQ level 3 qualification in Operating Department practice.
- The Scottish or National Vocational Qualification in Operating Department Practice, Level 3
- The Certificate of Assimilation issued prior to 1980
- The practitioner's name should appear on the register held by the Health Professions Council; any practitioner not so registered must be appropriately supervised.
- An Operating Department Practitioner is responsible to the Senior Anaesthetic and Recovery Nurse/Practitioner and ultimately to the Theatre Manager.

Deputy

A person who is authorised to act in place of another.

Pharmacist
A person registered as a practicing pharmacist by the General Pharmaceutical Council.

Director of Pharmacy
The Pharmacist who is professional head and manager of the hospital pharmaceutical service of the Trust.

Pharmacy Technician
A person registered as a practicing pharmacy technician by the General Pharmaceutical Council.

Chiropodists, Orthoptists, Physiotherapists and Radiographers
Persons registered by the relevant Board under the Professions Supplementary to Medicine Act l960.

External Use
Application to the skin, teeth, mucosa of the mouth, throat, nose, eye, ear, vagina or anal canal.

Writing
Includes any form of notation, whether by hand or by printing and "written" has a corresponding meaning.

Patient's Own Drug (Patient's Own Medicine)
An individually dispensed medicine that has been brought into the hospital by a patient (and therefore legally the patient's own property) or individually dispensed for them by the hospital pharmacy ready for discharge.

Prescribing (Initiation of) Treatment
To order in writing the supply of a medicine for a named patient.

Patient Specific Direction
The traditional written instruction, from a doctor, dentist or nurse prescriber, (or other legally allowed and Trust authorised person) for medicines to be supplied or administered to a named patient for example on the patient's prescription sheet. The majority of medicines are still prescribed, supplied or administered using this process.

Patient Group Direction (PGD)
A PGD is a written instruction for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment. They should be reserved for those situations where they offer an advantage for patient care (without compromising patient safety) and where they are consistent with appropriate professional relationships and accountability.

Authorised Prescribers
Prescribers authorised by the Trust to write prescriptions and patient specific directions.

4 RESPONSIBILITIES AND DUTIES

4.1 The Chief Executive of the Trust has overall responsibility for Medicines Optimisation in the Trust.

4.2 The Accountable Officer for Controlled Drugs is the. Associate Director - Medicines Optimisation

4.3 The Associate Director - Medicines Optimisation is responsible for the day to day operation of safe systems of Medicines Optimisation in the Trust and reports directly to the Chief Executive for this purpose across the whole of the organisation. The Medicines Safety Committee reports to the Trust's Clinical Governance Group, which reports to the Trust Board.

4.4 The Associate Director - Medicines Optimisation is responsible for reporting the Trust's compliance with the Essential Standards of Quality and Safety (as underpinned by the Health & Social Care Act 2008 (Regulated Activities) Regulations 2010) to the Patient Safety Committee every 6 months together with a report of the actions of the Medicines Safety Committee.

4.5 Appropriate risk control measures must be considered by the Medicines Safety Committee and added to the Medicines Policy when new medicines-related risks are identified. The Trust's Risk Register will be updated as necessary.

4.6 Medicine related untoward incidents must be reviewed not less than bi-monthly by the Lead Pharmacist for Medicines Safety and a report made to the Medicines Safety Committee. The Associate Director - Medicines Optimisation must be informed of serious untoward medicine-related incidents as soon as possible after they occur.

4.7 The Appointed HCP in Charge of a clinical area or department has responsibility for putting documented systems in place (i.e. the Trust Medicines Policy, Trust Medicine Policy Standard Operating Procedures, Trust Nursing Procedures plus appropriate local clinical area Standard Operating Procedures) for ensuring the safe and secure handling, storage, supply and administration of medicines within the area of their responsibility.

4.8 Healthcare staff involved with medicines should undertake continuing professional development, keep up to date with changes in medicines and Medicines Optimisation, and regularly update themselves on this policy.

4.9 Before undertaking any medicine related task it is a requirement of the Trust that the person undertaking the task has been appropriately trained to do so and that their competence has been initially assessed.

4.10 It is the responsibility of each individual to work ONLY within his or her own level of competence when undertaking any medicine related task.

4.11 Clinical Consultants are responsible for ensuring that**:**

- Each medical officer in their team has received Trust approved Medicines Optimisation training at induction and is trained to be competent in all aspects of prescribing and in any aspects of the administering, handling and dispensing of medicines that he or she will carry out.
- Each medical officer in their team is aware that all his or her actions associated with medicines must comply with the Trust Medicines Policy (this document) and its associated procedures.

4.12 The professional Head of Service for each staff group is responsible for ensuring that:

- Each person in their profession has received Trust approved Medicines Optimisation training at induction and is trained to be competent in any aspects of the prescribing, administering, handling and dispensing of medicines that he or she will carry out
- Each person in their profession is aware that all his or her actions associated with medicines must comply with the Trust Medicines Policy (this document) and its associated procedures

4.13 Managers responsible for clinical areas**,** wards, or departments must ensure that:

- Each person in their team receives Trust approved Medicines Optimisation training at induction and is trained to be competent in any aspects of the prescribing, administering, handling and dispensing of medicines that he or she will carry out.
- Each person in their team receives Medicines Optimisation updates as approved by the Trust's Medicines Safety Committee
- Their staff know how to access the Medicines Policy and associated procedures via the Trust intranet
- Their staff are fully aware of the policies and procedures applicable to their clinical area, ward or department
- Their staff are trained and competent to carry out any of their duties encompassed by these policies and procedures.

5 MEDICINES POLICY

5.1 PRINCIPLES FOR MEDICINES USE

5.1.1 Medicines used within the Trust must be clinically effective, safe (accepting that this means a benefits to risks judgement will be required) and appropriate for the patient and condition being treated.

5.1.2 It is a trust requirement that all prescribers comply with prescribing expectations set out in the contract with the Commissioners. These include to prescribe within the formulary; adhere to the criteria in NICE TAs and audit where appropriate; follow due process for IFRs and new drug requests and prescribe safely within their sphere of competence

5.1.3 Guidance on safe and appropriate prescribing will be considered and disseminated by the Trust's Medicines Safety Committee and the Worcestershire Area Prescribing Committee. New BNFs will be distributed by pharmacy as they are available, and the most up to date version is available on the Trust intranet (Clinical Systems). Up to date information sources must

always be used and the Medicines Information section of the pharmacy can advise on this. To improve prescribing safety, the Trust is introducing electronic prescribing which will require changes to this Policy as part of the implementation.

5.1.4 Rarely a non-formulary medicine will be required in an emergency situation. In such circumstances an attempt should be made to discuss this with the Associate Director - Medicines Optimisation who may authorise pharmacy to supply the medicine under the High Cost (and Non-Formulary) Medicines Procedure. If this is not possible a senior pharmacist may supply the medicine without authorisation.

5.1.5 When medicines are prescribed in the community but are not included in the Trust's/Worcestershire's formulary, the appropriate goal is to remove anomalous prescribing between community and hospital. When patients enter the Trust on medicines not on the formulary every effort should be made to ensure usage of the patient's own supply for the period of their stay, provided the stay is not prolonged. In such circumstances members of medical, nursing and pharmacy staff will have to play their part in establishing the authenticity of the patient's own supply.

5.1.6 Accepting free samples in the Trust is not permitted. Samples of medicines must NOT be accepted or left in any part of the Trust's facilities. Pharmacy may receive zero cost stock as part of an official clinical trial or Patient Access Scheme.

5.1.7 Medicines with EU market authorisations (Product Licences) may be used for indications or in doses not included in the authorisation ("Off Label") provided the prescriber is able to justify the prescription as being in accordance with a responsible body of professional opinion and complies with MedPolSOP06. It is recommended that when prescribing outside of a product's licence the reason should be explained to the patient. This should pertain particularly to drugs with high potential toxicity or incidence of side effects.

5.1.8 Medicines without an EU market authorisation (Product Licence) may not be used without the approval of the Trust's Medicines Safety Committee or the Associate Director - Medicines Optimisation on behalf of the Medicines Safety Committee unless they are special formulations for named patients of medicines in the Trust's formulary or are for clinical trials approved by the Trust. Prescribers and Pharmacy must comply with the Unlicensed Medicines Policy and Procedures (MedPolSOP05).

5.2 PRESCRIBING OF MEDICINES

All prescribers must act in accordance with national, regional and local prescribing practice. This includes compliance with the local formulary, adherence to NICE TAs. They must follow the agreed procedures to have new drugs added to the formulary or acquire one off specialist treatment via the Individual Funding Request procedures.

5.2.1 Categories of authorised prescribers

a. Medical and dental officers employed by the Trust and any other legally allowed person who has been authorised by the Trust may prescribe for patients.

b. Chiropodists employed by the Trust can authorise certain medicines for external use and those approved by the Chiropodists Board may inject certain local anaesthetics.

c. Dieticians employed by the Trust may specify enteral feeds and dietary supplements for individual patients.

d. Independent (non-medical) Prescribers who have been authorised by the Trust may prescribe medicines within their scope of practice and competence provided they are on the Trust Formulary. Supplementary (non-medical) Prescribers who have been authorised by the Trust may prescribe Trust Formulary medicines according to a Clinical Management Plan agreed with the responsible independent prescriber.

Note: supplementary prescribing is a voluntary prescribing partnership between the independent prescriber (doctor or non-medical independent prescriber) and supplementary prescriber to implement an agreed patient specific Clinical Management Plan (CMP), with the patient's agreement. Following agreement of the CMP, the supplementary prescriber may prescribe any medicine for the patient that is referred to in the plan, until the next review by the independent prescriber.

5.2.2 Non-medical prescribers must always comply with the Trust's Policy and Procedures for Independent and Supplementary Prescribing (WAHT-CG-581)

5.2.3 No staff other than authorised staff may prescribe.

5.2.4 Authorisation of non-medical prescribers

The Medicines Safety Committee is responsible for formulating the Trust's Policy and Guidelines for Non-medical Prescribing. A single register of all authorised non-medical prescribers will be maintained in the Trust by the Trust Non-Medical Prescribing Lead. It is the non-medical prescriber's responsibility to ensure he or she is appropriately registered before prescribing.

5.2.5 Doubts about prescriptions

If there is any doubt about how to interpret a prescription or patient specific direction, or its validity, the prescriber or his or her deputy must be contacted before the medicine is administered or as soon as the doubt arises. If a doubt remains, a pharmacist must be contacted (including the on-call pharmacist out of pharmacy working hours).

5.2.6 Transcribing of prescriptions by pharmacy staff or named nurse practitioners

This relates to the transcribing of the directions to administer medicines on an in-patients medicine chart onto an order form that may be used by pharmacy to prepare the take home medication. It is <u>not</u> prescribing. The order form must be a Trust-approved hard-copy or electronic patient discharge and TTO form.

a. Authorisation of staff to transcribe: Staff seeking permission to transcribe must follow the process detailed in Trust Policy WAHT-CG-581 "Policies and Procedures for transcription of medicines, independent and supplementary prescribing".

b. Controlled Drugs, variable dose medication or cytotoxic medication must be prescribed by an authorised prescriber. Transcribers (who are not independent prescribers), may not transcribe Controlled Drugs.

c. A transcribed TTO may not be dispensed until a pharmacist has professionally checked the TTO against the patient's current medicine chart.

d. If pharmacy has a query relating to a transcribed TTO, it is the individual transcriber's responsibility to resolve it, consulting with the medical team where necessary. If the transcriber has gone off shift or is not available for any reason, the medical team must take over this responsibility.

5.2.7 Prescription requirements

a. Guidance on prescription writing provided in the current British National Formulary (BNF) should be followed at all times.

b. Prescriptions must only be written on prescription charts, forms, or electronic systems approved by the Trust's Medicines Safety Committee. The content of standardised (e.g. pre-printed prescriptions, templates, or e-prescribed order sets) must be approved before use by Medicines Safety Committee (or according to a procedure approved by Medicines Safety Committee)

c. The date(s) and time(s) at which 'once only' and 'regular medicines' are to be administered must be shown clearly on inpatient prescription charts.

d. All analgesics, anti-emetics and any other medicines prescribed in theatre which may affect the choice or timing of subsequent doses on the ward MUST be prescribed on the patient's prescription chart.

5.2.8 The prescription must:

a. Show the patient's hospital number, full name, date of birth, weight (kg), allergy status (see 5.2.18), his or her hospital location (ward/clinic/department), the identity of the consultant responsible for the patient and the patient's address if the prescription is for a Controlled Drug.

b. Show the age of children – for children under 12 this is a legal requirement.

c. Be appropriate, complete, unambiguous, and easily legible (can be read correctly by a person without medical training).

d. When written be in black or dark blue indelible ink using a ball-point pen with sufficient pressure to register on all copies when NCR forms are used

e. Be signed, dated, and include the bleep number of the prescriber.

f. Include the prescriber's PIN number when written by a nurse on an FP10

g. The name of the drug should be written in full using the approved name where appropriate.

5.2.9 The prescription must state the dose must using metric measurements. **Acceptable abbreviations** are:

- 'g' for gram
- 'mg' for milligram
- 'ml' for millilitre.

a. Other abbreviations may cause confusion and must not be used.

5.2.10 "As required" prescriptions must state:

a. The maximum frequency at which treatment may be repeated.
b. Where appropriate, a maximum dose in 24 hours or the criteria under which a medical officer should be contacted.
c. The symptoms/indication for which treatment is prescribed.

5.2.11 Prescribing for children

a. Prescribe paediatric preparations whenever possible to avoid risk of giving adult dosage.
b. Show the age of children. For children under 12 this is a legal requirement on FP10
c. Show a child's weight in kg.
d. Show the intended dose in mg per kg especially for young children, and when prescribing medicines of high risk for any child.

5.2.12 When prescribing oral liquids and injections the dose must be specified by the amount of the active ingredient(s) not the volume to be administered unless the active ingredient is itself a liquid or the medicine is a mixture of several active ingredients (e.g. Peptac).

5.2.13 Abbreviations for route of administration Only those listed below are acceptable:

IV	Intravenous
IM	Intramuscular
INH	Inhalation
NEB	nebulised
NG	Nasogastric
O	Oral
PEG.	Percutaneous Endoscopic Gastrostomy
PR	Per Rectum
PV	Per Vagina
SC	Subcutaneous
TOP	Topical

a. Sublingual, Buccal, Intrathecal, Intradermal, and any other routes to be written in full.

5.2.14 Oxygen prescriptions and nebulised medicine prescriptions must state:

a. Delivery device
b. Percentage (for venturi masks), flow rate (for simple masks and nasal specs) or the oxygen saturation level to which oxygen dose should be titrated to
c. The circumstances in which the patient should be given oxygen if it is prescribed "when required"
d. Prescriptions for nebulised medicines must specify the driving gas (oxygen or air).

5.2.15 Alteration and discontinuation of prescriptions

a. No prescriptions may be altered.
b. Changes must be made by re-writing the prescription. N.B. Change in route, e.g. I/V to oral, constitutes an alteration.
c. Cancellations are made by drawing a diagonal line through the whole prescription, and the reason documented in the patient's notes. The cancellation must be initialled and dated by the authorised prescriber. If this is done by someone other than an authorised prescriber, the name of the prescriber who authorised the prescription to be discontinued should also be written on the prescription.

5.2.16 Number of prescription forms

a. It is essential that only one prescription form of each type is in use for a patient unless the first is completely filled with current treatments, when the two must be attached together with string laces. On both forms it must state that there is a second form e.g. Chart 1 of 2", and "Chart 2 of 2". Multiple charts containing several cancelled prescriptions should be amalgamated onto the minimum number of charts possible at the earliest opportunity. Superseded prescription charts must be cancelled by a diagonal line through the regular prescriptions page with signature of person cancelling.
b. When separate forms are used for prescribing anticoagulants, insulin, etc., these should be indicated on the main prescription chart in the boxes provided.

5.2.17 Validity of prescriptions – Prescriptions will remain valid up to the statutory time limit unless:

a. For in-patients:

a) It has been cancelled.
b) The duration of the course of treatment has been stated and reached. All antibiotic prescriptions must be reviewed daily and should only be continued beyond 5 days if the clinical condition requires it.
c) It is for a previous admission.
d) All administration recording spaces have been filled or cancelled.

e) A second opinion is required under Section 58 of the Mental Health Act 1983 (see relevant Trust Policies).

b. For out-patients:

a) It is more than three months old or for Controlled Drugs – more than 30 days old.

5.2.18 Documentation of risks, allergies and hypersensitivities

a. It is the responsibility of the admitting medical/dental officer to complete a VTE risk assessment and prescribe appropriate prophylaxis where indicated.

b. It is the responsibility of the admitting medical/dental officer to record the allergies, including the nature of the allergy, and hypersensitivities on the prescription chart as well as in the medical notes. Medical officers, pharmacists, nurses and midwives may also document any that become apparent during the in-patient stay. All prescription forms must specify whether or not the patient has any drug allergies / hypersensitivities. Except in a life-threatening emergency, medicines must not be administered to a patient until their allergy status has been confirmed.

5.2.19 Verbal prescriptions / instructions to administer a medicine

a. In exceptional circumstances, where medication has been previously prescribed and the prescriber is unable to issue a new prescription, but where changes to the dose are considered necessary a fax, text message or email may be used to confirm any verbal change to the original prescription. This must be followed up within 24 hours by a new prescription (written instruction to administer) signed by the prescriber.

b. A verbal prescription / verbal order from a remote prescriber is not acceptable on its own (NMC Standard 11).

c. A prescriber may not remotely prescribe a medicine for a patient that has not previously been prescribed for the patient if he/she has not assessed the patient, except in exceptional circumstances (e.g. life threatening situations).

d. In exceptional circumstances if a prescriber needs to remotely prescribe a previously un-prescribed medicine a fax, text message or email must confirm the verbal order before it is administered. This must be followed up within 24 hours by a new prescription (written instruction to administer) signed by the prescriber.

e. Controlled drugs must never be given on a verbal message.

f. The fax or email must be stapled to the patient's existing medication chart.

g. Verbal instructions may ONLY be taken BY THE TRAINED NURSE OR MIDWIFE IN CHARGE OF THE PATIENT/WARD and at his/her discretion. It is the prescriber's responsibility to check for possible interactions with existing therapy.

h. In all cases the nurse or midwife must be satisfied with the identity of the prescriber. If in any doubt about this the verbal prescription must not be accepted.

i. The verbal instructions must be written in the "Once Only" section on the patient's prescription sheet by the nurse or midwife and read back to the prescriber, confirming:

- The patient's name and their Date of Birth or home address
- Age and weight (if a child under 12 years old),
- Name of medicine (approved name where appropriate),
- Route of administration and dosage.
- Abbreviations must not be used.
- The trained nurse must also write:
- "VERBAL PRESCRIPTION",
- The date and time,
- The name of the prescriber,
- His/her own signature.

j. If the message is indistinct the trained nurse must ask for it to be repeated; if this is still not clear it must not be accepted. If the message is The reason for administration of the drug must be documented in the patient's records. The nurse receiving the order must give the medicine, having this checked against the message, as written

5.2.20 Faxing prescriptions from outside units

a. The faxing of prescriptions is only permitted from locations served by the Acute Trust where there is no on site pharmacy. Medicines to take home will generally be prescribed 24 hours in advance. Prescriptions should not be telephoned. Controlled Drug prescriptions may not be faxed or telephoned.

5.2.21 Clarifying prescriptions and patient specific directions

a. All communications with pharmacy on prescription amendments must be between a pharmacist or an authorised pharmacy technician and the prescriber or if the prescriber is absent with his or her deputy. At his or her discretion a pharmacist may clarify (or direct a pharmacy technician to clarify) prescriptions and patient specific directions with the nurse who is taking care of a patient.

b. Clarifications must be recorded clearly on the original prescription sheet, initialled and dated by the responsible pharmacist or authorised pharmacy technician.

c. A record must be maintained in the pharmacy department of pharmacy technicians authorised to clarify prescriptions.

5.2.22 Patient Group Directions (PGD)

a. The preferred way for patients to receive the medicines they need is for a prescriber to provide care for an individual patient on a one-to-one basis. (NICE Medicines Practice Guidelines 2013 https://www.nice.org.uk/guidance/mpg2) To this end the Trust is committed to developing non-medical prescribing further, by including it in Divisional

service reviews and developments Any request for a new PGD must be supported by the Divisional Director of Nursing before being considered for approval by the Medicines Safety Committee.

b. A PGD is a written instruction for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment. They should be reserved for those situations where they offer an advantage for patient care (without compromising patient safety) and where they are consistent with appropriate professional relationships and accountability. Health professionals working under a PGD must act within their own expertise and competence.

c. A multidisciplinary team that includes a senior doctor/dentist, a representative from the professionals who will be using the PGD and a pharmacist must be responsible for developing each PGD. These individuals should sign the PGD. Additionally, the PGD must be approved by the Trust's Medicines Safety Committee, and signed and authorised by the Chief Medical Officer and Chief Nursing Officer and the Chair of the Medicines Safety Committee.

d. The registered health care professionals who may supply or administer medicines under a PGD are specified by the statutory regulations and include: nurses, midwives, health visitors, paramedics, optometrists, chiropodists, radiographers, orthoptists, physiotherapists, pharmacists, dieticians, occupational therapists, prosthetists, and speech and language therapists.

e. Professionals use PGDs as named individuals, and no delegation of the supply or administration of medicines is permissible.

f. A list of who may use a particular PGD must be maintained in the clinical area where it is to be used, by the Health Care Professionals' line manager or the Health Care Professional in charge of the area. This person is responsible for ensuring that the users of the PGD are appropriately qualified, registered, trained and competent to do so.

g. Copies of approved PGD will be held:

- on the trust intranet
- in pharmacy (master copy with clinical and organisational signatures)
- where necessary by each approved practitioner (in the event of a specialist or supply direction).

h. Further details on the requirements for Patient Group Directions may be obtained from Lead Pharmacist for Medicines Safety or the pharmacy site on the Trust Intranet.

5.2.23 Trust Protocols

a. A Trust Protocol is a written instruction for the ADMINISTRATION (NOT supply) of named medicines in a hospital in an identified clinical situation to groups of patients who may not be individually identified before presentation for treatment. They should be reserved for those limited situations where they offer an advantage for patient care (without compromising patient safety) and where they are consistent with appropriate professional relationships and

accountability. Whenever possible a PGD should be used rather than a Trust Protocol.

b. A multidisciplinary team that includes a senior doctor/dentist, a representative from the professionals who will be using it and a pharmacist must be responsible for developing each Trust Protocol. These individuals should sign the Trust Protocol. Additionally the Trust Protocol must be signed and authorised by the Chief Medical Officer and Chief Nursing Officer and approved by the Medicines Safety Committee.

c. Only staff authorised by the Trust to administer medicines may administer medicines under a group protocol. Persons administering medicines under Trust Protocols do so as named individuals, and no delegation of the administration of medicines is permissible.

d. A list of who may use a particular Trust Protocol must be maintained in the clinical area where it is to be used by the Health Care Professional in charge of the area. This person is responsible for ensuring that the users of the Trust Protocol are appropriately trained and are competent to do so safely.

e. Copies of approved Trust Protocols will be held:

- In the clinical area where it is to be used
- In pharmacy
- If necessary by each approved user.
- On the Trust intranet

f. Further details on the requirements for Trust Protocols may be obtained from the Lead Pharmacist for Medicines Safety or the pharmacy site on the Trust Intranet.

5.2.24 Prescribing and Dispensing (Supply)

Separation of duties

There should, other than in exceptional circumstances, be separation of prescribing and dispensing (supply) roles, in keeping with the principles of safety, clinical and corporate governance. Planned exceptions to this for Nurse and Pharmacist Independent Prescribers may be approved by Medicines Safety Committee, provided that

- a clear clinical need has been demonstrated and risk assessment submitted,
- clear accountability arrangements are in place to ensure patient safety and probity, and
- there are audit and clinical governance arrangements in place.

Where the two roles do co-exist, MedPolSOPs 1-3 must be followed (including that another person must carry out a final accuracy check), and where possible, a check for clinical appropriateness should also be carried out.

A medicine may be supplied under a PGD without a prescription providing the supplier is authorised to use the PGD and complies with the requirements of the PGD. A medicine may be administered under a PGD or a Protocol providing the person administering the medicine is authorised, competent to do so, and complies with the

requirements of the Protocol. A medicine may not be supplied to a patient under a Protocol.

Retention of prescription sheet

All prescriptions (except Out-patient and FP10 (HNC) forms) must be filed in the notes and retained for a minimum period of 8 years after the conclusion of treatment (midwifery prescriptions 25 years).

5.2.25 Security of blank FP10 forms and hospital out-patient prescription forms

a. These are controlled stationery and the responsibility of the prescriber using them. This includes their safe (locked) storage but this may be delegated to the trained nurse or midwife in charge of the Department. The pharmacy is responsible for recording the issue of FP10s and Hospital Outpatient Prescription Forms to clinical areas and/or prescribers.

5.2.26 Specimen signatures - prescribers

a. It is the responsibility of the Human Resources Department to send specimen signatures of Medical and Dental Officers, including Locums, on appointment, to the appropriate hospital pharmacy department(s). It is the responsibility of the Professional Manager of non-medical prescribers to send specimen signatures to pharmacy.

5.2.27 Prescriptions amended by a pharmacist

The WAHT clinical pharmacy service operates at both the WRH and AH sites with the aim of providing a clinical pharmacist chart review for all in-patients admitted. The service provides an underpinning quality assurance on the accuracy of prescription charts (please see appendix 3) as well as aiming to optimise therapy, whilst minimising any associated risks.

The service is currently provided in two distinct ways:

I. Via a ward-based pharmacy team who deliver a comprehensive Medicines Optimisation system. The area of coverage for this is funding-dependant and operates over the whole working day (Monday to Friday).

II. Via a traditional pharmacist chart-checking service. This service is provided as a single visit within the working day (Monday to Friday).

The nature and frequency of service delivery is risk assessed and prioritised according to the pharmaceutical needs of patients and where, or when, a service cannot be provided due to resource constraints this is escalated to the Associate Director - Medicines Optimisation and Medicines Safety Committee and added to the Trust risk register.

a. A medicine may be administered against a prescription that has been amended by a pharmacist. Pharmacist amendments will be signed and in Worcestershire Acute Hospitals Trust usually in green ink.

b. A pharmacist may amend a prescription to prevent misinterpretation by the person administering the medicine, to correct an obvious prescribing error or omission, or to ensure the patient receives the appropriate medication or formulation for their condition without contacting the prescriber where the pharmacist is able to fully assess the clinical appropriateness of these changes and it is in the best interests of the patient to do so. This includes making changes to prescribed medicines on the patient's inpatient medication chart or changes necessary after taking a complete medication history. The pharmacist must individually assess the risks/benefits of making such changes without prior discussion with the prescriber.

c. A pharmacist may only initiate new medication if he or she is a qualified non-medical prescriber registered by the Trust, or under a Trust PGD or Trust Protocol.

d. A pharmacist may substitute a medicine, or change the dose of a medicine, after discussion with the prescriber or a member of the medical staff responsible for the patient's care or who is covering for the patient's medical team. Where one medicine has been substituted for another on an inpatient prescription chart after discussion with a prescriber the prescription should be countersigned by the prescriber at the earliest opportunity. On an out-patient prescription or TTO the pharmacist must document that the prescriber has been contacted on the prescription using the abbreviation "p.c."

e. Pharmacists may substitute one medicine for another in circumstances that have been agreed with the Medicines Safety Committee without prior discussion with the prescriber. A record of the change to be made in the patient notes.

f. A pharmacist is individually accountable and responsible for the amendments he or she makes to prescriptions.

5.2.28 Prescribing unlicensed medicines (see MedPolSOP05) and using a licensed medicine outside of its licence "off-label" (see MedPolSOP6)

a. The Medicines Act and Regulations (which incorporate the relevant EU directives) provide exemptions which enable doctors to:

I. Prescribe unlicensed medicines;
II. Use in particular (named) patients, unlicensed products specially prepared, imported or supplied;
III. Use medicines which are not authorised to be marketed, in clinical trials, after approval of the trial by the Medicines and Healthcare products Regulatory Agency (MHRA) either through the Doctors and Dentists Exemption Scheme or, in the case of pharmaceutical industry sponsorship, through the Trials Certificate (Exemption) Scheme;
IV. Use or advise the use of licensed medicines for indications, or in doses, or by routes of administration, outside the recommendations of the licence;
V. Override the warnings and the precautions given in the licence.

b. In each case, the doctor has to be able to justify the action taken as being in accordance with a respectable, responsible body of professional opinion.

c. For I, II, and III above the prescriber will be required to obtain prior approval of the Trust Medicines Safety Committee. The High Cost Medicines (and Non-formulary Medicines) Procedure also applies unless it is a formulation of a medicine in the Trust's Formulary prepared for a named patient.

d. For prescribing in clinical trials approval by a Research Ethics Committee is necessary (see Clinical Trials).

e. In an emergency authorisation to supply an unlicensed medicine may be given by the senior pharmacist on duty and retrospectively submitted to the Medicines Safety Committee through the Associate Director - Medicines Optimisation for approval.

f. The prescriber must ensure that the person(s) administering the medicine have sufficient information for them to do this safely and, wherever possible, provide acceptable evidence for the use of the medicine for the intended indication.

g. In exceptional circumstances the Trust's Medicines Safety Committee may approve Patient Group Directions for medicines to be used outside licensed indications, provided this is justified by best practice and the status of the product is clearly described.

5.2.29 Medicines Policy SOPs for higher risk medicines

a. Some Medicines Policy Standard Operating Procedures describe specific safety measures to be taken with certain medicines which have been identified locally and/or nationally as being associated with higher risks to patients, for example:

- MedPolSOP09 Supply, Administration, Storage and Transfer/TTOs of Insulin
- MedPolSOP14 Policy for reducing the risk of overdose with midazolam in adults
- MedPolSOP23 Supply, storage, prescribing and handling of strong potassium infusions and concentrated potassium solutions
- MedPolSOP28 Safe management of ONCE WEEKLY Methotrexate for non-malignancy on acute admission

5.3 ADMINISTRATION OF MEDICINES

5.3.1 Overall responsibility

a. The prescriber has responsibility for telling the Assigned HCP-in-Charge of a clinical area about any new prescriptions that have been written and that he/she has not administered themselves. It is that HCP's responsibility to ensure that, if necessary, the medicine is ordered from pharmacy and that there is an appropriate member of staff available to administer the medicine at the prescribed times.

b. The Appointed HCP-in-Charge of the clinical area has responsibility for putting documented systems in place (i.e. Trust Medicine Policy Standard Operating Procedures, Trust Nursing Procedures plus appropriate local clinical area Standard Operating Procedures) for ensuring the safe and timely

administration of medicines, for ensuring that medicines are available for administration when needed so that doses are not missed, this is particularly important for time critical medicines, and for allocating trained members of staff to administer medicines (or to supervise patient self-administration of medicines) at the prescribed times.

5.3.2 If a medicine is not available

a. In order to comply with NPSA 2010 RRR009 and other quality standards it is the trust expectation that no prescribed doses are omitted or significantly delayed unless agreed with the prescribing team and/or pharmacist.

b. It is the administering nurse's responsibility to ensure compliance with this on an individual patient basis. When it is needed and the pharmacy is open the person responsible for administering the medicine should request an urgent supply either from their ward-based pharmacy team or their pharmacy department.

c. the pharmacy is closed the medicine should be located using the "Drug Locator" database (click here) and then obtained from the pharmacy emergency drug cupboard or borrowed from another ward. If a supply cannot be located, call the on-call pharmacist.

d. It is the administering nurses responsibility to document the non-administration and raise the issue with the medical team

5.3.3 Competency and accountability

a. The Appointed HCP-in-Charge should ensure that nurses and any other persons authorised to administer medicines are competent in all aspects of the administration of medicines relevant to their level of authorisation, for example performing calculations. The person who administers a medicine is responsible and accountable for his/her actions.

5.3.4 Authorisation to administer medicines

a. Any appropriately trained and authorised member of Trust staff who has been assessed as competent to do so safely may administer medicines that have been prescribed by an authorised prescriber to an individual patient. The medicines may only be administered to that named patient. This principle applies to Trust staff at all levels.

b. An appropriately trained and authorised member of Trust staff may administer medicines under a Patient Group Direction (PGD) provided he or she meets all the conditions of PGDs and has been assessed as competent to do so.

c. The Medicines Safety Committee must approve the training and competency assessment procedure for each staff group. Training and assessment must be led by registered health-care professionals who are themselves authorised to administer medicines and must be under the control of a Trust Lead Health-care Professional e.g. Chief Nursing Officer. Training and assessment records must be maintained together with a Trust register of persons

authorised to administer medicines and the extent of this authorisation (that is which medicines and by which route of administration).

5.3.5 Administration procedures

a. Standard operating procedures (SOPs) must be in place for each staff group and/or clinical area describing a safe system for administering medicines which is designed to minimise the risk of errors and adverse incidents. For example, MedPolSOP20, 21 and 22 describe procedures for the administration of medicines on wards for adults, children and neonates. Suspected adverse drug reactions must be reported as patient safety incidents and following MedPolSOP15 'Reporting Adverse Drug Reactions'

b. The Appointed HCP-in-Charge of a clinical area is responsible for ensuring these SOPs are in place and that medicines are only administered by staff who have been appropriately trained, can demonstrate their competence, and have been authorised by the Trust to administer medicines.

c. Before administering any medicines the administering nurse must check the allergy status of the patient and if in any doubt check in the patient notes and/or with the prescriber before continuing. Except in a life-threatening emergency, medicines must not be administered to a patient until their allergy status has been confirmed.

d. In addition they must check that a completed VTE risk assessment has been completed before administering or withholding low molecular weight heparin e.g. enoxaparin.

5.3.6 Administration by other groups of staff

a. Nurses in training may only administer medicines under the direct supervision of a trained nurse. The supervising trained nurse is responsible for ensuring that the medicine is correctly administered. Nurses in training may NOT administer medicines via the intravenous route (other than replacing infusion bags without additives), via the epidural, intrathecal or spinal route, or by an infusion pump.

b. Physiotherapists may administer medicines by inhalation, topically to the skin, and to joints that have either been prescribed by an authorised prescriber or under a PGD if relevant to the exercising of their profession and provided their training programme has been approved by the Medicines Safety Committee and they can demonstrate competence.

c. Radiographers who have received extended training may administer those prescribed medicines relevant to a radiological examination which have been included in departmental protocols. The training and protocols must have been approved by the Trust Clinical Director for Radiology and the Medicines Safety Committee. Administration is to be checked by a radiologist, trained nurse or another radiographer.

d. A Cardio-pulmonary technician or a Cardiographer may advise the patient on the dose of an inhalation for specific tests provided this has been prescribed by a medical officer. Medicines may only be administered to patients by

Cardio-Respiratory technicians or Cardiographers in accordance with a current Trust Protocol.

e. Health Care Assistants who are not authorised to administer medicines may not be involved in the administration of medicines, except to continue administration of an oral or external medicine once a trained nurse has checked the medicine and the identity of the patient. The HCA must be sufficiently trained to ensure that the administration can be completed safely. The trained nurse remains responsible for ensuring that administration is complete. Similar arrangements may apply to a nursery nurse administering topical preparations during the course of his or her care of a baby.

5.3.7 Checking of administration

Checking of administration by a second person who is also authorised to administer the medicine, or who is a pharmacist, is required for injectable medicines in the following circumstances:

- where a patient's condition makes it necessary
- when administering controlled drugs and two authorised persons are available on duty
- when a dose calculation is required (e.g. volume of liquid, fraction of reconstituted vial to administer, or a weight-related dose is to be administered)
- when administering medicines by intravenous bolus or infusion, via epidural catheter, and by infusion pump
- where **continuous variable rate intravenous insulin infusion (**sliding scale insulin) is prescribed
- administration of cytotoxics by any route
- when the medicine is to be administered to a child under 12 years of age
- when a clinical area's standard operating procedures defines that local circumstances make the involvement of two persons desirable e.g. units dependant on temporary agency or other locum staff
- a person training to administer a medicine(s) must always be checked by a person trained and authorised to administer the medicine(s)

In addition to the above checking of administration requirements, registered **nurses, midwives and ODPs** (agency and Trust employees) must ensure that checking of administration by a second person who is also authorised to administer the medicine, or who is a pharmacist, takes place when administering medicines via the following route:

- intra-muscular injection
- direct subcutaneous injection including **insulin** and **treatment dose low molecular weight heparin**
- subcutaneous infusion
- intradermal injection

The **exceptions** to the second checking of administration requirement for registered nurses, midwives and ODPs are:

- Prophylactic dose of a low molecular weight heparin from a single dose pre-filled syringe (enoxaparin or dalteparin)
- Vaccinations administered by occupational health nurses
- Injectable medicines administered by midwives in an emergency situation or during a home birth when a second person is not present

Any planned variations from this must be approved by Medicines Safety Committee.

The Director of Nursing has authorised Third Party Agency Nurses/ODPs /Midwives and NHSP nurses/midwives/ODPs who are not employed by the Trust to undertake second checking of administration of all injectable medicines **except** chemotherapy, epidurals and paediatric medicines, provided that they have been inducted to the clinical area in line with the Trust agreed process and confirm to the Appointed or Assigned Healthcare Professional-in-Charge that they are trained and competent to do so and have read and understood the Trust's Medicines Policy and Injectable Medicines Policy. The registered practitioner administering the injectable medicine is responsible for informing the Third Party Agency Nurses/ODPs /Midwives and NHSP nurses/midwives/ODPs who are not employed by the Trust about MEDUSA and making it available to them in order for the second check to take place.

When the administration of a medicine is checked by another person, this check must incorporate the whole **administration process e.g. valid prescription, product accuracy, correct patient, check of infusion rate programmed into the appropriate device.**

If there are insufficient staff to administer and check according to this Policy, the Assigned Healthcare Professional-in-Charge must be informed at once who must escalate to the Matron or Nurse / Midwife bleep holder if the situation cannot be resolved, and complete a Datix incident report (with subcategory 'Medicines/Drugs').

5.3.8 Checking calculations

a. When checking calculations all calculations must be conducted independently and the results of the calculations must correspond. If they do not, calculations must be repeated independently. If there is still a discrepancy between the two calculations, assistance should be sought from a third authorised person, doctor or pharmacist.

5.3.9 Ultimate responsibility for administration

a. Except when a trainee is being trained the ultimate responsibility for correctly administering a medicine is that of the person actually administering the medicine.

5.3.10 Recording administration and omitted doses

a. A record of administration must be made, immediately after each administration, by the person administering the medicine and this record must include initialling or signing the relevant patient's in-patient prescription chart

with their own initials. Where a check of the administration is required by a second person their initials must also be recorded. For Controlled Drugs both must sign the register entry.

b. All analgesics, anti-emetics and any other medicines given in one clinical area which may affect the choice or timing of subsequent doses MUST be documented on the patient's prescription chart. If the initial dose is documented on an A&E or Anaesthetic record the prescription chart must be annotated "Drug/dose given in <location>" in the Once Only section of the prescription chart. The date and time of administration must be recorded and it must be signed by the person administering the medicine.

c. The separate administration chart for intravenous infusions, heparin infusions, insulin and oral anticoagulants must be used. A reference to any separate administration charts in use must be recorded on the patients main prescription chart.

d. No medicines are to be omitted or significantly delayed without the prescribing team and/or pharmacist's prior approval. The details of the reason for omission and actions taken to avoid the omission to be recorded in the patient notes.

e. The supervising person must countersign the signature of a student when supervising the administration of medicines.

5.3.11 Principles for the administration of medicines

a. Administration must only be according to a clearly written and unambiguous prescription (see also verbal orders, Patient Group Directions and Trust Protocols).

b. Any authorised person administering a medicine to a patient or checking the administration must be satisfied that she or he knows the therapeutic uses of the medicine, its normal dosage, side effects, precautions and contra-indications.

c. Medicines must be prepared at the time they are required, MEDICINES MUST NOT BE PREPARED IN ADVANCE OF ADMINISTRATION except antibiotic syrups or when it is done by pharmacy staff or when authorised by the Trust's Medicines Safety Committee.

d. For medicines being prepared to administer to patients with swallowing difficulties or via NG/PEG, see Trust NG and PEG Guidelines. The route of administration on the prescription must reflect the route of administration, as dispersing or crushing may render the medicine unlicensed.

e. Before administering a medicine, the person doing so and the checker if there is one must check:

- The identity of the patient, according to Trust Policy to identify all patients (including the use of standardised identity bands) WAHT-CG-019
- That the prescription meets the requirements of the Medicines Policy and the medicine is safe to administer.
- That the due dose has not already been given.

- The expiry date of the medicine has not passed (where a medicine has a 'once opened' expiry date this should be marked on the container)
- The patient is not allergic to the medicine.

f. Except in a life-threatening emergency, the patient's allergy status must be stated on the drug chart before any medicines are administered. If this is missing from the drug chart but a current record is in the patients' notes the nurse or midwife can copy this across signing and dating the entry on the drug chart. If there is no current record that can be transcribed, the nurse must confirm with the prescribing team before they administer any medicines. Wherever possible, the pharmacy team will support the process by ensuring allergy status is confirmed.

g. Ensure that the correct drug in the correct dose is given to the correct person at the correct time by the correct route and that the patient actually takes the medicine.

5.3.12 Doubts

a. If there is any doubt about the content or clarity of a prescription (or instruction to administer a medicine) the nurse or other person authorised to administer must contact the prescriber or his or her deputy before proceeding to administer the medicine. If there is still uncertainty a pharmacist must be contacted (including the on-call pharmacist outside pharmacy working hours). Unresolved uncertainty must be referred to the medical consultant responsible for the patient, without delay.

b. In an emergency, if the prescriber or his or her deputy is unable to attend, the nurse may cancel the doubtful prescription and accept a verbal prescription in its place (see verbal orders).

c. Administration may be according to a prescription amended by a pharmacist.

5.3.13 Where contra-indications to the prescribed medicine are discovered, where the patient develops a reaction to a medicine, or where assessment of the patient indicates that the medicine is no longer suitable, contact the prescriber or deputy without delay.

5.3.14 Any suspicion that a medicine may be defective should be discussed with the most senior pharmacist on duty in the supplying pharmacy (or the on-call pharmacy out of pharmacy working hours) and the procedures for Reporting Defective Medicines (see Section 5.8) should be followed.

5.3.15 Refusal of medicine

a. In general, patients have a right to refuse medicines and covert administration must not be used. Reasons for refusal must be documented.

b. In the following situations discuss with the appropriate medical officer/line manager and document in nursing notes/care plan. Consultation with relatives may also be appropriate - document if this happens:

- An unconscious patient

- A patient without capacity to consent (see relevant Trust Policies).
- Life-threatening situations.

5.3.16 Disposal of individual doses of unused or discarded medicines

a. No medicinal product may be removed from its container or packaging except for immediate administration or for counting purposes (when counting medicines only one container may be checked at a time).

b. Individual doses of unused or discarded medicines must not be returned to their container instead they must be placed in the appropriate waste container specified by the current waste procedures.

c. Apart from individual doses, unwanted medicines should be returned to pharmacy. Controlled Drugs must be collected by an authorised member of pharmacy staff.

d. When returning or discarding medicines liable to misappropriation such as Controlled Drugs a record of the return or destruction must be made and those involved identified.

e. The quantity of individual doses of discarded unused, partially used or partially administered Controlled Drugs must be witnessed and recorded in the Clinical Area's CD Register. If it is a partially administered dose the identity of the patient must be recorded. The witness should preferably be a trained nurse, doctor or pharmacist but if this is not possible another member of Trust staff may witness the disposal and sign the entry in the clinical area's Controlled Drugs register. Where an ampoule is partly used the excess must be discarded. This must be witnessed. Topical patches should be rendered unusable by removing the backing and folding the patch over upon itself.

f. Controlled drugs provided in ready-prepared syringes or infusion bags such as P.C.A. and epidural infusions may be disposed of by injecting or emptying the contents of the syringe or bag into an adequate supply of absorbent paper or pad that has been placed in an appropriate waste container as specified by the current clinical waste procedures. This should be done in the presence of a witness and an entry made in the Controlled Drug (CD) Register stating the volume and strength of drug destroyed and the patient's name. The entry should be countersigned by the witness.

5.3.17 Specimen signatures/initials for administering medicines

a. For Medical Staff specimen signatures see 5.2.26.

b. The Appointed HCP-in-Charge of each clinical area must keep records of signatures and initials of persons authorised to administer medicines.

c. The records of signatures and initials should be kept for as long as the documents on which they may appear.

5.3.18 Reporting of errors in administration of medicines

a. An error is deemed to have been made if one or more of the following circumstances apply:

a) Omissions - any dose not given other than in circumstances where professional judgement has been used. Where a single missed dose may have serious adverse consequences for the patient the prescriber should be contacted and the outcome documented.
b) Wrong dose administered.
c) Extra dose given - any dose given in excess of the total number of times ordered by the medical or dental officer.
d) Unauthorised medicine given - the administration to a patient of any medicine not authorised for that patient.
e) Wrong dosage interval - any medicine given at a time which reduces or extends the dosage interval before the next dose of the same medicine by more than 25% or which exceeds the dose frequency/interval of "As required" prescriptions. In exceptional circumstances local policy approved by the Trust's Medicines Safety Committee may allow the routine variation of medicines administration round times from that pre-printed on prescription sheets.
f) Wrong administration - administration of a medicine by a different route or in a different form from that specified by the prescriber.

b. Whenever an error in the administration of a medicine is found the following action should be taken:

a) The person discovering the error must immediately contact the appropriate medical or dental officer in charge of the patient so that, if necessary, remedial action can be taken to ensure the safety of the patient AND must immediately report the incident to the Assigned HCP-in-Charge of the area.
b) The notified medical officer has a duty to inform the appropriate Consultant as soon as possible within working hours (or at once if the patient has a severe reaction and consultant advice is needed)
c) The Assigned HCP-in-Charge must ensure the incident is documented in the patient's notes along with details of any remedial action taken and the individuals informed.
d) The patient (and/or relatives, depending on circumstances) should be advised at an early stage. How this occurs, and by whom, will need to take account of the nature of the error and any adverse consequences suffered by the patient but it is the responsibility of the Assigned HCP-in-Charge to ensure that it does happen. Any discussions should be documented in the patient's case notes.
e) The Assigned HCP-in-Charge must ensure that a clinical incident report is completed on DatixWeb.

c. For the subsequent investigation of the incident see the Trust Policy for Incident Reporting (WAHT-CG-008).

5.3.19 Administering controlled drugs in theatres

a. The Appointed Nurse, Midwife or ODP in Charge of an operating department is responsible for receiving, checking, and recording stock from pharmacy and for its secure storage and issue. Key holding may be delegated to an Assigned Nurse, Midwife or ODP but the Appointed Nurse, Midwife or ODP in Charge always retains responsibility.

b. Each anaesthetic room must have a Theatre Controlled Drugs Register; recovery rooms that serve more than one operating theatre will have their own register. Theatre registers must show receipt, issue, form of administration (including administration via intravenous infusion or syringe driver), patient details and ampoules/vials returned/disposed of.

c. CDs should be issued to the anaesthetist for a specific patient and any surplus drug not administered to the patient should be destroyed and witnessed (see 5.3.19.e).

d. For continuous administration (e.g. via intravenous infusion or syringe driver) there shall be a record of those involved in setting-up the medication, including the witness. The medical officer concerned in each transaction shall sign for the medicines received on the Theatre Controlled Drugs Register and record the amount of drug administered on the patient's anaesthetic record and as a cross reference on the patient's in-patient prescription chart (this cross reference will provide the necessary record of CD transfer when the patient moves from one clinical area to another AND ensure the patient's medication chart accurately reflects their current medication).

e. Individual doses of Controlled Drugs which are prepared, but not administered shall be destroyed by a qualified person (nurse, midwife, ODP, pharmacist, or anaesthetist) in the presence of a second qualified person. The anaesthetist is personally responsible for safely disposing of any unused drug in an open ampoule or in a syringe.

f. All other Controlled Drugs for destruction (e.g. disposal of out-of-date stocks) must be collected by a pharmacist and taken to the pharmacy to be destroyed. It is the responsibility of the anaesthetist to return any unopened ampoules to the Assigned HCP-in-Charge.

g. In all cases an entry shall be made in the Theatre Controlled Drugs Register that details how a controlled drug has been used or disposed of, including the names of those involved in any return to pharmacy or destruction.

h. Administration by a parenteral route - see Policy and Procedures on the Administration of Injectable Medication WAHT-CG-516. .

The 'Medusa' Injectable Medicines Guide, available on the Trust Intranet, will be used as the standard reference source for injectable medicines.

5.3.20 Administration of intrathecal chemotherapy

a. The administration of intrathecal chemotherapy MUST without exception comply in all aspects with the current national guidelines and the Trust Policy

and Procedures for adult intrathecal cytotoxic chemotherapy WAHT-HAE-004.

b. The Associate Director - Medicines Optimisation is the person responsible to the Chief Executive for ensuring the Trust complies with these guidelines, policies and procedures.

c. Intrathecal chemotherapy must NEVER be administered without the involvement of a pharmacist.

5.3.21 Administration of anaesthetics by an epidural or spinal route

a. The administration of anaesthetics by epidural / spinal cannula must only be performed by a person who has undertaken Trust training (which includes assessment of the epidural block) and who has been assessed as competent in the procedure and the observation and management of patients receiving epidural / spinal analgesia. Each administration must be checked by a person authorised to administer by an intravenous route.

b. The administration line must be labelled with the date and time and should be coloured yellow to identify it as an epidural / spinal line.

c. Standard Operating Procedures for the safe administration of epidural / spinal injections in the clinical area must be kept up to date and followed.

5.3.22 Administration by infusion pump

See Policy and Procedures on the Administration of Injectable Medication WAHT-CG-516

5.3.23 Additions to infusions and injections

See Policy and Procedures on the Administration of Injectable Medication WAHT-CG-516

5.3.24 Ophthalmic preparations

a. Single application units (e.g. "Minims") must be used wherever possible for pre-operative or post-operative procedures. These must be used once then discarded. In other circumstances, a multiple application dropper bottle or ointment tube must be used for single patient.

b. For infected eyes, separate bottles/tubes must be used for each eye if both eyes require treatment and they must be renewed every seven days. If there is no eye infection the same bottle/tube may be used for both eyes and they must be renewed every 28 days.

5.3.25 Administration of oxygen

a. At each medicine round and more frequently when necessary, the authorised person administering oxygen must check and adjust the delivery device and oxygen flow rate to keep the patient's oxygen saturation within the prescribed range. A record of this should be made on the appropriate prescription sheet.

5.3.26 Administration of oral / enteral liquid medicines (see MedPolSOP11)

a. Intravenous syringes MUST not be used to measure or administer oral or enteral liquid medicines.

b. A 5ml spoon or if the volume is 10ml or greater a graduated medicines measure should be used where possible otherwise a single-use (disposable) Oral / Enteral syringes must be used. Oral syringes supplied against out-patients or TTO prescriptions can be those designed for single-patient use.

c. An oral / enteral syringe must be used to administer potent medicines, volumes less than 5ml volumes not a multiple of 5ml. and when the medicine is to be administered via a feeding tube.

5.3.27 Safe handling of cytotoxic medicines (chemotherapy)

a. Handling of cytotoxic drugs is hazardous. Any member of staff involved in the preparation or administration of cytotoxic medicines by routes other than oral should have undergone specific education and training recognised by the Trust. Clinical areas where these drugs may be handled should have available a detailed chemotherapy procedure folder approved by the Lead Cancer Nurse and a Pharmacist. Reference should also be made to the RCN Clinical Practice Guidelines "The Administration of Cytotoxic Chemotherapy Recommendations" (1998 or as amended).

b. The pharmacy reconstitution service must be used whenever possible (normal working hours, Monday to Friday). Pharmacy on-call staff will generally not have received training in this specialist area of work. In clearly defined oncological emergencies alternative arrangements for preparation may have to be considered.

c. NB Suitable areas for preparation are described in the RCN Clinical Practice Guidelines.

5.3.28 Supervised administration of medicines by patients

a. It may be appropriate for some patients to administer certain of their own medicines under supervision of a person authorised to administer medicines. This is distinct from participation in a recognised self-administration scheme. The following categories of medicine may be administered in this way:

- Inhalers
- Glyceryl trinitrate sublingual tablets and spray
- Ointments or Creams
- Insulin preparations and GLP-1 agonist preparations

b. There must be a valid prescription for the medicine. The prescriber or patient's trained nurse may specify that the patient should have ready access to the preparation.

c. The patient must be willing and able to communicate to the trained nurse when a dose has been taken or used. The patient must also be capable of administering the medicine correctly. If this is not the case, the prescriber should be informed and advice from a pharmacist considered. It is the responsibility of the patient's trained nurse to encourage the patient to tell her/him when a dose has been self-administered, to record this on the

prescription chart and to review these records to ensure the medicine is being taken appropriately.

d. The patient's medicine locker need not be locked for these preparations unless there is a hazard to other patients. All medicines self-administered under supervision must meet the suitability criteria in paragraph 5.3.31.d.

5.3.29 Self-administration of medicines by patients (see MedPolSOP13)

a. To extend self-administration by patients beyond that described in "supervised administration of medicines by patients" above, MedPolSOP13 must be followed.

b. MedPolSOP13 allows greater independence of action for patients and there is no limit on the range of medicines covered.

c. Self-administration, with support from staff when necessary, aids compliance and understanding of the medicine and appropriate administration times. It also provides potential for patients to maintain their normal pattern of taking medication and staff the opportunity to reinforce teaching if required.

d. All patients assessed by a trained nurse as being able to self-administer without supervision must sign a Self-Administration Agreement Form (one copy to be filed in the patient's medical notes, one copy for the patient). The participation in self-administration must be shown on the main prescription chart by fixing a "Self Administration" sticker.

e. A medical officer or the Assigned HCP-in-Charge of a clinical area may veto self-administration where considered inappropriate or there is a security risk posed by keeping medicines in a patient's medicines locker.

f. The medicines (which may include Controlled Drugs if individually dispensed for the patient) must be kept in a locked cupboard or drawer and the key must be kept securely in the patient's possession at all times, but see also paragraph 5.3.28 for certain exceptions.

g. Patients who are authorised to self-administer may be requested to maintain a record of self-administration to ensure monitoring of the treatment regime. Alternatively the number of remaining doses may be checked at intervals by a trained nurse and noted on the administration recording section of the prescription chart. Errors discovered in this way are not subject to paragraph 5.3.18, although the patient's continued participation in the scheme should be reviewed.

h. Controlled Drugs that have been individually dispensed by a Trust pharmacy for the patient must NOT be entered in the Ward Controlled Drug register. They should be counted DAILY and the quantity remaining recorded on the patient's prescription chart- no entries in the Controlled Drugs register are required.

5.3.30 Medicines for staff

a. Medicines must not be taken from ward or department stock for personal use by staff. Normally a member of staff will see his/her General Practitioner. In an emergency, staff should attend Accident and Emergency. The

unauthorised taking of Trust medicines is theft and therefore a disciplinary offence.

b. At the discretion of the senior pharmacist on duty, medicines to enable a member of staff to remain on duty may be obtained from the hospital pharmacy on a hospital prescription form signed by a fully registered medical officer. Medicine for a maximum 24 hours treatment will usually be supplied. If for whatever reason the supply will last longer than 24 hours a prescription charge will be levied unless an exemption applies.

c. A Trust Occupational Health authorised prescriber may prescribe a short course of treatment for staff (i.e. maximum 2 weeks) on a hospital prescription form. Unless an exemption applies a prescription charge will be levied.

d. FP10 forms must NOT be used for staff to obtain medicines except following an official outpatient appointment or hospital admission.

e. Clinical areas may keep paracetamol 500mg and ibuprofen 200mg for staff to use but it must be ordered and stored as a controlled drug.

5.3.31 Medicines brought into hospital by patients

a. The person admitting a patient must ascertain whether he or she has brought any medicines into hospital and, if so, ensure safe keeping until seen by a medical officer, pharmacist or pharmacy technician. The patient's own medicines should not be administered unless they have been prescribed on the in-patient prescription chart and approved for use by a doctor, trained nurse, pharmacist or pharmacy technician.

b. Patients' own medicines should, with their agreement, be used whenever possible rather than issuing a new supply from ward stock or pharmacy. For patients on clinical trials medicines, contact Pharmacy.

c. Patients' own medicines may only be administered, returned or re-issued:

- To the same patient.
- Against a prescription written by an authorised prescriber.
- Following a verbal instruction to administer (see paragraphs 5.3.31.d.VI and 5.2.20).
- If the medicines can be approved for use (see below).

d. To be approved for use:

I. Medicines must be in date, in an apparently good condition, and should be medicines a patient has recently been taking (medicines must have been dispensed within the last six months, unless an expiry date is stated on the container).

II. Eye preparations must be used within 28 days of opening. This should be shortened to 7 days if the patient has an eye infection. A new supply should be obtained if the patient is having eye surgery. Patients with eye infections should use separate bottles/tubes of eye preparations for each eye.

III. Medication, other than loose strips, must be correctly labelled with the patient's name, product name and strength, supplier's name and address and date of dispensing. Loose strips should show a batch number and expiry date.

IV. Each container must hold only one type or brand of preparation from a single supply (i.e. mixed batches will not be accepted). Containers holding different drugs or dosage strengths must not be used and should be sent to Pharmacy.

V. Loose strips should be flagged with an addressograph label by the admitting nurse. These must be replaced as soon as possible according to Pharmacy procedures.

VI. If a dose is required before a patient is seen by a medical officer, the patient's own medicine may have to be used following a verbal instruction to administer (paragraph 5.2.21).

e. Patients' medicines should be stored locked in a patient's own medicine locker when these are available but see paragraph 5.3.28 for certain exceptions.

f. When patients are discharged from hospital their own medicines should be used as their discharge medication when this is safe and appropriate. There must be clear standard operating procedures for each clinical area and pharmacy that describes how this will be achieved depending on the type of pharmacy service provided (e.g. whether ward-based or not) see MedPolSOPs 01, 02 and 03.

g. In clinical areas without patient's individual lockable medicine lockers patients' own medicines should be kept in a bag labelled with the patient's name in a locked cupboard until the patient is discharged.

h. If it is necessary to discharge a patient outside Pharmacy working hours and a discharge prescription has not already been obtained, a patient's own medicines held in a clinical area may be returned to him/her by following MedPolSOPs 01, 02 and 03.

i. Medicines that have been retained on the ward but not returned to a discharged patient must be sent to Pharmacy for disposal as soon as practicable.

j. If a patient insists on their medicines being returned home, this must be via an identified adult, normally a relative. The patient and/or patient's agent must be advised if it is not safe for the medicines to be used and must sign that they have received this information (see MedPolSOP7)

k. Controlled Drugs brought into hospital by patients should be recorded in the back of the ward register, or in a separate bound book designated for this purpose. If they are returned to the patient to take home or self-administer, or they are sent to pharmacy this must be recorded. All entries must be signed and witnessed.

l. In a midwife-led unit midwives must ascertain whether an in-patient in the Maternity Unit has brought any medicines into hospital and, if so, remove them to storage in a locked box in the patient's locker. The patient is given a key. There is no requirement for the patient to be seen by a medical officer before they are taken but the midwife must enter details of the medicines, doses, time of administration, etc., on the "Regular Drugs" section of the in-patient prescription

chart. On discharge, medicines may be taken home by the patient unless, in the midwife's professional judgement, this is not appropriate; this must be documented.

5.3.32 Illegal controlled drugs or unidentified substances

a. If a patient is found in possession of suspected illegal drugs, then he or she will be asked to hand it over voluntarily to a member of staff. These will be returned to pharmacy for destruction. If, however, the quantity is so large that the drug could not be purely for personal use, the Accountable Officer Associate Director - Medicines Optimisation or their nominated deputy may decide that the public interest outweighs that patients right to confidentiality and that therefore the police need to be informed.

b. Any member of staff acquiring a known illegal or unidentified substance from a patient/client is required to hand it to the person in charge of the clinical area who will:

a) Put the package, labelled as 'Unidentified Substance', in the Controlled Drugs cupboard or other safe lockable place

b) Record receipt of the substance in the patient's record and inform the doctor caring for the patient

c. Under no circumstances can a known illegal or unidentified substance be handed back to the patient/client, as a person doing so could be guilty of an offence of unlawful supply of a Controlled Drug.

d. If handing over the substance to the police:

a) Check that the police officer, or nominated agent, has appropriate identification (the uniform is not sufficient).

b) The officer will have brought documentation for both parties to sign once the substance is handed over.

c) This document must be given to the Associate Director - Medicines Optimisation who will hold it in safe keeping for a period of two years.

5.3.33 Hazards

a. Some medicines are hazardous on contact to staff and patients (e.g. Cytotoxics). Handling of these substances and other CAUSTIC or TOXIC materials should be in accordance with COSHH Regulations. Special care must be taken. Medicines labelled as flammable must not be used near a naked flame or any equipment which may emit sparks; or stored in a refrigerator that is not spark-proof.

5.3.34 Retention of records of administration

a. All records of administration must be retained after the conclusion of treatment (see “For the Record – Managing Records in NHS Trusts and Health Authorities” HSC 1999/053 as amended and WAHT-CG-127).

b. When a Controlled Drug register is full it must be sealed and retained on the ward or department for a period of 2 years from the date of the last entry, after which time it may be destroyed.

5.4 PURCHASING, REQUISITIONING, SUPPLY, RETURN AND PHARMACY DISPOSAL OF MEDICINES

5.4.1 Overall responsibility

a. The Associate Director - Medicines Optimisation (with delegation as appropriate) is responsible for the procurement and issuing of all medicinal products for the Trust and for ensuring that they are of a suitable quality.

b. When purchasing medicines the purchasing for safety policy (see MedPolSOP19) will be used.

c. The requisitioning, supply (including dispensing), and return of medicines to other Trusts VIA ANY Service Level Agreement (SLA) will be governed by the Acute Trust Medicines Policy and within the specification within the MHRA Wholesaler License.

d. The Associate Director - Medicines Optimisation is not responsible for the quality of any medicine not obtained by the Trust's pharmacy departments.

e. Employees of Worcestershire Acute Hospitals NHS Trust are not empowered to administer medicinal products obtained by any other means unless the medicine has been individually dispensed for the particular patient concerned except that Patient's Own Drugs (see definitions) may be administered to the patient to whom they belong in accordance with the directions of an authorised prescriber.

f. The Appointed HCP in charge of a clinical area is responsible for ensuring that the system for obtaining medicines from the pharmacy and for returning medicines to pharmacy is followed. A 'stock list' should be agreed with Pharmacy.

g. It is the responsibility of the authorised individual requesting and checking receipts from the pharmacy to ensure that the medicines supplied are correct and for providing the issuing pharmacy with a signed receipt for items supplied as stock. The safe-custody of medicinal products in transit from a pharmacy is the responsibility of the messenger and his/her manager.

h. General Sales List (GSL) medicines may be sold to staff and visitors by retail outlets within the Trust's hospitals but the outlet must ensure safeguards are in place to prevent the sale of medicines to hospital inpatients.

i. Medicines belonging to patients who die whilst in hospital must be either returned to an appropriate relative/carer or, with their agreement, be returned to pharmacy for disposal

5.4.2 Obtaining medicinal products for supply or administration to patients and staff

a. All medicines used by the Trust, except patients' own medicines and medicines for use by community midwives MUST be obtained through the hospital pharmacy.

b. Medicines may be obtained by presenting either a requisition or a prescription to a member of the pharmacy team. The quantity, strength and form of each preparation required must be stated on a requisition. Systems should be in place to minimise the need to send in-patient prescription charts to the pharmacy.

c. For Controlled Drugs each preparation needs a separate requisition and the whole Controlled Drug Order book is required by the pharmacy. For other requisitions only the top page(s) of the order should be sent to the pharmacy.

d. Where a top up system is in place, an authorised Pharmacy Assistant may complete the medication order, within the confines of the agreed stock levels. This can be done using a secure login directly onto the Pharmacy Stock Management system, and sent to Pharmacy electronically, or via the printed ward stock lists, which are held in Pharmacy and only brought to the ward during the topping up activity by a Pharmacy Assistant. The top up process includes the monitoring of expiry dates of all those medicines included in the stock list. This does not change the overall responsibility of the Appointed HCP-in-charge as described in 5.5.1

e. Pharmacy Assistants are not authorised to sign stock or non-stock requisition forms from the ward requisition book, nor can they order controlled drugs. The responsibility of checking received medicines when they arrive on the ward lies with the Assigned HCP-in-charge, and any anomalies should be reported to Pharmacy immediately. Pharmacy staff may also record details of non-stock medicines for in-patient use for subsequent supply from pharmacy.

f. In an emergency, when medicines have to be obtained by telephone, the pharmacy record should include the name of the person requesting.

g. Controlled Drugs may not be supplied on telephoned or faxed orders

5.4.3 Requisitions

a. The requisition for medicines must be signed by one of the following:

  a. The Assigned HCP-in-Charge (N.B. the Appointed HCP-in-Charge still retains responsibility). For Controlled Drugs this must be a Nurse, Midwife or ODP.
  b. An authorised member of pharmacy staff providing ward-based supply services

b. Before signature any blank lines on the form must be cancelled.

c. Sample signatures of any staff likely to requisition medicinal products must be provided for the pharmacy.

d. When Controlled Drugs are ordered for stock (see MedPolSOP08 Controlled Drug Stock Lists) the signature on the requisition must be the Assigned

Nurse, Midwife or ODP-in-Charge, who must indicate their status on the form. In exceptional circumstances, following documented agreement by the Trust's Medicines Safety Committee and the Trust's Accountable Officer for Controlled Drugs, an alternative arrangement described in a local SOP may be accepted.

e. Unless otherwise approved by the Associate Director - Medicines Optimisation only one general pharmacy requisition book and one Controlled Drug Order book may be held by each ward or department at any given time and must be kept in a secure place. Loss or theft must be reported immediately to the Appointed HCP-in Charge and to a hospital pharmacist.

f. When full, books must be kept in the ward/department for two years from the date of the last entry. Full Controlled Drug Order books and general Pharmacy requisition books should be marked "Replaced by pharmacy on <Date> on the front cover".

g. The supply of Controlled Drugs by pharmacy to other Trusts must be organised in a manner that complies with the current statutory regulations and an appropriate SOP must be in place and complied with.

5.4.4 Labels

a. Labels on medicine containers must not be altered other than by pharmacy staff (but see paragraph 5.4.10.i). If the label is damaged, obliterated or needs amendment, the container must be updated by the pharmacy team.

5.4.5 Signatures for medicinal products in transit

a. There should be an audit trail for each stage of delivery of pharmacy boxes and packages containing medicinal products when the messenger is not from the Pharmacy or ward/department concerned.

5.4.6 Security in transit

a. All medicinal products which are issued from a pharmacy or returned to pharmacy must be in a locked or sealed tamper-evident container unless:

- Given direct to a patient
- The messenger is a member of the pharmaceutical staff, a nurse/midwife from the ward/department concerned, a community midwife, medical officer or a nursing auxiliary acting under direct instructions from a trained nurse.

b. Packages other than locked / sealed ward boxes must not be left unattended. Locked / sealed ward boxes must be kept in as secure an area as possible and must not be left unattended in a patient area. Delivery vans must be locked when unoccupied.

5.4.7 Receipt of medicines

a. Penicillin-containing stock medicines will be supplied by Pharmacy in a red bag marked 'Penicillin' and **must** be stored in designated Penicillin cupboards.

b. The Assigned HCP-in-Charge of a clinical area, with a witness where possible, must check received medicines as they are stored. Any discrepancies or anomalies must be reported to Pharmacy immediately The signed copy of the picking ticket (issued for all medicines except Controlled Drugs) is returned to the issuing pharmacy, where it will be kept for a minimum period of 2 years.

c. When Controlled Drugs are received, a qualified nurse, midwife, or ODP and another member of staff (a qualified person if available) must check receipt. They should sign the accompanying pink copy of the requisition in the "received by" section. Any errors must be recorded on each copy and countersigned by the witness. The pharmacist in charge of the issuing department must be notified as soon as practicable.

d. For Controlled Drugs the details of receipts must also be entered in the ward register, along with the signatures of the nurse who has received them and the witness.

5.4.8 Unwanted or out-dated medicines

a. Unwanted medicines must be returned to a pharmacy unless there is an exception identified in this policy. Security must be maintained as in paragraph 5.4.6.

b. When patients' own medicines are being returned to the pharmacy they must be sealed in envelopes or bags labelled with the patient's name, hospital number and ward.

c. Controlled Drugs that are no longer required must be handed to a pharmacist to return to the pharmacy. This return must be recorded in the ward register and the entry witnessed by the Assigned Nurse, Midwife or ODP in charge. (MedPolSOP07 must be followed by all persons involved). The appropriate entry in the Pharmacy Controlled Drugs register must be made.

5.4.9 Pharmacy disposal of medicines

a. All medicines must be disposed of according to the Environmental Pollution Act and the current statutory regulations.

b. Pharmacy departments will ensure their SOPs and actions relating to medicines disposal comply with these regulations.

c. The destruction of Controlled Drugs stocks by pharmacy must be recorded and witnessed by a person authorised by the Trust's Accountable Officer for CDs

d. The destruction of patients' own Controlled Drugs sent to the pharmacy must be recorded in a register kept for this purpose by the pharmacy and must be witnessed by a pharmacist.

5.4.10 Medicines to take home

a. Medicines may only be given to a patient to take home, or sent to a patient's home, on the authority of a prescription (written or electronic) from an authorised prescriber or a Patient Group Direction.

b. See paragraph 5.3.31.h for returning patients' own medicines when the pharmacy is closed.

c. Whenever practicable, prescriptions should be sent to pharmacy at least 24 hours before the medicines are required. Each pharmacy has a cut-off time after which TTOs will not be dispensed the same day. When medicines are urgently required from a pharmacy that is off-site the discharge prescription should be sent by fax with, if practicable, the in-patient prescription chart. The pharmacy must receive the original prescription as confirmation within 72 hours. Prescriptions should not be telephoned. Controlled Drug prescriptions must neither be faxed nor telephoned.

d. All medicines that have been dispensed for a patient to take home, whether by pharmacy, a qualified nurse or a doctor, must be checked against the prescription by a qualified nurse, pharmacist, accredited checker pharmacy technician, or a doctor as they are handed to the patient. The checker must not be the dispenser. Any compliance/dosage record cards must also be checked in the same way.

e. All dispensing of medicines by non-pharmacy staff for patients to take home must follow a standard operating procedure for dispensing that has been approved by the Medicines Safety Committee (MedPolSOPs 01, 02, and 03).

f. When a patient is being discharged at short notice and the hospital pharmacies are closed it is the medical officer's responsibility to ensure that discharge medicines are provided using procedures that have been agreed with the pharmacy department (such dispensing is not part of the pharmacy on-call service). The options are:

a) The patient's own medicines may be returned.
b) The patient may agree to obtain non-urgent supplies of their regular medicines from their GP, or other medicines (for example, simple analgesics) from a community pharmacy
c) A FP10 may be issued
d) A TTO or original pack may be issued.
e) If appropriate, any essential evening medicines are administered and the discharge medicines collected by the patient/carer the next morning
f) As a very last resort, a qualified nurse or doctor may dispense the medicine from ward stock or pharmacy emergency cupboard stock following the approved Standard Operating Procedures (MedPolSOPs 01, 02, and 03).

g. Where 'hospital only' medicines are needed for discharge the on-call pharmacist should be contacted.

h. In other extreme circumstances the on-call pharmacist may be asked to dispense medicines for discharge and he/she may agree to do so.

i. A qualified nurse (or doctor) may dispense a prescription for a medicine to take home at any time by adding dose instructions, the name of the patient, and the date of issue to a TTO pack that has been supplied by the pharmacy for this purpose, according to MedPolSOP01, 02 and 03. A qualified nurse (a second nurse if dispensed by a nurse) should check the medicine against the prescription before it is handed to the patient.

j. At the discretion of a qualified nurse, original packs of General Sales List (GSL) medicines and Pharmacy Only (P) medicines supplied by pharmacy for this purpose may be supplied against a prescription. A hospital address label, with the patient's name and the date of issue should be attached to the pack. An appropriate dose and instructions must be printed on the pack. This does NOT apply to Prescription Only (POM) medicines.

k. Suitably trained staff in radiography departments may issue, under local Standard Operating Procedures, a pre-pack of a medicinal product which has been supplied by the hospital pharmaceutical service for that purpose to patients on the patient specific written instruction of an authorised prescriber.

l. A Chiropodist may supply listed medicinal products to a patient for external use only. In all cases there should be a full record of the issue in the patient's notes.

m. In general, prescriptions for in-patients being discharged should be for a minimum of two weeks and normally up to 28 days. If a shorter/longer course is indicated e.g. of steroids or antibiotics the full course should be supplied. If it is appropriate, the pharmacist may apply discretion and supply the manufacturer's original pack.

n. At a pharmacist's or pharmacy technician's discretion a patient's own medicines may be utilised when dispensing discharge medicines. If it has been verified that a patient has sufficient of their own medicines to last 14 days or a supply of medicines at home no supply need be made. This will be recorded on the discharge prescription.

o. Inpatients must not collect their medicines from pharmacy except in exceptional circumstances and by prior agreement with pharmacy in which case Paragraph 5.4.10.d must be complied with.

p. Child resistant containers will normally be used unless otherwise requested on the prescription chart.

5.4.11 Acquiring drugs out of hours

a. Outside normal opening hours for the pharmacy the ward staff will

a) Check availability on other wards using "Drug Locator" on the Trust intranet. A signed order (from the pharmacy requisition book) must be given to the nurse in charge of the ward from which the preparation is taken and a pink copy receipt obtained as in paragraph 5.4.7 and retained on the ward supplying the medicine for not less than two years. For Controlled Drugs the administration to the patient is recorded in the register of the ward which supplies the drug. A nurse from the supplying ward or the designated nurse bleep holder must see the drug administered and signed for in the register and on the prescription chart.

One of the signatures must be a nurse from the borrowing ward (see MedPolSOP07).

b) If not available on another ward check availability in the Emergency Drugs Cupboard using "Drug Locator" on the Trust intranet.

c) Stock can only be taken from the Emergency Drug Cupboard by the nurse bleep holder, nurse in charge of the ward or a doctor. The medicine and quantity taken and patient's name and ward must be recorded in the requisition book provided and the entry signed.

b. If the drug cannot be obtained as in 5.4.11.a, the on call pharmacist should be contacted.

5.4.12 Medicinal products supplied as samples or for use in clinical trials

a. Samples of medicinal products must not be accepted from manufacturers or their representatives. If any are found they should be sent to Pharmacy. No responsibility for product recalls can be accepted unless this procedure is followed.

b. The Associate Director - Medicines Optimisation must be provided with a copy of all trial protocols, including codes, for all studies involving medicines. All medicines for use in clinical trials must be delivered to the Pharmacy (see Section 5.7 Clinical Trials).

5.4.13 Controlled stationery

a. The following items are designated as controlled stationery and are supplied by pharmacy:

- Out-patient and A&E prescription forms
- FP10 forms
- Stock requisition books
- Controlled Drug Order Books

b. Controlled stationery must be kept in a locked cupboard and the key kept on the person in charge of the ward/department. Blank prescription forms/pads must never be left unattended.

5.5 Storage of Medicines

5.5.1 Overall responsibility

a. The Associate Director - Medicines Optimisation is responsible for the safe and secure storage of medicines in the pharmacy and its associated areas.

b. The Appointed HCP in charge of a clinical area is responsible for the safe and secure storage of all medicinal products issued to that clinical area. This includes the monitoring of storage temperatures, expiry dates, the allocation of keys for medicines storage, and the management of stock medicines. She/he may delegate access to another appropriate registered professional,

pharmacist or member of the pharmacy department providing a ward based supply service, but retains responsibility.

5.5.2 Storage requirements

a) The safe and secure handling of medicines requires a patient-centred approach which balances the following needs:

- to have medicines readily available for patients
- to store medicines safely and securely to prevent misselection, maladministration, diversion or tampering
- to ensure the quality of the medicines is assured

Medicines should be stored under conditions which assure the quality of the medicine until the end of administration to the patient. Practice should mirror the RPSGB Safe and Secure Handling of Medicines: A Team Based Approach 2005 guidance

b) excursions in storage temperature requires a response to manage the temperature and a response to manage the risk to the quality of the medicines. This is detailed in MedsPolSOP29

c) the risk based approach to the storage of medicines in clinical areas must follow professional and quality control guidance

d) a pharmacist must be consulted whenever changes to existing medicines storage facilities are planned or new cupboards are proposed.

5.5.3 Medicine cupboards and trolleys

a. All medicines in clinical areas must be stored in a locked cupboard or other secure receptacle; "medicine keys" must be identifiable by the staff in the clinical area but not labelled as such to minimise risks if they are lost.

1. Medicine cupboard keys must be kept separate from other keys and carried on the person of a trained nurse, midwife, ODP, or other qualified person designated by the Appointed HCP-in-Charge.
2. A key safe with a combination lock may be used provided the combination is changed regularly.
3. CD cupboard keys must be carried on the person of the Appointed or Assigned HCP-in-charge when not in use, separate to other medicines keys.
4. CD cupboard keys may only be stored in a key-safe with an access control that automatically records who enters the safe (e.g. swipe card).
5. For areas that are not continually manned, the Senior Nurse Manager must make secure arrangements for storage of keys and the recording of signatures for them.

b. A single set of each of the following must be kept

1. medicine cupboard keys,
2. controlled drugs keys and
3. patient medicines lockers keys

- the nurse in charge or their deputy will hold the medicine cupboard keys and the controlled drugs cupboard keys

- patients medicines locker keys may be kept with the nurse responsible for the care of the individual patient

c. Arrangements for a second set of keys may be made by the appropriate nurse manager; on the exceptional occasion when this set has to be used, a record of its use

d. A set of ward, clinic, A&E and theatre medicines cupboard and bedside locker keys may be held by pharmacy to facilitate the delivery of the Trust's ward based Medicines Optimisation and stock distribution services. A register of keys should be maintained and kept in pharmacy in accordance with the pharmacy ward/department key security policy

e. Loss of keys must be reported to the senior nurse manager on duty, who will arrange an investigation and change of locks or authorise the temporary use of the second set of keys. Locks must be changed if, after a risk assessment by the senior nurse manager, it is considered necessary to prevent unauthorised access to the medicines cupboards.

f. If a CD key is lost this must be reported to the senior pharmacist on duty and MedPolSOP18 followed. Unauthorised access to CDs resulting from loss of keys must be prevented by appropriate means.

g. Medicine trolleys must be secured to the wall except during the medicine round; they must only be used for medicines in current use, but not Controlled Drugs. Pharmacy boxes for the transportation of medicines are to be locked or sealed at all times when containing medicines except during packing and unpacking of the contents and their transfer to the ward's medicine cupboards.

h. Each patient involved in a self-administration of medicines scheme must have a lockable receptacle (e.g. drawer) which is not readily portable.

i. The following need not be locked:

- Medicines in emergency kits
- Medicines administered by patients to themselves under supervision as in 5.3.28

j) The following may be stored within a designated locked area:

- IV fluids, antiseptic and irrigation solutions,
- a single box of water for injection and/or sodium chloride 0.9% for injection, in their original containers

5.5.4 Storage of controlled drugs

a. Controlled Drugs must be stored in the locked cupboard reserved solely for this purpose (not a medicine trolley) unless part of a self-administration scheme (paragraph 5.3.29.f). Stocks must be kept to the minimum practicable informing pharmacy when disposal is required (paragraph 5.4.8.c). A Controlled Drug register must be maintained and kept in a secure place.

5.5.5 Storage of epidural infusions

a. Epidural infusions must NEVER be stored in the same location as intravenous or sub-cutaneous infusions.

b. The storage location for epidural infusions must be clearly labelled and physically separate from other storage locations to prevent epidural infusions being selected in error and administered by the wrong route.

c. There is no requirement to store injections (ampoules, vials) of local anaesthetics separately from other.

5.5.6 Storage of injections

a. If any injection (ampoule or vial) is taken from its original container but not used it must NOT be returned to the container it must be discarded to prevent it being put back in the wrong place and subsequently selected and used in error.

5.5.7 Storage of IV and SC infusions

a. Infusions for intravenous or sub-cutaneous use must always be kept separate from epidural infusions.

5.5.8 Medicines for external use

a. Must be stored in a separate cupboard or, if space does not permit, on a separate shelf, BELOW medicines for internal use.

5.5.9 Refrigerators for medicines

a. Pharmacy staff will label medicines to show when they require refrigeration. A separate lockable medicine refrigerator fitted with a thermometer or other means of having its temperature monitored must be available for areas where medicines may need refrigeration. Refrigerated medicines must never be frozen. Although pharmacy staff will periodically check the temperature of medicine refrigerators it is the responsibility of the Appointed HCP-in-Charge to ensure that the temperature within refrigerators is continuously maintained between 2-8 degrees C. A record of this temperature monitoring must be maintained for inspection by pharmacy staff. Pharmacy must be alerted if the temperature is found to be outside this range for a decision about whether the refrigerator contents may safely be used.

5.5.10 Monitoring of Controlled drugs - daily check

a. The Appointed HCP-in-Charge of a ward or department is responsible for ensuring the ward stocks of CDs are checked at least once every 24 hours, or as agreed by the Associate Director - Medicines Optimisation following a risk assessment. The Appointed or Assigned HCP-in-Charge must carry out this check. The check must be witnessed by another person (preferably qualified) or if this is not possible by another member of staff who has been trained to witness this check. If the balance is correct a dated and initialled record must be made by the nurse and the witness. This record may be in the

Controlled Drugs Register or in a clearly identified bound book reserved for these checks.

b. Whenever a Controlled Drug is administered, the stock of that drug must be checked to verify that the balance is correct. The Controlled Drugs Register must be available at shift handover.

c. Report any of the following immediately to the nurse manager who will initiate an investigation. This must be cascaded up to a pharmacist as soon as possible:

- any entry found to be wrong or not witnessed
- any actual or suspected drug loss
- any incorrect balance
- daily checks not carried out or no record of checks
- any doubt

5.5.11 Monitoring of Controlled Drugs - monthly check

a. The Appointed HCP-in-Charge must personally check each Controlled Drug in stock against the Ward Register AT LEAST ONCE EVERY MONTH then sign and date the balance.

5.5.12 Monitoring of Controlled Drugs by pharmacy staff

a. Pharmacy will ensure independent monitoring of Controlled Drug stock balances at least every three months. This should include checking that Controlled Drugs issued to a clinical area have been entered into the clinical area's register and that there are no trends in Controlled Drug use that cannot be clinically accounted for. An action plan will be agreed between the ward manager and the pharmacist to address any deficiencies. It will be the responsibility of the ward manager to ensure the agreed actions are followed through within the agreed time scale.

5.5.13 Local Intelligence Network (LIN) reporting.

a. A quarterly report of any incident or discrepancy involving CDs must be made by pharmacy to the Trust Accountable Officer and to the Accountable Officer of the LIN.

b. It is expected that the relevant ward manager/sister investigates fully any CD related incidents using MedPolSOP17 or 18, including recording and closing them on Datix.

5.5.14 Monitoring of other medicinal products

a. The Appointed HCP-in-Charge will make ad hoc checks to ensure compliance with the Medicines Policy. Security will be checked and ward/department stocks inspected at least every three months by pharmacy staff.

5.5.15 Record of checks

a. A record shall be kept in each ward or department of all checks made, including the identities of the staff members carrying out those checks, and retained for a period of 2 years from the date of last entry.

5.5.16 Reporting of losses/misuse

a. The loss or suspected loss or misuse of any medicinal product must be reported to the Senior Nurse and a senior pharmacist no later than the next working day; they will jointly agree appropriate investigations. For CDs see also MedPolSOP17 'Investigating Missing CDs Procedure' and MedPolSOP18 'Investigating Missing CD Keys Procedure'. The Senior Nurse will be responsible for notifying any loss under Standing Financial Instructions.

5.6 Supply, Storage, Prescribing and Handling of Strong Potassium Infusions and Concentrated Potassium Solutions

See MedPolSOP23

5.7 Clinical Trial Medicines

5.7.1 Background

Clinical trial medicines (Investigational Medicinal Products - IMPs) are medicines used in any Phase I, II or III Trial, including open label studies, to discover or verify in humans their clinical, pharmacological and/or other pharmacodynamic properties, adverse effects, pharmacokinetics, efficacy or safety.

Clinical trials of medicinal products must be covered by an appropriate Clinical Trials Authorisation (CTA) issued by the MHRA whether or not the medicine has a product licence (marketing authorisation).

The role of the pharmacy service in relation to clinical trials is to safeguard patients, prescribers and the Trust by ensuring that all investigational medicinal products (IMPs) are ordered, stored, issued and used safely and in accordance with the Trial Protocol, the Clinical Trials Authorisation, the Ethics Approval Letter (MREC/LREC), and the Trust's Research and Development Approval Letter.

5.7.2 General principles

a. Official guidance concerning the purchasing, distribution and storage of clinical trial products is encompassed within "The Safe and Secure Handling of Medicines: A Team Approach - A revision of the September 1988 "Duthie Report" (2005). This document recommends that stocks of trial medicines should not be maintained on wards, clinics or in private offices.

b. Clinical trial sponsors must ensure that written procedures exist in the trial protocol for the handling, storage, and issue/dispensing/administration of clinical trial material. The trial's Chief Clinical Trial Investigator and Research Site Principal Investigators must (unless agreed otherwise by the Trust's Medicines Safety Committee) delegate responsibilities to the pharmacy department for:

- Correct receipt and recording of deliveries by a responsible person.
- The safe handling, storage and dispensing of trial medicines.
- Medicines returned from patients and surplus medicines.

- Returning to the sponsor, or destruction of, patient returns and surplus medicines.
- Maintaining IMP accountability records.
- Reconciliation of delivery records with usage, returns, and destruction of surplus stock.
- Safe keeping of randomisation code envelopes.
- Provision of information to trial subjects on how to take the study medication

c. The Associate Director - Medicines Optimisation has overall responsibility for Pharmacy Services to Clinical Trials and for the safe and secure handling of clinical trials medicines.

d. It is the responsibility of the Chief Pharmacists (WRH or AH) reporting to the Associate Director - Medicines Optimisation to ensure that:

e. Each active clinical trial involving IMPs has a Worcestershire Acute Hospitals Trust, Pharmacy Standard Operating Procedure.

f. All actions relating to IMPs are carefully documented including an auditable drug accountability record.

g. All trial materials are of a suitable quality and are stored correctly.

h. All organisations supplying medicines and related products for use in clinical trials must supply these products through the Trust Pharmacy Department.

5.7.3 The investigator

a. In addition to the statutory and regulatory requirements, the Trust's Principal Clinical Trial Investigator must submit the protocol for any clinical trial involving medicinal products whether licensed or not to the Trust's Medicines Safety Committee for approval of the arrangements for their safe and secure handling.

b. May not undertake clinical trials of medicines in the Trust before a EudraCT number has been issued, the MHRA CTA has been issued, a favourable Ethical Opinion has been received, the Trust R&D Committee has given its approval, and the Area Prescribing Committee has issued its approval in writing. The Medicines Safety Committee will only need to give approval where the Lead Pharmacist has identified a potential medicines safety issue which needs review.

c. Must store all trial material in a Trust pharmacy department unless this would seriously impair the process of the trial and an alternative arrangement is approved by the Trust's Medicines Safety Committee. A chief pharmacist or clinical trials pharmacist must approve and periodically inspect the alternative storage.

d. Must prescribe clinical trials medicines according to the format specified in the Trial Protocol. Where this is not specified in detail the investigator must

agree the format with the Trust's Clinical Trial Lead and this must be incorporated into the Pharmacy SOP.

5.7.4 The pharmacy

a. Must hold a copy of the trial information and randomisation codes within the pharmacy department before any trial commences.

b. Must issue clinical trial medicines in accordance with the Trial protocol, the pharmacy department's clinical trial procedures, and the pharmacy department SOP for the particular trial.

c. Must retain the prescription for clinical trials medicines.

d. Must retain the trial information and randomisation codes after the trial is completed unless a central archive is agreed.

5.8 REPORTING DEFECTS IN MEDICINES

5.8.1 When a defect in a medicinal product is discovered or suspected, medical, nursing or other professional staff should immediately report the defect to the senior pharmacist on duty (or the on-call pharmacist) and the senior nurse in the unit. All suspect material must be labelled so it can easily be identified and inadvertent use prevented then retained in a safe place for analysis.

5.8.2 A "Medicine Defect Reporting Form for Wards and Departments" must be completed at ward or department level by a pharmacist nominated by the senior pharmacist on duty together with the medical and nursing staff who discover or suspect the defect. The report must fully identify the product, the defect, the incident, and the person discovering the defect and any other important information.

5.8.3 The medical or nursing staff reporting an incident or defect should make themselves available to discuss the incident or defect with the senior pharmacist on duty.

5.8.4 Medicinal products that may be defective must be withdrawn from use elsewhere in the Trust and areas supplied by the Trust without delay. They must be labelled to prevent inadvertent use and returned to the pharmacy department that issued them. Instructions must be issued to all concerned regarding further use of the medicine.

5.8.5 An assessment of the defect must be made by the senior pharmacist on duty following the Medicines and Healthcare products Regulatory Agency (MHRA) "Guide to Defective Medicinal Products (MHRA 2004).

5.8.6 Assistance should be sought from an approved Quality Control Pharmacist. Other Trusts in the region should be notified of the possible defect if it is considered appropriate to do so.

5.8.7 After following the MHRA assessment procedure, if it is appropriate, the senior pharmacist must report the defect by telephone to the MHRA.

5.8.8 If the defect is in a medical device the current MHRA procedure for "Reporting Adverse Incidents and Disseminating Medical Device Alerts" must be used.

5.8.9 On completion of the investigation the pharmacy department will report back to the staff concerned at ward or departmental level.

5.9 MHRA DRUG ALERTS (INCLUDING RECALLS)

5.9.1 All MHRA Drug alerts are received and managed by pharmacy including, if necessary, outside of pharmacy opening hours via a regional on call cascade system. Wards, departments and clinical staff will be advised by pharmacy of any necessary action that needs to be taken following an MHRA Drug Alert, following internal pharmacy procedures. An audit trail of action taken by pharmacy is retained in pharmacy.

5.9.2 Ward, department and clinic action on receiving notification of a drug alert from pharmacy

a. The Appointed HCP-in-Charge is responsible for ensuring all their staff understand what to do in the event of a Drug Alert being received.

b. The Assigned HCP-in-Charge at the time the Drug Alert is received should make sure he or she has all the details of the defective product including the manufacturer and batch number.

c. Check all possible storage locations for defective stock against these details.

d. If defective stock is found remove it from use immediately. Mark it clearly "DO NOT USE" and return it to the pharmacy department within 24 hours.

e. Arrange with the pharmacy department for replacement stock to be supplied if necessary.

5.10 MIDWIVES – SUPPLEMENTARY POLICY

5.10.1 Midwives shall observe the rules set out in “Midwives rules and standards” (0410) (NMC), “Standards for Medicines Optimisation” (2007/2010) (NMC) and “The NMC code of professional conduct: standards for conduct, performance and ethics” (0410) (NMC) and follow any local policy and/or procedures specified by the Local Supervising Authority or the Supervisor of Midwives. Midwives Exemptions List – midwives may administer and/or supply certain POM medicines without a prescription in the course of their professional practice, in addition to using patient group directions.

5.10.2 Supply and administration of controlled drugs – community midwives

a. The drug of choice for home confinements is meptazinol. If after discussion the mother still wants pethidine, she should be advised to obtain a prescription from her GP and the patient herself shall collect the medicine from the pharmacy at about 36 weeks gestation. The medicine is therefore her property and her responsibility. If the midwife administers the medicine during the course of labour a clear record of administration shall be made on the patient's records. If the medicine is not used, the midwife should act in accordance with the Midwife Rule 7 p22 (NMC 0410) paragraph 7 - Advise mother to destroy in front of midwife or return to Pharmacy - Document this in client notes. NB: A midwife may not return the drugs to a Pharmacy.

b. Where the patient does not have a GP, only Meptazinol may be used.

5.10.3 Supply and administration of Controlled Drugs – hospital midwifery

a. Pethidine is obtained from the hospital pharmacy as in the main Medicines Policy. Midwives may administer pethidine in accordance with the current Maternity Unit midwife exemption practice guidance

5.10.4 Supply and administration of other medicines – community midwives

a. These will be obtained from a hospital pharmacy (Section 5.5 of main policy). For unwanted or out-dated medicines refer to paragraph 5.4.8 of main policy. Certain medicines may be given by a midwife without a prescription (see midwife exemption practice guidance and patient group directions) These practice guidance documents and PGDs are available to view on the intranet. The original document is kept in pharmacy.

5.10.5 Supply and administration of other medicines – hospital midwifery

a. For obtaining supplies and disposing of unwanted medicines refer to the main Medicines Policy.

b. Certain medicines may be given by a midwife using midwives exemptions practice guidance or patient group directions. These are available in each area on the Maternity Unit and on the intranet.

c. Medicines given must be recorded on the patient's Prescription Chart or Partogram with dosage, date, time and midwife's signature. Student midwives who have been appropriately trained to do so may administer medicines on the midwives exemption list under the direct supervision of a registered midwife (this is not the case with Patient Group Directions)

5.10.6 Storage of medicines by community midwives

a. Medicines must be stored in a locked cupboard out of reach of children in the midwife's home or community office. They should not be left in cars overnight.

6 IMPLEMENTATION

6.1 PLAN FOR DISSEMINATION

6.1.1 The implementation of the Medicines Policy and its associated Procedures is led by the lead pharmacists for clinical areas from the Pharmacy Directorate.

6.1.2 Medicines Policy and procedure documents will be published on the Trust inter and intranet, in accordance with the Trust's 'Policy for the development, approval and management of key documents'.

6.1.3 Changes to Medicine Policy and its associated procedures will have a Trust-wide implementation plan that will have been approved by and coordinated through the Medicines Safety Committee.

6.2 DISSEMINATION

6.2.1 A Trust bulletin board notice and Trust-wide email will be used to announce publication of the Medicines Policy and its associated procedures and to announce any changes.

6.3 TRAINING AND AWARENESS

6.3.1 Before undertaking any medicine related task it is a requirement of the Trust that the person undertaking the task has been appropriately trained to do so and that their competence has been assessed initially, and regularly reassessed thereafter. The lead professional for each staff group is responsible for the operation of a system to provide evidence that this requirement is complied with.

6.3.2 It is the responsibility of each individual to work ONLY within his or her own level of competence when undertaking any medicine related task.

6.3.3 Training needs analysis

a. The lead person for each profession is responsible for regularly (at least every year and when requirements change) undertaking a training needs analysis to identify the Medicines Optimisation (Medicines Policy and related policies and procedures) training requirements of their profession.

b. The training needs analysis should be submitted each February to the Medicines Safety Committee (to ensure it is consistent with the Medicines Policy) and to the Trust Training and Development Manager to ensure it is reflected in the Trust's Training Matrix for Medicines Optimisation, which is available on the Trust intranet.

6.3.4 Responsibilities of Consultants, Department Managers and Professional Leads

a. Clinical Consultants are responsible for ensuring that:

a) Each medical officer in their team has received Medicines Optimisation training at induction (Trust induction plus local induction appropriate to their clinical area and duties) and is trained to be competent in all aspects of prescribing and in any aspects of the administering, handling and dispensing of medicines that he or she will carry out.

b) Each medical officer in their team is aware that all his or her actions associated with medicines must comply with the Trust Medicines Policy (this document) and its associated procedures.

b. The lead person for each profession is responsible for ensuring that:

a) Each person in their profession has received Medicines Optimisation training at induction (Trust induction plus local induction appropriate to their clinical area and duties) and is trained to be competent in any aspects of the prescribing, administering, handling and dispensing of medicines that he or she will carry out

b) Each person in their profession is aware that all his or her actions associated with medicines must comply with the Trust Medicines Policy (this document) and its associated procedures

c. Managers responsible for clinical areas, wards, or departments must ensure that:

a) Each person in their team receives Medicines Optimisation training at induction (Trust induction plus local induction appropriate to their clinical area and duties) and is trained to be competent in any aspects of the prescribing, administering, handling and dispensing of medicines that he or she will carry out.
b) Each person in their team receives Medicines Optimisation refresher training on a regular basis according to the Trust's Training Matrix
c) Their staff know how to access the MEDICINES POLICY and associated procedures via the Trust intranet
d) Their staff are fully aware of the policies and procedures applicable to their clinical area, ward or department
e) Their staff are trained and competent to carry out any of their duties encompassed by these policies and procedures.

6.3.5 Medicines Safety Alerts and Training

a. The Trust Medicines Safety Committee is responsible for reporting the Trust's compliance with National Patient Safety Alert System and other medicines safety alerts and for advising the lead professionals of each staff group of the actions required to comply with Alerts.

b. The lead professional for each staff group is responsible for ensuring the training and actions necessary to enable their staff group to comply with safety alerts are implemented within the required time-scales A variety of methods including Medicines Safety Bulletins, trust wide email and intranet "wallpaper" will be used to notify staff of key information as appropriate to the urgency and content.

7 MONITORING AND COMPLIANCE

7.1.1 The Associate Director - Medicines Optimisation together with the Medicines Safety Committee is responsible for monitoring compliance with the Medicines Policy as described in Appendix 3

8 POLICY REVIEW

8.1.1 The policy receives a major review every 2 years, using a timetabled rolling programme which is a standing agenda item on the Medicines Safety Committee agenda

8.1.2 Possible amendments, corrections and changes to the policy are considered by the Medicines Safety Committee , for example in response to incidents and internal / external initiatives at the monthly Medicines Safety Committee meeting.

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10 BACKGROUND

10.1 CONSULTATION

10.1.1 Formal consultation is by the Chief Medical Officer, Chief Nursing Officer, Clinical Directors, Lead Pharmacists and members of the Trust Medicines Safety Committee.

10.1.2 The Medicines Policy and its associated Procedures are developed by the Associate Director - Medicines Optimisation and Trust Pharmacists with input from other disciplines including: Medicine (Chief Medical Officer, Clinical Directors, Clinicians, and Clinical Tutors), Nursing (Chief Nursing Officer, Deputy Chief Nursing Officer, Matrons, ward managers, Nursing Professional Development), Occupational Therapy, Physiotherapy, Dietetics, Radiographers and operating department practitioners (Professional Leads).

10.2 APPROVAL PROCESS

10.2.1 The Medicines Policy and its associated Procedures are formally approved by the Medicines Safety Committee in conjunction with the Trust Chief Medical Officer.

10.3 EQUALITY IMPACT ASSESSMENT

10.3.1 The Medicines Policy and its associated Procedures have been assessed by the Medicines Safety Committee as having NO IMPACT on equality and diversity on the grounds of race, religion/belief, or disability and NO IMPACT on Race Relations.

10.4 FINANCIAL RISK ASSESSMENT

10.4.1 The Medicines Policy and its associated Procedures have been assessed by the Associate Director - Medicines Optimisation and the Medicines Safety Committee as requiring no financial support that is additional to that already in place.

APPENDIX 1. MEDICINE DEFECT REPORTING FORM

Worcestershire Acute Hospitals NHS Trust
Medicine Defect Reporting Form for Wards and Departments
Where information is not readily available this should be indicated on the form.

1. Person reporting the defect

Print name:
Status:
Reporting Officer's telephone no.: Ext.:
Hospital: Ward/Department:
Date of report:

2. Identity of defective product

Brand name:
Generic name:
Manufacturer's name:
Supplier's name:
Dosage form:
Strength or size:
Route of administration:
Container type and size:
Batch/Lot No.: Number of defective items:
Expiry date:

3. Nature of Defect

The defect was linked to a clinical incident YES NO
(If NO go to section 4.)
Name of responsible doctor:
Address: Tel. No.:
Status/position:
Date of incident:

Describe the incident(s) stating whether the incident(s) occurred before, during, or after administration, the time of onset of rigors or other symptoms, etc.:

Record of readings, settings, position of switches, valves, dials, gauges, etc:

Signature of witness(es) to these readings:

Recollections of those present at the incident (attach separate sheet if necessary):

Details of other therapy if relevant (other infusions, drugs etc.): Details of action taken (specimens for blood culture, culture of catheter tip, urine samples taken, use of batch stopped locally, etc.):

Pharmaceutical observations
Name of pharmacist: Tel. No.:
Address:
Describe the defect:

Was the product stored at the correct temperature?
This report refers to:
ISOLATED CONTAINERS / ALL CONTAINERS (delete as appropriate)

Date the batch was introduced onto the market:
Estimated date when the batch was introduced into stock locally:
Estimated amount of batch used locally to date:

Manufacturer's telephone number:
Name of person contacted:
Manufacturer's comments:

Note: Attach a copy of any correspondence with the manufacturer and any manufacturer's report forms etc. that have been completed to this form.

Details of samples and IV giving sets etc sent for analysis (quantity, ref. nos., where sent etc.)
Note: A sample of the defective item(s) MUST be retained in the pharmacy.

Results of analysis:

Signature of pharmacist: Date:

ALL DEFECTS/INCIDENTS MUST BE REPORTED IN ACCORDANCE WITH the current MHRA Procedures WITHOUT DELAY

APPENDIX 2. SELF-ADMINISTRATION AND PATIENT'S OWN MEDICATION CONSENT FORM

Worcestershire NHS
Acute Hospitals NHS Trust

SELF ADMINISTRATION OF MEDICINES AND USE OF PATIENT'S OWN MEDICATION CONSENT FORM

ADDRESSOGRAPH

Name ..... Hospital No.

Address .....

.....

.....

..... D.O.B.....

I agree to be involved in the ward self administration of medicine system and I have received a clear explanation from..... on .....

I am confident to administer my own medication without supervision and I am willing to be responsible for my own actions in relation to taking my medicines.

I understand that my nurse / midwife will check with me daily that I am happy to continue self-administering medication and that I will request assistance if I have any queries or doubts.

I am happy for my own regular medicines to be used during my inpatient stay (for my treatment only) and for those that are no longer suitable for my personal use to be destroyed.

I agree to keep the medication locked in the drawer of my locker and will keep the key in my safe-keeping at all times. I will only give the key to a member of ward staff during my stay and will return the key to my nurse midwife when I go home.

Signature of Patient ..... Date .....

Signature of Ward Staff .....Date .....

WHITE copy: Medical Notes in patient section BLUE copy: Patient's Copy

MedPolSOP13 31/10/2008 PB

APPENDIX 3. MEDICINES POLICY (MEDICINES OPTIMISATION) PROCESS FOR MONITORING COMPLIANCE

ACTIVITY MONITORED	WHERE	AUDIT / MONITORING TOOL	FREQUENCY	BY WHOM	REPORT TO (and complete incident form for all incidents)	ACTION PLAN
Safe and secure handling, purchasing, storage and supply of medicines	Wards and Departments	Essential Standards of Quality and Safety Ward Audit Checklist (WMIDS)	Annual	Ward / Department Pharmacist and / or Technician	Associate Director - Medicines Optimisation and Ward or Dept Manager / Matron / Chief Nursing Officer	Implement plan to achieve compliance, review in 3months
	Pharmacy Departments	Essential Standards of Quality and Safety Pharmacy Department Audit Checklist (WMIDS)	Annual	Lead Operational Pharmacist and / or Dispensary Manager	Associate Director - Medicines Optimisation and Ward or Dept Manager / Matron / Chief Nursing Officer	Implement plan to achieve compliance, review in 3months
Safe and secure handling, purchasing, storage, supply and disposal of Controlled Drugs	Wards and Departments	Essential Standards of Quality and Safety Ward Controlled Drug Audit Checklist (WMIDS)	3-monthly	Ward / Department Pharmacist and / or Technician	Associate Director - Medicines Optimisation and Ward or Dept Manager / Matron / Chief Nursing Officer	Implement plan to achieve compliance, review in 3months Report deviations to Accountable Officer
	Pharmacy Departments	Essential Standards of Quality and Safety Pharmacy Department Controlled Drug Audit Checklist (WMIDS)	3-monthly	Lead Operational Pharmacist and / or Dispensary Manager	Associate Director - Medicines Optimisation and Ward or Dept Manager / Matron / Chief Nursing Officer	Implement plan to achieve compliance, review in 3months Report deviations to Accountable Officer
Prescribing of medicines	Acute Wards and Departments	Inpatient prescription chart check using Professional Checking SOP & Clinical	Daily	Pharmacist	Prescriber / Clinical Lead Pharmacist for Specialty escalate to	If repeated implement training to achieve compliance,

ACTIVITY MONITORED	WHERE	AUDIT / MONITORING TOOL	FREQUENCY	BY WHOM	REPORT TO (and complete incident form for all incidents)	ACTION PLAN
		Pharmacy SOP			Clinical Director	on-going review, escalate to competency procedure
	Non-Acute Wards and Departments	Inpatient prescription chart check using Professional Checking SOP & Clinical Pharmacy SOP	Minimum of Weekly	Pharmacist	Prescriber / Clinical Lead Pharmacist for Specialty escalate to Clinical Director	
	Wards / Depts / Dispensaries	**TTOs** using Professional Checking SOP	All pharmacy dispensed TTOs	Pharmacist	Prescriber / escalate to Clinical Director	
	Wards / Depts	**TTOs** using MedPolSOP 1 & 2	All non-pharmacy dispensed TTOs	Nurse / Midwife / Dr	Prescriber / escalate to Clinical Director & Associate Director - Medicines Optimisation	
	Dispensaries	**Chemotherapy** using Chemotherapy Checking SOP	All prescriptions	Pharmacist	Prescriber / escalate to Clinical Director	
		Intrathecal Chemotherapy using Intrathecal Chemotherapy Checking SOP	All prescriptions	Pharmacist	Prescriber / escalate to Clinical Director & Associate Director - Medicines Optimisation	
		Unlicensed medicines using MedPolSOP 5 & 6	All prescriptions	Pharmacist	Prescriber / escalate to Clinical Director	
		Clinical trial medicines using Clinical Trial SOP	All prescriptions	Pharmacist	Prescriber / escalate to Clinical Director	
Dispensing (non-sterile)	Dispensaries	Accuracy Checking and Error Monitoring SOPs	All prescriptions	Pharmacist / Accredited	Chief Technician / Lead Operational	Review competency and implement

ACTIVITY MONITORED	WHERE	AUDIT / MONITORING TOOL	FREQUENCY	BY WHOM	REPORT TO (and complete incident form for all incidents)	ACTION PLAN
				Accuracy Checking Technician	Pharmacist escalate to Associate Director - Medicines Optimisation	training, reassess
	Wards / Depts	**TTOs** using MedPolSOP 1 & 2	All prescriptions	Nurse / Midwife / Dr	Prescriber / escalate to Clinical Director & Associate Director - Medicines Optimisation	If repeated implement training to achieve compliance, on-going review, escalate to competency procedure
	Ward-based Pharmacy Staff	Pharmacy Training Programme for ward-based staff	On induction and then reassess every 2 years	Accredited Pharmacy Department trainers	Line Manager	Re-assessment every 2 years, implement remedial training, reassess
Sterile Dispensing	Pharmacy Aseptic Dispensing Suite	Farwell Inspection of facility, systems, training	Every 18 months	Regional QC Pharmacist	Chief Executive / Associate Director - Medicines Optimisation	Review facility & competency and implement training, reassess
		Cancer Peer Review	Every 2 years	Cancer Centre Oncology Team	Chief Executive / Oncology Lead Pharmacist / Associate Director - Medicines Optimisation	Review facility & competency and implement training, reassess
		Intrathecal Chemotherapy	Every 2 years	Cancer Centre Oncology Team	Chief Executive / SHA / Oncology Lead Pharmacist / Associate Director - Medicines	Stop Intrathecal Chemotherapy until rectified

ACTIVITY MONITORED	WHERE	AUDIT / MONITORING TOOL	FREQUENCY	BY WHOM	REPORT TO (and complete incident form for all incidents)	ACTION PLAN
					Optimisation	
	Pharmacy Nuclear Medicine Suite	Farwell Inspection of facility, systems, training	Every 18 months	Regional QC Pharmacist	Chief Executive / Associate Director - Medicines Optimisation	Review facility & competency and implement training, reassess
Administration of Medicines	Trust-wide	Medicines Optimisation Competency Assessment Process	At induction and then every 3 years	Nursing Professional Development / Pharmacy / Professional Lead	Line Manager / Professional Lead	Review competency and implement training, reassess
Administration of Injections	Trust-wide	Competency Assessment Process	After training and then every 2 years	Nursing Professional Development	Line Manager / Professional Lead	Review competency and implement training, reassess
Patients self-administration of medicines	Trust-wide	Medicines Optimisation Competency Assessment Process	At induction and then every 3 years	Nursing Professional Development	Line Manager / Professional Lead	Review competency and implement training, reassess
		MedPolSOP13	Yearly	Lead Pharmacist	Dept Manager / Matron / escalate to Associate Director - Medicines Optimisation	Review competency and implement training, reassess

ACTIVITY MONITORED	WHERE	AUDIT / MONITORING TOOL	FREQUENCY	BY WHOM	REPORT TO (and complete incident form for all incidents)	ACTION PLAN
Training Requirements are identified for ALL staff undertaking medicines related duties.	Trust-wide	Trust Training Needs Analysis Medicines Optimisation Training Matrix	Yearly	Trust Training & Development Manager	Line Manager / Professional Lead	Management action to rectify, review
Medicines Optimisation Training is completed for all identified training requirements.	Trust-wide	Trust Training Needs Analysis Medicines Optimisation Training Matrix / Trust Training Records / Training Programme and Competency Assessment Plan	Yearly	Clinical Tutors (Medical Staff), Professional Training Leads (Nursing, Pharmacy, others) / Trust Training Dept to maintain records	Line Manager / Professional Lead escalate to Chief Medical Officer, Chief Nursing Officer, Associate Director - Medicines Optimisation	Review skills, experience and competency and implement remedial training when required, reassess. Escalate to appropriate Management action

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	**Does the Policy/guidance affect one group less or more favourably than another on the basis of:**		
	Race	No	
	Ethnic origins (including gypsies and travellers)	No	
	Nationality	No	
	Gender	No	
	Disability	No	
	Religion or belief	No	
	Sexual orientation including lesbian, gay and bisexual people	No	
	Age	No	
2.	**Is there any evidence that some groups are affected differently?**	No	
3.	**If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?**	n/a	
4.	**Is the impact of the Policy/guidance likely to be negative?**	No	
5.	**If so can the impact be avoided?**	n/a	
6.	**What alternatives are there to achieving the Policy/guidance without the impact?**	none	
7.	**Can we reduce the impact by taking different action?**	no	

If you have identified a potential discriminatory impact of this key document, please refer it to Assistant Manager of Human Resources, together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact Assistant Manager of Human Resources

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	no
2.	Does the implementation of this document require additional revenue	no
3.	Does the implementation of this document require additional manpower	no
4.	Does the implementation of this document release any manpower costs through a change in practice	no
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	no
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval