

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
	For all amendments previous to March 2024 please see version control section 10.5	
March 2024	<p>3. Definitions - inclusion of paramedics and dieticians, update to ODP definition. Inclusion of Maternity Care Assistant and Maternity Support Workers. Update from Physician Assistant to Associate. Addition of Exemptions (to the Human Medicines Regulations 2012). Update to Prescribing and PSD to include electronic orders and pharmacist prescribers.</p> <p>5.1.3 Updated terminology e.g. <i>Herefordshire and Worcestershire Medicines and Prescribing Subcommittee</i> and Joint Medicines Formulary, removal of references to Medicines Information section in Pharmacy and distribution of hard copy BNFs</p> <p>5.2.6 Update to exclude transcribing for TTO (supply) and remove reference to the NMP Policy as transcribing no longer included.</p> <p>5.2.13 Addition of b. Where medicines are prescribed for alternative routes (e.g. IM or IV) the correct dose for each route must be clearly specified</p> <p>5.2.17 Validity of prescriptions – a planned variation to the 6-month limit may be approved by MSC</p>	Medicines Safety Committee

5.2.18 Addition of 'Trainee pharmacists and accredited pharmacy technicians may document allergies on the prescription chart, according to Pharmacy procedures.'

5.2.22 and 5.3.4.4 Reword to include reference to Discretionary Medicines Policy for administration of GSL/P medicines including use of HMR 2012 Schedules 17 and 19 exemptions instead of PGDs as per new MedPoISOP35

5.2.26 Security of Outpatient prescriptions – reword to replace NIC with Registered HCP in charge

5.2.29 Unlicensed and Off-label medicines - update to reflect revised MedPoISOP5 (combined with MedPOISOP6 which is withdrawn)

5.2.31 Retitled 'Prescribing of Systemic Anti-Cancer Therapy (SACT)', text replaced by signpost to WM Network Guidelines on the intranet which contains the same content

5.3.6.2 Update to replace the list of routes that a RNA can administer by with confirmation that RNAs will be supported by the Trust with appropriate levels of supervision and training for medicines management, including for safety critical medicines where a list is approved by Medicines Safety Committee.

5.3.6.5 Update to clarify that 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 an authorised prescriber (i.e. can be a non-medical prescriber)

5.3.7 Update to clarify that checking of administration requirement only applies to CDs recorded in the Controlled Drug Record Book, that Nursing Associates may second check medications they are permitted to administer, and the requirement to second check IM SC and intradermal injections also applies to RNAs. Additional exception to second checking of peer vaccinators.

5.3.10.7 Additional point to include that 'Where an electronic prescribing and administration system is being used, a record of the person administering and checking (and any omitted doses) will be made automatically'.

5.3.15 Covert administration – text unchanged for now but MedPoISOP to be developed containing proposed content from Head of Safeguarding and policy text will be updated to be consistent.

5.3.19 Administering CDs in Theatre
Signpost to MedPoISOP7 CD Procedure and 'Procedure for the safe and secure handling of medicines in Theatres WAHT-THE-019', removal of duplicated content

5.3.20 Update to clarify that the Intrathecal Chemotherapy Lead is the person responsible to the Chief Executive for overseeing compliance with the Trust Policy and Procedures for adult intrathecal cytotoxic chemotherapy WAHT-HAE-004

5.3.26.2 Addition of CDs to 'An oral / enteral syringe must be used to administer potent medicines (including CDs), 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 systemic anti-cancer therapies (SACT) - text replaced by signpost to WM Network Guidelines on the intranet which contains the same content (Section 6). Retention of local

	<p>detail i.e. re pharmacy reconstitution service and Trust Waste Management Policy.</p> <p>5.3.29 Self-administration of medicines by patients – removal of signpost to MedPolSOP13 and replaced by ‘a local procedure approved by MSC’.</p> <p>5.3.31.11 Inclusion of reference to recording Controlled Drugs brought into hospital by patients in the Patients’ Own Controlled Drug Record Book</p> <p>5.3.44 Additional point to recognise that where a PGD is not legally required to administer a medicine without a prescription (e.g. medicines with legal status GSL/P or legal exemptions exist for medicines given in an emergency), an appropriately trained and authorised member of Trust staff may administer medicines according to administration protocols or the Emergency and Discretionary Medicines Policy (MedPolSOP35).</p> <p>Renumbering of section 5.4</p> <p>5.4.1.2/3 Removal of reference to Falsified Medicines Directive</p> <p>5.4.1.4 Removal of contrast media from examples of medicines for which the Director of Pharmacy may delegate responsibility for procurement.</p> <p>5.4.6.3 Additional point ‘Where external contracted delivery drivers or taxis are used, their identity must be confirmed before the sealed package is handed</p> <p>5.4.10 Medicines to take home - signposting to MedPolSOP1 and removal of duplicated content. Addition of requirement for ward to supply a sharps bin if patient being discharged on injectables.</p> <p>5.4.13 Requirement to order Controlled Stationary in the CD Order Book added</p> <p>5.5.17 Storage of Medical Gas cylinders – addition of ‘The storage location should be visible to nursing staff and not in corridors close to ward exits’</p> <p>5.6.3 Clinical trials Investigator - reword to reflect that not all trial protocols have to be routinely submitted to MSC, but should be if safety concerns are identified by the Lead Pharmacist Clinical Trials</p> <p>5.8 MHRA Medicines Notifications/Recalls and Shortages – updated terminology</p> <p>5.9 Midwives Supplementary Policy – updated standards for midwives and to reflect that pethidine is used for home births (not meptazinol), student midwives cannot administer CDs using Midwife Exemptions, and that community midwives do not keep any drugs at home - all drugs for homebirths should be kept locked in community midwife offices (fridge or cupboard as required)</p> <p>6.3.5 Medicines Safety Alerts and Training</p> <p>updated in accordance with</p>	
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	<p>NHS England » Introducing National Patient Safety Alerts and to reflect the role of the Medicines Safety Officer and Committee</p> <p>References – updated, including addition of NHS England » Enduring standards and general principles from previously issued patient safety alerts and removal of individually referenced archived NPSA alerts</p> <p>Appendix 2 Medicines Policy SOPs – updated with new MedPoISOPs:</p> <p>MedPoISOP34 Potassium Permanganate Procedure and Patient Information</p> <p>MedPoISOP35 Emergency and Discretionary Medicines Policy</p> <p>MedPoISOP36 Automated Medicines Storage Cabinets (Omniceil)</p> <p>Withdrawal of MedPoISOP6 (now merged with MedPoISOP5), MedPoISOP13 Self-administration (now approved individually) and MedPoISOP25 Managing staff involved in medication errors</p> <p>Other minor updates to terminology and references throughout</p>	
March 2025	<p>Added MedCarts as alternative to medicine trolleys throughout</p> <p>2.3 Extended scope to include reference to electronic prescribing and medicines administration</p> <p>5.2.27 Updated section to state that signatures of medical staff are retained by Medical Staffing</p> <p>5.3.15.3 Expanded on and included advice regards covert administration</p> <p>5.3.31.11 Included reference to POD CDs destruction at ward level</p> <p>5.8 Removed reference to Supply Disruption Alerts, now Medicines Supply Notifications</p> <p>References: updated (Radiopharmaceuticals and Chief Pharmacist responsibilities)</p>	Medicines Safety Committee
June 2025	<p>Addition of wording at 2.4 and 5.2.18c to confirm that from 17th June 2025, Sunrise EPR will become the Trust's primary system for recording and viewing patient allergy and intolerance information.</p>	Medicines Safety Committee

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1. 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.

2. 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.
- 2.3. This policy will be supplemented by a MedPolSOP for Electronic Prescribing and Medicines Administration. Where there are references to the prescription and/or medicines administration chart in this document the principles will also apply to EPMA although the processes for managing these in the electronic system may be different.
- 2.4. From 17th June 2025, Sunrise EPR will become the Trust's primary system for recording and viewing patient allergy and intolerance information. Direct entry into PAS will be disabled, and only clinical staff will have permission to record allergies in Sunrise. While existing allergy processes on paper records or other clinical systems may continue in parallel, all allergy information must also be entered into Sunrise from the transition date. Non-clinical staff will not be permitted to add or update allergy information in Sunrise. See also 5.2.18c

3. Definitions

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.
Advanced Clinical Practitioner (ACP)	An experienced registered healthcare practitioner who demonstrates a level of practice characterised by a high level of autonomy and complex decision-making
Authorised Prescribers	Prescribers authorised by the Trust to write prescriptions and patient specific directions.
Chiropodists, Orthoptists, Paramedics, Dieticians, Physiotherapists and Radiographers	Persons registered by the Health & Care Professions Council relevant Board under the Professions Supplementary to Medicine Act 1960.

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.
Controlled Drugs Accountable Officer (CDAO)	A person nominated with responsibility for the safe and secure handling of controlled drugs in WAHT. This named person is the Director of Pharmacy/Associate Director of Medicines Optimisation.
Dental Officer/Dentist	A person on the Dentists' Register (Dentists Act 1984)
Deputy	A person who is authorised to act in place of another.
Director of Pharmacy/ Associate Director for Medicines Optimisation	The Chief Pharmacist is professional head and manager of the hospital pharmaceutical service of the Trust.
Exemptions (to the Human Medicines Regulations 2012)	These permit some medicines to be administered or supplied without prescription in defined circumstances (e.g. for the purposes of saving life) or by certain HCPs (e.g. midwives in the course of their practice)
External Use	Application to the skin, teeth, mucosa of the mouth, throat, nose, eye, ear, vagina or anal canal.
Health Care Support Workers (HCSW)	A person complementary to Nursing and Midwifery Services who has not received statutory nurse or midwifery training: Includes Health Care Assistants, Nursing Assistants, Team Assistants, Nursery Nurses, Maternity Care Assistants and Maternity Support Workers
Hospital	Any establishment maintained by the Trust for the prevention and treatment of human ailments.
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 (with the exception of oxygen where sections 5.2 and 5.3 of the main policy apply (i.e. prescribing and administration) and antiseptics used as cleansing agents for the skin and wounds. Barium contrast media are exempted from the requirements of section 5.2 and 5.3 (i.e. prescribing and administration).
Medication Incidents	are Patient Safety Incidents involving the prescribing, preparing, dispensing, administering, monitoring or providing advice on medicines. A Patient Safety Incident is 'any unintended or unexpected incident, which could have or did lead to harm for one or more patients receiving NHS care.'
Medical Officer/Doctor	A person registered in the Register of Medical Practitioners maintained in pursuance of the Medical Act 1983.
Medical Student	A student enrolled at a medical school, who is training to become a physician. They are not allowed to undertake prescribing.

Midwife, Practising Midwife	A Registered Midwife who is live on the NMC Register and has revalidated in accordance with the NMC requirements.
Nurse	Any member of the nursing profession, excluding Health Care Assistants, Health Care Support Workers and Nursery Nurses but including Nurses in training.
Nursing Associate	A band 4 registered nurse with the NMC foundation level nurse training
Trained Nurse, Qualified Nurse	A Nurse registered on the NMC register and who has a legal right to practice.
Operating Department Practitioner (ODP)	A qualified and registered member of the theatre team who is registered with the HCPC as an ODP
Paramedics	A qualified and registered member of the clinical team who is registered with the HCPC as a paramedic
Prescriber	As described in the prescribing section of this policy.
Pharmacist	A person registered as a practicing pharmacist by the General Pharmaceutical Council.
Pharmacy Technician	A person registered as a practicing pharmacy technician by the General Pharmaceutical Council.
Pharmacy Assistant	A person who works under the direction of a registered technician/pharmacist and has acquired the NVQ level 2 qualification
Physicians Associate	A person who supports doctors in the diagnosis and management of patients. They are not registered and not allowed to undertake prescribing.
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 or electronically the supply of a medicine for a named patient.
Patient Specific Direction	A written or electronic order from a doctor, dentist or nurse or pharmacist prescriber, (or other legally allowed and Trust authorised person) for medicines to be supplied or administered to a named patient. 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.
Transcribing	The accurate copy of previously prescribed medicines details to enable their administration in line with legislation i.e. in accordance with the instructions of a prescriber.
Written Instruction	A written and signed instruction (under Schedule 17 of the Human Medicines Regulations 2012) from a doctor, which can be used by the named registered nurse (s) providing Occupational Health Services to administer or supply a medicine. This arrangement is not subject to the legislated framework of a PGD
Writing	Includes any form of notation, whether by hand or by printing and "written" has a corresponding meaning.

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 Director of Pharmacy.
- 4.3. The Director of Pharmacy is responsible for the day-to-day operation of safe systems of Medicines Optimisation and Medicines Management 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 Quality Governance Committee, which reports to the Trust Board.
- 4.4. The Director of Pharmacy is responsible for reporting the Trust's compliance with the Fundamental Standards (Care Quality Commission (Registration) Regulations 2009 (part 4) (as underpinned by the Health & Social Care Act 2008 (Regulated Activities) Regulations 2014) to the Quality Governance Committee at least 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. All staff, including agency and contracted staff are required to report medication incidents and near misses to the senior member of staff on duty within their ward or department and record the event using Datix. (Trust Policy for Incident Reporting WAHT-CG-008)
- 4.7. Medicine related incidents causing harm must be reviewed quarterly as a minimum by the Lead Pharmacist for Medicines Safety/Medicines Safety Officer and a report provided to the Medicines Safety Committee. The Director of Pharmacy must be informed of serious medicine-related incidents as soon as possible after they occur.
- 4.8. 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.
- 4.9. 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.
- 4.10. 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.
- 4.11. It is the responsibility of each individual to work ONLY within his or her own level of competence when undertaking any medicine related task.

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

- 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.
- It is a Trust requirement that all prescribers comply with prescribing expectations set out in the contract with the Commissioners E.g. Commissioning for Quality for Medicines Management. These include to prescribe within the Formulary; adhere to the criteria in NICE Technology Appraisals (TAs) and audit where appropriate; follow due process for Individual Funding Requests (IFRs) and new drug requests and prescribe safely within their sphere of competence
- Guidance on safe and appropriate prescribing will be considered and disseminated by the Trust's Medicines Safety Committee and the Herefordshire and Worcestershire Medicines and Prescribing Subcommittee. The most up to date version of the BNF/BNFC is available on the Trust intranet (Clinical Systems). Up to date information sources must always be used and Pharmacy can advise on this. To improve prescribing safety, an Electronic Patient Record (EPR) has been implemented which includes electronic prescribing. This will require changes to this Policy as part of the implementation (during 2024/2025).
- 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 Director of Pharmacy or delegated deputy 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.
- When medicines are prescribed in primary care but are not included in the Herefordshire and Worcestershire Joint Medicines 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.
- The use of 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, Free of Charge scheme, compassionate medicines use or Patient Access Scheme.
- 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 MedPolSOP05. 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.
- Medicines without an EU market authorisation (Product Licence) may not be used without the approval of the Trust's Medicines Safety Committee or the Director of Pharmacy on behalf of

the Medicines Safety Committee unless they are special formulations for named patients of medicines in the 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 and indications and adherence to NICE Technology Assessments (TAs). They must follow the agreed procedures to request new medicines to be 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 and supply 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 Formulary. Supplementary (non-medical) Prescribers who have been authorised by the Trust may prescribe Formulary medicines according to a Clinical Management Plan agreed with the responsible independent prescriber.

5.2.2. Non-medical prescribers must always comply with the Trust's Non-Medical Prescribing Policy (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 guidance for non-medical prescribers. 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 they are appropriately registered before prescribing. Refer to Trust Non-Medical Prescribing Policy (WAHT-CG-581).

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

- a. This relates to the transcribing of the directions to administer medicines on an in-patient medicine chart. It is not 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 these medicines.

5.2.7. Prescription requirements

- Guidance on prescription writing provided in the current British National Formulary (BNF) should be followed at all times.
- Prescriptions must only be written on prescription charts, forms, or electronic systems approved by the Trust's Medicines Safety Committee. The content of standardised prescriptions (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)
- The date(s) and time(s) at which 'once only' and 'regular medicines' are to be administered must be shown clearly on inpatient prescriptions.
- 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 ward prescription.

5.2.8. The prescription must:

- 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.
- Show the age of children – for children under 12 this is a legal requirement.
- Be appropriate, complete, unambiguous, and easily legible (can be read correctly by a person without medical training).
- 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
- Be signed, dated, and include the bleep number of the prescriber. The use of stamps is recommended
- Include the prescriber's PIN number when written by a nurse on an FP10
- The name of the medicine should be written in full using the approved name where appropriate.

5.2.9. The prescription must state the dose, using metric measurements.

Acceptable abbreviations are:

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

Other abbreviations may cause confusion and must not be used.

5.2.10. "As required" prescriptions must state:

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

5.2.11. Prescribing for children

- Prescribe paediatric preparations whenever possible to avoid risk of giving adult dosage.
- State the age of children. For children under 12 this is a legal requirement on FP10
- 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. Route of administration

Only those abbreviations listed below are acceptable:

<i>IV</i>	Intravenous
<i>IM</i>	Intramuscular
<i>INH</i>	Inhalation
<i>NEB</i>	Nebulised
<i>NG</i>	Nasogastric
<i>O</i>	Oral
<i>PEG</i>	Percutaneous Endoscopic Gastrostomy
<i>PR</i>	Per Rectum
<i>PV</i>	Per Vagina
<i>SC</i>	Subcutaneous
<i>TOP</i>	Topical
Sublingual, buccal, intrathecal, intradermal and any other routes to be written in full.	
Where medicines are prescribed for alternative routes (e.g. IM or IV) the correct dose for each route must be clearly specified.	

5.2.14. Oxygen prescriptions and nebulised medicine prescriptions must state:

- Delivery device
- 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
- The circumstances in which the patient should be given oxygen if it is prescribed "when required"
- The driving gas (oxygen or air) for nebulised medicines

5.2.15. Alteration and discontinuation of prescriptions

- No prescriptions may be altered.
- Changes must be made by re-writing the prescription. N.B. Change in route, e.g. I/V to oral, constitutes an alteration.
- 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:

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 at least every 72 hours with a documented reason for continuation and should only be continued beyond 5 days if the clinical condition requires it.
- c. All administration recording spaces have been filled or cancelled.
- d. A second opinion or patient consent is given as required (refer to Use of the Mental Health Act in an Acute Hospital Setting (WAHT-KD-026))

For out-patients:

- a. It is more than 6 months old or for Controlled Drugs – more than 28 days old. A planned variation to this may be approved by Medicines Safety Committee.

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. All prescriptions must specify whether or not the patient has any drug allergies / hypersensitivities. 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 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. Trainee pharmacists and accredited pharmacy technicians may document allergies on the prescription, according to Pharmacy procedures.
- c. From 17th June 2025, Sunrise EPR will become the Trust's primary system for recording and viewing patient allergy and intolerance information. Direct entry into PAS will be disabled, and only clinical staff will have permission to record allergies in Sunrise. While existing allergy processes on paper records or other clinical systems may continue in parallel, all allergy information must also be entered into Sunrise from the transition date. Non-clinical staff will not be permitted to add or update allergy information in Sunrise.
- d. 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 secure email (nhs.net) 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. The email (as above) must be stapled to the patient's existing medication chart.
- c. A prescriber may not remotely prescribe a medicine for a patient that has not previously been prescribed for the patient if they have 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 secure 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. 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.
- g. 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.
- h. 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
 - 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.
- i. 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

- a. The use of faxes is not allowed. Alternative arrangements such as using secure emails must be used.

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.

5.2.22. Patient Group Directions (PGD)

- a. The preferred way for patients to receive the medicines they need is for a prescriber to prescribe treatment for an individual patient on a one-to-one basis. The Trust is committed to developing non-medical prescribing by including it in Divisional service reviews and developments. Requests 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.
- c. Health professionals working under a PGD must act within their own expertise and competence. Bank staff working regularly in the same area may be authorised to use PGDs, providing they have completed the same training and competency assessment process. Agency staff may not use PGDs.
- d. Where a PGD is not legally required to administer a medicine without a prescription (e.g. medicines with legal status GSL/P or legal exemptions recognised in this Policy for medicines given in an emergency or by certain HCPs), an appropriately trained and authorised member of Trust staff may administer medicines according to the Emergency and Discretionary Medicines Policy (see MedPolSOP35) or other administration protocols approved by Medicines Safety Committee

Refer to the procedure associated with the development, approval, review of PGDs (MedPolSOP31)

- e. Further details on the requirements for Patient Group Directions and Trust Protocols may be obtained from Lead Pharmacist for Medicines Safety/Medicines Safety Officer or the Pharmacy site on the Trust Intranet

5.2.23. Written Instructions

Under Schedule 17 of the Human Medicines Regulations 2012, Occupational Health Services are exempt from the restrictions that apply to prescription only medicines. However, they can only use PGDs to provide Occupational Health Services to their own staff, not to another organisation, be it private or publicly funded.

Medicinal products can also be supplied or administered in the course of the Occupational Health Service by a registered nurse acting in accordance with the written and signed instruction of a doctor; this instruction is commonly documented as a 'written instruction' and can be used to provide Occupational Health Services to the Trust's own staff and also to other organisations.

The written instruction is different to a PGD and is an arrangement between the named registered nurse(s) and the authorising doctor and is not subject to the legislated framework of a PGD. Under the current legislation only registered nurses (i.e. not nurse associates or midwives unless also registered as a nurse) can operate under a written instruction.

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 may be approved by Medicines Safety Committee, provided that:

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

Where the two roles do co-exist, MedPolSOP01 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.

5.2.25. 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 and paediatric prescriptions 25 years).

5.2.26. Security of blank FP10 forms and hospital out-patient prescription forms

These are controlled stationery, and the registered healthcare professional in charge of the department is responsible for the safe (locked) storage. When issued to the prescriber, they are responsible for ensuring the prescriptions are kept securely. The pharmacy is responsible for recording the issue of FP10s and Hospital Outpatient Prescription Forms to clinical areas and/or prescribers (refer to Safe & Secure Handling of Prescription Stationery MedPolSOP33).

Care should be taken to ensure that the medication has been prescribed for the correct patient and the prescription issued to the right person. Ensure the addressograph attached to the prescription is for the intended patient.

5.2.27. Specimen signatures - prescribers

Specimen signatures of Medical and Dental Officers, including Locums, on appointment, will be retained by the Medical Staffing department. It is the responsibility of the Professional Manager of non-medical prescribers to send specimen signatures to pharmacy.

5.2.28. 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 (see Appendix 1) 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-dependent 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 Director of Pharmacy and Medicines Safety Committee, an incident form completed 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. 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.
- c. 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."
- d. 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.
- e. A pharmacist is individually accountable and responsible for the amendments he or she makes to prescriptions.

5.2.29. Prescribing unlicensed medicines and using a licensed medicine outside of its licence "off-label" (see MedPolSOP5)

For good clinical reasons it is often necessary to prescribe a medicine which does not hold a product licence (unlicensed use) or to prescribe a medicine outside the approved marketing authorisation ("off-label" use). It is accepted that such practice continues in order to provide the best care for patients. However, it is necessary that prescribers, pharmacists and nurses are aware of the increased risk and medico-legal implications associated with the use of Unlicensed Medicines.

Unlicensed medicines should only be used when there are no licensed products available and if their use can be clearly justified clinically and pharmaceutically, to meet the special needs of individual patients.

It is recognised that in some specialties, such as paediatrics and palliative care, there are a significant number of medicines used in an unlicensed way, however as their use is covered in recognised texts, they fall within a lower risk category. These include Palliative Care Formulary, British National Formulary and British National Formulary for Children.

MedPolSOP5 describes how Unlicensed Medicines and medicines used off-label should be used within Worcestershire Acute Hospitals NHS Trust (WAHT) and sets out the responsibilities of all involved.

5.2.30. Medicines Policy SOPs for higher risk medicines

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 insulin, midazolam, strong potassium solutions and methotrexate.

5.2.31. Prescribing of Systemic Anti-Cancer Therapy (SACT)

The West Midlands Systemic Anti-Cancer Therapy (SACT) Management Policy for Adult Patients WAHT-NUR-064 (Section 5 –Prescribing) is available on the intranet and must be followed.

5.2.32. Reporting of medication errors

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

All staff, including agency and contracted staff, are required to report medication incidents and near misses to the senior member of staff on duty within their ward or department and record the event using Datix, see section 5.10

5.3. Administration of Medicines

5.3.1. Overall responsibility

- a. The prescriber has responsibility for informing the Assigned HCP-in-Charge of a clinical area about any new prescriptions that have been written and that they have 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. It is in the patient's best interests to receive the prescribed medicines without delay and 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 HCP'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. When the pharmacy is closed the medicine should be located using the "Drug Locator" database on the intranet and then obtained from the pharmacy emergency drug cupboard or from another ward. If a supply cannot be located, call the on-call pharmacist.
- d. It is the administering HCP's responsibility to document the non-administration and raise the issue with the medical team.

5.3.3. Competency and accountability

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. 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).

- c. 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. Refer to the procedure associated with the development, approval, review of PGDs (MedPolSOP31)
- d. Where a PGD is not legally required to administer a medicine without a prescription (e.g. medicines with legal status GSL/P or legal exemptions recognised in this Policy for medicines given in an emergency or by certain HCPs), an appropriately trained and authorised member of Trust staff may administer medicines according to the Emergency and Discretionary Medicines Policy (see MedPolSOP35) or other administration protocols approved by Medicines Safety Committee

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 HCP 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, the administering HCP must check that a completed VTE risk assessment has been completed before administering or withholding low molecular weight heparin e.g. enoxaparin.
- e. Suspected adverse drug reactions must be reported as patient safety incidents and reported on a yellow card by following MedPolSOP15 'Reporting Adverse Drug Reactions'

5.3.6. Administration by other groups of staff

- a. Nurses, midwives or nursing associates in training may only administer medicines under the direct supervision of a registered HCP. The supervising trained HCP is responsible for ensuring that the medicine is correctly administered. Nurses, midwives or nursing associates 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. Nursing Associates shall observe the rules set out in "Standards of Proficiency for Nursing Associates (NMC, 2018), "Administration of Medicines by Nursing Associates Advisory Guidance (HEE) and follow any local policy and/or procedures specified by the Local Supervising Authority.
- c. To ensure competency of medicines administration, Nursing Associates and Trainee Nursing Associates will be supported by the Trust with appropriate levels of supervision and training for medicines management, including for safety critical medicines where a list is approved by Medicines Safety Committee.
- d. Physiotherapists may administer medicines by inhalation, topically to the skin, and injected into 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.
- e. 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.

- f. 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 an authorised prescriber. Medicines may only be administered to patients by Cardio-Respiratory technicians or Cardiographers in accordance with a current Trust Protocol.
- g. Health Care Support Workers/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 registered nurse has checked the medicine and the identity of the patient. The HCSW must be sufficiently trained to ensure that the administration can be completed safely. The registered 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 in the following circumstances:

- where a patient's condition makes it necessary
- when administering those controlled drugs recorded in the Controlled Drug Record Book and two authorised persons are available on duty (this check includes all steps from removal of CD from cupboard to administration to the patient)
- 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 dependent 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)

Nursing Associates may second check medications they are permitted to administer.

In addition to the above checking of administration requirements, registered **nurses and nurse associates, 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 and nurse associates, 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 or peer vaccinators

- Injectable medicines administered by midwives in an emergency situation or during a home birth when a second person is not present
- Subcutaneous medication that has been checked and dispensed for an identified patient by Pharmacy, and where a dose calculation is not required. A specific medicine where this applies is the administration of omalizumab by the respiratory team

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

The Chief Nursing Officer 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 HCP 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 (Injectable Medicines Guide) and making it available to them in order for the second check to take place.

Independent checks

When the administration of a medicine is checked by another person, this check is undertaken independently and 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 'Medication Issue') to any report missed/delayed doses.

5.3.8. Checking of calculations

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. Care should be taken to avoid confusion of liquid doses in milligrams and volumes. (Refer to Administration of oral & enteral liquid medicines MedPolSOP11).

5.3.9. Ultimate responsibility for administration

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 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.
- 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 patient's main prescription chart.
- d. No medicines are to be omitted or significantly delayed unless there is a specific direction to withhold the medicine for a clinical reason by the prescribing team and/or pharmacist. The details of the reason for omission and/or actions taken to avoid the omission must be recorded in the patient notes.
- e. Where a medicine has been omitted or significantly delayed without a valid reason this should be reported on Datix.
- f. The supervising person must countersign the signature of a student when supervising the administration of medicines.
- g. Where an electronic prescribing and administration system is being used, a record of the person administering and checking (and any omitted doses) will be made automatically.

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 prescription before any medicines are administered. If this is missing from the prescription but a current record is in the patients' notes the nurse or midwife can copy this across signing and dating the entry on the prescription 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 medicine 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

- 5.3.12.1. 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 their 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.

- 5.3.12.2.** In an emergency, if the prescriber or their deputy is unable to attend, the nurse may cancel the doubtful prescription and accept a verbal prescription in its place (see verbal orders).
- 5.3.12.3.** 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).

5.3.15. Refusal of medicine

- 5.3.15.1.** In general, patients have a right to refuse medicines and covert administration must not be used. Reasons for refusal must be documented.
- 5.3.15.2.** In the following situations discuss with the appropriate medical officer/line manager and document actions taken/agreement 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.

5.3.15.3. Covert administration is giving medicines in a disguised form without the knowledge or consent of the person receiving them.
If this needs to be considered follow relevant Trust policies around mental capacity and refer to guidance from SPS: <https://www.sps.nhs.uk/articles/covert-administration-of-medicines-legal-issues/>

5.3.16. Disposal of individual doses of unused or discarded medicines

- 5.3.16.1.** 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).
- 5.3.16.2.** 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 Trust Waste Management Policy
- 5.3.16.3.** Apart from individual doses, unwanted medicines should be returned to pharmacy. Controlled Drugs must be collected by an authorised member of pharmacy staff.
- 5.3.16.4.** 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.
- 5.3.16.5.** 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 Record Book. Where an ampoule is partly used the excess must be discarded in a CD denaturing kit. This must be witnessed. Topical patches should be rendered unusable by removing the backing and folding the patch over upon itself.
- 5.3.16.6.** 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 a CD denaturing kit. This should be done in the presence of a witness and an entry made in

the Controlled Drug (CD) Record Book, 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

5.3.17.1. For Medical Staff specimen signatures see 5.2.27.

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

5.3.17.3. The records of signatures and initials should be kept for as long as the documents on which they may appear. Refer to Retention of Records Policy

5.3.18. Reporting of medication errors

All staff, including agency and contracted staff, are required to report medication incidents and near misses to the senior member of staff on duty within their ward or department and record the event using Datix, see section 5.10

5.3.19. Administering controlled drugs in theatres

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. Refer to Standard Operating Procedure (SOP) for Controlled Drugs (MedPolSOP7) and the Procedure for the safe and secure handling of medicines in Theatres (WAHT-THE-019).

5.3.20. Administration of intrathecal chemotherapy

5.3.20.1. 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.

5.3.20.2. The Intrathecal Chemotherapy Lead is the person responsible to the Chief Executive for overseeing compliance with these guidelines, policies and procedures.

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

5.3.21. Administration of anaesthetics by an epidural or spinal route

5.3.21.1. 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.

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

5.3.21.3. 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 of infusion pathway

See Policy and Procedures for the Prescribing and Administration of Injectable Medicines WAHT-CG-516

5.3.23. Additions to infusions and injections

See Policy and Procedures for the Prescribing and Administration of Injectable Medicines WAHT-CG-516

5.3.24. Ophthalmic preparations

- 5.3.24.1.** Single dose unit eye drops (e.g. "Minims") must be used wherever possible for peri-operative use, and out-patient procedures. These preparations must be used once then discarded.
- 5.3.24.2.** Where a single dose unit eye drop is not available (no suitable product or temporary shortage), use of multi-dose bottles can be considered, using aseptic technique and in accordance with a locally risk assessed and agreed policy.
- 5.3.24.3.** In other circumstances, a multiple application dropper bottle or ointment tube must be used for single patient
- 5.3.24.4.** 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.
- 5.3.24.5.** Shorter expiry dates may be required with some eye preparations (to be dispensed according to Pharmacy procedures) and/or should be considered for patients with severe sight threatening eye infections.

5.3.25. Administration of oxygen

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 MedPoISOP11)

- 5.3.26.1.** 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.
- 5.3.26.2.** An oral / enteral syringe must be used to administer potent medicines (including CDs), volumes less than 5ml, volumes not a multiple of 5ml, and when the medicine is to be administered via a feeding tube.
- 5.3.26.3.** Intravenous syringes MUST NOT be used to measure or administer oral or enteral liquid medicines.

5.3.27. Safe handling of systemic anti-cancer therapies (SACT)

- 5.3.27.1.** Handling of cytotoxic drugs is hazardous. The West Midlands Systemic Anti-Cancer Therapy (SACT) Management Policy for Adult Patients WAHT-NUR-064 (Section 6) is available on the intranet and must be followed.

- 5.3.27.2.** 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.
- 5.3.27.3.** Disposal of cytotoxic/cytostatic medicines – all medicines waste displaying toxic, carcinogenic, toxic for reproduction and mutagenic properties must be disposed of as ‘cytotoxic/cytostatic’ waste in accordance with the Trust Waste Management Policy. This includes empty syringes, giving sets and other disposable equipment that may have come into contact with any of the drugs.

5.3.28. Supervised administration of medicines by patients

- 5.3.28.1.** 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 (e.g. exenatide, liraglutide) preparations
 - Parkinson’s Disease medicines
- 5.3.28.2.** There must be a valid prescription for the medicine. The prescriber or patient’s trained nurse or Nursing Associate may specify that the patient should have ready access to the preparation.
- 5.3.28.3.** 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 or Nursing Associate 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.
- 5.3.28.4.** 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

- 5.3.29.1.** 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.
- 5.3.29.2.** To extend self-administration by patients beyond that described in “supervised administration of medicines by patients” above, a local procedure must be approved by Medicines Safety Committee
- 5.3.29.3.** A medical officer or the Assigned HCP-in-Charge of a clinical area may veto supervised or self-administration where considered inappropriate.

5.3.30. Medicines for staff

- 5.3.30.1.** 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.

- 5.3.30.2.** 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. Self-prescribing is not allowed. 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).
- 5.3.30.3.** 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.
- 5.3.30.4.** FP10 forms must NOT be used for staff to obtain medicines except following an official outpatient appointment or hospital admission.
- 5.3.30.5.** Clinical areas may keep paracetamol 500mg and ibuprofen 200mg for staff to use under the authority of the nurse-in-charge but it must be ordered and stored as a controlled drug.

5.3.31. Medicines brought into hospital by patients

- 5.3.31.1.** 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.
- 5.3.31.2.** 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.
- 5.3.31.3.** 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).
- 5.3.31.4.** To be approved for use:
- 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).
 - 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. For patients admitted with an eye infection a fresh supply is recommended.
 - 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.
 - 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.
 - 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.
 - 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).
- 5.3.31.5.** 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.

- 5.3.31.6.** 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 MedPolSOP01.
- 5.3.31.7.** 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.
- 5.3.31.8.** 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 the patient by following MedPolSOP01.
- 5.3.31.9.** 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.
- 5.3.31.10.** 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)
- 5.3.31.11.** Controlled Drugs brought into hospital by patients should be recorded in the Patients' Own Controlled Drug Record Book.
If they are returned to the patient to take home or self-administer, or they are sent to pharmacy this must be recorded. Where Patient's Own CDs are destroyed at ward level led by a trained registered technician or pharmacist, a record of this destruction will be made in the POD CD record book. All entries must be signed and witnessed.
- 5.3.31.12.** 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, store them in the medicine's cupboard designated for the purpose. The medication should then be prescribed by a medical officer if it is required during the inpatient stay on the midwife led unit. 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

If a patient is found in possession of suspected illegal drugs, they 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/Director of Pharmacy or their nominated deputy should inform the police.

Refer to Standard Operating Procedure (SOP) for Controlled Drugs (MedPolSOP7)

5.3.33. Hazards

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

- 5.3.34.1.** All records of administration must be retained in accordance with WAHT-CG-127 Corporate Records Management Policy after the conclusion of treatment. 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 and children's prescriptions 25 years).
- 5.3.34.2.** When a Controlled Drug Record Book 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.

5.3.35. Therapeutic Level Monitoring of Medicines

All Healthcare professionals involved in prescribing, monitoring and administering a medicine requiring therapeutic level monitoring for efficacy and/or toxicity are responsible for ensuring that the medicines is used safely and appropriately, that monitoring takes place and results are actioned in an appropriate and timely manner.

The prescriber has the overall responsibility to determine, communicate and document the monitoring plan for a prescription they have written. This includes planning of timing of any relevant blood tests, including drug level assays. It is good practice to annotate the date and time of the next monitoring on the prescription as well as relevant drug level results.

Before administering a medicine, the HCP administering the medicine must be familiar with the monitoring plan, competent in undertaking the monitoring, ensure that the monitoring has been undertaken and any required actions are instigated as determined by monitoring outcome.

Pharmacists undertaking the professional screen of a prescription for a medication requiring therapeutic drug monitoring must ensure that an appropriate monitoring plan is in place and that monitoring requirements for the next drug level are annotated on the prescription.

Clinical pharmacists should support prescribers and nursing staff in determining appropriate monitoring and action plans.

5.4. Purchasing, requisitioning, supply, return and pharmacy disposal of medicines

5.4.1. Overall responsibility

- a. The Director of Pharmacy/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, refer to the Purchasing for Safety Policy (see MedPolSOP19).
- c. The requisitioning, supply (including dispensing), and return of medicines to and from 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 Director of Pharmacy may delegate the purchasing of specific medicinal products via other departments e.g. blood products and radiopharmaceuticals (POM).
- e. Medicinal products may only be administered if obtained by pharmacy or other delegated clinical department. Patient's Own Drugs (see definitions) which have been assessed for suitability for use 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 and reviewed at least annually.
- 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 (sometimes provided by the patient's GP) 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. Refer to Standard Operating Procedure (SOP) for Controlled Drugs (MedPolSOP7).
- 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 by telephone.

5.4.3. Requisitions

- a. The requisition for medicines must be signed by one of the following:
- b. 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.
- c. An authorised member of pharmacy staff providing ward-based supply services
- d. Before signature any blank lines on the form must be cancelled. Only the top copy of a requisition will be accepted.
- e. Sample signatures of any staff likely to requisition medicinal products must be provided for the pharmacy.
- f. When Controlled Drugs are ordered for stock (see MedPolSOP08 Controlled Drug Access 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 e.g. Radiology, 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.
- g. Unless otherwise approved by the Director of Pharmacy, 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 pharmacist.
- h. 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".

- i. 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

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

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 Pharmacy staff, a nurse/midwife from the ward/department concerned, a community midwife, medical officer or a health care assistant 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.
- c. Where external contracted delivery drivers or taxis are used, their identity must be confirmed before the sealed package is handed over

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. All medicines received are of the quantity and quality specified and suitable for the purpose for which they are intended. Specific attention is applied to:
 - Confirm product identity and quantity
 - Ensure product integrity e.g. that the cold chain and other storage requirements have been maintained where appropriate, and
 - Confirm compliance with any legal and/or organisational requirements
- c. 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 via the ward box, where it will be kept for a minimum period of 2 years. 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.

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. Refer to Standard Operating Procedure (SOP) for Controlled Drugs (MedPolSOP7).

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 or medicines management technician 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 Protection Act 1990 and the current statutory regulations (refer to Trust Waste Management Policy WAHT-CG-481).
- 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.
- e. The Trust must ensure that a T28 is registered for each premise that denatures controlled drugs and the conditions of the exemption must be complied with.

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
 - i. or electronic) from an authorised prescriber or a Patient Group Direction
- b. Whenever practicable, prescriptions should be sent to pharmacy at least 24 hours before the medicines are required. Each pharmacy will triage requests for TTOs after an agreed time, after which TTOs will not normally be dispensed the same day. Child resistant containers will normally be used unless otherwise requested on the prescription chart.
- c. 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.
- 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.
- e. Any compliance/dosage record cards must also be checked in the
- f. same way.
- g. 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 (MedPolSOP01).
- h. 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, according to MedPolSOP1. When a patient is discharged and on-going care is required, medicines,

appliances and dressings will be supplied to last for either the complete course of treatment or 14 days, whichever is the shorter. It may be necessary to supply smaller quantities where clinical or safety concerns are identified. The full balance of the required amount should be supplied for medicines that are not on-going.

- i. Where patients being discharged usually receive their medicines in a compliance aid, providers should issue an FP10 to be dispensed by the patient's usual community pharmacy. If there is not sufficient time to arrange this, a routine supply of medicines will be made.
- j. Where patients being discharged indicate they have sufficient supplies of medicines at home, only the medicines that have changed or are new need to be supplied.
- k. 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.
- l. Child resistant containers will normally be used unless otherwise requested on the prescription chart.
- m. Patients being supplied with injectables from clinics or wards must be provided with a sharps bin and instructions as to how it should be disposed of e.g. community pharmacist (usual maximum 1 litre)

5.4.11. Acquiring drugs out of hours

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

5.4.11.1.1. 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.

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

5.4.11.a.3. 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.

5.4.11.a.4. Controlled Drugs are not included in "Drug Locator" and are not available in the Emergency Drug Cupboard however information about where they are stocked is available in the CD Stock Access Procedure (MedPolSOP8). 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 requesting ward (see MedPolSOP07).

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 Director of Pharmacy/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

- 5.4.13.1. The following items are designated as controlled stationery and are supplied by pharmacy on receipt of an order in the Controlled Drug Order Book:
- Out-patient and A&E prescription forms
 - FP10 forms
 - Stock requisition books
 - Controlled Drug Order Books and Record Books
- 5.4.13.2. 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. (Refer to MedPolSOP33 Safe and Secure Handling of Prescription Stationery).

5.5. Storage of Medicines

5.5.1. Overall responsibility

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

- 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 mis-selection, 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 RPS Professional Guidance on the Safe and Secure Handling of Medicines: 11 Dec 2018

- 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.
- the risk-based approach to the storage of medicines in clinical areas must follow professional and quality control guidance
- a pharmacist must be consulted whenever changes to existing medicines storage facilities are planned, or new cupboards are proposed.
- when a new clinical area is opened the pharmacy team will complete a ward safe and secure handling audit to ensure compliance with standards.

5.5.3. Medicine cupboards and trolleys (including MedCarts)

- 5.5.3.1. All medicines in clinical areas must be stored in a locked cupboard or other secure receptacle; this may include automated medicines storage cabinets (refer to MedPolSOP36) "medicine

keys" must be identifiable by the staff in the clinical area but not labelled as such to minimise risks if they are lost.

Where medicines lockers are available for patients, they can be used to store any or all medicines (except controlled drugs, unless part of a recognised self-administration scheme). However, a medical officer or the Appointed/Assigned HCP-in-Charge of a clinical area may veto the storage of any or all medicines in a patient's medicines locker where considered inappropriate or there is a security risk.

5.5.3.2. Medicines key security is detailed in MedPolSOP32 – Medicines Key Security – Use of a Key Safe on Wards/Clinical Area

- A key safe with a combination lock may be used provided the combination is changed regularly in accordance with local risk assessment but at least every six months
- 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.
- 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).
- 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

5.5.3.3. 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.

5.5.3.4. 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.

5.5.3.5. Medicine trolleys (including MedCarts) 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.

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

5.5.3.7. The following need not be locked:

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

5.5.3.8. 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

Controlled Drugs must be stored in the locked cupboard reserved solely for this purpose (not a medicine trolley or MedCart) 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 Record Book 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.

5.5.6. Storage of injections

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

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

5.5.8. Storage of medicines for external use

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

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°C. A record of this daily 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. See MedPolSOP29

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 Director of Pharmacy 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 Record Book 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 Record Book must be available at shift handover.
- c. Report any of the following immediately to the nurse manager who will initiate an investigation and inform a pharmacist as soon as possible in accordance with MedPolSOP17:
 - 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

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

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 Controlled Drug Record Book 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. Reporting to the Controlled Drugs Local Intelligence Network (LIN)

- a. A quarterly report is prepared by the CDAO which contains information regarding incidents involving controlled drugs. Concerns are reported to the Controlled Drugs 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

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 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

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.

5.5.17. Storage of Medical Gas Cylinders

- a. Must be stored in a designated secure area in either a 6 or 12-cylinder carriage. This will be dependent on the agreed stock holding based on usage. The storage location should be visible to nursing staff and not in corridors close to ward exits. These carriages must be removed from the department if the fire alarm is sounding continuously and be taken through the fire doors.
- b. Pharmacy will monitor compliance with the storage requirements annually as part of the ward/clinical area Safe and Secure Handling audit.

5.6. Clinical Trial Medicines

5.6.1. 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.

5.6.2. General principles

5.6.2.1. Official guidance concerning the purchasing, distribution and storage of clinical trial products is encompassed within Professional guidance on Pharmacy Services for Clinical Trials (National Pharmacy Clinical Trials Advisory Group (2013). This document recommends that stocks of trial medicines should not be maintained on the wards, clinics or in private offices.

5.6.2.2. 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
- Retaining temperature records where investigational medicinal products are stored
- Retaining records of orders and receipts

5.6.2.3. The Director of Pharmacy has overall responsibility for Pharmacy Services to Clinical Trials and for the safe and secure handling of clinical trials medicines.

5.6.2.4. It is the responsibility of the operational lead pharmacists (WRH or AH) to ensure that:

- Each active clinical trial involving IMPs must have a Worcestershire Acute Hospitals Trust Pharmacy Standard Operating Procedure.
- All actions relating to IMPs are carefully documented including an auditable drug accountability record.
- All trial materials are of a suitable quality and are stored correctly.

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

5.6.3. The investigator

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 Lead Pharmacist for Clinical Trials for approval of the arrangements for their safe and secure handling. Any safety concerns should be escalated to the Director of Pharmacy/Trust Medicines Safety Committee.

- a. 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 and the Trust R&D Committee has given its approval. The Medicines Safety Committee will only need to give approval where the Lead Pharmacist has identified a potential medicines safety issue which needs review.
- b. 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 clinical trials pharmacist must approve and periodically inspect the alternative storage.
- c. 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.
- d. Individual Funding Requests to the ICB for Clinical trial funding requests must be provided with a copy of the trial protocol together with an outline of the importance of the trial, the robustness of the trial and the benefits of this trial to the patient.

5.6.4. 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 prescriptions for clinical trial medicines.
- d. Must retain trial information and randomisation codes after the trial is completed unless a central archive is agreed.

5.7. Reporting defects in medicines

5.7.1. 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. Pharmacy staff will follow local procedures to investigate the issues regarding the concerns raised.

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

5.8. MHRA Medicines Notifications/recalls and shortages

All MHRA Medicines Notifications/Recalls and Medicines Supply Notifications 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 internal pharmacy procedures. An audit trail of action taken by pharmacy is retained in pharmacy and reported three monthly to the Medicines Safety Committee and Patient Safety Team. (Refer to Trust Policy Management of Safety Alerts WAHT-CG-086)

For National Patient Safety Alerts (NatPSA) see 6.3.5

5.9. Midwives – Supplementary Policy

5.9.1. Midwives shall observe the “The NMC code of professional conduct: standards for conduct, performance and ethics” 2018. and follow NMC Guidance ‘Practising as a Midwife’ 2020.

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.

5.9.2. Supply and administration of controlled drugs – community midwives

The drug of choice for home confinements is pethidine. The mother should be advised to obtain a prescription from her GP and shall collect the medicine herself 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 advise mother to destroy in front of midwife or return to a Pharmacy - Document this in client notes. NB: A midwife may not return the drugs to a Pharmacy.

5.9.3. Supply and administration of Controlled Drugs – hospital midwifery

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

5.9.4. Supply and administration of other medicines – community midwives

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.

5.9.5. 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 approved electronic records with dosage, date, time and midwife's signature. Student midwives who have been appropriately trained to do so may administer medicines (except Controlled Drugs) on the midwives' exemption list under the direct supervision of a registered midwife (this is not the case with Patient Group Directions)

5.9.6. Storage of medicines by community midwives

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

5.10. Reporting Medication Incidents

Medication Incidents are Patient Safety Incidents involving the prescribing, preparing, dispensing, administering, monitoring or providing advice on medicines. A Patient Safety Incident is 'any unintended or unexpected incident, which could have or did lead to harm for one or more patients receiving NHS care.'

All staff, including agency and contracted staff are required to report medication incidents and near misses to the senior member of staff on duty within their ward or department and record the event using Datix (Trust Policy for Incident Reporting WAHT-CG-008).

Incidents should be reported using the 'Medication Incident' form on Datix, including a brief factual description of how the incident occurred, the immediate action taken, and details of the Drug involved, Dose and strength, Route, and Correct drug, dose and route.

Examples of medication incidents (which can result from errors at the prescribing, dispensing, administration, monitoring or advice stage), include:

- Omitted medicine - any dose not administered other than in circumstances where professional judgement has been used to omit the medicine for a clinical reason - document on the prescription chart and in the patient's notes.
- Delayed medicine - any medicine administered 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.
- Wrong dose/strength/form of medicine.
- Medicine not intended for that patient
- Medicine is contra-indicated for that patient
- Wrong route of administration
- Medicine is unavailable, labelled incorrectly, unaccounted for, stored incorrectly or expired (not an exhaustive list)

(Unavoidable Adverse Drug Reactions are not medication errors but must also be reported on Datix as well as via the Yellow Card Scheme - see MedPolSOP15)

Whenever a medication incident is discovered that has or could lead to harm to the patient, the patient's medical team must be contacted so that, if necessary, remedial action can be taken to ensure the safety of the patient. 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)

All medication incidents must also be immediately reported to the Assigned HCP-in-Charge of the area, who must ensure the incident is documented in the patient's notes along with details of any remedial action taken, and the individuals informed.

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 to 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.

The Assigned HCP-in-Charge must ensure that a clinical incident report is completed on Datix.

Duty of Candour should be completed if the error has caused harm assessed as moderate or severe. Refer to Trust Policy: Being Open (Duty of Candour) Policy WAHT-CG-567)

For the subsequent investigation of the incident see the Trust Policy for Incident Reporting (WAHT-CG-008) and Investigating Serious Incidents policy (WAHT-CG-009)

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.

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

6.1.3. Changes to Medicines 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

The Trust Worcestershire Weekly newsletter, medicine learning bulletins and Trust-wide emails will be used to announce publication of the Medicines Policy and its associated procedures and 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. Essential to Role Training

6.3.3.1. Medicines management training is essential to maintain staff competencies in relation to the supply, prescription and administration of medicines across the Trust, and for compliance with the Trust Medicines Policy, associated procedures and changes to medicines legislation. The training also ensures learning from medicines incidents is cascaded and reflected on an individual level.

6.3.3.2. Mapping training requirements for staff groups involved in medicines supply, prescription and administration will be updated when new staff groups or roles are introduced

6.4. Responsibilities of Consultants, Department Managers and Professional Leads

6.4.1. 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 they 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.

6.4.2. 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 they will carry out
- b. Each person in their profession is aware that all their actions associated with medicines must comply with the Trust Medicines Policy (this document) and its associated procedures

6.4.3. 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 they will carry out.
- b. Each person in their team receives Medicines Optimisation Essential to Role training as in 6.3.3
- 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.

6.5. National Patient Safety Alerts (NatPSA)

- a. These 'safety critical' alerts involving medicines are received by the Trust CAS officer, who is required to ensure they rapidly reach the designated executive senior leader who will coordinate delivery of an alert's required actions – see [NHS England » Introducing National Patient Safety Alerts](#) and the Trust Policy for Management of Safety Alerts WAHT-CG-086
- b. They are also reviewed by the Medicines Safety Officer and discussed at the Trust's Medicines Safety Committee, to ensure that the appropriate knowledge and expertise has been identified and all clinical and operational aspects considered.
- c. 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 training, Medicines Learning Bulletins, Lesson of the Week, trust wide email and intranet "wallpaper" will be used to notify staff of key information as appropriate to the urgency and content.
- d. For MHRA Medicines Notifications/Recalls and Shortages see 5.8

7. Monitoring and compliance

The Director of Pharmacy/Associate Director - Medicines Optimisation together with the Medicines Safety Committee is responsible for monitoring compliance with the Medicines Policy as described in Appendix 1

8. Policy review

The policy receives a major review every 3 years, Interim 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.

9. References

- [Medicines Act 1968 \(legislation.gov.uk\)](#) as amended

- Human Medicines Regulation 2012 [The Human Medicines Regulations 2012 \(legislation.gov.uk\)](https://www.legislation.gov.uk)
- [NHS England » Enduring standards and general principles from previously issued patient safety alerts](#) (includes link to archived alerts)
- Specialist Pharmacy Service Guidance
Medicines Shortages and PGDs
PGDs - Bank and agency staff
[PGDs and Occupational Health Services](#) (Written Instructions)
- NHSE Patient Safety Directive 'Improving medication incident reporting and learning' March 2014
- RPS/RCN Professional Guidance on Administration of Medicines in Healthcare Settings January 2019
- For the Record – Managing Records in NHS Trusts and Health Authorities. HSC 1999/053 as amended and WAHT-CG-127)
- Department of Health (2013) Health Technical Memorandum 07-01: Safe management of healthcare waste (<https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste>)
- RPS Professional Guidance on the Safe and Secure Handling of Medicines: 11 Dec 2018
- WM Network Guidance – SACT and management policy for adult patients April 2018
- Guidance on Handling of Injectable Cytotoxic Drugs in Clinical Areas in NHS Hospitals in the UK. Edition 1 July 2018 (NHS Pharmaceutical Quality Assurance Committee 2018)
- A Guide to Implementing Nurse and Pharmacist Independent Prescribing within the NHS in England (2006)
- Advisory Committee on the Misuse of Drugs (2016) ACMD report on diversion and illicit supply of medicines
- Nursing and Midwifery Council (2018) The Code: Professional standards of practice and behaviour for nurses and midwives and nursing associates (<https://www.nmc.org.uk/standards/code/>)
- Specialist Pharmacy Service (2018) Best practice standards for managing medicines shortages in NHS hospital
(<https://www.sps.nhs.uk/wpcontent/uploads/2018/11/Best-Practice-Standards-for-managing-Medicines-Shortages-in-Secondary-Care-in-England-final-.pdf>)
- Royal Pharmaceutical Society (2015) Professional Guidance for the Procurement and Supply of Specials (/Portals/0/RPS%20document%20library/Open%20access/Support/toolkit/specials-professional-guidance.pdf)
- Specialist Pharmacy Service (2017) To PGD or not to PGD that is the question (<https://www.sps.nhs.uk/articles/to-pgd-or-not-to-pgd-that-is-the-question/>)
- Medicines and Healthcare products Regulatory Agency (2014) Medicines: packaging, labelling and patient information leaflets (<https://www.gov.uk/guidance/medicines-labelling-and-patient-information-leaflets>)
- Medicines and Healthcare Products Regulatory Agency (2014)
Best practice in the labelling and packaging of medicines
(<https://www.gov.uk/government/publications/best-practice-in-the-labelling-and-packaging-of-medicines>)
- British National Formulary – Trust intranet)
- Control of Substances Hazardous to Health (COSHH) Regulations 2002
- MHRA The Supply of Unlicensed Medicinal Products ('specials') MHRA Guidance Note 14 (2014)
- Misuse of Drugs (Safe Custody) Regulations 1973
- Misuse of Drugs Act 1971

- Misuse of Drugs Regulations 2001
- The Health Act 2006 (for 'CDAO' concept & SOPs)
(<http://www.legislation.gov.uk/ukpga/2006/28/contents>)
- The Controlled Drugs (Supervision of Management and Use) Regulations 2013
(<http://legislation.gov.uk/uksi/2013/373/regulation/2/made>) (England and Scotland)
- NICE (2016) NICE guideline 46: Controlled Drugs: safe use and management
(<https://nice.org.uk/guidance/ng46/chapter/recommendations>)
- NICE Clinical Knowledge Summary Adverse Drug Reactions Updated March 2017
- The Responsibilities for Chief Pharmacists for Radiopharmaceuticals, 3rd edition, July 2020
[The Responsibilities of Chief Pharmacists for Radiopharmaceuticals \(Yellow Cover\) – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](#)
(Department of Health (2006) NHS estates guidance for medical gas pipeline systems (HTM 02-01).
<https://www.gov.uk/government/publications/medical-gas-pipeline-systems-part-a-design-installation-validation-and-verification>)
- UK Radiopharmacy Group (2017) Responsibilities of Chief Pharmacists for the purchase and supply of radiopharmaceuticals
(https://www.bnms.org.uk/images/Responsibilities_of_Chief_Pharmacists_June_2917.pdf)
- Department of Health (2006) NHS estates guidance for medical gas pipeline systems (HTM 02-01).
(<https://www.gov.uk/government/publications/medical-gas-pipeline-systems-part-a-design-installation-validation-and-verification>)
- British Thoracic Society Emergency Oxygen Guideline Development Group (2017). Thorax.BTS Guideline for Oxygen Use in Adults in Healthcare and Emergency Settings. (<https://www.brit-thoracic.org.uk/document-library/clinical-information/oxygen/2017-emergency-oxygen-guideline/bts-guideline-for-oxygen-use-in-adults-in-healthcare-and-emergency-settings>)
- Department of Health (2013) Immunisation Against Infectious Disease – 'The Green Book'.
(<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>)
- NHS Pharmaceutical Quality Assurance Committee (2015) Risk Management of Medicines in Clinical Areas: Temperature Control
(<https://sps.nhs.uk/articles/content-page-for-yellow-cover-documents-yellow-cover/>)
- Royal Pharmaceutical Society of Great Britain Medicines, Ethics and Practice: A Guide for Pharmacists (current edition)
- Safer Management of Controlled Drugs A guide to good practice in secondary care (England) October 2007 (England) (Oct 2007)
- Safer management of controlled drugs: (1) guidance on strengthened governance arrangements – DOH (2006)
- Safer management of controlled drugs: (1) guidance on strengthened governance arrangements Department of Health January 2007
- Supplementary Prescribing by Nurses, Pharmacists, Chiropodists/Podiatrists, Physiotherapists and Radiographers within the NHS in England (2005)
- The Medicines for Human Use (Clinical Trials) Regulations 2004
- Updated national guidance on the safe administration of intrathecal chemotherapy HSC 2008/001 (2008)
- NICE Medicines Practice Guidance (for PGDs Updated 27th March 2017)
<https://www.nice.org.uk/guidance/mpg2>

10. Background

10.1. Consultation

This key document has been circulated to the following individuals for consultation: Chief Medical Officer, Chief Nursing Officer, Clinical Directors, Divisional representatives, Lead Pharmacists and members of the Trust Medicines Safety Committee.

The Medicines Policy and its associated Procedures are developed by the Director of Pharmacy and Trust Pharmacists with input from other disciplines including: Chief Medical Officer, Clinical Directors, Clinicians, and Clinical Tutors), Nursing (Chief Nursing Officer, Deputy Chief Nursing Officers and Divisional Nursing Leads, Matrons, ward managers, Nursing Professional Development, Occupational Therapy, Physiotherapy, Dietetics, Radiographers and Operating Department Practitioners (Professional Leads).

10.2. Approval process

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 requirements

Details of the Equality Impact Assessment can be found in Supporting Document 1

10.4. Financial Risk Assessment

Details of the Financial Risk Assessment can be found in Supporting Document 2

10.5. Version Control

This section should contain a list of key amendments made to this document each time it is reviewed.

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	<p>Update job titles and post holders' names throughout</p> <p>1.3 reference added to Medicines Optimisation</p> <p>5.1 Reference made to Francis enquiry and inclusion in policy.</p> <p>5.1.13 The most up to date version of the BNF is available on the Trust intranet</p> <p>5.2.6 Transcribing – updated to remove NMPs and clarify competency assessment.</p> <p>5.2.16 Multiple charts containing several cancelled prescriptions should be amalgamated.</p> <p>5.2.22 PGDs – remove requirement to keep hard copies of PGDs in clinical areas</p> <p>5.2.24 Prescribing and dispensing (supply) – separation of duties reworded to be consistent with NMP policy and MedPolSOPs 1-3.</p> <p>5.3.11 e) where a medicine has a 'once opened' expiry date this should be marked on the container</p> <p>5.4 Reference to Wholesaler Dealer Licence added.</p> <p>5.4.1 f) A 'stock list' should be agreed with Pharmacy</p> <p>5.4.3b Amendments to wording re CD requisitions.</p> <p>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 situation according to Trust policies and, where necessary, contact the Director of Pharmacy for advice about the medicines.</p>	Medicines Safety Committee

	<p>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.</p> <p>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.</p> <p>5.5.3.c) A single set of medicine keys should be in use.</p> <p>5.5.9 A record of this daily temperature monitoring must be maintained for inspection by pharmacy staff.</p> <p>5.5.14 Replaced PCT with LAT</p> <p>Removed references to bodies that are no longer legal entities e.g. NPSA</p>	
June 2015	5.5.3d reference to pharmacy key holding	Alan Catterall, Director of Pharmacy
August 2016	<p>Interim review v7.1</p> <p>Changes throughout</p> <p>Medicines Safety Committee replaced by Medicines Optimisation Expert Forum</p> <p>Clinical Director of Pharmacy replaced by Associate Director – Medicines Optimisation</p> <p>Medicines Management replaced by Medicines Optimisation</p> <p>4.2 Change of Controlled Drugs Accountable Officer to the Associate Director - Medicines Optimisation and Director of Pharmacy</p> <p>5.2.22 Move to NMP rather than PGDs strengthened, as per NICE MPG</p> <p>5.3.7 Inclusion of revised section on the checking of administration, approved June 2016 as part of the updated Injectable Medicines Polic</p> <p>5.3.11 Link to ID patient/wristband policy</p> <p>5.4.7 Addition of safe supply of stock penicillins and storage in designated cupboards</p> <p>5.5.3 Update of storage requirements</p>	Richard Cattell, Associate Director - Medicines Optimisation and Director of Pharmacy
June 2017	<p>5.2.8 Update of prescribing requirements to include patient's weight (kg) for adults</p> <p>5.5.2 Storage of medicines revised wording to better describe a patient-focused, risk based approach</p>	Medicines Optimisation Group
June 2018	<p>Medicines Optimisation Group to be changed to Medicines Safety Committee throughout</p> <p>5.2.7 The content of standardised (e.g. pre-printed prescriptions, templates, or e-prescribed order sets) must be approved before</p>	Medicines Safety Committee

	<p>use by Medicines Safety Committee (or according to a procedure approved by Medicines Safety Committee)</p> <p>5.3.1 inclusion of time critical medicines</p> <p>5.3.2 escalation of non-administration of medicines to the medical team</p> <p>5.3.15 In general, patients have a right to refuse medicine and covert administration must not be used.</p> <p>5.4.2 enabling policy for electronic ordering of stock medicines</p> <p>5.5.1 clarity of accountability for storage of medicines</p> <p>5.5.1 and 5.4.2 inclusion of checking expiry dates in responsibilities</p> <p>5.5.3 clarity of requirements relating to keys for medicines storage</p>	
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	
July 2020	<p>Typographical and grammatical amendments throughout the document</p> <p>Changed Chief Pharmacist title to Director of Pharmacy throughout</p> <p>Updated reference to key documents throughout</p> <p>Section 2: Definitions</p> <p>Added:</p> <p>Controlled Drugs Accountable Officer (CDAO), Medication Error, Nursing Associate (& responsibilities throughout)</p> <p>Medical students, pharmacy assistants, physician assistants</p> <p>Section 4: Updated CQC Regulations</p> <p>Staff responsibilities for reporting medication incidents (as per Trust Incident reporting Policy) added</p> <p>5.1.3 Changed Area Prescribing Committee to Medicines and Prescribing Committee (& throughout)</p> <p>5.1.6 Provided examples of zero cost stock</p> <p>5.2.8 Added recommendation to sign and use stamps on prescriptions</p>	Medicines Safety Committee

	<p>5.2.17 Validity of Prescriptions – updated for inpatients e.g. antibiotics review, and reference to Mental Health Act, and for outpatients, the legality of CD prescriptions</p> <p>5.2.19 Added requirement for email confirmation of verbal orders</p> <p>5.2.19 Removed references to faxing (& throughout) and replaced with secure email (where appropriate)</p> <p>5.2.22 Patient Group Directions – edited throughout following issue of new PGD MedPolSOP31, including use of PGDs by bank and agency staff.</p> <p>5.2.23 new section on Written Instructions (and added to Definitions)</p> <p>5.2.26 Security of blank FP10 forms – edited following issue of new MedPolSOP33</p> <p>Added advice for checks required to ensure prescription given to right patient</p> <p>5.2.31 Prescribing of oral chemotherapy – updated in accordance with new guideline WAHT-NUR-064</p> <p>5.3.24 and 5.3.31 updates re in-use shelf-life for eye drops and ointments</p> <p>5.3.32 Updated administration of other groups of staff to include Nursing Associates</p> <p>5.3.33 Further explanation for checks required for CD administration i.e. cupboard to patient</p> <p>5.3.33 Exceptions to second checking: added SC medication checked and dispensed for an identified patient by pharmacy. Applies when no dose calculation</p> <p>Added independent checks</p> <p>5.3.34 Checking calculations: added care required when using liquid doses to avoid mg and volume errors</p> <p>5.3.42.5 Added reference to CD denaturing kit following update to MedPolSOP7 CDs</p> <p>5.3.44 Updated section relating to medication errors</p> <p>5.3.44.2.6 Added Duty of Candour</p> <p>5.3.50 Ophthalmic preps – added advice to manage medicines shortages and expiry dates</p> <p>5.3.53 SACT – Updated to reflect use of these drugs outside cancer services too</p> <p>5.3.54.1 Supervised administration of medicines –added Parkinson's Disease Medicines</p> <p>5.3.56 Medicines for Staff – added self-prescribing not allowed</p> <p>5.3.5.7 Midwifery led units – updated storage of medicines</p>	
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	<p>5.3.58 Illegal CDs or unidentified substances – edited following update to MedPolSOP7</p> <p>5.3.61 Added Therapeutic Level Monitoring of Medicines</p> <p>5.4.27 Added reference to Falsified Medicines Directive</p> <p>5.4.27.6 Updated to state stock lists to be reviewed at least annually</p> <p>5.4.33.2 Added requirements for checking medicines on receipt e.g. product integrity</p> <p>5.4.36.11 Length of supply of medicines on discharge and outpatients – updated to reflect contract requirements</p> <p>5.5.28 Added statement that pharmacy will undertake safe and secure handling audits when new areas open up</p> <p>5.5.29 Section updated to accommodate key safes SOP</p> <p>5.5.39 Expanded requirements for reporting to CDLIN</p> <p>5.5.43 Added new section for Medical Gas Cylinders & audits</p> <p>5.7 Reporting Defects in Medicines – updated to reflect new procedure for pharmacy staff to follow</p> <p>5.8 MHRA Drug Alerts & Supply Disruption Alerts – updated to reflect updated guidance in Trust Policy Management of Safety Alerts</p> <p>5.9 Midwives Supplementary Policy – updated to reflect new standards</p> <p>5.10 new section Reporting Medication Errors with signposts from 5.3.18 and 5.2.32</p> <p>6.4 Training & Awareness – updated to reflect new Essential to Role training</p> <p>6.4.31 Medicines Safety Alerts & training – updated to reflect updated guidance in Trust Policy Management of Safety Alerts</p> <p>6.5.29.5 Added Individual Funding request for clinical trials to reflect HWCCG IFR Standard Operating Framework</p> <p>8 Policy Review – changed to 3 years in accordance with Trust Key Documents Policy</p> <p>9 References updated</p> <p>Appendix 1 – Medicines Defect Reporting Form – removed</p> <p>Appendix 2 – Self-Administration & patients own medicines consent form – removed</p> <p>Appendix 3 – changed to Appendix 1 and updated (Medicines Policy Monitoring Section)</p> <p>Appendix 2 List of the Medicines Policy supporting SOPs</p>	
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APPENDIX 1 Medicines Policy (medicines optimisation) process for monitoring compliance

Key Control	Where the check will be carried out	Checks to be carried out to confirm compliance:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to:	Frequency of Reporting
WHAT?	WHERE?	HOW?	WHEN?	WHO?	WHERE?	WHEN?
Safe and secure handling, purchasing, storage and supply of medicines	Wards & depts	Key Standards Audit	Monthly	Ward/dept pharmacist/technician	Divisional governance committees Medicines Safety Committee Clinical Governance Group	Quarterly/Monthly Quarterly Quarterly
	Wards & depts	Ward Audit Checklist (WM)	Annual In accordance with schedule for division in annual delivery plan	Ward/dept pharmacist/technician	Divisional governance committees Medicines Safety Committee Clinical Governance Group	Annual In accordance with schedule for division in annual delivery plan
	Pharmacy dept	Pharmacy Dept Audit checklist	Annual	Lead Operational Pharmacist and/or	Pharmacy Governance	Annual

		(WM)		Chief Technician	Committee Medicines Safety Committee Clinical Governance Committee	
Safe and secure handling, purchasing, storage, supply and disposal of controlled drugs	Wards/depts	Ward Controlled Drugs Audit checklist (WM)	Quarterly	Ward/dept pharmacist/technician	Divisional governance committees Medicines Safety Committee Clinical Governance Group	Quarterly
	Pharmacy dept	Pharmacy Dept Controlled Drugs Audit checklist (WM)	Quarterly	Lead Operational Pharmacist and/or Chief Technician	Pharmacy Governance Committee Medicines Safety Committee Clinical Governance Committee	Quarterly
Prescribing of	Wards & depts	Inpatient prescription	Daily or in accordance	Pharmacist	Prescriber/Clinical Lead Pharmacist for	On-going

Medicines		chart check using professional checking SOP Clinical Pharmacy SOP	with scheduled visit Annual	Pharmacist	Speciality to escalate to Clinical Director Divisional Governance Committees Medicines safety Committee	Annual
	Wards/depts./ Dispensaries	TTOs using professional checking SOP	All pharmacy dispensed TTOs	Pharmacist	Prescriber/escalate to Clinical Director	On-going
	Wards/depts	TTOs using MedPolSOP01	All non-pharmacy dispensed TTOs	Nurse/Midwife/doctor	Prescriber/ escalate to Clinical Director & Director Of Pharmacy	On-going
	Dispensaries	Chemotherapy using Chemotherapy checking SOP	All prescriptions	Pharmacist	Prescriber/escalate to Clinical Director	On-going
		Intrathecal Chemotherapy using Intrathecal Chemotherapy Checking SOP	All prescriptions	Pharmacist	Prescriber/escalate to Clinical Director	On-going
		Unlicensed Medicines	All prescriptions	Pharmacist	Prescriber/escalate to Clinical Director	On-going

Dispensing (non-sterile)	Dispensaries	Accuracy Checking & Error Monitoring SOPs	All prescriptions	Pharmacist/ Accredited Accuracy Checking Technician	Pharmacy Governance Committee	Quarterly
	Wards/depts	TTOs using MedPolSOP 01	All prescriptions	Nurse/midwife/doctor	Prescriber/ escalate to Clinical Director & Director Of Pharmacy	On-going
Sterile dispensing	Pharmacy Aseptic Dispensing Suite	Farwell Inspection of facility, systems & training	Every 18 months	Regional QA pharmacist	Chief Executive/ Director of Pharmacy Pharmacy Governance Committee SCSD Governance Committee	Every 18 months
		Quality Surveillance Programme Cancer Services	Annual	Quality Surveillance Team	Cancer Services Board SCSD Division	
	Radiopharmacy Nuclear Medicine Suite		Every 18 months	External Consultant Radiopharmacist	Radiology Governance Committee SCSD Governance Committee	Every 18 months
Administration	Wards/depts	Datix incident	On-going	Pharmacist/technician	Divisional governance	Monthly

of Medicines		reports		Nurse/midwife/doctor Other Healthcare professional	committees Medicines Safety Committee Clinical Governance Group	Quarterly Quarterly
Medicines SOPs & Patient Safety Alerts	Wards/depts./ pharmacy	Audit	In accordance with Forward Audit Plan & Annual Delivery Plan	Pharmacist/technician Nurse/midwife/doctor	Pharmacy Governance Committee Divisional governance committees Medicines Safety Committee Clinical Governance Group	On-going (min annually)
Medicines related incidents	Wards/depts./ pharmacy	Datix Incident Reporting	On-going	Healthcare Professional	Divisional Governance Committees Medicines Safety Committee Clinical Governance Group	Monthly Quarterly (themes & trends Trust wide report)

APPENDIX 2 Medicines Policy - Standard Operating Procedures

MedPolSOP01	Non-pharmacy dispensing
MedPolSOP03	Handing a medicine to a patient to take out of a clinical area (a TTO)
MedPolSOP05	Unlicensed and Off-label Medicines
MedPolSOP07	Controlled Drugs
MedPolSOP08	Controlled Drugs Stock Lists
MedPolSOP09	Supply, Administration, Storage and Transfer/TTOs of Insulin
MedPolSOP10	Prescribing / Dispensing / Supplying / Applying Paraffin Based Skin Products - reducing the associated Fire Hazard
MedPolSOP11	Administration of Oral and Enteral Liquid Medicines
MedPolSOP14	Reducing Risk of Overdose with Midazolam Injections in Adults
MedPolSOP15	Reporting Adverse Reactions
MedPolSOP16R	Bowel Prep Procedure in Radiology Departments
MedPolSOP17	Controlled Drugs Discrepancy Procedure
MedPolSOP18	Controlled Drug missing keys procedure
MedPolSOP19	Purchasing for safety
MedPolSOP20	Standard Operating Procedure (SOP) for Adult Ward Medicines Administration
MedPolSOP21	Standard Operating Procedure (SOP) for Paediatric Ward Medicines Administration
MedPolSOP22	Standard Operating Procedure (SOP) for Neonates Ward Medicines Administration
MedPolSOP23	Standard Operating Procedure (SOP) for Supply, Storage, Prescribing and Handling of Strong Potassium Infusions and Concentrate
MedPolSOP27	Outpatient Prescribing (including FP10s)
MedPolSOP28	Safe management of ONCE WEEKLY Methotrexate for non-malignancy on acute admission
MedPolSOP29	Monitoring and management of medicine fridge and room temperatures
MedPolSOP31	Patient Group Directions Procedure
MedPolSOP32	Medicines Key Security
MedPolSOP33	Safe and Secure Handling of Prescribing Stationery inc FP10s
MedPolSOP34	Potassium Permanganate Procedure and Patient Information
MedPolSOP35	Emergency and Discretionary Medicines Policy
MedPolSOP36	Automated Medicines Storage Cabinets (Omnicell)

Supporting Document 1 - Equality Impact Assessment Tool

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form

Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust	x	Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	Tania Carruthers Associate Director - Medicines Optimisation and Director of Pharmacy
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Details of individuals completing this assessment	Name	Job title	e-mail contact
	Alison Smith	Lead Pharmacist for Medicines Safety/Medicines Safety Officer	Alison.smith105@nhs.net
	Tania Carruthers	Associate Director - Medicines Optimisation and Director of Pharmacy	Tania.carruthers@nhs.net
Date assessment completed	30/06/2020		

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	Title: Medicines Policy
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What is the aim, purpose and/or intended outcomes of this Activity?	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.			
Who will be affected by the development & implementation of this activity?	<input type="checkbox"/>	Service User	<input type="checkbox"/>	Staff
	x	Patient	<input type="checkbox"/>	Communities
	<input type="checkbox"/>	Carers	<input type="checkbox"/>	Other _____
	<input type="checkbox"/>	Visitors	<input type="checkbox"/>	
Is this:	<input checked="" type="checkbox"/> Review of an existing activity <input type="checkbox"/> New activity <input type="checkbox"/> Planning to withdraw or reduce a service, activity or presence?			
What information and evidence have you reviewed to help inform this assessment? (Please name sources, e.g. demographic information for patients / services / staff groups affected, complaints etc.)	Information arising from monitoring of compliance with the policy (Appendix 1) Information arising from Incidents, Risks and Complaints			
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	The Medicines Policy describes the Trust's control measures for reducing medicine-related risks within a framework provided by legislation and official guidance. The content is reviewed every three years (with opportunity to input from representatives of staff required to follow it), and as required where safety or other issues are identified.			
Summary of relevant findings	No equality issues identified.			

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale.** Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential <u>positive</u> impact	Potential <u>neutral</u> impact	Potential <u>negative</u> impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age		X		
Disability		X		
Gender Reassignment		X		
Marriage & Civil Partnerships		X		
Pregnancy & Maternity		X		
Race including Traveling Communities		X		
Religion & Belief		X		
Sex		X		
Sexual Orientation		X		
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)		X		
Health Inequalities (any)		X		

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)				

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
	None			
How will you monitor these actions?	N/A			
When will you review this EIA? (e.g. in a service redesign, this EIA should be revisited regularly throughout the design & implementation)	Every three years as part of the Policy Review			

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc., and as such treat

them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	Alison Smith
Date signed	28/02/2024
Comments:	N/A
Signature of person the Leader Person for this activity	Tania Carruthers
Date signed	28/02/2024
Comments:	N/A

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