

Medicines Code

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Target audience:	All staff in York Teaching Hospital NHS Foundation Trust involved in medicines management and relevant staff from the Vale of York Clinical Commissioning Group and Scarborough and Ryedale Clinical Commissioning Group.
Relevant Regulations and Standards	The Medicines Act 1968, The Misuse of Drugs Act 1971, The Misuse of Drugs Regulations 1985, The Standards for Medicines Management 2008, RMSAT 4.10, 5.10 and CQC Outcome 9

Executive Summary

NHS Trusts are required to establish, document, maintain and monitor effective systems to ensure that medicines are prescribed, administered, stored and handled in a safe and secure manner. Such systems are a requirement of risk management and clinical governance. York Teaching Hospital NHS Foundation Trust is committed to this requirement. The purpose of this document is to help staff by describing the systems and procedures within the trust that support this aim.

These policies and procedures apply to **all** Trust staff. They also apply to staff from other NHS Trusts, or from private practices, who are contracted to work in the Trust on a sessional basis. Therefore all staff working in the Trust who are involved in some way with the use of medicines must familiarise themselves with the procedures contained within this document.

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Approved	Version Author	Status & location	Details of significant changes
3	26/02/2008	David Pitkin	Horizon	Addition of Appendix 2 – Training Needs Analysis for Medicines Management at YHNSHFT
3	26/02/2008	David Pitkin	Horizon	Addition of section 7.3 with specific reference to Training in accordance with Trust recommendation.
3	26/02/2008	David Pitkin	Horizon	Addition of 4 - Monitoring, Audit and Feedback Summary.
3	26/02/2008	David Pitkin	Horizon	Amendments to wording in section 9.2 to make reference to Appendix 4.
3	02/06/2008	David Pitkin	Horizon	Amendments to wording in sections 9 & 9.1
3	02/06/2008	David Pitkin	Horizon	Amendments to wording in Appendix 4.
3	02/06/2008	David Pitkin	Horizon	Added hyperlink to Training Profiles.
4	17/10/2008	David Pitkin	Horizon	Amendments to wording in section 10.1
5	17/10/2009	David Pitkin	Horizon	Amendments to appendix 1 – controlled stationery list
6	June 2010	Jennie Booth & Matt Cooke	Horizon	Full review and RMSAT format

Version	Date Approved	Version Author	Status & location	Details of significant changes
7	Feb 2012	Natalie Bryars & Jeremy Proctor	Horizon	All sections have been reviewed to ensure that they reflect practice in the community.
7	Feb 2012	Natalie Bryars & Jeremy Proctor	Horizon	All sections have been reviewed to ensure that they reflect practice in Scarborough and North East Yorkshire NHS Trust.
7	Feb 2012	Natalie Bryars & Jeremy Proctor	Horizon	All hyperlinked documents from YTHNHSFT intranet have been removed until appropriate access is available across all sites in the Trust.
7	Feb 2012	Natalie Bryars & Jeremy Proctor	Horizon	Sections on loading doses, critical medicines and high risk medicines have been added in response to NPSA alerts.
7	Jan 2012	Natalie Bryars & Jeremy Proctor	Horizon	Section 34 has been added to reflect the Trust antimicrobial formulary.
7	Feb 2012	Natalie Bryars & Jeremy Proctor	Horizon	Section 29 has been expanded to provide greater detail on medicines management processes in theatres.
7	Feb 2012	Natalie Bryars & Jeremy Proctor	Horizon	Section 12 has been updated to reflect Trust standards in controlled drug management.
7	Feb 2012	Natalie Bryars & Jeremy Proctor	Horizon	Section 11 has been expanded to include the covert administration of medicines.

8	Feb 2014	Natalie Bryars	Trust Intranet	References to the PCTs have been changed to CCGs
8	Feb 2014	Natalie Bryars	Trust Intranet	Section 4 has been expanded to allow student nurses, midwives and medical students to administer more medication under supervision
8	Feb 2014	Natalie Bryars	Trust Intranet	Section 6 has been expanded to provide guidance against prescribers prescribing for themselves or their families.
8	Feb 2014	Natalie Bryars	Trust Intranet	Section 10 has been expanded to include the new Trust requirements on the management of medicine keys
8	Feb 2014	Natalie Bryars	Trust Intranet	Section 13 has been expanded to include more guidance on the arrangements for prescribing medicines on discharge
8	Feb 2014	Natalie Bryars	Trust Intranet	Section 17 has been expanded to comply with MHRA guidance
8	Feb 2014	Natalie Bryars	Trust Intranet	Section 21 has been amended to comply with new standards for FP10 management
8	Feb 2014	Natalie Bryars	Trust Intranet	The section on community psychiatric nurses has been removed
8	Feb 2014	Natalie Bryars	Trust Intranet	Appendix 1 has been amended to only list general acute prescription charts.

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1. Introduction & Scope

This is Version 8 of the Medicines Code. This version supersedes all versions produced prior to 2014.

This Medicines Code has been produced following consultation with staff from York Teaching Hospital NHS Foundation Trust, the Vale of York Clinical Commissioning Group and Scarborough and the Ryedale Clinical Commissioning Group. Consulted staff groups include nurses, midwives, pharmacy staff, medical staff, the Drugs and Therapeutics Committee and the Medicines Policy Group.

It updates, extends and replaces the guidance issued in the York Health Services NHS Trust Policy Statement – Administration and Control of Medicines, which was issued in 2000.

The Medicines Code is designed to ensure safe and secure prescribing, supply, administration and storage of medicines. It is designed to protect patients, staff and the Trust.

The Medicines Code takes account of relevant legislation and guidance from the Department of Health as well as from professional bodies such as the General Medical Council, the Nursing & Midwifery Council and the Royal Pharmaceutical Society. It also incorporates existing good practice, which may not previously have been included in policies and procedures.

Comments on the content of the Medicines Code, which are consistent with the principles of clinical governance, are welcome and should be sent to the Principal Pharmacist in Clinical Governance, preferably by e-mail.

The Department of Health requires that NHS Trusts establish, document, maintain and monitor effective systems to ensure that medicines are prescribed, administered, stored and handled in a safe and secure manner. Such systems are a requirement of risk management and clinical governance. York Teaching Hospital NHS Foundation Trust is committed to this requirement. The purpose of this document is to help staff by describing the systems and procedures within the trust that support this aim.

These policies and procedures apply to **all** Trust staff. They also apply to staff from other NHS Trusts, or from private practices, who are contracted to work in the Trust on a sessional basis. Managers who contract for these services must make it explicit within the written contract that these sessional staff must follow the procedures described within this Medicines Code.

All staff working within the Trust who are involved in some way with the use of medicines, must familiarise themselves with the correct procedures contained in this Medicines Code. Those in charge of wards, departments and/or junior medical staff are responsible for ensuring that their staff,

especially new starters and locum staff, follow procedures in this Medicines Code, which may differ from procedures elsewhere.

Thanks go to all those who have provided many valuable comments on the content.

2. Definitions

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

Some terms are used as generic terms throughout this Medicines Code to identify a range of individuals who carry equivalent responsibility.

Directorate Manager/Assistant Directorate Manager/Matron

This is a nominal title for the professional manager responsible for a group of wards or departments and some community based nurses. In some circumstances the individual undertaking this role may be the directorate manager, assistant directorate manager or the matron.

Ward Sister/Charge Nurse

The senior person appointed in charge of the designated ward, department or team. The term may be read as applicable to members of non-nursing professions who have overall responsibility for staff handling medicines, e.g. superintendent physiotherapist.

Nurse/Midwife in Charge

The senior practitioner on duty for the team, ward or department, who has been rostered or designated as the professional in charge for that shift.

Authorised Pharmacy Staff

Any qualified pharmacist, pharmacy technician or pharmacy assistant authorised by the Chief Pharmacist as competent and appropriate to perform a specific function.

Authorised Employee

A member of staff who, following training, has been authorised by the Trust to undertake specific duties in relation to medicines.

Prescriber

Only appropriately qualified doctors and dentists, qualified and authorised non-medical independent prescribers and supplementary prescribers are at present legally entitled to prescribe. Other professionals may have authority to supply and/or administer under a Patient Group Direction (PGD) (see section 14). Some community-based nurses are entitled to prescribe for patients in primary care, in accordance with the Nurse Prescribers Formulary. See also Non-medical Prescribing Policy & Procedure.

Practitioner

This is used as a general term to describe a registered medical practitioner, nurse, pharmacist or other authorised healthcare employee.

Locum Practitioner

An individual temporarily fulfilling the duties of a practitioner (see above) normally employed through a third party.

Medicine

Any substance or preparation that may be administered for the purpose of diagnosis or for treating or preventing disease. The term includes contraceptives, larvae and leeches and other substances that may alter or induce physiological responses.

Dietary Product

A product included in the list of foods in Appendix 7 of the British National Formulary (BNF).

Prescribe

To authorise in writing the supply or administration of a medicine for a patient. During the lifetime of this Medicines Code, arrangements will be made to authorise these processes electronically and separate guidelines will be issued. (PGDs do not constitute prescriptions but are an authorisation to supply/administer).

Dispense

To prepare a clinically appropriate medicine for a patient for self-administration or administration by another. The act of dispensing includes supply and also encompasses a number of other cognitive functions (e.g. checking the validity of the prescription, the appropriateness of the medicine for an individual patient, quality and expiry of the product). These functions are performed under the supervision of a pharmacist.

Supply

To supply a medicine to a professional, patient or carer for administration.

Administer

To give a medicine by either introduction into the body (e.g. orally or by injection) or by external application (e.g. cream or ointment).

3. Policy Statement

This is Version 8 of the Medicines Code. This version supersedes all versions produced prior to 2014.

The Medicines Code gives guidance on matters relating to the use of medicines in the Trust. It sets the minimum standard for all aspects of medicines management.

The Medicines Code is not intended to supersede or conflict with professional standards or codes of practice which are in place. All activity relating to medicines within the Trust must comply with relevant law and the requirements of other external official agencies, for example relating to waste disposal. The Medicines Code does however reflect legal requirements and non-optional Trust approved procedures, but also gives guidance and good practice principles governing the use of medicines.

More detailed local policies and procedures are referenced within the Medicines Code document.

4. Equality Impact Assessment

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at an unreasonable or unfair disadvantage over others.

In the development of this policy, the Trust has considered its impact with regard to equalities legislation.

5. Accountability

The Chief Executive of each Trust has overall responsibility for the safe and secure handling of medicines. The Chief Pharmacist is responsible for establishing, monitoring and reporting on a system for assuring the safe and secure handling of medicines.

The Chief Pharmacist reports on these matters to the Chief Executive through executive performance management meetings.

The Risk and Assurance Committee is accountable to the Trust Board. It sets strategic direction for governance and ensures the implementation of the governance agenda at directorate level.

The Risk and Assurance Committee, therefore, has an interest in a range of issues relating to medicines, including accountability for the quality of clinical care (e.g. prescription writing) and clinical record keeping, risk management and Continuing Professional Development (CPD).

The Patient Safety Group reports to the Risk and Assurance Committee and is required to ensure the effective implementation of the Trust's risk management strategy. This includes ensuring that the responsibilities for managing risks are clear, integrating risk management with the Trust's corporate and clinical governance agendas and establishing and maintaining an on-going programme of risk identification and analysis throughout the Trust.

The Medicines Management Group (MMG) is a sub-committee of the Patient Safety Group (PSG) and reports to this group through exception return reporting at each of their quarterly meetings. The group provides assurance to the PSG on all risk and safety matters in medicines management in the Trust, and stimulate developments to annual medicines management work plans across the Trust.

The Drug and Therapeutics Committee reports to the Chief Executive via the MMG and is responsible for promoting safe and effective prescribing within the Trust and across the interface with the Vale of York Clinical Commissioning Group and the Scarborough and Ryedale Clinical Commissioning Group. The committee is responsible for approving the Trust formularies, shared care protocols, prescribing policies, prescription charts and the introduction of new drugs.

6. Consultation, Assurance and Approval Process

6.1 Consultation Process

This Medicines Code has been produced following consultation with nurses, midwives, pharmacy staff and medical staff from York Teaching Hospitals NHS Foundation Trust, the Vale of York Clinical Commissioning Group, the Scarborough and Ryedale Clinical Commissioning Group, the Drugs and Therapeutics Committee and the Medicines Policy Group.

6.2 Quality Assurance Process

Following consultation with stakeholders and relevant consultative committees, this policy has been reviewed by the approving committee to ensure it meets the NHSLA standards for the production of procedural documents.

6.3 Approval Process

Following completion of the Quality Assurance Process, this policy, and any subsequent policy revisions will require the approval of The Medicines Management Group.

7. Review and Revision Arrangements

Full review of the code will take place bi-annually, co-ordinated by the Principal Pharmacist in Clinical Governance, with involvement by representatives of all healthcare professions performing medicines management roles.

Significant changes are anticipated in medicines management practices within the lifetime of this policy. Revisions of the code will be made to reflect these changes as and when they occur.

8. Dissemination and Implementation

8.1 Dissemination

The policy will be available on the Trust intranet on the Clinical Policies page.

This policy is available in alternative formats, such as Braille or large font, on request to the author of the policy.

8.2 Implementation of this policy

Nursing staff will be advised of this policy through the Corporate Nursing Team and the Matrons. Nurse training on key elements of the policy are available within the Preceptorship Programme and as specific packages e.g. I.V drugs, Infusion Device Awareness, Syringe Driver Competency Package.

All junior doctors will be advised of the existence of the policy and key elements of the policy through the junior doctor's induction programme.

All pharmacy staff will be introduced to the policy on induction. Specific training requirements on all areas of the policy will be developed during induction as dictated by the individual's role within medicines management and the requirements of their job description/person specification.

Other members of Trust staff with any responsibility for medicines management should be aware of the existence of the code, through their heads of department, and understand its implications for their area of practice.

General Practitioners (GPs) working in Trust community hospitals will be advised on the existence of the policy and key elements of the policy by the Principal Technician for Community Services and the Specialist Nurse for Community Services.

9. Document Control including Archiving Arrangements

9.1 Register/Library of Policies

This policy will be stored on the Trust intranet, on the policies and procedures site and will be stored both in an alphabetical list as well as being accessible through the portal's search facility. All policies will be registered and a library kept by the Compliance Unit

9.2 Archiving Arrangements

The Compliance Unit will manage the archiving arrangements of all policies.

9.3 Process for Retrieving Archived Policies

To retrieve a former version of this policy from the Trust intranet, the Compliance Unit should be contacted.

10. Monitoring Compliance With and the Effectiveness of Policies

This policy will be monitored for compliance with the minimum requirements outlined in appendix 3. Where the minimum requirements for the policy are prescribed by the NHSLA Risk Management Standards, the Criterion number must be quoted.

This policy will be monitored for compliance with the minimum requirements of criterion 1.2 of the NHSLA Risk Management Standards for Acute Trusts.

10.1 Process for monitoring compliance and effectiveness

The findings of these audits will be reported to the Medicines Management Group. Any actions arising out of this monitoring will be progressed through the appropriate staff groups.

10.2 Standards/Key Performance Indicators

See Appendix 3.

11. Training

Any theoretical training requirements identified within this policy are outlined within the mandatory training profiles accessed via the Statutory & Mandatory Training Link that can be found on the home page of the Trust intranet or on Q:\York Hospitals Trust\Mandatory Training.

A yearly review of the training needs analysis for medicines management will take place in response to feedback from the Medication Safety Group, government initiatives, NPSA alerts and legislative changes. See Appendix 2 - Training Needs Analysis for Medicines Management in the Trust.

12. Trust Associated Documentation

See Appendix 1.

13. External References

The Medicines Code takes account of relevant legislation and guidance from NHS England and the Department of Health as well as from professional bodies such as the General Medical Council, the Nursing & Midwifery Council and the Royal Pharmaceutical Society. It also incorporates existing good practice, which may not previously have been included in policies and procedures.

MEDICINES CODE

2014 - 2016

**A guide to the safe and
secure handling of medicines**

Version 8

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1. FRAMEWORK

The relevant primary legislations concerning the prescribing, supply and administration of medicines are:-

- The Medicines Act 1968
- The Misuse of Drugs Act 1971
- The Misuse of Drugs Regulations 2001
- The Misuse of drugs (Safe Custody) Regulations 1973
- Health Act 2006

This policy is also based on the recommendations and requirements of:-

- NMC Standards for medicines management 2010
- NMC The Code: Standards of Conduct, Performance and Ethics for nurses and midwives 2010
- Nurses, Midwives, and Health Visitors, Rules Approval Order – Rule 18a 1983
- The safe and secure handling of medicines: a team approach, March 2005
- Crown Report 1998 and 1999
- Patient Group Directions HSC2000/026
- Guidelines issued by the GMC
- Guidelines issued by NICE
- Guidelines issued by NHS England
- A Spoonful of Sugar 2001, Medicines Management in NHS Hospitals Audit Commission
- The Responsible Pharmacist Regulations 2008
- Safer Management of Controlled Drugs – a guide to good practice in secondary care
- Building a safer NHS for patients – improving medication safety 2004

All staff involved with medicines must be familiar with the relevant rules and guidelines. In addition the policy is influenced by the requirements of: -

- Controls Assurance – Medicines Management, March 2000
- Clinical Governance and Risk Management
- Control of Substances Hazardous to Health (COSHH) Regulations 1989
- Continuing Professional Development
- The Care Quality Commission
- NHS Litigation Authority
- Risk Management Scheme for Acute Trusts

2. GENERAL PRINCIPLES

The multiplicity of medicines, their potency and potential toxicity means a heavy responsibility for doctors, nurses/midwives and pharmacists. Errors can occur in any of the procedures relating to medicines including prescribing, dispensing, interpretation of the prescription and administration.

All staff are accountable for properly discharging their duties and responsibilities in relation to medicines as detailed in this policy. Senior staff in Medicine, Nursing and Pharmacy are responsible for ensuring that duties are delegated to staff with appropriate knowledge and competence.

Medicines, whether for internal or external use, will be regarded, for the purpose of this Medicines Code, as comprising the following categories:

- Controlled medicines, including drugs controlled under the provisions of the Misuse of Drugs Act 1971, together with other medicines liable for misuse with stringent requirements for prescribing, supply, storage and record keeping.
- All other medicines and medicinal products prepared for administration to patients and which are controlled by the Medicines Act 1968.
- All complementary medicines e.g. aromatherapy, herbal or homeopathic remedies. These products are used for therapeutic purposes and require the same safeguards as other medicines. Leeches and larvae are included in this category.
- Other pharmaceutical preparations such as disinfectants, reagents and other preparations not used directly to treat patients also require rigorous safeguards.
- Some substances designated as Medical Devices under Medical Devices Directive (93/42/EEC) and the associated UK regulations implementing the directive (S1 1994 No 3017) but which are administered to patients as part of a medical or surgical procedure, e.g. collagen.
- Products defined by local medical devices management policies.

All medicines must be properly accounted for and treated with care. It is important to understand that procedures listed in this document apply to all medicines used in the Trust. These include topical lotions, applications, intravenous infusions, medicated dressings, emergency kits, complementary medicines, x-ray contrast agents, enteral and parenteral feeds, radio pharmaceuticals, medical gases and many diagnostic agents.

Clinical trial medicines are handled in the same way but may be subject to more stringent requirements (see section 17).

3. ACCOUNTABILITY ARRANGEMENTS

The Risk and Assurance Committee is accountable to the Trust Board. It sets strategic direction for governance and ensures the implementation of the governance agenda at directorate level. The committee, therefore, has an interest in a range of issues relating to medicines, including accountability for the quality of clinical care (e.g. prescription writing) and clinical record keeping, risk management and Continuing Professional Development (CPD).

The Patient Safety Group report to the Executive Board via the Risk and Assurance Committee and is required to ensure the effective implementation of the Trust's risk management strategy. This includes ensuring that the responsibilities for managing risks are clear, integrating risk management with the trusts corporate and clinical governance agendas and establishing and maintaining an on-going programme of risk identification and analysis throughout the Trust.

Medicines Management Group (MMG) is a sub-committee of the Patient Safety Group (PSG) and reports to this group through exception return reporting at each of their quarterly meetings. The MMG provides assurance to the PSG on all risk and safety matters in medicines management in the Trust and oversees developments to annual medicines management work plans across the Trust.

A number of other committees report to the MMG. These include the Drug and Therapeutics Committee, which is responsible for promoting safe and effective prescribing within the Trust and across the interface with the Vale of York Clinical Commissioning Group and Scarborough and the Ryedale Clinical Commissioning Group. The committee approves the trust formularies, shared care protocols, prescribing policies, prescription charts and the introduction of new drugs.

4. RESPONSIBILITIES OF STAFF

Chief Executive

The Chief Executive has overall responsibility for the strategic and operational management of the Trust, including ensuring that Trust policies comply with all legal, statutory and good practice requirements.

Chief Pharmacist

The Chief Pharmacist is responsible for:

- Ensuring that policies are developed and reviewed for all medicines management activities which meet current statutory, legislative and good practice requirements.
- The economical purchasing, appropriate storage and distribution of medicines and pharmaceutical products in accordance with good medicines management practice, value for money, appropriate contracts and financial probity.
- Providing basic prescribing training to all prescribers with a permanent contract (i.e. for all non-locum junior medical staff).
- Ensuring that the dispensing and supply of medicines from the pharmacy is carried out in a manner that minimises risks to patients and healthcare staff.
- Ensuring that appropriate standard operating procedures for ward and dispensary based pharmacy activities are prepared and disseminated to pharmacy staff.
- Ensuring that all pharmacists and pharmacy technicians are registered and that all pharmacy staff receive appropriate training at induction and ongoing training throughout their employment.
- Ensuring that the preparation of medicines is carried out in a manner that minimises risks to patients and healthcare staff and meets current statutory criteria / guidance.
- Ensuring that documentation relating to the preparation of medicines is retained according to NHS England and Department of Health guidance.
- Accurately maintaining the data held on the pharmacy computer system and advising on how the data can be used to monitor medicines use.

Prescribers (including Non-Medical Prescribers)

Prescribers are responsible for:

- Applying the relevant parts of this policy to their practice.
- Complying with appropriate legislation, professional guidance and local standards and prescribing within their competence. They must take account of the Summary of Product Characteristics (SPC), the Trust formulary, the evidence

/ expert opinion and the patient's condition when selecting which drug to prescribe.

- Complying with legislation, the formulary, antimicrobial formulary and associated medicines policies.
- Signing and clearly identify themselves on the drug chart/prescription.
- Preparing some none ready to use medicines in near patient areas in accordance with standard operating procedures, the instructions in the Summary of Product Characteristics and/or local guidance.
- Monitoring the effects of medicines by the use of indicators to ensure that individual patients obtain maximum benefit from the medicine with the minimum of unwanted effects.

Prescribers in training

Medical students and Non-Medical prescribers in training are not permitted to prescribe for patients.

Human Resources

Human resources are responsible for maintaining an up to date record showing the appointment and specimen signature of all prescribers (including locums).

Clinical Supervisors

Clinical Supervisors must ensure their supervisees maintain prescribing standards, supervise the adequacy of prescribing and investigate and report any inadequacies in prescribing reported to them.

Pharmacists

Pharmacists are responsible for:

- Applying the relevant parts of this policy to their practice.
- Managing the safe, effective and economic use of medicines in the Trust and ensuring patients can obtain maximum benefit from their drug therapy.
- Monitoring prescriptions in order to ensure that they meet current legal and local criteria for completeness, accuracy and clarity and are clinically appropriate for the patient taking into account the Trust formulary, authorised guidelines and protocols.
- Documenting interventions in an appropriate manner and informing the prescriber accordingly.
- Reporting prescribing inadequacies to Clinical Supervisors.
- Advising prescribers on appropriate therapy taking account of the Summary of Product Characteristics (SPC), the Trust formulary, the evidence / expert opinion and the patient's condition.

- Preparing medicines in the Pharmacy Department in accordance with standard operating procedures (Authorised and validated pharmacists only).
- Dispensing medicines in an appropriate form to facilitate administration in accordance with standard operating procedures.
- Supplying medicines requested on an authorised stock request in accordance with standard operating procedures.
- Advising prescribers and registered nurses and midwives on medicines administration and challenging apparently inappropriate medicines administration.
- Managing the stock of medicines held in the pharmacy, their preparation into user ready presentations according to standard operating procedures with appropriate documentation and their supply to wards and departments.
- Advising patients, carers, relatives etc on their medicines.
- Monitoring the safe, clinical and cost effective use of medicines for individual patients on the wards and in the dispensary and for the use of stock medicines for their allocated wards.

Pharmacy Technicians

Pharmacy Technicians are responsible for:

- Applying the relevant parts of this policy to their practice.
- Procuring medicines to satisfy a valid prescription or to meet anticipated demands (Authorised pharmacy technicians only).
- Handling medicines in the Pharmacy Department according to legal requirements and in accordance with standard operating procedures.
- Confirming details of patient's medication histories (Authorised pharmacy technicians only).
- Advising patients, carers, relatives etc on their medicines.
- Dispensing medicines in an appropriate form to facilitate administration in accordance with standard operating procedures.
- Preparing medicines in the Pharmacy Department in accordance with standard operating procedures (Authorised and validated pharmacy technicians only).
- Supplying medicines requested on an authorised stock request in accordance with standard operating procedures.

Registered Nurses and Midwives

Registered nurses and midwives are responsible for:

- Applying the relevant parts of this policy to their practice.

- Ensuring all requests for medicines are directed to the pharmacy in a timely manner.
- Reconstituting some medicines in near patient areas in accordance with standard operating procedures, the instructions in the Summary of Product Characteristics and/or local guidance.
- Administering medicines in accordance with standard operating procedures, the instructions in the Summary of Product Characteristics, NMC standards and/or local guidance.
- Documenting the administration of medicines in accordance with NMC standards and standard operating procedures.
- Undertaking all relevant training in relation to medicines and infusion devices.

Registered nurses and midwives, particularly clinical specialists, may suggest to prescribers medication that may contribute to the improvement in a patient's condition.

Operating Department Practitioners, Radiographers and Physiotherapists

Operating Department Practitioners, Radiographers and Physiotherapists are responsible for:

- Applying the relevant parts of this policy to their practice.
- Only administering medicines in accordance with standard operating procedures, the instructions in the Summary of Product Characteristics and/or local guidance.
- Only supplying and administering medicines in accordance with Patient Group Directions, approved clinical protocols, standard operating procedures, the instructions in the Summary of Product Characteristics and/or local guidance.

Clinical Support Workers and Healthcare Assistants

Clinical Support Workers and Healthcare Assistants are responsible for:

- Applying the relevant parts of this policy to their practice.
- Unregistered staff must only undertake medicines related tasks once they have received training and been deemed competent in line with Trust policy.

Student Nurses/Student Midwives/Medical Students

At all times students should act within their professional ability, ensuring that they have the underpinning knowledge and evidence to support their actions.

All practitioners supervising students must be competent in that aspect of care and are accountable for their own practice and for the supervision of the student.

Whilst under the direct supervision of a registered nurse, midwife or medical staff, student nurses, student midwives and medical students may administer

certain medicines for the purpose of instruction and learning. Under the direct supervision of a registered nurse, midwife or medical staff, these students may administer medicines via the oral, enteral, sublingual, subcutaneous, intramuscular, rectal, topical and vaginal route. They may also administer inhalers, nebulisers, eye drops, ear drops/sprays, nasal drops/sprays under supervision. They may also administer standard intravenous fluids under direct supervision. The supervisor maintains all responsibility for the administration process and must sign the drug chart following the administration of the medicines.

Prior to the administration of medicines by any route, the underpinning knowledge should have been covered within the undergraduate training program. Medical students may only administer medicines for the purpose of instruction and learning from their 3rd year.

Student nurses, student midwives and medical students must not administer high risk medicines. These include:

- Intravenous injections or infusions
- Colloids and emulsions.
- Epidural or intrathecal medication.
- Injectable controlled drugs.
- Medicines where access is restricted to specialist areas e.g. fluids containing potassium stronger than 40 mmol in 1000mL.
- Medicines via a central line.

Student nurses, student midwives and medical students must not use any function of an infusion device. This includes using the silence button.

Student nurses, midwives or medical students must not flush any central lines.

Student nurses, student midwives and medical students cannot formally witness the preparation and administration of any medicine that requires a second check, such as controlled drugs.

Ward Sisters/Charge Nurses

Ward Sisters and Charge Nurses are responsible for:

- Ensuring adequate dissemination, implementation and adherence to policies.
- Supporting staff whilst undertaking their duties to ensure compliance with this policy.

5. PROCUREMENT OF MEDICINES

Medicines purchased for use in the Trust must be procured or acquired by an authorised member of pharmacy staff using validated procedures. Refer to the Trust's Purchasing for Safety Policy.

Representatives of pharmaceutical and other companies expect to promote their licensed products direct to trust staff in order to secure or increase sales. If not carefully controlled these activities may undermine the trusts strategy for minimising risks associated with medicines. See section 37 and the Company Representatives Policy.

5.1 Samples of Medicines

Samples of medicines may represent a hazard to both staff and patients since they may not have been assessed by an appropriate body for use in the Trust. There is also no audit trail should a recall for safety reasons be necessary. Therefore samples of medicines must not be left on wards or departments. Representatives of pharmaceutical companies wishing to provide samples must be referred to the pharmacy department.

6. PRESCRIBING MEDICINES

6.1 Prescription Documents

Medicines may only be prescribed on official Trust prescription stationery, including electronic Discharge Notifications (eDN) and Chemocare, which has been approved by the appropriate committees (see appendix 1).

The purpose of the prescription chart is to provide a permanent record of the patient's medication and to direct and record the supply or administration of medicines. The main prescription chart must make reference to any separate special charts on which drugs have been prescribed. Continuation sheets for use with inpatient prescription charts are **not approved** for use in the Trust.

A zero-tolerance policy is now in place in relation to patient identification and allergies. All prescription charts and supplementary charts (e.g. infusion and warfarin charts) must have patient identification and allergy boxes completed in full. The minimum criteria are:

- Name (Patient's full name, spelt correctly, including aliases).
- Date of Birth.
- NHS number, Hospital number or other unique identifier, e.g. A&E number.
- Known allergies or sensitivities or a statement to indicate no known allergies.

Addressographs may be used.

Other details that must be included on each prescription are:

- Consultants name (where relevant).
- Current ward name, or number, or name of department (where relevant).
- Weight and height as appropriate.

The correctly completed prescription chart is the nurses/midwives authority for the administration of medicines.

Only one current prescription chart of each relevant type should exist at any one time for any patient. Where the number of medicines prescribed exceeds that which can fit on one chart, a second chart may be used. In such circumstances both prescription charts must indicate the existence of a second chart.

When a patient is re-admitted, a new prescription chart must be used. The prescription chart of patients transferred from one site to another within the Trust does not require rewriting. When patients are transferred from other Trusts, prescription charts must be rewritten.

Any act by which medicinal products are written from one form of direction to administer to another is "transcribing". This includes discharge letters, transfer letters, re-writing illegible prescriptions and copying old prescription charts onto new charts.

Transcribing should only be undertaken by a non-prescriber in **exceptional** circumstances and should not be routine practice. The individual practitioner is accountable for their actions and omissions. Any medication that has been transcribed **must** be signed by a registered prescriber before it can be administered. In exceptional circumstances this may be done in the form of an email or fax. In units where there are no doctors on site alternative procedures may be applicable, but these must first be agreed with the Chief Pharmacist.

Annotation of prescription charts by pharmacists must be done using a purple or green pen.

6.2 Authorised prescribers

The following registered healthcare professionals may prescribe within the confines of their competence, guidelines and Department of Health guidance:

- Medically qualified doctors or dentists.
- Independent non-medical prescribers - A registered nurse, pharmacist or physiotherapist, having undergone an accredited programme for independent prescribing and having passed the relevant assessments, may prescribe as in their stated personal scope of prescribing practice and area of competence and in line with the relevant Acts of Parliament.
- Community Practitioner Nurse Prescriber – Formerly District Nurse and Health Visitor prescribers may prescribe from a limited list of products detailed in the British National Formulary (BNF) and the Drug Tariff.
- Supplementary Prescribers – nurses, pharmacists, physiotherapists, radiographers, chiropodists / podiatrists and optometrists, having undergone an accredited programme and having passed the relevant assessments, may also prescribe as a supplementary prescriber in partnership with a doctor or dentist within the remit of an agreed clinical management plan.
- Dieticians are authorised to initiate the use of dietetic products by prescribing them on a patient's inpatient prescription chart or special chart.

No other staff may prescribe.

An individual new to post must seek the relevant authority before prescribing (e.g. from their service manager) and follow authorised procedures and complete necessary documentation before starting to prescribe.

6.3 Range of Medicines Available for Prescribing

Prior to prescribing, the prescriber should obtain an accurate record of the patient's current medication to ensure that medicines prescribed on admission correspond, where appropriate, to those that the patient was taking before admission. Details to be recorded include the name of the medicine(s), dosage, frequency and route of administration. Establishing these details may

involve discussion with the patient and/or carer and the use of records from primary care. See the Medicines Reconciliation Policy.

Initiation of new treatment must be in accordance with the Trust formulary and Antibiotic formulary, see Section 33 and 34. Previously prescribed therapy may be continued in hospital, if appropriate and if supplies are available. Exception is given to medicines undergoing clinical trial and specialist therapies for individual patients that have been agreed with the Chief Pharmacist.

Consultant medical staff may submit requests for new products to be made available in accordance with the trust New Products Procedure for medicines. This should be done via the Directorate Pharmacist or Formulary Pharmacist.

6.4 Safe Prescribing

Prescribers must:

- Clearly identify the patient (specify full name, date of birth, Hospital number/NHS number) on the drug chart in all identified places in line with the Policy for Documenting Patient Details on Prescription Charts throughout the Trust (See Section 6.1).
- Complete the allergy box with the patient's allergies or intolerances. The manifestation should also be stated where possible. **Medicines will not be dispensed or administered unless the allergy box is complete.**
- Write clearly and in permanent black ink. Each individual letter must be legible. Illegible prescriptions will need to be re-written before the drug can be administered and may result in a delay to patients receiving medication.
- Prescribe using the current BNF recommended generic name. The exceptions when brand name should be used are:
 - Drugs with a narrow therapeutic margin where differences in bioavailability exist between different products (e.g. lithium, theophylline, ciclosporin, phenytoin, carbamazepine and valproate).
 - Where the BNF recommends prescribing drugs by brand name because they are modified release (e.g. nifedipine, diltiazem etc).
 - If there is potential for confusion (e.g. oxycodone – Oxycontin, Oxynorm).
 - Combinations of drugs where there is no generic name.
 - Insulins (these should also include the device name).
 - Dressings
- Not use abbreviations for medications or fluid regimes, e.g. FeSO₄, ISMN, NaCl.
- Specify the dose by using mg, micrograms, nanograms or units. The word micrograms and nanograms must be written in full.
- Take particular care with the dose for paediatric prescriptions and specify the weight and date of birth on the drug chart/prescription. Where appropriate, the

intended dose, in mg/Kg, should also be stated on the drug chart / prescription.

- Always tell the patient and their nurse when making a change to the prescription of a self-medicating patient or in one-stop dispensing.
- Prescribe any controlled drugs required by patients to take home in accordance with the legal requirements as laid out in the section of the BNF titled “Controlled Drugs and Drug Dependence”. See Section 12.1.
- Specify multiple routes indicated for the same drug only where the dose is the same for each route. Where multiple routes are specified in this way the prescriber must specify the reason for using the alternative route in the ‘Additional Instructions’ section of the drug chart. The chart should be reviewed before changing the route to ensure any additional information or pharmacy annotations are still appropriate.
- Avoid the unnecessary use of decimal points, especially leading or trailing ones.
- Only prescribe within their own competence.

Further information on prescription writing can be found in the introduction section of the current BNF.

It is good practice to specify the indication for ‘prn’ medication. This ensures nurses administer medication appropriately (e.g. codeine for pain).

Medical gases must always be prescribed. The prescription must include the name and concentration of the medical gas, the method of administration and the rate of flow. See Section 27.

6.5 Routes of Administration

The following abbreviations are acceptable to indicate the route of administration:

ORAL	By mouth	IV	Intravenous	SC	Subcutaneous
PO	By Mouth	Neb	Nebulisation	SL	Sublingual
NG	By naso-gastric tube	PR	Per Rectum	Top	Topical
IM	Intramuscular	PV	Per Vagina	PEG/RIG	Via gastrostomy
INH	Inhalation	NJEJ	By naso-jejunal tube	JEJ	By jejunostomy
EYE	For Eye drops				

All other routes of administration must be written out in full, e.g. intrathecal, epidural.

6.6 Administration of drugs via Enteral Feeding Tubes

Essential medication can often be administered via an enteral feeding tube. Administering a drug via an enteral feeding tube usually falls outside the terms of the drugs product license, and is therefore “unlicensed”. The individual practitioners responsible for the prescribing, supply and administration of the drug may be liable for any adverse event. Alternative routes of drug administration should be considered. Regular drug therapy should be rationalised and any non-essential medication or medication with no clear indication discontinued.

Liquids or soluble tablets are the preferred formulations to be used and some injections can be administered via enteral tubes in order to minimise the risk of blocking the feeding tube. Only oral / enteral syringes (purple) should be used to measure and administer oral liquid medicines. These syringes **must not** be compatible with intravenous devices and intravenous syringes **must not** be used to measure or administer oral liquid medicines.

Crushing tablets or opening capsules should be considered only as a last resort. However, if tablets are to be crushed a “tablet crushing syringe” should be used to minimise exposure to crushed medication. These are available from the pharmacy department. Some types of medication (e.g. enteric coated, slow release, hormonal and cytotoxic medication) must not be crushed unless advice is sought from a pharmacist.

Interactions between medication and the enteral feed may be clinically significant. The enteral feed must be stopped and the enteral feeding tube flushed with water before and after each drug administration. Each drug should be given separately, unless advised otherwise. This will minimise the risk of blocking the tube and of medication interactions.

Medicines Information or the ward pharmacist can be contacted for specific drug information to enable the safe and effective prescribing and administration of drugs via enteral feeding tubes.

6.7 Times of Administration

The prescriber must specify the times of administration in the appropriate column on the inpatient prescription chart and ensure that such times are appropriate for the prescribed medicines.

Abbreviations such as 'bd' 'tds' are only to be used for as required ('prn') medicines and on discharge prescription forms. The following abbreviations are acceptable:

OM	Each morning	Mane	Each morning
ON	Each night	Nocte	At night
OD	Once a day	Protocol	As per protocol
BD	Twice daily	prn	As required (with indication and interval stated).
TDS	Three times daily	Stat	Give once only
QDS	Four times daily	PC	After food

All other dose regimens must be written out in full.

Certain injections, (e.g. depot and Vitamin B₁₂ injections) should be prescribed with the time interval expressed using the term "every" (e.g. every 3 weeks) rather than 3 weekly, which can be misinterpreted. This must not be abbreviated as every 3/52. When medicines are prescribed on the regular section of the inpatient prescription chart, any doses that are not to be administered should be cancelled individually with a bold cross (X). This applies to all medicines that are not administered on a daily basis (eg methotrexate, which should only be administered once every week).

6.8 Signature of Prescriber

The signature must be legible or the printed name of the prescriber should be written next to the signature together with the bleep number or method of contact.

Initials or abbreviated signatures are not an adequate means of identification or authorisation.

Electronic signatures can only be used as part of prescribing systems approved by the Chief Pharmacist.

6.9 Cancellation of Treatment

The prescription must be cancelled by drawing a bold, diagonal line across the drug name, dose and administration section. The cancellation must be

dated and signed in full. It is good practice to state a reason for stopping medication.

Old drug charts must be cancelled by drawing a bold line diagonally across all sides of the drug chart and endorsed with the word 'REWRITTEN', the doctor's signature and the date. All old drug charts must be filed in the appropriate section of the health records.

6.10 Amendment of therapy

Prescribers must ensure that the patient's prescription is up to date, is reviewed regularly and changed if necessary as the patient's need or condition changes. The prescriber must monitor the effectiveness of the medication and for any side effects or adverse drug reactions and amend the prescription accordingly.

When changing the dose, preparation, time or route of a drug the existing prescription should be cancelled and then rewritten. This ensures there is an accurate record of any changes in drug administration and who has authorised them.

Prescription charts become unclear after multiple deletions and revisions with a strong risk that some doses may not be administered. In such cases a prescriber will be required to rewrite the prescription chart.

6.11 Length of Treatment

The length of fixed term treatments, e.g. antibiotics, steroids etc, should be clearly stated.

6.12 Once Only Doses (Stat Doses)

Medicines that are intended to be given once only must be prescribed in the 'once only' section of the prescription chart. Consideration should be given to regular and 'prn' medication to avoid overdose of specific medications, e.g. paracetamol containing analgesics or concurrent medication. The doctor must inform nursing staff when once only medicines have been prescribed.

6.13 'As Required' Prescriptions (prn)

The 'As Required' section of the prescription chart must only be used for those medicines to be given at the practitioner's discretion according to the needs of the patient. The minimum interval between doses and indication for administration must be clearly specified by the prescriber. It is also good practice to stipulate the maximum dose to be given in a 24-hour period.

The 'as required' prescription must be reviewed regularly by a doctor to determine its clinical need. To prevent the accumulation of unnecessary 'as required' prescriptions they should be reviewed, continued if appropriate or cancelled if deemed necessary.

Medicines originally prescribed 'as required', but which are needed regularly, must be reviewed and the prn prescription cancelled and rewritten in the regular prescription section where appropriate.

Care must be taken not to duplicate medicines being taken regularly and thus overdose the patient. Combination analgesics frequently contain paracetamol, which may already be prescribed in the regular section of the prescription chart.

Rapid dose escalation using combinations of prn and/or regularly prescribed antipsychotic drugs is one of the most common causes of sudden death and neuroleptic malignant syndrome and therefore should be avoided.

Hypnotics initiated in hospital should not be prescribed at discharge.

6.14 Remote orders (Faxed or Verbal)

Prescribing without seeing the patient denies the prescriber the opportunity to reassess the case and check whether the patient's condition has changed. Therefore prescribers should be encouraged to make required amendments to prescriptions in person. Faxed or verbal orders are only acceptable in areas where no resident prescribers are present and in a clinical emergency.

In such an emergency, a written/typed prescription should be faxed to indicate what medication is to be administered. If this is not possible (e.g. if the nurse is in a patient's home and the urgency of the situation would not allow the nurse to collect a faxed order) then a verbal order may be given. A third party should be used to witness the verbal order wherever possible.

Faxed or verbal orders can only be used for a single dose of a drug and should be signed at the earliest possible opportunity and within 72 hours by a prescriber. Faxed or verbal orders cannot be used for Schedule 2 and 3 Controlled Drugs.

The practitioner retains the right to refuse to take a faxed or verbal message to administer a medicine. The reasons for refusal and action taken should be clearly documented in the patient's care record.

A pharmacist may receive a verbal order from a prescriber to alter or add a new prescription item. All alterations must be signed by the pharmacist. The pharmacist must paraphrase the alteration or addition back to the doctor who must then confirm it. The prescriber must sign any new inpatient prescription within 24 hours.

6.15 Lost or Missing Prescription Charts

As far as practicable, prescription charts should stay with the patient's records in a designated area or at the end of the patient's bed. They should leave a ward only when the patient leaves that ward for a procedure. Before sending a prescription chart to pharmacy for urgent medication or a discharge request, every effort

should be made to contact the ward pharmacist or pharmacy technician to find out if a supply can be organised without the prescription chart leaving the ward.

6.15.1 If a Prescription Chart is found to be Missing

Check the following locations:

- Drug trolley.
- Treatment room.
- Patient's medical records (including the filed prescription chart section).
- All end-of-bed records on the ward (especially patients with similar names).
- Other wards/theatres – if the patient has been on different wards the prescription may have been returned to an earlier ward.
- Pharmacy – if the chart was known to have been sent to the pharmacy department.

6.15.2 Writing up Medication When Prescription Charts go missing

It is not desirable that patients miss medication. If a prescription chart has gone missing it may be appropriate to ask a doctor to write a temporary prescription chart. The doctor must establish which medication the patient will need for the next 12 hours and prescribe it on the once only section of the prescription chart. Inhalers or nebulisers may be prescribed regularly if needed. Always check what has been written in the notes in case medication changes or a management plan have been documented. The aim is to avoid two duplicated prescription charts if the chart reappears. If the chart does reappear, the temporary prescription chart must be discontinued and filed in the patient's notes. If the chart continues to remain missing a new chart must be re-written by the team with responsibility for the patient.

6.16 Outpatient / FP10 Prescribing

Prescribers should cross through any unused space on outpatient / FP10 prescriptions issued to patients in order to prevent any unauthorised additions.

6.17 Non-Medical Prescribers in the Community

Non-medical prescribers are registered at the Prescription Pricing Division (PPD) as working for the Trust and all prescriptions generated by them are billed to the Trust. Therefore if a non-medical prescriber is working for another Acute Trust or other healthcare organisation they must use prescriptions from that particular Acute Trust.

Non-medical prescribers are able to use FP10SS forms for computerised prescribing. However, before computerised prescribing can commence, software must be configured to ensure the computer prescribing system accurately prints prescriber details. Required details, which must be printed on the form, are: -

- A 'prescriber identifier' e.g. Independent / Supplementary Prescriber
- The appropriate professional PIN number
- The hospital / clinic / unit address details, using the agreed format
- The appropriate hospital / clinic / unit code (for prescribing cost allocation purposes)

Changes to prescriber's details, change of role or termination of employment with the Trust should be notified by the individual's line manager to the local NMP/PGD governance team who will notify the PPD.

Prescription pads are the legal property of the Trust and must be returned by the prescriber on termination of employment with the Trust to their line manager. This must be done before or on their last day of duty. Also see Section 21.

6.18 Prescribing for Members of Trust Staff & Their Families

Both the GMC and the Nursing and Midwifery Council advise doctors or non-medical prescribers against prescribing for themselves or for anybody with whom they have a close personal relationship including colleagues.

Members of hospital staff, including doctors, nurses and their families, should be registered with a General Practitioner and obtain medicines for themselves in the same way as other members of the public. This gives them ready access to objective advice and avoids the conflicts of interest that can arise when doctors treat themselves or those close to them.

In an emergency situation and if it is appropriate to keep a doctor or non-medical prescriber at work, they may request a prescription as a patient via the Accident and Emergency department. This option is available for all Trust staff.

If in exceptional circumstances, prescribing for self, family or colleagues is deemed necessary, such prescriptions should not be written on Trust stationary but provided as a private prescription through a community pharmacy, following GMC guidance.

7. ORDERING MEDICINES

7.1 Stock Drugs

Wards and departments, including community, keep a stock of drugs that are in common use or for medical emergencies. The stock list is agreed between the ward sister/charge nurse and the ward pharmacist, and reviewed every 6 months.

Pharmacy staff are responsible for assessing stock levels and top-up requirements at agreed intervals. Pharmacy staff will also remove excess stock and, at appropriate intervals, will check storage arrangements and expiry dates of current stock. In some community settings a delegated member of staff is responsible for this.

The nurse/midwife in charge is responsible for obtaining additional stocks to meet unusual demands by use of the pharmacy requisition forms for urgent stock items. These forms must be signed by a registered nurse/midwife. In community setting a delegated member of staff is responsible for this.

If stock drugs are borrowed from another ward, the department lending the medicines must ensure that only authorised staff have access to medicines. The area lending a medicine must also ensure an audit trail of the transfer is maintained, keeping a record of:

- Medicines borrowed
- Amount borrowed
- Ward and name of the authorised staff receiving the supply

A good place to record this is in the ward pharmacy diary.

Controlled Drugs are dealt with in Section 12.

7.2 Non-Stock Drugs and One Stop Dispensing

Drugs that are not stocked on the wards will be dispensed in pharmacy, for the individual patient on sight of a valid prescription, see Section 9.

The ward pharmacist or pharmacy technician will review new prescriptions at each visit (normally daily, Monday to Friday) and assess the requirement for new drugs to be dispensed. These will be ordered on a non-stock request form and be supplied either with directions (one stop dispensing) or without (non-stocks).

The ward pharmacist will also assess safety and appropriateness of the prescription as well as compliance with formulary and other good practice guidelines.

Non-stock drugs should not be obtained by “borrowing” individually dispensed, named patient items from other wards.

Where non-stock drugs are required urgently, or after the pharmacists visit, the nurse must check the prescription chart to ensure that the patient, ward

and consultant details are correct and then send the chart to pharmacy by the most efficient means possible, together with an indication of what is required.

Arrangements for obtaining urgently required non-stock drugs, out of hours, are described in section 26.

7.3 Non-Stock Drugs for off-site units

Due to off-site units not receiving daily visits from a pharmacist, it may be necessary for them to order newly prescribed non-stock drugs by faxing a copy of the prescription chart to the supplying pharmacy.

The nurse must check the prescription chart to ensure that the patient's name, unit and consultant details are correct and then fax ALL sides of the chart to pharmacy, with a completed cover sheet clearly stating what is required.

8. DISPENSING MEDICINES

Medicines are dispensed in pharmacy by, or under the supervision of, a pharmacist, in accordance with standard operating procedures. Whenever possible, medicines will be labelled with detailed administration instructions and can be used for patient self-medication (see section 15) or as discharge medication (see section 13). These can also be administered by a nurse until discharge.

Non-stock medication for use by inpatients will be dispensed for an individual patient but will not have detailed administration instructions.

Medicines dispensed for one patient must not be handed over to or used for any other patient.

9. TRANSPORT, TRANSFER AND RECEIPT OF MEDICINES

9.1 Transport of Medicines

Medicines are delivered to wards and departments in security sealed or tamper evident containers, such as ward drug boxes or pharmacy bags. It should rarely be necessary for ward staff to collect drugs from pharmacy.

Security sealed ward drug boxes and pharmacy bags leaving the pharmacy on the regular bag runs must be signed for on collection by authorized staff.

On receipt on the ward/clinic area a signature must be obtained from a registered nurse, midwife or ODP. If it is not possible to obtain a signature for receipt, the ward drug box or pharmacy bag must be returned to the pharmacy on the same bag run.

Inpatients and their representatives must not be sent to pharmacy to collect medicines. Patient's relatives or other members of the public must not act as messengers to transport medicines.

Items requiring refrigerated storage will be transported in separate containers in the same way as other drugs. Deliveries of refrigerated and non-refrigerated drugs to wards and departments must be unpacked, on receipt, to ensure safe and secure storage.

Items to be returned to pharmacy must be returned in security sealed containers.

Pharmacy staff will liaise with the transport department to send any medicines that are urgently required by offsite units outside the normal transport schedules. When this is not possible staff at the offsite unit may be asked to organise a taxi.

Healthcare professionals based in the community, should not routinely collect medicines on the patient's behalf from a community pharmacy. However, in exceptional circumstances e.g. where there is an urgent need for medication and every option for the delivery and collection has been explored, a registered nurse may carry the medication from the community pharmacy directly to the patient's home or back to the community unit. All drugs should be kept out of sight during transportation.

Registered nurses working in the community, including school nurses, sexual health nurses and HCAs under the direction of a registered nurse, when necessarily transporting medicines and vaccines, should use suitable lockable containers. Medicines not used during the day's visits must be returned to the clinic base at the end of the day for storage in a locked medicines cupboard or with the out of hours nursing service.

At all times, the container should be either in the possession of the nurse or locked in the boot compartment of the car. Where there is no boot compartment the lockable container must be hidden from sight in the locked car.

Some medicines are affected by extremes of temperature, (e.g. excessive heat or excessive cold in a closed car) – if in doubt consult a pharmacist. Items that require refrigeration such as flu vaccines should be transported in a suitable cool bag.

For detailed advice on the transport of Controlled Drugs see Section 12.3

9.2 Transfer of Medicines with patients between wards/hospitals

It is the responsibility of the nurse or midwife transferring the patient to assemble all dispensed medication as prescribed on the patient's in-patient prescription chart and to ensure that the medication accompanies the patient to their new ward. Medication must be transferred in a ward transfer bag.

The nurse or midwife will need to check the:

- Drug trolley.
- TTO cupboard.
- CD cupboard.
- Fridge.
- Individual bedside locker/ cupboard.

Patient's own controlled drugs will need to be checked by two registered practitioners and signed out of the appropriate controlled drugs register, prior to the transfer.

It is the responsibility of the nurse or midwife receiving the patient to ensure that the inpatient prescription chart and all the appropriate medication has been transferred with the patient and is then securely stored as appropriate to the type of medication.

Patient's own controlled drugs will need to be checked by two registered practitioners and signed into the appropriate controlled drugs register.

9.3 Receipt of Medicines

The nurse in charge is responsible for ensuring that receipt of medicines are dealt with promptly and that:

- All medicines received are checked against any itemised delivery note.
- The delivery note is signed to indicate correct delivery.
- Discrepancies are followed up immediately with pharmacy. The delivery note must be kept until this has been completed.
- All drugs are immediately and securely stored in the designated place.

At community units, the nurse in charge must sign the transport form on receipt of any items delivered by hospital transport or taxi. One copy of the transport form must be retained at the offsite unit and the other must be returned to the pharmacy department as soon as possible.

10. STORAGE AND SAFEKEEPING OF MEDICINES

The Chief Pharmacist is responsible for establishing systems for the safe and secure storage of medicines. The ward sister or nurse in charge is responsible at all times for ensuring these systems are followed and the security of medicines is maintained.

Authorised pharmacy staff are responsible for approving the design and location of all ward or department medicine storage cupboards and for regularly monitoring storage arrangements.

All internal and external medicines and disinfectants must be stored in locked cupboards, trolleys or other secure cabinets - all reserved solely for medicinal products. This includes medicines for self-medication and for discharge. The only exceptions to this requirement are medicines for clinical emergencies, intravenous fluids, sterile topical fluids, dietetic products, reagents and some bulky medicated dressings which, because of their size or nature of their use, are stored in a clean area (as agreed between the ward sister/charge nurse and an authorised member of the pharmacy staff).

Internal medicines must be stored separately from medicines for external use. Under no circumstances must any medicines be transferred from one container to another, nor must they be taken out of their container and left loose.

For detailed advice on storage of Controlled Drugs see Section 12.5

10.1 Control of Substances Hazardous to Health (COSHH)

Some medicines, e.g. cytotoxic drugs, are, by their nature, hazardous. It is the responsibility of the ward or department manager to ensure an assessment of hazard and risk of medicines kept on the ward has been performed. The assessment forms part of the overall COSHH assessment system that is required by the trust. Specific product safety information can be supplied by the pharmacy.

10.2 Siting of Cupboards and Trolleys

Cupboards and trolleys must be sited where convenient for staff, allowing adequate space and permitting surveillance to afford maximum security against unauthorised entry. Medicine cupboards must be securely fixed to an internal wall and generally be sited in a clean utility room to which unauthorised persons do not have access. Cupboards must not be sited where they may be subjected to higher than average humidity or temperature. Reagent cabinets must be sited in areas where testing is carried out.

10.3 Storage Accommodation

Clinical areas may have some or all of the following lockable, medicine storage units:

- Controlled drug cupboards – refer to Section 12.5.
- Internal medicine cupboard(s) - for the storage of tablets, liquid medicines, injections etc.

- External medicine cupboard(s) - for the storage of creams, lotions etc.
- Medicine refrigerator(s).
- Reagent cupboard(s) - situated in the area where urine testing is carried out. Some wards may not require a separate cupboard if urine testing is only very rarely carried out but in such circumstances there should be a ward agreement about where such testing is to take place. These cupboards must be locked when not in use and the key kept on the ward key ring.
- A clean storage room - for bulk intravenous fluids and sterile topical fluids.
- Medicine trolley - for storage of medicines in current use on the medicine administration round. When not being used the medicine trolley must be locked and secured to the wall. The trolley must not be left open and unattended during the medicine round. If the trolley must be left it must be locked first.
- Medicines for clinical emergency – these must be readily accessible and in a position to afford supervision to prevent unauthorised access. They must be held in a tamper evident box and must not be in a locked cupboard. Once opened the box must be returned to the pharmacy for replacement.
- Individual patient lockers / cupboards - medicines dispensed for individuals (together with the PODs) can be stored in a lockable medicine cabinet at the side of the patient's bed. These cabinets must be kept locked when not in use and the keys held by a designated practitioner or where self-medication is occurring by the individual patient. Medication that is required urgently e.g. Salbutamol Inhaler or GTN spray can be stored on top of the individual patient locker/ cupboard.
- Enteral feeding products should be stored in a clean area of the ward. They do not need to be locked up.

10.4 Refrigerated Storage

Medicines requiring storage below room temperature will be marked "Store between 2°C and 8°C, in a refrigerator." Medicines are not to be stored together with food or pathological specimens but in a separate locked fridge.

Items requiring refrigerated storage must be placed in a designated medicines refrigerator immediately on receipt.

The ward sister/charge nurse is responsible for ensuring that:

- Staff that access the refrigerator are properly trained.
- Items other than medicines are not placed in the medicines refrigerator.
- The maximum and minimum temperature of the refrigerator is recorded daily. (The temperature of the refrigerator should be kept between 2°C and 8°C)

- The refrigerator is cleaned and defrosted on a regular basis. The date when the refrigerator is defrosted is recorded each time
- The refrigerator is not overstocked
- The refrigerator is kept locked

A member of ward staff, assigned by the ward or nurse in charge must record the minimum and maximum temperatures every day on a special record sheet kept on or on top of the refrigerator. The assigned member of staff must re-set the monitoring device after each reading.

The nurse in charge must seek immediate advice from pharmacy in the event of either the minimum or maximum temperatures being breached.

Where CDs need to be refrigerated, they should ideally be stored in a separate locked fridge used solely for that purpose. In some rare instances, after discussion with pharmacy, certain CDs may be stored in the normal locked ward drug fridge.

10.5 Flammable Liquids, Gases, Aerosols

See Section 10.1

10.6 Custody and Safekeeping of Medicine Keys

Overall responsibility for the safety and security of the keys for drug cupboards, Patient's Own Drug cabinets, Controlled Drug cupboards and the drug trolley lies with the ward sister/charge nurse.

Access to keys must be restricted. The ward sister/charge nurse may delegate responsibility to the nurse in charge/team leader who should ensure the safe custody of keys during his or her shift.

The ward sister/charge nurse should take steps to ensure staff cannot leave the ward with any keys. Keys should not be handed to a member of staff unless their current contact details are held by the ward sister/charge nurse and these should be available to the nurse in charge on each shift.

Responsibility for the safe custody of keys may be delegated temporarily to another registered practitioner e.g. nurse, pharmacist or a pharmacy technician/assistant. This will normally be to undertake a specific task, on completion of which the keys should be returned immediately to the nurse/midwife in charge. If a ward has more than one medicines trolley then it is permissible for the nurse in charge of each team to hold the key to their trolley and a duplicate set of drug cupboard keys including POD cabinet keys.

All keys should be accounted for before staff leave at the end of each shift. This must be done by the nurse/midwife in charge of the shift before handing them over to the nurse/midwife in charge of the next shift. Controlled drug (CD) keys should be held on separate key rings and each ward must only have one set of CD keys.

For wards/departments that close overnight, at weekends or bank holidays, keys must be locked in the ward/ departments combination key cupboard at the end of the day. The key cupboard will usually be situated in the ward sister/ charge nurse's office. Where possible the office and ward/ department must be locked. The keys to the ward/ department must be taken to the designated place for storage until they are required again. At the beginning of the next shift the designated staff member responsible for opening the ward/ department must obtain the keys from the designated place.

For wards/ departments that close long term, keys must be returned to pharmacy for storage until they are required again.

Refer to Standard Operating Procedures on the management of medicine keys on the Trust Intranet.

10.6.1 The Controlled Drug Cupboard

Controlled drugs keys must be kept separately from other keys and must be held by the nurse in charge. These keys should be on a key ring with a white fob. Under no circumstances should the controlled drug keys be handed to medical staff. See Section 12.6.

10.6.2 Other Medicine Cupboards, Trolleys & Refrigerators

The keys for the external medicine cupboard, internal medicine cupboard, medicine trolley, and medicine refrigerator must be kept together on one key ring reserved solely for these keys. These keys should be on a key ring with a red fob. They must be held by the nurse in charge.

At all times the keys on the red and white fobs must be held by a registered practitioner. In the event of no authorised practitioner being on duty in a ward or department, the keys must be handed to a registered practitioner on a ward or department in the near vicinity. This information must be made known to the staff on the ward.

At community team bases where a number of authorised practitioners may require access to the medicine cupboards at different times a secure system must be agreed between the ward sister and the Chief Pharmacist.

The keys to other medical equipment cupboards will be kept separately from all other medicine keys and can be held by anyone. They will be on a key ring with a blue fob.

10.6.3 Patient's Own Drug cabinets

The master key for individual POD cabinets opens all such cupboards on the ward. The master key must be kept on the ward medicine cupboard key ring, with a red fob, at all times and must never be issued to a patient.

Keys that open individual POD cabinets must be individually numbered and stored securely when not in use.

If a patient is to self-medicate the appropriate numbered key may be issued to the patient. The key that is issued to an individual patient only opens one medicine cupboard and must be kept securely by the patient. The patient must return the key to the nurse in charge on discharge or when they are no longer self-administering their own medicines.

10.6.4 Reagent Cupboard

The key to the reagent cupboard will be stored with the ward medicine cupboard keys, with a red fob.

10.6.5 Loss of a Medicine Cupboard Key

Every effort must be made to find the key or retrieve it from off duty staff. Should access to the medicine cupboard be required before the keys are retrieved the nurse in charge must be informed and where available, the duplicate set of keys may be used. The duplicate keys must be clearly identified, securely stored in the combination key cupboard and accessible to the nurse in charge. Where the cupboard keys are not found a new lock must be fitted to the cupboard. If there is no duplicate key, the nurse in charge will arrange for the cupboard to be broken open and a new lock fitted.

Maintenance staff should not be allowed to work on the cupboard unsupervised. The pharmacy department must also be notified as soon as possible during normal hours and a Trust Incident Reporting Form completed.

If the master key for a suite of patient's bedside medicine cabinets goes missing, all locks opened by the master key must be changed.

All new locks must be organised by the ward and funded from the ward budget.

10.7 Losses of Medicines

10.7.1 Controlled Drugs

See Section 12.7

10.7.2 Other Medicines

The practitioner discovering any loss of medicines must report the loss immediately to the senior manager responsible for the ward or department (via the ward sister/charge nurse) and to the Chief Pharmacist, who can then decide on a further course of action. A Trust Incident Reporting Form must be completed. Where theft is suspected, the Chief Pharmacist may institute arrangements that require records to be kept of all doses of the affected medicine(s), supplied and administered on that ward whilst an investigation is conducted.

Out of hours, the site co-ordinator or on-call manager for the community hospitals should be informed along with the emergency duty pharmacist.

10.8 Checks by Ward Staff

The nurse/midwife in charge of the ward/department should institute a regular programme of stock checks in order to rotate stock, identify out of date items and items no longer in use, which should be returned to the pharmacy.

10.9 Checks by Pharmacy Staff

Authorised pharmacy staff may undertake stock checks in wards and departments throughout the Trust. Checks of Controlled Drugs will be undertaken at not less than three monthly intervals and any discrepancies will be notified to the ward sister/charge nurse. Checks of other stocks will be undertaken where circumstances warrant, usually every 6 months.

10.10 Closure of a Ward or Department

If a ward or department is due to close the nurse/midwife in charge must hand over the Controlled Drugs and medicine cupboard keys to an authorised member of pharmacy staff, see section 10.6. All stock drugs will be returned to pharmacy. Pharmacy staff will arrange for Controlled Drugs to be returned to pharmacy ensuring that they sign the appropriate section of the ward controlled drug register.

11. PREPARATION AND ADMINISTRATION OF MEDICINES

Health Care professionals administering medicines are responsible and accountable for the correct administration of prescribed drugs to patients under their care.

In acute hospitals, only medicines that have been supplied from the pharmacy department may be administered to patients. In community settings medicines may also be supplied by a dispensing G.P practice or community pharmacist.

Exemptions to this may be patients own medication which has been assessed according to the re-use of patient's own drugs policy.

Consultant/G.P approval must be sought in order to use or administer homeopathic medicines or aromatherapy oils.

On admission to a ward a patient may continue to take, or have administered, medicines that have been previously prescribed by their GP and which are not available on the ward/hospital. There must be a valid in-patient prescription and the identity of the drugs in question must be confirmed. Steps should be taken to obtain further supplies from pharmacy.

Medicines must only be prepared, checked or administered to a patient by the following categories of healthcare staff:

- An authorised practitioner, e.g. registered nurse / midwife.
- A medical or dental practitioner.
- Authorised pharmacy staff (prepare and check only).
- A practitioner in training, but only under the direct supervision of a qualified practitioner who remains responsible for ensuring that the correct procedure takes place.
- Other employees who are specifically authorised, e.g. Operating Department Practitioner's (ODPs) and certain technicians.

11.1 Continuity of Pharmaceutical Care

It is imperative that patients admitted on finely titrated dosage regimens (e.g. anti-parkinsonian medication, carefully adjusted analgesia) should not have their care compromised due to missed doses. Under these circumstances administration of medicines should remain the patient's (or the patient's carer's) responsibility until the patient is fully clerked, the appropriate prescription stationery is completed and the correct medication is obtained from pharmacy.

11.2 Preparation of Medicines

It is often during the preparation of medicines for administration that errors can occur, particularly where dose calculation is involved. In the majority of cases, medicines are supplied in a ready-to-use form, where no further dilution or dose calculation is required.

Where the preparation of medicines is performed outside the Pharmacy Department, the following points must be observed:

- Read the prescription carefully. Determine the name of the medicine, dose, diluent, route for administration and expiry date of the prepared medicine. Refer to the package insert or Summary of Product Characteristics if necessary.
- If a dose calculation is required this information should be included as part of the prescription either by the doctor or the pharmacist. The practitioner administering the dose must be clear about the actual amount to administer and should check the calculation each time a dose is given.
- If the practitioner is unclear as to the correct medicine, diluent or precise method for medicine preparation, he/she must obtain this information from the package insert, Summary of Product Characteristics or the appropriate pharmacy before proceeding.

It is good practice for the practitioner to obtain a second check when calculating doses and/or manipulating medicines. The practitioner must clearly specify what is to be checked. The second practitioner must undertake the full calculation by his or her own method. They must not be asked to confirm the first practitioners answer until after they have performed the calculation.

An appropriate area for the preparation of intravenous infusions must be identified. Ideally, this area should be separated from the direct patient areas and enclosed (all doors and windows should be closed). Preparation should take place as one continuous process, followed through to completion. These precautions reduce the risk of microbial contamination and interruptions, which can lead to medicine errors.

11.3 Checking the Preparation and Administration of Medicines

Preparation and administration of drugs do not routinely need to be checked by two nurses except in accordance with local procedure. Independent practitioners however, are required to seek a second check in circumstances outside their normal experience that they judge may present an unknown risk. In community settings e.g. a patient's own home, it may not be possible to have a second check. In this instance advice can be sought by phoning a colleague.

CD's must be checked by two registered nurses wherever possible (see Section 12.9).

11.4 Administration of Medicines

Errors of drug administration to inpatients are often due to selection of the incorrect patient or selection of the incorrect drug. Interruptions to the medicine preparation and administration process contribute to the likelihood of error.

- Only doctors, dentists, nurses, midwives or designated persons working under a Patient Group Direction (PGD) and student nurses under supervision may administer medicinal products.
- ODPs may administer intravenous drugs only as directed by the anaesthetist.
- Practitioners administering medicines to patients will be held individually accountable for their actions.
- Staff should take steps to ensure that medicine administration, for any patient, can be completed without interruption.
- If an error occurs in the administration of medication to a patient the actions described in section 18 must be followed.
- A doctor, nurse, pharmacist or pharmacy technician must assess PODs according to the re-use of patient's own drugs policy before they may be administered. Medicines contained in a patient filled monitored dosage system, on admission to an inpatient unit should not be used.
- Medicines may only be administered to a patient.
 - On the written instructions of a doctor, dentist, non medical prescriber, supplementary prescriber or a verbal order given in accordance with Section 6.15
 - On the verbal instruction of a doctor who is present with a patient in the case of a cardiac arrest or similar emergency.
 - By a person working under a Patient Group Direction.

A record of all medicinal products administered to a patient must be made on the appropriate, approved prescription, administration record chart or community care plan.

11.5 Administration Check-list

Before any medicine is administered the prescription must be read carefully and the following must be checked:

- The patient's name, hospital, NHS Number or date of birth or address, using the patient's wristband and by asking the patient directly their name and date of birth as stated in the Policy for the Positive Identification of Patients or the NMC Code of Professional Conduct and Standards for Medicines Management.
- The patient is not sensitive or allergic to the medicine, by asking the patient, checking the allergy box on the prescription chart or for a record in the medical notes and checking for an allergy band.
- The date and route of administration.
- The dose and frequency of administration.
- That the medicine is due for administration at that time and has not already been given.
- The prescription is written using the approved medicine name and/or brand name or formulation, where appropriate.
- The correct product has been selected against the prescription.
- For infusions and injections, the concentration or total quantity for administration.
- For infusions, the name and volume of diluent and the rate and duration of administration.
- The product's expiry date where one exists.
- That any special instructions are being followed.
- Whether any further information is required about the product, e.g. method of preparation, or if detailed calculations need to be independently checked. If so the pharmacy department should be contacted.
- The duration of therapy or date on which treatment should be reviewed.
- The age and weight of any patient under 16 years of age where relevant.
- The prescription is signed by a valid prescriber.
- There are no obvious interactions between prescribed medicines or contraindications.

The practitioner should be aware of the therapeutic uses of the medicine to be administered, its normal dosage, side-effects, precautions and contraindications.

If there is any doubt about the legibility of the prescription or any other particulars such as the dose, route, mix of drugs or gases, allergies, time or frequency of

administration, the person administering the medicinal product must contact the prescriber or responsible doctor/dentist, prior to administration.

A zero-tolerance policy is in place within Trust in relation to drug allergy boxes. Practitioners must not administer medicines unless the allergies/sensitivities box has been completed.

If the patient is detained under the Mental Health Act 1983 the nurse must check the Authorization of Administration (forms 38 or 39) prior to administering the medicines (see also Section 35).

Medicines dispensed for an individual patient must be administered only to that patient unless otherwise authorised by a pharmacist.

The practitioner who has administered or supervised the administration of the medicine must, immediately following administration, sign with initials in the appropriate column of the official prescription chart or community care plan.

It is the responsibility of the practitioner to observe patients taking their medicines or that appropriate administration has occurred. Prepared medicines must not be left unsupervised unless the patient/carer self-administration procedure is being followed.

If any medicine is omitted the appropriate non-administration code must be entered on the prescription chart. Any actions taken to resolve this must also be documented in the section at the back of the prescription chart. If the omitted medicine is a critical medicine (see section 39), a Trust Incident Report must also be completed.

Where medicines have been dispensed for individual patients, a record of the supply is entered in the pharmacy box on the prescription chart. If such an entry has been made the nurse must make every effort to find the supply so that the dose can be administered.

Failure to record the administration of a medicine or an omission code constitutes a medication incident and must be reported. The scrutiny of such records will be the subject of regular audit.

Every effort must be made to administer medications in a timely manner and to avoid missing doses. If any doubt arises on whether or not to miss a dose of medication it should be confirmed with a prescriber or pharmacist.

Practitioners must not return to a drug container any dose of a medicine which has been removed from it.

11.6 Nil by Mouth

Patients classified 'Nil by Mouth' prior to a diagnostic or therapeutic procedure (including receiving an anaesthetic) must have all their prescribed oral medicines administered to them at the prescribed time unless specifically advised otherwise. The medicines should be taken with a small amount of water to enable the patient to swallow these medicines. Only medicines that

have been clearly marked on the prescription chart may be omitted. It is the responsibility of the prescriber to provide clear instructions to the nursing staff concerning the omission of prescribed doses. Nursing staff must be proactive in asking if the patient is strictly nil by mouth or nil by mouth except for medicines or in seeking if an alternative route of administration is needed.

11.7 Covert Administration of Medicines

In very rare instances covert administration of medicines (i.e. disguising medications in food and drink) may be considered for a patient. Prescribers considering covert administration must consider the treatment aims, intent and outcomes implied by the deceptive nature of a practice where the patient is led to believe that they are not receiving medication. Healthcare professionals are responsible and accountable for this decision and must therefore ensure such practice is only considered when in the best interests of the patient e.g. to save life, prevent deterioration of physical or mental condition and in full recognition of the individual's right to give consent (Mental Capacity Act and Human Rights Act 1998). The rationale for the decision to administer medicines covertly must be documented in the medical notes.

When covert administration is employed, the principles set out in the NMC's position statement Covert Administration of Medicines - disguising medicines in food and drink (NMC 2008) must be followed. In particular:

- Patients will have completed a prior assessment of capacity that shows they lack the capacity to make a decision on receiving prescribed medication.
- The decision to administer covert medication must be a multi-disciplinary team one and the discussion and decision must be recorded in the patient's notes.
- Where at all possible the patient's family or Independent Mental Capacity Advocate (IMCA) must be involved in the decision making.
- A care plan must be produced that instructs staff on the correct mode of administration of the covert medication, pharmacy staff will be able to advise on this.

Local services may wish to produce guidance and procedures to further support staff in this practice.

In considering the addition of a medicine to food or beverages as a covert means of administering the advice as to pharmaceutical stability should be sought from a pharmacist.

11.8 The preparation and administration of medicines by practitioners other than nurses and medical officers

Qualified Practitioners other than nurses and medical officers may only carry out medicine preparation and medicine administration procedures with the full approval of the medical team and only after a written procedure has been approved by the Trust. See also Section 29 and Section 31.

11.9 Mixing of medicines

Mixing of medicines where one is not a vehicle for the other results in a new, unlicensed medicine being produced. Doctors, dentists and independent prescribers may direct others to mix medicines. Independent and supplementary prescribers can mix medicines to administer to a patient.

These arrangements do not apply to controlled drug legislation but the Department of Health advise that existing good practice arrangements should continue.

Definition of mixing

Mixing is defined as the combination of two or more medicinal products together for the purpose of administering them to meet the needs of a particular patient. This does not include mixing where one product is used as a vehicle for the administration of another e.g. reconstituting an antibiotic powder with water and adding to a bag of Sodium Chloride but does include mixing at a Y site.

Standards/Principals

Mixing of medicines should only take place if clinically appropriate and essential to meet the needs of the patient. It should not be undertaken for the convenience of a healthcare professional.

Mixing should only take place on a ward if a licensed product is not available and the mixing is not possible in the pharmacy department.

Prescribers should seek advice from pharmacy in determining if there is an alternative available or if not, if the products can be mixed.

The instruction/direction to mix a medicine must be in writing. This may either be via an approved protocol or on an individual drug chart.

The prescriber takes responsibility for satisfying themselves that clinical governance arrangements are in place to ensure the 'mixer' is competent to undertake the task safely and effectively.

The person mixing the medicine must be competent to do so.

All mixed products must be labelled appropriately. The label must state the name and strength of both drugs, the diluents, the date and time mixed and the expiry date, the patients name and be signed by the person doing the mixing and the person who checked it.

Medicines mixed in near patient areas should only be prepared for individual patients and should be used immediately.

11.10 Staff Requiring Treatment for Minor Ailments

Such staff must be referred to occupational health or purchase items from the hospital pharmacy shop or a local pharmacy.

Medicines dispensed as ward stock or for individual patients must not be used to treat staff.

12. CONTROLLED DRUGS AND OTHER DRUGS SUBJECT TO SPECIAL RESTRICTIONS

The term "Controlled Medicine" is used to define a medicine or groups of medicines to which enhanced control of prescribing, supply and administration is applied due to the potential for inappropriate use or misuse. Medicines are included in this group if they are:

- a "controlled drug" as defined in Schedule 1, 2, 3, 4, or 5 of the Misuse of Drugs Regulations 1985 (as amended);
- a medicine which in the opinion of the Trust Medical Director, Chief Pharmacist and Chief Nurse warrants enhanced control.

Medicines currently classed as controlled are:

- **Controlled drugs.**
- **Potassium Chloride concentrate solutions and other strong potassium solutions.**
- **Botulinum toxin.**
- **Midazolam 10mg in 2ml, 5mg in 5ml, 1mg in 1ml (50ml) injection and buccal liquid.**
- **Ketamine injection.**
- **Flumazenil injection.**
- **Heparin 25,000 units in 5ml injection.**

Schedule 1 Controlled drugs, e.g. LSD, cannabis, and amphetamines may only be possessed or used by persons with a Home Office licence for research or other special purpose. See also section 35 on Illicit Substances.

Schedule 2 includes opiates and major stimulants such as dexamphetamine, and secobarbital. Subject to full control on storage/destruction and prescribing.

Schedule 3 includes temazepam, the barbiturates, buprenorphine, pentazocine and midazolam.

Schedule 4 contains anabolic and androgenic steroids and most of the benzodiazepines.

Schedule 5 contains preparations of certain controlled drugs e.g. codeine, pholcodine and morphine, which are exempt from full control when present in medicinal products of low strength. N.B. Oramorph 10mg in 5mL is subject to full control within the Trust, unless the ward on which it is being administered has completed deregulation of Oramorph training, as agreed by the Chief Pharmacist.

Standard Operating Procedures relating to the management of controlled drugs are available on the Trust Intranet and should be referred to.

12.1 Prescriptions for controlled drugs

Outpatient, discharge and FP10 prescriptions for Schedule 2, and 3 controlled drugs and Oramorph 10mg in 5mL must be written, signed, and dated by the doctor or dentist in their own handwriting in ink or otherwise so as to be indelible.

Addressograph labels may be used on outpatient and discharge prescriptions as long as the prescriber confirms the correct patient details by initialling or signing the printed details.

The prescription must state:

- Full patient details, including their hospital number where used or NHS number, full name and address.
- The generic name, form, and strength of the controlled drug. Where potential for confusion exists the brand name should also be included.
- The total quantity of the controlled drug, or the number of dose units to be supplied, **in both words and figures** (not necessary for temazepam or for inpatient prescription charts).
- The dose and frequency.
- Signature, bleep or contact details, printed name and date.

When prescribing Schedule 2 and 3 controlled drugs on in-patient drugs charts:

- All doses should be prescribed in whole numbers wherever possible, in order to reduce errors encountered as a result of unclear decimal points.
- It is good practice to prescribe doses in figures and confirm them in words, e.g. 5mg (five).

No doctor may administer or authorise the supply of cocaine or diamorphine, their salts or dipipanone to an addicted person except for the purpose of treating organic disease or injury unless the Secretary of State licenses him or her to do so.

Doctors are expected to report cases of drug misuse to their regional National Drugs Treatment Monitoring System (NDTMS) centre.

Notification to the regional (NDTMS) centre should also be made when a patient starts treatment for drug misuse. All types of problem drug misuse should be reported including opioid, benzodiazepine and CNS stimulant.

Further guidance on prescribing controlled drugs and drug dependence can be found in the current edition of the BNF or in the Drug Misuse: Policy and Procedure for Identification and Management of Patients.

12.2 Ordering controlled drugs

Hospital setting

For inpatient areas the registered nurse, midwife or ODP must order Schedule 2 and 3 controlled drugs and Oramorph products in a Controlled Drug Order Book. They must sign and print their name on the order and have their name and signature on the wards controlled drug Authorised Signature List held in pharmacy.

The order must contain the following information:

- Name of hospital and ward.
- Drug name, strength and form.
- Total quantity.
- Signature and printed name of the nurse requesting the medicine.
- Date.

Any requests for controlled drugs not usually stocked on a ward or unit must be authorised by the ward pharmacist or accompanied by a copy of the patient's drug chart.

Schedule 4 and 5 controlled drugs may be ordered in the same way as other medicinal products.

Schedule 2 and 3 controlled drugs must not be transferred as stock from ward to ward unless authorised by the emergency duty pharmacist. This should be recorded appropriately.

A copy of each order must be retained in the ward/department for two years.

Community setting

Patients are responsible for ordering their own controlled drugs. In exceptional circumstances where this is not possible the registered nurse can take responsibility for reordering of prescriptions of controlled drugs from the G.P on the patient's behalf.

12.3 Collection and transport of controlled drugs

Hospital setting

Pharmacy staff acting as messengers must collect the tamper evident sealed controlled drug pharmacy bags from the pharmacy controlled drug dispensing area.

The pharmacy copy of the order should be returned to pharmacy after it has been signed by the registered nurse, midwife or ODP on receipt of the controlled drugs. This must be retained in pharmacy for two years.

The messenger must not undertake any other errand while carrying controlled drugs.

Controlled drugs may be collected from pharmacy by a registered nurse, midwife or ODP. The individual collecting controlled drugs must take the ward Controlled Drug Register with them and will be expected to check the identity of the drugs against the ward order, the quantity supplied and to sign for receipt, documenting their identity. They must be carried in a tamper evident container. The safety and integrity of the controlled drugs remain the individual's responsibility until they obtain a signature from a registered nurse.

Transport drivers or porters delivering controlled drugs to wards or off site units will require a record of receipt from a registered nurse. This should be recorded on the Controlled Drug Receipt Form. The pharmacy copy of this form should be returned to the supplying pharmacy.

Community setting

Healthcare professionals should not routinely collect and transport medicines on the patient's behalf. However in exceptional circumstances e.g. where there is an urgent need for medication and every option for delivery and collection has been explored, a registered nurse may collect the medication from the supplying pharmacy and transport it to the patient's home.

If collecting a patient's controlled drugs from a pharmacy the registered nurse will be asked to sign for them and prove identity in the form of their professional identity badge. All drugs should be kept out of sight during transportation.

12.4 Receipt of controlled drugs

Hospital setting

Messengers must only hand controlled drugs to a registered nurse, midwife or ODP who must:

- Count the number of sealed boxes or unit doses received in the presence of the messenger. Any discrepancies in the delivery of controlled drugs must be notified to the supplying pharmacy immediately.
- Sign the ward copy of the order for controlled drugs and any accompanying Controlled Drug Receipt Forms and ensure that the pharmacy copy of this form is returned to the supplying pharmacy within 24 hours. The ward copy should be retained with the Controlled Drug Register for 2 years.
- Record the number of units of Schedule 2 + 3 controlled drugs received in the ward Controlled Drugs Register.

Each drug has its own section in the Controlled Drug Register. The registered nurse, midwife or ODP receiving controlled drugs must record the following details in the correct section of the Controlled Drug Register:

- Date of receipt.
- Quantity supplied.
- Running total.
- Signature.
- Requisition number.
- Received from pharmacy.
- Full signature of pharmacy messenger delivering and the registered nurse, midwife or ODP receiving the controlled drug.

All entries must be made in ink or otherwise be indelible. No cancellation, obliteration or alteration may be made in the Controlled Drug Register. If there is a need for a correction then this must be a dated note in the margin or footnote. This must then be signed (in full) and dated by two qualified practitioners. Initials or abbreviated signatures are not an adequate means of identification or authorisation. The correct information must be entered in the next available space.

The registered nurse, midwife or ODP signing for receipt of controlled drugs, must place them immediately in the controlled drug cupboard.

Section 12.10 of this Medicines Code gives guidance about controlled drugs brought into hospital by patients.

Community setting

On arrival at a patient's home the registered nurse is responsible for counting and recording as new stock on the Patients Controlled Drugs Stock Sheet any additional controlled drugs received from the supplying pharmacy.

12.5 Storage of controlled drugs

Hospital setting

All wards or departments storing controlled drugs must have an appropriately qualified person responsible for their storage and use. Controlled drugs must be stored in controlled drug cupboards reserved solely for the storage of controlled drugs and secured to the wall. These cupboards may be separate from others or be inside other locked medicines cupboards used to store internal medicines. Where controlled drug storage is in an outer compartment of a medicines cupboard no other medicines may be stored in the inner compartment.

The lock must not be the same as any other lock in the hospital. The cupboards must conform to the current British Standard BS2881.

Where controlled drugs need to be refrigerated, they should ideally be stored in a separate locked fridge used solely for that purpose. In some rare instances, after discussion with pharmacy, certain controlled drugs may be stored in the normal ward drug fridge.

High strength opiate injections should be segregated from other controlled drugs and labelled to highlight the requirement for extra vigilance.

Community setting

The registered nurse should provide advice and guidance on the safe storage of controlled drugs in the patient's home.

12.6 Custody of controlled drug keys

On in-patient areas the key must be kept on a key-ring separate to all other keys and held by the nurse in charge or practitioner nominated by them. The keys should be on a key ring with a white fob. Responsibility remains with the nurse/midwife in charge. The key must not be handed over to medical staff, student nurses or health care assistants.

In the event of the person in charge being inappropriately qualified, the key must be handed to a nurse/midwife in charge of a ward or department in the near vicinity where possible. This information must be made known to the staff in the ward or department and to the manager in charge of that section.

Section 10 gives general advice about loss of drug cupboard keys.

In the event of a missing/lost controlled drug key it is imperative to ensure the security of the stock and ensure patient care is not compromised. The Accountable Officer for controlled drugs needs to be informed. Out of hours, the emergency duty pharmacist should be informed and will provide advice on what action to take. A Trust Incident Reporting Form should also be completed.

12.7 Stock Balances of controlled drugs

Hospital setting

The ward sister/charge nurse is responsible for ensuring that stock balance checks are carried out appropriately. This should be as agreed locally, but at least weekly.

A registered nurse, midwife or ODP authorised by the nurse/midwife in charge must check with a second nurse, ward balances of controlled drugs. A record of the checked balances must be made in the Controlled Drug Register and Stock Check Record Book (obtained from pharmacy). All pages of the register must be checked against the physical balance. It is not sufficient to check that the physical stocks match the records in the register.

In the event of a discrepancy between the stock balance and register for controlled drugs, the ward sister/charge nurse or nurse/midwife in charge in

her absence must immediately and thoroughly investigate the loss. A missing entry or incorrect calculation or balance transfer must be sought.

After an unsuccessful investigation a Trust Incident Reporting Form must be completed. The discrepancy must be reported immediately to the senior manager responsible for the ward or department and the ward pharmacist. The Accountable Officer should also be informed. Out of hours the bed manager or on call Manager out of hours responsible for the ward or department should be informed. A Trust Incident Reporting Form is also appropriate for near misses. Where theft of controlled drugs is suspected the senior manager and Accountable Officer will notify the police.

Pharmacy staff will undertake 3 monthly controlled drug stock reconciliation. Any discrepancies or concerns identified about lack of adherence to controlled drug management standards should be reported to the duty ward / unit manager and thoroughly investigated.

Community setting

A registered nurse must check the balance of controlled drugs before any administration of controlled drugs.

12.8 Disposal of controlled drugs

Hospital setting

Controlled drugs must be destroyed in accordance with the recommendations laid down in the Misuse of Drugs Regulations.

Pharmacists are required to keep records of transactions involving controlled drugs and cannot destroy controlled drugs except in the presence of an authorised person. The designated pharmacy representative and the authorised person must retain a record of the name and quantity of Schedule 2 and 3 controlled drugs destroyed. This record must be endorsed with the signature of both the designated pharmacy representative and the authorised person.

Controlled drugs no longer required within wards and departments they must be returned to the Pharmacy Department. An entry must be made in the ward Controlled Drug Register and Controlled Drug Order Book and endorsed by the nurse/midwife in charge of the ward or department and authorised pharmacy staff.

Authorised pharmacy staff returning the drugs from the ward to the pharmacy department must record the return in the appropriate section of the pharmacy Controlled Drug Register.

Part used epidural infusions and Patient Controlled Analgesia (PCA) syringes must be disposed of in a sharps bin. A denaturing material called Gel-Vac sachets must be added to the sharps bin to denature the controlled drugs. An appropriate documentation must be made in the ward Controlled Drugs Register and signed by two registered nurses, midwives or ODPs.

Individual doses of controlled drugs that are prepared but not administered may be destroyed at ward or department level in a sharps bin containing Gel-Vac sachets if witnessed by a second registered nurse. If it is a Schedule 2 or 3 controlled drug, appropriate documentation must be made in the ward Controlled Drugs Register. This must be signed by two registered nurses, midwives or ODPs. This also applies to Oramorph unless the ward has completed deregulation of Oramorph training approved by the Chief Pharmacist.

Community setting

When a syringe driver is taken down the remaining volume should be recorded in the patient's notes and in the patient's own Controlled Drug Record Book. A sufficient number of swabs should be placed in a sharps box and used to absorb the contents of the syringe. The sharps box should then be sealed and disposed of as normal.

In the event that a patient dies at home leaving behind controlled drugs, it should be the role of the family to take these to a community pharmacy for destruction. If the nurse is requested to, or feels it important to, undertake this task he or she should:

- Obtain consent from the family to do so.
- Document the removal, ideally with two signatures, one from the nurse removing the controlled drugs and one from a witness i.e. a family member or a colleague.
- Obtain a signature from the community pharmacist taking receipt.

12.9 Administration and recording of controlled drugs

Hospital setting

A second staff member must witness the administration of all controlled drugs. The witness can include a registered nurse, a doctor or in theatre a registered ODP. In community units that have a smaller number of registered nurses, Healthcare Assistants may be trained to do this and may witness the administration of controlled drugs once they have a declaration of competence in their personal file.

When two members of staff are checking the administration of a controlled drug, the check must extend to the bedside in order to ensure administration to correct patient.

An entry must be made in the ward or department Controlled Drugs Register showing:

- Date and time of administration.
- Name of patient.

- Dose administered.
- Full signature of the practitioner and the witness where applicable.
- An updated running total which should be checked against the physical stock.

The ward Controlled Drug Register and Controlled Drug Order Book must be kept on the ward for 2 years after the final entry.

When opioid medicines are administered, in anything other than acute emergencies, the practitioner should:

- Check any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient.
- Ensure where a dose increase is intended, that the calculated dose is safe for the patient (e.g. for oral morphine or oxycodone in adults, not normally more than 50% higher than the previous dose).
- Confirm any bolus IV dose of morphine that is over 10mg with the prescribing doctor and document the confirmation in the nursing notes.
- Ensure they are familiar with the following characteristics of that medicine and formulation - usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects.
- Ensure the availability of naloxone injection (an antidote to opiate-induced respiratory depression).
- Any inpatient receiving their first dose of diamorphine or morphine injection should be observed at regular intervals for the first hour after administration.

See Section 11.4 for general guidance about drug administration.

Community setting

Controlled drugs dispensed to a patient are the property of that patient. If a registered nurse is engaged in the administration of patient's own controlled drugs, they should record the administration and stock balance in the patient's own Controlled Drug Record Book.

Registered nurses can check and administer controlled drugs without a second member of staff present.

12.10 Patients own controlled drugs (PODs)

Hospital setting

Patients may bring controlled drugs into hospital as part of their PODs. Whenever possible these should be sent back to the patient's home with a relative/carer. If this is not possible, the registered nurse or midwife must separate these from the rest of the patient's medicines, place them in a POD bag and retain them in the ward controlled drug cupboard. The registered nurse or midwife must make an entry in the POD/TTO Controlled Drug Register, on a

page specifically allocated for recording that patients' own controlled drugs. The entry must detail:

- Name of patient.
- Name, form and strength of the controlled drug.
- Quantity.
- Date and time of receipt
- The full signatures of two registered nurses, midwives or ODPs

On discharge, the patient's own controlled drugs should be returned to the patient. An entry detailing the return should be made in the POD/TTO Controlled Drug Register. If not required, patients' own controlled drugs may be transferred to pharmacy by a ward pharmacist or a pharmacy technician. Transfer of patient's own controlled drugs to pharmacy must be accompanied by an appropriate entry in the POD/TTO Controlled Drug Register and in the ward Controlled Drug Order Book and signed by a registered nurse from the ward.

Should it be necessary to use patient's own controlled drugs for administering to the patient, administration should be recorded in the POD/TTO Controlled Drug Register under the initial entry for receipt.

12.11 Discharge medicines containing controlled drugs

All controlled drugs, for the purpose of discharge, received on the ward, from community or hospital pharmacy must be entered into the ward POD/TTO Controlled Drug Register, on a page specifically allocated for the individual patient. When discharging the patient, the registered nurse or midwife should make an appropriate entry into the POD/TTO Controlled Drug Register at the time the medicines are handed to the patient.

(See also Section 13, Discharge Medicines.)

13. DISCHARGE MEDICINES

There are specific risks involved in the provision of discharge medication. These include:

- Patient confusion about their current regime.
- Omission of required therapy.
- The possibility of duplicating therapy with drugs the patient has left at home.
- Patients continuing to take discontinued medication.
- The possibility of the discharge communication being ambiguous, incomplete or delayed.

Medical, nursing and pharmacy staff all have a responsibility for minimising these risks.

It is the intention of the pharmacy service to provide routine discharge medication, where it is required, for all patients by the time of their planned discharge. This aim can only be achieved safely and efficiently with the full collaboration of medical, nursing and other ward staff.

Patients who self-administer during their inpatient stay will not normally require further medicines to be dispensed at discharge. For other patients whose medicine regime is stable, medicines may be dispensed as discharge medication, as early in the patients stay as possible. These drugs will normally be kept in secure bedside lockers for nursing staff to administer. Such drugs remain the responsibility of the appropriate nurse.

For all patients steps must be taken to plan the patient's discharge as early in their stay as possible in order to avoid undue delays at the end of the stay. Prescriptions should be written the day before discharge where possible. It is essential that discharge prescriptions clearly identify the following information before transmission to pharmacy:

- The patient's full name, title, hospital number and date of birth.
- The correct ward and consultant.
- The planned time of discharge or the specific delivery time for the drugs to be sent to the ward.

If a multi-compartment compliance aid is required the prescription must be sent to pharmacy the day before the patient is to be discharged

Pharmacy staff will help in the planning process, with respect to discharge medicines. Pharmacy staff will dispense discharge medicines only when a pharmacist has reviewed both the discharge prescription and inpatient prescription chart at the same time. A faxed copy of the prescription chart is acceptable if the discharge medication is not being dispensed at the same site as the ward/unit.

The pharmacy emergency duty service has never been intended or funded for the supply of discharge medication and the emergency duty pharmacist will not supply discharge medication out of hours.

Prescribers' responsibilities

Writing the discharge prescription as early in the patients stay as possible (exceptions may include those medicines which require dose titration or therapeutic monitoring to determine the appropriate dose). The discharge prescription should be completed accurately, ensuring all essential information about medicines is provided for the GP including reason for any medication changes, including medicines that have been stopped.

Pharmacy responsibilities

Supplying discharge medicines in original patient packs, where available, together with any relevant information leaflets. Patient's own drugs should be used wherever possible. The pharmacy team will ensure a minimum of 14 days of chronic medication is available to patient on discharge, either supplied by the hospital or using patient supplies at home. There are several exceptions where less than 14 days will be supplied:-

- Nutritional supplements and enteral feeds
- When required medicines such as analgesics or antiemetics
- Courses of medicines such as antibiotics, steroids and dalteparin.
- Patients on blister packs
- Palliative care patients
- Patients admitted with overdoses where less than 28 days treatment may be required.
- Benzodiazepines and hypnotics as per Trust policy (5 days)
- Non formulary items that are not routinely stocked in the Trust

Pharmacy staff will target patients that require further information about their medicines. Patients on high risk medicines e.g. warfarin or patients who have had multiple changes to medicines or patients with specific medicines adherence issues will be prioritised.

Registered Nurse responsibilities

Registered nurses are responsible for:

- Checking the dispensed medication against the discharge letter and the prescription chart and reporting any discrepancies in the medicines to the supplying pharmacy immediately.
- Explaining the medication to the patient or carer ensuring they understand the instructions for each item.
- Storing discharge medicine securely in the patient's own medicine cabinet (or refrigerator).

- Ensuring other relevant staff are aware of the whereabouts of the discharge medicines.
- Assembling the discharge medication after the last medication round before discharge as described in the procedure for medication on discharge and transfer.

It is not acceptable to issue unlabelled medication from ward stock

Supply of over labelled TTO packs

In some circumstances, as agreed with the Chief Pharmacist, authorised practitioners (prescribers, nurses and pharmacists) may issue ready labelled TTO packs of certain medicines to patients to take home, or for use as an inpatient. The practitioner is responsible for ensuring there is authorisation for supply, i.e. a prescription or Patient Group Direction.

The practitioner must:

- Select the appropriate TTO pack, checking the drug, strength and form.
- Check the medication is in date.
- Enter the dose instructions if appropriate.
- Enter the patient's name and date of supply on the label
- Record the supply on the appropriate record, i.e. the patient's notes and/or the patient's discharge letter and in the TTO pack register.

A second practitioner must check all medicines supplied in this way.

14. PATIENT GROUP DIRECTIONS (PGD)

All medicines administered by a practitioner must be given according to a written instruction in the form of a prescription, signed by an authorised prescriber. In some areas certain medicines are routinely supplied or administered by practitioners without a prescription. When this happens the medicines must be supplied or administered in accordance with a PGD. This is a written procedure, authorised by the Trust that allows the administration or supply of medication without a signed prescription in an identified clinical situation.

The PGD is drawn up by doctors, pharmacists and other appropriate professionals, and approved by the employer, advised by the relevant professional advisory committees. They apply to groups of patient who may not be individually identified before presenting for treatment.

It is the responsibility of the ward sister/charge nurse to ensure if medicines are supplied or administered without a written prescription that a valid and current PGD is available to guide practitioners and that each person using the PGD has received appropriate training and has signed the PGD.

Copies of the current approved PGD must be available in the area to which they pertain.

A record of administration under a PGD must be made on the inpatient prescription chart or patient record.

Refer to the Patient Group Directions policy.

15. SELF-ADMINISTRATION OF MEDICINES BY PATIENTS

In order to provide a patient centred service, patients may self-administer medicines in hospital where this is appropriate. This decision will be made on an individual patient basis and should involve the ward nurse, pharmacist or doctor.

The patient may begin to self-administer medicines only after an assessment of the patient's medication regime and the patient's ability to comply with it has been completed and documented. The pharmacist/nurse will also ensure the patient has a supply of medication and that the prescription chart clearly states that the patient is self-administering medicines.

All medicines for self-administration must be kept in a locked patient's own medicine cabinet. The patient or the nursing staff may be responsible for custody of the key. This will be documented in the self-administration assessment.

The nurse must check an individual patient's compliance daily and document this in the nursing records. If the patient is unable to take the medicines as prescribed the self-administration process must be discontinued, although it may be reintroduced at a later date.

Any changes to the medication regimen should be notified to the pharmacist/nurse as soon as possible to enable the supply of medication to be amended. Out of hours any medication which is no longer required or where the dose has changed should be removed from the cabinet and any medication required should be obtained as soon as practicable.

Doses administered by nursing staff in addition to or instead of the self-administration must be recorded in the normal way.

On discharge the usual discharge process should be followed. The nurse must also retrieve the key to the cabinet and return it to safe storage on the ward.

Patients may routinely administer their own inhalers and topical preparations. Medication should be locked in the patient's own drug cabinet, with the exception of bronchodilator inhalers or glyceryl trinitrate sprays. Patients should be asked to inform the nurse if they administer their bronchodilator or glyceryl trinitrate spray.

Patients may not self-administer Controlled Drugs.

Refer to the Self Administration Of Medications Policy.

16. DISPOSAL OF MEDICINES NO LONGER REQUIRED

16.1 Disposal of medicines

Pharmaceutical waste is classified as clinical waste. It may also be classified as special waste as it contains Prescription Only Medicines (POMs). Advice on the disposal of pharmaceutical waste can be obtained from the supplying pharmacy.

Containers with substantial amounts of their contents unused and all waste containing antibiotics, flammable or hazardous materials should be returned to the supplying pharmacy for safe disposal. This includes all out of date stock or stock no longer required. Effectively empty containers (the Environment Agency definition of 'effectively empty' is containing less than 1% of its original contents) can be disposed of as clinical waste i.e. in a yellow waste bin.

16.2 Pharmaceutical Hazardous (Cytotoxic/cytostatic) waste

The only medicinal products that are automatically deemed to be hazardous are cytotoxic and cytostatic medicines. 'Soft' cytotoxic or cytostatic waste e.g. tablets or capsules must be disposed of in yellow clinical waste bags, sealed by 'swan necking' the top. Unused or unopened solutions, powders, vials or ampoules should be returned to the supplying pharmacy.

Sharps contaminated with cytotoxic or cytostatic medicines must be disposed of in a yellow clinical waste sharps containers with purple lid and labelled (with a permanent black marker pen) "CYTOTOXIC WASTE".

16.3 Pharmaceutical Non Hazardous (Non-Cytotoxic and Non-Cytostatic) Waste

Liquid medicines

These can be disposed of to sewer (i.e. sluice, sink). However antibiotics, hazardous, cytotoxic or cytostatic products or controlled drugs must be returned to the supplying pharmacy for disposal.

Aerosols

A maximum of two empty or partially empty aerosol containers can be placed in any one waste container i.e. clinical waste bag. Larger quantities must be returned to the supplying pharmacy for safe disposal.

Tablets or capsules

'Odd' tablets or capsules e.g. dropped tablets, can be placed into a clinical waste bin. Larger quantities should be returned to the supplying pharmacy for safe disposal.

Creams or ointments

Should remain in their original container and be returned to the supplying pharmacy for disposal.

Intravenous fluids

Small quantities of non-pharmaceutically active intravenous fluids with no other hazard (e.g. risk due to contamination with body fluids or the addition of pharmaceutically active substances) can be disposed of to a sewer or placed in the medicines waste stream i.e. into a sharps bin.

Where an intravenous fluid contains a pharmaceutically active ingredient e.g. potassium, they must be placed in a Pharmaceutical Non-Hazardous Waste container i.e. a sharps bin.

Dietary supplements

Small quantities of liquid dietary supplements can be disposed of to sewer. The containers must be opened and emptied. The remaining container must be disposed of as non-clinical waste.

Powder supplements e.g. tinned powders or sachets must be placed into a clinical waste bin.

Sharps contaminated with pharmaceuticals

Sharps containing pharmaceuticals must not be discharged prior to disposal. They must be placed in a yellow sharps bin.

16.4 Patients Own Medicines

Medicines brought in by the patient remain the property of the patient and may only be sent to the pharmacy for destruction with the prior agreement of the patient or his or her representative.

16.5 Disposal of medicines in the community setting

Pharmaceutical waste produced as a by-product of patient care activities in the community setting should be managed in accordance with local procedures.

All sharps, whether contaminated or not by medicines, should be disposed of in a yellow sharps bin.

Medicinal products that are out of date or no longer required must be returned to the supplying pharmacy in a locked or sealed container. Expired items should be marked "Expired".

Doses of medicines that have been prepared but not administered to a patient should be destroyed in the clinic in the presence of a witness. A record of the destruction, signed by the person destroying the product and the witness, should be kept.

Medicines obtained for a patient on a GP's prescription are the property of the patient. Patients wanting to return waste medicines should be directed to return them to a community pharmacy for disposal.

Destruction of CDs must comply with current legislation and be carried out in accordance with local procedures.

17. CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS (CTIMPs)

17.1 Introduction

The Pharmacy department provides services to clinical trials of Investigational Medicinal Products (CTIMPs) being hosted or sponsored by York Teaching Hospital NHS Foundation Trust.

For the purposes of this document, an Investigational Medicinal Product (IMP) may be defined as follows: *'A Pharmaceutical form of an active substance or placebo being tested, or used, as a reference in a clinical trial, including products already with a marketing authorisation but, for the purposes of the trial, used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form'*.

Professional Guidance on Pharmacy Services for Clinical Trials has been produced by the National Pharmacy Clinical Trials Advisory Group (NPCTAG) (endorsed by the Royal Pharmaceutical Society) in October 2013 and this describes the role of Pharmacy in relation to clinical research as follows:

- a) To safeguard subjects, health care professionals and the Trust by ensuring that IMPs are appropriate for use and are procured, handled stored and used safely and correctly.
- b) To ensure that IMPs are managed and dispensed to patients in accordance with the duly approved current protocol.
- c) To ensure that all pharmacy clinical trials procedures comply with relevant guidelines and regulations.

It suggests that Pharmacy should provide input to (and regular review of) a policy document covering the safe handling of medicines used in clinical trials. The information contained within Section 17 of the York Medicines Code is provided with this aim.

17.2 Safe handling of medicines used in clinical trials

Pharmacy must be involved in (i.e. take an active role in or be aware of) all CTIMPs being hosted or sponsored by the Trust.

In 2012, The Medicines and Healthcare products Regulatory Authority compiled a Good Clinical Practice Guide (known as the grey guide) which states that 'the Investigator (or their delegate) is responsible for the management of IMP at their site'.

The Investigator is defined as; *'In relation to a clinical trial, the authorised healthcare professional responsible for the conduct of the trial at that site, and if*

the trial is conducted by a team of authorised health professionals at a trial site, the Investigator is the leader responsible for that team and may be called the Principal Investigator’.

In most circumstances, the management of the IMP at York Teaching Hospital NHS Foundation Trust is delegated by the Principal Investigator to, and therefore undertaken by, the Pharmacy department. Within the Pharmacy department there are dedicated, trained individuals who constitute the Pharmacy Clinical Trials Team who agree to undertake these responsibilities, which should be indicated by their signature on the delegation log for each individual study.

The procedures for safely managing IMP in Pharmacy at York Teaching Hospital NHS Foundation Trust are described in standard operating procedures available on the York R&D Unit website – www.northyorksresearch.nhs.uk under the SOPs and Guidance section.

These SOPs will be maintained in accordance with the current guidance provided within the document ‘Professional Guidance on Pharmacy Services for Clinical Trials’ produced by the National Pharmacy Clinical Trials Advisory Group (NPCTAG) in October 2013, and cover the following activities as suggested in the guidance (the name and reference of the corresponding York SOP is given in column 1):

Pharmacy approval of a clinical trial	Pharmacy Trial Assessment and confirmation of readiness (Pharm/S40)
Receipt and recording of the safe delivery of IMPs	Receiving Clinical Trial materials and IMP into Pharmacy stores (Pharm/S46)
Safe handling and storage of IMPs	Storage of Clinical Trial Supplies (Pharm/S47)
Temperature monitoring and reporting of temperature deviations	Temperature Monitoring (Clinical Trials) (Pharm/S48)
Risk assessment of storage areas for IMPs outside pharmacy	Storage and dispensing of IMP outside of Pharmacy (Pharm/S76)
Quarantine of IMPs	Quarantine of IMP (Pharm/S59)
Expiry date relabelling	Labelling (Pharm/S45)
Unblinding	Managing Code Break Procedures (Pharm/S54)
Preparation and dispensing of IMPs in accordance with professional standards	Pharmacy Trial Instructions (Pharm/T25)
Return and disposal of unused IMPs	Returning Clinical Trial materials and IMP to the Trial Sponsor (Pharm/S55)
Reconciliation of IMPs	Pharmacy Trial Instructions (Pharm/T25)
Drug alerts and recalls of IMPs	Actioning a Clinical Trial IMP recall (Pharm/S58)
Maintaining a pharmacy study file	The Pharmacy Clinical Trial File (Pharm/S44)
Training of clinical trial pharmacy staff	Training of Pharmacy Personnel (Pharm/S49)
Archiving of clinical trials documentation	Trial Closedown in Pharmacy (Pharm/S56)

These must be followed by all Pharmacy (and Research staff) who have responsibility for managing IMP for any individual study being hosted or sponsored by York Teaching Hospital NHS Foundation Trust.

There are exceptions to these circumstances, whereby, the study IMPs may be managed by the Investigator and consequently, stored outside of Pharmacy. These are likely to occur under the following circumstances (as listed in the MHRA Good Clinical Practice guide):

1. In emergency medicines, the trial team needs to have access to the IMP out of hours; therefore, it may not be practical to store it in the Pharmacy.
2. The Pharmacy is unable to provide the service in relation to the trial requirements but these can be provided by trial staff.
3. Out patient visits may occur at weekends or evenings when the Pharmacy is not open and it would be inconvenient for subjects to return on a separate visit for their medication.

In addition to this, there is also a Clinical Research Facility at York (YCRF) located within the Learning and Research Centre, in which Investigational Medicinal Product can be stored at -80°C (or similar), arrangements that cannot be accommodated in the main Pharmacy.

If one of these circumstances is applicable, prior to storage of IMP outside Pharmacy, the proposed storage area for the IMP must be assessed, and approved, by Pharmacy according to the procedures described in Pharm/S76 – Storage and dispensing the IMP outside Pharmacy.

In these circumstances, the arrangements for management of the IMP outside Pharmacy must also be detailed in a study specific Standard Operating Procedure (SOP), which should be written in line with the procedures described in;

1. R&D/S26 – preparation, review and approval of study specific Standard Operating Procedures for research.
2. Pharm/S76 – storage and dispensing the IMP outside Pharmacy.

The arrangements for management of the IMP outside Pharmacy must be authorised by the Principal Investigator, and evidenced by their signature on the front cover of the SOP.

17.3 Prescribing of IMP

Prescribing standards for CTIMPs are detailed in Pharm/S33 - Prescribing of Investigational Medicinal Products. It is the responsibility of all Doctors taking a role in prescribing for a clinical trial to follow the procedures contained within this document. Prescribing for a clinical trial is only acceptable from a medically qualified Doctor. Prescribing by a Nurse or Pharmacist is not acceptable.

Where possible, Investigational Medicinal Products will be prescribed on a trial specific prescription to provide an audit trail for the clinical trial.

17.3.1 The delegation log

Investigational Medicinal Product must only be prescribed by the Investigator, or another delegated medically qualified Doctor, who is present on the delegation log for the clinical trial. It is the responsibility of the Pharmacy Clinical Trials Team to check that the Prescriber is present on the delegation log for the study. No IMP will be dispensed if the Prescriber does not have authorisation to prescribe for the clinical trial (as evidenced by the delegation log).

With respect to this, it is the responsibility of the research team to ensure that a copy of the current delegation log is available for the Pharmacy clinical trials team during the conduct on the study.

17.4 Procurement of IMP

Where a trial is sponsored by York Teaching Hospital NHS Foundation Trust (or co-sponsored with the University of York or another organisation), IMP may be required to be manufactured specifically for the study. If this is the case, the Pharmacy department must be involved in the process of procuring the IMP from a third party manufacturer to ensure that the IMP manufacturer has the appropriate licenses to cover this activity, and that a Technical agreement is in place that covers this activity. Pharmacy will follow the procedures described in Pharm/S43 – Procurement of IMP.

17.5 Trials Governance and Pharmacy Approval

Information regarding the conduct of CTIMPs at York Teaching Hospital NHS Foundation Trust can be found on the York Foundation Trust R&D Unit website as follows http://www.northyorksresearch.nhs.uk/sops_and_guidance/.

The legal and indemnity issues surrounding supply of Investigational Medicinal Product for a clinical trial are complex. As part of the research governance process of granting NHS permission (described in SOP R&D/S14), the Chief Pharmacist will be asked to agree to supply clinical trial material through the pharmacy department for each CTIMP being hosted, or sponsored, by York Teaching Hospital NHS Foundation Trust. The Chief Pharmacist is responsible for ensuring that all pharmacy related legal, indemnity and professional issues are adequately covered prior to notifying the local R&D department of his or her agreement to the trial proceeding. The Chief Pharmacist may choose to delegate the granting of this approval to a designated Clinical Trials Pharmacist/Manager, and this will be formalised through the completion of a Pharmacy Assessment form (Pharm/F28) for the study through which Pharmacy Approval (or not) would be indicated.

In particular, all CTIMPs must comply with the NHS Research Governance Framework for Health and Social Care (2nd Edition, Department of Health, April 2005), and require the following approvals before participants can be recruited;

1. Clinical Trials Authorisation (CTA) from the Medicine and Healthcare Products Regulatory Agency (MHRA) – see the MHRA website (www.mhra.gov.uk) for more information.
2. Favourable opinion from an appropriate Research Ethics Committee.
3. NHS Permission from the Trust (if the study involves NHS patients, staff and / or resources).

As NHS permission will not be issued unless a CTA and Favourable opinion from a REC is in place, it is the responsibility of Pharmacy to ensure that Pharmacy readiness to commence a clinical trial is not issued until NHS permission is obtained from the York R&D unit. The procedures for issuing Pharmacy readiness for a clinical trial should be followed and are detailed in Pharm/S41 – Pharmacy assessment and trial readiness.

Once Pharmacy readiness has been given and the other conditions specified in R&D/S14 - granting NHS permission have been met, the R&D unit will issue the Participant Recruitment (green light) letter.

In no circumstance must Investigational Medicinal Product be supplied to patients (or subjects) before the Participant Recruitment (green light) letter has been issued. Medical/nursing staff would not be covered by Trust's indemnity arrangements if they supplied Investigational Medicinal Product to patients in an unauthorised manner.

17.6 Provision of IMP following a Trial and Insurance/Indemnity arrangements

At the end of a study a prescriber may wish to continue to prescribe the trial medicine for those patients who have benefited. The provision of such medicines, outside the clinical trial, is subject to the normal procedures for new medicines as defined in the Trusts procedure for obtaining new medicines (See Section 33 Trust Formulary).

Insurance and Indemnity arrangements are described in detail in the York Foundation Trust R&D Unit guidance document - R&D/G01.

18. MEDICATION ERRORS

Definition

A medication error is a preventable incident associated with the use of medicines that result in harm or potential for harm to a patient. Such incidents may be related to any step in the medicine use process. This includes prescribing, dispensing and administration of the medicine as well as the transfer of information. Inappropriate omission of a dose is considered to be a medication error.

The systematic reporting of medication errors is designed to protect patients, staff and the Trust as well as to identify areas where improvements in practice need to be made. It is not designed to apportion blame or as part of the disciplinary process.

All staff must be familiar with the Trust Incident Report Systems and all professionals must be familiar with the guidelines from their own professional bodies.

18.1 Medical Review of the Patient

The wellbeing of the patient is of prime importance following a medication error. The error must be reported as soon as possible to an appropriate member of the medical team who will decide whether further action is needed in terms of informing and managing the patient.

In addition, where the wrong drug or the wrong dose of a drug has been administered or the drug has been administered incorrectly, the consultant responsible for the patient and the nurse in charge must be informed as soon as possible.

All medicine containers, syringes, infusions and administration equipment must be retained for examination.

18.2 Monitoring and Reporting System

All medicines related incidents reported via the Trust Incident Reporting Systems will be reviewed by Medication Incident Review Groups which will advise the appropriate risk management and governance groups/committees. Incidents should also be reviewed in the division to which they relate.

The Medication Incident Review Groups should meet not less than bi-monthly to review medication error reports, to establish trends and to recommend action intended to prevent such errors. Action may involve system redesign and improvement and/or education, training and competency assessment of employees on any aspect of medicine use.

In the case of “near misses” it is still important that a Trust Incident Report is completed so that an appropriate review of procedures, training, documentation and other factors can be undertaken. Near misses are often a warning sign of errors waiting to happen.

Errors must be dealt with sensitively, the prime aims being to ensure the welfare of the patient and to prevent recurrences. Disciplinary action should only be considered where there is a breach of the duty of care by reckless practice.

18.3 Review of Medication Errors

The Medication Safety Group should receive bi-monthly reports on medication errors from the Medication Incident Review Groups and ensure that review is taking place regularly.

19. MEDICINE DEFECT REPORTING

Definition

A defect is present where the product, as supplied by the manufacturer, is not of the expected standard. Defects may involve, for example, inadequate or incorrect labelling, ineffective packaging, contamination or discolouration of the medicine and broken tablets etc.

19.1 Procedure for handling defective medicines or medicines suspected of being defective

Inform the supplying pharmacy who will advise on all reporting, recording and investigation of the defect.

Retain any remaining product and any associated products or equipment (e.g. administration sets, infusion devices etc.).

Record the details of the product and defect on the form provided by the pharmacy and return the form immediately to the supplying pharmacy.

If the product has been administered to a patient inform the doctor responsible for the patient and record the defect and any adverse events in the patients' notes.

Report the incident on the Trust Incident Reporting System.

If a drug defect is suspected that needs to be reported urgently after the pharmacy department's normal opening hours the emergency duty pharmacist should be contacted by the doctor or nurse/midwife in charge.

19.2 Product Recall

Where the pharmacy is notified of a defective product by the manufacturer, the Medicines and Healthcare Products Regulatory Agency (MHRA) or NHS England, pharmacy staff will instigate a product recall procedure to ensure identification and removal of all affected batches.

20. REPORTING ADVERSE REACTIONS

Definition

An adverse drug reaction is an unwanted or harmful reaction experienced following the administration of a drug or combination of drugs, and is suspected to be related to the drug. The reaction may be a known side effect or may be new and previously unrecognised.

Practitioners must report adverse effects to the medical staff responsible for the care of the patient. It may be also appropriate to report an adverse reaction to the Medicines and Healthcare products Regulatory Agency (MHRA).

Reports should be made online at www.yellowcard.gov.uk. Alternatively reporting forms can be found in the British National Formulary (BNF) or obtained from the pharmacy department.

Reports may be completed by doctors, nurses, pharmacists and patients and carers. The person completing the report should document this in the medical records (except in the case of patients or carers where a practitioner should do this on their behalf). A copy of the report will be sent to the consultant by the MHRA for filing in the patient's medical notes.

Reports should always be made to the MHRA for:

New Drugs: Designated by an inverted black triangle in the BNF. Report all suspected reactions *i.e.* any adverse or unexpected event, however minor, which could conceivably be attributed to the drug. Report even if the reaction is well recognized or if you are unsure of the causal relationship.

Established Drugs: Report serious suspected reactions (even if well recognised), including those that are fatal, life-threatening, disabling, incapacitating, or which result in or prolonged hospitalisation.

Unlicensed medicines: Report all adverse reactions.

Children under 18: Report all adverse reactions.

For further guidance on recognising adverse drug reactions and completing reports consult the BNF, your ward pharmacist or Pharmacy Medicines Information.

Drug companies are obliged by law to record and report to the MHRA all possible reactions brought to their attention. They can therefore often provide information on past reporting for their drugs.

21. CONTROLLED STATIONERY

21.1 Security and Safe Handling of Controlled Stationery

Controlled stationery is any stationery that, in the wrong hands, could be used to obtain medicines fraudulently. Stationery that is to be treated as controlled stationery by all staff of the Trust is listed below:

- Controlled Drug Order Books and registers.
- FP10 Prescription Pads (HP, SS, PN).
- Outpatient Prescription Pads.
- Blank Inpatient Charts.
- Controlled Drug Outpatient and Discharge Prescription Pads.
- TTO Pads.
- Healthcare at Home prescriptions.
- Requisition pads.
- Botulinum toxin order books.
- Botulinum toxin record books.

The department receiving bulk supplies will keep a record of the receipt of controlled stationery, including:

- Date of receipt.
- Serial numbers of requisition/prescription pads received.
- Identity of the person receiving the books/pads.

The issuing department will keep a record of the issue of controlled stationery, including:

- Date of issue.
- Serial numbers of the prescription pads issued.
- Identity of the person requesting the book/pad.
- Identity of the person issuing the book/pad.

These records should be examined at six monthly intervals for inconsistencies and any anomalies investigated by the person in charge.

Bulk stocks of controlled stationery shall be ordered, received, securely stored and issued by the pharmacy department.

Controlled stationery must be securely stored in all wards and departments. Loss or theft of any controlled stationery must be reported immediately to the person in charge of the ward/department and to the pharmacy department.

Any unused controlled stationery must be returned to the issuing department where a record of returns must be maintained.

Stationery for ordering and recording of controlled drugs

Each ward or department based at a site with a pharmacy must hold only one Controlled Drug Order Book at any given time. Wards or departments based at community hospitals may hold two Controlled Drug Order Books marked A and B to allow urgent requests to be made when one book is already in pharmacy. Authorised pharmacy staff will issue Controlled Drug Order Books and registers when the previous one is complete.

It is the responsibility of the nurse in charge to ensure the security of controlled stationery following receipt from the pharmacy department. Controlled Drug Order Books must be stored in the Controlled Drugs Cupboard. The Controlled Drug Register may be placed on top or next to the CD cupboard.

21.2 FP10 Prescription Pads

Prescription pads are the property of the Trust. They are uniquely numbered and need to be fully accounted for. It is the responsibility of a designated member of staff within the responsible department to order controlled stationery and ensure safe and secure handling.

Order and receipt of FP10 prescription pads

All FP10 prescription pads should be ordered in writing from the hospital pharmacy department, including those for use by non-medical prescribers. The issuing department will provide a receipt with all FP10 prescriptions issued. The receipt will state the serial numbers of the pads. The receipt document is to be signed on receipt of the prescriptions and returned to the issuing department.

Management of FP10s

The details of each pad of FP10 prescriptions must be recorded on an individual copy of a Record of Prescription Form. The unit or prescriber must document the receipt of all FP10 prescriptions on an individual copy of a Record of Prescriptions Form. The following details must be recorded:

- The unit or clinic name.
- The type of prescription form i.e. FP10 (HP), FP10 (PN) etc.
- Prescriber's name pre-printed on the form (if applicable).
- The date when the prescriptions were received.
- The number received.
- The serial numbers of the prescriptions i.e. the first and last serial number of each pad.

Record of Prescription Forms must be used to record the date and pertinent serial numbers of all prescriptions issued to prescribers. The prescriber, or the person responsible for issuing FP10 prescriptions to prescribers, must record the first and last serial number of each FP10 pad given out and record the same details when those remaining are handed back for secure storage.

Once all the prescriptions detailed on a particular record form have been completed and issued by the prescriber to his or her patients, the completed record form should be marked as "all used" and the form kept in a secure place for at least three years.

FP10 prescriptions issued to prescribers by units must always be booked back into secure storage at the end of each prescribers shift. Should any prescriber leave without booking these back in then he/she should be contacted straight away and instructed to return said prescriptions immediately. Any refusal to comply with this request is to be referred to the Head of Service, by email, immediately. The name of the prescriber, the prescription pad details and serial numbers should be detailed along with any reason the prescriber gave for refusing to immediately return the prescriptions.

The security of FP10 prescription pads is the responsibility of each individual prescriber, whilst in their possession, and they should ensure that the pads are kept as safe and secure as possible at all times.

Under no circumstances should unwanted FP10 prescription pads be destroyed locally. When FP10 prescription pads are no longer required, the supplying department should be contacted to collect them.

Prescribers who have been issued with FP10 prescription pads are responsible for the security of those pads.

The ward sister/charge nurse on each ward or unit that stores blank FP10 prescription pads has the responsibility of ensuring that they are secured and accounted for appropriately.

The Head of Service has overall responsibility for the appropriate security of FP10 prescription pads within units or wards.

Loss of FP10 pads

The loss should be reported immediately to the issuing department, who will provide further advice on required actions.

22. PARENTERAL THERAPY

Parenteral therapy involves certain inherent risks which staff must take every precaution to avoid. All staff involved in the prescribing, preparation or administration of parenteral therapy must receive specific training and follow the relevant policies. Refer to the Trust Injectable Medicines Policy.

Guidance is available on wards and departments providing information on the use, preparation and administration of common injectable medicines. Staff involved with intravenous therapy must be aware of this document and familiar with its content. In addition, they should also be familiar with dose calculations, specific drug delivery systems relevant to their area of practice, the management of extravasation and the therapeutic monitoring requirements for drugs relevant to their area of practice. Advice and information on aspects of intravenous therapy can be obtained from the ward pharmacist, the pharmacy department and also the Trust intranet.

22.1 Central Intravenous Additive Service

A CIVAS service is available in the Trust. The pharmacy aseptic units both produce items and purchase items from external partners. The pharmacy aseptic units concentrate on providing products which have been highlighted through NPSA alert 20 as high risk for preparation by the nursing staff. They also focus on products required for vulnerable patients, e.g. the immunocompromised.

Total Parenteral Nutrition (TPN) involves a number of serious inherent risks, not the least of which is line infection. TPN is managed by the multidisciplinary Nutrition Support Team. Any patient requiring parenteral nutrition should be referred to a member of the Nutrition Support Team who can provide further information. TPN must only be administered in the Acute Trust.

22.2 Chemotherapy

Staff involved in the prescribing, preparation and administration of cytotoxic drugs must be familiar with the contents of the current edition of the Trust chemotherapy protocols and have received specific training. See the Trust Chemotherapy Policy.

Chemotherapy is purchased from specialist manufacturers or prepared in the pharmacy aseptic units. All chemotherapy must be prescribed on chemotherapy prescription charts. Doses that are not administered must be safely returned to the supplying pharmacy as soon as possible.

22.3 Intrathecal Therapy

Intrathecal chemotherapy is only to be prescribed, prepared and administered at York Hospital by highly trained people specifically named in the Prescribing and Administration of Intrathecal Chemotherapy for Adults Policy.

There are important safety issues which surround the prescribing, dispensing, checking and administration of Intrathecal Chemotherapy. The inadvertent administration of Vinca Alkaloids (e.g. vincristine) is potentially fatal. It is essential that the guidelines outlined in the Prescribing and Administration of Intrathecal Chemotherapy for Adults Policy are adhered to.

A register of personnel designated to prescribe, dispense, issue, check and administer intrathecal chemotherapy is contained in appendix 1 of the Prescribing and Administration of Intrathecal Chemotherapy for Adults Policy.

Intrathecal Chemotherapy must be prescribed for administration on a separate day to intravenous therapy. Intravenous Chemotherapy must be administered before Intrathecal chemotherapy is administered.

Intrathecal drugs will be supplied from the pharmacy department in a ready to use form and marked "For Intrathecal Use Only". Such drugs will be supplied separately from other parenteral drugs.

22.4 Epidural Therapy

Epidural therapy requires specialist training and skills. Training can be accessed via the Acute Pain Team.

All epidural lines must be clearly identified and distinguished from intravenous lines.

Continuous epidural infusions should clearly state "For Epidural Use Only". Epidural infusions are only administered in the Acute Trust.

22.5 Radio pharmaceuticals

Radio pharmaceuticals are radioactively labelled medicines. Their preparation and administration is controlled under the Medicines (Administration of Radioactive Substances) Regulations (1978) [MARS] and the Ionising Radiation (Medical Exposure) Regulations (2000) [IRMER].

Three legal definitions are applied in this context:

REFERRER: The medical practitioner requesting the investigation.

PRACTITIONER: The holder of the ARSAC licence who is responsible for the radiation administered. This person must be identified for each examination.

OPERATOR(S): The person (or persons) involved in the preparation and/or administration of radioactive material.

The preparation of radio pharmaceuticals takes place in specially designed areas in the pharmacy or nuclear medicine department. Administration takes place in the nuclear medicine department but a small number of doses may be given in wards and other departments. If administration takes place outside the nuclear medicine department all staff taking part must be aware of the rules governing the activity.

22.6 Single use Containers

All injectable medicine containers should be viewed as single use unless they contain preservatives and are intended for multiple use e.g. Insulin. All single use containers should only be used to prepare a single dose for a single patient on one occasion and should not be retained for use at a later time. Using single use medicines on more than one patient/occasion is an unlicensed use of the medicine and increases the risk of preventable harm to patients.

This applies regardless of the presentation (ampoule, vial, pre-filled syringe, infusion bag, etc) and also includes situations where a single use product is given non-parenterally, such as for diluting nebuliser solution or flushing nasogastric tubes.

The use of devices which facilitate multiple access into bags or bottles of infusion solution, such as multidose adapters or needles with three-way taps, is forbidden in all clinical areas. Any exceptions to this policy must be authorised by the Chief Pharmacist.

22.7 Multidose Containers

Multidose containers are products which contain a combination of a drug and an antimicrobial preservative and are labelled for multidose use.

The fact that it is possible to remove a drug from a vial more than once via a septum or bung does not in itself mean a product is suitable for multiple uses. If unsure the practitioner must check the product Datasheet or Summary of Product Characteristics, or check with a pharmacist. Multidose containers must be labelled with the following information when use commences:

- Date use commenced
- Expiry date
- Special storage requirements e.g. in a refrigerator

If a multidose container is for single patient use e.g. insulin this should clearly be labelled with the patients name and stored in the patient's own drug locker, where possible.

23. PATIENT'S OWN MEDICINES

The Trust encourages patients to bring in their medicines from home and recognises that patient's own medicines are the property of the patient.

With the patient's agreement, suitable medication may continue to be used for the patient whilst in the care of the Trust. They will be stored securely and if appropriate returned to the patient at discharge. Patient's/carers have the right to refuse to have their medicines used in hospital or destroyed before discharge.

On admission to the Trust, nursing or pharmacy staff will assess the suitability of a patient's own medicines before they are used. If positively identifiable and they meet specific suitability criteria outlined in the local re-use of patients own drugs policy then they may be used whilst under care of the Trust. Consent from the patient or the patient's representative should be obtained.

If the medication is not suitable then it cannot be used or administered during the patients stay in the Trust. The patient should be informed and their agreement obtained if any medication is to be destroyed.

Refer to the Reuse of Patient's Own Drugs Policy.

24. USE OF COMPLEMENTARY THERAPIES INVOLVING THE ADMINISTRATION OF SUBSTANCES

Complementary therapies are therapies that may be used to complement orthodox medical, nursing and paramedical treatments to enhance patient well-being, quality of life and symptomatic relief.

Definition

'Complementary Therapies are used alongside orthodox treatments with the aim of providing psychological and emotional support through the relief of symptoms'

NICE Supportive and Palliative Care Improving Outcomes Guidance (2004)

The Drugs and Therapeutics Committee must approve any new therapy involving medicines or the administration of substances before it can be recognised by the Trust. Approved substances used in complementary therapies must be handled in the same way as medicines and as described in this code.

Practitioners should refer to specific policy/principles of care on the use of complementary therapies in cancer care and by nurses, midwives and allied health professionals.

Qualifications

The Complementary & Natural Healthcare Council (CNHC) has been set up as a national voluntary regulator in Complementary Therapies (www.cnhc.org.uk). Whenever possible it is recommended that complementary therapists are registered with this organisation.

The CNHC states that for the following listed therapies, complementary therapists must hold qualifications from one of the following organisations (qualifications that have been gained wholly by correspondence or over short courses will not usually be accepted):

Massage, Nutritional Therapy, Aromatherapy, Reflexology, Shiatsu & Sports & Remedial Therapy

- Federation of Holistic Therapists (FHT)
www.fht.org.uk
- Complementary Therapists' Association (CThA)
www.complementary.assoc.org.uk

Aromatherapy only

- International Federation of Professional Aromatherapists (IFPA)
www.ifparoma.org
- International Holistic Aromatherapy Foundation (IHAF)
www.ihaf.co.uk

Massage & Aromatherapy

- Aromatherapy & Allied Practitioners Association (AAPA)
www.aromatherapyuk.net

Aromatherapy & Reflexology

- Association of Physical & Natural Therapists (APNT)
www.apnt.org

Massage, Aromatherapy & Shiatsu

- Institute for Complementary & Natural Medicine (ICNM)
www.i-c-m.org.uk

Any Complementary Therapist working on Trust premises or cited/endorsed in the patient information of MDTs, chemotherapy services and radiotherapy departments, must have a qualification relevant to their therapy and must have current registration with the relevant body. The therapist's certificate of qualification and CHNC registration should be checked and a photocopy of the documents kept in the therapist's personnel file.

The therapist's line manager must review the following before any complementary therapy can be practised:

- The therapist's certificate of competence or training.
- Details of the organisation providing the training.
- Current membership of a recognised national body/professional body.

Complementary Therapies can only be undertaken by therapists with the written permission of the medical practitioner with responsibility for the patient's care where that practitioner has confirmed that the therapy will not be harmful to the patient.

Good practice standards and criteria for practice of complementary therapies must be adhered to and under these circumstances; the Trust will accept liability for the complimentary therapy under 'Vicarious Liability.' Private therapists contracted to provide a service must have personal indemnity insurance.

The therapist must have authorisation to practice from his/her line manager if they are acting within their role. There may be instances when a therapist may gain permission, client consent and there will be no conflict of interest with their role when the therapist is willing to carry out the Complementary Therapy within their own time. The therapist's line manager must be made aware that this practice is happening. However the therapist must also be aware that they will be personally accountable for their practice.

Competence

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

The therapist has responsibility for the whole course of treatment and any delegation of tasks to others must not take place.

Consent

The patient must give informed consent for the practice of a specific complementary therapy. The therapist must consult the multidisciplinary team members involved in the patient's care before any treatment is carried out.

Documentation

The complementary therapist must document within the patient's care plan the therapy practised, and maintain within the care plan notes of treatments given, dates and evaluations of the outcome of treatments. All documentation must be in line with the standards of the Trust on record keeping and the relevant accreditation body of the complementary therapist.

It is not appropriate for a patient (even if they are suitably qualified) to practice a complementary therapy on health services premises or to solicit other patients as prospective customers.

25. USE OF UNLICENSED MEDICINES

Prescribers must follow pharmacy guidance and procedures when unlicensed medicines are used in the Trust. Refer to the Trust Unlicensed Medicines Policy, which covers the following categories of medicine:

- Drugs that are not licensed in any similar form in the UK.
- Preparations of drugs where the drug is licensed in other forms.

Drugs used in clinical trials are covered elsewhere.

25.1 Background

The majority of medicines used in the Trust hold a product licence (PL) issued by the Medicines & Healthcare Products Regulatory Agency (MHRA) or a Marketing Authorisation (MA) issued by the European Medicines Evaluation Agency. The product licence/marketing authorisation specifies the clinical condition(s), dose(s), preparations, route(s) of administration and storage conditions appropriate to a particular product.

The liability for untoward events associated with the use of a medicine rests with the manufacturer when a product is used in accordance with its product licence.

This general rule does not apply to:

- Medicines that do not have a product licence.
- Medicines used for indications not included in the product licence.

25.2 General Principles

In general, if an untoward event occurs the individual who is injured is entitled to compensation if negligence by an individual or by the supplier of the medicine (the Trust) can be shown or if it can be shown that the producer has supplied a defective product.

The Trust is vicariously liable for any negligence by an employee acting in the course of their employment, except where a criminal act takes place.

The manufacturer of a licensed product is liable if problems arise associated with the quality of the product, or if clinical problems arise during its use for a licensed indication; provided the link between the product implicated and the manufacturer can be confirmed and there is confidence that the product has been stored correctly.

When a licensed medicine is used for an indication not included in its UK product licence, the manufacturer of the product would be responsible for product quality issues, but would disclaim responsibility for clinical issues.

Liability for untoward clinical events rest with the prescriber and the Trust. Many products are licensed only for an adult age range and hence become unlicensed when used in children.

The use of a licensed medicine for an indication not included in its UK product licence will be accepted by the Trust, provided the unlicensed use would command “peer group” support and is endorsed, where possible, by objective evidence of efficacy.

Medicines produced by a pharmaceutical manufacturing company, but which do not hold a U.K. product licence are sometimes used. In this situation the prescriber and the Trust are responsible for clinical harm associated with the use of the medicine for patient care. Responsibility for the quality of the medicine rests with the manufacturing company.

The use of medicines or other substances for patient care which do not have a UK product licence will be accepted by the Trust, provided the intended use is registered with the Drug & Therapeutics Committee.

A number of products traditionally thought of as medicines with product licences are now being CE marked. These products no longer fall within the scope of the Medicines Act. It is good practice to continue to consider them as medicines. This re-classification trend is likely to increase.

25.3 The Procedure

Unlicensed products

The consultant responsible for the care of a patient using an unlicensed product must register the intended use with the Drug and Therapeutics Committee (via the Pharmacy Department).

All unlicensed medicines must be ordered and dispensed by the Pharmacy Department.

The Pharmacy must maintain records for unlicensed medicines detailing:

- Prescribers.
- Patients.
- Suppliers.
- Batch numbers.
- Quantities received and issued.
- Dispensing dates.
- Indications (if required by the supplier).
- Any adverse events.

The prescriber must inform the patient that an unlicensed medicine is being used and document this in the patient's medical record. Informed consent must be obtained when a medicine is being used in this situation.

Where patients are to take home a supply of an unlicensed preparation they will be given an information leaflet about the medicine, where one is available, as well as information from pharmacy about how to obtain further supplies. Paediatric patients, or their carers, may be given a copy of the Royal College of Paediatrics and Child Health information leaflet on unlicensed medicines, if appropriate.

Where GPs may be asked to continue to prescribe unlicensed drugs, or drugs for use outside their Product License, they should be provided with a copy of the evaluated evidence supporting the use of the drug and information that enables the drug to be prescribed safely. This should be treated as a shared care arrangement where the consultant is able to provide further support to the GP should the need arise. GPs may not wish to continue such prescribing because of issues of liability.

All adverse drug reactions that occur in patients treated with unlicensed medicines must be reported to the MHRA. This should be done in the same way as for licensed drugs.

Where a patient does not have capacity, or is retained under the Mental Health Act, then professional or legal guidance should be followed prior to the prescribing or administration of unlicensed medicines.

Licensed medicine used for an indication not included in its UK product licence (“Off label use”).

Prescribers must be aware of their use of drugs outside the Product Licence. Pharmacists will assist in providing information to consultants and others, but prescribers have the principle responsibility for this.

The consultant responsible for the care of a patient using a licensed medicine used for an indication not included in its UK product licence must be satisfied that:

- a) Objective evidence of efficacy is available in reputable textbooks or peer reviewed journals **or**
- b) It is accepted “custom and practice” to use the medicine in that manner **or**
- c) That the unlicensed use would command “peer group” support

The prescriber must ensure that the patient has adequate information on the product to prevent confusion about the particular “off label use” of the medicine should they read the package insert or other information available to the public.

If pharmacy staff are aware that a licensed medicine is being used for an indication not included in its UK product licence they should discuss this with the prescriber.

26. EMERGENCY, CRITICAL AND URGENT MEDICINES

The NPSA Rapid response report (2010/009) suggests that Trusts should identify medicines where timeliness of administration is crucial.

Emergency Medicines including resuscitation medicines, glucagon, reversal agents, oxygen and drugs for therapeutic emergencies e.g. hyperkalaemia, severe acute asthma, DKA, bleeding varices should be given immediately as part of the medical treatment of the patient. These will generally be stock on all wards or in the area where they will be used.

Critical Medicines These are classes of medicines where timing of administration is critical and must be administered within 30minutes of the prescribed time. Consideration should be given to administering these medicines at the beginning of regular medicine administration rounds.

Urgent Medicines These are medicines which should be administered within 4 hours of the prescribed time.

Practitioners should be familiar with medicines designated as critical or urgent within their area of practice. Further information is available on the Trust intranet.

26.1 Obtaining Urgent Medicines

Hospital setting

If the pharmacy department is open critical and urgent medicines should be ordered preferably through the ward based technician/pharmacist or on a separate requisition and brought to pharmacy with the drug chart. The pharmacy staff should be told the medicine is required urgently.

If the pharmacy is closed, the pharmacy emergency cupboard list should be checked to see if the medicine can be obtained from there. If not available, the critical medicines list on the Trust intranet should be checked to see if the drug is available on another ward. If still not available the emergency duty pharmacist should be contacted via switchboard. They may advise an alternative product or may come in to supply the medicine.

If any of the above medicines are delayed past the time stated this should be reported as a clinical incident through the Trust Incident Reporting System. It should also be documented in the section at the back of the inpatient prescription chart, together with the actions taken to address this.

Location of and Access to Emergency Cupboards:

York Hospital Located outside Ward 35, keys held by the charge nurse on Ward 39.

Scarborough Hospital Located within the Nurse Collection Area adjacent to pharmacy. Keys held by the charge nurse on Cherry Ward.

Bridlington Hospital Located within the Nurse Collection Area adjacent to pharmacy. Keys held by the site coordinator.

Malton Hospital Located within the treatment room on Fitzwilliam Ward. Key held by the charge nurse on Fitzwilliam Ward.

Whitby Hospital Located within the treatment room of War Memorial Ward. Key held by the charge nurse on War Memorial Ward.

Community setting

In Community setting please refer to the Standard Operating Procedure for accessing/obtaining palliative care drugs including CDs by the out of hours service of unscheduled care.

27. MEDICAL GASES

All medical gases used in the Trust are Licensed Medicines. They are subject to the Medicines Act and must be treated in the same way as any other medicines.

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

- An inpatient prescription chart for an individual patient.
- A PGD authorising the administration of a medical gas in an emergency.

A practitioner administering a medical gas to a patient must make a written record that treatment with the particular medical gas has been initiated on the prescription chart.

27.1 Oxygen Treatment

Oxygen is a treatment for hypoxaemia, not for breathlessness. Local clinical guidelines and Guidelines for Emergency Oxygen Use in Adult Patients (British Thoracic Society 2008) require oxygen to be prescribed according to a target saturation range.

Prescribing

Oxygen should be prescribed to achieve a target saturation of 94%-98% for most acutely ill patients or 88%-92% for those at risk of hypercapnic respiratory failure. The target saturation should be written on the drug chart, together with the delivery system and flow rate.

Administration

Staff who administer oxygen therapy should be trained in the use of appropriate devices and flow rates to achieve the target saturation range.

Monitoring

Oxygen saturations and delivery systems should be recorded on the patients monitoring chart. Delivery devices and flow rates should be adjusted to keep the oxygen saturation in the target range. Oxygen should be signed for on the prescription chart on each drug round.

Weaning/Discontinuation

When the patient is in a stable state with satisfactory oxygen saturation, oxygen should be reduced and crossed off the prescription chart once it has been discontinued.

28. ILLICIT SUBSTANCES

The Trust does not condone the use of illicit substances. In accordance with its duties under the Misuse of Drugs Act the Trust does not knowingly permit the use of or dealing in illicit substances on its premises.

If a patient has a history of illicit drug use, is suspected of having used illicit drugs, or is already receiving substitute treatment, the Substance Misuse Liaison Service at York Hospital can be contacted for advice (extension 6559).

Refer to the Drug Misuse: The identification and management of patients' policy.

28.1 Suspected Illicit Substances Belonging to Staff

The use, supply or unauthorised possession of illicit substances by Trust staff while at work or on Trust premises is likely to result in internal disciplinary and possibly criminal proceedings.

28.2 Suspected Illicit Substances Belonging to Visitors

If visitors are seen to be in the possession of a suspected illicit substance they should be asked to leave the Trust premises and return only when they no longer have any illicit substances with them.

If visitors are suspected of passing illicit substances to patients or other visitors the ward sister/charge nurse of the ward or department should arrange to have the person evicted from the premises and discuss the matter with the nurse manager or matron with a view to informing the police.

28.3 Suspected Illicit Substances Belonging to Patients

The ward sister/charge nurse of the ward or department should request the suspected illicit substance from the patient. He or she should also inform the nurse manager or matron. Another nurse, a doctor, pharmacist or other professional should witness the actions of the ward sister/charge nurse.

Any suspected illicit substance found or handed over should be placed in an envelope which is then sealed and locked in the ward or department controlled drug cupboard. The ward sister/charge nurse and the witness should sign across the envelope flap. An entry should be made in the controlled drug register under the heading "suspected illicit substance".

The substance should be transferred, by secure means, to a pharmacist as soon as possible. The substance should not be sent directly to the pharmacy, the ward pharmacist must be involved. Under no circumstances should the suspected illicit substance be returned to the patient or a relative.

A pharmacist must take the suspected illicit substance from the ward or department to the pharmacy department to hand to a police officer. The pharmacist must make an appropriate entry in the ward or department controlled drugs register and the pharmacy department controlled drugs register.

If a patient refuses to hand over the suspected illicit substance, the ward sister/charge nurse in charge should refer the matter to the patient's consultant or GP.

If a patient is suspected of dealing in illicit substances on Trust premises the practitioner should discuss the matter with the patient's consultant or GP for further advice with a view to contacting the police.

Trust staff would not normally be at risk of disciplinary or criminal procedures as a result of following these guidelines, since it is not an offence under the Misuse of Drugs Act to be in possession of an illicit substance if one is doing so to prevent another person from committing an offence. A Trust Incident Report should be completed. If the incident involves an inpatient, the Substance Misuse Liaison Service should also be informed so the patient's care plan can be reviewed

In the Community setting, the nurse should document and report to their Manager and G.P if illicit substances are witnessed in the patients home, whether being taken by the patient or patient's visitors. This is to enable the patient's care plan and visits can be reviewed appropriately.

28.4 Drug Screening

There are occasions when the knowledge about whether a patient has taken an illicit substance may inform and assist clinical decisions.

These include:

- When the patient's behaviour suddenly deteriorates and the ingestion of an illicit substance is thought to be a possible cause.
- When there is a need routinely, to check that a patient is remaining free of illicit substances.
- When a patient is admitted or has been on leave and is suspected of taking an illicit substance.

Patient consent should be sought (see section 35). Urine drug screening can be useful to confirm recent reported history of illicit drug use. However, to rely on the results of urine screening tests, it is important to ensure that any sample is genuine, from the person concerned and un-tampered with. The Department of Health Orange book ("Drug Misuse and Dependence – UK Guidelines on Clinical Management") suggests obtaining witnessed urine samples; however this is not possible in a hospital environment without specialist training and facilities. Therefore all urine samples should be provided as soon as possible after the request is made and checked immediately for warmth and colour. Specimens should be body temperature (not cold or hot) and normal colour (not appearing discoloured or dilute).

There are occasions when a result of a drug screen is needed rapidly. On such occasions a positive result would result in immediate action by a

practitioner (e.g. discharge from the ward, refusal of admission). Urgent drug screening will be performed, on request, by biochemistry.

28.5 Prescribing and Administration of Substitute Opioids to Opiate Dependent Patients

Methadone and buprenorphine are synthetic opioids proven to be effective treatment choices for opiate addiction (“Drug Misuse and Dependence – UK Guidelines on Clinical Management, 2007”). Refer to the ‘Drug Misuse: The identification and management of patients’ policy for further information. The Substance Misuse Liaison Service should also be informed of all patients requiring treatment for opiate dependence at York Hospital.

Patients prescribed substitute opioids are at increased risk of overdose. This risk is greatest at the time of initiation to treatment and when used in conjunction with other sedative drugs, in particular alcohol, benzodiazepines and other opiates (heroin/codeine based products). Buprenorphine has mixed agonist-antagonist properties (dose related) which can limit the effectiveness of the use of other opiates for pain relief. If a patient is admitted in acute pain its use should be reviewed with advice from pharmacy and the Substance Misuse Liaison Service.

28.5.1 Prescribing methadone for pain control

Methadone may sometimes be prescribed for chronic pain by the palliative care team, and in these cases, prescriptions will be dispensed by the hospital pharmacy.

28.5.2 Sedation and intoxication

Nursing staff should observe the patient for signs of sedation and intoxication prior to administration. Intoxication may be caused by the interaction of substitute opioids with prescribed medication or by concurrent illicit drug use. Rarely patients may become overly sedated or intoxicated on their normal dose of substitute opioids due to a medical condition. Increased toxicity has for example been observed in patients on methadone with renal failure, therefore all patients should be observed prior to methadone administration not only those suspected of illicit drug use. If concerned nurses should withhold methadone and contact medical staff for review. Medical staff should then decide if administration of methadone is appropriate or not and inform nursing staff.

29. HANDLING MEDICINES IN OPERATING THEATRES

Handling of medicines in operating departments can represent a significant risk because of the circumstances in which medicines are prescribed and prepared. It is important, therefore, that all staff involved with the use of medicines take every possible care in ensuring their safe use.

Anaesthetists, theatre nurses, operating department practitioners (ODPs) and surgeons must be aware of the risks and causes of medication errors and must ensure that checking procedures are in place and adhered to, even for routine procedures. They must recognise that errors occur especially in situations of haste, distraction or fatigue.

29.1 Prescribing of Medicines

All medicines should normally be prescribed in accordance with the guidelines in section 6 of this Medicines Code.

All medicines must be prescribed on approved Trust stationery and prior to the administration of the medicine.

Only in exceptional circumstances e.g. a clinical emergency, should a medicine be administered prior to a prescription being written. In these situations, administration should only be on the verbal instruction of a medical practitioner and the medicine must always be prescribed retrospectively.

Prescriptions for continuous infusion must clearly specify the following:

- The name and volume of diluent and/or infusion fluid.
- The concentration of final infusion.
- The rate of administration.

Arrangements for fluid balance or clinical monitoring should be made on an individual patient basis and according to local protocol and clinical need.

It is recognised practice in the UK that anaesthetic drugs administered by an anaesthetist, are clearly documented on the anaesthetic record and are not prescribed separately. This is acceptable practice in the Trust.

If an injectable medicine is required to be given in theatre that is not part of the anaesthetic 'work up', it must be prescribed by the team whose care the patient is under on the front of the drug chart. This includes antibiotic prophylaxis. Medicines that are not prescribed will not be given by the theatre practitioners.

On the rare occasions where a scrubbed surgeon requires a second or further dose of antibiotics the anaesthetist should also record this on the front of the drug chart.

29.2 Ordering and Receipt of Controlled Drugs

Controlled drugs must be ordered from the pharmacy department by submitting an order in the ward Controlled Drugs Order Book.

The order must be signed by a registered nurse or ODP who has their name and signature on the controlled drug Authorised Signature List held in pharmacy.

Each anaesthetic room must have its own Controlled Drug Register and Controlled Drug Order Book. However, where agreed local policy exists, controlled drugs can be supplied from the pharmacy to one holding controlled drug cupboard where they are transferred to individual anaesthetic rooms. Any transfers of controlled drug must be witnessed and countersigned by a second practitioner to provide an audit trail.

All controlled drugs must be transported from the pharmacy department to theatres in a tamper-proof container and received into the operating department Controlled Drug Register by a registered nurse or ODP.

29.3 Preparation of Medicines

Wherever possible, any drugs required for a patient who is about to be anaesthetised will be drawn up before their arrival in the anaesthetic room.

Local anaesthetic drugs intended for epidural, plexus blockade, etc should not be prepared at the same time as drugs intended for intravenous administration. They should be drawn up in a sterile field or using an aseptic non touch technique for immediate use.

All drugs should be drawn up into syringes by, or under the direct supervision of an anaesthetist(s), after carefully checking the ampoule label(s) for the drug name, strength, and expiry date.

Once drawn up, syringes must be labelled with the approved name of the drug. (See section 29.3.3 regarding colour coded labels) The dose of the drug per mL of solution should also be written on the label on the syringe.

29.3.1 Preparing drugs to be administered during a sterile procedure

Sterile container:

When an injectable medicine is to be administered during a sterile procedure and the drug is manufactured and supplied in a sterile container, the scrubbed practitioner is to draw up the medicine. This is to be undertaken using an aseptic technique.

The scrubbed practitioner must show the ampoule and any diluents to the surgeon who positively identifies the drug before administering the medicine to the patient.

The administering surgeon assumes responsibility for any drug they administer and as such must be confident that what is being administered is correct.

After the sterile procedure the surgeon must document in the patient notes the name, dose, strength, volume, route and time of administration of the drug administered during the operation.

Non-Sterile container:

When an injectable medicine is to be administered during a sterile procedure and the drug is not manufactured and supplied in a sterile container, the circulating practitioner is to assist in the drawing up of the medicine.

The circulating practitioner must positively identify with the scrubbed practitioner the contents of the ampoule and any diluents to be used before the drawing up of the drug by the scrubbed practitioner.

The circulating practitioner then shows the ampoule and any diluents to the surgeon who positively identifies the drug, before the medicine is administered to the patient.

The administering surgeon assumes responsibility for any drug they administer and as such must be confident that what is being administered is correct.

After the sterile procedure the surgeon must document in the patient notes the name, dose, strength, volume, route and time of administration of the drug administered during the operation.

29.3.2 Labelling

All syringes, including flushes and infusions must be labelled immediately after preparation by the person who prepared them, unless preparation and bolus administration (push) is one uninterrupted process and the unlabelled product does not leave the hands of the person who prepared it.

Only one unlabelled medicine must ever be handled at one time. – NPSA Alert 20, 2007

29.3.3 Syringes

Uninterrupted processes rarely happen. When a drug has been drawn up, the syringe must be labelled immediately. This applies to all injectable medicines in theatre areas including ophthalmic injections.

Anaesthetic drugs used in the operating theatre have colour-coded labels, relating to the type of the drug. Each coloured label has the name of the drug printed on it. The colours are only a guide. It is important to check the drug ampoule and correctly label the syringe with the correct pre-printed label.

White blank labels should only be used in the absence of a coloured pre-printed label. They should be completed fully including the drug name and strength.

Emergency anaesthetic drugs e.g. anticholinergics and suxamethonium, may be drawn up in appropriate dilutions at the beginning of the list and labelled as

above. Drawing up and storage of these drugs remains the responsibility of the anaesthetist at all times.

If the operating list includes a number of short procedures and there is insufficient time between cases for drugs to be drawn up, it is acceptable, but only in these circumstances, to draw up drugs for more than one patient in advance. These must be labelled correctly and stored safely and securely prior to use. Storage of these drugs remains the responsibility of the anaesthetist at all times.

Any drugs that are drawn up in advance, including those prepared for emergency use, must be used within a single theatre session or 4 hours, whichever is the shorter. Nothing must be added to any syringe drawn up.

They must not be transferred from one theatre to another. Any exceptions to this require a risk assessment to be undertaken and the process to be approved by the Chief Pharmacist.

Propofol injection must always be drawn up immediately prior to use because of the increased risks associated with microbial contamination seen with this agent.

Any drugs given intravenously, should be drawn up by the anaesthetist who is to administer them.

In an emergency situation an appropriately trained practitioner may draw up these drugs. This can only be carried out with the agreement of the individual theatre practitioner, and must always occur under the direct supervision of the anaesthetist. Any practitioner administering a drug assumes some degree of responsibility so must ensure that what they are giving is correct.

29.3.4 Infusions

When adding a drug to an IV solution an 'IV additive' label must be attached to the solution bag. The following information should be recorded on the label:

- Patient name & Hospital Number.
- Name of the drug added.
- The dose of the drug added or strength of solution and volume.
- Date and time of addition.
- Lot/batch number of drug added.
- Signature of person adding the drug to the IV solution.
- Signature of person witnessing.

29.3.5 Guidelines for Multi-dose Vials and Devices

Multi dose preparations are vials and devices that contain antimicrobial preservatives (e.g. insulin cartridges, Lidocaine 1% 20ml ampoules etc). They have a limited storage time once the first dose has been withdrawn and can be used for multiple patients following strict guidance as detailed below.

Injections licensed for multiple uses should be used in accordance with their product licences.

Injection solutions in vials without preservatives are designed for **single use only** and must be discarded after a dose has been withdrawn. Examples include injectable antibiotics (e.g. cefuroxime, gentamicin etc.).

This applies regardless of the presentation (ampoule, vial, loaded syringe, infusion bag, etc.) and also includes situations where a single use product is given non-parenterally, such as nebuliser solution.

The use of devices which facilitate multiple access into bags or bottles of infusion solution, such as multi-dose adapters or needles with three-way taps, is forbidden unless a risk assessment has been undertaken and the product approved for use in the Trust.

29.4 Checking

29.4.1 Double checking anaesthetic drugs administered by anaesthetists

It is recognised practice in the UK that anaesthetists who prepare injectable anaesthetic medicines that they themselves administer, do not routinely have a second check prior to the administration.

In these situations the anaesthetist must as a minimum, carefully check the ampoule label(s) for the drug name, strength, and expiry date.

It is also recognised that some anaesthetists who prepare injectable medicines that they themselves administer, do request a second check and this process should be encouraged.

29.4.2 Double checking injectable medicines prepared by a nurse or ODP in theatre areas

All prescribed injectable medicines and infusions drawn up by a nurse or an ODP must be independently checked by another registered practitioner.

When preparing an injectable medicine for administration, a positive second check from a registered practitioner must be obtained (with the exception of anaesthetists as set out in section 29.4.1)

Where two members of staff are involved, the checking procedure must be a complete process.

Both must:

- Read the whole prescription where appropriate or follow the standard protocol for that procedure as directed by the operating surgeon.
- Check the selection of the drug.
- Check the preparation of the drug.
- Check the strength, concentration and volume of the drug.

- Check any diluents or infusion fluids.
- Check the route of the prescription.
- Check the patient's identification.

Any practitioner who administers a medicine that he or she has not personally prepared (such as the operating surgeon), assumes responsibility for that medicine and as such must make every possible effort to assure themselves that what they are giving is correct.

29.5 Patient Identification

All staff must positively check the identification of the patient prior to the generation of individual health records, on admission and prior to the delivery of any treatment or care. The allergy status should also be checked. Refer to the Trust Positive Identification of Patients Policy.

Positive identification involves asking the patient their name and date of birth. These details must be cross-referenced with either the medical or nursing notes or an identity bracelet worn by the patient. In the case of positively identifying children, the above procedure must be carried out and confirmed with the parent or guardian.

Asking a patient to confirm a date of birth or a name verbalised by a member of staff is not considered to be positive identification.

If the patient is unconscious or unable to confirm their identity, then the wrist band details must be checked against the medical records before any treatment is undertaken.

On moving to a new area of the theatre suite the patient's identity and allergy status must be re-confirmed.

29.6 Administration

Before administering any injectable medicine ensure that the patient has been positively identified and the following information has been ascertained as correct:

- The patient's name.
- The allergy status of the patient.

The following should also be confirmed for any medicine being administered:

- The approved medicine name.
- The dose, frequency and rate of administration.
- The prescriber's signature.

And where applicable:

- The date and route of administration.
- The type of rate-control pump or device(s) to be used.
- The date on which treatment should be reviewed.

Under exceptional circumstances it may be required that a practitioner administers some intravenous drugs under the direct supervision and instruction of the anaesthetist. These circumstances would involve an emergency where the anaesthetist's hands are otherwise occupied.

Before administering any injectable medicines on behalf of an anaesthetist the practitioner must have completed the Trust IV training and been assessed as competent in their work place. They too should carefully check the label on the syringe and the patient's allergy status before administering the drug. A practitioner should never be expected to do this against their will or without the direct observation and direction by an anaesthetist.

The contents of pre-drawn up syringes, including those which are supplied already drawn up by the manufacturer should only be used in a single patient and should not be retained for use in subsequent patients.

Ready-to-administer or ready to use products should be stocked in all clinical areas in preference to those needing preparation before use, or those, which are classified as high-risk. Concentrates should only be supplied where safer alternatives are not available. Every effort should be made to use a ready-to-administer product. Infusions prepared in clinical areas for IV use should be discarded 24 hours after preparation with the exception of epidurals.

Medicines must not under any circumstances be given via the arterial line. The only exception to this is the administration of sodium chloride 0.9% to maintain the patency of the cannula.

All components of the infusion system must be changed between patients.

29.7 Peri and Post Administration checks of Intravenous Infusions

29.7.1 During Administration

It is good practice to ensure that the infusion is checked at least hourly during administration especially if the infusion is known to be irritant.

Ensure that the pump is running at the calculated rate and is not alarming.

29.7.2 After Administration

After completion of administration, flush the access device.

Make a detailed record of administration.

Re-check the administration site for signs of leakage, infection or inflammation and continue to monitor the patient, contents of the infusion container and the rate of infusion.

At handover, both the relinquishing and receiving practitioner must check all continuous intravenous infusions or medicines against a valid prescription.

29.8 Documentation

All anaesthetic drugs administered by the anaesthetist must be documented on the anaesthetic record. The name of any drug not on the pre-printed anaesthetic record should be documented in full, abbreviations are not acceptable. Any fluids administered must be prescribed on the IV chart. The anaesthetist should sign all relevant documentation.

Any medicines administered peri-operatively by the surgeon must be documented on the operation note. The surgeon should sign all relevant documentation.

There is a risk of duplication of some drugs. As well as documentation on the anaesthetic record or operation note, some drugs should be documented on the front of the prescription chart/ or peri-operative drug chart to prevent administration of further inappropriate doses post operatively.

These include:

- Analgesics (e.g. paracetamol, NSAIDs).
- IV or IM Antibiotics.
- Anti-emetics.
- Local anaesthetics.
- Any other medicines that may be appropriate.

The prescription and administration record must be completed fully. Any additions or changes to an infusion rate or dose must be documented in the patient clinical notes and on the drug prescription and administration record, as soon as practicable.

30. COMMUNITY MIDWIVES

30.1 General Principles

Midwives must observe, in addition to all current legislation, the rules set out in the current NMC Handbook of Midwives Rules, the current NMC Standards, and any local policies and procedures specified by the Local Supervising Authority or the Supervisor of Midwives.

Midwives may supply and administer certain specified medicines on their own initiative.

Midwives may not supply or administer any other medicines except in accordance with the written instructions of a prescriber or under a Patient Group Direction.

Midwives Exemptions

There are exemptions for registered midwives from these restrictions which allow them to supply a list of specific prescription only medicines on their own initiative in the course of their professional practice. In addition, midwives are allowed to administer certain parenteral medicines in the course of their professional practice. These include certain controlled drugs which are also exempt from certain of the Home Offices' Misuse of Drugs Regulations.

Further information

The NMC Circular 06/2010 Changes to Midwives Exemptions can be downloaded from www.nmc-uk.org.

30.2 Administration of Controlled Drugs in the community

If a midwife in the community administers pethidine that was obtained on a general practitioner's prescription, the administration must be recorded in the patient's midwifery records.

Details of the medication administered must always be entered in the patient's midwifery record. The date, the name of the drug, its batch number, the manufacturer, the dose administered, the time and route of administration, must be recorded.

30.3 Prescription Only Medicines and Other Medicines

Under the Medicines Act 1968, medicines classed as prescription only (POM) and pharmacy (P) medicines may only be sold or supplied through registered pharmacy premises by or under the supervision of a pharmacist. POMs are subject to the additional requirement that they may only be sold or supplied against an appropriate practitioners' prescription. An appropriate practitioner is a doctor, dentist and independent non-medical prescriber.

The law also restricts the administration of parenteral medicines. Unless self-administered, they may only be administered by an appropriate practitioner or by anyone acting in accordance with the directions of an appropriate practitioner.

30.3.1 Supply

Midwives working on hospital wards must use the drugs ordered by the ward or department from the pharmacy department, not their own supplies.

30.3.2 Administration

A midwife may only administer a medicinal product if she or he has thorough knowledge of its use and is familiar with the dosage and route of administration or application.

The administration of medicinal products by midwives in hospital must comply with the policy and procedures in this document for the administration of medicinal products by nurses.

A PGD may authorise a midwife to administer in hospital the medicines listed by the local midwifery supervising authority in a similar way to the midwife's practice in the community.

30.3.3 Surrender and Destruction

Medicinal products that are no longer required must be returned to the supplying pharmacy. A record of the return of medicines must be made in the midwife's requisition book and a pharmacy receipt obtained.

30.4 Carriage and Storage of Medicinal Products

Medicinal products, once received by midwives working in the community, become their responsibility and must be kept in a locked receptacle.

When kept in the midwife's house the drugs must be placed in a secure locked receptacle, preferably fixed, which can only be opened by the midwife.

Should it be necessary to leave medicinal products in vehicles, they must be placed in a locked container in the locked boot of a car so that the container is hidden from view.

The community midwife must possess an authenticated identification card authorising her to carry drugs. The card must bear the name of the midwife and her date of authorisation.

30.5 Inhalation Gases

A midwife may only administer an inhalational analgesic gas on her own responsibility if:

- The apparatus is for the time being approved by the Council on a recommendation of the Board as suitable for use by a midwife,
or
- Exemption has been expressly given by the Council, on the recommendation of the Board, to enable a particular hospital to investigate a new method of administration,
and

- The midwife has ensured that the apparatus has been properly maintained.

To avoid separation of the gases, Entonox cylinders must be kept at a temperature above 10°C and stored horizontally for a period of twenty-four hours before use.

If this is not practicable Entonox cylinders must be maintained at a temperature above 10°C for at least two hours then completely inverted, or placed in warm water at a body temperature for five minutes and then completely inverted three times.

31. THE MEDICINES RELATED DUTIES PERFORMED BY UNREGISTERED HEALTH CARE WORKERS

There may be occasions where medicine related activities need to be delegated to unregistered health professionals. This may include providing a second check for the administration of controlled drugs. In all instances where it is identified that delegation needs to take place this must be brought to the attention of the Chief Pharmacist, via senior nursing staff in the first instance. If it is deemed that delegation is appropriate this must only take place following appropriate training, assessment of competence and by following a written protocol or Standard Operating Procedure.

The registered nurse delegating the task should be satisfied that the individual has an appropriate level of education and training and has been assessed as competent. Where this is not the case the registered nurse may refuse to delegate, even when requested to do so by another health professional. The registered nurse is accountable for her own actions. This includes delegation.

32. TRUST FORMULARY

The formulary contains a list of drugs approved for use locally as well as links to both local and national prescribing guidance. Although traditionally a Trust formulary, it is moving towards being a joint formulary with primary care. It can be accessed from clinical handbooks on CPD, via Staff Room.

Prescribers are expected to adhere to the guidance, which has been approved by the Trust's Drugs and Therapeutics Committee. Where the prescribing of a drug is referred out to the GP for initiation or ongoing supply, the Trust's Drug and Therapeutics Committee must ensure that the drug is formally commissioned by the individual CCGs. In some instances there may be differences in the commissioning position of a drug by different CCGs. Some drugs are commissioned by NHS England and cannot be referred out to primary care for prescribing.

When patients are admitted on non- formulary drugs these may be continued in hospital, if appropriate and if supplies are available. As the formulary develops to become a joint primary/secondary prescribing guide it becomes less likely however that patients will be admitted on non formulary drugs.

Where urgent new therapies for an individual patient are required these can be approved for use by the chair of the Trust's Drug and Therapeutics Committee or deputy. High cost drugs excluded from Tariff may require an individual funding request to be submitted to either the patient's CCG or NHS England for approval. Advice can be obtained from the Pharmacy Formulary Team.

Medicines undergoing clinical trials must follow a separate approval process and the Trust Research and Development Team can be contacted for advice.

Consultant medical staff may submit requests for new products to be made available in accordance with the Trust's New Products Procedure for medicines. Forms for such requests are available from Pharmacy Medicines Information.

33. TRUST ANTIBIOTIC FORMULARY

The Trust Antimicrobial Stewardship Team Antimicrobial Prescribing Pathway should be followed. This states that antimicrobials should only be started when there is clinical evidence of bacterial infection. Appropriate samples must be taken before antimicrobials are started (unless immediate empirical treatment is indicated). The choice of antimicrobials and the details of samples taken must be documented in the medical notes. There is current formulary guidance on prescribing and choice of antimicrobial available to all staff in various formats including a poster on each ward. Prescribers are expected to adhere to the guidance, which has been approved by the Trust's Drugs and Therapeutics Committee. Antimicrobials are to be prescribed only if clinically indicated according to the patient's clinical signs/symptoms of infection and/or sepsis and should be reviewed after 48 hours with a view to stopping, changing (based on culture and sensitivity results), switching to oral or continuing treatment. Any antimicrobial review must be documented in the medical notes. Restricted antimicrobials (as listed in the formulary) should only be prescribed with Consultant Microbiologist approval or in line with specific guidance. Patients with complex infections or a history of multiple recent antibiotic therapy must be discussed with a microbiologist.

Unless there are no alternative suitable agents, intravenous therapy should only be used for those patients who are severely ill, unable to tolerate oral treatment, or where oral therapy would not provide adequate coverage or tissue penetration.

Clinical indication, course length or review date, route and dose should be clearly documented in the patient's medical records and on the prescription chart. When antimicrobials are indicated for severe sepsis, treatment should be commenced within one hour of diagnosis.

34. COMPLIANCE AIDS

Non-compliance with medicines is multifactorial and is a major cause of relapse and admission to hospital. Compliance aids may be a means of improving compliance for patients with complex and problematic medication regimens that cannot be simplified.

They can also help patients who have problems remembering when they last took a dose. However they are not suitable for everyone.

Before a new compliance aid is supplied by the Trust, the ward pharmacist or pharmacy technician must ensure that the appropriateness of the device for the patient has been assessed and that an assessment form has been completed. During the assessment, the following points are considered:

- Is the patient medically stable?
- Why is the compliance aid required?
- Is the patient able to physically use the compliance aid?
- Does the patient have the cognitive skills necessary to use a compliance aid?
- What arrangements will be made for refilling the compliance aid after discharge?
- Are the prescribed drugs suitable for the compliance aid?
- What options are available for patients who would benefit from a type of compliance aid that is not available from the pharmacy department?

Most compliance aids require them to be replenished on a weekly basis. Arrangements must be made for their regular re supply e.g. by contacting an appropriate community pharmacy and the GP.

The act of filling a compliance aid involves re-dispensing. Only authorised pharmacy staff are allowed to re-dispense medicines, however, other practitioners may assist patients or carers to fill their own compliance aids or train patients how to use a compliance aid as part of a self-administration scheme, where appropriate.

Filling a compliance aid is a time consuming process and generally, 24 hours notice is required by the pharmacy department prior to the patient being discharged.

35. CONSENT TO TREATMENT

It is a legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation or providing personal care for a patient.

Wherever possible the medicines proposed to treat a patient should be discussed with the patient. The discussion should be carried out in such a way that the patient understands the treatment that is proposed and is able to express agreement or disagreement.

For consent to be valid, it must be given voluntarily by an appropriately informed person (the patient or, where relevant, someone with parental responsibility for a patient under the age of 16) who has the capacity to consent to the intervention in question. Acquiescence where the person does not know what the intervention entails, its risks, benefits and alternatives, is not "consent".

Where the patient is unable to give informed consent, comprehensive guidance, including guidance on consent of patients under 16 years of age and the implications of the Mental Capacity Act 2005, is given on the Department of Health website and the Trust's Consent to Examination or Treatment Policy.

Guidance about consent in relation to use of unlicensed medicines is given in Section 25.

Information given by pharmacists or other practitioners about the treatment should be provided in addition to that given by the prescriber rather than as an alternative.

35.1 Treatment of Those without Capacity to Consent

When a patient is incapable of consent to treatment, medicines may be prescribed for them in their best interests under the Mental Capacity Act 2005. The treatment must be:

- Necessary to save life, or prevent a deterioration of, or ensure an improvement in, the patient's physical or mental health
and
- In accordance with the practice accepted at the time by a reasonable body of medical opinion skilled in the particular form of treatment in question.

35.2 Treatment of Those Detained Under the Mental Health Act 1983

The Mental Health Act 1983 provides the prescriber with a 3 month period to develop a treatment programme to meet the patient's needs. Even though the Act allows treatment without consent the prescriber should observe the same principles of seeking consent described above. The 3 month period starts on the occasion when medicines for mental disorder were first prescribed.

A system must be in place to remind the Responsible Medical Officer (RMO) at least 4 weeks before the expiry of the 3 month period. The RMO should:

- Seek the patient's consent to continuing medication.
- Record the discussion in the medical notes including an assessment of the patient's ability to consent.
- If the patient consents to continued treatment a Form 38 must be completed.
- If the patient refuses consent or is deemed unable to provide a reliable consent the RMO must request a second opinion doctor (SOAD) visit from the Mental Health Act Commission.
- If the SOAD agrees with the RMO that treatment is necessary and should be given the SOAD will complete a Form 39.

Practitioners must not administer medicines to patients detained under the Mental Health Act 1983 after the 3 month period without first ensuring that a valid Form 38 or Form 39 has indicated that the treatment can be given.

36. PATIENT INFORMATION LEAFLETS

36.1 Leaflets produced by pharmaceutical companies

Patients have a right, established under European law, to receive a copy of an official patient information leaflet where one exists.

Outpatients, self-medicating patients and patients discharged from hospital will receive such leaflets as part of a 'patient pack' supply of medication. Pharmacy staff will supply other locally approved leaflets where appropriate.

If patients require an information leaflet about other medication they are receiving, e.g. as an in-patient or treatment received in an outpatient clinic these can be obtained from www.beta.medicines.org.uk/emc.

36.2 Leaflets produced by Trust staff

Information leaflets relating to medicines produced by Trust staff represent a risk to patients and staff if they are not carefully checked with respect to information included and information omitted.

Trust staff, including medical and nursing staff, must only issue patients leaflets that have been reviewed by the Patient Information Officer, Risk and Legal Services and approved for use by an appropriate Committee (eg the Trust's Drugs and Therapeutics Committee or Medicines Policy Group). All leaflets should be sent to Pharmacy Medicines Information who will then forward to the appropriate committee for approval.

All information must be produced in accordance with the standards set by the Risk Management Standards for Acute Trusts (RMSAT) under the National Health Service Litigation Authority (NHSLA).

37. GUIDELINES ON CONTACTS WITH REPRESENTATIVES OF THE PHARMACEUTICAL INDUSTRY

Relationships between the pharmaceutical industry and Trust's staff should be on a sound and professional footing. The industry, as represented by the ABPI, publishes its own Code of Practice which companies and representatives visiting the Trusts are bound by. The Code can be found in full at www.pmcpa.org.uk/the-code/pages/default.aspx.

For reasons of security, representatives must wear an identification badge on Trust premises.

Medical representatives are not allowed to enter clinical areas without a definite appointment with a consultant, directorate manager or professional head of a department. Requests for appointments should normally be made in the first instance by telephone. Medical representatives may not wander in hospitals looking for staff.

New medicines (i.e., those not currently approved for use in the Trust) will only be purchased following compliance with local procedures. The decision to purchase a new medicine is made only on the advice of the Drug and Therapeutics Committee. Medicine samples have no place in such decisions and will not be accepted in pharmacy. Medicine samples may not be left elsewhere on Trust premises. See section 5.

Medical representatives must respect their position as a guest on Trust premises and recognise that the Trust's interests and priorities may be different to their own.

Breaches of the Code must be reported to the Chief Pharmacist.

See the Company Representatives Policy.

38. LOADING DOSES

A loading dose is an initial large dose of medicine used to ensure a quick therapeutic response which is given for a short period before therapy continues with a lower maintenance dose. The use of loading doses can be complex and error prone and incorrect use of loading doses may lead to severe harm.

Medicines which involve loading doses have been risk assessed and the following have been identified as high risk:

- Aminophylline.
- Amiodarone.
- Digoxin.
- Unfractionated heparin.
- Phenytoin.
- Warfarin.

Medical, Pharmacy and Nursing staff should check that the dose is appropriate when prescribing, dispensing and administering any of the above medicines. Further information may be found in the BNF or on the Trust intranet.

A loading dose should be identified as such. Single loading doses should be prescribed on the front of the prescription chart. Longer loading doses, such as amiodarone, should clearly state which are loading doses in the additional instructions box. Warfarin and unfractionated heparin should be prescribed on a dedicated prescription chart.

The treatment plan for loading and subsequent maintenance dose should be clearly stated in the medical notes.

The nursing records should record when a loading dose has been prescribed and administered.

When a patient is discharged the discharge prescription should be clear as to the doses already given, the current dose and if any further dose adjustment will be necessary to ensure the GP has sufficient information to prescribe ongoing doses of medication.

If a patient is transferred to another hospital there should be sufficient information in the medical and nursing notes to show what loading doses have been prescribed and administered. A copy of the prescription chart must accompany the patient.

39. HIGH RISK MEDICINES

Certain medicines are considered high risk and require care in prescribing and/or additional monitoring. These include:

- Any medicine which has been the subject of an NPSA alert.
- Medicines with a narrow therapeutic index.
- Medicines requiring ongoing monitoring.

Medicines considered to be high risk have additional information to support their safe and effective prescribing, dispensing, administration and monitoring. These are available on the Trust intranet and as Trust approved prescribing stationery (see Appendix 1). Practitioners should be familiar with the high risk medicines used in their area of practice and be aware of the following guidance on the Trust intranet:

- Alcohol Misuse Policy and Procedure (York site only)
- Acute Pain Handbook
- Anticipatory Medicines in Palliative Care
- Antimicrobial Treatment Poster (Adults)
- Antimicrobial Prescribing Policy
- Antimicrobial Surgical Prophylaxis Poster (Adults)
- British National Formulary (eBNF)
- Chemotherapy Policy
- Critical Medicines Spreadsheet
- Conscious Sedation Policy
- Drug Misuse Policy and Procedure (York site only)
- Net Formulary
- IV monographs (a complete file is also available on each ward)
- Management of hyperglycaemia in a hospitalised patient with diabetes
- Management of hypoglycaemia in a hospitalised patient with diabetes
- Medicines Matters Issue 50 – Methotrexate Immediate Changes to Practice
- Medicines Matters Safety Bulletins
- Medicines Reconciliation Policy
- Oral Syringe Policy
- Palliative Care Analgesic Dose Spider Conversion Chart
- Palliative Care Formulary
- Potassium Policy
- Safer Use of Injectable Medicines Policy
- VTE (Venous Thromboembolism) Quick Reference Guide

Appendix 1

Prescribing stationery at York Teaching Hospital NHS Foundation Trust

A large number of prescription charts are in use throughout the organisation. These have been developed in response to national medicines management standards, organisational need, NPSA alerts and trends detected through medication error monitoring. All Trust stationery is approved through the Medicines Policy Group and, where appropriate, the Drugs and Therapeutics Committee. A full list is held by the chair of Medicines Policy Group and can be obtained by contacting Medicines Information at York.

General acute prescription charts are listed here:

- A & E Prescription
- Controlled Drug Discharge Prescription
- Chemocare Prescription
- Cytotoxic Drug Therapy Chart
- Electronic Discharge Notification Prescriptions
- Enteral Feeding Chart
- Gentamicin Prescription Chart
- Inpatient Prescription Chart
- Inpatient Anticoagulation with Dalteparin (Fragmin)
- Inpatient Anticoagulation with Unfractionated Heparin
- Inpatient Anticoagulation with Warfarin
- Insulin Prescription Chart
- Insulin Sliding Scale Prescription Chart
- Intravenous Fluid Chart
- Outpatient Prescription Form
- Outpatient Treatment Advice Notes
- Paediatric Prescription Chart
- Preliminary Discharge Letter
- Syringe Drivers Prescription Chart
- TPN Administration Chart

Appendix 2

Training Needs Analysis for Medicines Management

	Pharmacists	Pharmacy technicians	Pharmacy Support Workers	Medical and Non Medical Prescribers	Registered nursing staff	Unregistered nursing staff	ODP's	Porters	Other staff Handling Medicines e.g. radiology staff / dieticians
Principles of Pharmacy Practice And / Or medicines management	On the job training; competency based assessments during structured internship (national scheme)	On the job training; competency based assessments (QCF & BTEC Level 3 Pharmacy Services)	On the job training; competency based assessments (QCF & BTEC Level 2 Pharmacy Services)	Relevant modules of undergraduate programme; on the job training	On the job training; statutory mandatory training	Statutory mandatory training	Relevant modules of undergraduate programme; on the job training	N/A	Relevant modules of undergraduate programme; on the job training
Trust Medicines Policy (Medicines Code) especially safe and secure handling of medicines, and Medicines Management standards, and drugs Allergy policy	Self directed learning from Medicines Code; plus pharmacy induction programme	Self directed learning from Medicines Code; plus pharmacy induction programme	Self directed learning from Medicines Code, plus pharmacy induction programme	Self directed learning from Medicines Code, plus medical induction programme	Self directed learning from Medicines Code, statutory mandatory training	Self directed learning from Medicines Code, statutory mandatory training	Self directed learning from Medicines Code, statutory mandatory training	Self directed learning from Medicines Code,	Self directed learning from Medicines Code
Local procedures in Pharmacy (Tailored to relevant area) including software applications	Pharmacy Induction Programme	Pharmacy induction programme	Pharmacy induction programme	N/A	N/A	N/A	N/A	N/A	N/A
Specialist roles – Pharmacy checker, aseptics dispenser, medicines manager, aseptics releaser, clinical trials dispenser	On the job training; competency assessment to national or Regional standard	On the job training; competency assessment to national or Regional standard	On the job training; competency assessment to national or Regional standard	N/A	N/A	N/A	N/A	N/A	On the job training; competency assessment to national or Regional standard
Inpatient self medication	On the job training	Competency assessment to regional medicines manager standard	N/A	Self directed learning from Medicines Code, plus medical induction programme	Preceptorship booklet and on the job training	On the job training	N/A	N/A	N/A

	Pharmacists	Pharmacy technicians	Pharmacy Support Workers	Medical and Non Medical Prescribers	Registered nursing staff	Unregistered nursing staff	ODP's	Porters	Other staff Handling Medicines e.g. radiology staff / dieticians
Medical gas prescribing, handling, administration	On the job training	On the job training	N/A	On the job training; competency based assessments (simulated prescribing) & mentorship	On the job training	On the job training	On the job training	On the job training	N/A
Clinical Pharmacy Standards, clinical interventions, prescription validation	Pharmacy induction programme	Pharmacy induction programme	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Prescribing Standards, including dose calculations	If an accredited prescriber, see relevant box to the right	N/A	N/A	On the job training; competency based assessments (simulated prescribing) & mentorship	If an accredited prescriber, see relevant box to the left	N/A	N/A	N/A	N/A
Safe and Secure Handling of Controlled Drugs	On the job training	on the job training	on the job training	on the job training	Preceptorship booklet, plus on the job training, training swatches	N/A	on the job training	on the job training	N/A
Safe administration of IV medicines	N/A	N/A	N/A	Medical staff: Competency based assessments and mentorship	Attend formal training and half-day update every 3 years with Clinical Development Team	N/A	N/A	N/A	Radiography: on the job training every three years
Pumps, syringe drivers, Infusion devices	N/A	N/A	N/A	On the job training	On the job training - once only	N/A	On the job training – once only	N/A	N/A
Safe administration of injectable Chemotherapy	N/A	N/A	N/A	On the job training, and mentorship	In house training using undergrad module to Yorkshire cancer network competencies;	N/A	N/A	N/A	N/A
Chemocare software for chemotherapy management	On the job training	On the job training	N/A	On the job training	On the job training	N/A	N/A	N/A	N/A

	Pharmacists	Pharmacy technicians	Pharmacy Support Workers	Medical and Non Medical Prescribers	Registered nursing staff	Unregistered nursing staff	ODP's	Porters	Other staff Handling Medicines e.g. radiology staff / dieticians
Oral chemotherapy administration	On the job training	On the job training	N/A	On the job training	On the job training	N/A	N/A	N/A	N/A
Radio pharmacy management including software	E learning; On the job training	N/A	N/A	On the job training	N/A	N/A	N/A	N/A	E learning; on the job training
Intrathecal chemotherapy policy, including negative training	On the job training	On the job training	On the job training	Medical staff induction, and on the job training	On the job training	N/A	On the job training	On the job training	N/A
Anticoagulation management; DMARDS management, including software	E learning, mentorship	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Formulary awareness	Pharmacy Induction training	Pharmacy Induction training	Pharmacy Induction training	Medical induction training	N/A	N/A	N/A	N/A	N/A
Safe and Secure handling / transport of medicines including COSHH, ionising radiation, cytotoxic spillage as appropriate	On the job training	On the job training	On the job training	On the job training	On the job training, and self directed learning from the preceptorship booklet	On the job training	On the job training	On the job training	On the job training
Changes in clinical practice in the use of medicines	Clinical meetings; Audit & Governance meetings; Medicines Matters	Clinical meetings; Audit & Governance meetings; Medicines Matters	N/A	Clinical meetings; Audit & Governance meetings; Medicines Matters	Clinical meetings; Audit & Governance meetings; Medicines Matters	N/A	Clinical meetings; Audit & Governance meetings; Medicines Matters	N/A	Clinical meetings; Audit & Governance meetings; Medicines Matters
Error, incident, defective product reporting and response (including product withdrawal)	Corporate induction training, plus on the job training	Corporate induction training, plus on the job training	Corporate Induction training	Corporate Induction training	Corporate Induction training	Corporate Induction training	Corporate Induction training	Corporate Induction training	Corporate Induction training

	Pharmacists	Pharmacy technicians	Pharmacy Support Workers	Medical and Non Medical Prescribers	Registered nursing staff	Unregistered nursing staff	ODP's	Porters	Other staff Handling Medicines e.g. radiology staff / dieticians
Emergencies, contingencies, major incident plan	Corporate induction training, plus on the job training and simulations, particularly for on call participants	Corporate induction training, plus on the job training and simulations	Corporate induction training, plus on the job training and simulations	Corporate induction training, medical induction training	Corporate induction training,	Corporate induction training	Corporate induction training	Corporate induction training	Corporate induction training, plus on the job training (Radiological protection)

Appendix 3

Process for Monitoring Compliance and Effectiveness

Audit/ Monitoring Criteria	Audit / Monitoring questions	Audit / Monitoring performed by	Audit / Monitoring frequency	Audit / Monitoring reports distributed to	Action plans approved and monitored by
Pharmacist Intervention Monitoring (including prescribing and administration) (RMSAT min. requirement)	This audit is a prospective collection of data by pharmacists during their clinical work on wards particularly where there is an intervention in prescribing or administration and /or advice to a prescriber or nurse in relation to the specific use of a medicine by a patient.	Pharmacy	Annually	Chief Pharmacist MSG / MPG	Chief Pharmacist MSG / MPG
Adherence to Prescribing standards (RMSAT min. requirement)	This is designed to audit compliance with Trust prescribing standards by a medical or non medical prescriber in order to check prescribing responsibilities are being adhered to.	FY1/FY2 with senior pharmacists Or Clinical governance pharmacy technician	Every 2 years	Chief Pharmacist MSG / MPG	Chief Pharmacist MSG / MPG
Adherence to authorised prescriber status (RMSAT min. requirement)	This audit is a spot check of prescribing to ensure the prescriber is an authorised prescriber in the relevant situation and is a bone fide employee of the Trust.	Pharmacy	Every 2 years	Chief Pharmacist MSG / MPG	Chief Pharmacist MSG / MPG
Safe and Secure Handling of Medicines (RMSAT min. requirement)	This wide ranging audit is designed to assess compliance with the safe and secure handling arrangements as set out in the medicines policy. The audit covers responsibility arrangements / process control / transportation / security and storage / management of stock / product integrity / health and safety and COSHH / risk assessment and audit trails/patient self administration processes.	Internal Audit	Every 2 years	Chief Pharmacist MSG / MPG	Chief Pharmacist MSG / MPG
Patient self-administration (RMSAT requirement)	This audit is designed to ensure compliance with the self-administration for patient's guidelines. It includes auditing appropriate assessment of patients, appropriate recording and documentation on the pre-designed pro-forma and monitoring of patients who have been assessed.	Pharmacy	Every 2 years	Chief Pharmacist MSG / MPG	Chief Pharmacist MSG / MPG
Safe and Secure Handling of Controlled Drugs (RMSAT min. requirement)	This wide ranging audit is designed to assess compliance with the safe and secure handling of Controlled Drugs as set out in the Medicines Policy. The audit covers accountability / security and storage / transportation / policies and procedures / training / recording and receipt / TTOs and Patients' Own Controlled Drugs / safe disposal of controlled drugs.	Internal Audit	Every 2 years	Chief Pharmacist MSG / MPG	Chief Pharmacist (Accountable Officer) MSG / MPG
Adherence to Allergy Policy	This audit demonstrates compliance with the Allergy Policy	Pharmacy	Every 2 years	Chief Pharmacist MSG / MPG	Chief Pharmacist MSG / MPG

Audit/ Monitoring Criteria	Audit / Monitoring questions	Audit / Monitoring performed by	Audit / Monitoring frequency	Audit / Monitoring reports distributed to	Action plans approved and monitored by
Review and follow up of medication administration errors through Datix reports / incidents and complaints	This is an ongoing review and follow up of reported medication errors and incidents which cover prescribing and administration	MSG	Ongoing	Chief Pharmacist MSG	Chief Pharmacist MSG
Audit of missed dose administration (4s Audit)	This audit is designed to review the level of occurrence and reasons for missed doses	Pharmacy Nursing staff	Every 2 years Monthly	Chief Pharmacist MSG On signal	Chief Pharmacist MSG

MSG = Medication Safety Group

MPG = Medicines Policy Group

Appendix 4: Equality Impact Assessment Tool

To be completed when submitted to the appropriate committee for consideration and approval.

Name of Policy:	Medicines Code
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1.	What are the intended outcomes of this work?	
	<p>The Department of Health requires that NHS Trusts establish, document, maintain and monitor effective systems to ensure that medicines are prescribed, administered, stored and handled in a safe and secure manner. Such systems are a requirement of risk management and clinical governance. York Teaching Hospital NHS Foundation Trust is committed to this requirement. The purpose of this document is to help staff by describing the systems and procedures within the trust that support this aim.</p>	
2	Who will be affected? Staff, patients and service users	
3	What evidence have you considered?	
	<ul style="list-style-type: none"> • NMC Standards for medicines management 2010 • NMC The Code: Standards of Conduct, Performance and Ethics for nurses and midwives 2010 • Nurses, Midwives, and Health Visitors, Rules Approval Order – Rule 18a 1983 • The safe and secure handling of medicines: a team approach, March 2005 • Crown Report 1998 and 1999 • Patient Group Directions HSC2000/026 • Guidelines issued by the GMC • Guidelines issued by NICE • Guidance issued by NHS England • A Spoonful of Sugar 2001, Medicines Management in NHS Hospitals Audit Commission • The Responsible Pharmacist Regulations 2008 • Safer Management of Controlled Drugs – a guide to good practice in secondary care 	

	<ul style="list-style-type: none"> • Building a safer NHS for patients – improving medication safety 2004 • Controls Assurance – Medicines Management, March 2000 • Clinical Governance and Risk Management • Control of Substances Hazardous to Health (COSHH) Regulations 1989 • Continuing Professional Development • The Care Quality Commission • NHS Litigation Authority • Risk Management Scheme for Acute Trusts 	
a	Disability No	
b	Sex No	
c	Race No	
d	Age No	
e	Gender Reassignment No	
f	Sexual Orientation No	
g	Religion or Belief No	
h	Pregnancy and Maternity. No	
i	Carers No	
j	Other Identified Groups No	
4.	Engagement and Involvement	
a.	Was this work subject to consultation?	Yes
b.	How have you engaged stakeholders in constructing the policy	Individually and via MPG and D&T
c.	If so, how have you engaged stakeholders in constructing the policy	Individually and via MPG and D&T
d.	For each engagement activity, please state who was involved, how they were engaged and key outputs This Medicines Code has been produced following consultation with nurses, midwives, pharmacy staff and medical staff from York Teaching Hospitals NHS Foundation Trust, the Vale of York Clinical Commissioning Group, the Scarborough and Ryedale Clinical Commissioning Group, the Drugs and Therapeutics Committee and the	

	Medicines Policy Group.	
5.	Consultation Outcome	
a	Eliminate discrimination, harassment and victimisation	Yes
b	Advance Equality of Opportunity	Yes
c	Promote Good Relations Between Groups	Yes
d	What is the overall impact?	Positive
	Name of the Person who carried out this assessment: Natalie Bryars	
	Date Assessment Completed 3/1/14	
	Name of responsible Director David Pitkin	

If you have identified a potential discriminatory impact of this procedural document, please refer it to the Equality and Diversity Committee, together with any suggestions as to the action required to avoid/reduce this impact.

Appendix 5 Checklist for the Review and Approval

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1	Development and Management of Policies		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or procedures?	Yes	
2	Rationale		
	Are reasons for development of the document stated?	Yes	
3	Development Process		
	Is the method described in brief?	Yes	
	Are individuals involved in the development identified?	Yes	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	
	Has an operational, manpower and financial resource assessment been undertaken?	Yes	
4	Content		
	Is the document linked to a strategy?	Yes	

	Title of document being reviewed:	Yes/No/Unsure	Comments
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
5	Evidence Base		
	Is the type of evidence to support the document identified explicitly?	Yes	
	Are key references cited?	Yes	
	Are the references cited in full?	Yes	
	Are local/organisational supporting documents referenced?	Yes	
5a	Quality Assurance		
	Has the standard the policy been written to address the issues identified?	Yes	
	Has QA been completed and approved?	Yes	
6	Approval		
	Does the document identify which committee/group will approve it?	Yes	
	If appropriate, have the staff side committee (or equivalent) approved the document?	Yes	
7	Dissemination and Implementation		
	Is there an outline/plan to identify how this will be done?	Yes	

	Title of document being reviewed:	Yes/No/Unsure	Comments
	Does the plan include the necessary training/support to ensure compliance?	Yes	
8	Document Control		
	Does the document identify where it will be held?	Yes	
	Have archiving arrangements for superseded documents been addressed?	Yes	
9	Process for Monitoring Compliance		
	Are there measurable standards or KPIs to support monitoring compliance of the document?	Yes	
	Is there a plan to review or audit compliance with the document?	Yes	
10	Review Date		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so, is it acceptable?	Yes	
11	Overall Responsibility for the Document		
	Is it clear who will be responsible for coordinating the dissemination, implementation and review of the documentation?	Yes	

Individual Approval

If you are happy to approve this document, please sign and date it and forward to the chair of the committee/group where it will receive final approval.

Name		Date	
------	--	------	--

Signature			
Committee Approval			
<p>If the committee is happy to approve this document, please sign and date it and forward copies to the person with responsibility for disseminating and implementing the document and the person who is responsible for maintaining the organisation's database of approved documents.</p>			
Name		Date	
Signature			

Appendix 6 Plan for dissemination of policy

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

Title of document:	Medicines Code
Date finalised:	February 2014
Previous document in use?	Yes
Dissemination lead	Natalie Bryars
Which Strategy does it relate to?	RMSAT4.10,5.10, CQC Outcome 9
If yes, in what format and where?	
Proposed action to retrieve out of date copies of the document:	Compliance Unit will hold archive

Dissemination Grid

To be disseminated to:	1) All staff	2)
Method of dissemination	email	
who will do it?	Natalie Bryars	
and when?	February 2014	
Format (i.e. paper or electronic)	Electronic	

Dissemination Record

Date put on register / library	February 2014
Review date	February 2016
Disseminated to	All staff
Format (i.e. paper or electronic)	Electronic
Date Disseminated	February 2014
No. of Copies Sent	n/a
Contact Details / Comments	Natalie Bryars, ext 4136