Lincolnshire Community Health Services NHS Trust

Safe and Secure Handling of Medicines Policy

Reference No:	P_CIG_20
Version	4
Ratified by:	LCHS Trust Board
Date ratified:	10 September 2019
Name of originator / author:	Medicines Management Officer
Name of responsible committee / Individual	Safeguarding & Patient Safety Group
Date issued:	September 2019
Review date:	September 2021
Target audience:	All Clinicians and Service Leads
Distributed via	LCHS Website

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Version Control Sheet

Version	Section / Para / Appendix	Version / Description of Amendments	Date	Author / Amended by
1		Amalgamated policies – CIG04, PCIG12 and CCS50.	August 2016	Lorna Adlington
	13	Addition of guidance from NPSA alert re: open systems. New Section – procedure for prescribing / preparing and administering injectable medicines	September 2016	Lorna Adlington
1.1	12.4 Covert administration	Update in line with NICE guidance NG67 – defined processes for covert administration	May 2017	Lorna Adlington
1.2	Section 11.1	Storage and security of medicines	October 2017	Lorna Adlington
2	Scope Section 10. Prescription Stationery Appendix 3 Appendix 4 Appendix 5	Updated to include Nursing Associates. Updated to recognise new guidance from the Counter Fraud Authority New SOP – security of prescription stationery. SSHM SOP for Imms and Vaccs service SOP for opening and closing a new service	May 2018	Lorna Adlington

3	Section 10	Updated process regarding transfer and security of FP10 stationery	June 2018	
4	Throughout document	Wording of Non- Medical Prescriber removed and changed to Independent/ Supplementary Prescriber	June 2019	Helen Oliver
4	Throughout document	Wording of nurse removed and changed to registered healthcare professional	June 2019	Helen Oliver
4	Section 10	Delivery of secure stationary must be by secured and tracked document bag.	June 2019	Helen Oliver
4	Section 11	Information on ambient temperature used to store medicines including monitoring, recording and escalation	June 2019	Lorna Adlington
4	Section 11	Controlled drug cupboard keys should be kept separate	June 2019	Helen Oliver
4	Section 12	Addition of considering all aspects of patient consent	June 2019	Helen Oliver
4	Section 12	Addition of checking allergies or previous adverse drug	June 2019	Helen Oliver

4	Section 12	• Raising ambiguities or concerns with a prescriber • Calculations to be double checked where practicable possible with a second person • Information regarding minimising disruptions • opening date should be written on the bottle label		
4	Section 12	New section giving advice on remote prescribing	June 2019	Lorna Adlington
4	Section 12	New section giving information on transcribing	June 2019	Lorna Adlington
4	Section 13	• Use of safety blunt needles when drawing up from vials • Need for PPE	June 2019	Helen Oliver
4	Section 16	To reduce medicine errors prescribing, dispensing/ supply and administration should be performed by separate healthcare professionals. Healthcare records should be completed as soon as possible	June 2019	Helen Oliver
4	Section 17	Additional requirements for independent / supplementary prescriber to complete an annual audit of their prescribing practice and have specific prescribing objectives in their annual appraisal	June 2019	Helen Oliver

4	Section 18	Information regarding storing vaccines, thermometers and transport updated in line with LCHS G-IPC-34	June 2019	Helen Oliver
4	Section 21	References updated	June 2019	Helen Oliver

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Procedural Document Statement

Background Statement	The purpose of this guidance is to implement a co-ordinated and standardised approach to strategic, operational and clinical management of all processes involving medicines and their use. This policy offers 'best practice' advice and guidance to ensure that medicines are handled safely and securely.
Responsibilities	Compliance with the policy will be the responsibility of all staff and providers of services involving medicines. Managers and service leads are responsible for ensuring that Standard Operating Procedures are in place for all clinical situations involving handling of medicines.
Training	It is the responsibility of operational managers and service leads to ensure that appropriate mechanisms are in place to support the implementation of this policy, including appropriate training and maintenance of competency.
Dissemination	Organisational website, via operational managers and service leads, published through medicines management forums and non-medical prescribing forums.
Resource implication	This policy has been developed in line with Department of Health and wider National guidance to ensure the appropriate and safe management of medicines within all services within Lincolnshire. There are no identified additional resource implications
Consultation	

1. Introduction / Scope of the policy

1.1 This policy aims to offer practical advice and outline steps that must be taken to ensure medicines are handled safely and securely within all care environments and services and by directly employed staff.

1.2 The policy is underpinned by key legislation, for example, the Medicines Act, the Misuse of Drugs Act and associated regulations, the Health and Safety at Work Act, the Control of Substances Hazardous to Health Regulations and the regulations relating to the disposal of hazardous and other controlled wastes.

1.3 It is recognised that whilst individuals have a duty to ensure that medicines are handled safely and securely, the Organisation also has statutory responsibilities and a duty of care to staff and patients.

1.4 This policy provides outlines key responsibilities and expectations of all staff working within LCHS including nursing associates and bank and agency staff.

1.5 Senior managers will define the systems to ensure that:

- Standard Operating Procedures are validated for all service areas / health care settings;
- Staff involved in any aspect of medicines understand their responsibilities, are competent and have access to training if required;
- Suitable devices and clothing to protect the patient and staff from identified, avoidable hazards is provided;
- Facilities and equipment being utilised are provided and maintained to the required standards;
- Systems for routine audit, reviews of accidents, errors and patient complaints relating to the handling of medicines are in place.

1.6 However it must be recognised that compliance with this policy does not override any individual responsibility of healthcare workers to ensure that their practice:

- complies with current legislation;
- follows guidance issued by the Department of Health, professional bodies (e.g. Nursing and Midwifery Council, Royal Pharmaceutical Society (RPS), General Pharmaceutical Council (GPhC)) or other government departments such as the Home Office;

- Manages the risks to patients, relatives, carers and staff arising from the use of medicines;

1.7 It is therefore anticipated that as current primary care services develop and new services are established, this policy will support the safe use of medicines by detailing what must be done, but allowing local implementation depending on circumstances.

1.8 The policy considers the processes associated with the physical handling of medicines, including storing, supplying, transporting, prescribing, administering, recording and disposing safely of medicines, and applies to all care environments. Each area is outlined in generic terms and must be supported by service / health care setting specific Standard Operating Procedures (SOPs) which will detail the local operational implementation. Additionally this policy details the appropriate measures to ensure security and confidentiality of content of all prescription forms and prescription stationary.

1.9 It is the responsibility of operational managers and service leads to ensure that SOPs are in place which:-

- Describe processes so that the SOP is comprehensive and reproducible
- Describe each element precisely, comprehensibly and unambiguously and indicate who is authorised to perform it
- Specify the equipment, facilities and data associated with the process
- Include the acceptable form(s) in which instructions can be given.
- Specify the appropriate written and / or oral supporting information or instructions required in passing to the next stage

1.9 Ratification of service SOPs will be through the relevant assurance structures.

1.10 A list of all SOPs being used operationally must be approved and recorded with the relevant service by the Service Head / Operational Lead.

2. Terminology

2.1 The term ‘medicines’ is used throughout the document as a generic term that covers all products administered by mouth, applied to the body, or introduced into the body for the purpose of treating or preventing disease, diagnosing or monitoring illness, contraception or inducing anaesthesia.

2.2 The generic term ‘patients’ is used throughout to refer to people receiving medicines although individual services may refer to them for example as service users or clients.

2.3 Any paperwork such as requisition forms or prescription pads that can be used to obtain medicines is designated ‘Controlled Stationery’. Any unauthorised use may lead to the fraudulent acquisition of medicines.

3. Initiation of treatment / Prescribing

3.1 A patient’s treatment must be initiated through a formal process, which may be the production of a prescription or Patient Specific Direction (PSD) by an authorised prescriber or by an approved Patient Group Direction (PGD).

3.2 Any person issued with a blank prescription form / pad will be held accountable for its security. All prescription stationery should be kept secure

3.3 When writing a prescription the current guidelines for prescription writing, as documented in the British National Formulary (BNF), will be followed. Prescriptions are to be written legibly in ink or otherwise so as to be indelible, will be dated and will state the full name and address of the prescriber and provide an indication of the type of prescriber. Each prescription will be signed in ink by the prescriber.

3.4 It is mandatory that the NHS number be used as the national unique patient identifier (NPSA 2008). To ensure correct patient identification, the NHS number should always be used in conjunction with the other identifiers (usually first name, last name and date of birth) when identifying a patient.

3.5 It is a legal requirement to state the age of children under 12 if a prescription only medicine (POM) is being prescribed. It would be preferable to always state the age and date of birth of the patient.

3.6 The following are held to be good practice:-

- the unnecessary use of a decimal point should be avoided e.g. 3 mg and not 3.0 mg. Quantities less than 1 mg should be written in micrograms. Where decimals are unavoidable a zero must be written in front of the decimal point where there is no other figure e.g. 0.5 ml and not .5 ml;
- ‘micrograms’ and ‘nanograms’ shall always be written in full.
- Similarly ‘units’ should be written in full. Abbreviations such as ‘U’ and ‘IU’ should never be used;

- medicines should be prescribed by approved names unless the brand name is clinically significant;
- instructions shall be in English without abbreviations;
- due regard should be taken of any known hypersensitivity to medicines;
- dose and dose frequency should be stated; avoid vague dosage direction, i.e. as necessary, as before, as directed.

3.7 For computer-issued prescriptions the recommendations of the Joint GP Information Technology Committee should also be noted. Reference should be made to page 5 of the BNF (BNF 74).

3.8 Community Hospital prescribing will be on the authorised Community Hospital E-Prescription Charts and will be audited on a monthly basis using the chart checker tool; this process will be monitored by the Safeguarding and Patient Safety Committee.

3.9 If treatment is being initiated for administration or supply under a Patient Group Direction (PGD), then the requirements of that PGD must be adhered to as a legal document authorising medicines use under the Medicines Act (and amendments).

3.10 Independent non-medical prescribers must only prescribe within their scope of practice and competency and supplementary prescribers only under clinical management plans (individualised for each patient) and within their scope of practice. Further guidance is available in the Non-Medical Prescribing Policy.

3.11 Non-medical prescribers are prohibited from using Latin abbreviations on FP10 prescriptions. The use of Latin abbreviations by other prescribers is discouraged on FP10 prescriptions, directions should preferably be in English without abbreviation (BNF 70).

3.12 Prescribing for self, family or colleagues should only be done in emergency or exceptional circumstances.

3.13 Non-medical prescribers are advised not to issue private (non NHS) prescriptions due to the lack of a clear audit trail.

4. Who may prescribe?

4.1 Medical staff, licensed to practice with the General Medical Council, are responsible for the majority of prescribing of medicines for patients. They must comply with appropriate legislation, the Medicines Policy and professional guidance when prescribing.

4.2 Registered Healthcare Professionals who have successfully completed an appropriate nationally recognised prescribing course, who are registered with their professional body as a person qualified to prescribe, and are Trust approved non-medical prescribers, may prescribe according to their designation of supplementary or independent prescriber in accordance with the Trust Non-Medical Prescribing Policy.

4.3 Midwives (Prescription-Only Medicines (Human Use) Order 1977) may prescribe from a limited range of medicines.

4.4 The law contains 'exemptions' for certain professionals on the HPC register to administer, sell or supply from a list of specific medicines on their own initiative, when that would normally be restricted to independent prescribers. These groups include Paramedics, Podiatrists and Orthoptists.

5. Licensed / Unlicensed Medicines

5.1 Unlicensed medicines may be prescribed by medical prescribers; however responsibility for the use of these medicines rests with the prescriber, who remains professionally accountable for their judgement. The prescriber should inform the patient that the product does not have a marketing authorisation.

5.2 Registered healthcare professional and Pharmacist Independent Non-Medical Prescribers can prescribe unlicensed medicines for their patients, on the same basis as medical prescribers and dentists (DH 2010). The responsibility for the use of these medicines rests with the prescriber, who remains professionally accountable. Licensed products should be used for preference. The prescriber should agree the treatment choice with the patient and a clear rationale for choice of medicine should be documented.

5.3 Supplementary prescribers may prescribe an unlicensed medication as part of a clinical management plan however the following criteria must be followed:

- The doctor / dentist acting as the independent prescriber must have agreed the plan and must agree to take responsibility for prescribing the unlicensed medicine;
- Ensure an alternative, licensed medicine would not meet the patient's need;
- There is sufficient robust evidence to support use;
- The patient has agreed to the use of an unlicensed product;
- The medication chosen and the reason for doing so is clearly documented;

6. Specials

6.1 Special-order products (more commonly known as “specials”) are made-to-order unlicensed medicines designed to meet the needs of individual patients.

6.2 Specials are unlicensed and, like any unlicensed medicine, should ONLY be prescribed where a licensed alternative does not meet the clinical needs of the patient.

6.3 Prescribers are potentially liable for any adverse event or harm arising from the use of an unlicensed special and are professionally accountable for their judgement in prescribing an unlicensed product for their patient.

7. Dispensing

7.1 Dispensing services should be provided in a way that can be reasonably expected to support the safe, effective and appropriate supply and use of medicines.

7.2 Where dispensing takes place, this must be within an agreed medical or pharmaceutical contractual framework.

7.3 As a minimum standard, each service / healthcare setting must have Standard Operating Procedures (SOPs) in place as detailed in the relevant contractual arrangements.

7.4 Medicines must not be transferred from one container to another, except in a designated dispensary area.

8. Ordering and receipt of medicines

8.1 Nominated staff, with appropriate qualifications and competencies may order medicines from a number of sources including:

- a local community pharmacy;
- a pharmaceutical wholesaler;
- directly from the manufacturer;
- a hospital pharmacy;
- a dispensing doctor.

8.2 Orders for stock medicines should be made on an official requisition, signed and dated by the authorised person ordering the medicine.

8.3 Verbal requests should not be made for any medicines supply.

8.4 Order records should be retained for a period of 2 years for audit purposes by wholesaler.

8.5 On receipt of the medicines, the supply made should be checked against the requisition and any discrepancies investigated and documented. Depending on the outcome of the investigation, consideration should be given to reporting an untoward incident in accordance with local policy.

8.6 Products such as vaccines should have additional quality checks to ensure, for example, that the storage requirements through the 'cold chain' have been maintained. Reference should be made to the 'Green Book' through the following link
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/223753/Green_Book_Chapter_3_v3_0W.pdf

8.7 Other products such as controlled drugs will require confirmation of compliance with legal and / or local requirements. Reference should be made to the Organisations Controlled Drugs Policy.

8.8 If patients own drugs are being received for use, local procedures will document, where possible, the steps to be taken to ensure their integrity. As a minimum expectation the quality and accuracy of the labelling should be checked; it should be visibly intact and the packaging clean. The packaging should be clearly labelled with the patient's name, medicine name, strength of medicine, name and address of the supplier and the date of dispensing or the expiry date.

8.9 Samples of medicines (including dressings) must not be used to treat patients. Manufacturer's supply of identified wound management products may be used for evaluation stock for use in work associated with regional evaluations only. Reference should be made to the East Midlands Steering Group Standard Operating Procedure (SOP) for management of local evaluations (2010).

9. Transport and security

9.1 Medicines should not be transported unless it is absolutely necessary to do so and transfers should be initiated through a system in which all orders and dispatches are recorded.

9.2 If staff are authorised to transport medicines in the course of their duties, the competencies and equipment required to ensure that this occurs with minimum risk must be documented in the service SOP as dependent on local circumstances.

9.3 Medicines in transit, whether professionals' own stock or an individual supply, should not be left unattended even in a locked vehicle.

9.4 Cold chain control, within the limits appropriate to the individual product, should be maintained for items requiring refrigeration. (Specific vaccination information can be found in the 'Green Book' through the following link) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/223753/Green_Book_Chapter_3_v3_0W.pdf

9.5 Arrangements for the transport of controlled drugs must comply with the current legal requirements and as specified in the Controlled Drugs Policy. Reference should be made to the Trust Controlled Drugs Policy for specific issues in relation to the transportation of controlled drugs.

10. Secure Handling of Prescription stationary

10.1 Prescription Stationary

10.1.1 Reference should be made to 'Counter Fraud Authority, Management and control of prescription forms. A guide for prescribers and health organisations 2018'.

10.1.2 Outlined below are the appropriate measures to ensure security, and confidentiality of content, of prescription forms from printing by Xerox (UK) Ltd to LCHS, onwards to medical and non-medical prescribers (NMPs) and finally to NHS Business Services Authority, (NHSBSA).

10.1.3 The prescribing, dispensing and pricing of prescriptions in the community setting currently relies on paper. The move to electronic prescribing may in time lead to a paperless system.

10.1.4 The Councils of the British Medical Association (BMA) and the Royal Pharmaceutical Society (RPS) joint statement on the security and validity of prescriptions is quoted in the British National Formulary (BNF 70). The statement particularly highlights that prescription forms should not be left unattended at reception desks, should not be left in a car where they might be visible and should be kept in a locked drawer when not in use.

10.1.5 The Counter Fraud Authority highlight that prescription stationery has a financial value and is effectively a blank cheque that is open to misuse.

10.2. Terminology

10.2.1 The term ‘Prescription Stationery’ is used primarily to refer to many different versions of FP10. ‘Prescription Stationery’ also refers to associated forms such as FP57 (the receipt for NHS prescription charges), and any forms used to requisition medicines. The term ‘Prescription Stationery’ can be considered interchangeable with the term ‘Controlled Stationery’.

10.2.2 A ‘secure store/ safe’ with access limited to those responsible for prescription forms, with secured windows, security locked doors and door keys strictly controlled. The secure store should be intruder alarmed and linked to central alarm monitoring area.

10.3 Ordering, receipt and secure storage of prescription stationary

10.3.1 The Medicines Management team have the responsibility for ordering from the printers Xerox (UK) Ltd, taking delivery and secure storage of prescription stationery. (See Attached SOP – Appendix 3)

10.3.2 Designated staff will be available to receive the delivery of prescription forms.

10.3.3 The individual prescribers and services are responsible for contacting the medicines management team to notify that stationery is required and arrange for collection from Beech houses.

10.3.4 Prescription stationary must be kept secure in transit and not visible within the vehicle.

10.3.5 Upon delivery, prior to the delivery driver leaving, a full check should be made against the delivery note that the appropriate type of prescription form and the correct number of boxes have been received. Any discrepancies should be noted on the driver’s delivery note, queried with the supplier and documented in the organisation’s records. The delivery should only be signed for and accepted if the packaging is sealed and unbroken and appropriate assurance is received that the correct delivery has been received.

10.3.6 The serial numbers should be checked against the delivery note. The suppliers must be notified of any discrepancies immediately.

10.3.7 Prescription stationery should be treated as controlled stationery, should not be left unattended and kept within a locked cabinet within a locked room.

10.3.8 Clear records of prescription stationery ordered, received and distribution will be held on a central database held by the medicines management team.

10.3.9 Prescription stationery is designated a secure item and should be stored in a separate locked and secure vessel/container within the delivery vehicle which cannot be accessed when the vehicle is in transit. The courier driver should sign date and time receipt of prescription stationery identified by serial numbers. It is important to ensure that there is a record of the internal distribution of prescription pads.

10.3.10 The named prescriber or other nominated person should sign for the receipt of prescription forms and note the relevant serial numbers. Any discrepancy should be highlighted to the medicines management team.

10.3.11 Records of serial numbers received and issued should be retained for at least three years.

10.4 Distribution and onward delivery

10.4.1 A secure lockable container should be used to transport prescription forms from the central store to the prescriber. The container should be sealed during transit, to prevent access to the forms whilst in transit.

10.4.2 Items waiting to be collected will be stored securely in areas where there is no unsupervised access.

10.4.3 A clear record will outline the process of internal distribution of prescription stationery. – This will include serial numbers, where, when and to whom the prescriptions have been distributed. (See Appendix 3).

10.4.4 Each prescription pad will have a register of prescription numbers attached at the point of distribution. The use of each individual prescription should be identified and the stock record signed to ensure an accurate record of all stationery in use, supplied and destroyed.

10.5. Use of Prescription Forms

10.5.1 Prescription forms have a legal status, remain the property of the NHS and should be used appropriately.

10.5.2 Prescription forms have a number of functions including:

- legal entitlement to possession of a prescription only medicine
- transfer of confidential data from prescriber to dispenser

- claim/authorisation of payment for goods and services

10.5.3 Individual prescribers or services should ensure the security of prescription forms on receipt by:

- keeping storage of all prescription pads and individual batches of FP10SS (approx.50) to a minimal depending on service need
- record the number of the first remaining prescription form on the 'in use' pad at the end of each working day
- adding the date, name and signature to the order delivery form.
- retaining a copy of the order delivery form and returning the original to the MM team.

10.5.4 Any further transfer of prescription forms e.g. from secure store to individual prescriber should also be on the basis of signatures and recording of serial numbers. (See Appendix 3)

10.5.5 Patients should not be left unattended in any area where they could potentially access prescription forms (either blank or completed).

10.5.6 Where it is necessary for prescribers to carry prescription forms e.g. for home visits, the number carried should be kept to a minimum. Prescription forms should be carried in a locked case. Where it is necessary to leave prescription forms in a car they should be stored out-of-sight in the boot of a locked car.

10.5.7 At the end of the day / session prescription forms should be stored as securely as possible, as a minimum this should be in a locked drawer. The serial number of the top and bottom prescription form should be recorded for prescription pads in drawers or prescription forms in printer trays, and checked at the next session to ensure that no prescription forms are missing.

10.5.8 In multi- prescribing settings i.e. community hospitals and urgent care services prescription pads should be kept in a designated secure store / safe, used only for secure stationery. In line with guidance from NHS Counter Fraud Authority (March 2018) the following information should be kept to track secure stationery (Appendix 3)

- Date of delivery
- Name of the person accepting delivery
- What has been received (quantity and serial numbers)

- Where it is being stored
- When it was issued
- Who issued the prescription forms
- To whom they were issued
- The number of prescriptions issued
- Serial numbers of the prescriptions issued
- Details of the prescriber

10.5.9To ensure clarity regarding the identity of prescriber and the organisation for which they are working:

- GP Locums / agency staff should use the prescription forms of the service, and legibly add their own name, as well as signing the prescription.
- NMPs should only use a prescription pad which clearly shows their name, prescribing status and individual PIN / registration number.
- Prescribers using prescription forms that carry an organisation's name and prescribing code in place of an individual prescriber's name and code should legibly add their own name as well as signing the prescription.
- Prescribers working for more than one service must use the prescription stationery appropriate to that setting.

10.5.10 The FP10 register of individual prescriptions should be completed when each prescription is written / supplied or spoilt.

10.5.11 Blank prescriptions should never be pre-signed

10.5.12 Any completed prescriptions should be stored in a locked drawer / cupboard.

10.5.13 The secure storage of prescription stationery should be assured at all times – patients, temporary staff and visitors should never be allowed access to or left alone within areas where prescription stationery is stored.

10.5.14 A process of daily checking should be completed for all FP10 stationery. The register of prescriptions and the individual prescriptions should be checked and counted to ensure a clear trail is maintained of prescriptions used. This should be recorded in the daily checks register and signed by both the checker and the witness. Any discrepancies should be reported through Datix and escalated in line with local policy.

10.6 Home visits

10.6.1**.** In order to prevent loss or theft, when making home visits, prescribers within the community should ensure that prescription pads are carried in lockable transport container and kept out of site during home visits.

10.6.2 Before commencing visits the serial numbers of any prescription pads / forms that are being carried should be recorded. Only a small number of prescription forms (6 – 10) should be taken on home visits to minimise any potential loss.

10.6.3 All prescription forms must be stored out of sight during home visits. If they have to be left in a vehicle, they should be stored within the car boot and the car should be appropriately secured.

10.6.4 Prescriptions should never be left in a vehicle overnight.

10.6. 5 Appendix Two provides an Aide Memoire for prescribers regarding security of prescription stationary.

10.7 Physical storage

10.7.1 Access to a lockable room or area where prescription forms are kept should be restricted to authorised individuals. Access should be controlled and a record kept of who accesses and when.

10.7,2 In areas where there are multiply prescribers – for example out of hours / urgent care services – there should be a named person who is responsible for management of prescription stationery, ordering and storage and maintaining a record of all prescription stationery in use in that area.

10.7.3 All prescribers are responsible for prescription form stock issued to them and should ensure that it is securely locked away when not in use. Records of serial numbers issued and received should be maintained.

10.7.4 In those areas where FP10SS are in use the stationery should be secure at all times. It is best practice that FP10SS are removed from printers when they are not in use. A local process around lockable printers / safety devices is outlined in Appendix Three.

10.8. Destruction

10.8.1 Personalised forms which are no longer in use should be securely destroyed (e.g. by shredding) before being put into confidential waste, with appropriate

records kept. The person who destroys the forms should make a record of the serial number of the forms destroyed.

10.8.2 When a prescriber leaves the service or organisation, any unused prescription forms printed with that prescribers name should be shredded before being put into the confidential waste. The first and last serial number of the prescription pad should be recorded, register of individual prescriptions completed and all prescriptions shredded by the individual prescriber and witnessed by line manager or appropriate senior member of staff. A record of these shredded prescriptions should be shared with the Medicines Management team, via Beech House.

10.8.3 For those staff remaining as ‘bank (temporary) staff’ prescription pads should be securely stored by the line manager until required.

10.8.4 Records of prescription forms destroyed should be kept for at least 18 months.

10.8.5 NMPs, who leave the organisation, are new to the organisation or who move clinical areas should refer to the guidance outlined in the Trust ‘Non-Medical Prescribing Policy.

10.9. Audit

10.9.1 The prescription form’s journey from printer (Xerox (UK) Ltd) to LCHS Services, prescriber and ultimately to the patient should provide an auditable trail. This auditable trail should also enable unused, duplicate or wrongly issued prescriptions to be tracked and recovered.

10.9.2 It is the services responsibility to inform the Non-Medical Prescribing Lead of new prescribers joining and / or leaving a service.

10.9.3 The Medicines Management team maintain an up-to-date record of its prescribers and their associated prescribing code numbers. This record should be regularly audited for accuracy.

10.9.4 It is the responsibility of the Non-Medical Prescribing Lead to maintain an up to date database of all non-medical prescribers, their work address and prescribing qualification.

10.9.5 It is the responsibility of the individual prescriber to ensure any changes to registration details are reported to the Medicines Management Team to allow for updating of the databases.

10.9.6 The NHS BSA prescription service will be advised by the MM team or any prescriber changes

10.10. Prescription Fraud

10.10.1 Prescriptions for medicines are at risk of being stolen / forged or otherwise fraudulently obtained or amended. All staff should be alert to this possibility. All services involved must have systems in place to ensure that prescriptions are obtained only by the patient designated on the prescription form, or an appropriate deputy.

10.10.2 Pharmacists have particular responsibility for verifying prescriptions for authenticity. Unusual expensive items, large quantities or doses, evidence of alteration (that are not signed and dated by the prescriber) should always be queried with the prescriber. The level of suspicion should be raised for medicines liable to abuse or where the prescriber is not local / not known. Verifying the prescription includes checking prescriber details including registration and phone number. Specimen signatures of the non-medical prescribers can be obtained from the Non-Medical Prescribing Lead.

10.10.3 If a Pharmacist has concerns regarding a prescription which cannot be allayed by contact with the prescriber, the concern should be reported in the first instance to the Medicines Management Team, prior to the Local Counter-Fraud Specialists (LCFS) and / or the NHS Fraud and Corruption Reporting Line. If it is warranted, for example, if there has been an attempt to fraudulently obtain a Controlled Drug (CD), the police should be contacted immediately. Any action taken should not compromise staff safety.

10.11. Lost or Stolen Prescription Forms

10.11.1 See section 11.8 below.

10.11.2 NMPs should refer to guidance outlined in the ‘Non-Medical Prescribing Policy’.

10.11.3 Where prescription forms are lost (whether or not theft is suspected), this must be reported immediately to the appropriate manager of the premises / Service Manager or line manager, Medicines Management Officer and to the Trust CDAO.

10.11.4 The appropriate manager should immediately inform the local counter fraud specialist (Tel No: 01522 308972) and NHS England, Lincolns Contracting Team via email - england.primarycarelincoln@nhs.net This generic email is monitored daily.

10.11.5 The NHS England Contracting Team at Lincoln are responsible for:

- requesting the practitioner signs prescriptions in a designated alternative colour (usually red)

- alerting the NHSBSA Pharmaceutical Fraud Team
- informing the CD Accountable Officer,
- informing the Medicines Management Officer.
- informing Clinical Risk Management
- notifying the CD Liaison Officer at Lincoln Police Headquarters
- alerting local pharmacies

10.11.6 The NHS England Contracting Team at Lincoln maintain contact with their opposite numbers in bordering Trusts to ensure cross-border intelligence is shared regarding lost prescription forms and suspected drug users (see 9 below), and to ensure that relevant information reaches all appropriate individuals and organisations.

10.11.7 The incident will be reported to CD LIN by CDAO or designate.

10.11.8 The incident should be reported to the NHS Counter Fraud Authority – reporting line 08000284060 or online https://cfa.nhs.uk/reportfraud

10.11.9 A Datix should be completed. Any report of loss of prescription forms should as a minimum include: date and time of loss / date and time of reporting loss / place where loss occurred / type and quantity of prescription stationery / serial numbers / details of to whom the incident has been reported.

10.11.10 Should the lost prescription have been reported by a patient a risk assessment should be undertaken to ensure that the loss is genuine before a replacement prescription is issued. The process for reporting a lost prescription should be followed as above and escalated as appropriate.

10.11.11 It is good practice to undertake a post incident review including consideration of the security measures in place following any incident involving prescription stationery.

10.12. Suspected Drug User Alerts

10.12.1 Where an individual is suspected of attempting to fraudulently obtain prescriptions or medicines this should be reported to the Medicines Management Team. A process similar to that for lost or stolen prescription forms will then be instigated.

10.12.2The NHS England Contracting Team at Lincoln are responsible for alerts regarding persons trying to fraudulently obtain prescriptions or medicines. Mechanisms should be in place to alert all prescribers and NMPs in the defined appropriate geographical area.

10.13. Investigation

10.13.1 Where an IR1 / Datix is submitted, this is subject to investigation in line with organisational policy and procedures.

10.13.2 The Medicines Management Team should be alerted to loss of any prescription forms.

10.13.4 Depending on the nature of the incident it may be decided that the investigation would be more appropriately carried out by the local service. This should incur an initial fact finding investigation. Prior to such an investigation, consideration should be given to any potential hampering of a possible police investigation.

11. Storage of medicines

11.1 Storage and security of medicines

11.1.1 Every service will store medicines at a level of security appropriate to their proposed use and at a level appropriate to the staff present at any time.

11.1.2 At any time there will be a nominated person responsible for the safekeeping of all medicines stored in the health care setting.

11.1.3 All medicines, with the exception of medicines for emergency use and wound care products, must be stored in lockable cupboards, which comply with the current British Standards for Medicines Storage (BS 2881), at a temperature not exceeding 25^{o}C. For controlled drugs the Misuse of Drugs (Safe Custody) regulations apply as detailed in the Controlled Drugs policy. Refrigerated medicines should be stored as outlined in section 16.2.

11.1.4 All medicines must be storage according to manufacturers' recommendations. Failure to do so can invalidate the expiry date and cause manufacturers to disclaim responsibility for any apparent failure of the medicine as the safety and efficacy of such medicines can be significantly compromised or unknown. This can cause avoidable waste, often at considerable expense.

11.1.5 Refrigerated medicines must be stored at 2-8oC. Most non-refrigerated medicines must be stored at less than 25°C. However, some medicines can be stored at up to 30°C. Sensitivity to changes in temperature varies depending on the medicine.

11.1.6 Medicines that are for internal use (e.g. oral, injectables) and medicines for external use (medicated dressings, topicals) should be stored separately from each other in different medicines cupboards or different parts of the cupboard.

11.1.7 Storage requirements for controlled drugs are detailed in the Controlled Drugs Policy and must be adhered to.

11.1.8 Access to the cupboards should be restricted to authorised staff only. Staff in any supervisory position should be aware of signs that may indicate abuse or diversion of medicines (e.g. changes in an individual's behaviour, regular unexplained absences from the work area, loss of stock or excessive ordering) and take appropriate action as locally defined.

11.1.9 The location of medicines cupboards should be based on the following recommendations:

- in a room without direct access (i.e. door or window) to the exterior of the building;
- where it is not obvious to 'prying eyes' (e.g. not in front of a window);
- adjacent to storage units of similar appearance;
- in a room that can be secured when unattended;
- away from sources of heat and humidity (e.g. radiators and sinks).

Any additional security advice can be obtained from the Local Security Management Specialist (LSMS).

11.1.10 Drug cupboards & trolleys may not be left unlocked and unattended at any time. When not in use the drug trolley should be immobilised by securing to a wall.

11.1.11 If medicines are stored in readiness for domiciliary visiting, there must be clear procedures for access to these, and for their replacement if used during the visit.

11.1.12 Adequate provision must be made to facilitate access to medicines in an emergency. The local storage arrangements will by necessity be a balance between quick access and the risks associated with misappropriation.

11.1.13 Once an emergency drug kit has been used it should be checked and missing items replaced as soon as possible. There must be a system of checks in place for emergency kits that are assembled and stored ready for use, to ensure that they are complete and any medicine included is correct and within its expiry date.

11.1.14 Regular expiry dates checks should be carried out for all medicines. Stock must be rotated according to the expiry date so that the oldest stock is used first.

11.1.15 All medicines must be stored in their original containers. They should not be transferred from one container to another.

11.1.16 Injection ampoules and vials must be stored in the outer packaging in which they are supplied. It is good practice only to remove ampoules from their outer packaging at the time they are required and to avoid returning ampoules to boxes.

11.1.17 If medicines are stored in readiness for domiciliary visiting, there must be clear procedures for access to these, and for their replacement if used during the visit.

11.1.18 Community staff have responsibility to advise patients and their carers on the safe and secure storage of medicines in the home.

11.1.19 All incidents involving a breach of security that cause actual or potential loss or theft of medicines should be investigated and the appropriate corrective and preventative action taken in accordance. This may involve contacting the police.

11.1.20 Medicines Cupboards / Rooms with keypad entry access:

- Keypad codes must only be provided to staff who have authorised access to the cupboards.
- It is the team leaders responsibility to ensure codes are changed 3 monthly to maintain security. A record of change should be logged.

Medicines management team will collect audit data on compliance with this requirement.

11.2 Ambient Room temperature monitoring

11.2.1 The ambient temperature of any room used to store medicines outside of a refrigerator must be monitored and recorded at least once daily using a thermometer with a digital display and max/min reading. This should be documented on the temperature recording sheet.

11.2.2 It is best practice to record ambient temperature at the hottest time of the day for each site e.g. early afternoon. This time may vary according to site characteristics.

11.2.2 Where the ambient clinic room temperature is at risk of exceeding 25°C, action should be taken locally to reduce this by e.g. removing any heat sources, implementing a Trust approved fan or moving medicines to alternative secure storage sites or switching on available ventilation or air conditioning units.

11.2.4 If the above measures are insufficient to maintain the temperatures below 25°C a digital data logger will give additional evidence, aid tracking and probable causes of spikes in temperatures, especially when the area is not in use (e.g. weekends). Advice should be sought from the Estates and facilities department and medicines management team to ensure medicine integrity is maintained. Each circumstance will be assessed individually and actions taken will depend on the medicines involved. This may include expiry date reduction based on national Quality Assurance principles. Factors included are the duration and extent of exposure to temperatures above the manufacturers' recommended storage temperature. As most medicines must be stored below 25oC, the expiry date reduction can be expected to be 2 weeks for every 1 week stored at up to 30oC (4 weeks if up to 35oC) .

11.2.5 A Datix should be completed to provide a clear audit trail of the incident.

11.2.6 Medicine cupboards should have an internal electronic data logger to provide central continuous monitoring of room temperature. This will provide an electronic record of temperature measurement over a 24 hour period which can be used to highlight times of peaks and sustained raised temperature. To reduce the risk of impact to stock ensure limited stock and adequate, clear stock rotation especially during the warmer summer months.

11.3 Patients own medicines

11.3.1 Where patients own medicines are used in their treatment they should be checked for quality and accuracy of the labelling prior to use.

11.3.2 Reference should be made to the local standard operating procedures (SOP) for administration guidelines and audit processes.

11.4 Storage of refrigerated medicines

11.4.1 Reference should be made to section 18.2 of this document ‘Storage of vaccines and other refrigerated medicines’.

11.5 Storage of emergency medicines

11.5.1 Adequate provision must be made to facilitate access to medicines in an emergency.

11.5.2 The local storage arrangements will by necessity be a balance between quick access and the risks associated with misappropriation.

11.6 Custody and safe keeping of keys

11.6.1 At all times a designated member of staff will have responsibility for custody of keys to medicines cupboards/controlled stationery.

11.6.2 Keys will be kept securely in key cupboards with restricted access to authorised staff.

Controlled drug cupboard keys should be kept separate to other medicine keys

11.7 Loss of controlled stationery, keys or medicine

11.7.1 On discovering a loss, the member of staff must immediately inform the designated manager. The member of staff should complete a relevant incident report form (IR1).

11.7.2 The designated manager will immediately investigate any loss (including consideration of notifying the police) and follow the organisational incident reporting procedure.

11.7.3 The LSMS should be immediately notified of any incident reported to the police. Information to be provided to the LSMS should include the nature of the incident, police incident reference number and police officer in charge of case, collar number and name.

11.8 Loss of keys

11.8.1 If necessary a duplicate set of keys may be issued, to allow continued provision of clinical services, until such time as the original keys are located.

11.8.2 If duplicate keys are not available or if the lost keys are not found, the authorised person in charge in conjunction with their manager should arrange for new locks to be fitted and for the cupboard to be effectively secured. Maintenance staff should not be allowed to work on the cupboard unsupervised.

11.9 Loss of Prescription Pad

11.9.1 In the event of loss or suspected theft of a prescription pad the prescriber must report this loss or theft immediately it has been confirmed to the Trusts Local Security Management Specialist (Tel No: 01623 622515 or the main office number 01623 622515 ext 3792). In matters relating to incidents of suspected fraud, these should be reported to the organisations counter fraud specialists.

11.9.2 The incident should also be reported in line with the above policy to ensure the appropriate information cascade is initiated and that prescribers are informed of any further action required.

11.9.3 The NHS England Contracting Team will be responsible for notifying local Pharmacists and deciding upon action to minimise the abuse of prescriptions. This will include instructions to the prescriber to sign all scripts in a particular colour (usually Red) for a period of two months. The NHS England Contracting Team will also inform the Compliance Unit at the Business Services Agency. This whole process will normally be in writing and within a 24 hour period (excepting weekends).

11.9.4 An incident report form should be completed as soon as possible and in all cases the LSMS should be notified of the incident immediately.

11.9.5 For non-medical prescribers further information on this process can be found in the Non-Medical Prescribing Policy.

12. Administration

12.1 Process of administration

12.1.1 This process for administration covers all care environments.

12.1.2 No person should administer any medicine unless they are competent to do so and are acting within their sphere of professional practice. The Standard Operating Procedure (SOP) should define the qualifications and competencies required by service staff, including the provision for nurse associates and training student professionals

12.1.3 A health care professional must not administer medicines without the authorisation of a prescriber, a patient specific direction (PSD) or a dispensed medicine, or a patient group direction (PGD), unless they have legal exemptions during the course of their professional practice (e.g. midwives, podiatrists). Pre-registration practitioners must only administer or supply medicines under direct supervision (NMC 2008).

12.1.4 The identity of each medicine should be clear at all times up to and including the point of administration.

12.1.5 Medicines dispensed for an individual patient must only administer to that patient (supplies labelled for individual patients must not be shared).

12.1.6 When selecting the medicine, the following should be checked and any concerns clarified before proceeding:

- name of the medicine;
- strength;
- form;
- expiry date.

12.1.7 Medication must be prepared for administration at the time it is due to be given. Medication for multiple patients must not be prepared in advance.

12.1.8 Before administration, the following should be checked and any concerns raised with the prescriber before proceeding:

- patient's name;
- NHS number
- age and weight if appropriate;
- any allergies / hypersensitivities;
- date and time the dose is due;
- name of medicine, dose and frequency;
- time of previous dose if any;
- route of administration;
- signature of prescriber or requirements of a patient group direction.

Any calculations needed are double checked where practicable by a second person and uncertainties raised with the prescriber or pharmacy professional.

All aspects of patient consent should be considered

Allergies or previous adverse drug reactions must be checked.

12.1.9 A record of each medicine administered to a patient should be made and the administering person identified.

12.1.10 All omitted, refused or wasted doses should be documented and where appropriate recorded on the administration record using the appropriate code as indicated on the prescription chart.

12.1.11 Any dose prepared for administration and subsequently not given should destroyed. If a controlled drug is prepared and not used it must be destroyed by denaturing and placing in a sharps bin and a record must be made in the register in accordance with the Organisations Controlled Drug Policy.

12.1.12 Medicines shall not be returned to the container from which they were taken.

12.1.13 Omissions and refusals should be reported to the prescriber if it is considered that the non-administration may affect the patient's condition.

12.1.14 When two or more prescription charts are in use, it is essential that they are cross-referenced so that practitioners are aware of *all* prescribed medicines.

12.1.15 For further information regarding the administration of injectable medicines further reference should be made to Section 13 within this document.

12.1.16 Medicines reconciliation is a process designed to ensure that all medication a patient is currently taking is correctly documented on admission to a community hospital and at each transfer of care. An audit of medical records will provide evidence that:

- The collection of the medication history from an appropriate source has been checked (usually by a minimum of two) and has been accurately documented.
- Checks on admission to the ward that all medications prescribed are correct and signed for. The 'checking' step must involve assurance that the medicines and doses prescribed accurately reflect the sources consulted. Any discrepancies must be identified and documented.

- Written communication of any changes in medicines must be readily available to the next person (s) caring for the patient.

12.2 Minimising interruptions during medication rounds within ward environments.

12.2.1 To ensure safe and effective administration of medication to patients within the ward environment ---

1. Check at the beginning of the drug round that medicines have not already been administered by someone else (including / patient / carers) (RPS 2019)
2. Check at end of each drug round that there have been no omissions

Interruptions may lead to errors in medicine omissions; to reduce theses errors occurring within the ward environment all staff, undertaking the medicines round, will be expected to wear a red tabard indicating that the medicines round is in progress and that they should not be interrupted unless as a matter of priority.

12.2.2 Tabards alone cannot be expected to reduce interruptions; they are one tool to support registered healthcare professionals having protected time to undertaken medicines administration.

12.2.2 If a telephone call is taken or an interruption occurs which requires the attention of the wearing the tabard, then the member of staff, if unable to deal with the query directly, registered healthcare professionals will be expected to take a message for a reply at a more convenient opportunity.

12.2.3 Contact details of the caller / enquiry, should be taken and an explanation offered that the registered healthcare professionals will contact them when the medicines round has been completed.

12.2.4 In the event of an emergency / immediate need for a response, the registered healthcare professionals undertaking the medicines round, before responding to the query, will ensure that the medication trolley is locked and stored away securely in the treatment room, ensure that the patients drug locker is locked and any medication that has been administered has been signed for.

12.2.5 If appropriate, a Datix / IR1 should be completed giving reasons for the interruption.

12.3 Minimizing interruptions during administration of medicines in the community setting

To ensure safe and effective administration of medication with the community all staff undertaking administration of medicines should try and minimise interruptions by:

- Explaining to patient/ relatives/ carers the need for quiet whilst calculations and preparation of medicines
- Considering preparation of medicines in a different room to patient

12.4 Self administration of medicines

12.4.1 Reference should be made to the Trust Policy for Self Administration of medicines and any SOPs should be adhered to.

12.4.2 The transfer of responsibility should occur on the basis of an assessment of the patient's ability to manage the tasks involved and with the agreement of the patient.

12.4.3 Safe and secure processes will be needed to ensure that the patient has controlled access to an adequate supply of the correct medicines which are appropriately stored and are fit for purpose.

12.5 Covert Administration of Medicines (Disguising Medicine in Food or Drink):

12.5.1 The covert administration of medicines is only likely to be necessary or appropriate in the case of a patient who actively refuses medication but who is not judged to have the capacity to understand the consequences of their refusal.

12.5.2 The decision to administer a medicine covertly should not be considered routine, and should be a contingency measure. Such a decision may only be made following discussion and agreement between the range of professionals involved in the patients care and with the patient's carers/advocate. Any such decision must be fully documented in the patients notes, detailing the names of all those involved in the decision and regularly reviewed. . More detailed guidance and signposting can be found within the RPS (2019) guidance.

12.5.3 As outlined by NICE CG 67, ensure the process for covert administration clearly defines who should be involved in, and responsible for, decision-making, including:

- assessing a person's mental capacity to make a specific decision about their medicines
- seeking advice from the prescriber about other options, for example, whether the medicine could be stopped
- holding a best interests meeting to agree whether giving medicines covertly is in the person's best interests
- recording any decisions and who was involved in decision-making
- agreeing where records of the decision are kept and who has access
- planning how medicines will be given covertly, for example, by seeking advice from a pharmacist
- providing authorisation and clear instructions for covert administration within the individual patient's care plan
- ensuring health care professionals are trained and assessed as competent to give the medicine covertly
- when the decision to give medicines covertly will be reviewed.

12.6 Measurement/administration of liquid medicines via oral or other enteral routes

12.6.1 An appropriate oral / enteral syringe should be used to measure oral liquid medicine if a medicine spoon or graduated measure cannot be used.

12.6.2 When measuring controlled drug solution (e.g. oxycodone) an appropriate oral syringe and bung must be used. Oramorph should also be measured using bung and syringe.

12.6.3 A 5ml spoon should only be used for doses of 5ml or multiples thereof.

12.6.4 Only use well labelled oral / enteral syringes that do not allow connection to intravenous catheters or ports (NPSA 2007 Patient safety alert 20. Promoting safer use of injectable medicines).

12.6.5 When patients / carers are required to administer oral liquid medicines with a syringe, they should always be supplied with oral or enteral syringes.

12.6.6 Enteral feeding systems should not contain ports that allow connection to intravenous syringes. Adaptors that enable oral / enteral syringes to fit luer ports should no longer be used.

12.6.7 Catheter tip syringes should not be used to measure and administer large volumes of medicines and feeds as these syringes are not sufficiently accurate to measure or administer small volumes of these medicines.

12.6.8 All oral / enteral syringes should be clearly labelled (in large font) to aid selection and use. If these labels are not provided by the manufacturer then the practitioner has a responsibility to label the devices with this information.

12.6.9 All oral / enteral syringes containing oral liquid medicines must be labelled with the name and strength of medicine, patient's name, and date and time it was prepared by the person who has prepared the syringe, unless preparation and administration is one uninterrupted process and is administered by the practitioner who has prepared it. Only one unlabelled syringe should be handled at any one time.

12.6.10 Three way taps and syringe tip adaptors should not be used in enteral systems as these devices introduce additional risk, including additional risks of infections and increased risk of error.

12.6.11 Administration via PEG or NG tube – this is unlicensed use and consideration should be given to the following:

1. Use of liquid preparations were possible
2. Consideration should be given to which preparations are suitable for crushing prior to administration.
3. Do not crush any medication which is coated or modified or sustained release preparation unless confirmed correct by the drug information.

12.6.12 Senior staff should supervise newly trained staff to ensure they have the necessary work competences to undertake their duties safely and effectively. Additional training may be required when changes are made to procedures or devices used.

12.6.13 Service managers should ensure that systems are in place for routine audit and incident review.

12.7 Remote prescribing / remote order

12.7.1 Remote order (verbal order) – Prescribing by an independent prescriber who authorises administration of a medicine to a patient without face to face assessment within the current episode of illness.

12.7.2 Every effort should be made to obtain a written or electronic prescription for a patient. However, in exceptional circumstances i.e. where the need for the medicine is urgent and not to accept a remote order would compromise patient safety or care, remote instruction to a registered professional may be accepted for example by email. For example - a change in dose, route or frequency, re-prescribing of a previously prescribed medication.

12.7.3 Where exceptional circumstances exist, the registered professional is required to inform the prescriber of the patient's current drug regimen, symptoms and any other relevant information e.g. allergy status. They should request information from the prescriber regarding any contraindications and side effects of the remotely prescribed medicine.

12.7.4 Trust staff must not request or accept a remote order for Schedule 2 and 3 Controlled Drugs.

12.7.5 A remote prescribing order by telephone is not acceptable on its own. The prescriber must provide confirmation of the order using an electronic prescribing system or e-mail before drug administration. This confirmation must be entered in the patient's electronic record where it is accessible to the prescriber and administering nurse or paper copy attached to the paper prescription chart. The confirmation must be read by the administering nurse before drug administration.

12.7.6 Only a registered healthcare professional may accept a remote prescribing order.

12.7.7 When the above change is made to a paper prescription chart the prescriber must provide a newly written and signed prescription to confirm the changes within 24 hours or, when this is a bank holiday or weekend, the next working day.

12.7.8 An entry should be made in the patient record regarding the time of, and reason for, the remote prescribing.

12.7.9 Remote prescribing of new medicines for a patient may only be accepted if the prescriber has adequate information on which to base their decision to prescribe, sufficient to:

- Establish the patient's current medical conditions and history and concurrent or recent use of other medications including non-prescription medicines;
- Carry out an adequate assessment of the patient's condition;
- Identify the likely cause of the patient's condition;
- Ensure that there is sufficient justification to prescribe the medicines/treatment proposed;
- Ensure that the treatment and/or medicine/s are not contra-indicated for the patient.
- Make appropriate arrangements to follow the progress of the patient;

- Monitor the effectiveness of the treatment and/or review the diagnosis;

Where all these conditions cannot be satisfied remote prescribing should not occur.

12.7.10 The prescriber is then required to carry out a full patient assessment in person before any medicines are prescribed.

12.7.11 Registered healthcare professionals can refuse to accept remote orders from prescribers if:

a) they do not feel competent to do so,

b) there are communication difficulties and the prescriber's intentions are not clear,

c) they feel the request is not in the patient's best interest, or

d) they feel the circumstances are not exceptional.

12.7.12 Instruction by telephone to administer a previously unprescribed medicine is not acceptable, except in a life threatening situation.

12.8 Transcribing

12.8.1 Transcribing is the exact copying of previously prescribed medicines and due to electronic health care records and remote prescribing, should only occur in exceptional circumstances

12.8.2 Transcribing can only be used in the best interests of the patient to ensure safe and continuous care ensuring the medication is administrated accurately, without undue delay (RPS 2019)

12.8.3 Transcribing cannot be used to issue or add new medication/ change the original prescription

12.8.4 Medicines cannot be transcribed where details are illegible, unclear, ambiguous or incomplete. Particular care is taken in transcribing details of high risk medications such as insulin and, anticoagulants (RPS 2019)

12.8.5 If transcribing is required staff must have completed the in-house training package and associated competences and standards. Reference should be made to the Trust Transcribing policy.

12.9 Transcribing by Pharmacy technicians

12.9.1 Pharmacy technicians may order supplies of medicines from contracted pharmacies by transcribing from the inpatient prescription chart or electronic prescription chart.

12.9.2 Transcribing can only take place if all prescriptions are clearly written and unambiguous.

12.9.3 Orders can be sent to the community pharmacy providing they have been clinically screened by a prescriber / pharmacist.

12.9.4 When ordering medicines the transcription should be an accurate match of what is written on the drug chart.

12.10 Administration – Verbal Orders

12.10.1 Instruction by telephone to administer a previously unprescribed medicine is not acceptable, except in a life threatening situation.

12.10.2 A verbal order may **not** be given or taken for a controlled drug under any circumstances.

12.10.3 In exceptional circumstances, where the medication has been prescribed previously (not including Controlled Drugs (CDs) and the prescriber is unable to issue a new prescription but where changes to the dose are clinically necessary, technology, such as fax or email, may be used to confirm changes to the original prescription. However the practitioner must be satisfied that the prescriber's absence is unavoidable and change is essential. A clear record should be made in the relevant Trust documentation.

12.10.4 Written confirmation of the dosage adjustment must be provided within 24 hours by the prescriber who authorised the change remotely.

12.10.5 In exceptional circumstances a medical practitioner may need to prescribe remotely for a previously unprescribed medicine – the receipt of a fax or email must confirm the prescription before it is administered. The confirmation of the prescription change must be signed by the prescriber who gave the remote order within 24 hours.

12.10.6 Independent/ Supplementary Prescriber may not prescribe remotely a medication which has been not been previously prescribed if he / she has not assessed the patient, except in life threatening situations (NMC 2007).

12.10.7 The use of written instructions (for example fax or email) is the preferred method of dealing with such emergency situations. If a fax is used ensure that it is a 'safe haven' fax.

13. Use of Injectable medicines

13.1 Prescribing of injectable medicines

13.1.1 Medicines should only be given by injection when the practicality and appropriateness of other routes of administration have been excluded. The use of this route should be regularly reviewed in favour of switching to oral administration as soon as clinically appropriate (NPSA 2007).

13.1.2 Prescriptions for injections must clearly specify the medicine name, dose, frequency and route of administration. Where relevant, the prescription, or a readily available local protocol, must specify the following: name and volume of dilutent and/or infusion fluid, concentration of final infusion, rate of administration, duration and rate control pump or device to be used.

13.1.3 The practitioner who prepares a medicine for injection must be the practitioner who gives the injection. The exception to this is where a registered healthcare professional student is being supervised by a qualified registered healthcare professional inn which circumstances the student may prepare the injection under the direct supervision of the qualified registered healthcare professional who will then administer the injection.

13.1.4 NPSA alert (2016) 'Restricted use of open systems for injectable medication' specifies that 'open systems', including gallipots or other types of open container such as procedure trays, should not be used as a container for an injectable medicine as this runs the risk of confusion. The only exception is embolization procedures.

13.2 Mixing of medicines

13.2.1 The Medicines and Healthcare products Regulatory Agency (2010) (MHRA) states the mixing of two or more separate medicinal products will result in a new, unlicensed product if one product cannot be described as a vehicle for administration of the other e.g. as a reconstitution or diluting agent.

13.2.2 Mixing two licensed medicines, for example in a syringe driver, results in a new, unlicensed product being administered.

13.2.3 Following consultation by the MHRA, medicines legislation was amended:

- To enable doctors and dentists to direct other healthcare practitioners to mix medicines;
- To allow registered healthcare professionals and Independent/ Supplementary Prescribers to mix medicines themselves and to direct others to mix;

- To enable Independent/ Supplementary/ Prescribers to mix medicines themselves and to direct others to mix, only where this is clearly outlined within an individualised patient Clinical Management Plan;

- To allow registered healthcare professionals includingPharmacist independent prescribers to prescribe unlicensed medicines for their patients;

13.2.4 Optometrist prescribers are not authorised to prescribe unlicensed medicines (MHRA 2007).

13.2.5 Mixing should be avoided where possible; it must only be undertaken when clinically appropriate and essential to meet the needs of the patient.

13.2.6 All healthcare practitioners who prescribe, mix and administer unlicensed medicines must be satisfied that they have sufficient information to administer the drug safely and wherever possible ensure there is acceptable published evidence for the use of that product for the intended indication.

13.2.7 All practitioners who are required to mix medicines should ensure that they are competent to do so and are acting within their sphere of professional practice. Local guidance should be in place to support all those practitioners' involved in the mixing of medicines.

13.2.8 The changes in legislation do not apply to Patient Group Directions (PGDs). Mixing of two licensed medicines, resulting in a new unlicensed product, cannot be supplied or administered under a PGD. Only licensed products can be supplied / administered against a PGD.

13.3 Supply and storage

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

13.3.2 Injectable cytotoxics and parenteral nutrition must be supplied to clinical areas only as ready-to-administer products.

13.3.3 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.

13.3.4 Multiple use of an unpreserved injectable medicine should be eliminated. Most injectable medicines are licensed for 'once-only' use. Unless the manufacturer's

label specifically indicates the injection contains a preservative, the container should only be used to prepare a single dose for a single patient on one occasion.

13.4 Preparation

13.4.1 Injections should be prepared only by healthcare staff who:

- understand the risks involved
- have been trained to use safe procedures
- have demonstrated their competence for the task.

13.4.2 Preparation should only take place if there is a prescription; a Patient Group Direction (PGD) or other written instruction, for example Patient Specific Direction (PSD). Essential information must be available about the product(s) and processes needed for safe preparation and administration.

13.4.3 Aseptic (non-touch) techniques should be used during preparation and administration. Injectable medicines prepared in clinical areas should always be administered immediately after preparation. They should not be stored for a period of time before use. Administration of infusions prepared in clinical areas should be completed within 24 hours of preparation. In exceptional circumstances where infusion from a single container is intended to continue for more than 24 hours, a risk assessment should be undertaken to determine the safest course of action. Every effort should be made to use a ready-to-administer product.

13.4.4 All syringes, including flushes and infusions, must be labeled immediately after preparation by the person who prepared them. ‘Flag labeling’ should be used to ensure that volume graduations on small syringes are not obscured. The only exception to this is in situations where preparation and bolus (push) administration is one uninterrupted process and the unlabelled product does not leave the hands of the person who prepared it.

13.4.5 Only one unlabeled medicine must be handled at one time.

13.4.6 Medical devices with luer connectors must be used only for preparation and administration of injections. Medicines for oral/enteral use must be prepared and administered using only devices with non-luer connections.

13.4.7 Risk assessment is required to identify those products representing the highest risk to patients at the time of preparation. Consideration must be given to the use of safer products and systems, for example, double-checking.

13.5 Procedure for prescribing, preparing and administering Injectable medicines

13.5.1 Practitioners must not prepare substances for injection in advance of their immediate use or administer medication drawn up into a syringe by another practitioner when not in their presence (NMC 2007).

13.5.2 Injections should be administered only by healthcare staff or patients/carers who understand the risks involved, have been trained to use safe procedures, and who have demonstrated their competence for the task.

13.5.3 No practitioner should administer any injectable medicine unless they have been assessed as competent to do so and are acting within their scope of professional practice. All practitioners are accountable for their practice including acts and omissions regardless of advice or direction received from another professional (NMC 2006).

13.5.4 Before administration, the following should be available: a current prescription, a Patient Group Direction (PGD) or other written instructions for example a patient specific direction (PSD), essential technical information and a prepared and labelled injectable medicine. The patient's identity and details should be confirmed.

13.5.5 Where ever possible two practitioners should check the medication to be administered intravenously, one of whom should also be the practitioner who then administers the IV medication (NMC 2007).

13.5.6 The person administering the medicine should personally make a record of administration as soon as possible after the event. This is extremely important in circumstances where the person administering the medicines may also be the prescriber.

13.5.7 Risk assessment should be carried out to identify those products representing the highest risk to patients at the time of administration. Consideration should be given to the use of safer products and systems of administration, for example, double-checking, and the use of ‘smart’ infusion pumps or similar rate control technologies.

13.5.8 Infusions must be monitored to ensure safe administration of prescribed treatment.

13.5.9 **Prescribing –** All prescriptions for injectable medicines must specify the following:

- patient's name;
- the date;
- prescriber's signature;
- the approved medicine name;
- the dose, route and frequency of administration;
- the allergy status of the patient.

13.5.10 Where relevant, the prescription, or the authority to administer, must specify the following:

- brand name and formulation of the medicine;
- concentration or total quantity of medicine in the final infusion container or syringe;
- name and volume of diluent and/or infusion fluid;
- rate and duration of administration;
- stability information to determine the expiry date of the final product;
- type of rate-control pump or device(s) to be used;
- the age and weight of any patient under 16 years of age, where relevant;
- date on which treatment should be reviewed;
- arrangements for fluid balance or clinical monitoring should be made on an individual patient basis and according to local protocol and clinical need.

13.5.11 Preparation

- Read all prescription details carefully and confirm that they relate to the patient to be treated.
- Ensure the area in which the medicine is to be prepared is clean, uncluttered and free from interruption and distraction.
    - Assemble all materials and equipment. Check the following:
    - expiry dates;
    - damage to containers, vials or packaging;
    - medicines were stored as recommended, e.g. in the refrigerator.
- Beware of the risk of confusion between similar looking medicine packs, names and strengths. Read all labels carefully.

- Check that the formulation, dose, diluent, infusion fluid and rate of administration correspond to the prescription and product information. Clarify method of preparation.
- Clarify the patient has no known allergy to the medicine.
- Calculate the volume of medicine solution needed to give the prescribed dose. Ensure an independent second check.
- Prepare hands as per policy.
- Prepare the injection by following the manufacturer's product information.

13.5.12 **Withdrawing from an ampoule**:

- Tap the ampoule gently to dislodge any medicine in the neck.
- Break open the neck of glass ampoules, use an ampoule snapper if required.
- Attach a safety blunt needle, or filter straw device, to a syringe and draw the required volume of solution into the syringe. Tilt the ampoule if necessary.
- Invert the syringe and tap lightly to aggregate the air bubbles. Expel the air carefully.
- Remove the needle, or filter straw device, from the syringe and fit a new needle or sterile blind hub.
- Label the syringe.
- Keep the ampoule and any unused medicine until administration to the patient is complete to enable further checking procedures to be undertaken.
- If the ampoule contains a suspension rather than solution, it should be gently swirled to mix the contents immediately before they are drawn into the syringe.

13.5.13 **Withdrawing a solution or suspension from a vial into a syringe**:

- Remove the tamper-evident seal from the vial and wipe the rubber septum with an alcohol wipe. Allow to dry for at least 30 seconds.
- With the safety blunt needle sheathed, draw into the syringe a volume of air equivalent to the required volume of solution to be drawn up.
- Remove the needle cover and insert the safety blunt needle into the vial through the rubber septum.
- Invert the vial. Keep needle in the solution and slowly depress the plunger to push air into the vial.
- Release the plunger so that solution flows back into the syringe.
- If a large volume of solution is to be withdrawn, use a push-pull technique.

- Inject small volumes of air and draw up an equal volume of solution until the required total is reached. This ‘equilibrium method’ helps to minimise the build-up of pressure in the vial.
- Alternatively, the rubber septum may be pierced with a second needle to let air into the vial as solution is withdrawn. The tip of the vent needle must be kept above the solution to prevent leakage.
- With the vial still attached, invert the syringe. With the needle and vial uppermost, tap the syringe lightly to aggregate the air bubbles at the needle end. Push the air back into the vial.
- Fill the syringe with the required volume of solution then draw in a small volume of air. Withdraw the needle from the vial.
- Expel excess air from the syringe. Remove the needle and exchange it for a new needle or a sterile blind hub.
- The vial(s) and any unused medicine should be kept until administration to the patient is complete.
- If the vial contains a suspension rather than solution, it should be gently swirled to mix the contents, immediately before they are drawn into the syringe.

13.5.14 Reconstituting powder in a vial and drawing the resulting solution or suspension into a syringe

- Remove the tamper-evident seal from the vial and wipe the rubber septum with an alcohol wipe. Allow to dry for at least 30 seconds.
- Withdraw the required volume of diluent (e.g. water for injections or sodium chloride 0.9%) from ampoule(s) into the syringe.
- Inject the diluent into the vial. Keeping the tip of the needle above the level of the solution in the vial, release the plunger. The syringe will fill with the air which has been displaced by the solution (if the contents of the vial were packed under a vacuum, solution will be drawn into the vial and no air will be displaced). If a large volume of diluent is to be added, use a push-pull technique.
- With the syringe and needle still in place, gently swirl the vial(s) to dissolve all the powder, unless otherwise indicated by the product information. This may take several minutes.
- Withdraw the required volume of solution from the vial into the syringe.

- Alternatively, the rubber septum may be pierced with a second needle to let air into the vial as solution is withdrawn. The tip of the vent needle must be kept above the solution to prevent leakage.
- If a purpose-designed reconstitution device is used, the manufacturer's instructions should be read carefully and followed closely.

13.5.15 **Adding a medicine to an infusion**

- Prepare the medicine in a syringe.
- Check the outer wrapper of the infusion container is undamaged.
- Remove the wrapper and check the infusion container. It should be intact and free of cracks, punctures/leaks.
- Check the infusion solution, which should be free of haziness, particles and discolouration.
- Where necessary, remove the tamper-evident seal on the additive port according to the manufacturer's instructions or wipe the rubber septum on the infusion container with an alcohol wipe and allow to dry for at least 30 seconds.
- If the volume of medicine solution to be added is more than 10% of the initial contents of the infusion container (more than 50ml to a 500ml or 100ml to a 1litre infusion), an equivalent volume must first be removed with a syringe and needle.
- Inject the medicine into the infusion container through the centre of the injection port, taking care to keep the tip of the needle away from the side of the infusion container. Withdraw the needle and invert the container at least five times to ensure thorough mixing before starting the infusion.
- Do not add anything to any infusion container other than a burette when it is hanging on the infusion stand since this makes adequate mixing impossible.
- Before adding a medicine to a hanging burette, administration must be stopped. After the addition has been made and before administration is re-started, the contents of the burette must be carefully swirled to ensure complete mixing of the contents.
- Check the appearance of the final infusion for absence of particles, cloudiness or discolouration.
- Label the infusion.

13.5.16 **Diluting a medicine in a syringe for use in a pump or syringe-driver**

- Prepare the medicine in a syringe.
- Draw the diluent into the syringe to be used for administration by the pump or syringe-driver. Draw in some air (slightly more than the volume of medicine needed) and remove the needle.
- Stand the diluent syringe upright. Insert the needle of the syringe containing the medicine into the tip of the diluent (administration) syringe and add the medicine to it.
- Alternatively, a disposable sterile connector may be used to connect two syringes together directly.
- Check the following:
    - the total volume of injection solution in the syringe is as specified in the prescription and that the infusion can be delivered at the prescribed rate by the administration device chosen;
    - the rate of administration is set correctly on the administration device and according to the manufacturer's instructions.
- Fit a blind hub to the administration syringe and invert several times to mix the contents.
- Remove the blind hub. Tap the syringe lightly to aggregate the air bubbles at the needle end. Expel the air and refit the blind hub.
- Carefully check the syringe for cracks and leaks and then label it especially noting the requirements specific to syringe drivers.
- Check that the rate of administration is set correctly on the device before fitting the syringe, priming the administration set and starting the infusion device.

13.5.17 **Labelling injection and infusion containers**

- All injections should be labelled immediately after preparation, except for syringes intended for immediate push (bolus) administration by the person who prepared them. Under no circumstances should an operator be in possession of more than one unlabeled syringe at any one time, nor must an unlabeled syringe be fitted to a syringe driver or similar device.

- Labels used on injectable medicines prepared in clinical areas should contain the following information:
    - name of the medicine;
    - strength;
    - route of administration;
    - diluent and final volume;
    - patient's name;
    - expiry date and time;
    - name of the practitioner preparing the medicine.
    - Place the final syringe or infusion and the empty ampoule(s)/vials(s) in a clean plastic tray with the prescription for taking to the patient for administration.

13.5.18 **Administration of an injectable medicine**

- Before administering any injection check all the following:
    - patient's name, hospital/NHS Number or date of birth or address;
    - prescriber's signature;
    - the approved medicine name;
    - the dose and frequency of administration;
    - the date and route of administration;
    - the allergy status of the patient.
- Also check, where relevant:
    - brand name and formulation of the medicine;
    - concentration or total quantity of medicine in the final infusion container or syringe;
    - name and volume of diluent and/or infusion fluid;
    - rate and duration of administration;
    - type of rate-control pump or device(s) to be used;
    - the age and weight of any patient under 16 years of age, where relevant;

- date on which treatment should be reviewed.

- Check that the medicine is due for administration at that time and has not already been given.
- Assemble everything you need including any flushing solution(s) needed.
- Explain and discuss the procedure with the patient.
- Check any infusion already in progress. It should be free of haziness, particles and discolouration.
- Check that an appropriate access device is in place. Flush it immediately before and after administration of a medicine, and between doses of different medicine administered consecutively, according to local policy. Also check the administration site for signs of leakage, infection or inflammation.

13.5.19 **Administration of injections**

- Check infusions. They should be should be free of haziness, particles and discolouration.
- Use aseptic (non-touch) technique at all times.
- Attach administration sets to infusion containers carefully, on a flat surface and using the technique appropriate to the type of container.
- Prime the access device according to local policy immediately before starting an infusion.
- Before adding a medicine to a hanging burette, administration must be stopped. After the addition has been made and before re-commencement, the contents of the burette must be carefully swirled to ensure complete mixing.

13.5.20 **After Administration**

- After completion of an intermittent infusion, flush the access device according to local policy.
- Infusion device or giving set should be disposed of according to local policy.
- Ask the patient to report promptly any soreness at the injection site or discomfort of any sort. Record VIP score as per local policy.
- Make a detailed record of administration.

- Discard the empty ampoules/vials from which the injection was prepared and any unused medicine. Ampoules or vials should never be used to prepare more than one injection unless specifically labelled by the manufacturer for ‘multi-dose’ use.
- Re-check 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 according to local policy.
- Check arrangements for monitoring fluid balance or clinical parameters have been made. Ensure that relevant documentation is made available for subsequent regular monitoring to take place.

13.6 Administration of Insulin

13.6.1 All regular and single insulin doses should be measured and administered using an appropriate insulin syringe or commercial insulin pen device. Intravenous syringes must never be used for insulin administration.

13.6.2 An insulin syringe must always be used to measure and prepare insulin for an intravenous infusion. Insulin infusions are to be administered in 50ml intravenous syringes or larger infusion bags. Where appropriate consideration should be given to the supply and use of ready to administer infusion products (for example prefilled syringe of fast acting insulin 50 units in 50ml sodium chloride 0.9%).

13.7 Training

13.7.1 All practitioners and healthcare staff who prescribe prepare and administer injectable medicines, including insulin, must have access to or receive training and have the appropriate work competencies to undertake their duties safely.

13.7.2 All individuals are responsible for maintaining their professional knowledge and working within the limits of their competence.

13.8 Injectable medicines audit

13.8.1 Service Managers should ensure that they have systems in place for routine audit and review of incidents.

14. Administration and / or supply of medicines under a PGD

14.1 Reference should be made to the Trust Policy for the development and control of PGDs.

14.2 The supply and administration of medicines under Patient Group Directions (PGDs) should only be reserved for those limited situations where this offers an advantage for patient care without compromising patient safety (HSC 2000/026).

14.3 When supplying or administering a medicine under a Patient Group Direction, the patient must fall exactly into the criteria determined by the PGD. If not the patient must be referred in line with the guidelines outlined within the individual PGD.

14.4 If a medicine is unlicensed it should only be administered against a patient specific prescription and not under a PGD.

14.5 Medication that is licensed but used outside of its licensed indications may be administered under a PGD if such use is exceptional, justified by best practice and the status of the product clearly described. In such circumstances the patient should be informed that it is an unlicensed use and of any alternative treatments that are licensed.

14.6 Service leads have responsibility for ensuring that only fully competent, qualified and trained professionals operate within the PGD.

14.7 The use of PGDs does not remove inherent professional obligations or accountability. It is the responsibility of each practitioner to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct

15. Return and Disposal of Unwanted Medicines

15.1 Guidance on the disposal of pharmaceutical waste is governed by the 'Environment and Sustainability Health Technical Memorandum 07 – 01: Safe Management of Healthcare Waste (2013). Reference should be made to this document.

15.2 Ensure that disposal of all medicines waste is in line with relevant legislation including the provision of a robust audit trail. A record of medicines waste should be maintained in all service areas.

15.3 Medicines that are no longer to be administered to a patient, for whatever reason, should be returned to the relevant community pharmacy or dispensing doctor for disposal.

15.4 Medicines that have been issued directly to a patient should not be reused.

15.5 The storage, carriage and consignment of waste are all subject to stringent controls via Environmental, Waste, Transport and Health and Safety legislation.

15.6 Trust premises wishing to dispose of waste medicines will need to arrange for them to be collected by a suitable waste contractor.

15.7 Waste medicines should, as far as possible, be disposed of in their original packaging. Further guidance can be found in the 'Safe Management of Healthcare waste' Pg 55 – 56 and pg 84.

15.8 The waste medicines should be deposited in a rigid medicines container; blue lidded for non – hazardous medicines and purple lidded for hazardous medicines / Cytotoxic and Cytostatic medicines.

15.9 The definition of cytotoxic and cytostatic used in waste classification is much broader than the term 'cytotoxic' as used in the BNF. The BNF should be used for waste classification. An example list of cytotoxic and cytostatic medicines is provided in chapter 11 of the 'Safe Management of healthcare waste' – but note this list is not conclusive

15.10 Protective equipment such as gloves will also need to be provided and used.

15.11 When the rigid container containing hazardous medicines is transferred to the Trusts waste contractor, a separate list of the medicines and their hazardous properties should accompany the waste as per the instructions in 'Safe management of healthcare waste'.

15.12 When disposing of solid non-hazardous pharmaceutical waste (e.g. tablets and capsules) blister packs can be removed from outer cartons, but individual tablets and capsules should not be removed from blisters.

15.13 Liquids should generally not be decanted and mixed. Where liquids are being discarded they should be retained within their individual containers and placed in leak proof waste bins provided for the purpose.

15.14 For all matters relating to the return and disposal of Controlled Drugs, reference should be made to the Trust Policy relating to the prescribing, supply, storage and disposal of controlled drugs. This information should also be detailed within local operating procedures relating to the management of controlled drugs.

16. Untoward incidents

16.1 Untoward incidents involving medicines

16.1.1 To reduce medicine errors prescribing, dispensing/ supply and administration should be performed by separate healthcare professionals. Exceptionally where clinical circumstances make it necessary and in the best interests of the patient

the same healthcare professional can be responsible for the prescribing and supply / administration of medicines. Where this occurs an audit trail, documents and processes are in place to limit errors (RPS 2019).

16.1.2 To prevent duplication of the administration of medicines healthcare records should be completed at the time of administration/ refusal or as soon as possible thereafter and are clear , legible, accessible and auditable (RPS 2019)

16.1.3 If there is any risk of harm to an individual due to an incident involving medicines; priority must be given to the clinical care of that person(s).

16.1.4 **Any** incident or near miss in which medicines are involved must be reported in accordance with the Organisations incident reporting policy.

16.1.5 The incident must immediately be reported to and investigated by the appropriate line manager, or person delegated to act on their behalf.

16.1.6 An incident form (IR1) must be completed and a copy forwarded to the Clinical Governance Manager and monitored by the Medicines Management Officer. If the incident is linked to security then the Local Security Management Specialist should also be informed.

16.1.7 Governance managers and the Medicines Management Officer will identify any trends or recommended actions to ensure that risks relating to medicines are minimised and reported to the relevant business unit.

16.1.8 Lessons learned from incident analysis will be monitored at the Drugs and Therapeutics Committee and reported to the Clinical Governance and Risk Committees. Lessons learned will be disseminated by Matrons to the respective workforce.

16.2 Administration errors

16.2.1 As soon as it is realised that there has been an error of medicine administration:-

- The appropriate prescriber should be contacted and when necessary, remedial action taken to ensure the safety of the patient. The patient and or carer should be informed of the error, remedial action and possible consequences;

- Supporting statements may be required from all staff concerned. These are essential if there is any possibility of serious injury to the patient or of litigation. This is in addition to the responsibilities outlined above. Refer to the Policy for the Management of Medication errors (2016).

16.3 Adverse reactions to drugs

16.3.1 If any patient experiences an adverse drug reaction (ADR), action must be taken to remedy any resulting harm caused by the reaction. The reaction must be recorded in the patient notes and the prescriber should be notified.

16.3.2 Any drug may produce unwanted or unexpected adverse reactions. Detection and reporting of these is of vital importance. Doctors, dentists, coroners, therapists, registered healthcare professionals including nurses and pharmacists, are urged to report suspected adverse reactions on yellow cards and to the Medicines and Healthcare products Regulatory Agency (MHRA). Patients and carers can also now report ADRs to the MHRA using the yellow card system http://www.mhra.gov.uk

16.3.3 Yellow cards can be found in the back of the British National Formulary (BNF) and online at the following link http://www.yellowcard.gov.uk.

16.3.4 All suspected adverse drug reactions to “black triangle” drugs and any serious or unusual suspected reactions to established products should be reported.

16.3.5 Reporting should be carried out for all prescribed drugs, medicines obtained over the counter and herbal medicines.

16.3.6 Any adverse reactions should also be reported in line with the Trust Incident reporting policy and procedure.

16.4 Defective medicines

16.4.1 During the manufacture or distribution of a medicine an error or accident may occur whereby the finished product does not conform to its specification. Any suspected defect in a medicine should be reported to the Prescribing and Medicines Management team or the Defective Medicines Report Centre at the MHRA.

16.4.2 Reports on suspected defective medicinal products should include the brand or the non-proprietary name, the name of the manufacturer or supplier, the strength and dosage form of the product, the product licence number, the batch number and the nature of the defect.

16.4.3 If the defective medicine has been administered to a patient the prescriber should be notified and reported in accordance with the Trust incident reporting policy.

17. Training

17.1 All healthcare professionals and other staff who deal with medicines must undertake regular training as identified through the local training matrix to ensure they have the appropriate competencies to carry out their role safely and in line with local SOPs and service specific requirements. See SOP for training in Medicines Management. All individuals are responsible for maintaining their professional knowledge and working within the limits of their competence. Individual training will be monitored at appraisal and training records held on ESR.

17.2 All individuals are responsible for keeping up to date and maintaining their own professional knowledge and working within the limits of their competence.

Independent / Supplementary prescribers have an additional requirement to complete an annual audit of their prescribing practice and have specific prescribing objectives in their annual appraisal (see Non – Medical Prescribing Policy).

18. Storage, distribution and disposal of vaccines.

18.1 Management of vaccines

18.1.1 This section should be read in conjunction with Chapter Three of the 'Green Book' (DH 2006) accessible via

https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3

and Public Health England's document 'Protocol for Ordering, Storing and Handling Vaccines (2014) accessible via https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines

These resources are updated periodically and all practitioners should ensure they keep themselves up to date with changes.

18.1.2 This section outlines a summary of guidance provided by the 'Green Book', on storage, transport and equipment necessary for maintenance of the cold chain as well as highlighting the need for monitoring and audit.

This section outlines a summary of guidance contained in LCHS 'Maintaining the Cold Chain: The control and monitoring of storage temperatures of medicinal products Cold Chain' policy G_IPC_34

18.1.3 To ensure that the trend of low levels of disease notification continues into the future, it is essential to maintain the efficacy of the vaccines used. This requires maintenance of the 'cold chain' to ensure that the optimum temperature range for vaccine storage (between +2°C and +8 °C) is maintained throughout the distribution process from manufacture to user. Fluctuations and breaks in the cold chain can result in a reduction of the efficacy of the vaccine and a potential failure to produce satisfactory levels of immunity.

18.1.4 Vaccines are biological substances that may lose their effectiveness quickly if at any time they become too hot or too cold. Vaccines are biodegradable over time and storage outside the recommended temperature range may cause a loss of potency which cannot be reversed.

18.1.5 It is essential that all those handling vaccines follow appropriate recommendation and policy to ensure cold chain compliance. Appropriate guidance and policy includes 'National Patient Safety Agency advice on Vaccine Cold Storage and the associated Rapid Response Report January 2010';Public Health England Protocol for ordering, storing and handling vaccines.

18.1.6 At least two named, trained people need to be responsible for ordering, receipt and care of vaccines including rotation and checking of expiry dates as well as safe storage of vaccines and recording of refrigerator temperatures (PH England 2014)

18.1.7 All procedures being followed for storage, distribution and disposal of vaccines should be monitored and regular audits undertaken to ensure they comply with expected standards.

18.1.8 Some vaccines are packaged in multiple quantities. Care should be taken to order correctly to avoid waste.

18.1.9 Vaccines for routine immunisation programmes must be ordered via the ImmForm website as set out in the 'Public Health England Protocol for Ordering, Storing and Handling Vaccines' published March 2014 accessed via

https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines

18.1.10 All other vaccines are ordered directly from the manufacturer or through pharmacies and wholesalers. Details of suppliers are shown in the associated chapters of the 'Green Book'.

18.2 Storage of vaccines and other refrigerated medicines

18.2.1 In general vaccines / medicines should be stored at temperatures between +2° - +8°C a mid range of +5°C is good practice.

18.2.2 Vaccines should be appropriately stored to protect from the light. Exposure to ultraviolet light is known to cause loss of potency.

The refrigerator must be located inside a locked room not directly accessible to the public.

- Vaccines must not be stored in the door, or next to the freezer plate.
- The fridge must not be overfilled - allow space around the packaging for air to circulate.
- The fridge must be regularly defrosted (if not self-defrosting).
- Records must be maintained with regard to defrosting (if not self defrosting), servicing, calibration, and maximum/minimum /actual temperatures.

18.2.3 All vaccines are sensitive to extremes of heat and cold. Heat will speed up the decline in potency of most vaccines and will therefore reduce shelf life whilst freezing causes deterioration and can give rise to increased adverse reactions due to alteration of the composition of the vaccine or contamination as a result of cracks appearing in the vial or syringe.

18.2.4 Avoid over ordering, stockpiling and overfilling refrigerators. It is important that air must be able to circulate around the packages.

18.2.5 All vaccines are Prescription Only Medicines (POMs) and must be stored under locked conditions. Refrigerators must be lockable or within a room that can be kept locked when not occupied by a staff member. Vaccines should never be left unattended.

18.2.6 Vaccines should be kept in their original packaging to retain batch numbers and expiry dates. The package also helps to protect against changes in light and temperature.

18.2.7 Domestic refrigerators must not be used. All service areas should have a validated vaccine fridge.

18.2.8 Refrigerators for the storage of vaccines should not be situated near a radiator or heat source as this may affect their efficiency.

18.2.9 Regular servicing of the refrigerator should be undertaken and documentation should be maintained to demonstrate regular servicing, defrosting and cleaning. Ice should not be allowed to build up as this reduces effectiveness.

18.2.10 During defrosting or cleaning, vaccines should be transferred to another refrigerator or placed in an approved cool box to ensure that they remain under 8°C. They should not be left in the refrigerator where the temperature will fluctuate and water could leak onto packaging.

18.2.11 Vaccines should only be replaced in the refrigerator once it has returned to the correct temperature

18.2.12 Food, drink and clinical specimens must never be stored in the same refrigerator as vaccines.

18.2.13 Opening the refrigerator door should be kept to a minimum to ensure maintenance of a constant temperature.

18.2.14 Refrigerators must be maintained and defrosted in line with the manufacturers' guidelines.

18.2.15 The vaccine fridge must be wired into switch-less sockets to avoid them being turned off accidentally.

18.2.16 In the event of refrigeration breakdown or interruption in electricity supply then arrangements must be in place for alternative storage facilities to be made available.

18.2.17 As a minimum the fridge should be serviced annually and the temperature gauge calibrated.

18.2.18 A sample refrigerator temperature record chart can be accessed via NHS England Policy and procedure for maintaining the Vaccine cold chain and / or via 'The Green Book'. This can be accessed at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/223753/Green_Book_Chapter_3_v3_0W.pdf

18.3 Monitoring of Stock

Medicines should be stored in their original containers so that they retain their batch number and expiry date. The packaging also protects the product from light

18.3.1 Appropriate documentation should be completed to record receipt of vaccines. This includes vaccine types, brands, quantities, batch number and expiry dates.

18.3.2 Fridge stocks should be monitored once per week by the designated person to avoid over ordering and accumulation of waste / stockpiling.

18.3.3 Vaccine stock should be audited and recorded every month.

18.3.4 It is best practice to order small quantities on a regular basis and hold no more than two weeks supply of vaccines at any time as per the Protocol for ordering, storing and handling vaccines (Public Health England 2014).

18.3.5 Out of date stock should be labelled clearly, removed from the refrigerator and destroyed as soon as possible in line with local procedures.

18.3.6 Vaccines must never be used when past their expiry date.

18.4 Thermometers

18.4.4 Temperatures in the refrigerator should be monitored and recorded as described for best practice in the Protocol for Ordering, Storing and Handling Vaccines' (Public Health England 2014) and LCHS G-IPC-34.

The refrigerator must be capable of maintaining the temperature of its contents between 2°C and 8°C with the minimum of intervention. Temperature monitoring should be by electronic max/min thermometer, with an accuracy of + 0.5°C, which should where possible be readable from outside the refrigerator. The data logger should be placed within the load to record the load rather than the air temperature, and the max/min temperatures should be recorded daily.

The device must be calibrated annually against a certificated thermometer. Records of such should be maintained and stored locally for a period of 2 years.

The unit should have an auto-defrost facility and the temperature within the unit should not be affected during the defrost cycle. If an alarm is fitted, the correct functioning of the alarm should be checked annually at the high and low set points. It is good practice that a power failure alarm be fitted and that the thermostat which controls the chiller unit should fail safe - i.e. the temperature does not decrease if the thermostat fails.

The thermometer must be reset after recording and after any prolonged period of opening.

Advice should be sought from the Medicines Management team if the temperature falls outside of the required range of 2-8ºC.

18.5 Storage in a cool box

18.5.1 Domestic cool boxes should not be used to store, distribute or transport vaccines.

For transportation of small quantities of heat labile medicines (e.g. vaccines) needed for a domiciliary visits please refer to LCHS G-IPC-34

18.6 In the event of a fridge failure

18.6.1 The NHS England screening and immunisation team should be informed and any follow up advice given should be acted upon. The PH England team covering Lincolnshire, Leicestershire and Northamptonshire can be contacted via telephone number 01138253495 or england.llimms@nhs.net (Note this is the generic email for all immunisation enquiries).

18.6.2 All vaccines affected by the incident should be maintained within the cold chain but separated from all other vaccines. These vaccines should be labelled to ensure clear identification.

18.6.3 The incident should be reported via Datix and appropriate actions taken. Any medicines destroyed must be named within the Datix and financial loss detailed.

The incident will be notified to the Medicines Management Team who will support any subsequent investigation.

Further guidance is cited in LCHS G-IPC-34

18.6.4 The incident should be reported on the ImmForm website www.immform.dh.gov.uk

18.7 Spillage

18.7.1 Reference should be made to local policy and COSHH which should outline all cleaning requirements when dealing with spillage.

18.7.2 Initially the spillage should be soaked up with paper towels. Appropriate personal protective equipment (PPE) should always be worn. Care should be taken to avoid puncture wounds from associated glass or needles.

18.8 Disposal / Vaccine Waste

18.8.1 All vaccines should be used within the period recommended by the manufacturer or should be disposed of by sealing in a puncture – resistant sharps box intended for this purpose.

18.8.2 Sharps boxes should be disposed of once they are two-thirds full.

18.8.3 Any wastage of vaccine as a result of disruption of the cold chain must be reported to the NHS England Screening and Immunisation Team via the Immunisation Coordinator on 01162 950890. If the vaccine has been ordered from ImmForm then the wasted vaccine needs to also be recorded on the ImmForm site.

18.8.4 Any disruption to the cold chain must be recorded as an incident in accordance with the Organisations incident reporting policy.

18.9 Storage of Immunoglobulins

18.9.1 Immunoglobulins should be refrigerated immediately upon receipt and stored at temperatures of 2°C to 8°C.

18.9.2 They should be protected from light and should not be frozen.

18.10 Equipment suppliers

18.10.1 Advice on suppliers of refrigeration equipment and accessories is available from:

Immunisation Policy, Monitoring and Surveillance.
Department of Health
Area 512
Wellington House
133 – 155 Waterloo Road
London
SE1 8UG
Tel: 020 7972 1227

19. Implementation Strategy

19.1 Following approval the policy will be posted on the Trust website to aid dissemination.

19.2 In addition, policy information will be disseminated via the Medicines Management webpage. Staff will be advised that this policy replaces all previous policies.

19.3 Service leads will be requested to disseminate to all appropriate staff groups.

20. Audit / Monitoring / Review

20.1 The implementation of this policy will be audited by the service managers overseen by the Drugs and Therapeutics Committee. Audit tools are both service specific and also available in the Management of Errors Policy, Non-Medical Prescribing Policy and Controlled Drugs Policy.

20.2 A random survey of relevant practitioner groups should be undertaken to assess whether the policy has been implemented / actioned. All monitoring and operational audits should be presented to the Drugs and Therapeutics Committee for information and action as appropriate.

20.3 This policy should be reviewed in light of changes with local guidance, national guidance, national legislation and best practice.

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Appendix 1- Medication Chart-Checker:

Audit Area: **Date Completed**

Observations	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	Total
Has the medication been reviewed within the last 14 days by a Prescriber?																					
If the medication was omitted, has the reason for omission been recorded?																					
Have oral antibiotics been prescribed for no longer than 5 days (or 7 days for male UTIs) in the first instance?																					
Was a review undertaken for antibiotics after 5 (or 7) days?																					
Has correct antibiotic for presenting condition been prescribed? (Indication in notes)																					
Have IV antibiotics been prescribed for no longer than 48 hours in the first instance?																					
Was a review undertaken after 48 hours?																					
Has a specimen been taken for culture?																					
Has a review of medication been undertaken following lab result availability?																					
Have any interventions been made by Pharmacist?																					
Has a VTE assessment been undertaken?																					
Has VTE prophylaxis been prescribed appropriately where required?																					
Total number of Yes answers per chart																					
How many of the 20 charts scored														Total number of inaccuracies							

Please see action plan overleaf/below for completion following your audit

Action Plan

Please annotate chart below with an action plan and status for any observations completed with 'NO' on the Chart Checker.

Observations	Action Plan	Status/Assurance
Has the medication been reviewed in the last 14 days by a Doctor or Prescriber?		
If the medication was omitted, has the reason for omission been recorded?		
Have oral antibiotics been prescribed for no longer than 5 days (or 7 days for male UTIs) in the first instance?		
Was a review undertaken after 5 (or 7) days?		
Has correct antibiotic for presenting condition been prescribed? (Indication in notes)		
Have IV antibiotics been prescribed for no longer than 48 hours in the first instance?		
Was a review undertaken after 48 hours?		
Have any interventions been made by Pharmacist?		
Has a VTE assessment been carried out?		
Has VTE prophylaxis been prescribed appropriately where required?		
Has a specimen been taken for culture?		
Has a review been undertaken following lab result?		

Appendix 2 - Security of prescription forms

Aide-mémoire for prescribers

- Be aware that blank prescription forms in the wrong hands are like a blank cheque with an extremely high street value.
- Prescription form stock in possession of prescribers should always be stored securely when not in use.
- Prescribers should keep a record of the serial numbers of prescription forms issued to them. The first and last serial numbers of pads should be recorded.
- Prescribers should be encouraged to use prescription forms in number sequence order to aid tracking of usage, should a potential loss occur
- To reduce the risk of misuse, blank prescriptions should never be pre-signed.
- Patients, temporary staff and visitors should never be left alone with prescription forms or allowed into secure areas where forms are stored.
- Prescribers on home visits should, before leaving the practice premises, record the serial numbers of any prescription forms/pads they are carrying. Only a small number of prescription forms should be taken on home visits – ideally between 6 and 10 – to minimise the potential loss.
- Prescribers on home visits/working in the community should take suitable precautions to prevent the loss or theft of prescription forms. Keep them out of sight when not in use and do not leave any prescription forms in vehicles overnight.
- Prescribers using the FP10PCD forms should exercise extra caution as there is greater potential for misuse of these forms.
- Blank or signed prescription forms should never be left at patients' homes, care homes or community pharmacies for GP or locum visits.
- Personalised forms which are no longer in use should be securely destroyed (e.g. by shredding) before being put into confidential waste, with appropriate records kept.
- Spoiled or cancelled prescription forms should be retained for audit purposes.

- In the event of a loss or theft of prescription form stock, local procedures should be followed and the practice manager, area team, Controlled Drugs Accountable Officer and the police should be notified as required. The incident should also be recorded on the organisation's incident reporting system.

Appendix 3 - Monitoring Template

This template should be used to demonstrate compliance with NHSLA requirements for the procedural document where applicable and/or how compliance with the document will be monitored.

Minimum requirement to be monitored	Process for monitoring e.g. audit	Responsible individuals /group /committee	Frequency of monitoring /audit	Responsible individuals / group / committee (multi-disciplinary) for review of results	Responsible individuals / group / committee for development of action plan	Responsible individuals / group / committee for monitoring of action plan
The compliance with the Safe and Secure Handling of Medicines Policy	Self audit and quarter Medicines Management audit	Medicines Management	Quarterly audit	Individual service quality and governance groups	Individual service Quality and Governance Group	Safeguarding and Patient Safety Committee. / DTC

Appendix 4 - Equality Analysis

Introduction

The general equality duty that is set out in the Equality Act 2010 requires public authorities, in the exercise of their functions, to have due regard to the need to:

- Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Act.
- Advance equality of opportunity between people who share a protected characteristic and those who do not.
- Foster good relations between people who share a protected characteristic and those who do not.

The general equality duty does not specify how public authorities should analyse the effect of their existing and new policies and practices on equality, but doing so is an important part of complying with the general equality duty. It is up to each organisation to choose the most effective approach for them. This standard template is designed to help LCHS staff members to comply with the general duty.

Please complete the template by following the instructions in each box. Should you have any queries or suggestions on this template, please contact Rachel Higgins, equality and diversity lead.

Name of Policy/Procedure/Function*	
Equality Analysis Carried out by:	**Helen Oliver**
Date:	**31st July 2019**
Equality & Human rights Lead:	**Rachel Higgins**
Date:	**31st July 2019**
Director\General Manager:	
Date:	

***In this template the term policy\service is used as shorthand for what needs to be analysed. Policy\Service needs to be understood broadly to embrace the full range of policies, practices, activities and decisions: essentially everything we do, whether it is formally written down or whether it is informal custom and practice. This includes existing policies and any new policies under development.**

Section 1 – to be completed for all policies

A.	Briefly give an outline of the key objectives of the policy; what it's intended outcome is and who the intended beneficiaries are expected to be	The purpose of this guidance is to implement a co-ordinated and standardised approach to the strategic, operational and clinical management of all practices involving medicines and their use within all services within Lincolnshire Community Health Services NHS Trust		
B.	Does the policy have an impact on patients, carers or staff, or the wider community that we have links with? **Please give details**	The content is relevant to all staff and service users		
C.	Is there is any evidence that the policy\service relates to an area with known inequalities? **Please give details**	Not Known		
D.	Will/Does the implementation of the policy\service result in different impacts for protected?			
		Yes	No	
	Disability		√	
	Sexual Orientation		√	
	Sex		√	
	Gender Reassignment		√	
	Race		√	
	Marriage/Civil Partnership		√	
	Maternity/Pregnancy		√	
	Age		√	
	Religion or Belief		√	
	Carers		√	

	If you have answered 'Yes' to any of the questions then you are required to carry out a full Equality Analysis which should be approved by the Equality and Human Rights Lead – please go to section 2
The above named policy has been considered and does not require a full equality analysis	
Equality Analysis Carried out by:	Helen Oliver
Date:	31st July 2019