

Policy for the Safe and Secure Handling of Medicines

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Safe and Securing Handling of Medicines Policy

Version Control Sheet

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Safe and Secure Handling of Medicines Policy

Policy Statement

Background	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.
Statement	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 aspects of medicines handling and that this is evidenced through audit.
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	Lincolnshire Clinical Commissioning Groups Lincolnshire Community Health Services Website: www.lincolnshire.nhs.uk
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.

1. Introduction / Scope of the policy

- 1.1 This policy aims to offer practical advice and outline steps that must be taken to ensure that 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 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.
- 1.5 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;
 - Staff must practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct if applicable.
- 1.6 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.
- 1.7 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.

- 1.8 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
 - Specify the appropriate written and / or oral supporting information or instructions required in passing to the next stage
 - Include the acceptable form(s) in which instructions can be given
- 1.9 Ratification of service SOPs will be through the relevant organisational structures
- 1.10 A list of all SOPs being used operationally must be approved and recorded with the relevant organisational body by the Service Head / Operational Lead.
- 1.11 A standard operating procedure template is available and specific pharmaceutical advice is accessible on request from the Prescribing and Medicines Optimisation Service.
- 1.12 Further information, guidance and a local template for use can be found in the Policy on the development of Standard Operating Procedures (SOPs).

2. Terminology

- 2.1 The term 'medicines' is used throughout the document as a generic term that covers all products that are 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 and local arrangements must be documented in a SOP.
- 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. Reference should be made to the NPSA Safer Practice Notice 18th September 2008 *Risk to patient safety of not using the NHS number as the national identifier for all patients*.
- 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 6 of the BNF (BNF 67).
- 3.8 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).
- 3.9 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.
- 3.10 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 67).
- 3.11 Prescribing for self, family or colleagues should only be done in emergency or exceptional circumstances.

3.12 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 Nurses and other 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 Dentists are licensed to practice by the General Dental Council. Dental practitioners are restricted to prescribing from the Dental Practitioners Formulary contained within the BNF.

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. Further guidance is incorporated within PACE bulletin Vol 6 No 11 – Alternatives to prescribing unlicensed pharmaceutical specials September 2012.
- 5.2 Nurse 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 reference must first be made to the guidance outlined within the PACE bulletin and 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;
 - 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;
- 5.4 Optometrist prescribers are not authorised to prescribe unlicensed medicines (BNF 67).

6. Specials

- 6.1 PACEF have issued specific guidance in relation to the prescribing of pharmaceutical specials. Reference should be made to PACE bulletin Vol 6 No 11 – Alternatives to prescribing unlicensed pharmaceutical specials September 2012.
- 6.2 Special-order products (more commonly known as “specials”) are made-to-order unlicensed medicines designed to meet the needs of individual patients.
- 6.3 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.
- 6.4 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 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.

- 8.5 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/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3>
- 8.6 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.
- 8.7 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.
- 8.8 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/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3>
- 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 Organisations Controlled Drugs Policy for specific issues in relation to the transportation of controlled drugs.

10. Storage of medicines

10.1 Storage and security of medicines

- 10.1.1 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.
- 10.1.2 At any time there will be a nominated person responsible for the safekeeping of all medicines stored in the health care setting.
- 10.1.3 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°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.
- 10.1.4 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.
- 10.1.5 Storage requirements for controlled drugs are detailed in the Controlled Drugs Policy and must be adhered to.
- 10.1.6 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.
- 10.1.7 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).
- 10.1.8 All medicines must be stored in their original containers. They should not be transferred from one container to another.
- 10.1.9 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.
- 10.1.10 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.
- 10.1.11 Community staff have responsibility to advise patients and their carers on the safe and secure storage of medicines in the home.

10.2 Patients own medicines

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

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

10.3 Storage of refrigerated medicines

10.3.1 Reference should be made to section 17.2 of this document 'Storage of vaccines and other refrigerated medicines'.

10.4 Storage of emergency medicines

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

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

10.5 Custody and safe keeping of keys

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

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

10.6 Loss of controlled stationery, keys or medicine

10.6.1 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).

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

10.7 Loss of keys

10.7.1 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.

10.7.2 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.

10.8 Loss of Prescription Pad

10.8.1 This should be read in conjunction with the Organisational Policy for the Secure Handling of Prescription Stationary (2012).

- 10.8.2 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 Organisations Counter Fraud Specialist (Tel No: 07890821329).
- 10.8.3 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.
- 10.8.4 The Practitioner Services 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 Practitioner Service 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).
- 10.8.5 An incident report form should be completed as soon as possible.
- 10.8.6 For non-medical prescribers further information on this process can be found in the Non Medical Prescribing Policy.

11. Administration

11.1 Process of administration

- 11.1.1 This process for administration covers all care environments.
- 11.1.2 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 training student professionals.
- 11.1.3 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).
- 11.1.4 The identity of each medicine should be clear at all times up to and including the point of administration.
- 11.1.5 Medicines dispensed for an individual patient must only be administered to that patient (supplies labelled for individual patients must not be shared).
- 11.1.6 When selecting the medicine, the following should be checked and any concerns clarified before proceeding:-
1. name of the medicine;
 - strength;
 - form;
 - expiry date.
- 11.1.7 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.

11.1.8 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.

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

11.1.10 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.

11.1.11 Any dose prepared for administration and subsequently not given should be 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.

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

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

11.1.14 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.

11.1.15 For further information regarding the administration of injectable medicines further reference should be made to Section 12 within this document.

11.2 Self administration of medicines

11.2.1 Where services utilise the self administration of medicines, relevant organisational policies and local SOPs should be adhered to.

11.2.2 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.

11.2.3 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.

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

- 11.3.1 An appropriate oral / enteral syringe should be used to measure oral liquid medicine if a medicine spoon or graduated measure cannot be used.
- 11.3.2 A 5ml spoon should only be used for doses of 5ml or multiples thereof.
- 11.3.3 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).
- 11.3.4 When patients / carers are required to administer oral liquid medicines with a syringe, they should always be supplied with oral or enteral syringes.
- 11.3.5 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.
- 11.3.6 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.
- 11.3.7 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.
- 11.3.8 All oral / enteral syringes containing oral liquid medicines must be labelled with the name and strength of the medicine, the patient's name, and the 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.
- 11.3.9 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.
- 11.3.10 Administration via PEG or NG tube – this is unlicensed use and consideration should be given to the following:
1. Use of licensed 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.
- 11.3.11 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.

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

11.4 Administration – Verbal Orders

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

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

11.4.3 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 organisational documentation.

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

11.4.5 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.

11.4.6 Non medical prescribers 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).

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

12. Use of Injectable medicines

12.1 Prescribing of injectable medicines

12.1.1 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).

12.1.2 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 diluent and/or infusion fluid, concentration of final infusion, rate of administration, duration and rate control pump or device to be used.

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

12.2 Mixing of medicines

12.2.1 The Medicines and Healthcare products Regulatory Agency (2010) (MHRA) states that 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 the administration of the other e.g. as a reconstitution or diluting agent.

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

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

1. To enable doctors and dentists to direct other healthcare practitioners to mix medicines;
2. To allow Nurse and Independent Prescribers to mix medicines themselves and to direct others to mix;
3. To enable 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;
4. To allow Nurse and Pharmacist independent prescribers to prescribe unlicensed medicines for their patients;

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

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

12.2.6 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.

12.2.7 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.

12.2.8 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.

12.3 Supply and storage

12.3.1 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.

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

12.3.3 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.

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

12.4 Preparation

12.4.1 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.

12.4.2 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.

12.4.3 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.

12.4.4 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.

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

12.4.6 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.

12.4.7 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.

12.5 Administration of Injectable medicines

12.5.1 An up to date Standard Operating Procedure (SOP) should be available and accessible within all clinical areas to support all stages of the safe and secure handling of injectable medicines.

12.5.2 The SOP should be referred to at all times and should clearly outline the qualifications and competencies required by practitioners to enable them to undertake this role.

12.5.3 The SOP should clearly outline the requirements for prescribing, preparation and administration of an injectable medicine.

12.5.4 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).

12.5.5 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.

12.5.6 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).

12.5.7 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.

12.5.8 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).

12.5.9 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 and there may be no written prescription.

12.5.10 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.

12.5.11 Infusions should be monitored to ensure safe administration of prescribed treatment.

12.6 Administration of Insulin

- 12.6.1 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.
- 12.6.2 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%).

12.7 Training

- 12.7.1 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.
- 12.7.2 All individuals are responsible for maintaining their professional knowledge and working within the limits of their competence.

12.8 Injectable medicines audit

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

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

- 13.1 Reference should be made to the organisations standard operating procedures and Policy for the development and control of PGDs.
- 13.2 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).
- 13.3 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.
- 13.4 If a medicine is unlicensed it should only be administered against a patient specific prescription and not under a PGD.
- 13.5 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.
- 13.6 Service leads have responsibility for ensuring that only fully competent, qualified and trained professionals operate within the PGD.

13.7 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

14. Return and Disposal of Unwanted Medicines

- 14.1 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.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/167976/HTM_07-01_Final.pdf
- 14.2 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.
- 14.3 Medicines that have been issued directly to a patient should not be reused.
- 14.4 The storage, carriage and consignment of waste are all subject to stringent controls via Environmental, Waste, Transport and Health and Safety legislation.
- 14.5 Trust premises wishing to dispose of waste medicines will need to arrange for them to be collected by a suitable waste contractor. Currently this waste contractor is SRCL Ltd (formerly White Rose Environmental).
- 14.6 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.
- 14.7 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.
- 14.8 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 not 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
- 14.9 Protective equipment such as gloves will also need to be provided and used.
- 14.10 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'.
- 14.11 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.

- 14.12 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.
- 14.13 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.

15. Untoward incidents

15.1 Untoward incidents involving medicines

- 15.1.1 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).
- 15.1.2 **Any** incident or near miss in which medicines are involved must be reported in accordance with the Organisations incident reporting policy.
- 15.1.3 The incident must immediately be reported to and investigated by the appropriate line manager, or person delegated to act on their behalf.
- 15.1.4 An incident form (IR1) must be completed and a copy forwarded to the risk management department.
- 15.1.5 Risk/governance teams will supply details to the relevant Prescribing and Medicines Optimisation Specialist, who will identify any trends or recommended actions to ensure that risks relating to medicines are minimised and reported to the relevant organisational body.

15.2 Administration errors

- 15.2.1 As soon as it is realised that there has been an error of medicine administration:-
5. 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.

15.3 Adverse reactions to drugs

- 15.3.1 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.
- 15.3.2 Any drug may produce unwanted or unexpected adverse reactions. Detection and reporting of these is of vital importance. Doctors, dentists, nurses, pharmacists, coroners and therapists 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>

15.3.3 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>.

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

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

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

15.4 Defective medicines

15.4.1 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.

15.4.2 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.

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

16. Training

16.1 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.

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

17. Storage, distribution and disposal of vaccines.

17.1 Management of vaccines

17.1.1 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.

- 17.1.2 This section outlines a summary of guidance provided by the 'Green Book', on the storage, transport and equipment necessary for the maintenance of the cold chain as well as highlighting the need for monitoring and audit.
- 17.1.3 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.
- 17.1.4 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.
- 17.1.5 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.
- 17.1.6 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)
- 17.1.7 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.
- 17.1.8 Some vaccines are packaged in multiple quantities. Care should be taken to order correctly to avoid waste.
- 17.1.9 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>
- 17.1.10 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'.

17.2 Storage of vaccines and other refrigerated medicines

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

- 17.2.2 Vaccines should be appropriately stored to protect from the light. Exposure to ultraviolet light is known to cause loss of potency.
- 17.2.3 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.
- 17.2.4 Avoid over ordering, stockpiling and overfilling refrigerators. It is important that air must be able to circulate around the packages.
- 17.2.5 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.
- 17.2.6 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.
- 17.2.7 Ordinary domestic refrigerators must not be used. All service areas should have a validated vaccine fridge.
- 17.2.8 Refrigerators for the storage of vaccines should not be situated near a radiator or heat source as this may affect their efficiency.
- 17.2.9 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.
- 17.2.10 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.
- 17.2.11 Vaccines should only be replaced in the refrigerator once the refrigerator has returned to the correct temperature.
- 17.2.12 Food, drink and clinical specimens must never be stored in the same refrigerator as vaccines.
- 17.2.13 Opening of the refrigerator door should be kept to a minimum to ensure maintenance of a constant temperature.
- 17.2.14 Refrigerators must be maintained and defrosted in line with the manufacturers' guidelines.
- 17.2.15 The vaccine fridge must be wired into switch-less sockets to avoid them being turned off accidentally.
- 17.2.16 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.

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

17.2.18 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

17.3 Monitoring of Stock

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

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

17.3.3 Vaccine stock should be audited and recorded every month.

17.3.4 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).

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

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

17.4 Thermometers

17.4.1 All fridges should ideally have two thermometers, one of which is a max / min thermometer independent of the mains power.

17.4.2 If only one thermometer is used then a monthly check should be undertaken to ensure the accuracy of the calibration.

17.4.3 Care should be taken to ensure that the thermometer probe cable does not interfere with the door seal. This could cause the temperature of the fridge to fall outside of the permitted range.

17.4.4 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).

17.4.5 Thermometer calibration should be checked monthly against an independently powered external thermometer and records maintained for audit purposes.

17.5 Storage in a cool box

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

17.5.2 Should vaccines be required to be stored in cool boxes, e.g. for transportation, then a validated cool box with a facility to record a maximum / minimum temperature either electronic (i.e. plug in to a car cigarette lighter socket) or insulated box with cool packs (never ice packs) from a recognised medical supply company, should be used.

17.5.3 Specific manufacturer's instructions should be adhered to at all times.

17.5.4 Vaccines must be kept in their original packaging and wrapped in insulation material (for example bubble wrap) before being placed in a cool box. This will ensure that where cool packs are used they do not come into direct contact with the vaccines.

17.5.5 Cool boxes should only be packed immediately prior to transportation.

17.5.6 Vaccines should remain in the closed cool box until required for use / or placed in an appropriate refrigerator if the cool box is not electronic.

17.6 In the event of a fridge failure

17.6.1 The NHS England screening and immunisation team (Telephone number 01162 950890) should be informed and any follow up advice given should be acted upon.

17.6.2 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.

17.6.3 The incident should be clearly documented and reported in accordance with the Organisations Incident reporting policy.

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

17.7 Spillage

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

17.7.2 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.

17.8 Disposal / Vaccine Waste

17.8.1 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.

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

17.8.3 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.

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

17.9 Storage of Immunoglobulins

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

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

17.10 Equipment suppliers

17.10.1 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*

18. Implementation Strategy

18.1 Following approval the policy will be posted on the Organisations website to aid dissemination.

18.2 Staff will be advised that this policy replaces all previous policies.

18.3 For GP practices, information dissemination will be cascaded through the medicines management forums, Cluster groups and existing networks. Service leads will be requested to disseminate to all appropriate staff groups.

19. Audit / Monitoring / Review

19.1 The implementation of this policy will be audited by the service managers through audit.

19.2 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 relevant organisational body for information and action as appropriate.

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

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