MANAGEMENT PROCESS DESCRIPTION MPD599/6

Medicines Management in NHSBT

This Management Process Description replaces MPD599/5

Copy Number

Effective **23/04/18**

Summary of Significant Changes

Removal of sections refering to use of drugs on mobile collection teams following discontinuation of use of local anaesthetic for blood donation

Policy

To establish, document and maintain an effective system to ensure that medicines are handled in a safe and secure manner within NHSBT and which covers the Medicine Trail, including process for prescribing, ordering, dispensing, storing and administering of medicines

Purpose

To describe the principles to be followed within NHSBT for supply, administration, safe handling, storage and disposal of medicines

Responsibilities

Registered Health Care Professionals working within NHSBT are responsible for ensuring the correct receipt, storage, administration and disposal of medications in line with DoH, manufacturers, health and safety and pharmacy requirements

Relevant directorate's Clinical Governance Group is responsible for ensuring safe use of medicines and supports the overall reduction in medication incidents

Definitions

Medicines/Drugs – All substances defined under the Medicines Act as being medicinal products and for the purposes of apheresis donations and therapeutic services this definition may be extended to cover some products licensed as medical devices.

Medicinal products – As defined under the Human medicines Regulation 2012 as being "(a)any substance or combination of substances presented as having properties of preventing or treating disease in human beings; or
(b)any substance or combination of substances that may be used by or administered to human beings with a view to—
(i)restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or

Unlicensed Medicines – Drugs with no UK Product Licence

Patient Group Direction (PGD) – A written instruction for the supply or administration of a licensed medicine (or medicines) where the recipient may not be individually identified. A PGD must be signed by a doctor and a pharmacist as appropriate and approved by the organisation in which it is to be used

BNF – British National Formulary
NKDA – No Known Drug Allergy

Adverse Drug Reaction (ADR) – a response to a medicinal product that is noxious and unintended effects resulting not only from the authorised use of the medicinal product at normal doses, but also from medication errors and uses outside the terms of marketing authorisation, including the misuse and abuse of the medicinal product.

(ii) making a medical diagnosis".

POMs – Prescription Only Medicines Are described in the Human Medicines Regulations 2012 as "any of the following—
(a)a medicinal product that is covered by an authorization of which it is a term that the product is to be available only on prescription;
(b)a medicinal product that—
(i)is covered by an EU marketing authorization, and
(ii)is classified in the authorization as a prescription only medicine;
(c)a medicinal product that is a prescription only medicine by virtue of Part 1 of Schedule 1; or
(d)a medicinal product that is the result of—
(i)the assembly, or
(ii)the reformulation (including the combining with other substances),
of a medicinal product that is a prescription only medicine by virtue of sub-paragraph (a) or (b)."

Controlled Drugs – Includes those drugs classified under the 'Misuse of Drugs Act 1971 and its associated regulations and as specified in the Human Medicine regulations 2012 -controlled drug" means any substance or product for the time being specified in Schedule 1, 2 or 3 of the Misuse of Drugs Regulations 2001(**2**)

Medication Errors – any incident where there has been an error in the process of prescribing, preparing, dispensing, administration, monitoring or provision of medicines advice. This includes wrong medicine, wrong dose or errors of omission

CARE – Clinical Audit, Risk and Effectiveness

SNOD- Specialist nurse- Organ Donation

Applicable Documents

BNF British National Formulary

The Medicines Act 1968

The Misuse of Drugs Act 1971

The Health Act 2006

The Health and Social Care Act 2012

Crowne Report 1999 Review of Prescribing, Supply and Administration of Medicines

The Misuse of Drugs Regulations 2001

Audit Commission (2001) A Spoonful of sugar. Medicines management in NHS Hospitals

Medicines Matters, a guide to mechanisms for the prescribing and administration of medicines. Dept of Health 2006

NICE Medicines Practice Guidelines MPG2 - Patient Group Directions

Duthie Report (1988) Guidelines for the Safe and Secure Handling of Medicines

The Safe and Secure Handling of Medicines 2005 (revision to Duthie Report)

Health and Safety Regulations

Control of Substances Hazardous to Health Regulations 1988(COSHH)

Care Quality Commission – Essential Standards of Quality and Safety

Nursing and Midwifery Council – Standards for Medicine Management 2007/2010

MPD87 – Safe Handling and Disposal of Clinical Waste

Human Medicines Regulations 2012

Background

The NHSBT routinely makes use of a limited range of medicines in the course of treatments and collections undertaken on patients and donors.

The principles which govern medicines management must be applied to all activities in which medicines and their administrative and legal control are concerned.

The key principles are:
Compliance with current legislation
Adherence to guidance by the Department of Health
Management of the risks to patients and staff arising from the use of medicines.

Medicines include Prescription Only Medicines (POM), Pharmacy (P) General Sales List (GSL) and Controlled Drugs both licensed and unlicensed. Also included are Complementary and Pharmaceuticals (non-therapeutic items)

These principles must be applied to the management of the processes involved in:
- Initiation of treatment
- Prescribing
- Procurement
- Acquisition
- Storage
- Distribution
- Dispensing
- Administration to patients
- Safe handling and disposal

NHSBT procedures would not routinely involve the use of Controlled drugs and these must not be stored anywhere within NHSBT unless full compliance with the legislation and guidance covering the control of drugs liable to misuse can be adhered to. Where Controlled Drugs are required for specific patients it is preferable that these should where possible be obtained on an individual basis at the time required from a pharmacy rather than be stored as a stock drug. Where an inpatient is being treated at bedside on the ward and Controlled Drugs are required these should be obtained from ward stock and recorded in their records.

Patients or donors receiving medication as part of treatment or collection must do so in the correct and safe manner. Precautions must be taken to ensure that procedures followed in providing medication and in the storage and transport of any medication such as to ensure its integrity have been maintained thus minimising the risk to staff, patients, donors and the public. It must be ensured that patients or donors receive any medication in the correct dosage via the correct route at the correct time and for the correct duration, while all relevant public safety, clinical governance, regulatory, and legal requirements are adhered to and auditable records are maintained.

The relevant directorate's Clinical Governance Group ensures safe use of medicines and supports the overall reduction in medication incidents by the multidisciplinary review of medication incidents, identifying trends in medication incidents and ensuring appropriate investigation and management of reported medication incidents, both internally and externally.

1. Medicine and the Law

In line with The Medicines Act 1968 and subsequent amendments, medicines available only on prescription (POM) must be given as instructed by the authorised prescriber and changes to the dose or intended recipient must not be made without the authorised prescriber's permission.

Up to 1mg of Epinephrine 1:1000 injections given IM can be administered legally without a prescription (Patient Specific Direction) for saving life in an emergency situation such anaphylaxis.

2. Prescribing of Medicines

Only those authorised to prescribe may prescribe or write orders on a Patient Medication Chart for medicinal products unless the medicine is covered by a Patient Group Direction. In which case it may be dispensed by a registered nurse.

All details must be:

- Written Legibly
- Written in black ink
- Written in block capitals
- Written in Indelible ink

A Pre-printed addressograph labels should be used whenever possible and attached to the patients medication chart

The following patient details must be entered either by addressograph label or manually:

- Full name
- Address
- Donor Number or NHS Number /Hospital Number
- Date of Birth
- Consultant or GP if undergoing treatment by NHSBT (not required for blood component donors)
- Known drug allergies or sensitivities (if none annotated NKDA)
- Weight if paediatric patient and where dose adjustments by weight will be required

Medication details must be entered as follows:

- Approved name of the medicine (Proprietary name should only be used where no approved name exists or where proprietary names defines a specific formulation)
- Treatment commencement date
- Dose expressed in SI units (or total volume and rate of administration for IV prescriptions)
- Quantities less than a gram must be written in milligrams, micrograms or nanograms not as a decimal of a gram (If a decimal points are unavoidable great care must be exercised by the prescriber and administrator)
- Micrograms and nanograms must be written in full and not abbreviated
- Use only acceptable abbreviations
- Must be expressed as total dosage (or total volume) not multiples of a single ingredient
- Dose frequency – where abbreviations are used only those in the BNF are acceptable
- 24 hour clock must be used for regular medication administration times
- As required medicines must have either specific times for administration where relevant as well as maximum frequency and maximum dose in 24 hours
- Route of administration - Only Approved abbreviations must be used as follows:
  IM - Intramuscular INH - Inhalation IV- Intravenous NEB – Nebuliser PO – For oral PR – For rectal SC – Sub-cutaneous S/L – Sub-lingual TOP – Topical PV – For vaginal Other routes must be written in full
- Prescriber's name, signature and date

Discontinued medicines and incorrect entries

The date a medicine is discontinued must be entered in the administration box with the signature of the prescriber and a diagonal line drawn through the prescription to ensure cancellation is obvious but prescription not obliterated. Incorrect entries must be scored through and the word cancelled written against it by the prescriber.

Medicines with specific course lengths must have the administration spaces beyond the course length crossed through. Unless the course of a treatment is clearly specified the prescription will be considered valid until cancelled.

Changes to dose frequency or route must be made by way of a new entry and not through alterations to an original entry. The original entry must be crossed through and signed by the prescriber. Dates for re-written prescriptions must remain as the date the treatment commenced not the date of re-writing.

Authorised Charts

All medicines must be prescribed on authorised printed charts. Photocopies are not acceptable. Where more than one chart exists the front of the charts must be annotated 1of 2, 2 of 2 etc. Where separate additional charts are used for administration of specific drugs or fluids these must still be written on the main chart and the words 'see additional chart' written across the administration boxes.

Verbal / Faxed Prescriptions

These should only be used in exceptional circumstances and not where the medicine has not been previously prescribed. Where possible a fax or e-mail prescription should be supplied and followed up with a new prescription confirming the changes within normally a maximum of 24 hours (72 hours maximum – bank holidays and weekends). The changes must be authorised before the new dosage is administered.

The nurse receiving the order must document the medication required on the chart and clearly mark it verbal order. The order must be confirmed back to the prescriber and include the patient's identity, other medication the patient is on and any allergies the patients has, the name of the drug, the dose and the administration route. The name of the drug should be spelt out to avoid confusion and the nurse should be familiar with the drug.

Where text messaging is used to confirm an administration order a second signature should be obtained, where possible from another registrant, to confirm the documentation agrees with the text message. The complete text message, the time it was sent, the telephone number it was sent from and any response should be documented and the registrant should sign and date when it was received. The text message should then be deleted from the receiving hand set to maintain confidentiality.

The fax or e-mail where supplied should be printed and attached in the patient's records

3. Supply of Medicines

Sodium Chloride 0.9%, local anaesthetic, Human Albumin Solution, 8-Methoxypsoralen(Uvidex), Epinephrine (Adrenaline) 1:1000 and Inactivated Influenza Vaccine POMs used during component donation, therapeutic apheresis and annual seasonal flu vaccination programmes are purchased by NHSBT from the wholesaler. To allow this NHSBT has a Wholesale Dealers Licence under the Medicines act 1968. These POMs are stored in general stores at the centres designated on the Licence. The NHSBT Responsible Person named on the pharmacy licence is responsible for ensuring the storage of these POMs in the centres designated on the licence, in accordance with the manufacturer's instructions. These POMs will be issued from the centre stores on receipt of the appropriate requisition and transferred to team/unit stores where they will be receipted and stored according the procedures below.

POMs other than Sodium Chloride 0.9%, local anaesthetic and Human Albumin Solution 8-Methoxypsoralen(Uvidex), Epinephrine (Adrenaline) 1:1000 and Inactivated Influenza Vaccine should be obtained via an NHS hospital pharmacy or registered community pharmacy or for in-patients being treated in hospitals obtained from ward supplies. Appropriate documentation must be used for ordering to meet legal and local requirements and supplies of medication must only be obtained on receipt of a signed order.

A list of registered nurses authorised to order medicinal products will be required by pharmacies along with specimen signatures. A list of staff authorised to order medicines through electronic requisitions systems must be kept and access to the system controlled through password protection.

Medicines from pharmacies will be made under the authority of:

- A written prescription by an authorised prescriber
- A written requisition signed by a registered nurse from the department for use as stock for administering to patients in the department

Drugs may be carried by any authorised employee or authorised transport. All deliveries must be signed for before leaving the pharmacy (issuing store) and also signed upon receipt to ensure there is an audit trail.

Records of supply must be kept for:

2 years for medicinal products supplied by the pharmacy department
5 years for unlicensed medications
18 months for advice notes
18 months for delivery notes
12 months for issue notes

2 years for controlled drug registers and requisitions after date of last entry

Any discrepancies in dispensing or items supplied that do not comply with regulations must be reported to the pharmacist/general stores manager and Quality Department.

4. Receipt, Storage and Security of Medicines

Medicines should be stored as soon as possible after receipt and priority must be given to those with special storage conditions such as temperature sensitive and controlled drugs.

- All areas receiving drugs should have a designated place for the receipt of stock
- Drugs requiring refrigeration must be unpacked immediately and placed in a drug storage refrigerator
- A member of staff must check the stock issued through pharmacy or general stores into the department or team store.
- The issue note accompanying stock received from pharmacy or general stores must be checked against the order note and if these match the issue note should be signed, dated and retained for “medicines trail” audit purposes.
- Report any discrepancies or damaged products immediately to pharmacy or the appropriate Issuing manager and the Quality department.

In accordance with the Duthie report, and subsequent revisions, medicines must be stored:

- In secure locked cupboards or storage areas. Cupboards for the storage of medicines must comply with BS2881(1989) –NHS Estates Building Note 29
- In cool suitably sited areas within units.
- In appropriate cupboards if inflammable and hazardous.

Stock issued to team stores/base:

A stock record should be kept to record deliveries of medicines from general stores to Component Donation bases. The nurse in charge/designated nurse in the Component unit is responsible for checking the delivery of drugs against the delivery notes.

Drug refrigerators must be lockable, kept locked and temperature monitored daily. Drug cupboards and pharmaceutical storage areas must be adequately maintained, kept clean, well ordered and comply with current legislation

Drugs for internal and external use should be kept separately in separate cupboards if possible and if not then in discretely separated parts of the same cupboard or storage area with external being stored below internal.

Certain pharmaceuticals such as bulk sterile fluids may be stored in areas other than locked cupboards but these should be as secure as possible and away from public areas

Missing drug or refrigerator keys must be reported immediately and an incident form completed. Consideration should be given to changing locks. If keys to a Controlled Drug cupboard go missing the locks must be changed and pharmacy must be informed

Premises for the storage of medicines should be regularly inspected.

Therapeutic and component donation units

The nurse manager/nurse in charge/designated nurse is responsible for medicine cupboard and unit keys. Possession of the keys can be delegated to other registered nurses but responsibility remains with the nurse manager/nurse in charge/designated nurse. Medicine cupboard keys should be kept personally by staff or in a locked cupboard.

Medicines to be transported for therapeutic procedures away from base should be carried in lockable containers and remain and the responsibility of the designated nurse undertaking the procedure.

Medicine for use in clinical emergencies must:

- Not be kept in locked cupboards
- Be readily available in the area in which the patients or donors are to be treated or donate
- Be supplied in tamper evident containers
- Be within expiry date
- Wherever possible be stored out of direct view of the public
- Be returned to pharmacy if the tamper evident seal is broken

The nurse in charge and the nurse undertaking a procedure are responsible for ensuring that the appropriate emergency medicines are ordered and available for use.

When emergency medicines are removed from storage it must remain under the direct supervision of the practitioner using it and it their responsibility to ensure its safe custody

Specialist Nurse- Organ Donation

Specialist nurses in Organ Donation must adhere to all relevant policies and procedures at the Hospital/ Trust they work within. SNODs are expected to work within their sphere of competence.

5. Administration of Medicines

Medicines administered from a prescription must only be administered from a bottle or container if the patient's name, name of medicine, dose, frequency and expiry date can be checked. If practitioners are unsure about any of the above they must check with the authorised prescriber and obtain a repeat prescription.

Drugs must only be administered if the prescription is clearly written, the drug accurately prescribed, signed and dated by an authorised prescriber.

All drugs must be checked against the original prescription prior to administration. The patients ID and allergy status must be checked and confirmed immediately prior to administration. Allergies must be documented on the drug prescription chart and in the patient/donor file including the drug name, signs, symptoms and severity or the reaction and the date the reaction occurred. Patients with know drug may be identified with a red coloured wristband in place of a white wristband in accordance with Safer Practice Notice 24.

Medicines must:

- Be administered in accordance with a valid prescription chart.
- Only be administered by a registered health care professional with appropriate training and competencies
- Only be administered by patients under self-medication arrangements

- Only be administered by student nurses if under direct supervision of a registered nurse who is accountable for the administration process

With the exception of the procedures listed below the administration of medicines is normally a single person procedure. A second independent check by a registrant, or if a second registrant is not available, other competent person should be carried out for intravenous medication and controlled drugs. As a minimum a second independent check of dose calculations should be performed.

- Reconstruction of dry powders for injection into a solution
- Selection and mixing of drugs in syringes and infusion bags
- All administrations to neonatal/paediatric patients (one HCP should ideally be a registered paediatric nurse for children and registered neonatal trained nurse for SCBU)
- All controlled drugs
- All Cytotoxic drugs must only be administered by those specifically trained to do so
- Intravenous Drugs
- Where calculations are required
- The replacement of drug containing syringes or bags in IV pumps, set up and/or in use

Medicines used outside their product licence

Many medications used in specialist areas are not licensed for a particular indication, age group, dosage, or route of administration. This arises when the pharmaceutical company makes the application to the licensing authority for a marketing authorisation for use of the medicine for a specific indication. It may not however make an application to use the medicine in other ways, which are safe and legitimate.

It may be necessary to use a licensed medicine outside its product licence when there is no suitable alternative and to discontinue this practice would be detrimental to patient care overall. The following policy should therefore be adopted:

- A body of evidence should support routine use of medicines in this manner
- In the absence of such evidence efforts should be made to establish an evidence base
- Full patient consent must be obtained for unlicensed use.

6. Disposal of medication

Medicinal products must be disposed of in accordance with legislation and Clinical Waste procedures MPD87. Unused no longer required and out of date medicines should be returned to pharmacy or general stores for disposal. The nurse in charge/ designated nurse should be responsible for return of unwanted or out of date medicines

Part Used Syringes/Injections

It is not acceptable to dispose of liquid remaining in syringes, vials, and ampoules down the sink. Disposal of unused Controlled drugs in syringes, ampoules and vials must be witnessed by a second person and disposal documented and countersigned in the controlled drug register.

Used ampoules, vials, syringes and partly used infusions bags (including the giving set) must be placed in a sharps or designated clinical waste container and labelled in accordance with waste disposal procedures.

Certain drugs require special disposal arrangements; pharmacy should be contacted if any of these need destroying:

- Cytotoxic drugs
- Any radiopharmaceutical

- Any hormone containing drug
- Live vaccines
- Arsenic containing drugs

7. Reporting Defects

If defects in medicinal products, devices or dressings are discovered or suspected these must be reported via the Quality System. Defects in medicines should also be reported to pharmacy or the appropriate Issues manager. If a patient/donor is involved all materials and devices involved must be retained for inspection

8. Adverse Events

All adverse events/near misses involving medicines, whether there has been an injury or not, must be reported in accordance with relevant directorate incident reporting policies, procedures and systems and completion of relevant incident reporting forms/records. Managers must be informed of incidents are responsible for checking and investigating the information and decide on action to be taken to prevent recurrence. The relevant directorate CARE Group will ensure appropriate investigation and organisation wide learning for significant reported incidents and trends.

9. Adverse drug reactions

All untoward reactions must be reported via the relevant directorate and Trust adverse events reporting procedures. A note must be made in the patient or donor healthcare records. All staff should report suspected adverse drug reactions to the Medicines and Healthcare Products Regulatory Agency (MHRA). Reports can be made online at www.yellowcard.gov.uk. Prepaid yellow cards are also available in the back of the British National Formulary (BNF).

10. Covert Administration

Covert administration is only likely to be appropriate or necessary in patients who actively refuse medication but who have been accessed as lacking the capacity for decision making in this area under the Mental Capacity Act 2005.

Where covert administration is deemed necessary it must only be undertaken in full compliance with the relevant legislation e.g. the Mental capacity Act 2005 and nurses administering medication covertly should comply with the NMC guidance. Thorough consideration and discussion with the referring clinical team and family members should take place before a decision is taken to administer medication covertly. A written plan should be developed and agreed by all parties including review dates and confirmation that alternative means of seeking compliance and the risks resulting from failure to administer have been considered.

11. Research Clinical Trials

Registrants involved in the administration of treatment or placebos as part of a clinical trial will need to be informed that the trial is taking place in order to ensure informed consent is obtained from the patient. The registrant does not need to consent to taking part in the trial. There should be no reasons for the registrant to object to taking part in the trial as patients are not being deprived of a known effective treatment as a result of participating in the trial.

12. Self Medication

Self medication by patients is very unlikely to be appropriate due to the nature of the service provided by the different departments in NHSBT involving patient and donor procedures and the drugs used by NHSBT. Most drugs used by NHSBT are given by injection or intravenous infusion. Oral drugs used are normally used for one off events or symptoms on a PRN basis and as such are not part of a patient's regular medications. Patients attending NHSBT on an "outpatient" basis remain responsible for the administration of their own regular medication. "In patients" treated by NHSBT remain under the care of the referring trust for administration of regular medication.