North Somerset
Clinical Commissioning Group

NHS North Somerset

Clinical Commissioning Group

Medicines Policy - Safe and Secure Handling of Medicines

Approved by:	**Quality and Assurance Group**
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Contents

1. Introduction and Background

Activities involving medications occur in various settings within North Somerset and are undertaken by a variety of different staff groups. The policy has been updated to meet the demands of the various care settings and the various staff groups. This policy is intended to support compliance with the Care Quality Commission standards for medicines management. It incorporates guidance on the safe and secure handling of medicines as outlined in "The Safe and Secure Handling of Medicines: A Team Approach 2005" Royal Pharmaceutical Society of Great Britain and the Nursing and Midwifery Council "Standards for Medicines Management 2010".

2. Purpose and Scope

This policy has been developed to inform GP practices who are members of North Somerset Clinical Commissioning Group (CCG) and CCG employees on the safe management of activities involving medications with the aim of maintaining the safety of both patients and staff.

Activities involving medications should be undertaken safely and accurately in line with agreed best practice and in accordance with guidance issued by the relevant professional bodies, including but not limited to, the Secretary of State for Health, the General Medical Council, the Nursing and Midwifery Council, the General Pharmaceutical Council and local policies and procedures. All staff groups involved in activities concerning medication must be familiar with this policy including but not limited to prescribers, nurses, pharmacy technicians, health care assistants, pharmacists. This policy is designed to provide an umbrella under-which local standard operating procedures and protocols can be developed. All staff employed by North Somerset CCG must adhere to this policy. Other contractors would be expected to follow the principles of this guidance as good practice. If difficulties are encountered implementing this policy these should be discussed with your line manager, the Lead Clinician or the Medical Director or the Lead Pharmacist.

3. Responsibilities (individual posts/groups or committees)

The person with overall responsibility for a clinical area (e.g. Clinical Lead) is responsible for the medication related activity in his/her clinical area. They must protect service users against the risks associated with the unsafe use and management of medicines, by means of the making of appropriate arrangements for the obtaining, recording, handling, using, safekeeping, dispensing, safe administration and disposal of medicines used for the purposes of the regulated activity. They must also ensure that staff handling medicines have the necessary competencies and skills needed. The responsibility remains with this person even if this duty is delegated.

Individuals are professionally accountable for their actions and must be working in accordance with this policy (or its principles) and their professional body standards.

4. Process

Standard operating procedures should be in place for clinical settings where medication related activity is undertaken. These procedures should include the following:

- Placing orders for medication
- Receipt of medication deliveries
- Storage of medication including refrigerated storage and maintaining the cold chain & controlled drug storage
- Monitoring & recording fridge temperatures
- Recording/management of stock including discrepancies
- Control of access to medication
- Monitoring/managing medication expiry dates
- Preparation of medicinal products
- Prescribing or supply of medication via all mechanisms including Patient Group Direction (PGD) and Patient Specific Directions
- Administration of medication including 'as required' (PRN) medication, actions if medication is refused/unable to be administered, self-administration, allergies
- , aAdministration of medicines via different routes including the measuring and administering of oral liquid medicines via an oral or enteral syringe, IM, IV, SC, etc
- Recording of medication administration, prompting and delayed or omitted doses
- Monitoring
- Reporting of errors, near miss and adverse events
- Medicines reconciliation and discharge medication
- Medicines required for resuscitation or other medical emergencies
- Disposal of medication
- Disposal of sharps waste
- Processes for controlled drugs

4.1 Supplies, Storage and Security of Medicine

To ensure product quality is not compromised medication must always be obtained from an appropriate source in the medication supply chain, such as an NHS hospital pharmacy, a registered community pharmacy, a holder of a wholesaler dealer's license or the holder of a manufacturer's license.

Where medicines are supplied directly to patients, these must be appropriately labelled in accordance with the requirements of the Medicines Act.

All healthcare practitioners have a responsibility for ensuring medicinal products are stored in accordance with the manufactures instructions as this ensures the product will be of the expected quality when it is used.

Although this section does not apply to the storage of medication in patient homes, advice should be given to patients regarding appropriate storage of medication, so that medication quality is maintained as well as the safety of the public.

All sites where medication storage occurs must have the appropriate designation and registration to ensure medication storage activity is authorised. When not in use all medication must be stored in a dedicated locked cupboard, locked refrigerator or locked medicine trolley. The only exception to this rule is the storage of drugs for use in an emergency such as cardiac arrest boxes and anaphylaxis boxes which should be stored away from public areas but quickly accessible in a life threatening emergency. These medicines should be stored in tamper evident packaging. All storage units must meet the required standards set out below and items other than medicinal products should not be stored in these dedicated receptacles. Checking the expiry dates of stored medicinal products, recording this check and acting on the findings should be completed on a regular basis.

4.2 Medicines Reconciliation

in a timely manner for example at registration with the practice, on admission and discharge from hospital, and following any changes in medication.

4.3 Controlled Drugs

A controlled drugs cupboard contains those drugs controlled by the Misuse of Drugs Regulations (1971) as amended and such storage MUST comply with the Misuse of Drugs (Safe Custody) Regulations 1973. A controlled drug stock check should take place regularly according to local protocol. Further guidance can be found in the standard operating procedures for controlled drugs, including guidance on keeping a stock balance.

4.4 Internal Medicine Cupboard

Contains preparations for internal administration other than those which are controlled drugs. Such storage must comply with the British Standard Specification for Cupboards for the storage of medicines in health care premises (BS2881:1989).

4.5 Refrigerator

Refrigerators used must be designed for the storage of pharmaceutical products, must continually monitor internal temperature with a maximum–minimum thermometer and be calibrated annually. A fridge temperature audit should be undertaken annually and fridge temperature readings should be reviewed and recorded at least once each working day.

4.6 Access to medication

Any staff member may be granted access to medications at the discretion of the service manager if they legitimately need access to a particular medicine in order to fulfil their role. For the purpose of this document these individuals will be referred to as authorised persons. Authorised persons will generally be registered nursing staff, but could also include medical staff and allied health professionals.

If keys to medicines cupboards are mislaid, following the resolution of access issues, any loss of medicine cupboard keys or removal of medicine cupboard keys from a clinical site must be reported as a clinical incident. If the keys provide access to controlled drugs, the Controlled Drug Accountable Officer must also be informed. Further information about the Controlled Drugs Accountable Officer role can be found in the Controlled Drugs Standard Operating Procedure and from the Medicines Management Team.

4.7 Transport of medication

Authorised persons may have need to transport medication which legally belongs to a patient or transport medication required for that member of staff to undertake their clinical duties.

Transportation of patient's medication should only occur where not doing so may compromise patient care and other methods of timely transportation have been exhausted or where leaving medication in the patient's home constitutes an unacceptable risk to patient safety. Where this occurs, the reasoning should be documented in the patient's notes and receipt should be signed for wherever possible.

Any authorised person who undertakes collection of medicines on behalf of patients must assume responsibility for safe transmission and delivery of the medication.

Once received medicines should be transported as soon as practically possible. Medicinal products must be stored in accordance with the manufacturer's instructions during transportation. Care must be taken not to exceed maximum or minimum temperatures, particularly in extreme weather conditions i.e. very hot or very cold weather. Validated cool boxes which contain ice-packs and maximum – minimum thermometers should be used to transport medicinal products when maintaining the cold chain between 2 -8C is required.
During transportation medicines must be kept out of sight and under control of the authorised person, ideally in a locked receptacle.
During the authorised person's hours of duty, the locked receptacle may be the locked boot of the authorised person's car, ensuring the temperature of the boot meets the manufacturer's storage requirements.
Medication should not remain in possession of the authorised person once their shift has ended.

4.8 Prescribing

Prescribing is “to order in writing the supply of a prescription only medicine or any other medicine for a named patient”. The following professional groups are able to act as prescribers in the UK and prescriptions written by them may be encountered by staff members:

- Doctors with current General Medical Council registration
- Dentists with current General Dental Council registration
- Pharmacist Independent Prescribers registered as such with the General Pharmaceutical Council
- Nurse Independent Prescribers registered as such with the Nursing and Midwifery Council (NMC)
- Optometrist Independent Prescribers registered as such with the General Optical Council
- Community Practitioner Nurse Prescribers registered as such with the Nursing and Midwifery Council
- Supplementary prescribers registered as such with their professional body and may include nurses, pharmacists, physiotherapists, chiropodists or podiatrists, radiographers and optometrists working under a patient specific clinical management plan, agreed with a doctor.

North Somerset Community Partnership eEmployees must have their role as a prescriber listed in their job description before they may take on this activity. Please see the non-medical prescribing policy for further information.

A prescription may take the form of an NHS prescription form, a non-NHS prescription (private) and in a hospital or in the ‘community’ a written patient specific direction to supply and/or administer a medication via a medication administration chart. No-one should attempt to amend or alter a prescription unless they belong to one of the groups listed above or are cancelling the prescription on the advice of a prescriber (see “cancelling a prescription”). Where an amendment is required to a prescription best-practice is for the original prescription to be cancelled and re-written. Where following best-practice is not possible any amendment made to a prescription should be clear and unambiguous and dated and signed or initialled by the prescriber.

A prescription should include the following:

- Be written legibly in indelible ink.
- State the name and address of the patient
- State the age of the patient if they are under 12 years old
- Substance name (not abbreviated and using approved titles only)
- Formulation e.g. slow release tablet, tablet, suppository, liquid
- Route of administration
- Dosage
- Dosage frequency
- Minimum dose interval for preparations to be taken ‘as required’ e.g. one to be taken as required, up to every three hours
- Number of doses to be supplied or the duration of treatment

- Be signed in ink by the prescriber
- Be dated

Prescriptions written on an NHS prescription form should also:

- State the address of the prescriber
- Indicate the type of prescriber e.g. doctor, pharmacist independent prescriber, nurse independent prescriber, supplementary prescriber etc

Prescriptions for controlled drugs written on an NHS prescription form must also state:

The strength of the preparation to be supplied
The total quantity (in both words and figures) of the preparation
OR
The number (in both words and figures) of dosage units to be supplied

The Department of Health have recommended that for controlled drugs schedule 2, 3 and 4, the maximum quantity prescribed should not exceed thirty days.

To ensure that prescriptions are unambiguous the following must be adhered to:

The unnecessary use of decimal points must be avoided, 3mg, not 3.0mg
'Micrograms' must not be abbreviated
'Nanograms' must not be abbreviated
'Picograms' must not be abbreviated
'Units' must not be abbreviated

4.9 Medical Gases

Oxygen should be regarded as a drug and as such should be prescribed, and stored correctly.

4.10 Cancelling a prescription

A prescription or a written patient specific direction to supply and/or administer will only be valid for a set time period, usually six months, or 28 days in the case of controlled drugs. Where patient care demands a change in therapy a prescription or written patient specific direction to supply and/or administer may need to be cancelled. When cancelling a prescription or a written patient specific direction to supply and/or administer, it is good practice for the person making the cancellation to print their name and designation (e.g. pharmacist) and to sign and date the cancellation and ensure the prescription/direction has been clearly marked to ensure further inadvertent medication administration does not occur. This may also include contacting the patient's regular pharmacy, particularly if the patient uses a monitored dosage system or repeat dispensing. An entry in the patient's notes indicating the reason for the cancellation is also required, particularly when there is multi-disciplinary involvement in a patient's care.

4.11 Considerations for Prescribing

The prescribing of medicines should be appropriate for and tailored to the individual and should take into account their age, personal preferences, cultural and religious beliefs, any allergies and intolerances, existing medical conditions,

other medication, previous adverse drug reactions. Prescribing is expected to follow local and national guidelines e.g. BNSSG (Bristol North Somerset South Gloucestershire) Formulary, NICE guidance etc.

4.12 Unlicensed and off-label prescribing

Medicines licensed in the United Kingdom should be prescribed wherever possible. In a limited number of circumstances, medicines licensed in the United Kingdom may need to be prescribed for use outside of their license (off-label) or unlicensed preparations may be required. When prescribing off-label or unlicensed preparations prescribers should be satisfied that an alternative licensed medicine or appropriately licensed medicine would not meet the patient's needs. Information must be given to patients or those authorising treatment on their behalf to allow them to make an informed decision about their treatment, particularly where proposed treatment is an unlicensed preparation.

4.13 Mixing of Medicines

Medicines should not be routinely mixed prior to administration as mixing two or more medicines together produces an unlicensed preparation. In some circumstances, mixing of medicines may be required for the benefit of patients (e.g. palliative care syringe drivers). In these cases a prescriber may direct a practitioner to mix two or more medicines together and this should be done using a patient specific direction or prescription.

4.14 Administration of Medicines

Authorisation to administer a medication may take many various forms as discussed above and includes the use of Patient Group Directions (See Procedure for the development, approval and implementation of patient group directions for further details), patient specific directions, homely remedies, prescriptions and Medicines Act exemptions.

The person with overall responsibility for a clinical area (e.g. Clinical Lead) is responsible for authorising the medication related activity in his/her clinical area. Where a registered professional delegates tasks to another person, the individual delegating the task is responsible for any aspects of administration and is accountable for ensuring that the person to whom the task is delegated is competent to carry out the task.

Persons administering medication must have a legal mechanism to do so and must have achieved the relevant competencies to undertake the task. This activity must form part of their job description.

Before administering a medicinal product you must always check that:
The authorisation to supply and/or administer is written by a person authorised to prescribe or is otherwise appropriately authorised (e.g. patient group directions)
The authorisation to supply and/or administer meets the prescription requirements listed in the prescribing section (above)

The medicine is safe and appropriate to administer, ensuring any monitoring or review required has been undertaken according to the patient's condition including checking expiry date.
The patient or the person authorising treatment on their behalf has received sufficient information about the proposed course of treatment, including any known serious or common side-effects or adverse reactions. This is to enable them to make an informed decision about receiving treatment. Patients must receive a patient information leaflet for the medicine that is prescribed for them. These are available from www.medicines.org.uk and should normally be supplied by the dispensing pharmacy.

When administering a medicinal product you must:

- Clearly identify the patient for whom the medication is intended
- Check the direction is based on the patient providing informed consent and their awareness of the treatment purpose.
- Record the weight of the patient for all children and where the dosage of medication is related to weight or body surface area.
- Check it is not for a substance the patient is allergic to or unable to tolerate
- Know the therapeutic uses of the medicine to be administered, its normal dosage, side effects, precautions and contra-indications
- Be aware of the patient's plan of care, including an up-to-date list of other medicines being taken, including homeopathic, herbal and over the counter medicines
- Be aware of any special considerations for prescribing relating to the patient i.e. in children, the elderly, renal or hepatic impairment, pregnancy and breast-feeding, which may require dose or treatment modification
- Check the expiry date of the medication to be administered
- Have considered the dosage, method of administration, route and timing
- Administer or withhold in the context of the patient's condition and co-existing therapies.
- Never prepare a medicine in advance of its immediate use. Medicines should be administered by the practitioner preparing the medicine or have been prepared in the presence of the practitioner administering.
- Contact the prescriber or another authorised prescriber without delay where contraindications to the prescribed medicine are discovered, where the patient develops a reaction to the medicine, or where assessment of the patient indicates that the medicine is no longer suitable.
- Make a clear, accurate and immediate record of all medicine administered, prompted, intentionally withheld or refused by the patient, ensuring the signature is clear and legible; it is also your responsibility to ensure that a record is made when delegating the task of administering or prompting medicines. Where appropriate record batch number and expiry date
- Following the resolution of immediate patient safety issues, any medication error relating to medication administration must be reported as a clinical incident and to the prescriber.
- Where a medicine is not administered, the reason for doing so must be recorded; the prescriber informed and further advice should be sought.

4.15 Administration via Percutaneous Endoscopic Gastrostomy (PEG)

Administration of medication via PEG tubes requires care as the majority of medicines are not licensed for administration via this route and this constitutes off-label prescribing. Advice of suitability of medications for crushing and/or administration via a PEG tube should always be sought from a pharmacist and full administration directions must form part of the prescription.

4.16 Administration of Medicines to Children

Where children's drug doses are calculated according to the weight of the child, it is essential that weight is recorded on the patient record. Weight and dose prescribed should be reviewed and recorded at regular intervals.

4.17 Medicines Adherence

Adherence to medication should be assessed whenever medication is prescribed, dispensed, administered or reviewed. This should be done in a non-judgmental way and recognised that it is a common problem. Patients may need individualised support to help with adherence to medication and advice should be sought from a pharmacist. Considerations may include side effects, timing of medication and the number of times a day a medicine is taken. Further information on the medicine may need to be provided to the patient. When prescribing, patients should be involved in any decisions about medicines and options provided that may improve adherence. For further information see NICE CG 76: Medicines adherence: Involving patients in decisions about prescribed medicines and supporting adherence. (www.nice.org.uk)

4.18 Remote Directions

In exceptional circumstances, where medication (not including controlled drugs) has been previously prescribed and the prescriber is unable to issue a new prescription to amend directions or dose, changed instructions must be confirmed in writing e.g. by fax or email. This method should only be used to confirm changes to the original prescription rather than for administration of a new medicine.

4.19 Use of Samples

Samples of medicines must not be used as the supply chain and product integrity cannot be guaranteed. Foodstuff samples e.g. sip feeds may be used to facilitate patient choice and appropriate product selection.

4.20 Covert administration

A best interests meeting must be held with people who know and understand the patient to decide whether this is in the patient's best interest.

4.21 Disposal of medication

Medicinal products should be disposed of in accordance with pharmaceutical waste legislation and local policy. It should be remembered that all items issued to an individual patient via an NHS prescription form are the property of that patient and disposal of them without the patient's permission constitutes theft. Patients can return unwanted medicines to any community pharmacy for safe disposal. Care homes registered to provide nursing care must have their own disposal arrangements in place.

4.22 Safety: Reporting of errors, a near miss and adverse events

There should be systems in place which allow reflection and learning from the findings of local reporting of adverse events, incidents, errors and near misses relating to medicines. The learning which occurs within the service and elsewhere should be actively disseminated and policies updated to reflect any changes required so that the risk of the incidents being repeated is reduced to a minimum and an open and fair culture of safety is promoted.

Patient safety alerts, rapid response reports and patient safety recommendations which are disseminated by the National Patient Safety Agency and which require action must be acted upon within the required timescales. The arrangements for local reporting of adverse events, adverse drug reactions, incidents, errors and near misses should link in to national reporting systems where applicable. Separate policies or procedures may be required to support and implement such alerts and should be read in conjunction with this policy where available.

Any drug may produce unwanted or unexpected adverse reactions. All serious adverse reactions to established medicines and any reaction to black triangle (newly licensed) medicines should be reported to the Medicines Healthcare Regulatory Authority using the yellow card system (www.yellowcard.gov.uk) . All patient records should be updated to reflect any adverse events.

4.23 Medicines Management following Death of a Patient

Following the death of a patient, the medicines become the property of the deceased's estate. Family should be encouraged to return these medicines to a community pharmacy for disposal. Where there are concerns that these medicines may be misused, diverted or pose a risk to safety, staff may take them directly to a community pharmacy upon leaving the patient's home. Where this occurs, the reasons for removal should be documented in the patient's notes and where possible, witnessed. Receipt of the medication by the pharmacy should be confirmed in writing.

5 Training requirements

Staff administering medicines should be competent according to the National Occupational Standards for medicines (see appendix one)

6 References

- 'The safe and secure handling of medicines: a team approach' March 2005 (A revision of the Duthie Report (1988)RPSGB, 2005.
- Department of Health (2000) HSC 2000/026: Patient Group Directions [England only]
- The Health Bill 2006 – In relation to Accountable Officers and their responsibility relating to Controlled Drugs.
- Safer Management of Controlled Drugs **-**A guide to good practice in secondary care (England) *October 2007*
- Controls Assurance standard: Medicines Management (Safe & Secure handling) 2003.
- BNSSG Formulary available from www.bnssgformulary.nhs.uk .
- The current British National Formulary (updated every six months) must be available wherever drugs are administered and current British National Formulary for Children (updated annually) in those areas where children are cared for. Also available online at www.bnf.org.uk
- NMC Standards For Medicines Management 2010
- Safer management of controlled drugs: Guidance on strengthened governance arrangements (DH, 2007)
- Safer management of controlled drugs: Guidance on standard operating procedures for controlled drugs (DH, 2007)
- The handling of medicines in social care (RPSGB, 2007)
- National Patient Safety Agency (NPSA) – alerts relating to medicines
- National Institute for Health and Clinical Excellence (NICE)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Department of Health (DH)
- Royal Pharmaceutical Society of Great Britain (RPSGB)
- Social Care Institute for Excellence (SCIE)
- Medical and other clinical royal colleges, faculties and professional associations

7 Associated documents

Only reliable and up-to-date sources of medicines information should be used. This may include accessing online reference sources. The following sources are recognised as providing reliable information

www.bnf.org.uk
www.evidence.nhs.uk
www.medicines.org.uk
www.nice.org.uk

If you require information and need individualised patient advice on medicines, this should be sought from a pharmacist or the prescriber. Medicines information is also available through regional United Kingdom Medicines Information (UKMI) centres. Details of which can be found in the current edition of the BNF. Further information can be found in the references section of this document.

Medicines Management Competencies **Learner name…….. Role: ……..Base……**						
	Assessor to state O (observed) and V (Verbal)					
Assessor- initial and date successful completion of <u>all</u> criteria						
Underpinning Knowledge						
Identify current legislation, guidelines, policies and protocols relevant to the administration of medication						
Explain personal responsibilities and accountability for medicines administration						
Explain the different routes of medicine administration						
Understand the common types of medicines and the rules for their storage						
Identify situations where it may be inappropriate to give a prescribed medicine and the alternative action to be taken.						
Explain the hazards and complications which may arise during the administration of medications and how you can minimise such risks						
Describe the actions to be taken in the event of an error or adverse incident associated with medicine administration.						
Be able to order, store, maintain security and dispose of drugs, including Controlled Drugs (CD) appropriately and safely.						
Be familiar with the equipment used in administration of medication by routes other then oral e.g. syringe driver, IM injection, NG. Medical gases and be aware of hazards.						
State the correct method of patient/client identification						
Identify the required information from prescriptions/ medication administration charts.						
Read the prescription accurately and question any part which may cause concern						
Have knowledge of each drug prescribed, it's indications for use, effects, dose range, route, frequency, side effects and contraindications.						
Understand the roles of other healthcare staff when delegating, administering and checking medications, including CD's and other medications.						
Understand the implications of "crushing" medications, administering "un-licensed" and "out-of licence" use of medications.						

Identify which medicines may require specific clinical measurements and why these are needed.						
Understand the importance of checking for and recording allergies and adverse reactions, including yellow card reporting, where appropriate.						
Demonstrate how to prepare a medicine using a non-touch technique and apply standard precautions for infection prevention and control						
Explain the appropriate timing of medication, including checking that the individual has not already taken the medication.						
Understand the need and importance of educating the patient about their medication and the effects of medication on their health.						
Describe appropriate and safe use of taking orders for medications that are not prescribed, including transcribing.						
Understand the importance of accurate record keeping and the implications of poor record keeping, including omissions						
Clinical Skill						
Demonstrate safe and competent technique in administering medicines, minimizing pain, discomfort or trauma to the individual						
Check and confirm that the individual actually takes the medication						
Uphold the role of advocate for the patient and treat with respect and maintain dignity at all times						
Involve the patient in all decisions about their care and ensure they have enough information to be able to give informed consent to treatment						
Describe how to report any problems with administration, including any previous discrepancies						
Monitor the individuals condition throughout, recognise any adverse reactions and take any appropriate action without delay						
Comments:						

As the assessor the signature states that you have either observed practice or verbally questioned the learner against **all** of the stated criteria and they have successfully completed or shown appropriate knowledge. You will need to use this sheet and the criteria for each observation.