NHS
Telford and Wrekin
Clinical Commissioning Group

Policy on the Safe and Secure Handling of Medicines

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Introduction

1. This policy aims to provide 'best practice' guidance to ensure that all staff members working for independent contractors within NHS Telford & Wrekin CCG, are aware of the requirements to ensure medicines are handled safely and securely.

2. Ultimately the policy aims to ensure that the patient receives the correct medication in a safe and timely manner.

3. 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 Waste.

4. 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 their Professional Code of Conduct
   - Complies with current Statutory Legislation
   - Follows guidance issued by the Department of Health, professional bodies (e.g. Nursing and Midwifery Council, General Pharmaceutical Council) or other government departments such as the Home Office
   - Manages the risks to patients, relatives, carers and staff arising from the use of medicines

5. Heads of Services/Managers shall be responsible for:

   - Putting in place Standard Operating Procedures (SOPs) to detail the specific activity elements, which will support the requirements of this policy.
   - Safe and Secure Handling of Medicines
   - Ensuring staff involved in any aspect of medicines use are aware of this and other relevant policies, that they understand their responsibilities, have access to the policies and undertake training if required
   - Adhering to the Health and Safety at Work Act and COSHH regulations when handling medicines
   - Ensuring that systems for routine audit, relating to the safe and secure handling of medicines, are in place to ensure compliance with policies.
   - Ensuring that reviews of incidents and patient complaints relating to the handling of medicines take place.

6. It is acknowledged that there may be changes in practice and new situations may arise before the next formal review of this policy. Staff should use their professional judgment, be aware of their own limitations and seek advice or consult with senior staff where necessary.

7. The document aims to direct the practice of ALL staff who handle medication within their professional role, it illustrates good practice and as such will be shared with colleagues across the healthcare community.

Terminology

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

9. Patient is used throughout to refer to people receiving medicines although individual services may refer to them, for example, as service users or clients.

10. Controlled stationery is any paperwork such as requisition forms or prescription pads that can be used to obtain medicines as designated.

11. Prescriber means any professional with the authority to prescribe, namely, doctor or dentist (as used in the Medicines Act 1968) and nurse (as recorded by the Nursing and Midwifery Council as a Nurse Prescriber) or pharmacist (as recorded by the General Pharmaceutical Council).

12. Registered Nurse means a person who is registered in the professional register of the Nursing and Midwifery Council.
The following may order, have custody of, and administer medicines:-

- Registered Nurse (1st and 2nd level) (RGN)
- Registered Midwife (RM)
- Registered Mental Nurse (RMN)
- Registered Nurse in Mental Handicap (RNMH)
- Registered Sick Children's Nurse (RSCN)

13. Patient Group Direction (PGD) is a written direction relating to the supply and administration (or administration only) of a licensed prescription-only medicine by certain classes of healthcare professional; the direction is signed by a doctor (or dentist) and by a pharmacist. It applies to groups of patients who may not be individually identified before presenting for treatment. Further information on Patient Group Directions is available in Health Service Circular HSC 2000/026 and the CCG Policy on the Management of PGDs.

14. Standard Operating Procedure (SOP) details responsibility, record keeping and reconciliation at each stage of the medicines supply process, providing an audit trail to minimise the risk of harm to patients or staff, and to reduce the incidence of theft or fraud.

15. A Patient Specific Direction (PSD) is a written instruction, from a doctor or dentist to another health care professional, to supply or administer a medicine to a specified patient.

Initiation of Treatment/Prescribing

16. A patient's treatment must be initiated through a formal process, which may be the production of a prescription or PSD by an authorised prescriber or by an approved Patient Group Direction (PGD). For further guidance on PGDs refer to the CCG Policy on the Management of PGDs.

17. Any person issued with a blank prescription will be held accountable for its security and local arrangements must be documented in a SOP.

18. When writing a prescription the current guidelines for prescription writing, as documented in the British National Formulary (BNF), will be followed:

- Written legibly in ink or otherwise so as to be indelible.
- Must be dated.
- Should state the full name and address of the patient.
- Specify the approved name and form of the drug.
- Should be signed in ink by the prescriber.
- The age and date of birth should preferably be stated (this is a legal requirement if the prescription is for a prescription only medicine issued to a child under 12 years of age).
- The unnecessary use of decimal points should be avoided e.g. 3mg not 3.0mg.
- 'Micrograms' and 'nanograms' should not be abbreviated. Similarly 'units' should not be abbreviated.
- The term 'millilitre' (ml) is used in medicine and pharmacy, and cubic centimeter, c.c., or cm^2 should not be used.
- Clear directions should be given – avoid using 'as directed', 'as necessary', 'when required'.
- The drug name should be written clearly and not abbreviated, using approved titles only.
- Although directions should preferably be in English, without abbreviations, it is recognised that some Latin abbreviations are used.

19. Independent non-medical prescribers must only prescribe within their area of competence and supplementary prescribers must only prescribe in accordance with an agreed clinical management plan (individualised for each patient) and within their scope of practice. See the CCG's Non-Medical Prescribing Policy.

20. Prescribers should avoid prescribing for themselves or anyone with whom they have a close personal relationship.

21. Medical, dental and non-medical prescribers may prescribe unlicensed medicines (i.e. those without marketing authorisation) or withdrawn

medicines. In such cases the manufacturer will accept no liability for any harm and this will rest with the prescriber. The prescriber should inform the patient or the patient's carer, that the product does not have a marketing authorisation.

22. Specific requirements for anticoagulants and injectables.
Prescribers who prescribe anticoagulants, methotrexate and/or injectables are required to have the necessary competencies as outlined in the NPSA Patient Safety Alerts (18 and 20 respectively) www.nrls.npsa.nhs.uk. Injectables should not be prescribed unless a risk assessment has been completed.

A SOP is required for the prescribing of injectables.

23. Where prescribers are prescribing high doses of Controlled Drugs, it is recommended that specialist advice and support is sought, wherever feasible. Any actions resulting from such a contact should be recorded in the patient's notes.

24. If a prescriber is prescribing high doses of CDs for a patient, particularly where prolonged use is expected, then it is recommended that this is reported to the CCG CD Responsible Officer to aid the interpretation of routine prescribing data.

Storage of Prescription Pads and other Controlled Stationery.

25. Prescription pads are controlled stationery (i.e. stationery which, in the wrong hands, could be used to obtain medicines and/or medical items fraudulently) and are the property of the employing organisation.

26. The security of the prescription pad is the responsibility of the prescriber. This includes both individual prescription pads and single sheet prescription forms (computerised).

27. For prescription pads, the prescriber must keep a record of the serial numbers of the first and last prescription numbers on receipt of a new pad. It is advisable that the prescriber is aware of all prescriptions used/written so that, in the event of a pad being lost or stolen, the number remaining can be estimated.

28. For computerised prescription forms, the practice must ensure that a record is kept of the serial numbers of each new box of prescription sheets upon arrival. A record needs to be kept of which serial numbers have been issued to each consulting room. At the end of each session, all sheets must be removed from the printer and stored securely. The same batches of prescription sheets should then be returned and used in the same consulting room at the beginning of the next session. Best practice is to record the serial number of the first prescription sheet at the beginning of each session.

29. Under no circumstances should blank prescription forms be pre-signed before use.

30. Prescription pads should not be left unattended or accessible to others. They should be locked away securely and access should be restricted to the individual prescriber. This includes single sheet prescription forms left in printer trays.

31. Further detailed information regarding security of prescription forms can be found in 'Security of prescription forms guidance' obtained from NHS Business Services Authority at Security of prescription forms guidance NHSBSA updated Aug 2013

32. When travelling, the prescription pad should not be visible and should be locked in the car boot. The prescription pad should be removed when the car is left unattended.

33. The prescription pad is the property of the employing organisation and must be returned to the Logistics Team at PCSS Logistics Services, Parkside House, Quinton Road, Coventry CV1 2NJ upon termination of employment or when the prescriber ceases prescribing duties.

34. All controlled stationery must be stored in a locked cupboard or drawer when not in use including single sheet prescription forms left in printer trays.

35. Each practice should have a Standard Operating Procedure for the management of controlled stationery.

Lost or stolen prescription pads

36. In the event of loss/theft of prescription pads, the prescriber must, **as a matter of urgency,** contact the Local Counter Fraud Specialist on 07774332194 or by e-mail to counterfraudteam@cwaudit.org.uk. If the situation is urgent then contact the police directly on 08457 444888.

    The pad holder will need to inform the Local Counter Fraud Specialist of the following details:

    - approximate number of prescriptions lost/stolen
    - the serial numbers of the prescriptions lost/stolen
    - when and where the pads or forms may have been lost/stolen
    - the practice/trust code
    - your contact details

Dispensing

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

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

39. As a minimum standard, each service/healthcare setting must have SOPs in place as detailed in the relevant contractual arrangements.

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

Ordering and Receipt of Medicines

41. 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

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

43. Verbal requests for medicines supply should not be made.

44. 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 through the normal channels.

45. Products such as vaccines should have additional quality checks to ensure, for example, that the storage requirements through the 'cold chain' have been maintained.

46. If patients own drugs are being received, local procedures will document the steps to be taken to ensure their integrity, in so far as it is practical to do so. As a minimum, the quality and accuracy of the labelling should be checked.

47. Samples of medicines, including free samples of medicines or dressings provided by the manufacturer of that product, must not be used to treat patients.

Transport and Security

48. Transportation of medication is not encouraged but staff may carry medicines from a community base, pharmacy or GP to a patient's home (and vice versa). In such an instance the member of staff is acting on behalf of the patient as their agent.

49. The healthcare professional must only transport medicines to a named client on the day of administration.

50. Wherever possible, medicines should be transported in a locked box or case. This must be transported out of sight in a locked car boot. If the container is lost or stolen it must be reported immediately to the line manager.

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

52. Cold chain control, within the limits appropriate to the individual product, should be maintained for items requiring refrigeration as outlined in Chapter 3 of the 'Green Book' Chapter 3 Green Book and the CCG's vaccine cold chain standards policy http://www.telfordccg.nhs.uk/vaccines

53. Unused/unwanted medicines are the responsibility of the patient. Any such medicines should be returned to a pharmacy by the patient or carer. However, the practitioner at his/her discretion can do this if the patient is unable to do it themselves. A clear audit trail must be maintained.

54. 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.

55. Arrangements for the transport of controlled drugs must comply with the current legal requirements.

Storage and Security.

56. 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.

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

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

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

60. Access to the cupboards should be restricted to authorised staff only. Staff in any supervisory position should be aware of the 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.

61. 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 or door)
    - 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)

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

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

64. 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.

65. Healthcare staff should advise patients and their carers on the safe and secure storage of medicines in the home.

Storage of Refrigerated Medicines

66. Medicines that require storage below room temperature should be stored in a medicines refrigerator. By definition refrigeration is a temperature of 2^{o}C -8^{o}C.

67. Medicines refrigerators should be cited in a locked room or in a position to allow continuous surveillance and maximum security against unauthorised entry.

68. Storage of refrigerated medicines should mirror the security afforded to other medicines stored in practices e.g. if the refrigerator is cited in a dispensary where the medicines are stored on open shelves, then a lockable refrigerator should be unnecessary.

69. The power supply to the refrigerator should be clearly identified to avoid accidental interruption of electrical power. Ideally, the supply of electricity to the refrigerator should be via a hard wired fuse system.

70. The temperature of the refrigerator should be monitored and recorded on each working day using a calibrated maximum-minimum thermometer and

a written procedure should be in place indicating the action to be taken if the temperature falls outside of the normal range.

71. In the event that a medicine has not been stored at the correct temperature for any reason, the viability/pharmaceutical stability should be checked with the manufacturer before use.

72. Food and/or drink should not be stored in the medicines fridge. Medicines should not be stored in a food fridge.

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

74. See CCG's vaccine cold chain standards policy for further information http://www.telfordccg.nhs.uk/vaccines-

Storage of Emergency Medicines

75. Adequate provision must be made to ensure access to medicines in an emergency. For local guidance see Emergency drugs for GP practices

76. The local storage arrangements will, by necessity, be a balance between quick access and the risks associated with misappropriation. It is recommended that medicines for emergency use be stored in a tamper evident container, kept in an easily accessible place.

Custody and Safe Keeping of Keys

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

78. Where practical, keys will be kept securely in key cupboards with restricted access to authorised staff only.

Loss of Controlled Stationery, Keys or Medicine

79. On discovering the loss, the member of staff must immediately inform the designated manager/clinical lead.

80. The designated manager/clinical lead will immediately investigate any loss (including consideration of notifying the police) and follow the incident reporting procedure.

81. 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.

82. If duplicate keys are not available or the lost keys not found, the authorised person in charge, in conjunction with their manager or clinical lead 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.

Administration

83. No person should administer any medicine unless they are competent to do so and are acting within their sphere of professional practice. A SOP should define the qualifications and competencies required by service staff, including the provision for training student professionals. Nurses must adhere to the Nursing Midwifery Councils – Standards of Medicines Management.

84. A health care professional must not administer medicines without the authorisation of a prescriber, a patient specific direction, a dispensed medicine or a patient group direction, unless they have legal exemptions during the course of their professional practice e.g. midwives, podiatrists.

85. A carer/relative can administer a CD that has been individually dispensed for a patient designated under their care. (In order to do so, it should be ensured that adequate information has been supplied to support the carer and that they are considered competent to administer the medication). Medication MUST only be administered under the guidance and advice of a prescriber.

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

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

- patient's name
- 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.

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

- name of the medicine
- strength
- form
- expiry date
- that the dose has not already been given.

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

90. Staff administering controlled drugs in the patient's home will keep a record of administration and the number of dose units remaining.

91. All omitted, refused or wasted doses should be recorded.

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

93. Medicines shall not be returned to the container from which they were taken; dispensing of medication from one container to another is not allowed outside of a designated dispensary area.

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

Administration - Verbal Orders

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

96. An independent prescriber, in exceptional circumstances, may make a telephone request to a registered nurse for a medicine to be given without a written prescription. This should only be done as a last resort, if no other options are available (for example, delivery of prescription by courier or taxi, or use of a fax). The prescriber must state the following:-

- name of the patient
- name of the drug
- the dose to be given
- the route of administration
- the timing and frequency of administration

The registered nurse must:-

- be satisfied that the individual they are speaking to is genuine, and is a registered prescriber.
- be satisfied that the circumstances justify accepting the verbal request
- repeat the information back to the prescriber in order to confirm it
- make an immediate record in the nursing notes and sign it, recording:
  - that a verbal order was taken and the details of that order
  - the prescribers details
  - the time
  - the date

The registered nurse should, wherever possible, ask the prescriber to repeat the information to a second nurse for confirmation.

It is the responsibility of the prescriber to ensure that written confirmation of the verbal request is received within twenty-four hours.

Administration and/or supply of Unlicensed Medicines under a PGD

97. An unlicensed medicine is the term used to refer to a medicine that has no product license. If an unlicensed medicine is administered to a patient, the manufacturer has no liability for any harm that ensues. The person who prescribes the medicine carries the liability.

98. If a medicine is unlicensed, it should only be administered to a patient against a patient-specific prescription and not against a PGD. However, medication that is licensed, but used outside its licensed indications, may be administered under a patient group direction if such use is exceptional, justified by best practice and the status of the product is clearly described.

Return and Disposal of Unwanted Medicines

99. The disposal of pharmaceutical waste is governed by the Hazardous Waste Regulations 2005 and compliance must be ensured within each service health service setting.

100. Operationally the acceptable method of disposal will be determined by the volume of waste produced and local circumstances.

101. All medicines that are no longer required should be returned to a dispensing doctor or pharmacy, or be disposed of using an approved waste contractor depending on local circumstances.

102. Within the regulations cytotoxic and cytostatic agents are automatically deemed to be hazardous. Therefore staff will need to identify and segregate cytotoxic and cytostatic waste from other waste pharmaceuticals and place in the correct hazardous waste bin. Protective equipment such as gloves will also need to be provided.

103. Most pharmaceutical waste is not classified as hazardous waste. The usual 22 litre bins are to be used for all other pharmaceutical waste (i.e. non-hazardous waste not returned to the original dispensary).

104. 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.

Storage of Waste

105. If pharmaceutical waste is stored there is an obligation to notify the premises to the Environment Agency (EA) and hold a Waste Management License (WML). However, there is an exemption from holding a WML for sites accepting unwanted dispensed medicines returned from individuals, households and residential homes.

106. Exemptions from a WML for storage of waste must be registered with the EA by submission of a completed registration form (WMX00) to the EA. The EA has specifically asked that they be contacted on 08708 506506 before completion of the form.

Untoward Incidents involving Medicines

107. 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.

108. Any incident in which medicines are involved must be reported via the CCG incident reporting policy and Datix reporting system.

109. If you have any concerns relating to controlled drugs contact the Controlled Drugs Accountable Officer (CDAO) at NHS England.

110. The Incidents will be logged by the Medicines Management Team, who will identify any trends/recommended actions to ensure that risks relating to medicines are minimised. Learning from all incidents will be disseminated as necessary.

Administration Errors

111. As soon as it is realised that there has been an error of medicine administration the following action must be taken:-

- the appropriate doctor 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;
- the incident should immediately be reported to and investigated by the appropriate line manager, or person delegated to act on their behalf;
- a DATIX incident form must be completed and forwarded to the CCG's Medicines Management Team.

112. 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.

Adverse Reactions to Medicines

113. Any drug may produce unwanted or unexpected adverse reactions. Detection and reporting of these is of vital importance. Doctors, dentists, nurses, pharmacists, therapists and patients are urged to report suspected adverse reactions on 'yellow cards' Yellow Card reporting scheme

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

Defective Medicines

115. 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 via Yellow Card reporting scheme

116. 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 license number, the batch number and the nature of the defect.

117. If the defective medicine has been administered to a patient the prescriber should be notified and reported in accordance with the CCG Incident Reporting policy.

References

NHS Executive, HSC 2000/026: Patient Group Directions [England Only], 9 August 2000.
National Prescribing Centre, Patient Group Directions: A practical guide and framework of competencies for all professionals using patient group directions, March 2004.
NHS Modernisation Agency, Medicines Matters A guide to current mechanisms for the prescribing, supply and administration of medicines, March 2005.
Royal College of Nursing, Patient Group Directions: Guidance and information for nurses, July 2004.
Royal Pharmaceutical Society of Great Britain, The Safe and Secure Handling of Medicines: A Team Approach. A revision of the Duthie Report (1988), March 2005.
CCG PGD Policy (Development and Control of Patient Group Directions)
CCG Vaccine cold chain standards Policy
CCG Non-Medical Prescribing Policy
Standards of Medicines Management. NMC November 2008.
Security of prescription forms guidance. NHSBSA updated August 2013