Medicines Management Policy

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Version	Date	Control Reason	Accountable Person for this Version
v1	December 2012	Original Policy	Clinical Governance Manager
v2	November 2014	Updated in line with Medicines Management Guidelines	Clinical Leads/Clinical Governance Manager
v3	October 2015	Change of responsible Director	Medical Lead/ Governance Manager
v3.1	November 2015	Process update	Medical Lead OOH
v4	May 2016	Major update following external review	Interim Medical Director
v4.1	July 2016	Update including internal revision from committee and HR	Interim Medical Director
v4.2	January 2020	Reviewed and updated	Head of Medicines Management

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1. Introduction

A prescribed medicine is the most frequent treatment provided for patients in the National Health Service (NHS). Medicines must be prescribed, dispensed and administered safely and effectively. The storage and handling within NHS organisations must be safe, secure and comply with current legislation.

Health care organisations must keep patients and staff safe by having systems in place to ensure that medicines are handled safely and securely This is a core standard within the safety domain of the Safe Care and Treatment, Health and Social Care Act (2008).

The Department of Health (DH) requires that there are appropriate policies, procedures and quality assurance systems to ensure that medicines are prescribed, supplied, administered, stored and handled in a safe and secure manner in line with Risk Management Frameworks and Clinical Governance requirements.

This Medicines Management Policy highlights the procedures and guidelines to be followed within PC24 for the prescribing, ordering, storing, administering and issuing of medicines.

All staff contracted to work within PC24 who are involved with any activity related to the use of medicines, must familiarise themselves with this policy.

This policy and its associated procedures also apply to medical staff, nursing staff and other healthcare staff from other NHS Trusts or from private agencies, who are contracted to work in PC24 on a sessional basis. Managers who contract for these services must make it explicit within the written contract that such staff must follow this code.

The clinical elements of the management of medicines (such as choice of medicine, dose, route of administration, frequency of administration and duration of treatment) are beyond the scope of this policy.

2. Purpose

The PC24 Medicines Management Policy is based on relevant primary legislation concerning medicines and reflects recommendations and requirements of relevant professional bodies.

The Medicines Management Policy aims to identify the circumstances and activities involving the use of medicines. The activities covered include ordering, storage, prescribing, supply, administration, transportation and delivery, disposal, spillage and communication regarding medicines and information relating to them.

It describes the principles and the processes by which medicines are to be handled safely and securely, in order to manage the risks associated with medicines in all care environments.

The associated procedures:-

- Clearly outline the responsibility of the employer and the employee and where their accountabilities lie

- Describe in detail the recognised procedure to ensure safe practice for the benefit of patients, public and staff
- Provide references for further guidance
- Sets audit criteria
- Provide additional information in the form of Appendices e.g. approved documentation relevant to that activity

The following standard operating procedures relate to the Medicines Policy:

- CL067 - Prescription Writing
- CL002 - Storage and Handling of Medication Boxes
- CL007 - Repeat Medication Requests, Repeat Prescription Pool and Community Pharmacy Pool
- CL003 - Standard Medication - Urgent Care Centre Trolleys
- CL001 - Prescription Journey
- CL008 - Management of Drug Misuse including Methadone
- CL061 & OP250 - Adastra Electronic Prescribing

3. Scope

- This policy and its associated Standard Operating Procedures (SOPs) applies to all staff involved in the handling of medicines directly or indirectly employed by Primary Care 24. This includes GPs, Non-Medical Prescribers including Pharmacists and Nurses, and any other Primary Care 24 staff who work with or handle medicines.
- This policy does not cover safe storage and handling of Controlled Drugs – refer to Controlled Drugs Policy.

4. Responsibilities of the organisation

- It is responsibility of PC24 to establish policies and procedures and to designate a lead pharmacist to be responsible for the organising, monitoring and reporting of a system for assuring the safe and secure handling of medicines. In the PC24 the senior pharmacist is the Head of Medicines Management
- It is the responsibility of PC24 to ensure that appropriate training and supervision related to the safe and secure handling of medicines is made available to staff.
- It is the responsibility of PC24 to have a named Accountable Officer (AO) who has a statutory responsibility for the monitoring of the safe use and management of controlled drugs as set out in the Controlled Drugs Regulations (updated 2013).
- Controlled Drugs (CDs) are liable to misuse and there are strengthened governance arrangements in place regarding their safe and secure prescribing, storage and supply.
- The AO operates an intelligence network with local agencies to share concerns and promote safe and secure use of controlled drugs. In PC24 the Accountable Officer is the Head of Medicines Management.
- The Accountable Officer is responsible for ensuring the governance

arrangements relating to CDs within the Trust are robust.

- Any concerns relating to individuals or organisations regarding any aspect of controlled drugs must be reported to the Accountable Officer at the earliest opportunity (refer to Controlled Drugs Policy).

Responsibilities of Managers

- It is the responsibility of managers to ensure that this policy is accessible in all bases and that staff are familiar with the policy (and the associated procedures relevant to their role) and are in a position to implement it in practice.
- Managers are responsible for ensuring that duties are only delegated to those staff with the appropriate knowledge and competence to carry out the duty.
- Individual staff in training must be given every opportunity to become proficient in medicines related activities under appropriate supervision. The supervising Designated Practitioner is responsible for ensuring medicines procedures are followed. Duties can be delegated but responsibility cannot be delegated.
- It is the responsibility of managers to report any incidents that may breach this policy through the Datix system and to their line manager.
- It is the responsibility of managers to manage any incidents that may breach this policy during a shift

Responsibilities of Individual Staff

- It is the responsibility of individual staff to ensure they are familiar with the policy and to rectify any gaps in knowledge or competence to ensure standards of care are safeguarded. Training needs must be identified in the individual's Personal Development Plan (PDP).
- Practitioners in training must be given every opportunity to become proficient in medicines related activities under appropriate supervision. The supervising Designated Practitioner has responsibility for such medicine procedures at all times.
- Individual staff are personally accountable for properly discharging their duties and responsibilities in relation to medicines, including storage, handling, prescribing, and administration.
- Individual Clinicians including GPs and Non-Medical Prescribers are personally accountable for their professional practice according to their Code of Professional Conduct or other Code of Ethics.
- Any queries on the application or interpretation of this policy must be discussed with the author of this policy prior to any action taking place.

Responsibilities of Employees and Workers

- All employees and workers who are involved with any part of the administration of this policy or supply of medications are required to adhere to this policy. Any failure to do so may result in disciplinary measures in line with organisational policies.
- All employees and workers have a responsibility to report any incidents that may breach this policy through the Datix system and to their line manager/operational shift manager

Responsibilities of the Medicine Management Team

- Ensure systems are in place to ensure the safe and secure handling of medicines in Primary Care 24
- Advise on and monitor the safe clinical and cost effective use of medicines
- Procurement of medicines
- Advise on medicine security, safety and governance issues
- Provide information on medicines to staff, patients and carers
- Support and monitor prescribing
- Audit the safety and effectiveness of policies and procedures
- Facilitate regular training throughout the year for clinical and non-clinical employees

Responsibilities of Chief Executive:

- The Chief Executive has ultimate accountability for safe medicines practice within Primary Care 24. Responsibility is delegated through to the Medical Director for Medicines Management.

Responsibilities of Medical Director / Head of Medicines Management

The Medical Director has responsibility for:

- The statutory responsibility for the safe and secure handling of medicines within Primary Care 24

    i. Acting as the Accountable Officer for the management of controlled drugs in the organisation.
    ii. Ensuring systems are implemented to ensure medicines are managed safely and securely throughout Primary Care 24 to meet patients" needs
    iii. Ensuring the implementation of the medicines policy across the organisation.
    iv. Planning, receiving, commenting and deciding upon revisions and additions to the Medicines Management Policy.
    v. Ensuring changes to the Medicines Management Policy are communicated throughout PC24
    vi. Supporting the development of relevant training packages for safe medication practice.
    vii. Managing and approving exceptions and local variations to the Medicines Management Policy.
    viii. Performance managing the implementation of the Medicines Policy, including training, through PC24 audit processes.
    ix. Providing support to the medicines management team in implementing the provisions of this policy

Responsibilities of Executive Director of Nursing and Quality

The Executive Director of Nursing and Quality has responsibility for:

    x. Ensuring adequate provision of training is available, facilitated by the Medicines Management Team and is provided at regular intervals throughout the year for clinical and non-clinical employees.
    xi. Ensuring the audit requirements and processes set out in this policy are met.

Responsibilities of Information Technology Team

- The information technology team are responsible for validating the NHS Smartcards for all new prescribers for use in Primary Care 24 to allow access to support services available through the National Spine, such as EMIS Web and the Summary Care Record.

5. Audit

- The medication management system will be subject to regular audit. This includes examining the prescribing practice of Clinicians, individual audits of prescribing practice in particular areas of practice, an audit programme providing process assurance for aspects of care that are not readily evidenced and monitoring of the effectiveness and safety of policies and procedures.

6. Review

- This policy will be reviewed every three years. Where review is necessary due to legislative changes, this will happen immediately.

7. Prescribing

Prescribing Medicines (refer to Prescription Writing Procedure)

- Clinicians must exercise professional judgement and apply their knowledge and skill in a given situation. Clinicians must be able to justify their decisions to their peers, and to any person or organisation, which may be affected by their actions, including individual patients, the public, NHS, the organisation, and other health care professionals.

- Medical staff and other professionals who are authorised prescribers employed by PC24 are responsible for prescribing medicines for patients in a safe, appropriate and effective way. They must comply with this policy and any relevant associated procedures.

- Prescribers are individually and professionally accountable for their prescribing decisions, including actions and omissions, and cannot delegate this accountability to others.

- They must comply with current legislation and professional guidance when performing these duties. They are accountable to their own professional body and professional codes of conduct and ethics. Prescribers must prescribe within the scope of practice within their role.

- Prescribers must only prescribe where it is anticipated that the potential benefits of medication are expected to outweigh any potential adverse effects.

- All prescribers must check with the patient for any known allergies or sensitivities prior to prescribing. Nurses and other practitioners must assist in identifying medicine sensitivities.

- All prescribers must ensure they have adequate professional indemnity insurance.

- When prescribing is included as part of the professional duties of that individual with the consent of the employer, the employer is held vicariously liable for their actions.

- The organisation must ensure that the individual prescriber's prescribing qualification is registered with the relevant professional body and that the prescriber is in possession of a current Disclosure and Barring Service (DBS) declaration (formerly Criminal Records Bureau (CRB) check).

- PC24 Prescribers are not allowed to prescribe for themselves, their families, staff members or anyone with whom they have a close personal or emotional relationship.

- Prescribers must be able to recognise and deal with pressures (e.g. from the pharmaceutical industry, patient/ service users/ families or colleagues) that might result in inappropriate prescribing.

- Prescribers must issue the minimum quantity of medication to meet the clinical needs of the patient.

- Prescription writing is a potential area of risk. It must be undertaken with accuracy and clarity.

Guidance for prescription writing can be obtained in the current version of the BNF http://www.medicinescomplete.com/mc/bnf/current/PHP71-prescription-writing.htm

Controlled Drugs (CDs) are liable to misuse and there are strengthened governance arrangements in place regarding their safe and secure prescribing, storage and supply, refer to the Controlled Drugs Policy.

8. Administration of Medication

- Administration of medication is defined as the introduction of a medicinal product into the body, or by external application, to a patient. This is a key activity in the medication use process and is the point at which there are many opportunities for error.

- Safe medicine administration in all care environments involves the 5 rights: right medication, right dose, right person, right route, at the right time.

- All medical gases are Licensed Medicines and as such are subject to the Medicines Act and must be treated with the same care and control as other medicines.

- Under normal circumstances, written authority from a prescriber must be obtained before a medical gas is administered to a patient. However, in an emergency situation, (e.g. in the treatment of anaphylactic shock), the assigned practitioner in charge may undertake to administer oxygen to a patient in the absence of a prescription and without referral to a medical practitioner

- Medicines may be administered on the written directions from a qualified prescriber (Prescription) by the patient, a relative/carer or a practitioner (Patient Specific Direction). The only medication administered by an Primary Care 24 Clinician is an immediate dose of medication in emergency situations.

- The prescriber must ensure that the person administering the medicine has sufficient information to enable the patient to derive the maximum benefit from it. The prescriber will need to use their judgement about the competence of the patient or carer to administer the medicine safely and according to instructions. This will include a consideration of whether the patient understands the reason for taking the medicine and the consequences of not doing so and if the medication is stored safely and securely.

9. Supply of Medicines

- Prescription Only Medicines may legally be supplied by a valid prescription from a qualified prescriber and dispensed from an Urgent Care Centre drug provision or via a community pharmacy on receipt of a prescription.

- There is a supply of medications in PC24's Urgent Care Centres medicines trollies for exceptional circumstances when there is a need for the patient to have urgent medication and local pharmacies are closed. Clinicians should only prescribe and dispense in this way in exceptional circumstances, where the need for the medicine is urgent and not dispensing it may cause harm to the patient.

- In the case of Controlled Drugs, refer to the Controlled Drug Policy.

10. Ordering, Receipt, Storage and Transport

- Medicines are transported in securely sealed or tamper evident containers. Employees in receipt of drugs must ensure that the delivery has not been tampered with or damaged in transit.

- All drugs requiring ambient temperature storage are held at a temperature of 25 degrees Celsius or less. PC24 does not stock any medication requiring refrigerated storage. All fleet cars are air conditioned allowing for appropriate temperature control for the safe transport of medications.

- Medicines must not be left unattended at any time during transport.

- When medicines are received at their final destination they must not be left unattended or unsecured. They must be locked away in an appropriate storage facility at the earliest opportunity

- All medicines stored for PC24 must be held in secure, locked medicines cupboards / trolleys approved and authorised by the Medicines Management Team.

- The safekeeping of medicines stored in PC24 designated buildings is the responsibility of the Medicines Management Team.

- Medicines storage facilities must be sited where most convenient for staff, whilst also allowing adequate space and permitting surveillance to afford maximum security against unauthorised entry.

- Storage facilities must not be sited where they may be subjected to higher than average humidity or temperature.

- All medical gases used in the Trust must be handled and stored in accordance with the Medical Gases Procedure.

11.0 Pharmaceutical Waste

- Pharmaceutical waste must be disposed of appropriately in accordance with current legislation and national requirements.
- It must not be disposed of via the foul water system in a sink or sluice. Pharmaceutical Waste can be categorised as Hazardous or Non-hazardous.
- Appropriate waste receptacles must be obtained for all categories of pharmaceutical waste generated.
- Destruction of controlled drugs is covered in the Controlled Drugs Policy.
- Used ampoules of medication and needles must be disposed of using the clinical waste sharps bin. Bins are available in the centres and the cars. The sharps bin should not be filled to the top, but closed before it reaches the designated maximum level on the container. Please refer to the Infection Control policy for further information.

12. Safety

12.1 Incident Reporting

- In the event of any kind of medication error or near miss, the incident must be reported in Primary Care 24 Risk Management Reporting System (Datix) in accordance with Primary Care 24's Managing Incidents and Serious Incidents Policy (PC24POL32) and investigated at an appropriate level as defined in the Datix risk matrix according to level of harm or near miss. All appropriate actions should be implemented. The lessons learned from the care delivery and service delivery perspectives must be cascaded across the service in order that employees and Clinicians avoid making the same errors.

- In the event of a patient being harmed by an incident Primary Care 24 supports the NPSA 'Being Open' principles which encourages a culture of transparency, honesty and offering an apology and explanation to patients and their families/carers on what has happened. This is stated in our Complaints Policy (PC24POL34).

12.2 Adverse Drug Reaction (ADR) Reporting

- If a severe unexpected reaction is suspected from a prescribed medicine, the prescriber should use the Adverse Drug Reaction (ADR) Reporting Form or "Yellow Card Scheme" (YCS) to report this to the Commission on Human Medicines (CHM).

12.3 Medicines Defect Reporting

- A defect is present where the product as supplied by the manufacturer is not of the expected standard. Defects may involve inadequate or incorrect labelling, ineffective packaging, contamination or discoloration of the medicine and broken tablets.

- When a defect is found or suspected in a medicine, the following action should be taken:

- Inform the pharmacy or supplier from where the medicines were obtained. They will advise and implement any necessary reporting, recording and investigation of the defect through the Medicine & Healthcare products Regulatory Agency (MHRA).

- Retain any remaining product and any associated products or equipment.

- If the product has been administered to a patient, inform the doctor responsible for the patient and record the defects in the patient's notes.

- Make a written report of the incident by completing an Incident Report Form on Datix and submit it to the Quality and Patient Safety Team, who will assign it for investigation to the appropriate Service Delivery Unit. The report should include detail of the specific batch number of the product.

- Adverse incidents arising from the use of a medicinal product thought to be defective should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) Defective Medicines Reporting Centre (DMRC).

12.4 Drug Alerts

- Drug alerts including product re-calls are cascaded electronically via the Central Alerting System (CAS) cas.alerts@dh.gsi.gov.uk and distributed to the appropriate personnel as required. Internal distribution of relevant reports is managed by the Medicines Management Lead under the guidance of the Medical Director.

- The Central Alerting System is a web-based system for issuing patient safety alerts and other safety critical guidance to the NHS and other health and social care providers. It will be accessible at any time from any web connected device. It brings together the Public Health Link (PHL) and the Safety Alert Broadcast System (SABS). Safety alerts, emergency alerts, drug alerts, letters/broadcasts to Associate GPs and medical device alerts will be sent through this IT system on behalf of the Medicines and Healthcare Products Regulatory Agency, the National Patient Safety

Agency.

- Refer to the CAS Alerts Policy (PC24POL110)

12.5 Security Issues

- Controlled stationery is any stationery, which in the wrong hands, could be used to obtain medicines and or medical items fraudulently. Prescription forms, including FP10 prescription pads are considered controlled stationery.
- The security of prescription forms is the responsibility of the employer and the prescriber. This includes computer-generated prescriptions and related IT software. Prescription forms must be held securely at all times and locked away when not in use. It is advisable to hold only minimal stocks of prescription forms. Any security breaches must be reported immediately to the line manager and Medicines Management Team.
- If a security breach related to medicine, such as the theft or loss of medicines, prescription forms/pads or attempts to obtain such items by deception occurs, these will be reported to the shift manager who will be responsible for any immediate necessary action and reporting it to the operational manager on call. The incident must be recorded at the time on Datix via a completed Incident Report Form, which will be processed by the appropriate Service Delivery Unit under the guidance of the Quality and Patient Safety Team.

12.6 Consent

- It is a legal and ethical principle that consent must be obtained before starting treatment or physical investigation or providing personal care for the patient. Wherever possible, the medicines proposed to treat a patient should be discussed with the patient. The discussion should be carried out in such a way that the patient is able to express agreement or disagreement with the proposed treatment. A concordant consultation with shared decision making is promoted to enable the patient to get the most from their medicines. Please refer to Primary Care 24's Consent to Treatment and the Mental Capacity Act 2005 Policy.

13.0 Training

- Under the direction of the Director for Quality and Patient Safety and the Medical Director, Medicines Management Policy training is facilitated by the Medicines Management Team and is provided at regular intervals throughout the year for clinical and non-clinical employees.

- The learning outcomes of this training are:

  - To raise awareness of the Medicines Management Policy.
  - To inform individuals of the Standard Operating Procedures in relation to specific aspects of the safe and secure handling of medicines.
  - To highlight need for feedback and audit in the review process.

- It is the responsibility of the Line Manager to identify which SOPs are relevant to an individual's role and whether that individual is competent and authorised to perform activities contained in that SOP. Other training packages aimed at improving medicines management services have been developed and are available to targeted groups.

- Under the direction of the Director for Quality and Patient Safety and the Medical Director, the medication management system will be subject to regular audit. This includes examining the prescribing practice of Clinicians, individual audits of prescribing practice in particular areas of practice, an audit programme providing process assurance for aspects of care that are not readily evidenced and monitoring of the effectiveness and safety of policies and procedures.