Safe and Secure Handling of Medicines NHSGGC Core Policy

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Produced in consultation with multidisciplinary teams across NHS GG&C

Contents

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If you have any suggestions that you would like taken in to account during the review of this document or any general queries please e-mail your comments to: sshm@ggc.scot.nhs.uk

1. Introduction

The use of a medicine to manage or diagnose disease is the most common intervention delivered within any healthcare setting. NHS Greater Glasgow and Clyde (NHSGGC) have a responsibility to ensure medicines are used safely, effectively and efficiently in both therapeutic and practical terms, to ensure patient and staff safety. This policy deals with the **practical arrangements** relating to all aspects of medicines **handling** (e.g. procurement, ordering, storage, transport, administration, supply and disposal). Therapeutic considerations (e.g., choice of medicine / dose / appropriateness in an individual patient) are outwith the scope of this policy. Clinical guidelines and therapeutic policies used within NHSGGC can be found **here** (Clinical Info section of Staffnet).

This policy is supported by more detailed subject-specific **Guidance** documents, covering procedural aspects of medicine handling processes.

(Please note – supporting documents that are hyperlinked to this electronic document may change at short notice and render the hyperlink unusable. Where possible, the location of the supporting document has been included to facilitate navigation to the most up-to-date version of the supporting document if the hyperlink changes).

2. Definition of a medicine and scope of policy

In the context of this policy, a "medicine" refers to –

Any substance or combination of substances presented as having properties for treating or preventing disease in human beings and / or any substance or combination of substances which may be used in, or administered to, human beings, either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

This policy is therefore applicable to ALL human medicines, including advanced therapy medicinal products, investigational medical products, vaccines, medical gases, radiopharmaceuticals and licensed products derived from blood. It is not applicable to blood itself or unlicensed blood products or to industrial / laboratory gases and cryogenic agents.

(Other non-medicinal products may be considered as being subject to this policy and associated guidance in certain circumstances e.g. nutritional food supplements / medical devices containing a medicinal product (local risk assessment and procedures will define these products and arrangements).

This policy is based on relevant UK legislation and best practice guidance on the practical handling of medicines. In particular, guidance produced by the Royal Pharmaceutical Society (RPS) and endorsed by the Royal College of Nursing (RCN) (*Guidance on the Safe and Secure Handling of Medicines (update to the 'Duthie Report') (2018), RPS*) has been used as a framework for developing this policy. In accordance with that guidance, this policy applies in **ALL healthcare settings where medicines are handled –** but not every aspect of this policy will be applicable in every situation**.** Medicines that are obtained and stored by patients in their own homes are not within the scope of this policy, however, some of the principles outlined in the policy and supporting guidance documents

will be applicable in certain situations e.g. healthcare staff administering medicine within a patient's home.

3. Roles and responsibilities

All healthcare staff are personally responsible for putting patients and their safety first and practising within their own scope and competence (which may include delegation of tasks). The policy applies equally to all staff working within NHSGGC who handle medicines in any way, including locum staff, contractors, those on honorary contracts etc. The policy also applies to all student learners (e.g. medical, nursing, midwifery, pharmacy, operating department practitioners etc.) who are training / working in NHSGGC environments in any capacity. Student learners may observe and participate with medicines management as part of a practice learning experience under the guidance and supervision of a suitably qualified practitioner, and following appropriate training and education.

The development, implementation and review of this policy and supporting guidance documents is a multidisciplinary responsibility.

4. Governance principles

The RPS guidance outlines a quality management approach to safe and secure handling of medicines (SSHM), which NHSGGC advocates in all healthcare settings. Four key governance principles apply in all situations where medicines are handled. These are briefly summarised below - further guidance can be found in the RPS documents.

4.1 Establish assurance arrangements – 'say what we do and why we do it'

Describe accountability for SSHM both locally and organisationally / describe the "named individual" with overall responsibility for SSHM framework and policy in NHSGGC / describe how procedures are developed and reviewed / audited by named "accountable individuals" / establish procedures for all aspects of SSHM using risk assessment etc. (*See Figure 1 below for further definition of terms).*

Core SSHM policy statements from the RPS/RCN document, which generally apply in all healthcare settings, are reproduced below. Additional procedural level detail is included in the Guidance sections.

4.2 Ensure capacity and capability – 'train people and ensure they have the necessary competencies and resources'

Describe the resources necessary to support SSHM, including the people required, their knowledge, experience and skill mix; the competencies, performance standards and responsibilities of these people; training requirements (induction and ongoing); any relevant environmental / equipment standards etc.

Please see the Guidance sections for more detail on specific training requirements / competency etc. relating to individual tasks.

4.3 Seek assurance – 'do what we say and prove it'

Develop and support proactive audit and monitoring processes; review and learn from incidents, near misses and complaints; there is a system to ensure policies and processes are effectively implemented and remain fit for purpose**.**

4.4 Continually Improve – 'improve what we do'

A quality systems approach is developed to facilitate proactive qualitative and quantitative evaluation of systems / procedures; systems are developed to detect and share incidents (locally and nationally); good practice is identified and shared / spread).

Figure 1 SSHM policy and procedure in NHSGGC – roles and responsibilities

NHSGGC Board Clinical Governance Forum Overall accountability for ensuring safe and secure handling of medicines in NHSGGC healthcare settings
NHSGGC Area Drug and Therapeutics Committee Responsible for the strategic and practical leadership, oversight and review of the policy and guidance documents
Named individual Responsible for setting the overall framework and policy standards for SSHM *(in NHSGGC this is the **Director of Pharmacy**)*
Accountable Individuals Ensure that appropriate procedures are developed / approved / reviewed / audited, that take account of relevant risk assessments and new practices / changes in practice *(e.g. Senior Charge Nurse / Lead Nurse / Senior Pharmacist / Senior Radiographer / Operating Department Practitioner etc.)*
Individuals Handling Medicines Any staff member who handles medicine in any way, who must be legally entitled to do so, is competent, appropriately trained and authorised to do so *(e.g. Nursing staff / portering staff / pharmacy staff / medical staff / allied health professionals / healthcare support workers / delivery drivers etc.)*

5. Overarching SSHM statements

The RPS *Guidance on the Safe and Secure Handling of Medicines (update to the 'Duthie Report') (2018)* contains core statements relating to the safe handling and security of medicines under specific subheadings. These are applicable in all settings in NHSGGC and are broadly reproduced below. These statements, however, often do not provide the detailed level of guidance required by staff in relation to specific processes. Additional GUIDANCE appendices have been produced with respect to NHSGGC processes and provide procedural-level detail. These should be consulted by staff when seeking NHS GGC-specific guidance / information on SSHM. In addition, many areas will work under Standard Operating Procedures for certain processes – these must have a robust system of approval and review and make reference to this SSHM document, where applicable.

Note on Administration of Medicines

NHSGGC have also produced detailed guidance on the Administration of Medicines in Acute / inpatient areas. This is based on the RPS / RCN "*Professional Guidance on the Administration of Medicines*" *(2019)* document and best practice consensus. The RPS / RCN document can be accessed for general information on best practice in medicine

administration – link here Admin of Meds prof guidance.pdf (rpharms.com) (RPS website), and the NHSGGC Guidance should be consulted for detailed GGC-specific guidance.

5.1 Obtaining medicines

5.1.1 Medicines are obtained from a reputable source and due diligence applied to ensure quality, their safe onward use and to minimise the risk of falsification.

5.1.2 Organisational and legal requirements such as the Falsified Medicines Directive, Standing Financial Instructions and data protection are complied with.

5.1.3 Medicines are ordered/procured/requisitioned by legally entitled and authorised persons.

5.1.4 Issues such as availability, lead times and shelf life as well as the method of obtaining are considered.

5.1.5 Policies and procedures to reduce risk are available for obtaining medicines, including those that cover specific categories of products such as investigational medicinal products and unlicensed medicines.

5.2 Receipt of medicines

5.2.1 Where medicines are received from an external source, from the patient, or by transfer from one location to another within the organisation, an audit trail exists.

5.2.2 Where medicines are being redistributed within an organisation this is done in accordance with organisational policies/procedures, e.g. dispensary or ward stock being moved to different sites within an organisation or to other pharmacies.

5.2.3 All medicines received are of the quantity and quality specified and are suitable for the purpose for which they are intended. Specific attention is applied to:

- confirm product identity and quantity
- ensure product integrity, e.g. that the cold chain and other storage requirements have been maintained where appropriate, and
- confirm compliance with any legal and/or organisational requirements.

5.2.4 The physical condition of medicines is protected by controlled storage, stock levels are monitored and records kept where appropriate. Policies and procedures consider environmental and security aspects of all storage locations, as well as the processes by which records of stock are maintained.

5.2.5 Organisations have a policy in place and procedures for managing medicines (including items purchased ‘over-the-counter’, fridge items and controlled drugs) that patients bring with them into the healthcare setting, including that the medicines are assessed as fit for administration. These are drawn up in consultation with an appropriate pharmacy professional.

5.2.6 Policies and procedures consider current guidance on consent.

5.2.7 Where medicines are brought into the healthcare setting by a patient one of the following processes is followed and all actions recorded:

- The medicines are retained in the healthcare setting for the sole use of the patient during their stay. These are assessed and approved for use by appropriately trained staff following positive identification and assessment against defined quality criteria (including appropriate labelling).
- The medicines are securely stored by the organisation until they are returned to the patient prior to or upon discharge unless a risk assessment indicates otherwise.
- If no longer required, and the patient or the patient's carer agrees, the medicines are disposed of or sent to a pharmacy or waste management company for destruction, as appropriate. . If the patient requests, the medicines may be returned to the place where the patient lived via an identified adult. Responsibility for security is given to that adult. The patient and/or patient's carer is advised if the medicines are not safe and/or appropriate for use.

5.2.8 Policies and procedures for self-administration in appropriate patients are developed, and reviewed regularly.

5.3 Providing medicines to patients or a healthcare setting

5.3.1 Medicines are supplied to the place where they will be administered/used in response to formal requisitions. This can include patient labelled packs to supply under Patient Group Directions and medicines that will be supplied/administered under the Human Medicines Regulations 2012 exemptions (Schedules 17 and 19). Medicines are also dispensed directly to named patients in response to prescriptions, Patient Specific Directions or under the Human Medicines Regulations 2012 provision, e.g. emergency supply by a pharmacist.

5.3.2 Presentation and labelling of the medicine provided is consistent with legislation and is of a consistently acceptable standard.

5.3.3 Automated and semi-automated systems are used to reduce risk and error where feasible and appropriate.

5.3.4 Where a care setting holds medicines as stock, a list of stock medicines and quantities to be held is determined by the relevant multidisciplinary team and is subject to regular review at agreed intervals.

5.4 Preparation of medicines in a pharmacy prior to administration

5.4.1 Where medicines are manufactured, prepared, manipulated or modified prior to administration these activities may be carried out in a suitably equipped pharmacy, or contracted out to NHS or non-NHS operated manufacturers under the appropriate licences.
Activities include:

- manufacturing of medicines from ingredients
- repackaging of medicines into small packs from bulk supply (including the use of multi-compartment compliance aids)
- over-labelling

- aseptic preparation of parenteral nutrition solutions, eye preparations, cytotoxics, biological and advanced therapy medicinal products
- reconstitution of injections, powders and oral suspensions
- addition of parenteral medicines to intravenous solutions, and the preparation of radiopharmaceuticals.

5.5 Preparation of medicines outside of pharmacy prior to administration (near patient preparation)

5.5.1 Manipulation of medicines outside the pharmacy is minimised. Injectable medicines are presented as prefilled syringes or other 'ready-to-administer' preparations wherever possible, e.g. infusion bags. However, some form of preparation of the medicine may be necessary immediately prior to its administration. For example, the preparation of injections from vials or ampoules of dry powder and the preparation of mixtures. In these circumstances, measures are taken to prevent cross-contamination and to ensure infection prevention and control.

5.5.2 The activities associated with the preparation and labelling of injectable medicines are particularly high risk as these are fundamental to ensuring the correct dose of the correct medicine is administered to the intended patient. The injectables which present the highest level of overall safety risk include parenteral cytotoxic anticancer medicines, medicines subject to national alerts and any locally identified 'high-risk' injectable medicines. Their manipulation is as far as possible carried out under pharmaceutical supervision in a suitable controlled environment.

5.6 Removal and disposal of surplus and waste medicines

5.6.1 National regulations and all legal requirements are met, e.g. Waste Management Regulations, Misuse of Drugs Regulations, and there is full compliance with organisational policy.

5.6.2 Waste medicines are appropriately segregated and stored securely, pending their disposal.

5.6.3 Medicines that patients bring in with them into the care setting, which are no longer required, are removed and/or disposed of with the agreement of the patient or the patient's carer or in the interests of the patient/general safety.

5.6.4 Unused or unwanted stocks of medicines are returned to a pharmacy or a waste management company with appropriate security precautions.

5.6.5 Healthcare settings ensure that medicines which are out-of-date, damaged, no longer required or unsuitable for their intended use are disposed of or destroyed in a safe and secure manner in accordance with organisational policies/procedures.

5.6.6 Organisational policies/procedures identify medicines at risk of diversion and/or illicit supply and such medicines are removed promptly and disposed of as soon as possible.

5.6.7 Records of destruction are kept where appropriate.

5.7 Transport and transfer

5.7.1 This covers the transport and transfer of medicines between sites within the same organisation as well as between one organisation and another and vehicles transporting medicines to treat patients (e.g. ambulances).

5.7.2 Organisational procedures are compliant with legal requirements and cover situations where staff transport medicines in the course of their duties.

5.7.3 Where third-party carriers (agents) are used, approved systems and controls are present, including the recording of collections and deliveries.

5.7.4 Transfers are managed under a system in which all orders and dispatches are authorised and recorded, and receipt of goods recorded. Staff engaged in the transport of medicines are identified, authorised and appropriately trained.

5.7.5 Procedures and equipment used in the transport of medicines are designed to ensure that the integrity and quality of the medicines are not compromised, e.g. to minimise temperature excursions within the cold chain.

5.7.6 The security of medicines whilst being transported is risk assessed and steps are taken to ensure that risks are eliminated or minimised.

5.7.7 Arrangements for transport of controlled drugs medical gases and radiopharmaceuticals comply with any legal requirements and best practice guidance.

5.8 Storage

5.8.1 It is essential to ensure that planning and design of new premises incorporates appropriate facilities and sufficient capacity for the safe and secure storage of medicines.

5.8.2 Policies and procedures are consistent with the general security arrangements within the organisation and relevant staff are involved from the design stage for new premises or equipment for storage.

5.8.3 From the time of receipt until use or removal, all medicines are kept secure and safeguarded from unauthorised access. Medicines are stored at a level of security appropriate to their proposed use at a level appropriate to their risk of diversion or risks in the local environment.

5.8.4 The level of security to be applied and the way in which this is achieved is balanced against the need to ensure timely access to medicines when they are required.

5.8.5 Medicines are stored at a level appropriate to the staff present at any time and access is restricted.

5.8.6 Procedures are in place to ensure that security is maintained in any storage area. These may be different in locations that are staffed continuously compared with those that are staffed intermittently even when the use of the medicine is the same in each area. Following risk assessment this may include remote monitoring and alarms.

5.8.7 At each stage where a medicine changes hands, there are clear policies/procedures explaining where the responsibility for security lies at that stage and the records required. The legal requirements related to the category of medicine are considered when developing these policies.

5.8.8 The security of medicines storage, including that in clinical areas, is checked regularly by a designated member of the multidisciplinary team and periodically independently scrutinised in accordance with organisational policy and procedures.

5.8.9 Pharmacy professionals apply this guidance in their own setting and also in care settings and clinical areas where they work, supporting other healthcare staff in these settings to apply the guidance where appropriate. Poor practice in relation to medicines storage, by any group of staff, is challenged, investigated and reported wherever and whenever it is identified.

5.9 Product integrity

5.9.1 All medicines, from whatever source, are subject to appropriate assessment of their fitness for use. Appropriate storage and environmental conditions are specified for all medicines.

5.9.2 Processes are in place to ensure that medicines are kept within the specified conditions to the point of use or disposal in all locations where they may be held or during transportation.

5.9.3 Ensure that any equipment or devices used for storage or administration (e.g. air tubes, IV lines and cannulae) do not threaten the integrity of the product.

5.9.4 Processes specify the required condition of a medicine at the time of use and the checks that are made to ensure it is used according to these conditions.

5.9.5 Sufficient data and information about the medicine is available to the staff and/or patient to enable them to identify the medicine and use it correctly.

5.9.6 The temperature of storage facilities is controlled and monitored. For items that require refrigeration or freezer conditions, the cold chain is maintained, and equipment used conforms to current guidance.

5.9.7 When patients assume responsibility for their medicines under self-administration schemes, information and advice about maintaining the security and integrity of the medicine is given.

5.9.8 Where conditions relating to product integrity have not been met or cannot be guaranteed any decision to use the medicine or not is fully risk assessed. Specific guidance is available for vaccines.

5.9.9 The organisation has a policy for dealing with safety alerts and product recalls ensuring that affected products are quarantined as necessary (e.g. Drug Alerts issued by the Medicines Healthcare products Regulatory Agency).

5.10 Health and safety of staff

5.10.1 The risks associated with the processes of handling of any medicine are assessed for both staff and patients. This includes reference to legislative requirements, where necessary, such as Control of Substances Hazardous to Health (COSHH) and ionising radiation regulations.

5.10.2 Processes to minimise risks during transport, receipt, storage, preparation, and disposal of medicines are in place.

5.10.3 Equipment, devices, protective clothing and decontamination equipment (e.g. for cytotoxics) are available at the point of handling, as specified in the risk minimisation procedure.

5.10.4 Training is given to those handling any medicine and, where appropriate, competency checks are carried out at suitable intervals.

5.10.5 Policies/procedures cover actions to be taken in the event of unplanned incidents such as spillages of hazardous medicines; including recovery processes, record keeping and reporting.

6 Impact assessment

6.1 Cost implications

There are unlikely to be any additional cost implications associated with this policy as it describes arrangements that are already considered to be current practice.

6.2 Workforce and staff requirements

There are unlikely to be any additional workforce implications associated with this policy as it describes arrangements that are already considered to be current practice

6.3 Service delivery implications

There are unlikely to be any additional service delivery implications associated with this policy as it describes arrangements that are already considered to be current practice

6.4 Risk (clinical or financial)

This policy aims to reduce clinical risk by outlining accepted practice in relation to safe and secure handling of medicines. Financial risk: None

6.5 Impact on environment

None.

6.6 Equalities impact (EQIA)

This policy was subject to initial Equality Assessment when first developed. In discussion with the Equalities team an Equality Impact Assessment has not been required due to the limited scope for this review in the content of the policy. Individual supporting guidance documents, which contain more procedural-level detail, will undergo EQIA during their review / development (as required, dependent on content).

7. References

(This list is not exhaustive)

The Medicines Act (1968) as consolidated by the Human Medicines Regulations 2012, as amended

The Misuse of Drugs Act (1971), as amended

Misuse of Drugs Regulations (2001), as amended

Controlled Drugs (supervision of management and use) Regulations 2013

Royal Pharmaceutical Society *Professional Guidance on the Safe and Secure Handling of Medicines* (update to the 'Duthie Report') (2018)

General Medical Council *Good Practice in Prescribing and Managing Medicines and Devices* (2013)

General Medical Council *Good Medical Practice (2014)*

General Pharmaceutical Council *Standards for pharmacy professionals* (2017) and *Standards for registered pharmacies (2018)*

Nursing and Midwifery Council *The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates (2018)*

Royal College of Nursing / Royal Pharmaceutical Society *Professional guidance on the administration of medicines in healthcare (2019)*