Medications Management Policy

POL013

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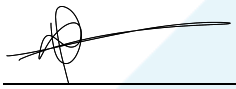

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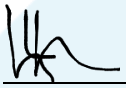

Document Change History

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1.0	Creation of document.

Contents

1. Introduction

Regional Safety Group Ltd. ("RSG") is committed to the safe and secure management of medications.

1.1 Key Principles

The principles which govern the management of medications must be applied to all the activities in which medications are involved. The key principles are:

- Compliance with current legislation;
- adherence to guidance issued by the Department of Health and other national guidance;
- management of the risks to patients and staff arising from the use of medications.

This policy should be read in conjunction with the Standard Operational Procedures (SOPs) approved by the Clinical Lead for each of the activities concerned with the safe use and security of medications. The SOPs should define responsibilities, competencies, training, and performance standards of staff involved in the activity.

2. Scope

This policy applies to all individuals employed by, or working for RSG, including those that work under a contract for services, and those supplied to do work by a third party, including volunteers and agency staff.

3. Aim

The aim is to ensure that RSG complies with relevant legislation governing the storage, supply, and administration of medications and to ensure that all RSG staff are aware of the procedures for the safe and effective management of medications.

4. Roles and responsibilities

4.1 The Directors have overall responsibility for ensuring that systems for the safe and secure management of medications are followed and that the security of medications handled by RSG is maintained.

4.2 The Directors and Clinical Lead(s) are responsible for managing the process for the safe and secure management of medications in RSG.

4.3 The Operations Director has responsibility for the procurement of medications and ensuring that they are of a suitable quality.

4.4 The Operations Director has responsibility and accountability for the safe and secure handling of medications within RSG.

4.4 The Directors and Clinical Managers are responsible and accountable for the day to day safe and secure handling of medications within the operational environment and must ensure that:

- Copies of the Medications Management Policy and MSOPs are available to staff;
- Staff understand and are competent to carry out the duties described by these policies and procedures.

4.5 Clinical staff have a responsibility to maintain their competency in the management of medications and to ensure their familiarity with changes to therapeutic guidelines as they are adopted by RSG.

5. Definitions

5.1 Adverse Drug Reaction

An adverse drug reaction is an unwanted or harmful reaction experienced following the administration of a drug or combination of drugs under normal conditions of use that is suspected to be related to the drug.

5.2 Controlled Drugs

The management of Controlled Dugs is governed by the Misuse of Drugs Act (1971) and its associated Regulations. Additional statutory measures are laid down in the Health Act (2006) and its associated Regulations.

5.3 Medical Product/Medication/Medications

For this policy a `medicinal product' (or a `Medication'/'Medications') is defined as a substance or article, or an ingredient of either of these, (not being an instrument, apparatus, or appliance) supplied for administration to human beings for a medicinal purpose. Medicinal purpose means any one or more of the following:

a) treating or preventing disease;

b) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.

Exclusions:

a) Disinfectants (being applied to inanimate objects);
b) Sterile Non-Injectable Water;
c) Unmedicated dressings, ligatures and sutures;
d) Antiseptics used as cleansing agents for the skin and wounds.

5.4 Medical SOP

A Medical Standard Operating Procedure (MSOP) is a specific written instruction for the supply and administration of a named medication to a group of patients in an identified clinical situation. An RSG MSOP is drawn up by prescribers, pharmacists and other health professionals and must meet certain legal criteria. Further guidance is contained in "NICE Medications Management Guidance 2 Patient Group Directions (August 2013)". The qualified practitioners who may supply or administer medications under an MSOP are First Responders, Medical Technicians, Paramedics, Nurses, Doctors, and other professionals as identified by each MSOP.

6. Medications Policy

6.1 Supply of medications

The Operations Director (with delegation as appropriate and with the advice of the Clinical Lead) is responsible for obtaining all medicinal products through a licensed Wholesale Dealer, ensuring that they are of a suitable quality.

To ensure safe procurement of medications, the following must apply:

- All purchases for medicinal products will be made from trusted sources of supply to ensure the suitability of products purchased and minimise the possibility of counterfeit medications.
- Suppliers and wholesalers are required to hold an appropriate licence from the Medications and Healthcare products Regulatory Agency (MHRA) and this will be checked for authenticity by the pharmacy procurement staff.
- Any concerns with a supplier will be raised with MHRA via the "Yellow Flag" system online, and if deemed necessary audit reports undertaken to access the supplier performance.
- Each medication order shall be overseen and approved by the RSG clinical lead.

All medications (except for patients' own) administered or supplied to patients will be supplied and/or purchased by RSG. Medications will be issued in their original manufacturers packaging and medications labelled for administration under a Medical Standard Operating Procedure (MSOP) or by a medical practitioner must be administered from packs produced by a pharmacist.

The list of medications carried in each pack (specific to the clinical skill grade) can be found within each medication bag. This list is reviewed and approved by the clinical governance team. MSOPs will document the method of supply from the pharmaceutical supplier to the authorised staff.

6.2 Ordering and record keeping

Medications are requisitioned for each authorised location, by individuals authorised by the RSG clinical lead.

An evidential trail of orders must always be kept and should be filed appropriately to ensure easy auditing and reference.

The pharmaceutical supplier has the responsibility to ensure that medications are only supplied on the instruction of an authorised person. Upon arrival at an authorised location, the quantities of medications received will be recorded by the appropriate person.

Unwanted or Outdated Medications

All unwanted medications should be labelled for return to the pharmaceutical supplier as soon as practicable.

- Out of date, recalled and medications unsuitable for use should be stored in a locked cupboard, separate from medications available for use.
- Pharmaceutical waste must be disposed of in accordance with the Waste Management Policy.

Medication Bags

- Medication bags should be secured with tamper-evident seals and once opened a record of medications used must be documented.
- Medications must be stored in a locked cupboard in a safe environment in an area that is not accessible by the public.

6.3 Storage of medications

Medications will be stored under the control of the Operations Director.

Medications must be stored in a locked cupboard in a safe environment in an area that is not accessible by the public.

Health professionals are personally responsible for the security of all medications while they are in their possession.

Medications may only be issued by authorised non-clinical staff for whom training is in place.

Reporting of Losses/Misuse

- The loss or suspected loss or misuse of any medicinal product must be reported using the "Incident Report" system, no later than the next working day.
- The Directors and Clinical Lead may be asked to carry out an investigation

Monitoring of Storage

- The Operations Director will make checks to ensure compliance with the medications policy at least every three months.
- A record folder must be kept on each location of all checks made, including the identities of the staff members carrying out those checks, and retained for a period of two years from the date of last entry.

6.4 Administration of medication to patients

The following groups are authorised to administer medications:

- Competent registered health professionals (within the legislative framework)
- The patient (to him/herself) either under supervision or by self-administration

Consent to Treatment

In general, patients have a right to receive information about a medication prior to use and to refuse administration. Consent should always be obtained, except in the case of "lack of capacity" where the respective health care professional has deemed administration of a medication a "best interest decision" in line with the "Mental Capacity Act 2005". Where it is deemed that a patient lacks capacity, the decision making process must be documented in their patient clinical record.

Checking of Medications Before Administration

- Wherever possible a second suitable person e.g. clinical staff, the patient or member of the public must check all medications for accuracy before administration.
- Staff are encouraged to seek additional information about possible medication interactions prior to administering a medication (when appropriate). The Clinical Lead, other RSG clinicians, the "British National Formulary" and the JRCalc are useful resources for such information.
- Staff must check appropriateness of any medication, including its contra-indications, in the JRCalc Clinical Practice Guidelines and/or MSOPs.
- Any medication that is found or thought to be defective should not be used and should be reported using the RSG "Incident Reporting System".

Administration

- Administration to the patient should be in accordance with a prescription written by an authorised health professional or in accordance with RSG MSOPs.
- All calculations must be conducted in accordance with the JRCalc or RSG MSOPs.
- A record of administration should be made, including the administering person and the quantity, timing, and route of each medication given, this can be achieved by completion of an RSG PRF on the Zoho system.
- Adverse effects should be recorded via the "Incident Reporting System".
- Medications refused, wasted, or disposed of should be recorded.
- Medications must not be prepared in advance of administration.

Unused Medications

- Medications removed from their container/packaging and not immediately administered must be discarded.
- Unused or discarded medications must be disposed of in an appropriate waste disposal bin.

Medication Administration Errors

A medication administration error occurs when a patient has received:

- the wrong medication
- the wrong dosage of the intended medication a dose at the wrong time
- a medication administered by the wrong route
- a medication that is wrongly prescribed or given without an authorised prescription or a current authorised MSOP.
- the medication is omitted without a documented clinical reason.

Whenever an error in the administration or supply of a medication is found it should be reported using the RSG "incident reporting system".

Near Misses

- A near miss is any situation in which either a patient or staff member was close to suffering injury in relation to a medication.
- Staff should report near misses using the RSG "incident reporting system"
- A near miss provides an opportunity for learning in the same way as an actual incident.

Self-administration of medications by patients

- Any medication taken by a patient in the presence of ambulance personnel must be documented.
- The only medications offered by RSG for self-administration by the patient is Nitrous Oxide 50% - Oxygen 50% (Entonox).

Medications for staff

- Staff must not take medications from stock for personal use. Medications may only be administered to staff by another authorised RSG clinician, in an urgent or emergency care scenario, all of which must be documented in a comprehensive patient report form, which is to include the administered medication(s). Staff having received medications must follow up their care with an emergency department or their General Practitioner as required.

Hazards

- Handling of hazardous substances should be in accordance with COSHH Regulations.

6.5 Reporting defects in medicinal products

In the event of a defect or suspected defect in a medicine:

- The medicine must be labelled and stored separate from other medicines to prevent inadvertent use.
- The Operations Director and/or Clinical Lead must be notified and will decide, in consultation, if it is appropriate to withdraw from use all medicine of the same batch in accordance
- The defect or suspected defect must be reported via the MHRS "Yellow Card" system
- Replacement medication will be procured at the earliest convenience for continuation of operation.

6.6 Adverse Drug Reactions (ADRs)

The following ADRs should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) by completing a yellow card (https://yellowcard.mhra.gov.uk/).

This can be done either via the yellow card app, online or via paper copy, this includes:

- all serious adverse reactions in adults;
- all serious and minor reactions in children (under 18);
- Serious reactions including those that are:
    - Fatal
    - life threatening
    - disabling
    - incapacitating
    - result in or prolonged hospitalisation and / or are medically significant congenital abnormalities.

If in doubt about the seriousness of a reaction, report it.

6.7 Liability

RSG generally accepts responsibility for the negligence of its qualified staff who, in emergency situations within the company, administer medicines in the treatment of patients. This applies only during working hours whilst a member of staff acts in accordance with his or her training and not for any other organisation.

RSG is not liable for the activities of staff undertaking work for other trust, private or voluntary organisations. In these circumstances, to avoid the imposition of personal liability, staff are advised to check beforehand that appropriate insurance cover is in place.

6.8 Monitoring

All authorised locations and medication bags are subject to a monthly medication audit, to be completed by the Operations Director. Quarterly medication audits are to be completed by both the Operations Director and the Clinical Lead. The audits are inclusive of the following.

Monthly Audit

- Audit of stock levels
- Audit of administration records
- Renewal of medication bag paperwork

Quarterly Audit

- Audit of stock levels
- Audit of administration records
- Renewal of medication bag paperwork
- Renewal of medication cabinet paperwork (if required)
- Assessment of storage suitability
- Assessment of medication bag sanitation
- Assessment of medication bag security

7. Bibliography

MHRA Yellow Card System
https://yellowcard.mhra.gov.uk/

Mental Capacity Act 2005
https://www.legislation.gov.uk/ukpga/2005/9/contents

Department of Health & Social Care
https://www.gov.uk/government/organisations/department-of-health-and-social-care

Misuse of Drugs Act 1971
https://www.legislation.gov.uk/ukpga/1971/38/contents

Health Act 2006
https://www.legislation.gov.uk/ukpga/2006/28/contents

NICE Medications Management Guidance 2 Patient Group Directions (August 2013)
https://www.nice.org.uk/guidance/mpg2

Medicines & Healthcare products Regulatory Agency (MHRA)
https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

Joint Royal Colleges Ambulance Liaison Committee (JRCalc)
https://www.jrcalc.org.uk/

British National Formulary (BNF)
https://bnf.nice.org.uk/

Control of Substances Hazardous to Health (COSHH)
https://www.hse.gov.uk/coshh/