GIG CYMRU NHS WALES | Iechyd Cyhoeddus Cymru Public Health Wales	**Reference Number:** PHW26 **Version Number:** V3 **Date of next review:** February 2029

Medicines Management Policy

Policy Statement

Public Health Wales (PHW) does not routinely have responsibility for administering medicines directly and, thus, has only limited involvement in direct medicines management. Consequently, PHW does not require the wider range of clinical governance infrastructures for medicines management established within other NHS healthcare organisations. However, there are some clinical care situations that require or potentially require PHW staff to supply or administer medicines to members of the public and to staff.

Policy Commitment

The aim of this policy is to ensure that there is a clinical and corporate governance framework to support safe and secure systems for the controlling and handling of all medicines supplied or administered by PHW staff. It aims to protect service users by ensuring the control of medicines through safe administration, storage, and disposal and through the reporting, monitoring and review of any medication incidents.

Objectives

The objectives of the policy are for all PHW employees administering, ordering, transporting, storing, and disposing of medicines to act in compliance with legislation, professional guidance and PHW procedures and requirements.

Linked Policies and Procedures

All corporate policies and procedures are available on the Public Health Wales website

Diabetic Eye Screening Wales (DESW) Minims® Tropicamide 1% Eye Drops Administration Protocol

Records Management Procedure

Public Health Wales Vaccines (Handling and Storage) Cold Chain Management Procedure Chain Management Procedure 2022

Putting Things Right Incident Reporting and Management Procedure

Waste Management Policy

Related Documents

All Wales Policy for Medicines Administration, Recording, Review, Storage and Disposal (MARRS 2015)

BNF (British National Formulary) | NICE

Duthie Report: Guidelines for the Safe and Secure Handling of Medicines published by the Royal Pharmaceutical Society (2005)

Eye Drops instillation by unregistered health care professionals for use within NHS Ophthalmic Services

Information | Making medicines and medical devices safer (mhra.gov.uk)

Patient Group Directions: who can use them MHRA

Professional guidance on the safe and secure handling of medicines

SmPC

Standards for Health Services in Wales: Standard 15 – Medicines Management

The Green Book: Immunisations against Infectious Disease

Tools and resources | Patient group directions | Guidance | NICE

Scope

This policy applies to all staff who are involved in ordering, transporting, storing, administering and disposing of medicines.

Equality and Health Impact Assessment	An Equality, Welsh Language and Health Impact Assessment has been completed and can be viewed on the policy webpages.
Approved by	Quality, Safety and Improvement Committee
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Accountable Executive Director	Executive Medical Director

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Disclaimer

If the review date of this document has passed, please ensure that the version you are using is the most up to date by contacting the document author or the Board Business Unit

Summary of reviews/amendments

Version number	Date of Review	Date of Approval	Date published	Summary of Amendments
1	2013	31.01.13	04.03.13	First Policy (Medicines Management policy and code of practice)
02	2023	13.12.23	04.01.24	Updated the content and clarified roles and responsibilities
03	2024-26	24.02.26	02.03.26	Updated the content to reflect changes within the PHW structures Updated with roles and responsibilities, amendments made to reflect current PHW requirements around medicines management Added links and updated information related to actions required if defects in medicines are identified.

Contents

1. Introduction

Public Health Wales (PHW) is required to establish, document and maintain an effective system for the safe handling, storage and administration of medicines in line with legislation and best practice. This Medicines Management Policy describes the responsibilities of ordering, storage, dispensing and administration of medicines and aims to ensure the highest standards of medicines management and minimise risks associated with use of medicines[1].

This policy is not a detailed procedure for any aspect of Medicines Management. Divisional procedures must be drawn up where necessary to supplement this policy, providing specific detail on medicines management relevant to each service provided. The PHW governance structures relating to Medicines Management are outlined in Appendix 1.

2. Roles and Responsibilities (Appendix 2)

2.1 Chief Executive

The Chief Executive has overall responsibility for Medicines Management in PHW. The provision of resources to ensure the safe ordering, transport, administering and disposal of medicines is the responsibility of the Chief Executive and Board. It is their responsibility to ensure that guidance is consistent with the legal requirements. The leadership of the organisation should put mechanisms in place to monitor adherence to this policy. Where there is non-compliance, the Board is responsible for ensuring that there are appropriate actions in place to mitigate any risks identified.

2.2 Executive Medical Director

The above is delegated to the Executive Medical Director (the Board lead for Medicines Management), who is responsible for ensuring the implementation and review of this policy in consultation with other Health Care Professionals.

The Executive Medical Director is responsible for ensuring systems are in place within the clinical area/departments in their directorates to facilitate the processes within this policy and that the information and guidance is available to staff and adhered to.

2.3 Medicines Safety Officer

The Medicines Safety Officer (MSO) provides a leadership role within the organisation to set and deliver the medication safety agenda. The MSO will be

[1] Duthie Report: Guidelines for the Safe and Secure Handling of Medicines published by the Royal Pharmaceutical Society (2005)

involved in organisational discussions regarding medicines. MSO role is held by the Clinical Governance Manager within the Office of the Medical Director (OMD).

The MSO is responsible for[2], but not limited to,

- Planning, improving and sustaining medicines safety.
- Acting as the organisational link with the Medicines and Healthcare Products Regulatory Agency (MHRA) to receive essential communications, review, distribute as appropriate and escalate concerns related to the safe use of medications.
- Implementing local actions to improve medication safety which align with national safety initiatives and national patient safety alerts.
- Overseeing medication incident reporting in the organisation, improving reporting and learning.
- Being an active member of the Medicines Management Group (MMG) within PHW.

2.4 Clinical Governance Manager

The Clinical Governance Manager (CGM) will provide assurance that there is compliance with this policy and associated Standard Operating Procedures (SOPs) and that there are adequate mechanisms in place to monitor and report on the usage on medicines throughout PHW. The CGM will focus providing organisational oversight for assurance purposes.

The CGM will have oversight of medication incidents and undertake trend and root cause analysis where necessary.

The CGM is responsible for collating the divisional audits and reporting to the Quality, Safety and Improvement Committee as appropriate. The CGM will ensure that the quality standards are regularly audited as part of PHW's audit cycle.

2.5 Medicines Management Group

The purpose of the MMG is to ensure that there is compliance with legislation, regulatory and professional and local guidance for all aspects of medicines management.

The MMG is responsible for ensuring key issues such as, but not limited to, providing and seeking expert advice and leadership on untoward incidents. The MMG will co-ordinate actions required in the event of national safety alerts and produce and issue any local safety alerts deemed appropriate for areas. The MMG has the authority to initiate action, which may involve system redesign and

[2] Collaboration opportunities to improve medication safety – NHS SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

improvement and/or education, training and competency assessment of healthcare professionals on any aspect of medicines use.

New medicines for use within PHW must be conveyed to the MMG.

The MMG will receive assurance reports from the Professional Programme lead that audits have taken place and be a forum for sharing of learning.

2.6 Programme Lead Professional

Each programme must have a named person with professional responsibility to ensure that there are appropriate systems in place for providing a timely, safe, effective, efficient and secure system for medicine stocks and distribution held within PHW sites. The Programme Lead Professional is responsible for:

- Providing a system for monitoring medicine usage and advising on appropriate stock range, expiry dates and stock holding levels in a timely manner.
- Ensuring appropriate environmental storage conditions.
- Ensuring safe and proper means of disposal of unused/unwanted medicines.
- Ensuring risk assessment forms are completed and updated accordingly and escalated where appropriate to MMG.
- Ensuring safe and effective systems and arrangements for medicine administration. This includes reviewing and managing medicine near misses and errors reported via a Concerns Management System e.g. Datix Cloud and identifying recommendations and lesson learnt.
- Ensuring transport of medicines and other pharmaceuticals in line with this policy.
- Recording the administration including dosage and batch numbers.
- Ensuring the supply of medicines to participants/staff is carried out in accordance with Patient Group Directions (PGDs)/local policy.
- The induction of appropriate staff with respect to this policy, code of practice and any local supporting procedures.
- Monitoring and reviewing competence and ensuring all training and competence assessments are documented.
- Auditing annually the compliance with this policy and the implementation of remedial action.
- Being a member of MMG.

2.7 Healthcare Professionals Involved in the Medicines Management Process

Healthcare Professionals involved in the medicines management process should:

- Read and understand this policy.

- Comply with this policy and their professional Code of Practice (e.g. GMC/NMC/HCPC guidance).
- Ensure that they have the required qualifications, competence and or authority to complete the tasks.
- Not undertake tasks beyond their qualifications, competency, or authorisation.
- Maintain the security of medicines within their practice area.
- Report any incidents where this policy is not adhered to.

3. Medicines Management Service Level Agreement- Pharmacy Advice

Through a Service Level Agreement (SLA) with Cardiff and Vale University Health Board (CAV UHB), the Director of Pharmacy Welsh Medicines Advisory Service (WMAS), is responsible for advising on effective medicines management, its systems and procedures.

4. Prescribing

PHW does not have responsibility for prescribing. PHW employees who prescribe within Health Boards and Trusts are covered under honorary contracts. They will need to refer to the local medicines management policy.

5. Patient Group Directions

A PGD is a specific written instruction for the supply and/or administration, of a named medicine in an identified clinical situation. It applies to groups of service users who may not be individually identified before presenting for treatment.

The use of a PGD does not constitute a form of prescribing. A PGD must not be confused with a Patient-Specific Direction (PSD). The template for a PGD is available at NICE[3].

5.1 Healthcare Professions Able to Operate Under a PGD

The MHRA[4] advise on who may use a PGD.

Practitioners may only operate under a PGD as named individuals.

A senior person in each profession should be designated with the responsibility to ensure that only fully competent, qualified, and trained professionals are authorised to operate within the PGDs.

[3] Tools and resources | Patient group directions | Guidance | NICE

[4] Patient Group Directions: who can use them MHRA

5.2 Circumstances Under Which PGDs are Permissible Within PHW

To authorise the supply or administration of medicines by PHW employed staff where PHW is directly responsible for the care of patients or group of individuals, e.g. Breast Test Wales.

Unlicensed medicines or licensed medicines for an unlicensed indication are not covered under the PGD.

5.3 Criteria Required to Ensure Valid PGD Within PHW

Within PHW the following criteria must apply when developing and authorising a PGD:

- It should be drawn up by a multi-disciplinary group involving a doctor, a pharmacist and a representative of any professional group expected to supply and/or administer medicines under the PGD.
- It must be signed by the relevant healthcare professionals involved in the preparation of the PGD.
- It must be signed by the Director of Pharmacy WMAS
- It must be signed by the individual(s) that may supply administer medicines under the PGD, who must belong to one of the classes of person specified above.
- Be in effect (and in date) at the time of administration or supply.
- The PGDs are reviewed as documented and according to guidance.

5.4 National PGD Support Advisory Functions

It should be noted that PHW has an advisory role in the development of national immunisation PGDs working with the Welsh Medicines Advisory Service. This activity is not covered by this policy.

6. Protocol

A protocol has been developed, in line with guidance from the Royal College of Ophthalmologists[5], to provide direction for the users of the policy allowing the safe administration of Minims® Tropicamide 1% eye drops to participants attending for diabetic eye screening[6].

The MHRA have confirmed that the administration of eyedrops for diabetic eye screening is not in breach of the Medicines Act. No prescription, PGD, PSD or other order is required.

The protocol is reviewed every 2 years and this is covered in the SLA.

[5] Eye-Drops-Instillation-by-Unregistered-Health-Care-Professionals-for-use-within-NHS-Ophthalmic-Services.pdf (rcophth.ac.uk)
[6] Tropicamide Protocol 2024.docx

7. Medicines Requiring Special Consideration

7.1 Administration for the Purpose of Saving Life in an Emergency

Regulation 238 of the Human Medicines Regulations 2012 allows for certain prescription only medicines to be administered by anyone for the purpose of saving life in an emergency without a prescription. Adrenaline 1 in 1000 (1mg/mL) by intramuscular injection can be administered for the emergency treatment of anaphylaxis[7]. Current clinical guidelines should be followed. The full list of exemptions can be found in The Human Medicines Regulations.[8]

7.2 Controlled Drugs

PHW does not hold any controlled drugs.

8. Ordering Stock Drugs and Pharmaceuticals

8.1 Responsibility

The Programme Lead Professional of each department is responsible for all aspects of the control and security of medicines within their area and must ensure that this policy is followed. Duties may be delegated but accountability remains with the Programme Lead Professional.

Medicines may only be supplied or administered in accordance with this policy. PHW employees must not take medicines supplied to departments for their personal use, or another employee's use, unless the product has been supplied in a first-aid kit for employee first aid.

8.2 Stock Drugs and Ordering

The process of ordering and receiving medication from a pharmacy as stock medication must ensure that certain controls are in place to cover the safety and security of the medicines (to include a proper audit trail) prevent overstocking of the area, ensure safety of staff and service users, and clearly show who has the direct responsibility for each stage of the process.

The Programme Lead Professional in each department and the supplying pharmacy department will agree a list of medicines which are either used regularly or are required in case of an emergency to be kept in stock by the department and the stock level. The department and the regional supplying pharmacy department must each keep a copy of this list. This will be reviewed at regular intervals (minimum annually) by the Programme Lead Professional. A

[7] Adrenaline BNF
[8] The Human Medicines Regulations (2012)

named pharmacist within the supplying pharmacy will be provided as a point of contact to discuss and address any ongoing issues or concerns.

The Programme Lead Professional has responsibility for all the medicines in that department. Duties can be delegated but the responsibility cannot be transferred to anyone else since it covers the strategic elements of medication handling in the department which ensures that day to day practice is in line with current legislation, local and national policies/guidance.

Adequate stocks should be ordered and kept for the day to day running of the department/clinics. Medicines with the earliest expiry date must be used first.

9. Delivery and Transport

Drugs may be carried for delivery by authorised PHW staff. Medicines must never be given to patients to deliver.

9.1 Transport of Medicines from the Supplying Pharmacy Department by Authorised Transport

Once order received, assembly and transfer to the department will be the responsibility of the supplying pharmacy. The pharmacy will highlight medicines needing special storage or temperature conditions, to ensure the security and stability of the medicines until they are delivered to the location.

All medicines will be transported securely and safely to the designated Trust location. The authorised person accepting the delivery must sign the documentation on receipt. Once delivered to the department/clinic, the responsibility for the security of the medicine rests with an appropriate registered healthcare practitioner, who will arrange that the contents be unpacked, checked against the delivery note and put away securely as soon as possible.

9.2 Storage Conditions in Transport

Whenever medication is to be transported from one area to another, the recommended storage conditions, temperature and humidity must be considered, and the method of transfer must take these storage conditions into account and consider the cold chain described in the National Patient Safety Agency Rapid Response directive[9].

9.3 Packaging for Transportation

When transporting any medicine, due regard must be taken of the fragility of the item being dispatched. Those items known to be fragile, e.g. items already packed in a glass container, or items which are known to have a COSHH hazard must be packed carefully (these may require additional packaging around the

[9] NPSA Rapid Response directive (RRR008 Cold Storage)

container) in order to remain intact and present no external hazard throughout the transport process.

9.4 Transport Documentation

For any transfer, the person carrying out the delivery must sign on collection. Carriers sign for the outer transport bag or box and not the individual contents. A transport log will be maintained and held locally.

10. Storage and Administration of Medicines

Medicines received by departments must immediately be placed in the appropriate locked cupboard or locked refrigerator (with the exception of emergency drug boxes) and should comply with guidance and legislation including patient safety notices which are contained on AMaT (Audit Management and Tracking) system.

If it is found that the storage conditions are inappropriate, the Programme Lead Professional must be informed.

10.1 Medicine Refrigerators

Medicines labelled 'Store in a refrigerator' shall be stored between 2°C and 8°C in a dedicated locked medicines refrigerator per PHW Vaccines (Handling and Storage) Cold Chain Management Procedure 2022[10].
Non-medicines, e.g. milk or food, must not be stored in a dedicated medicines refrigerator.

Fridge excursions can be referred to Welsh Medicines Advice Service to assess whether the breach is significant

10.2 Safe Custody

The responsibility for safe custody (continuing responsibility) is that of the programme lead professional. The person with continuing responsibility can delegate such responsibility for the possession and custody of the keys to the medicine storage. All medicines storage keys must be stored in a locked key box out of hours or when left unattended. Unauthorised persons must not be permitted access to medicines. Risk assessments must be completed and the Risk recorded on the Risk Register where usual practice is not achievable.

[10] Public Health Wales Vaccines (Handling and Storage) Cold Chain Management Procedure Chain Management Procedure 2022

11. Administration

The purpose of this section is to establish the principles for safe practice in the management and administration of medicines by registered nurses, midwives and other healthcare professionals[11,12].

Administer is 'to give a medicine either by introduction into the body, whether by direct contact with the body (e.g. orally or by injection) or by external application (e.g. application of an impregnated dressing); overseeing the self-administration of medication by a patient or assisting the patient with administration of a medicine.'

11.1 Standards of Practice for the Administration of Medicines

Medicines may only be administered by persons who are qualified to do so. They must be employed and authorised by PHW to administer and have the appropriate knowledge and experience to administer e.g. a doctor, a dentist, or an appropriately accredited healthcare practitioner e.g. a nurse. All employees administering medicines will be held individually accountable for their actions. In administering any medication, the healthcare professional must exercise their professional judgement and apply their knowledge and skills in a given situation.

When administering medicines, healthcare professionals must act within the framework of the current PGD and protocol and in accordance with their Code of Professional Conduct, the current standards of administration of medicines and the relevant policies of PHW.

Medicines may only be administered to a patient by a person working under a PGD or protocol.

In order to administer medicines, the person administering must take the following actions:

- Establish the identity of the service user in accordance with local requirements and the three point ID check.
- Be guided by the 5Rs principles- the widely adopted safety framework in healthcare (RIGHT patient, medication, time, route, dose; NO allergy).
- Check the expiry date of the medicine to be administered.
- Use the opportunity to emphasise the importance and implications of the prescribed treatment and enhance their understanding of the effects and side effects and provide additional relevant information when requested or required (PIL).
- Check the medicine for any defects e.g. box/vial has not been tampered with. If it is a liquid, check that it is clear with no deposits/cloudy (refer to para 14.1).

[11] All Wales Policy for Medicines Administration, Recording, Review, Storage and Disposal (MARRS 2015)
[12] Professional guidance on the safe and secure handling of medicines

- Make a clear and accurate recording of initials on medicines administration chart once you are sure all medicines administered have been taken/applied
- Monitor and evaluate and record the effects of the medicines administered and report to the appropriate prescribing medical practitioner or pharmacist immediately if any adverse reactions to the prescribed medication are identified.
- Medicines must never be left unattended and must be securely stored when not in use.

11.2 Patient Information Leaflets (PIL) and Labelling

Service users must receive sufficient information about the medicines to allow them to make an informed decision. It is a legal requirement that the manufacturer's PIL is provided each time a medicine is supplied. All service users must have an opportunity to discuss and agree to receiving medication. Specific labelling requirements apply equally to medicines supplied under PGDs.

11.3 Safe Administration of Medicines

It is the responsibility of the healthcare professional to ensure that standards of medicines practice are adhered to and ensure they have received the relevant training and education to enable them to safely administer medicines.

11.4 Training and/or Communication with Staff

PHW will ensure that all healthcare professionals directly involved in medicines use have the appropriate levels of training to comply with the medicines management policy. Training is delivered in various ways (group sessions, self-learning via Intranet, etc).

This policy may be communicated to all staff via Staff Induction and the intranet.

12. Disposal

All waste must be disposed of in line with the PHW (and/or local clinical waste disposal procedures) policy on waste.

Medicines that are no longer needed retain their legal status as medicines until such time as they are assessed and destroyed when their legal status becomes controlled under Waste Regulations. It follows that the management and handling of excess or unwanted medicines requires equal diligence to the management and handling of other medicines in current use.

13. Additional PHW Requirements

13.1 Master Copies

The PGDs and medicines protocols are held within the relevant programmes. A copy of all PHW PGDs and medicines protocols will be held by the OMD.

13.2 Staff's Own Medication

There are situations where staff will need to bring in, or keep, their own medication in the work environment. The medication must be stored securely in a location that does not permit service user access. PHW takes no responsibility for the use or quality of such medication and in all except life threatening conditions, it should be administered by the staff member themselves.

14. Incident Reporting

When an incident is discovered or suspected, the first duty of the person discovering it is to ensure the service user or member of staff receive prompt care and then instigate any remedial action[13].

If at any time, during or following the administration, or supply of medication, it is suspected that an incident has occurred which could result in incorrect administration of a drug to a service user, it must be immediately reported to the most senior healthcare professional in charge of the department or division. This individual should inform the service user and it should be recorded in the clinical notes[14].

If a medicine is administered in error, the person administering the medicine must report the incident to their line manager so that the situation can be assessed and determine that any appropriate medical action is taken. The appropriate person will inform the service user/staff member of the incident. The person administering the medicine must report the incident to their line manager.

Both 'near misses' and 'incidents' must be reported using a Concerns Management System e.g. Datix Cloud as soon as possible once the incident has been made safe and any required remedial action has been taken.

In the event of an adverse reaction to a medicine, the participant's GP must be informed by the responsible clinician for the service.

[13] Putting Things Right Incident Reporting and Management Procedure
[14] PSA003

Adverse Drug Reactions can be reported to the MHRA by the Yellow Card scheme[15]. The purpose of the Yellow Card scheme[16] is to provide an early warning that a product may require further investigation.

14.1 Defects in a Medicine

On receipt, if a defect in a medicine is discovered or suspected, medical, nursing or other healthcare professional staff must immediately report the defect to a senior pharmacist at the supplying pharmacy department and the Lead Healthcare Professional. At the point of use, if a defect in a medicine is discovered or suspected, staff must contact the WMAS immediately. All suspect material must be identified and quarantined in a safe place for analysis. Instructions will be issued to all concerned regarding further use of the medicine. A Datix entry must be submitted. On completion of the investigation the pharmacy department will report back to the staff concerned at departmental level.

14.2 Loss/Discrepancy of Medication

Loss or suspected loss or misuse of medicines should be reported to the Programme Lead Professional and to the named Director of WMAS or deputy. A Datix entry must be submitted.

15. Pharmaceutical Public Health Links (Hazard Warning)

Each division must ensure a robust mechanism exists for receipt and action of pharmaceutical public health links (hazard warnings) from the Welsh Government.

16. Audit and Information Governance

A proper audit trail must be in place for any medicines, supplied or administered by PHW staff. All medicines to be supplied in accordance with a PGD or protocol authorised by PHW must be supplied in original packs or pre-packs made up by a licensed manufacturing unit. A proper audit trail must be in place. This requires a secure system for the recording of medicine used under the PGD. This will include the reconciliation of receipts and supplies of medicines on an individual service user basis. It must be possible to identify what service user has had which medicine. The names of the health professionals administering medication must also be recorded.

[15] Yellow Card | Making medicines and medical devices safer (mhra.gov.uk)
[16] Information | Making medicines and medical devices safer (mhra.gov.uk)

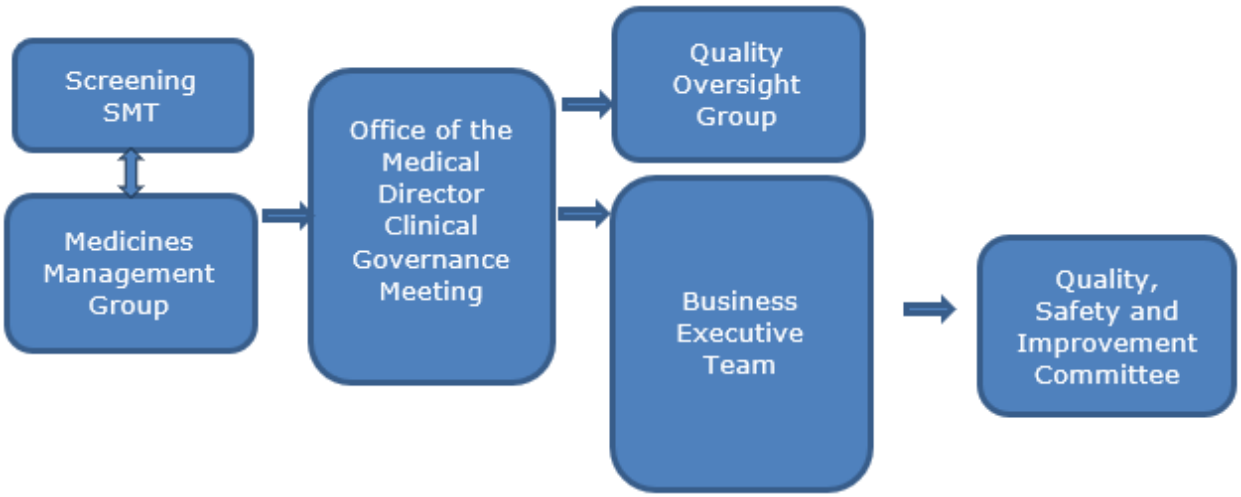
The Clinical Audit Programme will provide assurance that relevant medication management audits are undertaken. These audits will be added to the PHW Annual Quality and Clinical Audit plan, for which the CGM will have oversight.

The same rules apply to PGD records as to all other participant records as outlined in the Records Management Procedure for PHW[17]. For adults, all documentation must be kept for eight years; and for children until the child is 25 years, or for eight years after a child's death.

[17] Records Management Procedure

17. Appendices

Appendix 1- Flow chart: Medicines Management Governance Structures



Appendix 2- Flow chart: Medicines Management Roles and Responsibilities