1 MANAGEMENT AND LEADERSHIP

OVERVIEW OF MANAGEMENT AND LEADERSHIP

Effective management of a Pharmacy begins with understanding the various responsibilities and authorities of individuals in the pharmacy practice, and how these individuals work together. The pharmacy practice manager ensures that policies and procedures appropriate to the various teams within the pharmacy practice are developed and implemented. The responsibilities of the pharmacy practice manager are documented and are known to the pharmacy practice personnel.

Documents prepared by each team define their goals and identify current and planned services. The lines of communication for achieving these goals are represented on an organisational chart. Effective leadership is essential for the pharmacy practice to be able to operate efficiently, achieve its goals and fulfil its mission.

It is important that the pharmacy practice team has identified leaders in areas such as quality management, information management, complaints/patient feedback and human resources. It is possible that a single individual within the pharmacy practice may assume all these leadership responsibilities. In some pharmacy practices, however, leadership will be undertaken by different members of the pharmacy practice team, although quality management should remain the responsibility of a designated quality officer/manager.

Standards

1.1 Mission statement

1.1.1 The pharmacy practice's managerial leaders are identified and are collectively responsible for defining the pharmacy practice's mission and creating the plans and policies needed to fulfil the mission.

Standard Intent:
A pharmacy practice's mission statement usually reflects the needs of its patient population and pharmaceutical service services are designed and planned to respond to those needs. It is important that all members of the pharmacy practice team are recognised and included in the process of defining the pharmacy practice's mission. Effective leadership is essential for a pharmacy practice to be able to operate efficiently and fulfil its mission. Leadership is provided by individuals working together or separately, and can be provided by any number of individuals.

Pharmaceutical service services are planned and designed to respond to the needs of the patient population. The leaders of the pharmacy practice determine what primary care services are essential to the community, ideally in collaboration with the community, as well as the scope and intensity of these services. A strategic plan outlining the proposed development of the pharmacy practice over the coming year is a useful tool to support the pharmacy practice in achieving its mission and meeting identified patient needs. To ensure effective implementation, the plan should be revisited regularly throughout the year to document progress against agreed, predetermined, time-bound targets. The pharmacy practice's strategic plan should be reviewed yearly to ensure that it remains reflective of the current needs of the pharmacy practice population.

Criteria

1.1.1.1 The leaders of the service are formally or informally identified.

1.1.1.2 The pharmacy practice has a mission statement that reflects the strategic objectives of the pharmacy practice and matches the needs of the community served by the pharmacy practice.

1.1.1.3 The leaders are collectively responsible for implementing the pharmacy practice's mission and creating a strategic plan to fulfil the mission.

1.1.1.4 The leaders, in liaison with the whole practice team co-ordinates the compilation of an annual strategic plan and budget.

1.1.1.5 The leaders are collectively responsible for implementing the practice's mission and strategic plan.

1.1.1.6 The strategic plan is reviewed on an annual basis.

1.1.1.7 Regular monitoring of the implementation of the strategic plan against envisaged timeframes is documented at intervals determined by the practice, but at least quarterly.

1.1.1.8 Progress in achieving the objectives of the strategic plan is reviewed regularly throughout the year at a frequency determined by the practice.

1.1.1.9 Where appropriate, the leadership roles in various positions are documented, agreed to and known by the personnel.

1.1.1.10 The health facility manager promotes networking with the leaders of other relevant organisations in the community.

1.1.1.11 There is evidence of interaction with Community Health Committee members.

1.2 Management systems

1.2.1 A manager is responsible for operating the pharmacy practice within relevant laws and regulations.

Standard Intent:
The pharmacy practice manager is appointed to be responsible for the overall, day-to-day operation of the Pharmacy Pharmacy practice. These responsibilities are documented and known to the pharmacy practice personnel. The pharmacy practice manager is responsible for promoting and monitoring the implementation of the policy and procedure framework of the pharmacy practice.

Criteria

1.2.1.1 The manager is responsible for the day-to-day running of the pharmacy practice.

1.2.1.2 The manager has the education and/or experience necessary to carry out his or her responsibilities.

1.2.1.3 The manager ensures that there is a system in place to monitor the implementation of applicable laws and regulations.

1.2.1.4 There is evidence of response to any reports from inspecting and regulatory authorities.

1.2.1.5 The manager implements processes to manage and control human, financial and other resources.

1.2.1.6 The manager promotes networking with other individuals and leaders of relevant pharmacy practices in the community.

1.2.1.7 There is a current budget for the pharmacy practice.

1.2.2 The pharmacy practice facilitates communication between teams and individuals within the pharmacy practice and with referral services.

Standard Intent:
The leaders develop a culture that emphasises co-operation and communication. Relevant personnel members become part of the communication network.

Criteria

1.2.2.1 The leaders facilitate communication between teams where relevant and between individual personnel members.

1.2.2.2 Agendas are prepared for meetings in order to allow those attending to prepare for participation.

1.2.2.3 Minutes of meetings are taken and are circulated to all relevant personnel.

1.2.2.4 There is a procedure to make sure that important matters resulting from management meetings are communicated to and acted upon by personnel.

1.2.2.5 The lines of communication between the pharmacy practice and referral services are clearly defined.

1.2.2.6 Relations are established and contact maintained with other relevant services and agencies, including both governmental and non-governmental agencies.

1.2.2.7 The pharmaceutical service is organised to provide a safe and effective service and is co-ordinated with other relevant services including prescribing physicians, suppliers and manufacturers etc. in the community.

1.3 Policies and procedures

1.3.1 The pharmaceutical service (pharmacy practice manager) has documented

policies and procedures which support the activities of the pharmacy practice.

Standard Intent:
Safe pharmaceutical practices should be guided by the pharmacy practice's policies and procedures. All policies which apply to the pharmacy practice should be available to personnel and should reflect the mission, purposes and goals of the pharmacy practice. They should be consistent with national and international guidelines and Codes of Ethics, and should identify:

- How planning will occur
- The documentation required, e.g. professional guidelines and legislation, order forms, communication forms, etc., for the care team to work effectively
- Special consent considerations
- Monitoring requirements
- Special qualifications or skills of personnel involved in the care process

The policies and procedures should include as a minimum:

a) Safe ordering, storage, prescribing, dispensing and administration of medication in the pharmaceutical service (prescription details should contain as a minimum two patient identifiers, name and formulation of the drug, route, frequency and duration of administration, amount to be dispensed, date and name and signature of prescriber)
b) How to manage illegible prescriptions, including the reduction and elimination of illegible prescriptions
c) Use of verbal medication orders
d) Availability and use of medication samples
e) Documentation and management of any medication brought into the pharmaceutical service for or by the patient
f) Self-administration of medication by the patient
g) Dispensing of medication at the time of the patient's discharge
h) Pre-packing and labelling of medication
i) Preparation, handling, storage and distribution of parenteral and enteral nutrition products
j) Location, labelling, storage, handling, distribution and dispensing of controlled, high-alert and hazardous medication (e.g. insulin, chemotherapy drugs, heparin, etc.)
k) Storage, handling, distribution and dispensing of look-alike, sound-alike medication
l) Labelling of medication administered via intravenous infusion must include the patient name, drug, dose, rate of infusion, signature of the person who prepared the infusion, date and time of initiation of infusion and anticipated date and time of completion of infusion.
m) Management of medication used in clinical trials
n) Security of personnel, equipment and stock
o) Adverse drug reactions (ADR)
p) Drug-related adverse events
q) Medication errors
r) Medication recall
s) Destruction of expired or outdated medication and related products

Please note that it is not necessary to have a separate policy to cover each of the areas listed above – several areas may be covered adequately and appropriately in a single policy.

Criteria

1.3.1.1 Policies and procedures, which include (a)–(s) in the standard intent above as a minimum, are developed and implemented.

1.3.1.2 Policies and procedures are signed and dated by persons authorised to do so.

1.3.1.3 Policies and procedures are correctly indexed and filed.

1.3.1.4 Each policy and procedure is reviewed when indicated and then dated and signed.

1.3.1.5 A designated pharmacy practice manager ensures that policies and procedures which support the activities of the pharmacy practice are accessible to personnel, effectively implemented and regularly monitored.

1.3.1.6 Policies and procedures that guide and support the different services offered by the pharmacy practice are implemented.

1.3.1.7 The pharmacy practice manager ensures that personnel are familiar with relevant policies and procedures.

1.3.1.8 There is evidence that policies and procedures have been developed collaboratively with all relevant regulatory bodies.

1.4 Human Resources

1.4.1 There is a plan for the provision of adequate numbers of suitably qualified personnel

Standard Intent:
The leaders of the pharmacy practice define the desired qualifications, skills, knowledge and any other requirements as part of projecting personnel complements and needs.
Personnel retention rather than recruitment provides greater long-term benefit. Retention is increased when leaders support personnel development. It is therefore advisable for the pharmacy practice to plan and implement uniform programmes and processes related to the recruitment, retention and development of all personnel.
The pharmacy practice has a written plan which identifies the numbers and types of personnel required and the skills, knowledge and other requirements needed in each team.
The planning process includes

- Personnel recruitment
- Numbers and categories of personnel required
- Desired education, qualifications, skills and knowledge
- Assignment and reassignment of personnel
- Personal development of personnel
- Personnel retention

Criteria

1.4.1.1 There are documented processes for staffing the pharmacy practice.

1.4.1.2 The desired education, qualifications, skills and knowledge are defined for

personnel members.

1.4.1.3 Personnel employed by the pharmacy practice are managed in terms of the employer's policies and procedures relating to job descriptions, orientation and induction.

1.4.2 There is an effective process for gathering, verifying and evaluating the credentials (registration, education, training and experience) of those health care professionals who are permitted to pharmacy practice independently.

Standard Intent:
The pharmacy practice needs to ensure that it has qualified professional personnel who appropriately match its mission, resources and patient needs.

An individual's credentials consist of an appropriate current registration, evidence of completion of professional education and any additional training and experience. There is a process for gathering this information and verifying its accuracy. The process applies to all pharmacists employed by the pharmacy practice, including locums, pharmacy assistants and admin personnel. Evaluating an individual's credentials is the basis for two decisions: whether this individual can contribute to fulfilling the pharmacy practice mission and meeting patient needs and if so, what service/s this individual is qualified to perform.

These two decisions are documented and the latter decision is the basis for evaluating the individual's ongoing performance.

Criteria

1.4.2.1 There is a reliable, documented process for evaluating and verifying the credentials (license, education, training and experience) of personnel.

1.4.2.2 There is a reliable, documented process for evaluating and verifying the credentials (license, education, training and experience) of nurses and other health professionals.

1.4.2.3 Personnel files contain copies of diplomas and/or licenses for support staff, nurses and other health professionals.

1.4.2.4 The registration, education, training and experience of these individuals are documented and have been verified by the appropriate registration body.

1.4.2.5 A determination is made about the annual registration of the individual to provide pharmaceutical service services.

1.4.2.6 All personnel members with direct contact with the public have had a police check, a copy of which is kept in their personnel file. Police checks are repeated every 3 years/as appropriate.

1.4.3 Personnel participate in continuing education, research and other educational experiences to acquire new skills and knowledge and to support job advancement.

Standard Intent:

The pharmacy practice supports opportunities for continuing education and training of personnel to ensure they remain up to date with current best pharmacy practice and to acquire advanced or new skills. These opportunities may be offered by the pharmacy practice, by a professional association or through educational programmes in the community. The pharmacy practice supports such opportunities as appropriate to its mission and resources. Such support may be given through tuition support, scheduled time away from work, recognition for achievement and in other ways.

Criteria

1.4.3.1 The pharmacy practice supports continuing education for its professional personnel and maintains records of this in personnel files.

1.4.3.2 There is a development strategy for the pharmacy practice that ensures that the pharmacy practice manager and administrative personnel receive the training required to fulfil their responsibilities.

1.4.3.3 Personnel members are informed of opportunities to participate in advanced education, training, research, and other experiences.

1.5 Finances

1.5.1 The pharmacy manager is responsible for the implementation and maintenance of a financial strategy.

Standard Intent:
Financial planning and management need to be conducted by a person who is suitably qualified or skilled and experienced in all matters relating to the finances of the pharmacy practice. The pharmacy management need to be included in planning the financial requirements of the pharmacy practice if this is an outsourced service. They require information relating to the funds available to them for the management of the pharmacy practice and up-to-date statements of current expenditure.
Sound accounting and auditing pharmacy practices are implemented to ensure transparency. These pharmacy practices are guided by documented policies and procedures. The pharmacy practice manager ensures that these policies and procedures are implemented.

Criteria

1.5.1.1 A designated person is responsible for the implementation and maintenance of a financial strategy.

1.5.1.2 This person is suitably qualified and/or experienced in accounting and financial management.

1.5.1.3 The responsibilities of this person include ensuring that policies and procedures for all functions are implemented.

1.5.2 Budgeting and reporting processes are consistent with statutory requirements and accepted standards.

Criteria

1.5.2.1 There is a current budget for the organisation.

1.5.2.2 A report is produced at least quarterly for the owners of the pharmacy practice, setting out the financial position to date.

1.5.2.3 There is a mechanism for establishing the reason for budget variation in either income or expenditure.

1.5.2.4 Capital investment proposals are subject to unanimous agreement among the partners or are agreed according to a voting system acceptable to all partners in the pharmacy practice.

1.5.3 The practice provides patient services in line with accepted business, financial, ethical and where relevant legal standards.

Standard Intent:
The pharmacy practice has ethical and legal responsibilities to its patients, personnel and the wider community. The leaders understand these responsibilities as they apply to the business and pharmaceutical practice activities of the pharmacy service.

Criteria

1.5.3.1 The pharmacy practice has documented ethical and legal policies and procedures for the management of the pharmacy practice.

1.5.3.2 Internal and external financial audit systems which meet audit requirements are maintained. Requires MOH feedback

1.5.3.3 Where required, annual audited financial statements are produced within the required time frame. Requires MOH feedback

1.5.3.4 There is a capital asset register, which is routinely maintained.

1.5.3.5 Assets are insured.

1.5.3.6 All health professionals provide evidence of professional indemnity insurance. MOH feedback.

1.6 Supply Chain Management

1.6.1 There is an effective system to ensure that equipment and supplies are ordered, stored and distributed.

Standard Intent:
A competent person ensures that equipment and supplies are ordered timeously, stored safely and distributed appropriately.
Policies and procedures are developed for the various provisioning functions. Such policies should include as a minimum:

- Ordering of and payment for supplies and equipment
- Safe storage of supplies
- Condemning procedures

- Security of order books and other face-value documents
- Condemning of equipment

The organisation needs to ensure that appropriate control measures are in place and that finances are made available for the purchase of those items of equipment and supplies which have been identified as being required by personnel.

Criteria

1.6.1.1 An individual is designated to control the ordering, storage, distribution and control of equipment and supplies used in the organisation.

1.6.1.2 Policies and procedures relating to all aspects of provisioning/supply chain management as discussed in the intent statement above are implemented.

1.6.1.3 Secure storage facilities are available.

1.6.1.4 Prescription pads, letterhead, administrative records and other official documents are accessible only to authorised persons.

1.7 Risk management

1.7.1 The pharmacy manager and personnel work collaboratively to develop, implement and maintain effective risk management systems in the pharmacy.

Standard Intent:

To plan effectively, the pharmacy practice must be aware of all relevant risks. The goal is to prevent accidents and injuries, maintain safe and secure conditions for patients, families and personnel and reduce and control hazards and risks. Risk management includes:

- Comprehensive risk assessment of the pharmacy practice
- Designing all aspects of the risk management plan (financial, physical, environmental, medico-legal, operational etc.)
- Implementation of the programme
- Personnel education
- Testing and monitoring the programme
- Periodic review and revision of the programme

Monitoring of all aspects of the programme provides valuable data to make improvements in the programme and further reduce risks within the pharmacy practice.

Criteria

1.7.1.1 There are documented risk management processes for identifying all risks (physical, environmental, medico-legal, operational, etc.) relating to organisational processes and systems, personnel, patients, visitors to the pharmacy practice and physical facilities.

1.7.1.2 The pharmacy manager ensures the development and implementation of written policies and procedures for risk management processes and activities.

1.7.1.3 A nominated individual with relevant qualifications, skills and/or experience supervises the implementation of the risk management system.

1.7.1.4 Ongoing in-service training of all personnel in these policies, procedures and risk management principles is documented.

1.7.1.5 Risk management systems are reviewed whenever there are changes in organisational systems and processes or physical facilities.

1.7.2 The pharmacy practice designs and implements a co-ordinated programme to reduce the risk of infections in patients and personnel.

Standard Intent:
For an infection prevention and control programme to be effective, it must be comprehensive, encompassing both pharmaceutical service and employee health. The programme is appropriate to the size and geographic location of the pharmacy practice, the services offered by the pharmacy practice and the patients seen by the pharmacy practice. Infections can enter the pharmacy practice via patients, their families, personnel, other individuals and vectors.
Hand washing and disinfecting agents are fundamental to infection prevention and control. Soap and disinfectants are located in those areas where hand washing and disinfecting procedures are required. Personnel are educated in proper hand washing and disinfecting procedures.

Criteria

1.7.2.1 A nominated individual is responsible for infection control in the pharmacy practice and pharmacy personnel are aware of the nomination.

1.7.2.2 Written policies and procedures guide personnel in the implementation of the infection control programme.

1.7.2.3 All medication dispensing and preparation areas of the pharmacy practice are included in the documented infection control programme.

1.7.2.4 Regular in-service training is given to all personnel in the field of infection control and is documented.

1.7.2.5 Infection control is on the agenda of all personnel meetings of the pharmacy practice and discussion points are documented.

1.7.2.6 Hand washing and disinfecting facilities, including water, soap, paper towels or hand sanitizers are available in all relevant areas.

1.7.2.7 Personnel are constantly reminded of the importance of effective hand washing, e.g. posters are displayed.

1.7.2.8 A nominated individual has been trained in and is responsible for sterilization procedures within the pharmacy practice, where applicable and can describe the process in detail.

1.7.2.9 Infection control processes include prevention of infection while undertaking sterile procedures.

1.7.2.10 Infection control processes include prevention of water contamination during preparation of suspensions/liquid medications.

1.7.3 The pharmacy practice has a written policy which takes into account the need for infection control procedures relating to the handling, storing and disposing of waste.

Standard Intent:
Protocols need to be developed to guide personnel in ensuring their own safety, the safety of others and the safety of the environment when implementing waste removal systems.

Household waste, hazardous wastes (such as chemicals and hazardous gases), pharmaceutical and healthcare waste are identified by the pharmacy practice and are safely controlled in accordance with a written policy. All healthcare waste is regarded as hazardous or potentially hazardous. The policy is included in the pharmacy practice's risk management plan.

Criteria

1.7.3.1 The pharmacy practice has a waste management policy that includes the safe handling, storing and disposing of all different types of waste.

1.7.3.2 The policy is consistent with current local by laws and regulations.

1.7.3.3 Waste is segregated in accordance with policies, procedures, municipal by-laws and regulations.

1.7.3.4 The colour of bag and type of container appropriate to the type of waste generated are available.

1.7.3.5 Waste is protected from theft, vandalism or scavenging by animals.

1.7.3.6 Waste is collected at appropriate times so that hazards are not caused.

1.7.3.7 The policy makes provision for the appropriate management of confidential waste.

1.7.4 The pharmacy practice has a documented policy for formal review of adverse events within the pharmacy practice.

Standard Intent
As a minimum, the pharmacy practice should have a system for recording, analysing, discussing and learning from adverse events within the pharmacy practice. This should include pharmaceutical practice, managerial, administrative and all other adverse events. The data collected, analysis of the data, discussions surrounding the event, decisions based on the discussions and any suggested changes should be documented and kept on file. A nominated personnel member must be responsible for this process and for the implementation, monitoring and review of the changes. This ensures that the organisation learns from its mistakes and prevents recurrence of the same mistakes, thereby providing continuous improvement in service delivery. Lessons learned could be shared with other pharmacy practices to provide benchmarking.

Clinically significant events such as medication errors, e.g. dispensing a drug to a patient when the records indicate that the patient is allergic to the drug, should always precipitate intense analysis to understand the cause and prevent recurrence.

All records relating to these discussions should be anonymised.

Criteria

1.7.4.1 A documented procedure for the monitoring of negative incidents/near misses/ adverse (sentinel) events is available, which includes the documentation of interventions and responses to recorded incidents.

1.7.4.2 Formal significant event analyses are undertaken when necessary.

1.7.4.3 Notes are kept regarding the data analysis and actions arising from the review.

1.7.4.4 Any change suggested as a result of these case reviews are documented as policies/plans/procedures.

1.7.4.5 The implementation of these new policies/plans/procedures is delegated to a nominated individual who is responsible for monitoring the effectiveness of the changes and arranging reviews if appropriate.

1.7.5 The pharmacy practice makes provision for the safety and security of personnel, visitors, patients and facilities.

Standard Intent:
Consideration is given to the safety and security of personnel, visitors, patients and facilities during working hours and after hours. Plans are developed and implemented to provide protection from attack, theft or damage to the property.

Criteria

1.7.5.1 Security systems, including guards if required, provide for internal security.

1.7.5.2 Security systems, including guards if required, provide for external security.

1.7.5.3 Sufficient light sources are available to provide adequate light (no dark areas) in all areas such as the entrance, waiting rooms, halls and offices.

1.7.5.4 There is effective control of access to restricted areas in the facility, e.g. medicine store.

1.7.5.5 There is effective control of access to dispensing areas and store areas.

1.7.5.6 Alarm systems, if installed, and signals are tested every month.

1.7.5.7 A mechanism known to the personnel is available for summoning the assistance of security/police/protection service in the case of an emergency.

1.7.5.8 Reasonable measures are taken to ensure the safety of lone workers.

1.7.6 The pharmacy practice implements structured systems to ensure fire safety.

Standard Intent:

Fire is an ever-present risk in a pharmacy practice. As such the pharmacy practice needs to plan for:

- the prevention of fires through the reduction of risks, such as the safe storage and handling of potentially flammable materials
- safe and unobstructed means of exit in the event of fire
- clearly depicted fire escape routes
- inspection reports from the local fire departments
- suppression mechanisms such as water hoses, chemical suppressants or sprinkler systems

These actions when combined give patients, families, personnel and visitors adequate time to exit the facility safely in the event of a fire or smoke. These actions are effective irrespective of the age, size or construction of the facility.

The fire safety plan for the pharmacy practice includes:

- the frequency of inspection, testing and maintenance of fire protection and safety systems, consistent with requirements
- the process for testing the plan for the safe evacuation of the facility in the event of a fire or smoke
- a mock evacuation to be carried out at least twice a year
- the necessary education of personnel to protect and evacuate patients effectively when an emergency occurs
- the need for each personnel member to participate in at least one emergency preparedness test per year
- the required documentation of all inspection, testing and maintenance systems

The pharmacy practice develops and implements a policy and plan to eliminate smoking in the pharmacy practice's facilities or to limit smoking to designated non-pharmaceutical service areas.

Criteria

1.7.6.1 There are structured systems and processes in place to ensure that all occupants of the pharmacy practice's facilities are safe from fire or smoke.

1.7.6.2 Documented certification is available from the relevant authority to show that the facility complies with applicable laws and regulations in relation to fire safety (e.g. fire clearance certificate)

1.7.6.3 Firefighting equipment is regularly inspected and serviced at least annually and the date of the service is recorded on the apparatus.

1.7.6.4 Flammable materials are clearly labelled and safely stored.

1.7.6.5 Sufficient electrical socket outlets are provided in all areas to avoid overloading of individual outlets and to minimise fire risks.

1.7.6.6 Easily recognised and understood signs prohibiting smoking are displayed in areas where flammable materials and combustible gases are stored.

1.7.6.7 A floor plan showing the location of firefighting equipment, electrical distribution board, evacuation routes and emergency exits is displayed.

1.7.6.8 Annual personnel training in fire prevention and evacuation procedures is documented.

1.7.6.9 A mechanism known to the personnel is available for summoning the fire service.

1.7.7 The pharmacy practice develops a written plan to respond to emergencies.

Standard Intent:
Community emergencies, epidemics and major events such as damage to pharmaceutical service areas as a result of a natural disaster or influenza that affects personnel may directly involve the pharmacy practice. Pharmacy practices should also be prepared for bomb threats, fire, flooding, natural disasters, explosions and the consequent loss of vital services, failure of water and electrical supplies and hostage taking.

There may be a time when it is necessary to evacuate patients, visitors and personnel. This can only be done quickly and effectively if personnel are trained in evacuation procedures. To respond effectively, the pharmacy practice develops a plan and rehearses it.

Criteria

1.7.7.1 There is a written plan to deal with emergencies (including bomb threats, fire, flooding, natural disasters, failure of water and electrical supplies).

1.7.7.2 There are site and floor plans that depict the locations and layout of the main services (e.g. water, sanitation, electricity supply).

1.7.7.3 Documented evidence is available to show that the personnel participate in a rehearsal of the plan at least annually.

1.7.7.4 First aid kits and materials for healthcare workers are available.

1.8 Information Management and Quality Improvement

A comprehensive approach to quality management and improvement includes the following:

- planning for improvement in quality
- monitoring how well processes work through indicator data collection
- analysing the data
- implementing and sustaining changes that result in improvement

When performed well, these activities provide the framework for the practice to achieve improvements in quality and safety for patients in areas such as practice structures, systems and clinical care. The data can be gathered from patient or staff feedback, an audit of clinical databases or the analysis of incidents and near misses.

This approach is rooted in the daily work of individual healthcare professionals and other staff members. As GPs/FPs and nurses assess patient needs and provide care, this performance indicator can help them understand how to make real improvements to help their patients. Similarly, managers, support staff and others can apply these standards to their daily work to understand how processes can be made more efficient and resources used more wisely.

The continuous monitoring, analysis and improvement of clinical and managerial processes must be well organised and have clear leadership to achieve maximum benefit. This organised approach considers that most clinical care involves more than one profession. Efforts to improve processes must therefore be guided by an overall framework for quality management and improvement activities in the organisation. These standards address the full spectrum of clinical and managerial activities of a practice and include the framework for improving those activities and reducing the risks associated with variation in practice.

The framework presented in these standards is suitable for a wide variety of structured processes and less formal approaches to quality management and improvement. It can also incorporate traditional monitoring processes such as those related to unanticipated events (risk management) and resource use (utilisation management).
Over time, organisations that follow this framework will:

- develop greater leadership support for practice-wide processes
- train and involve more staff in monitoring and improvement activities
- set clearer priorities for what to monitor and what to improve
- base decisions on indicator data
- make improvements based on comparison with other organisations, nationally and internationally

1.8.1 The practice has a system to ensure that data and information is made available to meet user needs.

Standard Intent:
To provide co-ordinated and integrated services, practices rely on information relating to individual patients, care provided, results of care and their own performance.

Every practice seeks to obtain, manage and use information to improve patient outcomes as well as individual and overall practice performance. The information management process makes it possible to combine information from various sources and generate reports to support decision making. The combination of clinical and managerial information supports the leaders of the practice to plan collaboratively. Information is also supplied to medical aids to facilitate payments.

Those individuals in the practice who generate, collect, analyse and use the information are educated and trained to participate effectively in the management of information and to understand the need for security and confidentiality of this information.

To facilitate health planning at district, regional and national level, local authorities and the department of health require accurate and complete data from clinicians. Data that is required nationally, such as notifiable diseases, maternal and perinatal mortality statistics, death certificates, etc. are checked for accuracy before leaving the practice and are supplied within the legislated timeframes.

Criteria

1.8.1.1 Clinical, managerial and administrative personnel participate in developing and implementing an information system to support patient care and practice management.

1.8.1.2 Documented procedures which are implemented outline the processes to provide required information to individuals and agencies outside the practice.

1.8.1.3 Clinical and managerial data and information are integrated as needed to support decision-making.

1.8.1.4 Required technology and other resources support the implementation.

1.8.1.5 The practice contributes to external reference databases when required by laws or regulations.

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1.8.1.6 The practice manager or delegated person checks data leaving the facility for completeness, correctness and consistency, including ICD 10 codes supplied to medical aids.

1.8.2 The practice meets the information needs of those who plan and manage the service and those outside the practice who require data and information from the practice.

Standard Intent:
Information that is generated during patient care can be used to safely and effectively managing a practice. The ability to collect and provide information requires effective planning. Planning incorporates input from a variety of sources:

- the care providers
- the administration team
- the practice managers
- those inside and outside the practice who require information about the practice's operational and care processes

The most urgent information needs of those sources influence the practice's information management strategies and its ability to implement those strategies. The strategies are appropriate for the practice's size, complexity of services, availability of trained personnel and other human and technical resources. The plan is comprehensive and includes all the various teams within the practice.
The collection of data is based on the need for information within the practice. The quality improvement programme focuses on, amongst others, patient access, chronic disease management and health promotion activities.

Criteria

1.8.2.1 There is a documented policy for collection, collation, validation and distribution of data which is implemented.

1.8.2.2 The policy has been designed in collaboration with those collecting and using the data.

1.8.2.3 There is a documented policy that defines those permitted access to each category of data and information.

1.8.2.4 The practice collects data relevant to the quality improvement programme for the monitoring and improvement of patient care.

1.8.3 There is a system for the analysis of data.

Standard Intent:
To reach conclusions and make decisions, data must be aggregated, analysed and transformed into useful information. Data analysis is done by individuals with an understanding of information management who also have skills in data aggregation methods and in the use of various statistical tools. To maximise effectiveness, data analysis involves the individuals responsible for the process or outcome being measured. These individuals may be clinical, managerial, administrative or a combination. When implemented in this way, data analysis provides continuous feedback of quality management information to help those individuals make decisions and continuously improve the process under review.

The practice determines how often data are aggregated and analysed. The frequency depends on the activity or area being measured, the frequency of measurement, and the practice's priorities. For example, clinical data may be analysed once or twice yearly to monitor care in chronic disease management and the performance of contracted services may be analysed quarterly to ensure on-going adequacy of service provision. Aggregation of data at points in time enables the practice to judge a process's stability or an outcome's predictability in relation to expectations. Computers are a useful tool in this process.

The goal of data analysis is to be able to compare a practice in four ways:

- with itself over time
- with other similar health facilities
- with standards
- with evidence based practice and guidelines.

These comparisons help the practice to understand the source and nature of undesirable change and help to focus improvement efforts.

Understanding statistical techniques is helpful in data analysis, especially in interpreting variation and in deciding where improvement is needed. Run charts, control charts, histograms and Pareto charts are examples of statistical tools useful in understanding trends and variations in health care.

Criteria

1.8.3.1 Data is aggregated, analysed and transformed into useful, relevant information for monitoring and improving the service.

1.8.3.2 The frequency of data collection and analysis is appropriate to the process under study.

1.8.3.3 Statistical tools and techniques are used in the analysis process when suitable.

1.8.3.4 Information relating to the quality of the services delivered by the practice is made available to the patients of the practice and other relevant parties.

MANAGEMENT OF QUALITY IMPROVEMENT

1.8.4 The practice appoints an individual or committee which represents all services within the practice to guide the quality improvement process.

Standard Intent:
Leadership and planning are essential if a practice is to initiate and maintain improvement. All leaders participate in establishing the practice's commitment and approach to improvement as well as programme management and supervision.

Improvement programmes are most effective when they are planned practice-wide. The framework for these is provided in a written plan for the programme, which is inclusive of all services in the practice and of all related quality activities such as infection control and risk management activities.

The quality improvement process must:

- be consistent with the practice's mission and strategic plans
- meet the needs of patients, families, staff and other healthcare team members
- use current clinical practice guidelines and other relevant evidence-based information
- include sound business practices
- incorporate relevant risk management information

Leaders and staff prioritise those critical, high-risk, high cost, high volume or problem-prone processes that are most directly related to the quality of care and the safety of the environment. Available data and information are used to identify priority areas.

Participation in data collection and analysis and the planning and implementation of quality improvement programmes require knowledge and skills. Staff receive training consistent with their role in the planned activity. The practice identifies or provides a knowledgeable trainer for this education. Personnel are permitted to attend training as part of their assigned responsibilities. Managerial and clinical personnel participate in the process.

Criteria

1.8.4.1 An individual or committee is appointed to oversee quality management and improvement processes.

1.8.4.2 All practice personal are informed about the appointment and function of the quality management individual/committee.

1.8.4.3 There are formal systems and processes for quality management and improvement.

1.8.4.4 Personnel are trained in the implementation of quality management processes.

1.8.4.5 The leaders allocate resources (including time) for the assessment and improvement of the practice's management, clinical and support processes and this is reflected in the strategic plan/business plan for the practice.

1.8.4.6 The leaders provide technology and support, consistent with the resources of the practice, for tracking and comparing monitoring results.

1.8.4.7 The leaders set priorities for improvement activities based on high risk, high cost and/or high volume or problem-prone areas.

1.8.4.8 Each team within the practice implements relevant quality improvement activities.

1.8.4.9 The objectives, scope, implementation and effectiveness of the activities to assess and improve quality are evaluated regularly and revised as necessary.

1.8.5 Key monitoring, measurement and evaluation processes are planned and implemented.

Standard Intent:
A comprehensive approach to quality management and improvement includes the following processes:

- planning for improvement in quality
- monitoring developments regarding best practice and implementing these as appropriate
- monitoring processes through indicator data collection
- analysing the data
- implementing and sustaining changes that result in improvement

These processes provide the framework for the practice team to achieve ongoing quality improvement thereby assuring their patients of quality care, reflective of current best practice in the rapidly developing world of health care.

The monitoring of clinical and management functions results in the accumulation of data and information. An understanding of how well the practice is doing rests on repeated analysis of the data, information over time and comparison with other practices. The leaders of a practice make the selection of key measures to be included in the practice's monitoring activities.

Criteria

1.8.5.1 Targets (goals) are set for the desired levels of patient care and practice management.

1.8.5.2 Measurable indicators are selected to monitor the quality of important aspects of patient care and practice management.

1.8.5.3 Data are collected for each indicator.

1.8.5.4 As part of clinical monitoring, structured clinical audits are done to monitor the implementation of clinical guidelines.

1.8.6 Analysed data is used to improve the quality of managerial and clinical services.

Standard Intent:
Staff selected to participate in the management and supervision of improvement programmes are those closest to the activities or processes being monitored, studied or improved.

When negative incidents or adverse events occur, the practice and its leaders evaluate the processes that led to the error or event. Faulty processes are redesigned, tested and monitored to ensure that the same or similar errors or events do not occur again.

Case reviews are performed for all new diagnoses of significant, life threatening diseases, unexpected deaths and management of emergency cases that present at the surgery. The routine review of these cases assists in the identification of what went well and what could have been done better to inform continuous improvement in clinical care and enable sharing of best practice.

When the practice detects or suspects an undesirable change from what is expected, it initiates intense analysis to determine where best to focus improvement. In particular, intense analysis is initiated when levels, patterns or trends vary significantly or undesirably from:

- what is expected
- those of other practices or
- recognised standards

Each practice establishes which events are significant and the process for their intense analysis. When undesirable events can be prevented, the practice works to carry out preventive changes.

Criteria

1.8.6.1 Information from the findings of quality assessment and improvement activities is used to detect trends, patterns and opportunities to improve or prevent potential problems.

1.8.6.2 The practice holds regular meetings to discuss significant clinical issues.

1.8.6.3 Information from a validated patient/family satisfaction audit tool is used to improve the quality of service delivery.

1.8.6.4 The tools used to measure patient feedback need to be rigorous to ensure the integrity of data subsequently used by practices for quality improvement purposes.

1.8.6.5 When appropriate an improvement plan is developed in collaboration with all relevant team members and an implementation process agreed.

1.8.6.6 An acceptable timeframe for implementation is agreed by all relevant team members.

1.8.6.7 A time for repeat data collection and analysis is agreed.

1.8.6.8 Repeat data collection and analysis is completed as agreed and the results discussed by the relevant team members.

1.8.7 The practice regularly assesses the quality and the completeness of the patient record content.

Standard Intent:
The clinical record of each patient needs to contain sufficient information to support the diagnosis, justify the treatment provided, and document the care given. Where carry cards

are used, there are summaries of each attendance in the service which will provide this information. A standardised format and content of patient's records will help promote the integration and continuity of care among the various providers of care to the patient. The practice determines the specific data and information recorded in the clinical record. Each service has a process to assess the quality and completeness of patient records. This is a part of the performance improvement activities of the practice and is carried out regularly. This information is used to improve the quality of clinical record keeping.
Clinical record review is based on a representative sample of the GPs providing care and of the types of care provided.

Criteria

1.8.7.1 Patient records are reviewed regularly and results analysed as part of the quality improvement process.

1.8.7.2 The review uses a representative sample.

1.8.7.3 Records comply with professionally acceptable norms (including legal requirements where applicable) relating to signature, use of abbreviations and legibility.

1.8.7.4 Standardised diagnosis and procedure codes are used.

1.8.7.5 Symbols and definitions are standardised. Requires MOH feedback.

2 FACILITY MANAGEMENT AND CONTRACTED SERVICES

OVERVIEW OF FACILITY MANAGEMENT AND CONTRACTED SERVICES

Laws, regulations and inspections by national governmental and local authorities determine in large part how a facility is designed, used and maintained. All pharmacy practices, regardless of their size and resources, must comply with these requirements as part of their responsibilities to patients, families and personnel. Pharmacy practices begin by complying with relevant laws and regulations. Over time they become more knowledgeable about the details of the physical facility they occupy. They begin to gather data proactively and carry out strategies to reduce risks and enhance the pharmaceutical service environment.

Buildings, grounds and equipment provided are maintained and do not pose hazards to the occupants. The personnel providing the maintenance service are knowledgeable and competent. Buildings, grounds and utilities are provided and maintained to an acceptable standard in order to ensure that they do not present a risk to the safety and wellbeing of the occupants.

Ensuring that buildings, grounds and utilities are provided and maintained requires that the relevant personnel member/s is/are knowledgeable and competent.

Where service contracts/agreements are awarded to outside agencies, the pharmacy practice must ensure that there is a written contractual agreement outlining the service and standard of service to be delivered. Contracted agencies must undertake to provide services in accordance with infection control and health and safety requirements. Where applicable the contracted personnel receive training with regard to waste disposal and infection control if this has not been undertaken to a satisfactory level by the contracted company.

2.1 Access to care

2.1.1 Measures are in place to ensure that patient access to the pharmacy practice is facilitated by adequate infrastructural arrangements.

Criteria

2.1.1.1 Directional signs to the pharmacy practice are clearly readable and up to date.

2.1.1.2 A telephone/emergency number is available and provided to patients on registration and on request.

2.1.1.3 Parking is provided close to the building entrance for patients, including the physically challenged.

2.1.1.4 There is wheelchair access to and within the building.

2.1.1.5 Ramps and stairs include safety features such as rails.

2.1.2 Functional facilities are available to provide safety and comfort for clients, personnel and other visitors.

Standard Intent:
In order to provide a safe environment for patients and staff, the pharmacy practice requires adequate resources. The building is appropriate for a pharmacy practice in terms of size and layout.

The physical facilities required include adequate office accommodation for personnel, dispensing areas which are hygienically clean at all times, medication preparation areas which has adequate space for benchtop and necessary equipment. Cleaning equipment is safely stored in a room or cupboard used for this purpose only. There are adequate toilet facilities for the number of patients as determined by country-specific legislation. There is adequate lighting and ventilation.

Each area, which may include an attached examination room/consulting room:
- is free from excessive noise
- has adequate lighting
- is maintained at a suitable temperature for both patient areas and medication storage areas.

Buildings and grounds are provided and maintained and do not pose hazards to the occupants. The construction of the building in terms of walls, ceilings, floors, doors and windows must be sound. The general appearance will be examined for neatness, condition of paintwork, signs of leakage, mould spots etc.

Criteria

2.1.2.1 Laws, regulations and other requirements applicable to the pharmacy practice's facilities are available in writing to the personnel.

2.1.2.2 The building is appropriate as a pharmacy facility in terms of size and lay-

out which is suitable for the services provided.

2.1.2.3 The lay-out of the facility allows for effective workflow.

2.1.2.4 The waiting area is sufficient to accommodate the usual number of patients and other people who could be waiting at any given time.

2.1.2.5 The waiting area caters for the specific needs of children.

2.1.2.6 There is at least one consulting area for every member of the pharmacy team working in the pharmacy practice at any time.

2.1.2.7 Sufficient office/administrative space is available for the personnel.

2.1.2.8 All rooms are adequately ventilated.

2.1.2.9 The walls, ceilings and floors are smooth, easy to clean, impermeable to liquids and resistant to chemicals.

2.1.2.10 Toilet/washroom facilities are clean and in working order.

2.1.2.11 Separate sanitary facilities are provided for personnel. MOH feedback

2.1.2.12 There is a separate, secure area for personnel with adequate secure storage facilities for outdoor clothing, handbags and personal possessions.

2.1.2.13 Hand washing facilities, including water, soap and towels are available for patients and personnel.

2.1.2.14 Separate restroom facilities where personnel can eat and drink are available.

2.1.3 Pharmaceutical service fixtures and fittings are adequate to provide a safe and effective pharmaceutical service.

Standard Intent
The pharmaceutical service should be constructed in such a way that it can provide the projected pharmaceutical services. The pharmaceutical service should have sufficient properly constructed benches, washing and staining facilities, sufficient power and water and preferably a controlled temperature. Specific details that should be monitored include:

- Pharmaceutical service benches and equipment should be of a material that can support the pharmaceutical service instruments (strong) and cannot affect the surface of the table. Wooden tables are not acceptable.
- At least one washing unit must be available for standard cleaning and washing activities.
- The number and quality of the available sockets should be sufficient for the projected activities.
- The water supply should be guaranteed, to provide washing and staining activities.

Criteria

2.1.3.1 Required furniture and equipment is available according to established lists and functioning properly.

2.1.3.2 Space around and under dispensing areas should allow for ease of cleaning and maintenance.

Guideline Statement:
This will be assessed by observation in the department.

2.1.3.3 Storage space is adequate to hold supplies for immediate use and to prevent clutter of bench tops.

2.1.3.4 Each pharmaceutical service compartment has adequate ventilation, room temperature is maintained below 25°C and a temperature record is kept.

Guideline Statement:
The pharmaceutical service needs to be temperature controlled, because when the temperature is high, it can influence the pharmaceutical service procedures and instruments.
The availability of an air-conditioning system is desirable, in order to guarantee a constant temperature.
Documented evidence of temperature records is required.

2.2 Equipment

2.2.1 Pharmacy equipment is adequately available and properly maintained to provide a safe and effective pharmaceutical service which meet the needs of the patient population.

Standard Intent:
Pharmacy practices are responsible for ensuring that appropriate pharmacy equipment is available relative to the services provided and ready for use at all times. There is an accountable, systematic approach to ensuring that cost-effective, safe and appropriate pharmacy equipment is available to meet the demands of quality pharmaceutical service.

Pharmaceutical service management and personnel takes responsibility for ensuring that pharmacy equipment is available, appropriately maintained and calibrated according to manufacturer's instructions, and that the relevant personnel are competent to use it.

The pharmacy practice ensures that it has the minimum required critical instruments for comprehensive pharmaceutical service services as detailed below.

- Electronic balance
- Refrigerator with freezer compartment
- Graduates
- Mortar and pestles
- spatulas
- Pipet, thermometer and timer

A standard list to be determined by MOH for each discipline according to the patient population.

Criteria

2.2.1.1 A designated individual supervises the management of pharmacy equipment in the pharmacy practice.

2.2.1.2 The responsibilities of this individual include selecting, acquiring and replacing of equipment.

Guideline Statement: *Documented evidence is required of the inclusion of these steps. This criterion may be scored NA in instances where these functions are performed at a higher level (regional/national/corporate head office).*

2.2.1.3 There is an inventory of the pharmacy equipment available at the pharmacy practice.

2.2.1.4 Policies and procedures guide the management of pharmacy equipment.

2.2.1.5 The supply of pharmacy equipment is adequate to meet the needs of the pharmacy practice.

2.2.1.6 Records are kept of the checking and maintenance of pharmacy equipment.

2.2.1.7 There is a documented procedure known to the personnel for reporting defects in pharmacy equipment.

2.3 Maintenance management

2.3.1 The maintenance service is managed to ensure the provision of a safe and effective service.

Standard Intent:
Management ensures that sufficient competent personnel are available to manage routine and emergency functions and meet the needs of a safe and effective health service. Personnel may be in the employ of the pharmacy practice or be contracted out. Where there are contracted personnel, there must be clearly specified contracts, outlining their roles and responsibilities.

Criteria

2.3.1.1 A designated, competent individual is responsible for supervising the maintenance of buildings, grounds and utilities.

2.3.1.2 Where these services are outsourced the pharmacy practice personnel have access at all times to a list of these private contractors/service providers with their contact numbers.

2.3.1.3 Written agreements ensure technical back-up services are available at all times during the opening hours of the pharmacy practice.

2.3.1.4 Written policies and procedures guide pharmacy practice personnel in the implementation of all service-related requirements e.g. routine maintenance, payment of bills.

2.3.1.5 Basic maintenance equipment and tools are available.

2.3.1.6 Basic technical spare parts are available.

2.3.2 The pharmacy practice implements a documented preventative planned maintenance programme for buildings, grounds and utilities.

Standard Intent:
The pharmacy practice plans for regular in-house inspection of facilities to avoid hazards.
Building maintenance includes the monitoring of the following aspects:
a) The general appearance of the inside and outside structure which includes the construction of walls, floors, doors and windows.
b) The condition of the paintwork
c) Water leaks, mould spots
d) Electrical wiring, e.g. exposed wires, switches, electrical sockets
e) Maintenance of the grounds (no litter, neat garden and grass kept short)

Criteria

2.3.2.1 The pharmacy practice plans and budgets for the upgrading or replacing of systems, buildings or components needed for the continued operation of a safe and effective facility.

2.3.2.2 The pharmacy practice has a documented preventative maintenance management plan in place.

2.3.2.3 The buildings and grounds are inspected at regular intervals determined by the pharmacy practice according to a documented policy that includes at least a) to e) listed above.

2.3.2.4 Regular inspections of the facility are documented.

2.3.2.5 There is a documented procedure known to the personnel for reporting defects.

2.3.3 ICT equipment is available and properly maintained to meet the needs of the services.

Standard Intent:
The pharmacy practice is responsible for ensuring that appropriate ICT equipment is available and ready for use at all times. There is an accountable, systematic approach to ensuring that cost-effective, safe and appropriate ICT equipment is available to meet the demands of quality pharmaceutical service.

Managers take responsibility for ensuring that ICT equipment is available and appropriately maintained and that personnel are competent to use it.

Criteria

2.3.3.1 Policies and procedures guide the management of ICT equipment.

2.3.3.2 A designated individual supervises the management of ICT equipment in the organisation.

2.3.3.3 There is an inventory of all ICT equipment.

2.3.3.4 All desktop and server computers are provided with surge protection and the server is protected by an uninterruptable power supply.

2.3.3.5 A documented policy is available clearly describing appropriate back up procedures for electronic records.

2.3.3.6 Regular checks are made and documented to ensure that backup has been successful.

2.3.3.7 Records are kept of the checking and maintenance of ICT equipment.

2.3.3.8 The pharmacy practice has appropriate virus protection software and firewall protection to ensure adequate security and confidentiality of patient related information

2.3.3.9 There is documented evidence that relevant personnel are regularly trained to use/operate ICT equipment.

2.4 Cleaning

2.4.1 The cleaning service is managed to ensure the provision of a safe and effective service.

Standard Intent:
Pharmacy practice managers must ensure that a documented policy is available detailing the cleaning duties to be undertaken and the frequency with which these need to be performed. Where the cleaning service is outsourced a contract defines the details of the service to be provided.

The pharmacy practice manager must ensure that facilities and equipment are adequate for the provision of a safe and effective cleaning service.

Criteria

2.4.1.1 A written agreement is available where the cleaning service is outsourced.

2.4.1.2 Written policies and procedures relating to cleaning duties and the frequency with which these duties are carried out are implemented and monitored.

2.4.1.3 Adequate and secure storage areas are available for equipment and chemicals.

2.4.1.4 Chemicals for cleaning are safely stored out of the reach of patients, children and visitors.

2.4.1.5 There is adequate storage place for brooms and mops.

2.4.1.6 Mops and brooms are cleaned and dried before being stored.

2.4.1.7 Cleaning cupboards are adequately ventilated.

2.4.1.8 The pharmacy practice manager ensures the cleaners are appropriately trained regarding waste management, infection control procedures, confidentiality issues and any other relevant matters.

2.5 Contracted Services

Overview
This section relates to support services that have been contracted to outside agencies, such as cleaning, building maintenance, gardening, IT management, etc. The management and supervision of these services is delegated to one nominated individual who ensures that services comply with criteria relating to management, infection control, environmental safety and health and safety requirements.

2.5.1 Where contracts/service agreements for pharmaceutical and/or managerial services exist, these are monitored.

Standard Intent:
Where services are provided through an agreement with an external provider a designated individual is responsible for monitoring these contracts or other arrangements. In all cases the leaders must supervise such written contracts/agreements to ensure that the services meet patient needs and are monitored as part of the quality management and improvement activities.

Criteria

2.5.1.1 Copies of contracts for outside service providers are available to those who ensure they are implemented.

2.5.1.2 Services provided under contracts and other arrangements are formally monitored and compliance with the contract is documented.

2.5.2 There is an adequate number of suitably trained contract personnel to provide a safe and effective service.

Standard Intent:
The pharmacy practice manager identifies the numbers and types of required personnel for contracted services and defines the desired education, knowledge, skills and any other requirements needed.
Orientation and induction programmes ensure the competence of personnel before they begin to carry out their functions. The personnel act in accordance with job descriptions, and are evaluated in accordance with their assigned responsibilities.
Where appropriate personnel in the employ of the contractor are made aware of issues relating to infection control, waste management, confidential waste and health and safety.

Criteria

2.5.2.1 Contracted personnel are managed as determined in the written service agreement.

2.5.2.2 The pharmacy practice ensures that contracted personnel are oriented to relevant pharmacy practice policies and procedures.

2.5.2.3 The pharmacy practice ensures that contracted personnel participate in relevant pharmacy practice in-service training programmes (e.g. infection control, health and safety).

3 PHARMACEUTICAL SERVICE

3.1 Patient rights

3.1.1 The practice has a patient rights policy.

Standard Intent:
The leaders of a pharmacy practice are primarily responsible for the way in which that practice treats its clients. The leaders need to know and understand patient and family rights and the practice's responsibilities as specified in laws, charters and regulations. The leaders then provide direction to ensure that personnel throughout the practice assume responsibility for protecting these rights. To protect and advance patient rights effectively, the leaders work collaboratively and seek to understand their responsibilities in relation to the community served by the practice.

Patient and family rights are a fundamental element of all contact between practice personnel, patients and families. Policies and procedures are developed and implemented to ensure that all personnel are aware of and respond to patient and family rights issues including their role in supporting patients' and families' rights to participate in the care process and the right to the provision of all information requested by patients and families to enable them to do so. The patient's rights policy is appropriate to the patient's age, understanding and language. When written communication is not effective or appropriate, the patient and family are informed of their rights in a manner they can understand.

Criteria

3.1.1.1 Patient and family rights are identified and documented in accordance with relevant and current laws, charters and regulations.

3.1.1.2 There is a patient rights charter which is prominently displayed.

3.1.1.3 The policy includes the right to confidentiality of patient records.

3.1.1.4 The policy demonstrates that the patient's cultural values, requirements and variations has been considered in the planning and delivery of the pharmaceutical service.

3.1.1.5 The policy demonstrates that practice personnel are required to respect and be sensitive to the patient's spiritual, emotional, social and physical needs.

3.1.2 The practice takes measures to protect patient privacy.

Standard Intent:

The practice ensures that the patient's need for privacy is respected, especially when the patient is providing personal information. Patients may desire privacy from other personnel, other patients/clients and even from family members.

Medical and other health information, when documented and collected in a patient record or other form, is important for understanding the patient, his or her needs and for providing care over time. The practice respects such information as confidential and has implemented policies and procedures that protect such information from loss or misuse. The personnel respect the confidentiality of patient information by not leaving patient records, patient prescriptions, etc. where they might be visible to members of the public and by not holding patient-related discussions where they may be overheard by other patients or visitors. Such carelessness with patient information can result in loss of dignity or employment for the patient and may result in damage to personal or family relationships. These consequences can follow carelessness by the personnel of the practice, or by family members or others not authorised to have access to the information who have obtained information due to the carelessness of personnel.

Criteria

3.1.2.1 The patient's need for privacy is protected.

3.1.2.2 Patient privacy is protected when providing personal information.

3.1.2.3 The patient's right to privacy is protected for all forms of counselling.

3.1.2.4 Policies and procedures to prevent the loss or misuse of patient information are implemented.

3.1.3 The practice has a clearly defined process for obtaining consent.

Standard Intent:
One of the main ways that patients are involved in their care decisions is by granting informed consent. The patient must be provided with all information relating to planned care to enable him or her to make decisions. The consent process is clearly defined by the practice in policies and procedures. Relevant laws and regulations are incorporated into the policies and procedures.

Informed consent for care sometimes requires that people other than or in addition to the patient be involved in decisions about the patient's care. This is especially true when the patient does not have the mental or physical capacity to make care decisions, when culture or custom designate that others make care decisions or when the patient is a child. When the patient cannot make decisions regarding his or her care a surrogate decision-maker is identified. When someone other than the patient gives consent, that individual is noted in the patient's record.

Criteria

3.1.3.1 The practice has a documented policy outlining the procedure for obtaining general consent for treatment.

3.1.3.2 The practice has a documented policy outlining the procedure for obtaining consent which is in accordance with the relevant laws and regulations.

3.1.3.3 Documented consent is obtained from patients for health information to be provided to a third party.

3.1.3.4 Where practice members use patient information for research, approval has been obtained from the relevant ethics committee and from patients themselves where required.

3.1.4 The practice informs patients and their families about the processes which it has instituted to receive and act on complaints, conflicts and differences of opinion regarding the pharmaceutical service and the patient's right to participate in those processes.

Standard Intent:
Patients have a right to voice complaints about the service received and to have those complaints reviewed and where possible resolved. The practice has established processes for seeking resolution to such complaints. The practice identifies in policies and procedures those who need to be involved in the processes and how the patient and family participate.

Criteria

3.1.4.1 There is a documented policy outlining the mechanism to allow for the hearing of complaints and how to act upon them.

3.1.4.2 Patients/clients are aware of their right to voice complaints and the processes by which to do so, internally as well as externally where applicable.

3.1.4.3 A nominated individual within the pharmacy practice is responsible for managing the complaints and ensuring that the complaints policy is implemented.

3.1.4.4 A nominated individual within the practice is responsible to oversee the investigation of and response to the complaint.

3.1.4.5 Complaints are monitored and repetitions or patterns are identified.

3.1.4.6 Any opportunities for improvement identified from the investigation of complaints are implemented.

3.2 Communication with patients and partner services

3.2.1 Patients and partner services in the community are informed of the processes to access the pharmacy practice services.

Standard Intent:
Patients and services working in collaboration with the practice need to know how and when to contact the practice to access pharmaceutical services. It is reasonable to expect most pharmacy practices to offer care during normal office hours.

Criteria

3.2.1.1 Information on services, hours of operation and processes for obtaining

care is provided to services in the community who work in collaboration with the practice (e.g. community nursing teams, step down care, PAMs etc.)

3.2.1.2 When patients initially register their details with the pharmacy practice they are informed of the opening hours and contact details.

3.2.1.3 Where the practice has an 'on hold' telephone message, it includes a message for an alternative number to be used in an emergency.

3.2.1.4 The practice renders services based on the needs of the population, during the hours that they publish.

3.2.2 At registration, sufficient details are taken from the patient to ensure that the patient can be contacted by the practice when necessary and that personnel seeing the patient for the first time has sufficient background information to provide adequate care to the patient.

Standard Intent:
Accurate contact details are essential in order to recall patients for chronic disease monitoring and contact patients for collection of medication. The required medical information is essential to the provision of adequate care, but can be adequately obtained by administrative personnel in the first instance with further detail elicited during the registration or dispensary process if necessary:

The following details should be obtained at registration of a new patient as a minimum:

a) Patient name
b) current address
c) Unique patient identification number
d) Clinical diagnosis
e) Gender
f) Date of birth
g) Identity of the prescribing clinician
h) Medication prescribed
i) Date of prescription
j) telephone numbers

Criteria

3.2.2.1 New patients to the practice are asked to complete a form detailing a) – j) as a minimum:

3.2.2.2 Patients are asked to update the practice if their contact details change.

3.2.3 Patients are able to obtain advice or information related to their care by telephone and electronic means.

Standard Intent:
Where patients who are known to the pharmacy practice request information, the patient has access to the relevant information by telephone or electronic communication. The practice has a documented policy regarding such communication that clearly outlines:

a) Limitations of use
b) Positive identification of the patient
c) Timeframe for a response
d) That the patient was made aware of any costs involved
e) Documentation of the communication in the patient record

Criteria

3.2.3.1 The practice implements a policy on telephonic and electronic communication with patients that details at least a) – e) in the standard intent

3.2.3.2 There is a practice policy on communication with patients that details how the practice uses telephone and electronic communication with patients.

3.2.3.3 There is evidence of practice/patient telephone or electronic advice and information in the patient health records.

3.2.3.4 The practice can demonstrate how it receives and returns telephone and (if applicable) electronic messages from patients.

3.2.4 Patient and family education promotes the concept of taking responsibility for one's own health care.

Standard Intent:
Every patient is offered the information and education he or she requires. All personnel within the practice work collaboratively to provide education in a co-ordinated manner. Personnel collaboration helps to ensure that the information patients and families receive is comprehensive, consistent and as effective as possible.

Education is focused on the specific knowledge and skills the patient and his or her family will need regarding their prescribed treatment. Variables such as educational literacy, beliefs and limitations are taken into account. Each practice decides on the placement and format of educational assessment, planning and delivery of information. Education regarding high risk health issues relevant to the local population is routinely provided by the pharmacy practice. Standardised materials and processes are used where possible.

Information provided by the pharmacy practice may include preventive practices relevant to the patient's condition and, when appropriate, information on coping with disease or disability.

Criteria

3.2.4.1 The practice offers relevant health education to its patients in a planned and consistent manner which enables patients to meet their on-going health needs and achieve their health goals.

3.2.4.2 Posters and pamphlets are available for commonly treated conditions in the community.

3.2.4.3 Information regarding high risk conditions relevant to the local population (e.g. HIV, TB, nutrition) is visibly displayed and accessible (e.g. posters,

pamphlets) and routinely provided to clients and patients.

3.2.4.4 Patient and family education provided is noted. Are instructions given to patients for administering of meds recorded? (for TWG)

3.2.4.5 The practice identifies community resources which support continuing health promotion and disease prevention education and has contact details of these resources available.

3.2.4.6 Information is provided in a way and in a language that is understood by those receiving treatment.

3.3 Patient records

3.3.1 A system for the storage of health records that meets the needs of confidentiality and safety is implemented.

Standard Intent:
Policies and procedures as well as managerial supervision ensure the safety and confidentiality of files. The policy will define who has access to information, the information to which an individual has access, the user's obligation to keep information confidential and the process followed when confidentiality and/or security are violated. The policy will also make provision for the protection of records against fire, flood, theft and electronic failure.

Personnel members responsible for health record management must have suitable training and experience.

The pharmacy practice should have policies in place for the safe storage and retrieval of patient records. Files must be readily available each time the patient visits the pharmacy practice and therefore must be filed in such a way that they are easily identified. There is going to have to be some mention in here of the patient carried documents. Further discussion points – safety of electronic records

Criteria

3.3.1.1 Designated individuals are responsible for the storage, maintenance and retrieval of patient prescription records.

3.3.1.2 There is a documented policy for the storage and retrieval of patient prescription records.

3.3.1.3 The filing system allows for incorrectly filed records to be easily identified (e.g. through colour coding of the records)

3.3.1.4 Policies and procedures that relate to the safeguarding of information in the record (both paper and electronic) against loss, damage, levels of access for individual staff members, breach of confidentiality or use by unauthorised persons are documented and implemented.

3.3.1.5 A documented policy details how to respond when confidentiality and/or security of patient records are violated.

3.3.1.6 Storage space for health records is sufficient and secure against unauthorised entry.

3.3.1.7 The designated area for notes storage is out of public view.

3.3.2 The pharmacy practice has a policy on the archiving, retention and destruction of patient records

Standard Intent:
The pharmacy practice develops and implements a policy that guides the retention of patient records and other data and information. Patient records and other data and information are retained for sufficient periods to comply with law and regulation and support pharmaceutical service, the management of the pharmacy practice, legal documentation, research and education. The retention policy is consistent with the confidentiality and security of such information. When the retention period is complete, patient records and other data and information are destroyed appropriately.

Criteria

3.3.2.1 The pharmacy practice has a policy on the retention of patient records and other data and information which is implemented.

3.3.2.2 The retention process provides the necessary confidentiality and security.

3.3.2.3 Policies and procedures are developed for health record destruction, specifying the criteria for selection and the method of destruction.

3.3.2.4 Destruction of the record maintains confidentiality of the content.

3.3.3 Patient prescriptions contain the required information. (to include the patient carried notes???).

Standard Intent:
The prescription record of each patient, whether handwritten or electronic, clearly documents the plan of care, responses to treatment, changes in patient/client status relative to the treatment and discharge/discontinuation of treatment. A standardised format and content of a patient's prescription record will help promote the integration and continuity of care among the various providers of care to the patient. The pharmacy practice determines the specific data and information recorded. The patient's prescription sheet contains the following as a minimum for each dispensary:

a) prescriber name, address, telephone number and signature
b) date on which the prescription is written
c) patients full name and address
d) patient's date of birth
e) the quantity to be supplied in words and numerals

Criteria

3.3.3.1 Notes for each prescription dispensed contain as a minimum points (a)-(e) above.

3.3.3.2 Handwritten notes are legible.

3.3.3.3 Notes are recorded contemporaneously.

3.3.3.4 All abbreviations are standardised according to recognised local and national standards.

3.3.3.5 The patients' records, including contact details, are up to date to ensure the transfer of the latest information between care providers.

3.3.3.6 There is evidence of review of prescribed medication which could have potentially harmful effects. (Should be in cases of opiods, and other medication which could have potentially harmful effects). Should be done collaboratively with prescriber, for TWG.

3.3.3.7 The patient is fully informed regarding the estimated costs of any treatment, investigation, procedure or referral prior to these costs being incurred and the discussion is documented.

3.4 Management of the pharmaceutical service

3.4.1 Medication management within the pharmaceutical service is organised to meet the needs of patients.

Standard Intent

The management of medication in a pharmaceutical service must be organised effectively and efficiently throughout. Medication management is not only the responsibility of clinical care providers, but also of the managers of a pharmacy service provider. Applicable laws and regulations must be incorporated into the organisational structure and the operations of the pharmaceutical service. A registered pharmacist who is qualified by education, training and experience should be responsible for the direct supervision of the activities in the pharmacy.

Documentation which guides the management of the service should be available and consulted, for example:

- Current country-specific acts and regulations relating to medication control
- Guidelines relating to professional practice, e.g. Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services. [1]

The pharmaceutical service should collaborate with all other pharmaceutical service providers to ensure safe medication usage and control and limit adverse drug reactions, drug-related adverse events and medication errors.

The forum for such collaboration can be provided by Pharmaceutical Committee's, Drug Regulatory Unit. Minutes of these meetings should be circulated to all relevant personnel.

Criteria

3.4.1.1 The pharmaceutical service is managed by a registered pharmacist with clearly defined responsibilities and accountability for all aspects of the service.

Guideline Statement: *This refers to a person appointed to the management position in terms of the job specifications.*

Where pharmacy technicians or similar individuals are employed, country-specific regulations will apply.
This criterion will be scored as PC if:
- *There is no documented job description or job specification*
- *The position is filled by someone in an acting capacity for longer than six months*

In the case where an unqualified person manages the service, the score will be NC.

3.4.1.2 A registered pharmacist is designated as deputy to act in the absence of the manager.

Guideline Statement:
The designation must be documented.
The situation occurs sometimes in small pharmacies where only one pharmacist is available and another person takes charge of the pharmacy in the absence of the pharmacist. In this case the criterion will be scored NC.

3.4.1.3 The responsibilities of the pharmacy manager include ensuring compliance with laws and regulations relating to the service.

Guideline Statement:
It is important to note that this criterion can only be scored after all the services where medication is managed have been assessed.
Country-specific regulations will apply.
This criterion will be scored compliant by default, but a PC rating is given whenever there is actual evidence of non-adherence to any particular legal requirement, either within the pharmacy service or any other area where pharmaceuticals are handled.

3.4.1.4 The responsibilities of the pharmacy manager include ensuring compliance with pharmacy practice and current pharmaceutical and other health professional guidelines.

Guideline Statement:
Country-specific laws, regulations and professional arrangements will apply.
Examples of such professional guidelines are:
- *Martindale*
- *Current medicine formularies*
- *Good Pharmacy Practice*
- *Professional guidelines for doctors and nurses, with regard to all aspects pertaining to medication management*

3.4.1.5 The pharmacy manager facilitates collaboration between pharmacy personnel and the relevant clinical care team (TWG) to ensure safe prescribing, ordering, storage, preparation, dispensing and administration of medications.

Guideline Statement:
Country-specific laws, regulations and professional arrangements will apply.

The formulation of medication-related policies and procedures should be seen as part of this collaboration, as well as the provision of drug information to all health professionals, which could include:

- *New medicines, withdrawal/availability, alternatives, generics*
- *Drug utilisation report, changes in usage patterns, out of stock items*
- *Interactions, adverse reaction reports*
- *Results from quality monitoring processes such as medication errors, antibiotic usage, expired stock, aged stock, etc.*
- *Departmental meetings (e.g. Drug & Therapeutic, Pharmacovigilance)*

3.4.1.6 The manager ensures that reliable drug information is readily accessible.

Guideline Statement:
This information can be available in paper or electronic format. All medication should be included in this reference information as well as medication likely to be brought in by patients. Access to information on medication which is rarely seen or used as well as access to information on medication used in other countries should also be available. Where the internet is used, reliable sites should be identified by the pharmacy manager in collaboration with more senior colleagues where relevant, e.g. the pharmacy manager should confirm the selection with the regional pharmacist, if applicable or pharmaceutical committee.

3.5 Access to appropriate medication

3.5.1 An appropriate selection of medication for prescribing or ordering is stocked or readily available.

Standard Intent
Those responsible for managing and prescribing medication must decide which medication to make available. This decision should be based on the pharmacy's mission, patient needs and the types of services provided. The pharmaceutical service should develop a list of all the medication it stocks or that are readily available from outside sources. In some cases, laws or regulations may determine the medication on the list or the source of those medications. Medication selection should be a collaborative process which considers patient needs and safety as well as financial factors. The pharmaceutical service should have a method to maintain and monitor this medication list and to monitor the use of medication within the pharmaceutical service, e.g. Pharmaceutical and Therapeutics Committee. Those who prescribe or order medication should know what medication is available and how to obtain them.

Pharmacists should be familiar with the indications for medication not routinely stocked within the pharmaceutical service and where to obtain them when required.When patient emergencies occur, quick access to appropriate emergency medication is critical. Each pharmaceutical service must plan the location of emergency medication and the medication to be stocked in these locations. To ensure access to emergency medication when needed, the pharmaceutical service must establish a procedure or process to prevent theft or loss of the medication and to ensure that medication is replaced when used, damaged or out of date.

Occasionally, medication used routinely in the provision of services may not be available due to circumstances beyond the control of the pharmaceutical service management. In such cases, prescribers must be informed of the non-availability of such medication and advised

of suitable available alternatives. Procedures must be in place to locate and obtain stocks of the usual medication as soon as possible to minimise the disruption to services.

Criteria

3.5.1.1 Medication available for prescribing and ordering are appropriate for the pharmaceutical service's mission, patient needs and services provided.

Guideline Statement:
The scoring will depend on the availability and appropriateness of medicines to be able to treat all conditions relevant to the level of care.

3.5.1.2 There is a list of medication stocked in the pharmaceutical service or readily available from outside sources.

Guideline Statement:
This list should be updated regularly according to the pharmaceutical service policy and made available to prescribers and dispensers.

3.5.1.3 There is a method for control of medication use within the pharmaceutical service.

Guideline Statement:
This criterion covers a number of aspects.
This includes all stock control measures reasonably expected to be in place and also includes the authorisation to prescribe and dispense.
Examples are: Drug utilisation reviews, adherance to protocols, use of specialised drugs, control of stock, other control mechanisms, e.g. secure movement of medication through the pharmaceutical service, signature for the receipt of medication, , prescription patterns by doctors e.g. poly-pharmacy, etc.

3.5.1.4 There is a process to obtain required medication which are not routinely stocked or normally available to the pharmaceutical service.

Guideline Statement:
At government pharmaceutical services there is usually a clearly defined process guided by a governmental pharmaceutical supply policy framework.
In the private sector there should be a documented directive/policy available – this is often a reciprocal arrangement with other pharmacies or pharmaceutical services and can be verified by requesting records of relevant communications between concerned parties.

3.5.1.5 Emergency medication is available in the pharmaceutical service within a time frame to meet emergency needs.

Guideline Statement:
This criterion refers to the identification of emergency medication and their availability. Emergency medication includes, poison antidotes,

Personnel should be made aware of the storage location of these medication and how to obtain them.
The pharmaceutical service needs to assess the poison risks in the population served. This could include organophosphate poisoning, dog, scorpion and/or snake bites. There should be telephone/internet links to a poison center and the number should be easily accessible.
The time frame can be measured in an indirect manner i.e. assess the availability according to pharmaceutical service checklists
Consideration should also be given to the supply of emergency medication from suppliers, medication for disasters and in case of epidemics.

3.5.1.6 Emergency medication is monitored and replaced in a timely manner, after use or when expired or damaged.

Guideline Statement:
This criterion refers to the availability as well as expiry dates of emergency medication and does not only refer to the monitoring of the emergency trolley.(if one is kept and available, to workshop with TWG)

3.5.1.7 In the event of medication stock outs, prescribers are informed of the stock out and advised of suitable alternatives.

Guideline Statement:
Pharmacy management should take steps to ensure that stock outs do not happen. However, in the event of a stock out, this requirement seeks to ensure that patients are provided with the most suitable alternative and that all prescribers are aware of this option for affected patients.

3.6 Dispensing

3.6.1 Medication is dispensed in accordance with legislation, regulations and professional standards of practice.

Standard Intent
A registered pharmacist must review each prescription or order for medication. When queries arise, the individual who prescribed or ordered the medication must be contacted. The dispenser must sign the prescription. When pharmacist assistants, technicians or interns dispense, they must be supervised and their signatures to confirm dispensing must be countersigned by a registered pharmacist. The pharmaceutical service must dispense medication in the most ready-to-administer form possible to minimise opportunities for error during distribution and administration. The central pharmacy and other medication distribution points throughout the pharmaceutical service (including related facilities such as satellite clinics, etc.) must all use the same dispensing system. The system must support accurate dispensing of medication in a timely manner.

It is generally accepted that the dispensing process is divided into three phases:
Phase 1: Interpretation and evaluation of a prescription
Phase 2: Preparation and labelling of the prescribed medication.
Phase 3: Provision of information and instructions to the patient to ensure the optimum use of medication

Criteria

3.6.1.1 Medication is prepared and dispensed in a safe and clean environment.

Guideline Statement:
This refers to the use of the required personal protective equipment and the availability of appropriate facilities for the various types of functions performed. Attention to be given when specialised functions are performed e.g. the preparation of total parenteral nutrition, sterile compounding, the preparation of cytotoxic medication, etc.

3.6.1.2 There is a uniform medication dispensing and distribution system throughout the pharmaceutical service.

3.6.1.3

Guideline Statement:
Where satellite pharmacies/distribution points e.g. emergency/ after-hours cupboards exists, uniform processes are applied.
Distribution will include the delivery methods to patient care areas in the pharmaceutical service.
It is important to note that the way in which dispensing/issuing is done after-hours may affect the score if it does not conform to the same rules as day time practice.

3.6.1.4 The system supports accurate and timely dispensing.

Guideline Statement:
In order to measure compliance the pharmacy/ pharmaceutical service should provide data on the monitoring of waiting times (for both out patients and discharged inpatients) and dispensing errors. In the absence of such data, a judgement call may be required by observing queues and movement of patients in the outpatient department of public pharmaceutical services, assessing the number of inpatient records piling up in the pharmacy, etc.

3.6.1.5 Medication is securely and legibly labelled with relevant information as required by pharmaceutical service policy.

Guideline Statement:
This will be assessed in the pharmacy and in all areas in the pharmaceutical service where medication is handled.
Country-specific regulations must be applied, but must include at least the following:

- *Name of prescribing physician (if applicable)*
- *Name of patient and pharmaceutical service number*
- *Proprietary name/approved name or name of each active ingredient*
- *Direction with regard to manner in which medicine must be used*
- *Number of dose units in the container*
- *Date of dispensing*
- *Expiry date and batch number*
- *Additional labels with warnings and storage instructions according to local instructions*

3.6.1.6 Where computer programs are used to check for contra-indications and potential drug interactions for prescribed medication, there is a process to

ensure that the program is current and updated according to the manufacturer's recommendations.

Guideline Statement: *Although such programs are helpful, it is essential to ensure that the information they provide is up to date. The pharmacy team should therefore develop and implement a procedure to ensure that the information remains up-to-date.*

3.7 Control and storage of medication

3.7.1 Medication is stored in a secure and clean environment.

Standard Intent

Secure storage systems ensure that pharmaceuticals and related substances are held under conditions which conform to statutory and manufacturer's requirements.

Arrangements should be in place to ensure the security of medicines, including alarm systems, door access controls and safes/vaults used to store controlled medicines.

The pharmacy or pharmaceutical service stores and dispenses medication in a clean and secure environment, which complies with legislation, regulations and professional practice standards. In particular, medication must be clearly labelled, stored correctly and in an orderly fashion and protected from heat, light and moisture to maintain product stability when necessary.

Deep freeze, refrigeration, cold room and cool area facilities must be provided for safe storage of medication that requires these conditions. There must be a mechanism in place to ensure that the temperature has been maintained throughout the life of the medication. Deep freezers and refrigerators must be defrosted when necessary. Doors, hinges and seals must all be functional.

Medication stored and dispensed from areas outside the pharmacy, should comply with the same safety measures, including labelling requirements for pre-packed medications.

There must be a registry, log or other mechanism to monitor and account for controlled substances.

Criteria

3.7.1.1 Separate designated storage areas for the receipt and unpacking of incoming goods are provided.

Guideline Statement: *This criterion measures the availability of space for the two functions mentioned. The ideal situation should be the availability of a separate enclosure, but a "functional" separate area would be accepted.* *This will be assessed only in the pharmacy.*

3.7.1.2 Hazardous and flammable materials are stored in accordance with relevant regulations.

Guideline Statement: *With regard to flammables, the permissible amount stored in the pharmacy will be determined by country-specific regulations. The guiding principle here*

should be the requirements from the local Fire Authority. This implies that the inspection by the Fire Authority should include a visit to the pharmacy.
This will be assessed only in the pharmacy(ies).

3.7.1.3 Separate designated storage areas for materials under quarantine are provided.

Guideline Statement:
These products, e.g. expired stock or compounded products, should be clearly marked and kept separately, ensuring that these items are not mixed with other pharmaceutical supplies that are still in use. These products can be stored on a shelf (as long it is a small volume and clearly marked in a container) or a room.
This will be assessed only in the pharmacy responsible for the storage of these items.

3.7.1.4 Safe and secure storage facilities are available, including smoke detectors, security alarm systems and/or barriers.

Guideline Statement:
The pharmacy must be lockable and exclude any unauthorised entry. The responsible pharmacist or another pharmacist must keep the key on his or her person. This refers to the pharmacy and pharmacy stores.

3.7.1.5 Stock control systems are managed in the pharmacy and other related services.

Guideline Statement:
Stock control systems in the pharmacy and related services can either be a manual or electronic system, or both. Some pharmacies have a dual system: bulk stock in the store is controlled, but open stock is often not controlled unless an electronic dispensing system is in use. Under these conditions this criterion will be scored PC.
It is important to note that this criterion also refers to all satellite services where medication is stocked.

3.7.1.6 A management information system is available, which provides accurate statistics relating to pharmaceutical receipts and issues.

Guideline Statement:
This criterion measures a number of aspects, e.g. statistics with regards to stock control, the monitoring of financial aspects, out-of-stock items, aged items, drug availability, etc.
This will be assessed only in the pharmacy.

3.7.1.7 Medication is stored in a clean environment.

Guideline Statement:

It is important to note that this criterion also refers to all departments where medication is stored.

3.7.1.8 The cold chain is maintained for medication where necessary.

Guideline Statement:
Protocols should be available addressing the cold chain all the way from the manufacturer to the end user. It is the responsibility of the pharmacist to ensure that the cold chain is maintained. It is also the responsibility of the pharmacist to ensure that medicines which must be stored at low temperatures have not had the cold chain broken when received by the pharmaceutical service. It is important to ensure that the cold chain is not broken during transport to the pharmacy as well as in the pharmacy.
A refrigerator equipped with a thermometer should be available to store products between 2 and 8 degrees Celsius. Temperatures must be monitored and logged twice daily. The designated refrigerator should be used only for the storage of pharmaceuticals. A WHO-approved dial thermometer, alcohol or mercury thermometer, and not necessarily a min/max thermometer is required.
A freezer for the storage of polio and measles vaccines, where applicable, and ice packs must be available. Freezers/refrigerators must be connected to the emergency power supply.
Note that some medication is provided with colour coded blocks, which indicate if the cold chain has been broken.
It is important to note that this criterion also refers to all departments where medication is stored.

3.7.1.9 Medication storage areas are protected from heat, light and moisture and temperatures are monitored and recorded.

Guideline Statement:
The room temperature must be maintained below 25 degrees Celsius. If required, air-conditioners must be installed. It is important that medication is not exposed to direct sunlight.
*This applies to **all areas** in the pharmaceutical service where medication is stored.*

3.7.1.10 Appropriate action is taken when temperatures are higher or lower than recommended limits.

Guideline Statement:
The action required is two-fold; firstly to correct the temperature of the refrigerator and secondly to deal with the medication which has been exposed to high or low temperatures. Actions taken to correct the temperature of the refrigerator should be documented and the temperature monitored more frequently until it is confirmed that the action taken has been sufficient to achieve and maintain the recommended temperature range. The medication should be dealt with according to the manufacturer's instructions. Where necessary, medication should be discarded to avoid patients receiving inactive or degraded substances which have the potential to cause harm.

3.7.1.11 Medication identified for special control by law or pharmaceutical service policy are stored in a cabinet of substantial construction, for which only authorised personnel have a key.

Guideline Statement:
Country specific laws and regulations will determine the nature of these medications.
Scheduled (controlled) drugs/narcotics/barbiturates and other dangerous drugs needs to be stored under lock and key at all times, but country specific requirements will apply.
"Substantial construction" is interpreted to be a cupboard/container that is mounted to the wall or fixed to the floor. Mostly these are steel cabinets but solid wooden cupboards are also acceptable.
This applies to all areas in the pharmaceutical service where medication is stored.

3.7.1.12 Medication identified for special control by law or pharmaceutical service policy are accurately accounted for.

Guideline Statement:
Compliance is measured against the local medication control regulations. Controlled medication in storage will be tallied with the recorded amount in the register. Please note that any discrepancy identified will result in a NC score, as all such dispensing should be recorded immediately as part of the dispensing process. Any observed discrepancy therefore demonstrates that procedures are not consistently implemented.
This applies to all areas in the pharmaceutical service where medication is stored.

3.8 Quality improvement

3.8.1 A formalised proactive quality improvement approach is maintained in the service.

Standard Intent
This refers to the implementation of pharmaceutical service quality improvement processes.

It is the responsibility of the management of the pharmaceutical service to ensure that standards are set throughout the pharmaceutical service. It is the responsibility of the pharmacy manager to ensure that standards are set for the particular department. This requires coordination with the pharmaceutical service's central coordinating quality improvement structures or systems. The pharmacy managers use available data and information to identify priority areas for quality monitoring and improvement.

Quality monitoring could include:
a) Completion of prescriptions
b) The use of antibiotics and other medication
c) Medication errors
d) Adverse medication effects
e) Patient and family expectations and satisfaction
f) Audits of medication storage

g) Monitoring of financial aspects
h) Out-of-stock items, aged items
i) Analysis of complaints, negative incidents, client satisfaction
j) Monitoring of illegible scripts

The following will be evaluated:
- Problems identified in this service for which quality improvement activities were initiated
- The processes put in place to resolve the problems
- Identification of indicators to measure improvement
- The tool(s) used to evaluate these indicators
- The monitoring of these indicators and corrective steps taken when goals were not achieved
- Graphed results, where appropriate

A once-off project, for example, supplying a thermometer for a refrigerator, will be scored as NC.

25.6.1 Criteria

3.8.1.1 There are formalised quality improvement processes for the service that have been developed and agreed upon by the personnel of the service.

Root Criterion
Guideline Statement:
Once the pharmacy has analysed its mission, defined its objectives, and identified all its stakeholders, there needs to be a way in which progress towards achieving these objectives can be measured.
The minimum requirement for considering compliance will be the availability of evidence of:
- *Participation in documentation (patient record) audit*
- *Participation in monitoring near misses, sentinel and adverse events*

3.8.1.2 Indicators of performance are identified to evaluate the quality of the service.

Guideline Statement:
Performance indicators are quantifiable measurements, determined beforehand, that will reflect the quality of the service.
Performance indicators should include at least medication errors and adverse effects.
The information gained must be used to identify and implement improvement programmes. Statistical reports without documented evidence of continuous quality improvement will be scored PC.

3.8.1.3 The pharmacy has a system in place to monitor the appropriate use of antibiotics within the pharmaceutical service.

Guideline Statement"
This could include minutes of the meetings of the Antibiotic Stewardship Committee or equivalent.

3.8.1.4 Data relating to medication errors and adverse drug reactions is used to improve medication management within the pharmaceutical service and

monitor the effectiveness of actions taken to prevent recurrence of such events.

3.8.1.5 The quality improvement cycle includes the monitoring and evaluation of the standards set and the remedial action implemented.

Guideline Statement:
Regular measurements should be done to check on the performance indicators as above and these results will allow for ongoing monitoring of either poor performance against the standards, or improvements over time. Ongoing monitoring is required in order to demonstrate that improvements are sustained.

3.8.1.6 A documentation audit system is in place.

Guideline Statement:
Documented evidence of such audits must be provided.
These audit processes can include auditing of prescriptions, order forms, the audit trails that take place with the use of electronic systems, etc.
Evaluation of results and remedial action taken must be documented.

3.10 Emergency care

3.10.1 The practice provides emergency treatment and care.

Criteria

3.10.1.1 Written guidelines are available and followed relating to the provision of primary emergency services.

3.10.1.2 Guidelines for paediatric emergency triage, assessment and treatment (ETAT) are available and followed.

3.10.1.3 Information on cases and the outcome of emergency treatment are recorded in a register/logbook.

3.10.1.4 Case reviews are undertaken within the practice to assess the quality of treatment and care of patients requiring emergency care.

3.10.1.5 There is a protocol that delineates how the practice evaluates, manages, stabilises and transfers patients with emergency conditions.

3.10.2 The practice provides resuscitation in accordance with practice policy.

Standard Intent:
Practices in urban areas with adequate emergency service cover may prefer not to have defibrillators or emergency drugs on site, but are still required to be proficient in the provision of basic life support when necessary. The level of service provided by the practice is agreed by all clinical personnel and documented in a policy.

For practices that offer advanced life support, local paramedics can be consulted on necessary drugs and equipment.

Criteria

3.10.2.1 The practice has a policy on resuscitation, which includes the level at which resuscitation is provided, by whom and training and equipment requirements.

3.10.2.2 The policy includes the availability of resuscitation equipment and medicines with clear instructions for use.

3.10.2.3 Identified practice personnel are trained in basic resuscitation techniques at least every two years, with records of their attendance at such training.

3.10.3 Equipment for resuscitation is available in accordance with the policies of the practice.

Standard Intent:
Resuscitation equipment and medication is available according to the practice's policy and protocol. There is access to a defibrillator or automated external defibrillator (AED) within 3 minutes of any patient collapsing. Resuscitation equipment includes at least:

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- a bag-mask manual ventilator
- a selection of Guedel airways

Criteria

3.10.3.1 There is a designated resuscitation area.

3.10.3.2 There is a mechanism for the summoning of medical help in an emergency.

3.10.3.3 The practice provides resuscitation equipment according to the practices emergency response policy.

3.10.3.4 Equipment as listed in the standard intent above for early cardiopulmonary resuscitation is available within one minute in each area of the practice.

3.10.3.5 The practice has access to Ambulance Services (EMS).