1 MANAGEMENT AND LEADERSHIP

OVERVIEW OF MANAGEMENT AND LEADERSHIP

Effective management of a Medical Laboratory begins with understanding the various responsibilities and authorities of individuals in the practice, and how these individuals work together. The practice manager ensures that policies and procedures appropriate to the various teams within the practice are developed and implemented. The responsibilities of the practice manager are documented and are known to the 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 practice to be able to operate efficiently, achieve its goals and fulfil its mission.

It is important that the 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 practice may assume all these leadership responsibilities. In some practices, however, leadership will be undertaken by different members of the practice team, although quality management should remain the responsibility of a designated quality officer/manager.

Standards

1.1 Mission statement

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

Standard Intent:
A practice's mission statement usually reflects the needs of its patient population and patient care services are designed and planned to respond to those needs. It is important that all members of the practice team are recognised and included in the process of defining the practice's mission. Effective leadership is essential for a 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.

Patient care services are planned and designed to respond to the needs of the patient population. The leaders of the 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 practice over the coming year is a useful tool to support the 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 practice's strategic plan should be reviewed yearly to ensure that it remains reflective of the current needs of the practice population.

Criteria

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

1.1.1.2 The practice has a mission statement that reflects the strategic objectives

of the practice and matches the needs of the community served by the practice.

1.1.1.3 The leaders are collectively responsible for implementing the 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 practice within relevant laws and regulations.

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

Criteria

1.2.1.1 The manager is responsible for the day-to-day running of the 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 practices in the community.

1.2.1.7 There is a current budget for the practice.

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

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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 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 service is organised to provide a safe and effective service and is co-ordinated with other relevant services in the referral hospital and in the community.

1.3 Policies and procedures

1.3.1 The medical laboratory practice manager has documented policies and procedures which support the activities of the practice.

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Standard Intent:
All policies which apply to the medical laboratory practice should be available to personnel and should reflect the mission, purposes and goals of the practice. They should be consistent with national and international guidelines and Codes of Ethics, and must include as a minimum:

a) Criteria for initiation and continuation of care
b) Criteria for referral to other appropriate health care providers
c) Infection prevention and control
d) Equipment maintenance
e) Patient management which includes reference to clinical and best practice guidelines
f) Patient feedback and complaints policies
g) Patient consent and information policies
h) Emergency plans (for example, in the event of a fire, emergency resuscitation)
i) Criteria for termination of care

Criteria

1.3.1.1 Policies and procedures that guide and support the services offered by the practice are 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 Policies and procedures are reviewed according to practice policy and then dated and signed.

1.3.1.5 There is a process to ensure that personnel are familiar with relevant policies and procedures.

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 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 practice to plan and implement uniform programmes and processes related to the recruitment, retention and development of all personnel.
The 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 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 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 practice independently.

Standard Intent:
The 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 clinical practitioners employed by the practice, including locums. Evaluating an individual's credentials is the basis for two decisions: whether this individual can contribute to fulfilling the practice mission and meeting patient needs and if so, what clinical services 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 health professionals. Phlebotomists and lab assistants are not registered and therefore don't have a scope of practice – this needs clarification from MOH

1.4.2.3 Personnel files contain copies of qualifications and licenses/registration from the relevant authority for all 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 There is a system to track the annual registration of all health professionals.

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. Clarification from MOH but feedback is that they will require it.

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1.4.3 Clinical and administrative personnel participate in continuing education,

research and other educational experiences to acquire new skills and knowledge and to support job advancement.

Standard Intent:
The practice supports opportunities for continuing education and training of personnel to ensure they remain up to date with current best practice and to acquire advanced or new skills. These opportunities may be offered by the practice, by a professional association or through educational programmes in the community. The 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 practice supports continuing education for its clinical personnel and maintains records of this in personnel files.

1.4.3.2 There is a development strategy for the practice that ensures that the 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 practice 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 practice. Clinical and managerial personnel both need to be included in planning the financial requirements of the practice. They require information relating to the funds available to them for the management of the practice and up-to-date statements of current expenditure.
Sound accounting and auditing practices are implemented to ensure transparency. These practices are guided by documented policies and procedures. The 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 practice.

1.5.2.2 A report is produced at least quarterly for the owners of the 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 practice.

1.5.2.5 The practice uses a fee schedule that is consistent with the cost of medical laboratory services and that is within customary norms and reason and fairness. MOH feedback required.

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

Standard Intent:
The 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 clinical activities of the practice.

Criteria

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

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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, prescription pads 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 clinical and managerial 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 Pathology request forms, letterheads, administrative records and other official documents are accessible only to authorised persons.

*1.7 **Risk management***

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

Standard Intent:
To plan effectively, the 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 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 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 practice and physical facilities.

1.7.1.2 The practice manager ensures the development and implementation of written policies and procedures for risk management programme.

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 practice designs and implements a co-ordinated programme to reduce the risk of infections in patients and healthcare workers.

Standard Intent:
For an infection prevention and control programme to be effective, it must be comprehensive, encompassing both patient care and employee health. The programme is appropriate to the size and geographic location of the practice, the services offered by the practice and the patients seen by the practice.

Infections can enter the practice via patients, their families, personnel, visitors, other individuals and vectors. Thus, all areas of the practice where these individuals or vectors are found must be included in the programme of infection surveillance, prevention and control.
Certain infections require patients suffering from these infections to be isolated from non-infected patients, such as patients with TB or high risk influenza. These patients are identified when requesting an appointment and appropriately triaged. If it is necessary for these patients to attend the surgery, they are directed to a separate waiting area to prevent transmission of the infection to non-infected patients.
The programme is managed by a nominated individual within the practice and all practice personnel are informed of the nomination. Their qualifications depend on the activities they will carry out and may be met through education, training and experience. Co-ordination involves communication with all parts of the practice to ensure that the programme is continuous and proactive.
Whatever the mechanism chosen by the practice to co-ordinate the infection control programme, medical and nursing personnel are represented and engaged in the activities. The individual, committee, or other mechanism must also monitor those support services in the practice which may lead to the spread of infection, e.g. cleaning and waste disposal.
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 practice and practice 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 patient and personnel areas of the 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 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 The practice reports on notifiable diseases to appropriate external public health agencies.

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

1.7.2.10 Relevant personnel members are immunised against Hep B according to practice policy.

1.7.2.11 There is a documented policy for the management of exposure to high risk infections and needle-stick injuries.

1.7.2.12 Post HIV and Hep B exposure prophylaxis is available to the personnel in accordance with practice policy.

1.7.2.13 There is a documented policy for the management of body fluid spills.

1.7.2.14 There is a documented policy for the handling of potentially high risk infection specimens.

1.7.3 The 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 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 practice's risk management plan.

Criteria

1.7.3.1 The practice has a waste management policy that includes the safe handling, storing and disposing of all different types of waste. GS for Labs re cleaning staff.

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

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

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

Standard Intent

As a minimum, the practice should have a system for recording, analysing, discussing and learning from adverse events within the practice. This should include clinical, 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 practices to provide benchmarking.

Clinically significant events such as specimen contamination, needle-stick injuries, incorrect labelling, 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 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 clinical 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 practice implements structured systems to ensure fire safety.

Standard Intent:
Fire is an ever-present risk in a practice. As such the 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 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 practice develops and implements a policy and plan to eliminate smoking in the practice's facilities or to limit smoking to designated non-patient care areas.

Criteria

1.7.6.1 There are structured systems and processes in place to ensure that all occupants of the 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 practice develops a written plan to respond to emergencies.

Standard Intent:
Community emergencies, epidemics and major events such as damage to patient care areas as a result of a natural disaster or influenza that affects personnel may directly involve

the practice. 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 practice develops a plan and rehearses it.

Criteria

1.7.7.1 There is a written plan to deal with emergencies (including bomb threats, active shooter, 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 practices, regardless of their size and resources, must comply with these requirements as part of their responsibilities to patients, families and personnel. 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 patient care 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 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 practice is facilitated by adequate infrastructural arrangements.

Criteria

2.1.1.1 Directional signs to the 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.

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2.1.1.3 A phone number for the after-hours service of the practice is clearly displayed in the waiting room.

2.1.1.4 Parking is provided close to the building entrance for patients, including

the physically challenged.

2.1.1.5 There is wheelchair access to and within the building.

2.1.1.6 Ramps and stairs include safety features such as rails.

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

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

The physical facilities required include adequate office accommodation for personnel, phlebotomy rooms which are hygienically clean at all times, sampling laboratory which has adequate space for benchtop and 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 consulting room, which may include an attached examination room/area:
- is free from excessive noise
- has adequate lighting
- has an examination couch
- is maintained at a comfortable ambient temperature
- ensures patient privacy when the patient needs to undress for a clinical examination (e.g. the use of adequate curtains or screens and gowns or sheets)

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 practice's facilities are available in writing to the personnel.

2.1.2.2 The building is appropriate as a medical laboratory 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/examination room for every member of the clinical team working in the practice at any time.

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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 Temperature and ventilation control mechanisms are installed and maintained in the medicine store and other relevant areas.

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

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

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2.1.2.12 Separate sanitary facilities are provided for personnel.

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

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

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

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

2.1.3 Laboratory fixtures and fittings are adequate to provide a safe and effective laboratory service.

Standard Intent

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

- Laboratory benches and equipment should be of a material that can support the laboratory instruments (strong) and cannot affect the surface of the table. Preferably the laboratory tables should be constructed of concrete that is tiled. Wooden tables are not acceptable.
- At least one washing unit must be available for standard cleaning and washing activities. When staining is performed, two units are preferred.
- 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.

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2.1.3.2 There are sufficient laboratory benches for the projected activities.

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Guideline Statement:
The number and size of the laboratory tables should provide sufficient space for laboratory instruments and the laboratory activities to be performed.
When instruments are close to each other thereby preventing the operation and/or performance of other activities or when instruments are placed on the floor, the number of laboratory benches should be expanded.
When electrical instruments are close to the washing or staining area, consideration should be given to moving them to a different location.

2.1.3.3 Laboratory benches are strong enough for the projected activities (e.g. large instruments).

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Guideline Statement:
Benches must be made from tiled concrete or other strong, dedicated materials.
Bench surfaces should preferably be covered with a material resistant to chemicals (no wood).
Benches should be level in order to allow the instruments to be positioned horizontally.
Benches should be reinforced when heavy or shaking instruments are used.

2.1.3.4 Space around and under benches should allow for ease of cleaning and maintenance.

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

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

Guideline Statement:
Sufficient space should be available for supplies to be organised neatly and logically for ease of retrieval, which in turn assists in the prevention of adverse events.

2.1.3.6 There is either an uninterrupted power supply (UPS), or battery backup system, and an automated voltage stabiliser (AVS) present for critical equipment, which are tested regularly and the results of testing are fully documented.

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Guideline Statement:
Critical equipment should be connected to the power supply using an UPS or battery back-up and an AVS, according to manufacturer's instructions.
The size of the UPS/AVS is dependent on the capacity of the equipment.
Documented evidence of testing is required.

2.1.3.7 Each laboratory compartment has adequate ventilation, room temperature is maintained below 25°C and a temperature record is kept.

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Guideline Statement:
The laboratory needs to be temperature controlled, because when the temperature is high, it can influence the laboratory 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 **Medical equipment and supplies including reagents, chemicals and kits***

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

Standard Intent:
Practices are responsible for ensuring that appropriate medical laboratory 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 medical laboratory equipment is available to meet the demands of quality patient care.

Laboratory management and personnel takes responsibility for ensuring that medical laboratory equipment is available, appropriately maintained and calibrated according to manufacturers instructions, and that the relevant personnel are competent to use it.

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

a) Microscope
b) Centrifuge (complete configuration)
c) Refrigerator with freezer compartment
d) Rocking platform (where applicable)
e) Chemistry analyser
f) Haematology analyser
g) Pressure cooker / autoclave (if preparing the culture medium on site)
h) UPS/AVS for critical instruments
i) Pipet, thermometer and timer
j) Fume hood (TB related activities)

Criteria

2.2.1.1 A designated individual supervises the management of medical laboratory equipment in the 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 medical laboratory equipment available at the practice.

2.2.1.4 Policies and procedures guide the management of medical laboratory equipment.

2.2.1.5 The supply of medical laboratory equipment is adequate to meet the needs of the practice and includes the equipment as listed a) - j) in the standard intent, as a minimum.

2.2.1.6 Records are kept of the checking and maintenance of medical laboratory equipment.

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

2.2.2 The supplies of laboratory consumables, reagents, chemicals and kits are adequate to provide a safe and effective laboratory service.

Standard Intent
The practice should identify those reagents and supplies required to deliver the necessary laboratory services to its patients. There should be an effective process for ensuring that essential reagents and other supplies are available at all times. All reagents should be stored and dispensed according to defined procedures. The periodic evaluation of all reagents, e.g. monitoring of expiry dates, will ensure accurate and precise results. Documented procedures should be available to ensure the complete and accurate labelling of reagents and solutions.

22.3.1 Criteria

2.2.2.1 The available supplies, consumables, reagents, chemicals and kits are sufficient for projected activities.

Guideline Statement:
Consider the level of service, the range of tests offered, and the type of equipment in use. Assess the available materials in relation to the stock management and procurement activities.

2.2.2.2 Specific laboratory reagents, chemicals and kits are used appropriately.

Guideline Statement:
Pay particular attention to the following:
- *Consumables are not re-used*
- *Reagents and kits are not expired*
- *Proper specimen collection materials are used e.g. Vacutainer (or similar) system for blood collection should be mandatory*
- *Products are from quality assured manufacturers*
- *Kits used are part of the national algorithms*
- *Reagents and kits are stored according to the manufacturer's guidelines*

2.2.2.3 All reagents and chemicals are stored and dispensed according to guidelines.

Guideline Statement:
Documentation should be available in the form of policies, guidelines, safe work procedures and/or manufacturer's guidelines, against which the actual arrangements will be assessed. The assessment needs to include all storage areas such as refrigerators, cupboards, work stations and storerooms as well as the processes involved with receiving, issuing and disposing of substances.
The materials should be checked on such aspects as:
- *Expiry date*
- *Storage temperature*
- *Protection from heat and sun*

- *Labels and dates*

2.2.2.4 All reagents and solutions are completely and accurately labelled.

Guideline Statement:
Labelling identification requirements include:
- *Name of the person who prepared the reagent/solution*
- *Name of the reagent/solution*
- *Strength or other reagent specification*
- *Date prepared or received*
- *Expiry date*

A random check needs to be done in all areas of the laboratory where these items used and stored.

2.2.2.5 All reagents are periodically evaluated for accuracy and results.

Guideline Statement:
Service policies/procedures/protocols/guidelines should be available to guide this practice and assessment of compliance will be done against these documents. Records should be available of periodic evaluations performed on reagents, including water used in the laboratory according to departmental policy.
The evaluation outcomes are usually recorded in the IQC log-books.

2.2.2.6 All chemical reagents are stored in a lockable storage room or cupboard.

Guideline Statement:
The working materials must be readily available and, therefore, do not have to be locked away during the operational hours of the laboratory.
At the end of the day, the laboratory must be closed in order to prevent unauthorised access and/or use.

2.2.2.7 A named person is responsible for the specimen and reagent fridges.

Such designation should be evident in writing e.g. duty roster.

*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 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 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 practice.

2.3.1.4 Written policies and procedures guide 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 practice implements a documented preventative planned maintenance programme for buildings, grounds and utilities.

Standard Intent:
The 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 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 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 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 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 patient care.

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 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 and laundry management***

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

Standard Intent:
Practice managers must ensure that a documented policy is available detailing the cleaning and laundry 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 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 and laundry service is outsourced.

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

2.4.1.3 There is evidence that laundry that has been used for patients is washed

separately from domestic laundry.

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

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

2.4.1.6 There is adequate storage place for brooms and mops.

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

2.4.1.8 Cleaning cupboards are adequately ventilated.

2.4.1.9 The practice manager ensures that the cleaning and laundry personnel 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 clinical 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 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 practice ensures that contracted personnel are oriented to relevant practice policies and procedures.

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

3 LABORATORY SERVICE AND QUALITY MANAGEMENT

*3.1 **Patient rights***

3.1.1 The practice has a patient rights policy.

Standard Intent:
The leaders of a practice are primarily responsible for the way in which that practice treats its patients. The leaders need to know and understand patient and family rights and their 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 patients cultural values, requirements and variations has been considered in the planning and delivery of the

medical laboratory service.

3.1.1.5 The policy demonstrates that practice personnel are required to respect and be sensitive to the patients 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 and/or having specimens taken. Patients may desire privacy from other personnel, other patients 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 files, results, 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 during relevant procedures.

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.

3.1.2.5 When appropriate, patients are permitted to be accompanied by a family members or care-giver during consultations.

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 in the case of patients who are unable to grant consent for themselves by way of age or mental/physical incapacity, 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 laboratory 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 and 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 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 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 care. It is reasonable to expect most practices to offer care during normal office hours.

For efficiency of service delivery, appointment systems are recommended as best practice.

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 register with the practice they are informed of the opening hours, contact details and after hours care arrangements of the practice where applicable.

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.

3.2.1.5 There is a policy for those patients who need an appointment system in place.

3.2.2 The practice has a system for recognising cases requiring more urgent attention and providing patients with longer appointments when appropriate.

Standard Intent:
The practice has a flexible system for determining the order in which patients are seen to accommodate patients' needs for urgent care, non-urgent care, complex care, planned chronic disease management, preventive healthcare and longer consultations.

If the practice is involved in training or research which makes it necessary for third parties to be present during the consultation, the patient is informed of this and given the opportunity to offer or withhold consent.

Criteria

3.2.2.1 There is a system for fast-tracking the very ill, the elderly and frail, and pregnant women.

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3.2.2.2 Patients who are waiting are advised of any delays that may be experienced in receiving attention.

3.2.2.3 There is a system to ensure that patients are seen within the shortest possible time.

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3.2.3 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 follow up results, recall patients for chronic disease monitoring and contact patients or nominated next of kin in emergency situations that may arise. Background 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 consultation 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 details
e) Gender
f) Date of birth
g) Identity of the requesting clinician
h) Sample type
i) Test requested
j) Date and time of sample collection
k) Result where applicable (e.g a previous result before this test is done) and medical aid authorisation
l) Telephone numbers

Criteria

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

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

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

Standard Intent:
Where patients who are known to the practice request information or follow up regarding an investigation they have had, 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

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

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

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

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

3.2.5 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 clinical 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 to make care decisions, participate in care and continue care at home. 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 practice. Standardised materials and processes are used where possible.

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

Criteria

3.2.5.1 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.

3.2.5.2 Posters and pamphlets are available for commonly investigated conditions in the practice.

3.2.5.3 Information regarding high risk conditions relevant to the practice population (e.g. HIV, TB, is visibly displayed and accessible in the waiting room (e.g. posters, pamphlets) and routinely provided to patients during the consultation when appropriate.

3.2.5.4 Patient and family education provided is noted in the patient record.

3.2.5.5 The practice identifies community resources which support continuing

health promotion and disease prevention education and has contact details of these resources available.

3.2.5.6 There is documented evidence that patients are referred to these resources, where appropriate.

3.2.5.7 Information is provided in a way and in a language that is understood by those making the care decisions.

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.

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Standard Intent:
Policies and procedures as well as managerial supervision ensure the safety and confidentiality of patient information. 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 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 practice and therefore must be filed in such a way that they are easily identified.

Criteria

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

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

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 the patient records are violated.

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

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

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

records

Standard Intent:
The 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 patient care, the management of the 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 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 records contain the required information for the relevant investigation.

Standard Intent:
The clinical record of each patient, whether handwritten or electronic, clearly documents all aspects of the patient/client management, including a)-e) below A standardised format and content of a patient's record 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 but it contains as a minimum for each consultation:

a) The date of the test
b) Who conducted the test
c) Patient reason for investigation
d) Results of the investigation
e) Re-examination
f) Any referral to other medical laboratories for specialized tests/investigations
g) Any special advice or other instructions
h) Follow up instructions given to the patient

Criteria

3.3.3.1 Notes for each consultation contain as a minimum points a) – h?) 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.

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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 the results of investigations performed by the laboratory service.

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

3.4 Management of specimens and results

3.4.1 Procedures are followed for collecting, identifying, transporting and tracking specimens or samples and reporting the results.

Standard Intent

Procedures are developed and implemented for:
a) Requesting laboratory tests (laboratory request form)
b) Specimen collection and identification
c) Specimen storage, preservation and transport
d) Reviewing and authorising the laboratory results
.

There should be at least two log-books: only one patient log-book and at least one log-book for laboratory results. Dependent upon the size of the provider and the national requirements of the MOH, different log books for various disciplines may be required or mandatory. Log-books for laboratory results should not be directly linked to names. Patient log-books should contain name, date of visit, date of birth, gender, which services are requested, what material should be collected and the unique laboratory identification number. In the laboratory log-books only the unique laboratory number and results should be registered. In other words, both log-books are required to match results to patient names.

Ideally, monthly overviews of the number of tests performed should be generated.
Procedures should be available for administration, collection and reporting activities of specimens tested on site or sent to outside referral laboratories.

Criteria

3.4.1.1 Policies and procedures or standard operating procedures (SOPs) for handling specimens are implemented and include a)-d) in the standard intent as a minimum.

Guideline Statement: *Procedures and guidelines should be available for all specimens that are collected and investigated. Topics such as proper collection, safe handling and storage must be addressed.* *Policies for specimen acceptance and/or rejection should be available. These criteria should be based on information available in the manufacturer's manual and general guidelines.*

3.4.1.2 There is a collection and delivery service for specimens from the referrers, every weekday.

Guideline Statement:
This will be measured against service policies and procedures.

3.4.1.3 Specimens are given a laboratory specimen accession number.

Guideline Statement:
This can be done either manually or electronically.

3.4.1.4 Procedures guide the ordering of tests.

Guideline Statement:
Arrangements should be defined in policies and procedures. These policies and procedures should be available in the various referral practices

3.4.1.5 Procedures guide the collection and identification of specimens.

Guideline Statement:
SOPs should clearly define how these actions should be completed. All personnel involved in the process should be familiar with the content of the SOPs and implementation of the SOP should be monitored.

3.4.1.6 Procedures guide the transport, storage and preservation of specimens.

Guideline Statement:
SOPs should clearly define how these actions should be completed. All personnel involved in the process should be familiar with the content of the SOPs and implementation of the SOP should be monitored.

3.4.1.7 Procedures guide receiving, logging-in and tracking of specimens.

Guideline Statement:
SOPs should clearly define how these actions should be completed. All personnel involved in the process should be familiar with the content of the SOPs and implementation of the SOP should be monitored.

3.4.1.8 Emergency results may be obtained by telephone.

Critical Criterion
Guideline Statement:
These arrangements will be defined by service policies and procedures and records should be kept (either manually or electronically) with details of such calls – name of laboratory personnel member, details of results, name of call receiver, date, time, etc.
The call receiver must read back the test or result to confirm accuracy of information. The name of the personnel member receiving the results must be documented by the laboratory personnel member providing the result. In private facilities, these names, times and dates are included in the final result form that goes to the ward/department.

3.4.2 Established norms and ranges are used to interpret and report clinical laboratory results.

Standard Intent
The laboratory must establish reference intervals or "normal" ranges for each test performed. The range must be included in the clinical record, either as part of the report or by including a current listing of such values, approved by the laboratory director. Ranges should be provided when an outside source performs the test. The reference ranges must be appropriate to the practice's catchment population and should be reviewed and updated when methods change.

Criteria

3.4.2.1 Policies and procedures or standard operating procedures regarding reporting and reviewing results are implemented.

Guideline Statement:
Standard Operating Procedures (SOPs) should clearly define how these actions should be completed. All personnel involved in the process should be familiar with the content of the SOPs and implementation of the SOPs should be monitored.

3.4.2.2 The laboratory has established reference ranges for each test performed.

Guideline Statement:
A list of current, up-to-date reference and critical values should be available. The reference ranges and critical values should be based on the laboratory services provided and will be determined by factors such as country-specific arrangements, type of equipment and requirements for the medical staff etc. In many instances, these ranges may be determined at national or regional level in which case, this criterion will be scored NA with an explanatory comment.
This reference list should be used for the review and final authorisation of the laboratory results.
In the case of a test indicating a critical value, there is a system in place to ensure that the result is communicated to the requesting physician immediately.

3.4.2.3 The range is included in the clinical record at the time test results are reported.

Guideline Statement:
Test ranges should be available to the medical personnel.
Ranges should be appropriate to the organisation's patient profile and should be reviewed and updated as needed. Ranges should be available for tests performed by outside sources (referral laboratories).

3.4.2.4 Ranges are provided when tests are performed by outside sources.

Guideline Statement: *This requirement should form part of the SLA with the contractor.*

3.4.2.5 Ranges are appropriate to the practice's catchment population.

Guideline Statement: *Documentation should be made available to confirm that ranges are appropriate to the catchment population. Where necessary, alternative reference ranges should be made available for significant subsections of the catchment population, e.g. male/female, child, particular ethnic groups, etc.*

3.4.2.6 Ranges are reviewed and updated, as needed.

Guideline Statement: *The service manager should ensure that the reference ranges provided are updated when required.*

*3.5 **Quality management***

3.5.1 Quality control procedures are implemented and documented.

Standard Intent
The quality of the laboratory services can be monitored using internal and external quality control guidelines. Designing and implementing internal and external quality control activities is essential for the final quality assurance of the laboratory results. Sound quality control systems are essential to providing excellent pathology and clinical laboratory services.

Quality control procedures could include:
a) Validation of the test methods used for accuracy, precision and reportable range
b) Daily surveillance of results by qualified laboratory facility
c) Rapid corrective action when a deficiency is identified
d) Testing of reagents
e) Documentation of results and corrective actions

Proficiency testing determines how well an individual laboratory's results compare with other laboratories that use the same methodologies. Such testing can identify performance problems not recognised by internal mechanisms. Therefore, the laboratory should participate in an approved proficiency testing programme when one is available. Alternatively, when approved programmes are not available, the laboratory should exchange samples with a laboratory in another medical laboratory for peer comparison testing purposes. The laboratory must maintain a cumulative record of participation in a proficiency testing process. Proficiency testing or an alternative must be carried out for all speciality laboratory programmes, when available.

Criteria

3.5.1.1 There is a quality control process for the clinical laboratory.

Guideline Statement: *A quality control system should be implemented that describes the range and frequency of the internal quality controls on the services offered by the laboratory. (e.g. select a few Malaria slides each week to be scored by all personnel.)*

3.5.1.2 The process includes the verification and validation, where applicable, of test methods.

Guideline Statement:
Documented evidence of compliance will be required.

3.5.1.3 The process includes the daily surveillance of test results.

Guideline Statement:
Documented evidence of compliance will be required.

3.5.1.4 The process includes the rapid correction of deficiencies.

Guideline Statement:
Documented evidence of compliance will be required.

3.5.1.5 There is a current register of quality control results and of the corrective and preventive actions taken.

Guideline Statement:
A quality control register is available and up to date. Check the last entries and check if at any time corrective and preventive actions have been taken, recorded and controlled.

3.5.1.6 The laboratory participates in a proficiency testing programme, or an alternative, for all speciality laboratory services and tests.

Guideline Statement:
Monitor if the laboratory participates in and external quality assessment (EQA) programme. The programme can be national and /or international. When the laboratory participates in such a programme, accurate records should be maintained. Inter-laboratory comparison programme is the acceptable standard

3.5.1.7 A cumulative record of participation is maintained.

Guideline Statement:
A quality control register should be available and up to date. Check the last entries and check if at any time corrective and preventive actions have been taken, recorded and controlled.

3.5.1.8 The medical laboratory practice regularly reviews quality control results from all outside sources of laboratory services.

Critical Criterion
Guideline Statement:
This criterion will apply when some services are provided by an outside laboratory. As part of the selection process, the quality control results from potential providers should be reviewed. Once the provider is selected, the designated individual responsible for monitoring the SLA should periodically review the QC results from the provider laboratory to ensure that a quality service is being delivered.

3.5.1.9 Copies of the quality control audits for the past six months verify that accurate/reliable results are being provided.

Guideline Statement:
Documented evidence of audits, which include identification of problem areas and corrective action taken, will be required.

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

Standard Intent
This refers to the implementation of the practice's quality improvement process (Under management and leadership).

The senior management team is responsible for ensuring that standards are set throughout the practice. Managers should use available data and information to identify priority areas for quality monitoring and improvement. This should be done in collaboration with the practice's central quality management structure to ensure coordinated quality improvement activities within the practice.

The following will be evaluated:
- The manner in which problems were identified and prioritised in this service, for which quality improvement activities were initiated
- The processes put in place to resolve the problems
- The 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 and/or tabled results, as appropriate

A once-off project, such as acquiring a specific item of equipment, will be scored NC.
Quality improvement processes not related to the clinical quality of patient care, but to the environment within which care is provided, e.g. monitoring the temperature of the refrigerator over time, will be scored PC.

22.5.2 Criteria

3.5.2.1 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 laboratory service 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/adverse events/sentinel events.*

3.5.2.2 Indicators of performance are identified to evaluate the quality of service offered by the laboratory.

Guideline Statement:
Performance indicators are quantifiable measurements, determined beforehand, that will reflect the quality of the service or department.
Performance indicators could include:
- *Turnaround times*
- *Quality of specimens received e.g. Leaking specimens*
- *Correct tubes used;*
- *Correct completion of request forms*
- *The time between when the specimen was taken and the time that it actually reaches the laboratory*

The information gained from the examples above must be used to identify and implement improvement programmes. Statistical reports without documented evidence of continuous quality improvement will be scored PC.

3.5.2.3 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.

3.5.2.4 A documentation audit system is in place.

Guideline Statement:
Documented evidence of such audits must be provided.
These audit processes can include a documentation audit of request forms, the patient register, auditing of stock control records, etc.
Evaluation of results and remedial action taken must be documented.

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3.6 Emergency care

3.6.1 The practice provides emergency treatment and care.

Criteria

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

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

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

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

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

3.6.2 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

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

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

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

3.6.3 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:

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

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Criteria

3.6.3.1 There is a designated resuscitation area.

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

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

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

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