

Botswana Private Eye Care Standards

1 MANAGEMENT AND LEADERSHIP

OVERVIEW OF MANAGEMENT AND LEADERSHIP

Effective leadership is essential for the practice to be able to operate efficiently, achieve its goals and fulfil its mission. This 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.

It is important that the practice team has identified leaders in areas such as clinical care, information management, financial management, human resource management, complaints and patient feedback. 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 leadership of clinical care should remain the responsibility of a principal practitioner.

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:

It is important that all members of the practice team are recognised and included in the process of defining the practice's mission. 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.

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 practice are formally or informally identified.**

Where a practice consists of more than two practitioners the leaders of the practice must be formally identified.

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

The mission statement is critical to the strategic planning process since it provides clear, guiding principles that further define who the healthcare provider is as an organisation and why the practice exists. Mission statements create the foundation for action planning and a basis for accountability with the community.

1.1.1.3 The leaders are collectively responsible for ensuring that the mission statement is known to all personnel, patients, carers and the community served.

*This can be achieved in many ways. For example, by public display of the mission statement on notice boards, in the waiting area or included in printed information leaflets given to each patient when they first visit the practice. If the practice has a website, the mission statement can also be published on the website.
Documented evidence that personnel have read the mission statement must be provided for full compliance with this criterion.*

1.1.1.4 The practice participates in community health activities.

The mission of a practice needs to meet the needs of the community. To be compliant with this criterion evidence must be provided of interaction with Community Health Committee members and participation in community health activities.

1.1.1.5 The leaders, in liaison with the whole practice team, coordinates the compilation of an annual strategic plan and budget.

*This criterion requires all departments within the practice to be involved in the compilation of the annual strategic plan and budget to ensure that the needs of each department are discussed, considered and met if possible within the scope of the practice budget.
Compliance will be demonstrated by documented evidence, for example, minutes of meetings.*

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

Evidence of an action plan for achieving the practice's mission and strategic plan will be required.

1.1.1.7 The strategic plan is reviewed on an annual basis.

Compliance will be measured by providing documented evidence that the practice's strategic plan has been reviewed.

1.1.1.8 Regular monitoring of the implementation of the strategic plan against envisaged timeframes and progress in achieving its objectives is documented at intervals determined by the practice.

*This criterion requires that practice leaders adhere to the timeframes that were set at the beginning of each year for achieving the strategic plan.
For any plan to be implemented effectively, it is essential to monitor the progress that is being made towards achieving the outcomes that have been planned. This criterion further requires the practice to document the progress that is being made during the year towards achieving the strategic plan.*

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

This may, for example include personnel responsible for monitoring infection control practices, resuscitation, stock control, patient files etc.

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 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.

This criterion is assessed on evidence of effective management found throughout the practice during the survey.

If this criterion is scored PC or NC, the transgressions need to be recorded in detail to motivate for the PC/NC rating and it should be based on accurate facts.

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

If the practice manager is a solo practitioner or partner in the practice this criterion will be scored based on the evidence of effective management found throughout the practice during the survey.

If the practice manager is an employee of the practice, compliance will be assessed against the requirements set out in the position description.

1.2.1.3 The practice is licensed in terms of relevant legislation for the level and type of services provided.

Documented evidence is required.

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

This criterion will be scored compliant by default, although a PC rating is given whenever there is definite evidence of non-adherence to any legal requirement. In these cases, the transgression needs to be recorded in detail to motivate for the PC rating and it should be based on accurate facts.

Common examples of non-conformance with legal requirements include the following deficiencies:

- *The required certificates are not available, for example, fire clearance certificates, electrical installation certificates, commissioning certificates (for example, ethylene oxide sterilisers), pressure test certificates for vessels under pressure*
- *Internal/external financial audits are not conducted*
- *Nurses transcribe doctors' prescriptions and/or dispense medication*
- *Pharmaceutical items are incorrectly labelled*
- *Proof of current registration of professional personnel with the relevant councils is not available*

In order to demonstrate compliance, practices may wish to compile a template listing the accreditation criteria requiring demonstration of compliance with country-specific legislation and regulations against the relevant national acts, regulations, etc. applicable to the criterion.

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

This requires documented evidence for whatever inspections may have been conducted.

Examples may include inspections by the following authorities:

- *The local fire authority for fire clearance purposes*
- *The national authority responsible for radiation safety aspects*
- *The national authority responsible for health and safety compliance*
- *The national authority responsible for financial compliance*
- *The national authority responsible for maintenance requirements such as boiler inspections and pressure tests, autoclave pressure tests*

- The local authority responsible for testing of water supplies
- The relevant professional bodies where student training is provided
- Licensing authorities for facilities such as the pharmacy, etc.

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

The criterion will be scored after the final assessment of Management and Leadership criteria and will be scored according to the findings of financial and human resource management and other criteria dealing with adequate supply and effective management of resources (medication, consumables, equipment etc.).

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

Standard Intent:

The leaders develop a culture that emphasises cooperation and communication. Relevant personnel members become part of the communication network.

Criteria:

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

*“Teams” refer to all the groups of employees and practitioners involved in the practice, for example administration, cleaning and clinical personnel.
Evidence of for example, minutes of personnel meetings, memos and communication tools can be provided as evidence.
There must be evidence of at least quarterly personnel meetings.*

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

An assessment of a sample of agendas of meetings should be undertaken to determine the trend and “general” compliance as the criterion should not be penalised on one or two exceptions.

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

*An assessment of a sample of minutes of meetings should be undertaken to determine the trend and “general” compliance as the criterion should not be penalised for one or two exceptions.
The manner in which minutes are circulated should be assessed and should consist of documented evidence of the circulation and acknowledgment of receipt.*

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.

The existing “mechanism” should be assessed for effectiveness in conveying this information to personnel but surveyors must further note the importance of searching for evidence of “and acted upon”. This generally requires that minutes should reflect the allocation of responsibilities for carrying out tasks and that these are reported on at subsequent meetings.

1.2.3 The practice engages with a range of health, community and disability services to plan and facilitate optimal patient care.

Standard Intent:

Coordination of care for individuals, families and communities is part of the accepted definition of medical care. For patients with complex care needs, for example, frail elderly, severe disabilities or

multiple comorbidities, practices are encouraged to coordinate patient care with other health services including allied health and pharmacy as well as social, disability and community services.

It is important for practices to identify relevant services within the local area that can enhance patient care, to have updated registers of such services at hand and to build sound working relationships with these service providers to facilitate good, collaborative care.

Criteria:

1.2.3.1 The practice plans and coordinates comprehensive care by establishing relations and maintaining contact with other relevant services and agencies, including both governmental and non-governmental agencies.

*The purpose of this criterion is to ensure that practitioners are aware of members of the multidisciplinary team in both the private and government sector and engage them when required to ensure that the patient receives the best possible care.
Documented evidence of such networking (for example, minutes of the meetings or email correspondence) should be made available for assessment.*

1.2.3.1 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.

*This information needs to be provided for example, to community nursing teams, step down care, allied health professionals etc.
Compliance can be demonstrated by for example, email correspondence with the various services or by providing information pamphlets about to the practice to these services.*

1.2.3.1 The practice determines that the receiving individual/organisation can meet the patient's continuing care needs and establishes arrangements to ensure continuity.

Documented evidence is required.

1.3 Policies and procedures

1.3.1 The practice manager ensures that policies and procedures which support the activities of the practice are implemented.

Standard Intent:

The practice manager ensures that all policies which apply to each team within the practice are available to personnel and that they are implemented and monitored.

Criteria:

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

*The criterion will be scored at the end of the survey.
If this criterion is scored PC or NC Surveyors must document examples of non-compliance.
This criterion will automatically be scored NC if there is evidence of non-compliance with policies and procedures that effect patient and personnel safety.*

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

The initial implementation date and the name, designation and signature of the person authorising the policy must be clearly legible on each policy and procedure.

1.3.1.3 Policies and procedures are correctly compiled, indexed and filed.

- *Title: Each policy should have a name or title for identification and reference.*
- *Identifying number: This is to facilitate indexing, locating the policy when required and communicating about the policy accurately*
- *Policy statement: What is to be achieved and why*
- *Procedure: How the policy is to be achieved. This is a step-by-step description of what needs to be done (like a recipe – following each step should result in a predictable outcome irrespective of who follows the steps)*
- *Associated references: This is required when the policy is directly associated with specific laws, regulations or policies or corporate policies and procedures*
- *Dates: The date of the original policy, the date(s) of any revision(s) and the date of the next planned review*
- *Signature: This is the signature of the person identified and authorised to approve policies and procedures*

If policies and procedures are only available electronically, all personnel must be able to demonstrate how to access the documents.

1.3.1.4 Policies and procedures are reviewed according to practice policy and then dated and signed.

Policies and procedures must be reviewed at least every 5 years and when changes in evidence-based practice requires earlier review.

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

Compliance with this criterion can be achieved by means of, for example, signature sheets attached to each policy and procedure or by attendance registers at in-service training relating to policies and procedures.

1.4 Human Resource Management

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

Standard Intent:

It is advisable for the practice to plan and implement uniform programmes and processes related to the recruitment, retention and development of all personnel. Personnel retention rather than recruitment provides greater long-term benefit. Retention is increased when leaders support personnel development.

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
- Personal development of personnel
- Personnel retention

Criteria:

1.4.1.1 There are documented processes for staffing the practice.

Compliance with this criterion will require the practitioner to show documented evidence that patient load and patient acuity were studied and considered when planning the staffing for the practice. This must be evident for both the number of personnel required as well as their qualifications.

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

These requirements must be discussed and agreed by all relevant personnel during the recruitment process and form part of the position description.

1.4.1.3 The processes include measures to improve personnel retention.

Retention of personnel as opposed to the recruitment of new personnel is more cost effective and more likely to result in better patient care due to improved continuity of care and service provision and the accumulation of experience. It is therefore strategically important for retention to be considered as part of the recruitment process. As an additional benefit, measures taken to improve retention are likely to improve personnel satisfaction, and satisfied personnel provide better services. For a practice to be compliant with this criterion evidence must be provided of at least a personnel satisfaction survey.

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 health care 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 personnel employed by the practice, including locums.

Criteria:

1.4.2.1 There is implementation of a reliable, documented process for evaluating and verifying the credentials of all health professionals.

*This can be achieved for example, by having a standardised checklist of requirements that must be verified. This should include reference checks.
The completed document can then be retained in the employee's personnel file.
Compliance will be verified during an audit of the personnel files of various categories of professional personnel.*

1.4.2.2 Personnel files contain copies of qualifications and licences/registration from the relevant authority for all health professionals.

*Copies of all the relevant original degrees/diplomas/certificates must be available, as well as evidence of registration with the relevant registration bodies.
Compliance will be verified during an audit of the personnel files.*

1.4.2.3 There is a system to track the annual registration of all health professionals.

The system must reflect the date that each category of health professional's licence is due for renewal and document that the original, renewed licence has been seen.

1.4.2.4 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 or as appropriate.
Compliance will be verified during an audit of the personnel file.*

- 1.4.3** *Clinical and administrative personnel are orientated to the practice and participate in continuing education, research and other educational experiences to acquire new skills and knowledge and to support job advancement.*

Standard Intent:

The decision to appoint an individual to a position within the practice sets several processes in motion. To perform well, new personnel need to understand the functioning of the entire practice and how his or her specific role and responsibilities contribute to the practice's mission. This is accomplished through a general orientation to the practice and his or her role in the practice and a specific orientation to the responsibilities of his or her position. The orientation process should include for example infection control practices, confidentiality etc.

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** **There are documented processes for orientation of personnel to the practice.**

This includes general orientation and position-specific orientation as discussed in the standard intent above.

- 1.4.3.2** **The practice supports continuing education for its clinical personnel and maintains records of this in personnel files.**

This refers specifically to professional personnel and the requirements for continued registration with the relevant professional bodies, where applicable. Management must have a clear strategy for assisting professional personnel to maintain their continued registration.

- 1.4.3.3** **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.**

This training could include billing, medical aid codes and triaging, (which is particularly important when administrative personnel are responsible for the initial assessment of waiting room patients).

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

Compliance will be verified during an audit of the personnel files of various categories of personnel or other training records. Personnel members may also be interviewed.

1.5 **Financial Management**

- 1.5.1** *The practice manager is responsible for the implementation and maintenance of a financial strategy.*

Standard Intent:

Financial planning and management needs 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. This is 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.

This requires that an individual in the practice has the officially assigned duties of overseeing and taking responsibility for all aspects of financial management. This may be the practice manager, a financial manager or a shared responsibility between practice manager and a financial officer.

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

*This criterion will automatically be scored compliant where a solo private practitioner manages the practices' finances.
Where a financial manager or financial officer is employed, compliance will be assessed against the requirements set out in the position description.*

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

*This criterion will automatically be scored compliant where a solo private practitioner manages the practices' finances.
Where a financial manager or financial officer is employed, policies and procedures must guide their functions.*

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

Standard Intent:

An approved budget should be available in the management documentation. There should be evidence of the allocation of resources in accordance with the approved budget. This ensures that the practice plans for and is able to meet its financial obligations.

Criteria:

1.5.2.1 There is a current budget for the practice.

*For practices that comprise of more than one practitioner there should be an approved budget available in the management documentation. For practices that comprise of a solo practitioner there should be evidence of a practice budget. The budget must demonstrate allocation of resources.
The budget will include, for example, salaries, rent, utility costs (water and electricity), consumable stock etc.*

1.5.2.2 A report is produced at least annually, setting out the financial position to date.

This criterion requires that at least the most recent financial report that is prepared annually for submission to the Botswana Unified Revenue Service (BURS) must be available during the survey.

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

Evidence should exist in the format in which financial statements are produced. Generally, these statements contain a column/section indicating the variance, i.e. under- or over-expenditure.

Evidence showing what is done about this variance (especially over-expenditure), should be available, for example, in the minutes of relevant financial management meetings, personnel meetings or memos.

- 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.**

*Documented evidence must be provided to demonstrate agreement.
This criterion will be scored "not applicable" in practices owned by a solo practitioner.*

- 1.5.3 The practice provides patient services in line with legally and ethically accepted business and financial 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 activities of the practice.

Criteria:

- 1.5.3.1 The practice has documented ethical and legal policies and procedures for the financial management of the practice that are implemented.**

Examples of compliance with this criterion can be found in the policies and procedures for billing or referral to partners within the practice (for example partners in a poly clinic).

- 1.5.3.2 Internal and external financial audit systems which meet audit requirements are maintained.**

Compliance will be measured in accordance with the requirements of the Botswana Companies Act.

- 1.5.3.3 Where required, annual audited financial statements are produced within the required time frame.**

Compliance will be measured in accordance with the requirements of the Botswana Companies Act.

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

Documented evidence will be required.

- 1.5.3.5 Assets are insured.**

This includes the practice assets and where applicable the physical structure.

- 1.5.3.6 All health professionals provide evidence of professional indemnity insurance.**

Compliance will be measured during the personnel file audit.

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:

- a) Ordering of and payment for supplies and equipment
- b) Safe storage of supplies
- c) Condemning procedures
- d) Security of order books, prescription pads and other face-value documents

The practice 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 practice.

This criterion will automatically be scored compliant where a solo private practitioner manages the practices' equipment and supplies.

Where a supply chain manager/stock controller is employed, or the function is performed by someone other than the solo practice manager, compliance will be assessed against the requirements set out in the position description.

1.6.1.2 Policies and procedures relating to all aspects of provisioning/supply chain management are implemented.

As a minimum, the policies and procedures discussed in a) – d) in the standard intent above should be available, accessible to personnel and implementation should be monitored.

1.6.1.3 Secure storage facilities are available.

The store must be lockable and exclude any unauthorised entry.

1.6.1.4 Prescription pads, letterheads, investigation request forms, administrative records and other official documents are accessible only to authorised persons.

Compliance will be verified by observation and personnel interviews.

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. A risk management programme includes:

- Comprehensive risk assessment of the practice
- Designing all aspects of the risk management plan (financial, physical, environmental, medicolegal, 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 relating to practice processes and systems, personnel, patients, visitors to the practice and physical facilities.

*Compliance with this criterion requires documented evidence that the practice personnel have collaboratively identified risks within the practice. This document will be used to develop an action plan to eliminate or minimise risk. The risk management process should include all relevant aspects and services of the practice, for example patient, personnel and visitor related risks; financial, corporate and legal risks; physical facility, security and environmental risks; etc. This does not necessarily require a single integrated document, provided all components are dealt with in documented systems for the relevant operational processes/functions/sections.
(NOTE: doing only monthly workplace inspections does not qualify for a compliance rating).*

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

These policies and procedures must define the routine risk management processes, for example, monthly inspections to monitor risks, and the actions to be taken when risks materialise as adverse events.

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

In small practices, this will usually be the practice manager. Larger practices may have a designated risk manager.

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

A record must be kept of such training and must include all personnel.

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

This will include for example, during building renovations, changing from paper-based to electronic patient records or financial documentation, changing service providers etc.

1.7.2 The practice designs and implements a coordinated programme to reduce the risk of infection 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. All areas of the practice where these individuals or vectors are found must therefore be included in the programme of infection surveillance, prevention and control. Certain infections require patients suffering from these infections to be separated from non-infected patients such as patients with TB or high-risk influenza. These patients are identified when requesting an appointment and appropriately triaged.

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. Coordination 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 coordinate 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, for example, 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 handwashing and disinfecting procedures are required. Personnel are educated in proper handwashing 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.

It is this nominated individual's responsibility to ensure that infection control policies and procedures are implemented and monitored.

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

These policies and procedures must be available and accessible in the practice and their implementation monitored.

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

*The infection control education programme needs to include policies/guidelines as well as relevant issues as they are identified. All personnel should be included in information sharing and training at regular scheduled meetings or other fora.
Documented evidence (for example, minutes of meetings/attendance records) must be provided.*

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

Documented evidence must be provided.

1.7.2.5 All patient and personnel areas of the practice are included in the documented infection control programme.

This includes for example, all clinical areas, the waiting area, personnel and patient toilets, kitchen etc.

1.7.2.6 Handwashing and disinfecting facilities, including water, soap, paper towels or hand sanitisers are available in all relevant areas.

Compliance will be measured by observation.

1.7.2.7 Personnel are constantly reminded of the importance of effective hand washing.

For example, posters are displayed at basins, hand hygiene audits are regularly conducted etc.

1.7.2.8 The practice reports on notifiable diseases to appropriate external public health agencies.

Documented evidence is required.

1.7.2.9 A nominated individual has been trained in and is responsible for sterilisation

procedures within the practice and can describe the process in detail.

*Evidence of training is required.
This criterion is only applicable to those practices that have onsite sterilisers.*

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

This requires the practice to formally identify the categories of personnel who are at risk (including cleaning personnel if they handle healthcare related waste) and to ensure that there is a system to track that their Hepatitis B immunisations remain up to date.

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

Documented evidence must be provided to demonstrate that personnel are aware of the policy and have been trained on its content and implementation. Compliance will further be verified by personnel interviews.

1.7.2.12 Post exposure prophylaxis is available to personnel in accordance with national policy and includes the management of the patient from whom the needle was withdrawn.

This includes exposure to high risk infections and needlestick injuries (for example body fluid splashes etc.) The national policy must be available and known to personnel.

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

The policy must include as a minimum:

- *The correct cleaning procedure following a body fluid spill*
- *The correct procedure to follow when sluicing/washing contaminated linen*

1.7.2.14 There is a documented policy for the triage of patients with potential communicable diseases.

These patients are identified when requesting an appointment and appropriately triaged. If it is necessary for these patients to attend the practice, they are directed to a separate waiting area to prevent transmission of the infection to non-infected patients. Where there is no separate waiting area, the practitioner must attend to the patient immediately.

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

Standard Intent:

Policies need to be developed to guide personnel in ensuring their own safety, the safety of others and the safety of the environment is protected 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 is consistent with country-specific laws and regulations and includes the safe handling, storing and disposing of all different types of waste.

The policy must include all relevant aspects of waste management, for example, identification, colour coding, handling, storage, disposal of etc. with special reference to clinical/healthcare waste, personal protective equipment (PPE), the management of spills and the reporting and investigation of waste related incidents.

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

Confidential waste includes all patient and personnel related documentation and practice-specific documentation for example, financial statements.

1.7.3.3 Waste is segregated in accordance with policies, procedures, country-specific laws and regulations.

Compliance will be measured by observation.

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

Compliance will be measured by observation.

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

Compliance will be measured by observation.

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

Compliance will be measured by observation and by documented evidence that demonstrates when and by whom waste is collected.

1.7.4 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:

1.7.4.1 Security systems, including guards if required, provide for internal and external security.

*If the security system is outsourced (alarms/guards) the service contract must be available during the survey.
As a minimum, a practice must be secured with burglar bars and security gates.
Compliance will be further measured by observation of the security measures in place and whether they are appropriate for the individual setting.*

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

Compliance will be measured by observation.

1.7.4.3 There is effective control of access to clinical areas and store areas.

Compliance will be measured by observation.

1.7.4.4 Alarm systems and signals are tested every month.

*This criterion will only be applicable to those practices that have alarm systems and signals (for example panic buttons) installed.
Documented evidence of testing must be provided.*

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

This can be achieved for example, by including the information in the orientation programme for new personnel and by displaying emergency numbers next to all telephones in the practice.

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

*This criterion is only applicable where practitioners consult with patients after hours. Reasonable measures can include for example, the installation of panic buttons or notifying another person or security company that the practitioner is alone in the practice.
Sufficient arrangements should be in place to ensure that a personnel member who is alone in the practice is safe. These arrangements must be outlined in a policy which all personnel should be aware of.*

1.7.5 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 must be 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 necessary education of personnel to protect and evacuate patients effectively in the event of fire or smoke
- 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 once a 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:

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

There are documented fire safety systems which include all the relevant aspects of fire safety, for example training, rehearsals, servicing and storage of equipment, escape route signage, storage and handling of flammable materials, etc.

1.7.5.2 Documented certification is available from the relevant authority to show that the

facility complies with applicable laws and regulations in relation to fire safety (fire clearance certificate).

As per the intent statement, compliance with this criterion requires documented evidence of an official inspection to confirm that the building complies with national fire safety requirements. The practice manager must obtain a copy of the documentation from the landlord if the practice does not own the building.

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

Abatement systems as per country specific requirements will be reflected in the certification as required in 1.7.5.2. It is essential that the testing and servicing of all fire safety equipment is up to date, automatic abatement systems are regularly tested, fire and smoke detection systems are tested, and automatic abatement doors are not forced to remain open by means of wedging or putting objects against them. Documented evidence of inspection, testing and maintenance of fire safety equipment is required. This may include the fixing of service labels onto the equipment itself.

1.7.5.4 Flammable materials are clearly labelled and safely stored.

Flammable materials are identified by the practice and stored in accordance with the national safety regulations. The storage precautions are applicable to all areas/services/departments where flammable materials are used. The appropriateness of the storage facility will be determined by the quantity and flashpoint of the materials stored. Bulk storage requirements and registration will be determined by country specific regulations.

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

Compliance will be measured by observation.

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

Compliance will be assessed during the assessment of the areas where such materials are stored.

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

The display of such plans throughout the practice will be observed during the visit to each area.

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

A fire safety evacuation plan must be developed by the practice. Personnel training must be provided, and evacuation exercises held annually. Documented evidence that the plan is physically rehearsed will be required.

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

This can be achieved for example, by including the information in the orientation programme for new personnel and by displaying emergency numbers next to all telephones in the practice.

1.7.6 The practice develops a written plan to respond to emergencies.

Standard Intent:

Personnel may be affected by community emergencies, epidemics and major events such as damage caused by natural disasters and this in turn may affect the functioning of the practice. Practices should also be prepared for bomb threats, 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.

The emergency plan for the practice includes:

- 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

Criteria:

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

The documented plan is up to date and is available in all areas of the practice.

- 1.7.6.2 There are site and floor plans that depict the locations and layout of the main services (for example, water, sanitation, electricity supply).**

*It is very important that all personnel know where to switch off the main services, for example, water, electricity and, where installed, oxygen supply.
Compliance will be measured on documented evidence and personnel interviews.*

- 1.7.6.3 Documented evidence is available to show that the personnel participate in a rehearsal of the emergency plan at least annually.**

*The emphasis of this rehearsal must be on the emergency situations mentioned in the standard intent.
Documented evidence must be provided.*

- 1.7.6.4 First aid kits and materials for healthcare workers are available.**

*Botswana specific occupational health laws and regulations should dictate the contents of the first aid kits.
Please note that doctors may stock the required content as part of their regular stock. Other healthcare service providers will need to have a dedicated first aid kit.
Compliance will be measured on the availability of the required stock.*

1.8 Information Management and Quality Improvement

- 1.8.1** *The practice has a system to ensure that data and information is made available to meet user needs and the needs of those outside the practice who require data and information from the practice.*

Standard Intent:

To provide coordinated 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.

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

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.

Criteria:

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

The policy must define those permitted access to each category of data and information.

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

This does not have to be a single system, nor does it have to be electronic. Paper-based information system/s are also acceptable. The information required by the criteria must encompass at least information relating to individual patients, care provided, results of care and the practice's own performance.

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

Assessment of compliance is based on the availability of reports on the various types of data as well as documented evidence (for example, minutes of meetings or other form of communication) of discussions on the information and how this is taken into consideration to assist with decision-making processes. This needs to happen at all levels of the practice and not just at management level, as information also needs to be available on departmental operations such as personnel matters, financial aspects, supply management, outcomes of quality improvement programmes, results from clinical and patient record audits, negative incidents, etc.

1.8.1.4 Required technology and other resources support the implementation of the data and information management system.

Resource requirements may differ vastly between paper-based and computerised systems and the assessment of compliance needs to take these factors into account.

1.8.1.5 Security and confidentiality of data and information is maintained.

Security relates to access control in terms of passwords, back up processes as well as archiving of paper-based records. Up to date antivirus/antimalware software is in place. Confidentiality aspects need to be documented as part of the information management processes for the various types of information, whether it be financial data, personal information on personnel, patient information, etc. Where applicable, country-specific legal requirements need to be considered.

1.8.1.6 Documented procedures which outline the processes to provide required information to individuals and agencies outside the practice when required by laws or regulations are implemented.

Documented evidence of reporting is required. This includes notifiable disease reporting, other statistics required according to country-specific legislation and information provided to healthcare funders.

1.8.1.7 The practice manager or delegated person checks the integrity of data leaving the facility for completeness, correctness and consistency.

*The integrity of data refers to the validation of raw data to ensure accuracy of information. Evidence of quality checks of the data before it leaves the practice and action taken when deficiencies in data quality and timeframes of reporting are identified.
This includes for example, ICD 10 codes supplied to healthcare funders, national statistics etc.*

1.8.2 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 is 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:

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

*The information generated by data collection tools, for example infection control audit tools, patient satisfaction surveys etc. must be analysed.
This criterion will be scored non-compliant where there is only raw data available.*

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

Compliance will be measured on documented evidence that the frequency of data collection is established for each process under study.

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

Documented evidence will be required for compliance.

1.8.2.4 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.

*This can be achieved by displaying the results in the waiting area, on personnel notice boards, on the practice website etc.
The method of information sharing and the parties with whom it is shared will depend on the nature of the information.*

1.8.3 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, personnel 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

Practice managers and employees 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. Personnel 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:

1.8.3.1 A designated individual oversees the information and quality management and improvement processes.

*This requires that an individual has the assigned duty of overseeing and taking responsibility for all aspects of information and quality management and improvement processes. The training and experience required will depend on the level of care provided by the practice and the complexity of the information systems for which the individual is responsible.
In some practices this may be the practice manager of the solo practitioner, in other practices a quality manager may be appointed.*

1.8.3.2 All practice personnel are informed about the function of the information and quality

management individual.

Compliance will be measured during personnel interviews.

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

This includes all aspects of the practice. Such processes may exist in different formats for example, a detailed single document, different documented systems or electronic modules. Whatever format exists, the intention is that the “processes” should be comprehensive and reflect all components of quality management and improvement in the practice.

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

Evidence of compliance could exist in the form of attendance registers at such training sessions, information sharing meetings, availability of training manuals, policies and procedures etc.

1.8.3.5 The practice manager provides technology, support and 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.

The technology, support and resources required will be determined by the design and complexity of the quality management and improvement framework. This may include aspects such as training in quality methodology, aligning work schedules to allow for time to spend on relevant activities, providing assistance with data management (manually or electronically), etc.

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

As part of the practice’s quality management and improvement framework, the leaders should play an active role in collaborating with teams and individuals in the practice to decide which activities to include in the formal monitoring for quality improvement purposes.

1.8.3.7 Each function within the practice implements relevant quality improvement activities.

The practice quality management and improvement framework needs to guide personnel on how to establish quality improvement processes and initiatives with regard to the development of relevant standards for their service, for example, administration, housekeeping, clinical care etc., the development of measurable indicators for monitoring purposes, and the implementation of remedial actions.

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

Documented evidence must be provided to demonstrate that the quality management and improvement programme is evaluated and revised as necessary.

1.8.4 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:

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

Documented evidence is required.

1.8.4.2 The practice collects data relevant to each identified indicator in the quality improvement programme for the monitoring and improvement of patient care and practice management.

Documented evidence is required.

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

Clinical audits should measure actual performance against current best practice identified in guidelines compiled from evidence-based practices. Indicators of performance should be selected from these guidelines.

Measurement of these indicators will provide information on current performance and evidence of change over time following the implementation of quality improvement plans.

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

Standard Intent:

Personnel 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 practice. 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
- 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:

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

This requires evidence that areas for improvement are identified from all the data collected during practice activities.

- 1.8.5.2 When appropriate, an improvement plan is developed in collaboration with all relevant team members and an implementation process and acceptable timeframe is agreed to by the team and implemented.**

Documented evidence must be provided.

- 1.8.5.3 A time for repeat data collection and analysis is agreed and completed and the results discussed by the relevant team members.**

Documented evidence must be provided.

- 1.8.5.4 The practice holds regular meetings to discuss significant clinical issues.**

*Evidence of significant clinical issues can be determined from the incident management processes and during patient record audits and personnel interviews.
Minutes of meetings and attendance records must be provided as evidence of compliance with this criterion.*

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

This requires that the practice does more than just provide information about the complaints process. Formal patient/family satisfaction surveys must be conducted regularly using an audit tool that is specifically designed to elicit information about the practice and the services that it offers. The tools used to measure patient feedback need to be rigorous and include all areas of the practice (for example waiting times, attitude of personnel, cleanliness of toilets, communication with clinical personnel, education etc.) to ensure the integrity of data subsequently used by practices for quality improvement purposes. The practice must decide on the method, frequency and number of patients to be surveyed but compliance with the criterion requires that it is representative of the size of the practice and the services offered. The practice needs to further provide documented evidence that the information from the survey was used to improve the quality of service delivery.

- 1.8.6 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 retained. A nominated personnel member must be responsible for this process and for the implementation, monitoring and review of the changes. This ensures that the practice 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 medication errors, for example, prescribing a drug to a patient when the records indicate that the patient is allergic to the drug or patient identification errors, for example, performing a laboratory or radiological test on the wrong patient should always precipitate intense analysis to understand the cause and prevent recurrence.

All records relating to these discussions should be anonymised.

Criteria:

- 1.8.6.1 A documented procedure for the monitoring of near misses/incidents/adverse (sentinel) events is available, which includes the documentation of interventions, responses and corrective actions taken to recorded incidents.**

*A policy and procedure should be available to all personnel detailing the steps to follow in the event of such an incident occurring. This includes the reporting, recording and investigation of the event as well as the response to the event and the actions taken to prevent recurrence of the event, or minimise harm should the event recur.
Personnel will be interviewed to confirm that they are familiar with the contents of these documents.*

- 1.8.6.2 Formal significant event analyses are undertaken when necessary.**

*The practice manager/risk manager must identify those events where formal event analyses must be conducted as required by law, regulation and practice policy.
All events that meet the definition must be assessed by performing a credible root cause analysis. When the root cause analysis reveals that systems improvement or other actions can prevent or reduce the risk of such events recurring, appropriate action must be taken to achieve this risk reduction.*

- 1.8.6.3 Notes are kept regarding the data analysis and actions arising from formal incident reviews.**

Documented evidence will be required for compliance.

- 1.8.6.4 All changes to policy and procedure that are identified as a result of these formal incident reviews are documented and included in new policies or incorporated into existing policies.**

Documented evidence will be required for compliance.

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

Documented evidence will be required for compliance.

- 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 practitioners 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.

Documented evidence of such audits must be provided. Evaluation of results and remedial action taken must be documented as well as maintenance of achieved improvements over time.

1.8.7.2 The review uses a representative sample.

A representative sample is a sufficiently large sample which includes records for all practitioners providing patient care and all types of care provided. The review should be conducted by clinical professionals authorised to make entries in the patient record.

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

Compliance will be verified during the patient record audit.

1.8.7.4 Standardised diagnosis and procedure codes are used.

Compliance will be assessed by comparing the codes used in the practice with country-specific directives. The responsible department should therefore have both the directives and the practice's coding system available for comparison.

1.8.7.5 Symbols and definitions are standardised.

The use of abbreviations provides an opportunity for miscommunication and confusion which can result in patient harm. Best practice is therefore not to use them at all. However, where they are permitted, their use must be standardised, and all relevant personnel must be made aware of the meaning of each abbreviation.

2 FACILITIES, EQUIPMENT AND CONTRACTED SERVICES

OVERVIEW OF FACILITIES, EQUIPMENT 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, utilities and equipment 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.

Practices need to have the necessary equipment for comprehensive primary care and emergency resuscitation. To meet the standards, equipment must be in good working order. There is a wide range of equipment that practices may need in order to provide services which meet national and local needs, serve the nature of the practice and support any procedures that the practice performs.

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.

Standards:

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.**

This requirement ensures that members of the public, both locals and visitors, who are not familiar with the location of the practice will be able to find it when necessary.

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

This can be in the form of a business card or patient information leaflet. Where the practice does not provide emergency services the emergency number must reflect the closest emergency facility to the practice.

2.1.1.3 **A phone number for the after-hours service of the practice is clearly displayed on the outside of the facility.**

Where the practice does not offer an after-hours service, an emergency number must be displayed. Compliance will be verified by observation.

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

Surveyors will make a judgement based on the size of the practice and services provided.

2.1.1.5 **There is wheelchair access to and within the building.**

This will be assessed during the visit to each practice.

2.1.1.6 **Ramps and stairs include safety features such as rails.**

The provision of such safety features will be assessed during the visit to each practice.

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

Standard Intent:

In order to provide safe patient care, each unit requires adequate resources. The building is appropriate for a healthcare practice in terms of size and layout.

The physical facilities required include adequate office accommodation for personnel, a designated sluice area which is hygienically clean at all times, and sufficient treatment/consulting rooms. 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 treatment/consulting room:

- Is free from excessive noise
- Has adequate lighting
- Is maintained at a comfortable ambient temperature
- Ensures patient privacy

Buildings and grounds are 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 implemented and are available to the personnel.

A copy of the "Permit to Occupy" issued in terms of the Building Control Regulations must be available during the survey. Where the practice is a tenant, a copy must be obtained from the landlord.

Copies of the laws, regulations and other requirements applicable to the structure of the facility should be available and accessible to personnel in either hard copy or electronic format and should include at least the Building Control Act and regulations.

2.1.2.2 The building is appropriate as a healthcare facility in terms of size and lay-out.

Compliance will be measured by observation.

2.1.2.3 The lay-out of the facility allows for effective flow of patient care.

Compliance will be measured by observation.

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.

Compliance will be measured by observation and by examination of daily patient attendance figures.

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

This includes for example, no open electrical sockets, measures to prevent children leaving the practice unnoticed, measures to prevent injury from inappropriate toys (ingestion of small objects, sharp protrusions, easily cleanable), measures to secure hazardous substances etc.

2.1.2.6 There is at least one treatment/consulting room for every member of the clinical team working in the practice at any time.

Compliance will be measured by observation.

2.1.2.7 All areas of the facility, including treatment/consultation rooms are clean, well ventilated and well maintained.

Compliance will be measured by observation.

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

Compliance will be measured by observation.

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

Compliance will be measured by observation.

2.1.2.10 Separate sanitary facilities are provided for personnel.

Compliance will be measured by observation.

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

Compliance will be measured by observation.

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

The practice must compile and maintain an inventory of furniture which must be available at the survey.

As a minimum, a practice must have at least the following:

- *Chairs (in the waiting area, for administrative personnel, for clinical personnel and for patients and families in the treatment areas)*
- *Desks/workstations (sufficient for the size of the practice)*
- *File cabinets*
- *Locking cabinet (for all confidential documentation)*
- *Refuse bins for domestic waste in each functional area*

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

Compliance will be measured by observation.

2.2 Medical equipment**2.2.1 Medical equipment is available and properly maintained to meet the needs of the patient population.****Standard Intent:**

Practices are responsible for ensuring that appropriate medical equipment is available and ready for use at all times. There is an accountable, systematic approach to ensuring that cost-effective, safe and appropriate medical equipment is available to meet the demands of quality patient care.

The practice manager takes responsibility for ensuring that medical equipment is available, appropriately maintained and calibrated and that the relevant personnel are competent to use it.

Each practice ensures that it has the required equipment for comprehensive primary care as detailed below (the specific requirements will depend on the scope of eye care offered by the practice):

- Blood glucose monitoring equipment
- Diagnostic set
- Disposable syringes and needles
- Examination light
- Gloves (sterile and non-sterile)
- Ophthalmic chair unit
- Specimen collection equipment
- Sphygmomanometer with small medium and large cuffs
- Stethoscope
- Surgical masks
- Thermometer
- Torch
- Tourniquet

Criteria:

2.2.1.1 Implemented policies and procedures guide the management of medical equipment.

Policies and procedures that detail how equipment is to be used, maintained and repaired and the level of personnel training required to use the equipment are implemented.

2.2.1.2 A designated individual supervises the management of medical equipment in the practice.

The responsibilities of this individual include as a minimum:

- *Ensuring that the required medical equipment as listed in the standard intent above is available in the practice*
- *Audits on available medical equipment (for example to ensure that it is correctly used, calibrated, stored etc.)*
- *Compiling an inventory of medical equipment, which includes description, make, manufacturer, model, serial number, tracing number, date of purchase, purchase price, list of accessories, supplier details and guarantee expiry dates*
- *Regular inspections of medical equipment*
- *Testing of medical equipment, as appropriate to its use and requirements*
- *Ensuring planned preventative maintenance of equipment*

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

Documented evidence is required.

2.2.1.4 The supply of medical equipment is adequate to meet the needs of the practice.

Compliance will be verified by observation and during personnel and patient interviews.

2.2.1.5 Records are kept of the checking and maintenance of medical equipment.

Documented evidence is required.

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

Compliance will be measured during personnel interviews.

2.3 Maintenance management

2.3.1 Facility maintenance 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 Written policies and procedures guide practice personnel on the implementation of all maintenance service requirements.

This criterion is assessed based on the evidence of effective maintenance found throughout the practice during the survey.

If this criterion is scored PC or NC, the transgressions need to be recorded in detail to motivate for the PC/NC rating and it should be based on accurate facts.

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

*If this role is fulfilled by the practice manager or solo practitioner, compliance will be measured on evidence of effective maintenance of the buildings, grounds and utilities.
Where a designated individual has been identified to fulfil this role, compliance will be measured in accordance with the requirements set out in the employee's position description.*

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

Compliance will be measured on documented evidence and during personnel interviews.

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

Documented evidence is required.

2.3.1.5 Basic maintenance equipment, tools and spare parts are available.

The type and number of items available will vary in each practice according to the size of the facility and the services offered but should be suitable and sufficient to prevent unnecessary risk to patients, visitors and personnel or cessation of services due to deficiencies that are easily rectifiable.

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

Standard Intent:

The practice plans for regular inhouse 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, for example 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.

Documented evidence must be provided for example in the budget and/or strategic plan.

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

Where the practice is a tenant, parts of the preventative maintenance plan may be the function of the landlord. There must however still be documented evidence provided to the surveyors to demonstrate that the landlord has a preventative maintenance plan for the facility. This will allow the surveyors to assess the responsibilities of the landlord and the responsibilities of the practice.

2.3.2.3 Documented inspections of the buildings and grounds are conducted at regular intervals as determined by the practice policy.

The policy must include at least a) – e) in the standard intent above.

Documented evidence will be required.

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

Compliance will be measured during personnel interviews.

2.3.3 Information and communication technology (ICT) equipment is available and properly maintained to meet the needs of the service.

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 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 that guide the management of ICT equipment are implemented.

All key processes that relate to the management of ICT equipment should be identified and the correct manner of performing the tasks documented. The purpose of this requirement is to ensure that important tasks are performed correctly and consistently.

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

*If this role is fulfilled by the practice manager or solo practitioner, compliance will be measured on evidence of effective management of ICT equipment.
Where a designated individual has been identified to fulfil this role, compliance will be measured in accordance with the requirements set out in the employee's position description.*

2.3.3.3 There is an inventory of all ICT equipment.

This does not have to be a separate inventory, it can form part of a single inventory document for the practice. All ICT equipment must be included in the inventory (printers, laptop computers, desktop computers etc.)

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

Compliance with this criterion will ensure that data is not lost due to loss of power and that ICT equipment is not damaged, with potential loss of data, due to power surges.

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

Documented evidence will be required.

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

Documented evidence will be required.

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

Documented evidence will be required.

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

Documented evidence will be required.

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

Documented evidence will be required.

2.4 Patient record and personal information safety

- 2.4.1 A system for the storage, retrieval, retention and destruction of health records and personal information that meets the need for confidentiality and safety is implemented.**

Standard Intent:

Policies and procedures as well as managerial supervision ensure the safety and confidentiality of patient records and personal information.

The practice develops and implements a policy that guides the storage, retrieval, retention and destruction of patient records. 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.

The policy will define:

- a) Levels of access for individual personnel members
- b) The user's obligation to keep information confidential
- c) The process followed when confidentiality and/or security are violated
- d) Secure storage and retrieval of paper based and electronic patient records and personal information
- e) The protection of records against damage, fire, flood, theft, loss and electronic failure
- f) The arrangements for succession of patient records in the event of closure of the practice or death of the practitioner
- g) The criteria for selection and method of destruction of patient records and personal information

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

Patient records 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:

- 2.4.1.1 Policies and procedures for the storage, retrieval, retention, destruction and confidentiality and safety of patient records and personal information are implemented.**

Policies and procedures must include at least a) – g) in the standard intent above.

- 2.4.1.2 Designated individuals are responsible for the storage, maintenance and retrieval of patient files.**

Only those designated individuals may have access to the patient records. There must be evidence of signed confidentiality agreements with each individual who has access to patient information.

- 2.4.1.3 The filing system allows for incorrectly filed records to be easily identified (for example, through colour coding of the records).**

Compliance will be measured by observation.

- 2.4.1.4 Storage space for health records is sufficient and secure against unauthorised entry.**

Compliance will be measured by observation.

- 2.4.1.5 Records that have been removed from the designated storage area for use are kept out of public view.**

Compliance will be measured by observation.

- 2.4.1.6 The retention process provides the necessary confidentiality and security.**

This will be confirmed by observation.

2.5 Cleaning and laundry services

- 2.5.1 The cleaning and laundry 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 these services are 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 and laundry service.

Criteria:

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

Policies and procedures must detail how the core functions are to be performed. Implementation of these policies and procedures should be monitored to ensure consistent service delivery according to agreed standards of practice.

Compliance will be verified by documented evidence of monitoring activities and by observation of implementation of the policies.

- 2.5.1.2 There is evidence that laundry used for patients is washed separately from domestic laundry.**

Compliance will be verified during personnel interviews.

- 2.5.1.3 Adequate, secure and well-ventilated storage areas are available for cleaning and laundry equipment and chemicals.**

Chemicals for cleaning and laundry are safely stored in a well-ventilated, locked cupboard or room out of the reach of patients, children and visitors. There is adequate storage place for brooms and mops.

Compliance will be measured by observation.

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

Compliance will be verified during personnel interviews and by observation.

2.5.1.5 The practice manager ensures that cleaning and laundry personnel are appropriately trained regarding waste management, infection control procedures, confidentiality issues and any other relevant matters.

Evidence of such training will be required.

2.6 Contracted Services

2.6.1 Where contracts/service agreement exist for clinical, managerial or hotel services (cleaning, laundry, food) they provide for adequate number of suitably trained contract personnel to provide a safe and effective service.

Standard Intent:

Where support services have been contracted to outside agencies such as cleaning, building maintenance, gardening, ICT management, etc., the practice leaders must ensure supervision of these services to ensure that they comply with the terms of the contract, meet patient needs and are monitored as part of the quality management and improvement activities.

The practice manager identifies the number of personnel required 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. Contract personnel must act in accordance with position 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 requirements.

Criteria:

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

*It is very important that those who are required to monitor compliance with a contract have access to the deliverable elements of the document. The criterion does not require that leaders share the financial details of the contract.
Documented evidence must be provided.*

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

Documented evidence is required.

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

Documented evidence is required.

2.6.1.4 The practice ensures that contracted personnel are oriented to the practice and to relevant practice policies and procedures.

Documented evidence of orientation to both the facility, the position and relevant policies and procedures is required.

2.6.1.5 The practice ensures that contracted personnel participate in relevant practice in-

service training programmes.

*In-service training must include for example, infection control, health and safety, fire and evacuation etc.
A record must be kept of such training and must include all contracted personnel.*

3 CLINICAL SERVICES AND PATIENT CARE

OVERVIEW OF CLINICAL SERVICES AND PATIENT CARE

The main purpose of a healthcare facility is to provide healthcare services to patients. Providing appropriate care in an environment that supports and responds to each patient's unique needs requires a high level of planning and coordination. Certain activities are basic to patient care, such as planning and delivering appropriate care to each patient, monitoring the patient's response to the care provided, modifying care when necessary and completing the follow-up.

Throughout all phases of care, patient needs are matched with appropriate resources within and, when necessary, outside the practice.

Processes for continuity and coordination of care among physicians, nurses and other healthcare providers must be implemented in and between all services. These processes should be designed collaboratively and implemented by the leaders of the various settings and services to ensure coordination of care.

Standards:

3.1 *Diagnosis and management*

3.1.1 *In consultation with the patient, the practice provides care that is consistent with best available evidence and in accordance with patient needs and values.*

Standard Intent:

Clinical guidelines should be selected and agreed by all clinicians. Consideration should be given to providing guidelines for high risk, high volume and high cost conditions. In addition, guidelines should be available for conditions which are rarely seen but may have severe consequences for patients if misdiagnosed or mismanaged.

Guidelines are found in the literature under many names including practice parameters, practice guidelines, patient care protocols, standards of practice, care pathways, etc. National guidelines for selected conditions are further provided by the Ministry of Health and Wellness. Regardless of the source, the scientific basis of guidelines should be reviewed and approved by the clinical leaders and clinical practitioners before implementation. This will ensure that they meet the criteria established by the leaders and are adapted to the community, patient needs and practice resources.

Once adopted, guidelines should be reviewed on a regular basis to ensure their continued relevance. Consistency in the approach to diagnosis and management of care among those who are involved in the clinical care of an individual patient is an important aspect of continuity of care. Patients value consistency in the quality of treatment they receive from a practice and expect that treatment and advice given by different medical practitioners within the practice will not be in conflict.

Clinical practice guidelines provide important recommendations for clinical care and should be accessible at the point of care. Practices need to check that clinical practice guidelines are current.

Criteria:

3.1.1.1 **The clinical team uses current clinical guidelines relevant to its practice, to assist in the diagnosis and management of patients.**

Guidelines must be available at the point of care and should include high risk, high volume, high cost and rarely seen conditions. The practitioner must consider national guidelines where these are available.

The emphasis in this criterion is on the availability and use of clinical guidelines and evidence of both must be provided for compliance.

3.1.1.2 The clinical team set criteria to select clinical practice guidelines.

Every effort should be made to identify and adopt guidelines that have been rigorously and scientifically developed, internationally accepted and adapted for local use.

3.1.1.3 The clinical team can describe how they ensure consistency of diagnosis and management of patients.

Compliance will be measured during personnel interviews and the patient record audit.

3.1.1.4 The clinical team can demonstrate how they communicate about clinical issues and support systems in the practice.

Compliance will be measured during personnel interviews and the patient record audit.

3.2 Communication with patients

3.2.1 Patients are informed of the range of services and 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.

Criteria:

3.2.1.1 When patients register with the practice they are informed of the range of services offered by the practice, opening hours, contact details and after hours' care arrangements.

It is advisable to provide this information in printed form as patients may not remember what has been told to them.

As a minimum, patients must acknowledge receipt of the information by signing (on the registration form) that they have been informed.

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

This criterion is only applicable to practices where the telephone system diverts to an 'on hold' message when the line is busy during business hours. The purpose of this requirement is to assist patients who are dealing with an emergency during peak business hours when it might be difficult to get through to the practice because of the high volume of calls.

If the practice does not have an 'on hold' system this criterion will be not applicable.

3.2.1.3 A message on the practice's telephone answering machine, call diversion system or paging system provide information to patients on how to obtain care outside the practice's normal opening hours.

The intention of this criterion is to ensure that patients are assisted with the relevant information outside of business hours.

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

Documented evidence can be provided by time cards, duty rosters etc. and can also be verified during patient and personnel interviews.

3.2.2 There is a process for appropriate referral of patients for specialised consultation/investigations at other healthcare facilities.

Standard Intent:

In some cases, practitioners refer patients for a secondary consultation to confirm an opinion, to request more extensive diagnostic evaluations than may be available to the practitioner or to have patients receive specialised treatment that the referring practice may be unable to provide. The practice must clearly describe the referral process. Practices may wish to consider the use of a standard referral form which includes a tear off slip for the receiving doctor's response following the consultation.

The referral must contain the following as a minimum:

- a) At least three approved patient identifiers
- b) Relevant history, examination findings and current management
- c) Known allergies, adverse drug reactions and current medication
- d) The name of the referring doctor
- e) The name of the doctor/service referred to
- f) Stated purpose of the referral
- g) Request for feedback following the consultation with the specialist

Criteria:

3.2.2.1 There is a documented process to refer patients.

Compliance will be verified during the patient record audit.

3.2.2.2 The lines of communication between the practice, referral hospital and community services are clearly defined.

Practice personnel must clearly describe the referral process, especially where patients are sent to another healthcare organisation for specialist consultation or special investigations and then return to the referring practice for continuation of treatment.

Compliance will be verified during the patient record audit.

3.2.2.3 The clinician informs the patient if he/she has any financial interest in the referral service.

Surveyors must pay particular attention to services that are offered in the same facility by different practitioners for example, where a clinician refers a patient to a radiology or laboratory practice in the same facility.

3.2.2.4 Referrals are to specific individuals and/or agencies in the patient's home community wherever possible.

Compliance will be verified during the patient record audit.

3.2.2.5 Patients and as appropriate their families are given follow-up instructions which are provided in an understandable form and manner.

Compliance will be verified during the patient record audit.

3.2.2.6 A copy of the referral note is available in the patient record.

Compliance will be verified during the patient record audit.

3.2.2.7 The referral is made on appropriate stationery or electronically.

Compliance will be verified during the patient record audit.

3.2.2.8 The referral contains as a minimum a) – g) in the standard intent above.

Compliance will be verified during the patient record audit.

3.2.2.9 The practice keeps a record of replies received following the referral of patients.

Documented evidence must be provided of the system that is used in the practice to record and act upon replies received from referral practitioners.

3.2.2.10 There are written guidelines for the referral of emergency patients.

Documented evidence is required.

3.2.2.11 Follow-up care based on the findings of investigations/consultations performed outside the practice are noted in the patient record.

Compliance will be verified during the patient record audit.

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

Standard Intent:

For efficiency of service delivery, appointment systems are recommended as best practice. The system must be flexible in 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.

Members of the practice team should be sensitive to the need for longer consultations when the need for a longer consultation could be anticipated (for example, when the patient is attending for multiple or complex problems, chronic disease management or procedures).

Continuity of care is best achieved when a patient has ongoing care from the same clinician. The clinician-patient relationship is central to the provision of care. In recognition of this, patients are offered an appointment with their preferred clinician when possible.

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:

3.2.3.1 There is a flexible appointment system for consultations.

This criterion will be scored compliant in practices that do not utilise an appointment system if it can be demonstrated that patients who request a consultation at a specific time (for example, because of business commitments, travel arrangements etc.) are accommodated.

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

Both clinical and administrative personnel must be able to describe the practice's system for fast-tracking patients and the process for seeking urgent medical assistance from a clinical personnel member.

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

Compliance will be measured during patient and personnel interviews.

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

To be compliant with this criterion personnel must be able to describe the patient journey from arriving at the practice until they leave. Administrative processes must be simple, standardised and streamlined as far as possible.

3.2.3.5 Patients are offered longer appointments when clinically indicated.

The practice must identify those instances where experience has shown that longer appointments will be required. This criterion links to 3.2.3.4 above where patients will not be seen in the shortest possible time if appointments run over time with preceding patients.

3.2.3.6 The patient is offered an appointment with their preferred clinician when possible.

This criterion will not be applicable where there is a solo practitioner.

3.2.3.7 The patient's consent is obtained if third parties are expected to be present during the consultation.

*This can apply to students, researchers, other practice personnel and even to the patient's family and care-givers.
Documented evidence must be provided.*

3.2.4 At registration, sufficient details are taken from the patient to ensure that the patient can be contacted by the practice when necessary and that the medical practitioner 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) Current address
- b) Telephone numbers
- c) Next of kin
- d) Who to contact in an emergency
- e) Previous medical history
- f) Previous surgical history
- g) Current medication (prescribed and over the counter medications)
- h) Allergies
- i) Health risk factors, for example, smoking, alcohol consumption, physical activity
- j) Patient/guardian signature

Criteria:

3.2.4.1 New patients to the practice are asked to complete a form detailing at least a) – j) in the standard intent above.

Compliance will be verified during the patient record audit.

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

Compliance will be verified during the patient record audit.

3.2.4.3 Health funder details are accurately recorded for each new patient when required.

Compliance will be verified during the patient record audit.

3.2.5 Patients can obtain advice or information related to their clinical care by telephone and electronic means.

Standard Intent:

Where patients, who are known to a medical practitioner, request information or follow up regarding a condition for which they have previously consulted, and the practitioner determines that it is clinically safe not to review the patient in a face to face consultation, 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 from a clinician
- d) That the patient was made aware of any costs involved
- e) Documentation of the communication in the patient record

Criteria:

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

Compliance will be verified during personnel and patient interviews, patient record audits and by observation.

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

Compliance will be verified during the patient record audit.

3.2.5.3 The practice can demonstrate how it receives and returns telephone and electronic messages from patients.

Personnel must be able to describe the process detailing which telephone calls are immediately put through to the medical practitioner and what process is followed to ensure that calls are returned timeously when they are not.

Electronic messages can take the form of e-mails, text messages or messages received on messaging applications.

3.2.6 The practice has a system for the follow up and review of tests and results.

Standard Intent:

The information gained from tests and results can have a considerable impact on the choices patients and medical practitioners make in patient care. There may be considerable risk in not following up clinically significant tests and results. There is a system to track all results and where potentially serious

pathology is suspected, doctors have a system to track that the investigation is completed and the result is received and acted upon.

To minimise clinical risk, results of investigations are reviewed by the medical practitioner, signed or initialled (or the electronic equivalent), acted on in a timely manner and incorporated into the patient health record.

Many practices provide the results of investigations to their patients by telephone. The person responsible for giving the results should ensure that the recipient of the information is correctly identified using three patient identifiers so that patient confidentiality is not compromised. Acceptable patient identifiers are name, date of birth, address, identification number, practice patient number.

Criteria:

3.2.6.1 A documented policy on the review and management of pathology results, imaging reports, investigation reports and other clinical correspondence received by the practice is implemented.

The practice needs a documented system for the follow up of all tests and results with a strong focus on risk management. This policy must include that there is documented evidence that every report and result was seen, reviewed and acted upon by a medical practitioner.

3.2.6.2 Patient health records contain evidence that all pathology results, imaging reports, investigation reports and clinical correspondence received by the practice have been handled in accordance with practice policy.

Compliance will be verified during the patient record and practice documentation audit.

3.2.6.3 There is evidence of review of the results of procedures and diagnostic tests performed by a medical practitioner.

Compliance will be verified during the patient record audit.

3.2.6.4 There is a system to advise patients of the process to follow up on results.

Patients must be encouraged to take responsibility for their own health. The practice must therefore provide the patient with information about what to expect following any investigation. For example, how long it takes to get the results, the method by which the patient will be informed of the results etc.

Compliance will be verified during patient interviews and patient record audits.

3.2.6.5 A documented system to identify, follow up and recall patients with clinically significant results is implemented.

The system must be implemented in such a way that a patient who is not immediately contactable remains flagged for follow up. Documented evidence is required.

3.2.6.6 When patients are informed of results over the telephone, the patient is identified with 3 approved identifiers before the information is given.

Compliance will be verified during the patient record audit.

3.2.6.7 When results are given over the telephone, the result is given to the patient themselves or the patient's consent is obtained before giving the result to a nominated third party.

Compliance will be verified during the patient record audit.

3.3 Patient education

3.3.1 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 coordinated 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 considered. 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:

3.3.1.1 The practice offers relevant health education to its patients in a planned and consistent manner which enables patients to meet their ongoing health needs and achieve their health goals.

*This will be assessed based on the evaluation of the patient education activities in relation to the services offered as well as the individual patient education during consultation for example, lifestyle advice, when to seek medical attention - how urgently and at what level of care, etc.
Compliance will be verified during patient interviews and patient record audits.*

3.3.1.2 Posters and pamphlets regarding high risk and commonly treated conditions relevant to the practice population are visibly displayed and accessible in the waiting room and routinely provided to patients during the consultation when appropriate.

Compliance will be verified during patient interviews, patient record audits and by observation.

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

Compliance will be verified during the patient record audits.

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

*The practice must identify those resources that are specific to its patient population for example, breastfeeding support, mental health support, diabetes society etc.
Documented evidence is required.*

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

Compliance will be verified during the patient record audits.

3.3.1.6 Information is provided in a manner and in a language that is understood by those

making the care decisions.

Compliance will be verified during patient interviews.

3.4 Clinical record keeping

3.4.1 Patient records contain the required information for the relevant condition.

Standard Intent:

Medical records are intended to support patient care and should authentically represent every consultation (including by telephone and electronic mail). The clinical record of each patient, whether handwritten or electronic, needs to contain sufficient information to support the diagnosis and justify the treatment provided. It also needs to document the care given and the course and results of treatment. 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 consultation
- b) Who conducted the consultation
- c) Reason for the consultation
- d) Relevant clinical findings
- e) Vital signs, including weight and height
- f) Diagnosis
- g) Recommended management plan and, where appropriate, expected process of review
- h) Any medication prescribed for the patient (including name, strength, directions for use/dose frequency, number of repeats and date medication started/ceased/changed)
- i) Complementary medication used by the patient
- j) All requested investigations and procedures
- k) Any relevant preventive care undertaken
- l) Any referral to other healthcare providers or health services
- m) Any special advice or other instructions
- n) Follow up instructions given to the patient
- o) Health education
- p) For emergency cases, relevant times are recorded, i.e. time patient seen, time drugs administered, etc.

Abbreviations and symbols are standardised. Such standardisation is consistent with recognised local and national standards.

Patient contact details are kept up to date.

All relevant costs are discussed with patients prior to these costs being incurred and the discussion is documented in the patient record.

Criteria:

3.4.1.1 Notes for each consultation contain as a minimum points a) – p) above.

Compliance will be verified during the patient record audit.

3.4.1.2 Handwritten notes are legible.

Compliance will be verified during the patient record audit.

3.4.1.3 Notes are recorded contemporaneously.

Compliance will be verified during the patient record audit.

3.4.1.4 All abbreviations are standardised in accordance with recognised local and national

standards.

Compliance will be verified during the patient record audit.

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

Compliance will be verified during the patient record audit.

- 3.4.1.6 Adverse drug reactions are noted in the patient's record.**

Compliance will be verified during the patient record audit.

- 3.4.1.7 The patient is fully informed regarding the estimated costs of any treatment, investigation, procedure or referral and the discussion is documented.**

Compliance will be verified during the patient record audit.

3.5 Continuity of care

- 3.5.1 The practice has an effective clinical handover system that ensures safe and continuing healthcare delivery for patients.**

Standard Intent:

Clinical handover needs to occur whenever there is an interface of care by different providers.

Examples of clinical handover include:

- A medical practitioner covering for a fellow medical practitioner who is on leave or is unexpectedly absent
- A medical practitioner covering for a part time colleague
- A medical practitioner handing over care to another health professional such as a practice nurse physiotherapist, podiatrist or psychologist
- A medical practitioner referring a patient to a service outside the practice
- A shared care arrangement (for example, team care of a patient with mental health problems)

Criteria:

- 3.5.1.1 There is implementation of a documented policy on clinical handover to ensure that standard processes are followed.**

*The complexity and comprehensiveness of the content of handover information required to achieve continuity of care will differ for different types of handover situations. The details to be included in each situation should be agreed upon by all stakeholders and formalised in a practice to ensure a standardised approach at all times. The transfer of information must be documented, preferably using standardised forms (electronic or paper-based) for the various handovers.
Compliance will be verified during patient record audit.*

- 3.5.1.2 Patients share in decision making regarding the handing over of clinical information.**

*Patients also have a responsibility for their own health and must share in the decision of who will continue with their care.
Compliance will be verified by documentation that the patient has been informed and shared in the decision of handing over.*

- 3.5.1.3 Handover of clinical information is recorded in the patients' health records.**

Compliance will be verified during the patient record audit.

- 3.5.1.4 Information relating to those patients requiring special attention, such as the chronically ill or those with infections which require specific infection control measures, is provided in a patient held letter, a copy of which is kept in the patient record.**

Compliance will be verified during the patient record audit.

- 3.5.2 The practice ensures safe and reasonable arrangements for medical care for patients outside of normal opening hours.**

Standard Intent:

Medical care outside normal opening hours needs to be provided by recognised medical practitioners. The method of providing such care can be achieved in one of the following ways:

- The practice's medical practitioners provide their own care for patients outside normal opening hours, either individually or through a roster
- Formal arrangements for cooperative care outside the normal opening hours exist through a cooperative of one or more local practices
- Formal arrangements exist with a medical deputising (locum) service
- Formal arrangements exist with a local hospital or after hours' facility

When the practice's medical practitioners cannot safely or reasonably deliver care outside normal opening hours themselves, the practice can clearly document the alternative system of care that is available for their patients.

The practice is responsible for ensuring the alternative care provider offers care to an acceptable standard.

- 3.5.2.1 There is evidence of one (or a combination) of arrangements for patients to access care outside of normal opening hours.**

Regardless of the arrangements used to provide care outside normal opening hours, documented evidence of the system the practice uses to provide such care needs to be available.

- 3.5.2.2 The credentials of alternative care providers are verified.**

*This criterion will be not applicable where patients are referred to public and private hospitals after hours.
Evidence must be provided that the credentials of locums and practitioners in partner practices have been verified.*

- 3.5.2.3 Patient health records contain reports or notes of consultations occurring outside normal opening hours by or on behalf of the practice.**

*This criterion will not be applicable to consultations that occur at public health facilities.
Evidence must be provided on how and when the practice receives notes of consultations occurring through all other after-hours arrangements.
Compliance will be verified during the patient record audit.*

3.6 Emergency care

- 3.6.1 The practice provides emergency treatment and care.**

Standard Intent:

The arrival of emergency patients may be unpredictable, particularly in practices that do not form part of a 24-hour service. The practice must be prepared to provide primary emergency treatment as required to stabilise a patient while waiting for further assistance from emergency medical services.

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

*As a minimum, the Basic Life Support algorithm must be available and followed.
Documented evidence of training must be provided.*

3.6.1.2 Guidelines for emergency triage, assessment and treatment are available and followed for all types of patients seen at the practice (for example adult, paediatric and neonatal).

*The practice's policy on triage must make distinction between triage undertaken by members of the clinical team and triage undertaken by personnel with non-clinical roles. Appropriate training must be provided to assist both administrative personnel and members of the clinical team to identify patients in need or urgent care.
Documented evidence of training must be provided.*

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

Documented evidence must be provided.

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

*This can take the form of morbidity and mortality meetings or debriefing sessions.
Documented evidence must be provided.*

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

Documented evidence must be provided.

3.6.2 The practice provides resuscitation in accordance with practice policy.**Standard Intent:**

Resuscitation policies and equipment should be standardised throughout the practice.

Standardised resuscitation processes require:

- a) The level at which resuscitation is provided and by whom
- b) Coordination among those who provide and maintain the equipment
- c) Availability of required equipment
- d) Initial and ongoing training of personnel in the use of equipment and execution of procedures
- e) Maintenance and monitoring of equipment
- f) Current, evidence-based guidelines for resuscitation

Deficiencies in the system regarding equipment, its use and the knowledge and skills required by those who carry out resuscitation should be identified, documented and acted upon. Each practice should identify those members of personnel to be trained in emergency life support and the level of training (basic or advanced) appropriate to their role in the practice. The person(s) providing the training must be currently registered and/or accredited with a recognised body as a resuscitation trainer. Training in many instances can be outsourced.

Criteria:**3.6.2.1 The practice has an implemented resuscitation policy.**

Documented policies and procedures that include at least a) – f) must be available and implemented.

Evidence of implementation of all of the listed policies is required for a compliance rating, otherwise this criterion will be scored PC.

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

Documented evidence of nationally accepted training must be provided.

3.6.2.3 A designated person documents monthly checks to ensure that resuscitation equipment is available, in working order and that consumables are not expired and reports any adverse findings for immediate remediation.

Documented evidence must be provided.

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

Standard Intent:

Resuscitation equipment and medication is available at the point of need within 1 minute. In addition, there is access to a defibrillator or automated external defibrillator (AED) within 3 minutes of any patient collapsing. Resuscitation equipment includes at least:

- a) A defibrillator/AED with adult and infant paddles/pads
- b) A bag-mask manual ventilator
- c) A selection of oropharyngeal airways

Criteria:

3.6.3.1 There is a designated resuscitation area.

This does not have to be an area that is used exclusively for resuscitation, it may be in the normal consulting area.

The area must however allow easy access for resuscitation equipment and emergency personnel, have a suitable surface on which to perform resuscitation and ensure the privacy of the patient.

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

This refers to the summoning of medical help both from within the practice itself (to alert personnel that there is an emergency) and from outside the practice. Various methods such as an alarm, intercom, alert button, telephone etc. acceptable.

Personnel must be able to demonstrate the procedure to be followed when an emergency situation arises.

3.6.3.3 The practice provides resuscitation equipment according to the services provided.

Resuscitation equipment and documented evidence of the checking thereof according to the practice's resuscitation policy must be available but must include at least a) – c) in the standard intent above.

Checking must include the identification of expiry dates on consumables such as airways. Documented evidence of this checking is required.

3.6.3.4 Equipment for early cardiopulmonary resuscitation is available within one minute in each area of the practice and access to a defibrillator or automated external defibrillator (AED) within three minutes of any patient collapsing.

Resuscitation equipment must be available at the point of need within one minute. In addition, there must be access to a defibrillator or automated external defibrillator (AED) within three minutes of any patient collapsing.

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

The practice personnel must be able to describe the process for contacting ambulance services and the contact details must be readily available at all telephones in the practice.

3.7 Medication management

3.7.1 Prescribing and dispensing of medications adheres to laws, regulations and professional standards of practice.

Standard Intent:

The practice must ensure that those responsible for prescribing, dispensing and ordering of medication are suitably qualified and registered.

The practice dispenses medication in the most ready-to-administer form possible to minimise opportunities for error during reconstitution and administration. The system supports accurate dispensing of medication in a timely manner.

The practice implements systems to ensure that all pharmaceutical practices are in accordance with current legislation.

Criteria:

3.7.1.1 A designated individual who is suitably qualified has clearly defined responsibilities and accountability for all aspects of medication management.

This requires that an individual in the practice has the officially assigned duties of overseeing and taking responsibility for all aspects of medication management. This may be the practice manager or a suitably qualified health professional.

3.7.1.2 Medication is prescribed and dispensed in accordance with legislation and current pharmaceutical, medical and eye care guidelines.

Compliance will be verified during the patient record audit.

3.7.1.3 The scope of and limitations to the responsibilities and activities of the personnel who manage medication are clearly defined in written policies.

*This is particularly relevant where certain medication may only be prescribed by designated specialists.
Compliance will be verified with reference to practice policy and country-specific legislation.*

3.7.1.4 Medication is securely and legibly labelled with relevant information as required by practice policy.

Country-specific regulations apply, but must include at least the following:

- Name of patient and patient record number (if applicable)
- Proprietary name/approved name or name of each active ingredient
- Direction with regard to the manner in which medication must be used
- Strength and number of dose units in the container
- Date of dispensing
- Expiry date and batch number
- Additional labels with warnings and storage instructions in accordance with practice policy

3.7.1.5 A register is maintained of all medication dispensed.

Documented evidence is required.

- 3.7.1.6 The person prescribing and dispensing the medication has access to patient information that would contra-indicate prescription of particular medication.**

Compliance will be assessed during the patient record audit.

- 3.7.1.7 The person dispensing medication informs the patient of available generic equivalents.**

Compliance will be assessed during the patient record audit.

- 3.7.1.8 Controlled medication is prescribed in accordance with legislation and practice policy.**

Compliance will be measured during the patient record audit.

- 3.7.1.9 Verbal/telephonic medication orders are documented in the patient's record.**

Compliance will be verified during the patient record audit.

- 3.7.1.10 Prescriptions conform to all legal requirements.**

Compliance will be verified during the patient record audit.

- 3.7.2 The practice has a nominated personnel member who is suitably trained to oversee cold chain management.**

Standard Intent:

The potency of medication depends on suitable storage. The cold chain is the system of transporting and storing temperature sensitive medication within the safe temperature range of 2 - 8°C.

Deep freeze, refrigeration, cold room and cool area facilities are provided for safe storage of certain medications. There is a mechanism for ensuring that the correct temperature is maintained throughout the life of the medications. Deep freezers and refrigerators are defrosted when necessary. Doors, hinges and seals are all functional. Foodstuffs must not be stored in the medication refrigerator.

Criteria:

- 3.7.2.1 Policies and procedures are implemented to ensure that medication is transported to the practice and stored within the practice according to manufacturers' guidelines, with specific emphasis on maintenance of cold chain requirements.**

*Policies must be available that address the transportation of medication and particularly the maintenance of the cold chain all the way from the manufacturer to the end user. It is the responsibility of the dispensing practitioner to ensure that the cold chain is maintained.
Documented evidence of cold-chain monitoring will be required for compliance with this criterion.*

- 3.7.2.2 A dedicated refrigerator is available for medication requiring storage at low temperatures.**

The refrigerator must be used exclusively for the storage of medication. The records should also reflect regular defrosting of the refrigerator with documented evidence of maintenance of the cold chain for medication during the defrosting process.

- 3.7.2.3 A monitoring log is kept of the temperature within the refrigerator and/or cold-chain monitors and is available for inspection.**

Temperature records should demonstrate maintenance of the temperature between 2 and 8 degrees Celsius.

3.7.2.4 The fridge thermometer is calibrated at regular intervals determined by the practice and the calibration is documented.

*The calibration method will depend on the type of thermometer.
Documented evidence is required.*

3.7.2.5 Any remedial action taken is recorded.

When the refrigerator temperature is out of range, appropriate action should be taken and documented, and effectiveness of the action monitored. This will require evidence of action both in relation to the refrigerator and the medication stored in the refrigerator. Medication should be discarded when necessary according to manufacturer's guidelines. Continued monitoring of refrigerator temperature should demonstrate return to the required range within an expected timeframe, failing which further action should be taken.

3.7.2.6 The integrity of door seals, door and hinges is checked at regular intervals and documented accordingly.

Compliance will be measured by observation and on documented evidence.

3.7.3 Medication is stored in a secure and clean environment.

Standard Intent:

The practice stores and dispenses medication in a clean and secure environment which complies with laws, regulations and professional practice standards. In particular, medication is clearly labelled, which includes the following:

- Generic name
- Strength of medicine
- Dose, frequency and duration of course
- Date of dispensing and expiry date
- Name of patient
- Name/address of supplier
- Child safety warning
- Batch number

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

There are arrangements for ensuring the security of medication including alarm systems, door access controls and safes/vaults for storing controlled medicines.

Criteria:

3.7.3.1 Medication storage areas are protected from heat and light and effectively ventilated.

Note must be made of provision for medication that should not be exposed to direct sunlight. Where the ambient temperature in the cupboard/room cannot be maintained at 20-25 degrees Celsius there should be evidence that the environmental temperature is monitored and complies with the manufacturer's requirements for medication storage.

3.7.3.2 Stored medication is legibly marked and securely labelled.

Country-specific regulations apply, but must include at least the following:

- Proprietary name/approved name or name of each active ingredient
- Strength and number of dose units in the container
- Expiry date and batch number

- 3.7.3.3 All pharmaceuticals and medical consumables are regularly checked for expiry dates and checks are recorded.**

Compliance will be measured by observation and documented evidence is required.

- 3.7.3.4 An inventory management system either manual (stock cards) or automated, is in place to monitor maximum and minimum stock levels and control stock losses.**

This requires the practice to identify maximum and minimum stock levels based on records of medication use over time.

Compliance will be measured by comparing the actual stock levels to the records.

3.8 Procedure room

- 3.8.1 The procedure room and sedation services are managed and staffed to provide a safe and effective service.**

Standard Intent:

The procedure room management team should work with the practice management team to ensure adequate and appropriate management processes and an adequate staffing complement for the procedure room, sedation service and recovery area.

The qualifications of sedation practitioners must be documented, together with the level of sedation which they are qualified to perform and the functions they can fulfil within the sedation team.

Criteria:

- 3.8.1.1 During all phases of care, there are qualified and experienced individuals with airway management certification responsible for the patient's care.**
- 3.8.1.2 Procedure room rosters ensure that sufficient numbers of personnel with suitable qualifications and experience are present at all times for procedure room duties, sedation assistance and recovery area duties.**
- 3.8.1.3 Sedation is administered only by sedation practitioners who have the necessary qualifications and who have received specific theoretical and supervised practical training, including updated airway certification.**
- 3.8.1.4 Assistance for the sedation practitioner is provided in accordance with professional guidelines.**

A dedicated observer is always required to monitor a patient when an operator sedation practitioner administers sedation for procedures lasting longer than 30 minutes. For brief, simple procedures lasting less than 30 minutes the assistant can help the operator sedation practitioner with monitoring and rescue if required. The observer/assistant should have at least the equivalent of nursing training and must be proficient in maintaining airway patency and the monitoring of vital signs (airway certification).

- 3.8.2 The procedure room is equipped with facilities for safe sedation and surgical care.**

Standard Intent:

The procedure room should provide space for the reception, induction of sedation, surgery, recovery and monitoring of patients.

There must be areas for the disposal and collection of used equipment and waste including contaminated waste and sharps. Safe and adequate storage space for pharmaceutical and surgical

supplies must be available including separate, lockable cupboards for high risk and scheduled medication. Flammable substances must be stored in cupboards which are fire-resistant and contain spills.

Facilities should be equipped according to the requirement lists approved for use in the service and according to international sedation guidelines.

There must be scrubbing facilities with hot and cold running water and elbow-operated or hands-free/self-closing taps.

Criteria:

- 3.8.2.1** There is direct access to the procedure room from the receiving, scrubbing-up and recovery areas.
- 3.8.2.2** The design of the procedure area provides space for the reception, induction of sedation, surgery, recovery (where applicable) and monitoring of patients.
- 3.8.2.3** The procedure area is equipped in accordance with approved requirement lists.
- 3.8.2.4** Access to the procedure room is controlled.
- 3.8.2.5** There is a system for controlling the environmental temperature that ensures safe limits for sedated patients in accordance with professional society guidelines.
- 3.8.2.6** There is safe and adequate storage space for pharmaceutical and surgical supplies.
- 3.8.2.7** There is a dedicated medication refrigerator in the procedure area, the temperature of which is measured and recorded daily.
- 3.8.2.8** Appropriate action is taken and recorded when the temperature of the refrigerator is outside the recommended range.
- 3.8.3** *Sterilising processes are managed to ensure the provision of a safe and effective service.*

Standard Intent:

There are many methods of sterilising equipment and supplies. Whatever methods are used, personnel should ensure that the sterilising equipment and processes are effective. Systems must therefore be in place to confirm that sterility is obtained through the sterilisation processes.

Criteria:

- 3.8.3.1** A designated individual is responsible for the sterilising and disinfecting of required items.
- 3.8.3.2** Autoclaves/sterilising units are appropriate to their use and comply with licensing requirements.
- 3.8.3.3** There is a mechanism to ensure that the required level of sterility is obtained from the methods used.
- 3.8.3.4** Sterilising equipment is used and maintained according to manufacturer's recommendations.
- 3.8.3.5** There is a system for the ordering, storage, maintenance and distribution of sterile supplies not processed on site.
- 3.8.3.6** There is a mechanism to ensure that sterile supplies are dated and used on a first

expired first out basis.

3.8.3.7 The maintenance of sterility is checked before any sterile items are issued.

3.8.4 *Sedation equipment, medical equipment, supplies and medication comply with current guidelines.*

Standard Intent:

Sedation risks for adverse events are significantly reduced when appropriate, well-functioning equipment is used to administer sedation and monitor patients according to sedation guidelines. Adequate supplies of medication and medical supplies must be available for routine and emergency use. Recommendations regarding equipment, supplies and medication are available from government agencies, national or international professional sedation organisations or other authoritative sources. An effective equipment maintenance programme must ensure that adequate equipment is available for the provision of safe sedation and analgesia.

Criteria:

3.8.4.1 The recommendations of current guidelines guide the provision and use of sedation equipment, supplies and medication.

3.8.4.2 The recommendations of current guidelines guide the provision and use of devices to administer oxygen and assist with ventilation, where indicated.

3.8.4.3 The recommendations of current guidelines guide the provision and use of airway devices and equipment.

3.8.4.4 The recommendations of current guidelines guide the provision, maintenance and use of monitoring equipment.

3.8.4.5 The recommendations of current guidelines guide the provision and use of equipment with which to gain intravenous access and administration/infusion of sedative/analgesic medication.

3.8.4.6 Medication is available and used according to the requirements of the level of consciousness necessary to provide safe procedural sedation and analgesia.

3.8.4.7 The medication storage area is in close proximity to the procedure room.

3.8.4.8 A medication trolley with a sharps bin is available for the exclusive use of the sedation practitioner in each procedure room.

3.8.4.9 Equipment and instrumentation for surgery must be available for the level of care provided.

3.8.4.10 There is appropriate shielding and protective clothing in the presence of biohazards (including lasers) or radiographic equipment.

3.8.4.11 Hazard or warning notices are displayed.

3.8.5 *Recovery facilities and equipment are available to provide safe and effective recovery care.*

Standard Intent:

The number of beds/recliner chairs/trolley spaces in the recovery area provides sufficient space for at least one patient from each procedure room that it services and is sufficient for peak loads. Enough space must be available in case of a CPR or medical emergency. The provision, use and maintenance

of recovery area equipment and discharge criteria comply national or international professional sedation organisations or other authoritative sources.

Criteria:

3.8.5.1 There are recovery facilities within the procedural area.

Patients may be recovered in the procedure room provided that enough time is allowed for recovery and discharge between patients.

3.8.5.2 There is at least one recovery bed/recliner chair/trolley for each procedure room.

3.8.5.3 Non-invasive vital signs monitoring is available for each bed/recliner chair/trolley.

3.8.5.4 Oxygen and vacuum facilities are available and easily accessible.

3.8.5.5 There are two electrical sockets for each bed/recliner chair/trolley.

3.8.5.6 The provision, use and maintenance of recovery area equipment complies with current guidelines.

3.8.6 *Clinical practice guidelines guide patient care and reduce undesirable variation in the procedure room.*

Standard Intent:

Clinical practice guidelines assist practitioners in making clinical decisions in accordance with current best practice. Guidelines are found in the literature under many names, including practice parameters, practice guidelines, patient care protocols, standards of practice and/or care pathways but they are usually country specific. Guidelines are written by experts in the field and have to be approved by official societies. Sedation guidelines are for all risk categories and are very specific in that only ASA 1 and 11 patients qualify for sedation outside the hospital environment.

Once implemented, guidelines are usually reviewed on a regular basis to ensure that they remain up to date and reference the latest evidence-based practices.

Criteria:

3.8.6.1 Clinical practice guidelines, relevant to the patients and services of the procedure room are available to guide patient care processes.

As a minimum, the most current guidelines for procedural sedation and the most common procedures performed in the practice must be available.

3.8.6.2 The implementation of guidelines is monitored as part of a structured clinical audit.

3.8.6.3 Guidelines are reviewed and adapted on a regular basis according to practice policy.

3.8.7 *Patients and their families receive sufficient information to make informed decisions regarding their care.*

Standard Intent:

During the care process, patients and their families should receive sufficient information to enable them to participate in decisions regarding their care. Information must be provided on their diagnosis, proposed care, expected results of care, alternative care options, consequences of refusing care and any expected cost to the patient or family for that care. The consent process should be clearly defined by the practice and incorporate relevant laws and regulations.

When obtaining informed consent from patients and/or their legal representatives, they must be provided with all information relating to the planned care to enable them to make informed decisions.

Informed consent for care sometimes requires that people other than, or in addition to, the patient are 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 must be identified. When someone other than the patient gives consent, this individual's name, contact details and relationship to the patient must be documented in the patient's record. The information given to the patient and/or others in the course of obtaining informed consent must be documented either on the consent form or in the patient record.

Criteria:

- 3.8.7.1** There is a documented process for obtaining informed consent which is implemented.
- 3.8.7.2** A legally valid, informed consent document for surgical or other invasive procedures is completed comprehensively and available in the patient records.
- 3.8.7.3** A legally valid, informed consent document is obtained by the sedation practitioner before any sedative medication is administered.
- 3.8.8** *A pre-sedation assessment is conducted and recorded after evaluation of the medical history questionnaire. Special attention is paid to a focused airway examination.*

Standard Intent:

The patient's pre-sedation assessment is the basis to develop a sedation plan for the entire procedure including postoperative care. The pre-sedation assessment provides information needed to:

- Select the level of sedation to be administered
- Identify any medication sensitivities and allergies
- Safely administer the appropriate sedation level by selecting the correct medication for a specific sedation technique
- Know how to interpret the results and implications of patient monitoring
- Identify the patient that does not qualify for sedation

The plan considers information from the medical history questionnaire and the patient assessment done by the sedation practitioner. The sedation practitioner will then decide which level of sedation is appropriate for the patient, the sedation technique to be used, other medication and fluids, monitoring procedures and post-sedation monitoring and care.

Criteria:

- 3.8.8.1** There is a pre-sedation assessment and examination, including evaluation of a medical history questionnaire, to evaluate risk and indication for sedation need for the specific patient.
- 3.8.8.2** The medical history questionnaire and preoperative patient assessment are used to assist the sedation practitioner to identify the possible risks of allergic or adverse medication interactions.
- 3.8.8.3** The patient/guardian signs for receipt of documented pre- and post-procedure information and instructions.
- 3.8.9** *Patient safety measures for sedation are implemented intraoperatively and the patient's haemodynamic status is evaluated and recorded on specified documents*

during sedation and surgery and in the recovery period.

Standard Intent:

The following statement by the ASA must be taken into consideration with every sedation procedure: "Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than that initially intended. Individuals administering moderate sedation and analgesia (conscious sedation) should be able to rescue patients who enter a state of deep sedation and analgesia, while those administering deep sedation and analgesia should be able to rescue patients who enter a state of general anaesthesia. The rescue of a patient from a deeper level of sedation than that intended is an intervention by a practitioner proficient in airway management and ALS. The qualified practitioner corrects adverse physiological consequences of the deeper-than-intended level of sedation, such as hypoventilation, hypoxia and hypotension, and returns the patient to the originally intended level of sedation".

The sedation practitioner and observer monitor and record the haemodynamic status, of the patient during sedation and in recovery on a sedation flow sheet.

Similarly, the sedation practitioner must record the medication and doses administered and the time of administration. Any intravenous fluids administered must be recorded. For patients undergoing sedation, the recording must include the following parameters:

- Level of consciousness or depth of sedation
- Breathing and airway patency
- Observation of the breathing pattern
- Movements of the chest and abdomen
- Maintenance of neck extension
- Heart rate and rhythm
- Blood pressure
- Oxygenation (pulse oximeter) and colour of skin and mucosae
- Pain and degree of comfort
- Anxiety levels and behaviour
- Signs of confusion, restlessness and agitation
- Operator-dependent factors, for example, airway manipulation and dose of administered local anaesthetic medication
- Environmental factors, for example, room temperature

The sedation practitioner and team must have access to information regarding the health status of the patient.

All the criteria related to this standard will be assessed by undertaking an audit of randomly selected records of patients who have undergone sedation for surgical procedures.

Criteria:

- 3.8.9.1 A qualified sedation practitioner and observer, where indicated, monitor the patient during sedation and during recovery from sedation and documents all parameters monitored.**
- 3.8.9.2 The patient's haemodynamic status is continuously monitored and recorded during sedation, surgery and recovery.**
- 3.8.9.3 The sedation medication used is entered on to the patient's sedation flow-sheet.**
- 3.8.9.4 Analgesia administered on conclusion of the surgical procedure and during recovery, is documented in the patient's record.**
- 3.8.10 There is a system to monitor and document each patient's post-sedation status and to safely discharge the patient from the recovery area.*

Standard Intent:

Haemodynamic monitoring provides reliable information about the patient's health status during sedation and in the recovery area. The levels of consciousness are evaluated by the relevant sedation scales and clinical monitoring. These are subjective scales. Objective sedation monitoring is available when indicated using the Bispectral Index (BIS) monitor. In all cases, the monitoring process is continuous, starting before administration of sedation and continuing until discharge. The results are recorded on the sedation flow sheet and entered into the patient's record.

Only a suitably qualified and experienced registered nurse or a designated member of the medical personnel may carry out monitoring in the recovery area.

Patients may only be discharged from the post-sedation recovery area when discharge criteria are met. The patient can be discharged by a nurse or similarly qualified individual in accordance with the post-sedation criteria. The sedation practitioner will however take responsibility for the discharge of the patient. The discharge is documented in the patient's record.

The time of arrival in and discharge from the recovery area must be recorded. Signatures of those who hand over and those who receive the patient are recorded.

Criteria:

3.8.10.1 The sedation practitioner is responsible for supervising the recovery period and for discharging the patient according to established criteria.

3.8.10.2 Monitoring is appropriate to assess the patient's condition during the post-sedation recovery period.

3.8.10.3 Monitoring findings are documented in the patient's record.

3.8.10.4 The sedation practitioner gives permission for the patient to be discharged.

The sedation practitioner either signs the discharge in the patient record or a verbal discharge order is signed in compliance with the practice's verbal discharge policy.

3.8.10.5 Times of arrival in and discharge from the recovery area are recorded.

3.8.10.6 Details of continued care are provided in writing to the person accompanying the patient at discharge.

3.8.10.7 The patient is taken from the procedure room to their transport by wheelchair.

3.9 Patient rights

3.9.1 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 the practice personnel and 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:

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

Patient and family rights are internationally accepted and implemented. Country specific patient rights charters must be referenced in the policy. The practice policy must include at least the right to:

- *A healthy and safe environment*
- *Participation in decision-making*
- *Access to health care*
- *Ethical health care*
- *Choice of health services*
- *Confidentiality and privacy*
- *Culturally sensitive care*
- *Informed consent*
- *Refusal of treatment*
- *A second opinion*
- *Complaints about health services*

3.9.1.2 Documented evidence of personnel training in relation to these policies and procedures is available.

Evidence of such training can exist in various forms such as formal in-service training sessions, meetings where policies and procedures are discussed, personnel acknowledging in writing that they have studied policies and procedures, etc.

3.9.1.3 There is a patient rights charter which is prominently displayed, and patients are made aware of their rights.

Compliance will be measured on observation and by documented evidence that patients are made aware of their rights. This can be achieved by drawing their attention to the poster or by having copies of the charter available.

3.9.2 The practice respects the rights of patients and their families to refuse or discontinue treatment.

Standard Intent:

Patients or those making decisions on their behalf (i.e. in the case of minors or patients who lack mental capacity due to physical or mental illness) may decide not to proceed with the planned care or treatment or not to continue care or treatment after it has been initiated. The practice informs patients and families about their right to make these decisions, about the potential outcomes that could result from these decisions and about their responsibilities related to such decisions. Patients and families are given information on any care and treatment alternatives. Personnel are informed of their responsibility to implement and respect the choices of patients.

Criteria:

3.9.2.1 Patients are informed about their condition and the proposed treatment.

Compliance will be assessed during the patient record audit and/or patient interviews.

3.9.2.2 The practice informs patients and their families about their rights to refuse or discontinue treatment, and the consequences of such decisions.

Compliance will be assessed during the patient record audit and/or patient interviews.

3.9.2.3 When patients/carers refuse or discontinue treatment, the consultation regarding their decision is accurately and contemporaneously recorded and includes the

details of the discussion regarding the consequences of the decision.

Compliance will be assessed during the patient record audit.

3.9.3 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 undergoing clinical examination. 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:

3.9.3.1 The patient's need for privacy is protected during all examinations, procedures and treatments.

This must be evident in all patient care areas.

3.9.3.2 Patient privacy is protected when providing personal information.

This must be evident in all patient care areas including administrative areas and waiting areas. Patient privacy should be safeguarded at all times, including when providing personal information to nonclinical personnel. It is not always necessary to provide privacy by means of physical barriers such as walls and doors. Distance between waiting patients and those speaking with practice personnel can also provide the required privacy when less sensitive information is being exchanged. For example, a line can be drawn on the floor some distance away from the registration desk or pharmacy counter. Patients can be requested to wait behind the line and approach the counter only when providing their details or receiving their medication. Background noise, for example, music or patient education videos, can help to prevent conversations with patients being overheard.

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

This must be evident in all patient care areas.

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

This criterion measures more than just the information contained in the patient record. The confidentiality agreement that is signed by personnel must include the protection of all patient related information including for example, discussing patient details with anyone not involved in the patient's care, comments on social media etc. Compliance will be measured by evidence of a signed confidentiality agreement and by examining the incident management system in the practice to establish if any complaints or incidents have been reported involving a breach of patient confidentiality.

3.9.3.5 When appropriate, patients are permitted to be accompanied by a family

member/care-giver during consultations.

Compliance will be verified during patient interviews and observation.

3.9.4 *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:

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

This can be achieved for example by obtaining general consent for treatment from patients when they register at the practice.

Compliance will be assessed during the patient record audit.

3.9.4.2 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.

Compliance will be assessed during the patient record audit.

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

Evidence of compliance with this criterion may be found in different documents. For example, patients may give consent for information to be shared with health funders as part of their membership registration. Consent is required whenever health information is shared for example with employers, family members or carers, lawyers and insurance companies.

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

Documented evidence will be required.

3.9.5 *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 about patient care and the patient's right to participate in those processes.*

Standard Intent:

Patients have a right to voice complaints about their care and to have those complaints reviewed and where possible resolved. Decisions regarding care sometimes present questions, conflicts or other dilemmas for the practice and the patient, family or other decision-makers. The practice has established

processes for seeking resolution to such dilemmas and 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:

- 3.9.5.1 There is a documented policy outlining the mechanism to allow for the hearing of complaints and how to act upon them which is implemented.**

Documented evidence of implementation of the complaints procedure, for example, complaints log and the documentation relating to the investigation and resolution of complaints, must be made available for assessment.

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

*The complaints process must be prominently displayed in the practice.
Results obtained from patient interviews and observation will determine the level of compliance.*

- 3.9.5.3 A nominated individual within the practice is responsible for managing the complaints and ensuring that the complaints policy is implemented.**

This should be a senior person in the practice and is usually the solo practitioner or the practice manager.

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

*Complainants must be kept informed of the progress of the investigation into the complaint. If there is a legitimate delay, they should be informed of the reason for the delay and provided with regular updates as to the progress of the management of their complaint.
Documented evidence is required.*

- 3.9.5.5 Complaints are monitored, and repetitions or patterns are identified.**

Documented evidence of such monitoring must be available.

- 3.9.5.6 Any opportunities for improvement identified from the investigation of complaints are implemented.**

Documented evidence is required.