Safe Care

BASIC HEALTHCARE STANDARDS

STANDARDS v3

Facility Guide

PharmAccess FOUNDATION

Health Insurance Fund

MEDICAL CREDIT FUND AFRICA

Safe Care BASIC HEALTHCARE STANDARDS

PHARMACCESSGROUP

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Contents:

SE01 - MANAGEMENT AND LEADERSHIP

1.1 - Governance of the health facility

1.1.1 - The governance structure as well as responsibilities and accountability of the governing body are documented and are known to the health facility managers.

Standard intent

Facility leadership comes from many sources. The following governing structures can be identified, aside from the governance on operational facility level (management).

1. Public facilities: governed on two levels, namely on district/county level and on national level (Ministry of Health)
2. Faith based facilities: governed within their network (possibly regional or national)
3. Private facilities: generally governed by a Board (with the exception of facilities owned and run by a single person).

In (almost) all structures mentioned above, there is a governing body responsible for overseeing the healthcare facility's operation and accountable for providing quality health care services to its community or to the population that seeks care. It is important that this entity's structure, responsibilities, and accountabilities are described in a document(s) and that this document is known to the staff. This can be done in an organizational chart or other document that shows lines of authority and accountability. The individuals represented on the chart are identified by title or name.

1.1.1.1 - The governance structure is documented (organogram/chart).

1.1.1.2 - The relationship between the facility leaders and the first level of governance above is documented.

1.1.1.3 - The governance structure provides for support to health facility staff.

1.1.1.4 - Regional or district managers (if applicable) perform regular supervisory visits

SE01 - MANAGEMENT AND LEADERSHIP

1.1 - Governance of the health facility

1.1.2 - The operational responsibilities of the governing entity are carried out in accordance with organizational policy.

Standard intent

The governing entity has important responsibilities that must be carried out for the healthcare facility to have clear leadership, to operate efficiently, and to provide high-quality health care services. The governing entity's responsibilities are documented and clearly describe how they are to be carried out. These responsibilities are primarily at the approval level and include:

• approving the healthcare facility's various strategic and operational plans and the policies and procedures needed to operate the healthcare facility on a daily basis;

• approving and periodically reviewing the hospital's mission and ensuring that the public is aware of the healthcare facility's mission;

• approving or providing operating budget(s) and other resources required to operate the healthcare facility and to meet the healthcare facility's mission and strategic plan;

• appointing or approving the facility manager or leadership team, and providing for an annual evaluation of the individual's performance using organizational policy or process.

1.1.2.1 - Those responsible for governance approve the health care facility's strategic plans, operational plans and policies.

1.1.2.2 - Those responsible for governance approve or provide the healthcare facility's operating budget(s) required to meet the healthcare facility's mission.

1.1.2.3 - Those responsible for governance appoint and periodically evaluate the facility manager.

1.1.2.4 - Those responsible for governance approve, (periodically) review and make public the healthcare facility's mission statement.

SE01 - MANAGEMENT AND LEADERSHIP

1.1 - Governance of the health facility

1.1.3 - The healthcare facility operates under a valid license.

Standard intent

It is important that a healthcare facility complies with national laws and regulation regarding the provision of healthcare services and operates legally.

Licensing requirements for private, faith-based and public healthcare facilities are country specific and are assessed in the applicable context. In East-African countries the term 'gazettement' is used to define that a facility is considered to be compliant to national law and regulation.

Apart from valid licenses for both the facility as a whole as well as any specialized services for which a separate license is required, it is required that healthcare facilities have a system in place to ensure timely renewal of these licenses for continuous compliance to the standard.

1.1.3.1 - The facility has a current license, issued by an acknowledged healthcare licensing authority, to operate as a healthcare facility.

1.1.3.2 - The facility has valid licenses for specific services (e.g. pharmacy, diagnostic imaging, laboratory, dental) issued by an acknowledged authority, according to local legislation.

1.1.3.3 - There is a process that ensures that licenses are renewed within the required timeframe.

1.1.3.4 - There is a dedicated file that has all the license related documentation.

SE01 - MANAGEMENT AND LEADERSHIP

1.2 - Management of the health facility

1.2.1 - A healthcare facility manager or a leadership team is responsible for operating the health facility and complying with applicable laws and regulations.

Standard intent

It is important that a competent facility leader(s) is appointed or recognized by the governing body of the facility to operate the facility.

The facility leader(s) works (if applicable collectively and collaboratively) to develop the programs, policies, and services needed to provide safe health care services and fulfill the facility's mission.

When the mission and policy framework are set by owners or agencies outside the facility, the facility leader(s) work collaboratively to carry out the mission and policies and ensure compliance with laws and regulations.

1.2.1.1 - A facility leader(s) is appointed and is responsible for operating the facility and carrying out the healthcare facility's mission.

1.2.1.2 - The facility leader(s) has the education and experience to carry out his/her responsibilities.

1.2.1.3 - The facility leader(s) is responsible for creating and carrying out of the policies and procedures to support the activities of the healthcare facility and guide staff, patients and visitors.

1.2.1.4 - The facility leader(s) ensures compliance with policies, applicable laws and regulations.

SE01 - MANAGEMENT AND LEADERSHIP

1.2 - Management of the health facility

1.2.2 - The healthcare facility leader(s) identifies and plans for the type of services required to meet the needs of the patients served by the facility.

Standard intent

Patient care services are planned and designed to respond to the needs of the patient population. The care and services (as well as scope and intensity) to be provided are documented and are consistent with the healthcare facility's mission and comply with national rules and regulations. Planning patient care services also involves healthcare facility leaders defining its communities and patient populations, identifying community needs for services, and planning ongoing communication with those key community stakeholder groups. The communications may be directly to individuals or through public media and through agencies within the community or third parties. The facility leader(s) are aware of and utilize the capacity of relevant health care providers in the area for effective referral of patients and continuity of care.

1.2.2.1 - The facility leader(s) defines the care and services to be provided compliant with national rules and regulations and documents this in a service charter.

1.2.2.2 - A regular needs assessment is performed to ensure that the services provided are consistent with the needs of the population served.

1.2.2.3 - The facility leader(s) communicates information about its patient care services with key stakeholders in the community.

1.2.2.4 - The facility leader(s) is aware of services that are provided by other provider facilities operating in the area and has a current referral list available.

SE01 - MANAGEMENT AND LEADERSHIP

1.2 - Management of the health facility

1.2.3 - The facility leader(s) ensures that supplies and provisions are ordered, received, safely stored and provided to departments in time to meet their needs.

Standard intent

Supply chain management is an important to ensure that necessary supplies are available on time, but also to prevent drugs, medical technology, and supplies that are contaminated, fake, or from diverted sources reach the facility's patients. Although there is no single global standard for supply chains, or even national standards in many countries, it is the responsibility of facility leadership to ensure that a system is implemented to protect the integrity of their most important supplies and assets used.

1.2.3.1 - A qualified or experienced individual is designated for supply chain management.

1.2.3.2 - There is a system for ensuring that equipment and supplies are ordered, available, monitored for quality, correctly stored and distributed/dispensed.

1.2.3.3 - Secure adequate storage facilities are available.

1.2.3.4 - There is a system regarding the 'first expired first out' principle for stock.

SE01 - MANAGEMENT AND LEADERSHIP

1.2 - Management of the health facility

1.2.4 - The facility leader(s) plans, develops and implements a quality improvement and patient safety program.

Standard intent

If a healthcare facility is to successfully initiate and maintain quality improvement and reduce risks to patients and staff, leadership and planning are essential.

Healthcare facility leaders are responsible for establishing and providing ongoing support for an organizational commitment to quality. They develop the quality and patient safety program and determine how the program will be directed and managed on a daily basis, such as by establishing a quality team, and ensures that the program has adequate resources to be effective.

Healthcare facility leaders also implement a structure and process for the overall monitoring and coordination of the program throughout the healthcare facility.

Regular communication of information about the quality improvement and patient safety program to staff (as well as feedback to the governing entity) is essential. This flow of quality communications is through effective channels, e.g. newsletters, staff meetings, and human resources processes.

1.2.4.1 - A quality (improvement) team is in place.

1.2.4.2 - Facility management mandates the QIT and provides sufficient resources.

1.2.4.3 - Corrective and preventive actions (CAPA) are defined and implemented.

1.2.4.4 - The leadership team communicates quality improvement and patient safety information to all stakeholders concerned on a regular basis.

SE01 - MANAGEMENT AND LEADERSHIP

1.2 - Management of the health facility

1.2.5 - Books of accounts, utilization data and budgets are kept and used as a source of management information.

Standard intent

Effective management requires timely insight in actual financial performance (books of accounts), clinical performance (utilization data) vis-à-vis annual budgets. The performance overviews are an important source of information for management to improve the facility's financial and clinical performance. By benchmarking the data to external data sources (e.g. from the MoH), to targets or to previous years, management is able to decide upon measures to improve performance, where and when needed.

1.2.5.1 - Books of accounts are kept in a manner that is appropriate for the size and complexity of the healthcare facility and external financial reporting meets national bookkeeping standards.

1.2.5.2 - There is a system for gathering utilization data of all departments.

1.2.5.3 - There is an annual budgetting cycle, whereby budgets have an adequate level of detail, based on prudent assumptions regarding projected income and expenditures.

1.2.5.4 - Books of accounts, budgets and utilization data are systematically and integrally reported and analyzed and used as a management information tool.

SE01 - MANAGEMENT AND LEADERSHIP

1.2 - Management of the health facility

1.2.6 - The health facility manages its money in an effective manner.

Standard intent

Cash is the lifeblood of any business. A lack of internal 'rules and regulations' about how to handle and manage cash and claims/invoices, inevitably leads to leakage and pilferidge. Therefore it important to have proper cash management and banking practices in place, to maintain an effective system for claims submission/invoicing, to actively monitor claims/invoice payments and to actively monitor cash flows

1.2.6.1 - The health care facility has laid down adequate cash management practices in Standard Operating Procedures.

1.2.6.2 - The health facility deploys adequate banking practices.

1.2.6.3 - There is an effective system for claims submission/invoicing to insurance companies/corporate clients and the monitoring of claims/invoices to ensure that the level of debtors is kept to a minimum.

1.2.6.4 - The health facility actively monitors its cash flows.

SE01 - MANAGEMENT AND LEADERSHIP

1.2 - Management of the health facility

1.2.7 - There is evidence that the healthcare facility keeps track of fixed assets and related maintenance activities.

Standard intent

Fixed assets can be defined as assets which are generally used longer than one year. Assets which last less than one year are generally referred to as current assets. These are seen as part of an inventory. A fixed asset register (FAR) is a way of recording and tracking all the fixed assets that an organization owns. This helps to identify loss of assets through theft or carelessness, provides a place where deprecation can be calculated and details of insurance can be recorded and can serve as a maintenance planning list.

In health care facilities the FAR mainly consists of office furniture and (medical) equipment which are held for the purpose of rendering services. The facility needs to define in writing how often the fixed assets are crosschecked with the FAR register for accountability purposes and how frequent the FAR register is being updated (e.g. is this event based or are there set periods for updates). A fixed asset register must be kept in order to be in compliance with in-country legislation and where applicable, requirements of governing bodies. As a rule of thumb, the format/details to be provided in a FAR generally depend upon the following factors:

- Basic asset list containing things like, general name, supplier, manufacturer, model/type, procurement date, procurement cost, location.
- Define if the fixed assets in a maintenance program, specify cost.
- Extent of owned, and assets taken on lease / hire purchase & insurance details where applicable
- Identification number/tagging of fixed assets
- Status of asset (working, in repair, replaced, disposed, etc.).

1.2.7.1 - There is a Fixed Asset Register (FAR) which contains the relevant information for all fixed assets in the facility.

1.2.7.2 - There is a designated staff member who is responsible for the FAR.

1.2.7.3 - There is a maintenance program in place that ensures that fixed assets are kept in good quality.

1.2.7.4 - There is a guideline describing the frequency of crosschecks of fixed assets and the FAR, including how and when to update the FAR.

SE01 - MANAGEMENT AND LEADERSHIP

1.2 - Management of the health facility

1.2.8 - The facility regularly monitors (audits) key processes and health care services provided in order to continuously improve medical, financial and managerial performance.

Standard intent

In order to enable appropriate management of activities and sustained quality of services, it is important to monitor adherence to particular processes and guidelines applicable within the healthcare facility. The healthcare facility leadership should therefore identify which core processes should be monitored, how often this should be done, by whom and how to follow-up on findings in order to improve performance. Performing these monitoring cycles by using auditing templates will facilitate a standardized approach for setting and monitoring KPIs (Key Performance Indicators).

1.2.8.1 - The facility leader(s) has defined which processes and services require auditing.

1.2.8.2 - There are auditing templates available to guide staff in the different auditing processes.

1.2.8.3 - Regular audits of specified guidelines and processes take place.

1.2.8.4 - The audit outcomes are recorded, discussed and corrective actions defined to improve performance.

SE02 - HUMAN RESOURCE MANAGEMENT

2.1 - Personnel planning

2.1.1 - There is a plan for the recruitment of healthcare staff.

Standard intent

Appropriate and adequate staff are critical in order to provide sound patient care. The health facility's leaders define the desired education, skills, knowledge and any other requirements to meet the needs of patients.

To project staffing needs, healthcare facility leaders use factors such as the following:

- The services provided by the facility
- The volume of inpatients and outpatients/bed occupancy
- Catchment area population

Staffing levels for professional staff should be based on laws and regulations and/or accepted national norms/standards.

2.1.1.1 - There is a staffing establishment list based on accepted national or international norms.

2.1.1.2 - There is a document that defines the recruitment process.

2.1.1.3 - Utilization data is used to project staffing requirements.

2.1.1.4 - Staff absenteeism, sickness rates and turnover rates are recorded and analyzed.

SE02 - HUMAN RESOURCE MANAGEMENT

2.1 - Personnel planning

2.1.2 - There is a (performance) review process for all staff in the facility.

Standard intent

The performance of healthcare staff has to be reviewed regularly. This process ensures that the staff member's skills and preformance remain consistent .

Ongoing evaluation ensures that training occurs when needed and that the staff member is able to assume new or changed responsibilities. While such evaluation is best carried out in an ongoing manner, there is a least one documented evaluation each year for each staff member.

2.1.2.1 - Certificates and/or licences (depending on the country regulations) are in place for nursing/midwifery staff.

2.1.2.2 - New staff members are evaluated at least once a year.

2.1.2.3 - The department or service to which the individual is assigned conducts the evaluation.

2.1.2.4 - The evaluation for each staff member is recorded.

SE02 - HUMAN RESOURCE MANAGEMENT

2.2 - Personnel files and credentials

2.2.1 - Each staff member's responsibilities are defined in a current job description.

Standard intent

Individual staff members have their responsibilities defined in a job description that is kept up to date.

The job description/performance agreement provides details of accountability, responsibility, formal lines of communication, principal duties and entitlements. It is a guide for an individual in a specific position within an organization.

The job descriptions are the basis for their assignments, orientation to their work, and evaluation of how well they fulfill job responsibilities.

This standards applies to all types of “staff” (for example, full-time, part-time, employed, voluntary, or temporary).

2.2.1.1 - Each staff member has a written job description which defines their responsibilities.

2.2.1.2 - Each staff member signs their job description/performance agreement to show that that they accept it.

2.2.1.3 - Job descriptions are kept in individual staff files.

2.2.1.4 - Job descriptions/performance agreements are kept current and reviewed according to organizational policy.

SE02 - HUMAN RESOURCE MANAGEMENT

2.2 - Personnel files and credentials

2.2.2 - Personnel files are maintained for all staff.

Standard intent

Personnel records should be kept for all employees and should minimally contain the following information: name, address and other applicable contact information (including telephone number) as well as a copy of national identification document. The record also contains information about his/her qualifications, licenses if applicable, results of evaluations, and work history.

These records are kept up to date according to the healthcare facility policy. Because of the private nature of the files it is important to limit access to the files to authorized personnel only.

2.2.2.1 - The required information is documented for each staff member.

2.2.2.2 - A designated staff member is responsible for the storage and retrieval of personnel records.

2.2.2.3 - Only authorized staff has access to the personnel files.

2.2.2.4 - Personnel files are kept current and reviewed annually.

SE02 - HUMAN RESOURCE MANAGEMENT

2.2 - Personnel files and credentials

2.2.3 - There is an effective process for gathering, verifying and evaluating the credentials (registration, education, training and experience) of healthcare professionals working in thehelathcare facility.

Standard intent

Healthcare professionals who are registered to provide patient care without clinical supervision are primarily responsible for patient care and care outcomes. These professionals usually include doctors, dentists, professional nurses, radiographers, and members of other professions allied to medicine. The healthcare facility needs to ensure that it has qualified health professionals who appropriately match its mission, resources and patient needs.

An individual's credentials consist of an appropriate current registration, completion of professional education, and any additional training and experience. There is a process for gathering this information, verifying its accuracy where possible, and evaluating it in relation to the needs of the health facility and its patients. This process can be carried out by the health facility or by an external agency such as a ministry of health in the case of public health facilities. The process applies to all types and levels of employed persons (employed, honorary, contract and private practitioners) who render patient care in the healthcare facility.

Evaluating an individual's credentials is the basis for two decisions: whether this individual can contribute to fulfilling the healthcare facility's mission and meeting patient needs, and, if so, what clinical services this individual is qualified to perform.

2.2.3.1 - There is a process for evaluating and verifying the credentials (license, education, training and experience) of nurses and other health professionals (non physicians) working in the healthcare facility.

2.2.3.2 - The registration, education, training and experience of nurses and other health professionals (non physicians) is documented.

2.2.3.3 - There is a process for evaluating and verifying the credentials (license, education, training and experience) of physicians.

2.2.3.4 - The registration, education, training and experience of physicians are documented.

SE02 - HUMAN RESOURCE MANAGEMENT

2.3 - Staff orientation and education

2.3.1 - All staff members are orientated and inducted to the health facility and to their specific job responsibilities at the time of appointment.

Standard intent

The decision to appoint an individual to the staff of a health facility sets several processes in motion. To perform well, a new staff member needs to understand the workings of the entire health facility and how his/her specific responsibilities contribute to the health facility's mission. This is accomplished through a general orientation to the health facility and his/her role in the facility, and a specific orientation to the job responsibilities of his/her position. It is important to orientate and induct all doctors. Contract workers and volunteers are also orientated to the health facility and their specific assignment or responsibilities, such as patient safety and infection control.

Contract workers, volunteers, and students and trainees are also oriented to the healthcare facility and their specific assignments or responsibilities, such as patient safety and infection prevention and control.

2.3.1.1 - New clinical staff members are oriented to the health facility and to their job responsibilities and any specific assignments.

2.3.1.2 - New non-clinical staff members are oriented to the health facility and to their job responsibilities and any specific assignments.

2.3.1.3 - Contract workers, students and volunteers are orientated to the health facility, their job responsibilities and their specific assignments.

2.3.1.4 - There are written programs for orientating and inducting staff to the health facility.

SE02 - HUMAN RESOURCE MANAGEMENT

2.3 - Staff orientation and education

2.3.2 - Each staff member receives on-going in-service education and training to maintain or advance his/her skills and knowledge, based on identified needs.

Standard intent

The health facility has a responsibility to ensure that the staff are educated in matters that affect their functioning in the specific health facility. In particular, the staff are trained in for example health and safety matters, infection control and cardiac life support. The health facility also collects and integrates information from several sources, such as staff evaluation, to understand the ongoing educational needs of the staff.

Education is relevant to each staff member as well as to the continuing advancement of the health facility in meeting patient needs and maintaining acceptable performance, teaching new skills, and providing training on new equipment and procedures.

2.3.2.1 - All staff are provided with on-going in-service education/training.

2.3.2.2 - There is a schedule for in-service education.

2.3.2.3 - The healthcare facility uses various sources of data and information to identify the in-service training/education needs of the staff.

2.3.2.4 - Health care facility management actively facilitates and supports Continuous Medical Education (CME) activities for all staff.

SE03 - PATIENT AND FAMILY RIGHTS & ACCESS TO CARE

3.1 - Patient and Family rights

3.1.1 - The health facility leader(s) implements a patient's rights policy.

Standard intent

A visit or admission to a health facility can be a frightening and confusing experience for patients, making it difficult for them to understand and act on their rights. Thus, the health facility prepares a written statement of patient and family rights, and this is shown to patients when they enter the health facility for care, and is available throughout their stay. For example, the statement may be displayed as a poster in the facility. The statement is appropriate to the patient's age, understanding and language.

Although patient and family rights charters differ between countries, there is consensus that patients are entitled to these basic rights. For example:

- Privacy
- Confidentiality of health information
- To consent to receive treatment or refuse treatment
- To be informed about the risk of certain medical procedures
- Participation in the care process
- To voice complaints

Facility staff need to know and understand patient and family rights and their health facility's responsibilities as specified in laws, charters and regulations. The leaders then provide direction to ensure that the staff throughout the health facility assume responsibility for protecting these rights.

3.1.1.1 - The patient and family rights charter is clearly displayed in the facility and in line with national and international laws and regulations

3.1.1.2 - There is a police that defines the patient rights and related responsibilities of staff.

3.1.1.3 - Staff is aware of patient's rights and related staff responsibilities.

3.1.1.4 - The patients are aware of their rights.

SE03 - PATIENT AND FAMILY RIGHTS & ACCESS TO CARE

3.1 - Patient and Family rights

3.1.2 - The healthcare facility takes measures to protect patient privacy and confidentiality of health information.

Standard intent

Patient privacy is important, particularly during clinical interviews, examinations, procedures/treatments, and transport.

Patients may desire privacy from other staff, other patients, and even from family members. Thus, as staff members provide care and services to patients, they inquire about the patient's privacy needs and expectations related to the care or service and respect the patient's privacy in all applicable situations.

For instance, healthcare facility staff respect the privacy and confidentiality of patient information by not posting information on the patient's door or at the nursing station and by not holding patient-related discussions in public places.

The healthcare facility checks patient satisfaction on this periodically.

3.1.2.1 - The patient's privacy is protected during registration, clinical interviews, examinations, counselling procedures and treatments.

3.1.2.2 - Policies and procedures to safeguard privacy ensure health information confidentiality.

3.1.2.3 - There is evidence of implementation of policies and procedures for patient privacy and confidentiality.

3.1.2.4 - Patient satisfaction is periodically measured by the healthcare facility.

SE03 - PATIENT AND FAMILY RIGHTS & ACCESS TO CARE

3.1 - Patient and Family rights

3.1.3 - The health facility provides (health) education to patients and families.

Standard intent

The healthcare facility supports and promotes patient and family involvement in all aspects of care (e.g., making decisions about care, asking questions about care, requesting a second opinion, and even refusing diagnostic procedures and treatments). Every patient is offered the information and education he or she requires. For this, the healthcare facility plans health education tailored to the needs of the patient population. Staff is trained on their role in supporting patient and family rights and enhancing participation of patients and family members in their care process.

3.1.3.1 - The healthcare facility plans patient and family health education in a coordinated way.

3.1.3.2 - Staff is assigned to provide health education to patients and families and activities are recorded..

3.1.3.3 - The patient and his/her family are educated in a manner and language they can understand.

3.1.3.4 - The health center identifies and establishes relationships with community resources, which support continuing health promotion and disease prevention education.

SE03 - PATIENT AND FAMILY RIGHTS & ACCESS TO CARE

3.1 - Patient and Family rights

3.1.4 - The health facility informs patients about all aspects of their medical care and treatment as well as their rights and responsibilities to refuse or discontinue treatment.

Standard intent

For patients and families to participate in care decisions, they need basic information about the medical conditions found during assessment, including any confirmed diagnosis, and on the proposed care and treatment. During the care process patients have a right to be told of the risk of unanticipated outcomes of their care and treatment.

Patients, or those making decisions on their behalf, may decide not to proceed with the planned care or treatment or to continue care or treatment after it has been initiated. The health facility 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. The staff are informed of their responsibility to implement and respect the choices of patients.

3.1.4.1 - Patients are informed about their medical condition, any confirmed diagnosis and the planned care and treatment and the risk of certain medical procedures.

3.1.4.2 - Patients and families are informed about their right to participate in care decisions to the extent they wish, including the right to refuse or discontinue treatment.

3.1.4.3 - Patients are informed about the consequences of the decision to refuse or discontinue treatment.

3.1.4.4 - Staff is informed of their responsibility to implement and respect the choices of patients.

SE03 - PATIENT AND FAMILY RIGHTS & ACCESS TO CARE

3.1 - Patient and Family rights

3.1.5 - The healthcare facility has a clearly defined process for obtaining informed consent in a manner and language that a patient can understand.

Standard intent

One of the main ways that patients are involved in their care decisions is by granting informed consent. To consent, a patient must be provided with all information relating to the planned care to enable him or her to make an informed decision. Informed consent may be obtained at several points in the care process, for instance when the patient is admitted for inpatient care and before certain high risk procedures. The consent process is clearly defined by the healthcare facility in 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 dictate 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 the consent, that individual is recorded in the patient's record. In all cases, the patient file should contain evidence of the informed consent given.

3.1.5.1 - There is a guideline describing the process of gaining and recording informed consent from the patient, including for which procedures this is required.

3.1.5.2 - Policies include specific guidance on gaining and recording informed consent when the patient is unable to give consent for any reason.

3.1.5.3 - Patients learn about the process for granting informed consent in a language and manner they understand.

3.1.5.4 - Evidence of informed consent forms are present in the patient's record, where relevant.

SE03 - PATIENT AND FAMILY RIGHTS & ACCESS TO CARE

3.1 - Patient and Family rights

3.1.6 - The healthcare facility has a process to receive and to act on complaints, conflicts and difference of opinion.

Standard intent

Patients have a right to voice complaints about their care, and to have those complaints reviewed and, where possible, resolved. Also, decisions regarding care sometimes present questions, conflicts or other dilemmas for the healthcare facility and the patient, family or other decision-makers. These dilemmas may arise around issues of access, treatment or discharge. The health facility has established processes for seeking resolutions to such dilemmas and complaints and informs patients about this. The process also identifies who need to be involved in the process and how the patient and family participate.

3.1.6.1 - There is a process to allow complaints to be heard.

3.1.6.2 - Patients are informed about the process for voicing complaints, conflicts and differences of opinion.

3.1.6.3 - Complaints, conflicts and differences of opinion are investigated and resolved.

3.1.6.4 - Patients and families are able to be involved in the resolution process.

SE03 - PATIENT AND FAMILY RIGHTS & ACCESS TO CARE

3.2 - Access to care

3.2.1 - Patients have access to the health facility based on their identified healthcare needs and the health facility's mission and resources.

Standard intent

Healthcare facilities frequently serve communities with a diverse population. The patient population may be aged, have disabilities, speak multiple languages or dialects, be culturally diverse, or present other barriers that make the process of entering the healthcare facility and receiving care very difficult. The healthcare facility can serve the needs of the community by providing consistent opening hours, facilitating transportation services, and becoming familiar with potential barriers to accessing care, so that processes can be implemented to eliminate or reduce these barriers to ensure all patients have access to the facility and to treatment and care.

3.2.1.1 - Healthcare facility's opening hours are displayed and compliant with country regulations.

3.2.1.2 - Barriers to special patient populations served are identified and reduced.

3.2.1.3 - The health facility has access to adequate patient transport services during all opening hours.

3.2.1.4 - An appointment system is available for specialized services and adequately communicated to patients.

SE03 - PATIENT AND FAMILY RIGHTS & ACCESS TO CARE

3.2 - Access to care

3.2.2 - Adequate infrastructural arrangements are in place to ensure that patients have access to the facility.

Standard intent

Adequate infrastructural arrangements, including entry and signage, ensure that patients can access the healthcare facility's services when needed. The facility should be safely accessible for all patients. Ramps and stairs, if available, should be safe for all users.

3.2.2.1 - There is a clearly readable sign on site, indicating the name and the designation of the facility, matching the services provided.

3.2.2.2 - The road to the healthcare facility allows for unrestricted access.

3.2.2.3 - Direction signs to the facility are clearly readable and up to date.

3.2.2.4 - Safe access to the building is provided for all patients.

SE03 - PATIENT AND FAMILY RIGHTS & ACCESS TO CARE

3.2 - Access to care

3.2.3 - Patients are given adequate information about the services provided by the healthcare facility and how to access those services.

Standard intent

To ensure access to its services, the health facility provides information to the community on its services and hours of operation and how to obtain care. Information on access to care is provided to patients both on site as well as through agencies and referral sources in the community.

3.2.3.1 - Patients are given information about the range of services and related fees.

3.2.3.2 - Information is provided in a way and in a language that is understood by the population served.

3.2.3.3 - The healthcare facility has a publicly available telephone/emergency number for patients to call the facility for all purposes, including emergencies.

3.2.3.4 - Clear directions to the various clinical service areas are in place through signage throughout the facility.

SE04 - MANAGEMENT OF INFORMATION

4.1 - Information planning and usage

4.1.1 - The health facility meets the data and information needs of those in and outside the healthcare facility.

Standard intent

Information is generated and used during patient care and for safely and effectively managing the healthcare facility. The ability to capture and provide information requires effective planning. In planning information management strategies, a healthcare facility should take into account a variety of sources:

- The healthcare practitioners;
- The healthcare facility's managers and leaders; and
- Those outside the healthcare facility who need or require data or information about the facility's operational and care processes.

The most urgent information needs of those sources influence the facility's information management strategies and its ability to implement those strategies. The strategies are appropriate for the facility's size, complexity of services, availability of trained staff and other human and technical resources. The plan should be comprehensive and include all the departments and services of the organization.

4.1.1.1 - The health facility has a Health Information System (HIS) that shows the data collected about provision of health services.

4.1.1.2 - The planning and design is based on the facility's size and complexity and includes all information needs, both from internal (clinical and managerial) and external sources (i.e. national registries).

4.1.1.3 - The system identifies staff permitted access to each category of data and information.

4.1.1.4 - Data for external reference databases are collected and distributed timely and in a correct format when required by laws or regulations.

SE04 - MANAGEMENT OF INFORMATION

4.1 - Information planning and usage

4.1.2 - Data are used to provide relevant information for improving managerial and clinical practice.

Standard intent

It is important that staff have access to the relevant data so as to incorporate the information in the execution of their job. Periodic sharing of findings and reviewing significant adverse incidents, institutional mortalities and morbidities are vital to understand the cause and prevent recurrence. To reach conclusions and make decisions, data must be aggregated, analyzed and transformed into useful information. Thus, data analysis provides continuous feedback of quality management information to help decision makers and continuously improve clinical and managerial processes.

The health facility determines how often data are aggregated and analyzed. The frequency depends on the activity or area being measured, the frequency of measurement, and the health facility's priorities.

4.1.2.1 - There are regular scheduled meetings, to identify the most frequently diagnosed diseases and morbidities.

4.1.2.2 - Staff have access to the data and information needed to carry out their job responsibilities.

4.1.2.3 - Data is aggregated, analyzed and used to provide relevant information for improving the managerial and clinical service.

4.1.2.4 - The frequency of data analysis meets the requirements for the health facility and its staff.

SE04 - MANAGEMENT OF INFORMATION

4.2 - Patient health records

4.2.1 - The healthcare facility maintains a standardized clinical record for each patient assessed and/or treated and determines the record's content, format and location of entries.

Standard intent

Every patient assessed and/or treated in a healthcare facility as an inpatient, outpatient, or emergency care patient has to have a clinical record, whether it is a file held at the clinic or a carry card. The record is assigned an identifier unique to the patient, or some other mechanism is used to link the patient with his or her clinical record. A single record and a single identifier enable the facility to easily locate patient clinical records and to document the care of patients over time. The content, format, and location of entries for a patient's clinical record is standardized to help promote the integration and continuity of care among the various practitioners of care to the patient.

4.2.1.1 - Each patient has a health record which has a unique identifier number.

4.2.1.2 - The specific content of entries (assessment and treatment notes) for health records is determined by the healthcare facility.

4.2.1.3 - Patient records are kept in a standardized format.

4.2.1.4 - There is a system that allows rapid retrieval and smooth distribution of health records so they are readily available on each patient visit.

SE04 - MANAGEMENT OF INFORMATION

4.2 - Patient health records

4.2.2 - Patient records contain the required information to support the diagnosis, justify the treatment, and to document the course and results of treatment.

Standard intent

The patient record needs to present sufficient information to identify the patient, support the diagnosis, to justify the treatment provided, to document the course and results of the treatment, and to facilitate the continuity of care among health care practitioners.

4.2.2.1 - Patient records contain patient identification information.

4.2.2.2 - Patient records contain adequate information about physical findings, assessment and diagnosis.

4.2.2.3 - Patient records contain adequate and up to date information about care and treatment.

4.2.2.4 - Patient records contain adequate information to document the course and results of treatment including errors/adverse events.

SE04 - MANAGEMENT OF INFORMATION

4.2 - Patient health records

4.2.3 - The healthcare facility has a record keeping system that ensures the reliability of information.

Standard intent

Access to information contained in the patient clinical record is based on need and defined by job title and function. An effective process defines

- who has access to patient clinical records;
- which information in the patient clinical record to which an individual has access;
- the user's obligation to keep information confidential; and
- The process followed when confidentiality and security are violated.

One aspect of maintaining the security of patient information is to determine who is authorized to obtain a patient clinical record and to make entries into the patient clinical record. The hospital develops a policy to authorize such individuals. There is a process to ensure that only authorized individuals make entries in patient clinical records and that each entry identifies the author of the entry and the date.

4.2.3.1 - The staff who enters clinical information to a patient health record signs and dates the entry.

4.2.3.2 - The patient entry records are clearly readable.

4.2.3.3 - There is a process to ensure that only authorized individuals make entries in patient clinical records.

4.2.3.4 - Patient records are reviewed regularly and results analyzed as part of the quality improvement process.

SE04 - MANAGEMENT OF INFORMATION

4.2 - Patient health records

4.2.4 - There is a 'medical records' storage system that ensures confidentiality and safety.

Standard intent

Medical record storage is sufficient and secure against unauthorized entry and ensure confidentiality. Health record management must be implemented by a suitable person, who controls the safe storage and retrieval of files. Files must be readily available each time the patient visits a healthcare professional. The healthcare facility develops and implements a policy that guides the retention of patient records and other data and information for sufficient periods to comply with law and regulation (e.g. on confidentiality) and support patient care, the management of the organization, legal documentation, research and education. When the retention period is complete, patient records and other data and information are destroyed appropriately.

4.2.4.1 - Storage space for medical records is of sufficient size and secured against unauthorized entry to ensure confidentiality.

4.2.4.2 - A designated individual is responsible for the storage, maintenance and retrieval of health records.

4.2.4.3 - There is provision that ensures authorized access to patient records at all times.

4.2.4.4 - Guidelines related to health records storage retention and destruction are available.

SE05 - RISK MANAGEMENT

5.1 - Program Planning

5.1.1 - Facility managers and leaders develop, implement and maintain an effective risk management program in the organization.

Standard intent

In order to prevent accidents and injuries to patients, staff, and visitors within a healthcare facility, managers and leaders must be aware of potential risks and work to reduce them. As variation and risk are always present in healthcare facilities, they must be identified and managed by everyone. Facility managers are responsible for developing and maintaining a risk management program that includes the following elements:

- one or more qualified and/or skilled and/or experienced individuals supervise the implementation of the risk management program,
- identifying all risks (physical, environmental, medical, legal, operational, etc.) relating to organizational processes and systems, staff, patients, visitors and physical facilities,
- Maintaining an accurate current risk register, which is reviewed when there are changes in systems, processes, or physical facilities.
- the development and implementation of risk management processes and activities,
- a system for monitoring negative incidents/near misses/ adverse (sentinel) events and it includes the documentation of interventions and responses to recorded incidents, and organization,
- on-going in-service training of all staff in risk program, including reporting of adverse events, is documented.

5.1.1.1 - A qualified/experienced individual/team is responsible for risk management.

5.1.1.2 - All risks, both clinical and non-clinical, are identified and recorded in a risk register.

5.1.1.3 - Based on the identified risks corrective and/or preventive actions (CAPA) are defined and implemented.

5.1.1.4 - All staff receive on-going in-service about risk management.

SE05 - RISK MANAGEMENT

5.1 - Program Planning

5.1.2 - The healthcare facility develops and implements a plan(s) to respond to likely emergencies.

Standard intent

Every organization needs to be aware of the likely internal or external events for which a rapid and organized response is necessary to protect patients, staff and others. Thus, if seasonal flooding is a possibility, or interruption of water or electricity, or brush fires are likely, the healthcare facility develops, implements and tests the response plan.

Besides the plan for emergencies like, floods, fires etcetera there should be also an emergency plan for outbreaks of e.g. infectious diseases (e.g. Ebola).Because such events are rare, the response plan is written and all staff are trained on and rehearse the plan to be prepared when an event suddenly occurs.

5.1.2.1 - There are documents that describe the organizations response to emergencies (including bomb threats, fire, flooding, natural disasters, failure of water and electrical supplies).

5.1.2.2 - There is document that describes the healthcare facility's response to a contagious disease outbreak (e.g. Ebola).

5.1.2.3 - Staff participates in a rehearsal of the emergency plan(s).

5.1.2.4 - There is documentation that the emergency plan(s) is reviewed.

SE05 - RISK MANAGEMENT

5.1 - Program Planning

5.1.3 - The healthcare facility provides a occupational health and safety (OHS) program.

Standard intent

A healthcare facility staff health and safety program is important to maintain staff physical and mental health, satisfaction, productivity, and safe conditions for work. Because of their contact with patients and patients' infective material, many health care workers are at risk for exposure to and possible transmission of vaccine-preventable diseases. Identifying epidemiologically important infections, determining staff at high risk for these infections, and implementing screening and prevention programs (such as immunizations, vaccinations, and prophylaxis) can significantly reduce the incidence of infectious disease transmission.

How a healthcare facility orients and trains staff, provides a safe workplace, maintains equipment and medical technology, and many other factors determine the health and well-being of staff. A staff health and safety program can be located within the healthcare facility or be integrated into external programs. Whatever the staffing and structure of the program, staff understand how to report, to be treated for, and to receive counseling and follow-up for injuries such as those that may result from needle-sticks, exposure to infectious diseases, or workplace violence; the identification of risks and hazardous conditions in the facility; and other health and safety matters. The program may also provide for initial employment health screening, periodic preventive immunizations and examinations, and treatment for common work-related conditions, such as back injuries, or more urgent injuries.

5.1.3.1 - Staff have access to an occupational health and safety (OHS) program that meets applicable legislation and/or regulation.

5.1.3.2 - A dedicated staff member monitors the staff occupational health and safety (OHS) program.

5.1.3.3 - The facility has written procedures that guide the staff for occupational health and safety activities defined in the OHS program

5.1.3.4 - Facility staff receive continuous occupational health and safety (OHS) training and this is documented.

SE05 - RISK MANAGEMENT

5.2 - Safe and Secure Environment

5.2.1 - Security of staff, volunteers, patients, and visitors is ensured.

Standard intent

Patients and staff rely on the healthcare facility to provide a safe environment. This is also true for the families of patients, volunteers, and other visitors. Places where individuals may be at risk are recorded in the risk registry and actions are taken to reduce the risks. Such actions may include security lighting outside when it is dark, restricting access to certain areas that may have vulnerable or young patients, removing or locking up medications and other potentially dangerous materials.

When a situation arises or an incident has occurred (such as an assault on a staff member by a patient), staff must know how to obtain assistance.

5.2.1.1 - There is a security system for limiting access to restricted areas in the facility.

5.2.1.2 - There is a process to report safety and security issues.

5.2.1.3 - The health facility has a process for protecting patients and staff from assault and a mechanism is available for summoning the assistance of security/police/protection service in the case of an emergency.

5.2.1.4 - Alert systems and signals are in working order and tested every month.

SE05 - RISK MANAGEMENT

5.2 - Safe and Secure Environment

5.2.2 - The healthcare facility ensures that all persons present in the healthcare facility are safe from fire and smoke.

Standard intent

The basic elements of a fire safety program ensure the following:

- Staff are trained on the early detection of fire and/or smoke,
- Staff know how to use various means of suppression (fire extinguishers or fire blankets) to manage flammable and hazardous materials, and this equipment is readily available
- There are designated safe exits and floor plans to assist visitors and staff in exiting the building safely.

The building size, number of levels, type of building materials and number of staff determine what types of fire equipment is available and ready for use at all times. Staff are trained in how to respond to fire and smoke (including evacuation procedures) and who outside the organization needs to be notified when an incident occurs.

The organization complies with applicable local, regional or national fire regulations and corrects problems identified on inspections.

5.2.2.1 - Sufficient firefighting equipment is available and operational according to the facility needs and local, regional or national fire regulations.

5.2.2.2 - Firefighting equipment is regularly inspected and serviced.

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

5.2.2.4 - A fire safety program for staff includes information and training on fire prevention and evacuation procedures.

SE05 - RISK MANAGEMENT

5.3 - Infection prevention and control (IPC)

5.3.1 - The healthcare facility designs and implements a IPC program to reduce the risk of infections in patients and healthcare workers.

Standard intent

Infections are frequently brought into a health care organization or can be endemic within the organization. Infections associated with healthcare facilities (nosocomial infections) contribute to numerous patient deaths each year worldwide. Thus, infections are a significant patient and staff safety issue. To combat infections, each healthcare facility needs to have an infection control program that names responsible staff, cleaning and sterilization procedures, early identification of containment of infections and the use of personal protective materials such as gloves, masks, gowns, etc. Since healthcare-facility-acquired infections can be a public health issue, they are often reported to public health agencies. Because the knowledge regarding infections changes often and because the behaviors needed for good infection control practices are frequently forgotten, constant reminders and in-service are essential to an effective program.

5.3.1.1 - Policies and procedures on infection prevention control (IPC) are in place and guide the staff in the implementation.

5.3.1.2 - A qualified member of staff monitors the infection control program.

5.3.1.3 - Regular in-service training is given to all staff on the subject of infection control.

5.3.1.4 - Data from IPC monitoring is analyzed for internal use and external reporting to the appropriate external public health agencies.

SE05 - RISK MANAGEMENT

5.3 - Infection prevention and control (IPC)

5.3.2 - The facility handles, stores and disposes of waste in a safe, and coordinated manner.

Standard intent

Health care organizations each day generate a considerable amount of waste that must be disposed of correctly to prevent injury, infection and contamination. Some wastes are considered “infectious” and thus are managed according to a written plan to protect the community, workers and patients compliant with local bylaws and regulations. Color coded containers are effective ways to separate waste into the different types. Each staff member is trained on the correct disposal of waste and plays an important role in the waste disposal process. Monitoring of correct disposal and removal therefore is key. This is also the case when contract workers dispose of the waste for the healthcare facility.

5.3.2.1 - Healthcare waste collection assets are available and allow for color-coded segregation.

5.3.2.2 - There is a waste management plan, consistent with current local bylaws and regulations.

5.3.2.3 - A training program for staff on waste management is available and implemented.

5.3.2.4 - The waste disposal and removal according to the waste management plan is monitored.

SE06 - PRIMARY HEALTH CARE SERVICES

6.1 - Management and staffing

6.1.1 - Delivery of primary healthcare services is sufficient to meet patient needs.

Standard intent

Appropriate and adequate staffing is critical to patient care. It's the responsibility of the department/service leaders to define staffing requirements and to ensure that qualifications of all OPD staff, medical and non-medical, are in line with these requirements. An adequate number of staff is needed to cover for regular outpatient hours, and for after-hours in case (a limited) number of services are provided outside the regular hours of operation. For services which are not provided by the health care facility, patients need to be informed where to go in order to ensure continuity of care.

6.1.1.1 - The number of staff members correspond with the patient needs.

6.1.1.2 - A qualified staff member is responsible for managing the primary healthcare services.

6.1.1.3 - An on-call roster is available for after hours, weekend and holidays, and emergency coverage. Facilities without 24/7 care, display where to go for after hour services.

6.1.1.4 - For primary healthcare services not provided in the facility, there is a referral mechanism.

SE06 - PRIMARY HEALTH CARE SERVICES

6.2 - Infrastructure and supplies

6.2.1 - The infrastructure/layout is adequate for providing safe care to patients.

Standard intent

In order to provide safe patient care, the lay-out of the facility should be logical and well-marked to allow patients to find their way easily. A designated area should be indicated for emergency care and should be accessible for stretchers and portable diagnostic imaging equipment, if available. There is a separate room for staff, to handover between shifts, write reports, put personal belongings and have nurse meetings, lunch etc.

6.2.1.1 - The lay-out of the facility allows for effective flow of patients in the OPD.

6.2.1.2 - There are designated hand over rooms for staff.

6.2.1.3 - A designated area has been indicated for emergency care.

6.2.1.4 - The waiting area is sufficient for the number of patients and services provided.

SE06 - PRIMARY HEALTH CARE SERVICES

6.2 - Infrastructure and supplies

6.2.2 - The waiting areas are adequate and safe for patients.

Standard intent

To provide patient safety and comfort in the waiting area, there should be enough opportunity to sit or lie down according to individual needs. Airborne precautions, like patient education via posters, are necessary to prevent the transmission of infectious agents that can remain suspended in the air for long periods of time. It is crucial that areas are not congested and well ventilated to reduce the risk of infection transmission.

6.2.2.1 - The waiting areas are well ventilated, well maintained, tidy, clean, and not congested.

6.2.2.2 - There are enough chairs/benches for the waiting patients.

6.2.2.3 - Stretchers and wheel chairs are available and are functioning properly.

6.2.2.4 - Patient education is displayed in waiting areas.

SE06 - PRIMARY HEALTH CARE SERVICES

6.2 - Infrastructure and supplies

6.2.3 - The consultation rooms are adequate to provide safe patient care.

Standard intent

To provide safe and organized care, the number of consultation rooms needs to be sufficient for the daily number of patients that visits the healthcare facility. The consultation rooms must offer enough privacy in order to ensure doctor-patient confidentiality and need to be sufficiently furnished and equipped to allow for adequate and timely patient assessments.

6.2.3.1 - The (number of) consultation rooms are adequate for the number of patients seen and are organized and clean.

6.2.3.2 - The consultation rooms are sufficiently furnished.

6.2.3.3 - Equipment for conducting assessments is available within close proximity of the consultation room.

6.2.3.4 - Each consultation room provides adequate privacy for patients.

SE06 - PRIMARY HEALTH CARE SERVICES

6.3 - Infection prevention and control (IPC)

6.3.1 - Hand-washing and sanitary facilities are adequate for patients and staff.

Standard intent

Hand hygiene is fundamental for proper infection prevention and control and thus handwashing facilities need to be available in all OPD areas where patients are assessed, in sanitary facilities and in all areas where staff manages contaminated material or infectious waste. Water, soap, disinfectants and hand drying facilities (e.g. paper towels) should be available in those areas. If no water and soap is available, a disinfectant agent (e.g. gel or sanitizer) should be used. Staff needs to be educated and reminded of proper hand-washing and hand-disinfection methods.

6.3.1.1 - Adequate hand washing facilities, including water, soap and (paper) towels, or alternatives e.g. gel or sanitizers are available.

6.3.1.2 - Posters on hand-hygiene are displayed at hand-washing facilities.

6.3.1.3 - Sanitary facilities for staff and patients are available

6.3.1.4 - The sanitary facilities are in working order and are clean.

SE06 - PRIMARY HEALTH CARE SERVICES

6.3 - Infection prevention and control (IPC)

6.3.2 - Staff and patients are guided in the prevention of person to person transmission of infections.

Standard intent

Preventing transmission in health-care settings requires the application of procedures and protocols referred to as “controls”. These are, in order of Infection Prevention and Control (IPC) effectiveness: managerial controls, environmental and engineering controls, and personal protective equipment (PPE). Although PPE is the most visible control used to prevent transmission, it must be used in conjunction with e.g. standardized work flows and organization of day-to-day activities, water and sanitation, hand hygiene infrastructure and waste management. The health care facility needs to identify those situations in which personal protective equipment such as masks, eye protection, gowns, or gloves are required and must provide training in their correct use. Also, the proper management of sharps, waste, laundry and soiled equipment can result in reduced infection risk, thus adequate equipment for disposal of contaminated material or infectious waste needs to be available, including guidelines on safe disposal.

6.3.2.1 - Adequate PPE is available for staff (gloves, gowns, etc.) and staff can explain how and when to use these.

6.3.2.2 - Assets for disposal of contaminated materials (e.g. infectious laundry) or infectious waste are available and used properly.

6.3.2.3 - Patients are informed on infection prevention (e.g. posters on handwashing and coughing).

6.3.2.4 - Staff can explain guidelines and implementation is observed.

SE06 - PRIMARY HEALTH CARE SERVICES

6.3 - Infection prevention and control (IPC)

6.3.3 - Staff is guided in disinfection and sterilization procedures to prevent infections.

Standard intent

Infection risk is minimized with proper cleaning, disinfection, and sterilization processes. There should be checklists for cleaning and disinfection of medical equipment (stethoscope, blood pressure cuffs etc.) and surfaces (examination benches, computer keyboards) and guidelines should be available for sterilization of surgical supplies. Cleaning, disinfection, and sterilization can take place in a sterilization area, which has adequate space to handle and store soiled, clean and sterile equipment/packs.

6.3.3.1 - There is (access to) sterilization equipment (autoclave or equivalent) which is functional and sufficient for the workload.

6.3.3.2 - Adequate materials for proper handling of contaminated materials and disposal of infectious waste are available (e.g. body fluids, contaminated linen).

6.3.3.3 - There is a document to guide staff in processing of contaminated materials and infectious waste.

6.3.3.4 - Staff is aware of correct wrapping, handling and checking sterility of packs.

SE06 - PRIMARY HEALTH CARE SERVICES

6.3 - Infection prevention and control (IPC)

6.3.4 - Where midwifery services are provided, staff is guided in disinfection and sterilization procedures to prevent infections.

Standard intent

Infection risk in the delivery room is minimized with proper cleaning, disinfection, and sterilization processes, such as the cleaning and disinfection of medical equipment and delivery table and the sterilization of obstetrical supplies. An assessment is done on the availability of sterilization equipment and equipment for disposal of contaminated equipment and infectious waste. There should be a dedicated area for cleaning, disinfection, and sterilization which has adequate space to handle and store soiled, clean and sterile equipment/packs. Guidelines should be available and implemented correctly.

6.3.4.1 - Staff is aware of correct wrapping, handling and storing of sterile packs.

6.3.4.2 - There is sufficient storage capacity for sterile packs which is well ventilated.

6.3.4.3 - Adequate materials for proper handling of contaminated materials and disposal of infectious waste are available. (e.g. body fluids, contaminated linen).

6.3.4.4 - There is a guideline for the processing of contaminated materials and infectious waste.

SE06 - PRIMARY HEALTH CARE SERVICES

6.4 - Care processes and guiding documents

6.4.1 - There is a standardized process for triaging patients at the point of first contact.

Standard intent

Patients with urgent, or immediate needs (such as airborne infections) need to be identified by an evidence-based triage process. Once identified as urgent, or requiring immediate needs, these patients must to be assessed and receive care or adequate referral as quickly as necessary. The triage process may include physiologic-based criteria, where possible and appropriate. The hospital trains staff to determine which patients need immediate care and how their care is given priority, which completes the system to ensure that patients are seen within acceptable time frames. This can be facilitated by a computerized system or a designated individual, e.g. triage person, which records waiting times.

6.4.1.1 - There is a document/checklist to guide staff in patient identification, triage and record keeping of triage findings.

6.4.1.2 - Designated, qualified staff members are responsible for patient identification, triage and giving correct directions on arrival of the patient at the facility.

6.4.1.3 - There is a document/checklist to guide staff in recognizing patients who need immediate attention and how to fast track them.

6.4.1.4 - There is a system in place to record waiting times and ensure that patients are seen within acceptable time frame.

SE06 - PRIMARY HEALTH CARE SERVICES

6.4 - Care processes and guiding documents

6.4.2 - Assessments in consultation rooms lead to identification of patient's healthcare needs.

Standard intent

Health care facilities need to identify staff members who are qualified to provide comprehensive assessments according to national guidelines. The day-to-day activities and responsibilities need to be reflected in job descriptions to ensure that staff members know what is expected. The health facility needs to provide (national) clinical guidelines to guide staff in assessment and management of the most common communicable and non-communicable diseases and provide guidance what should be documented in the patient records to facilitate continuity of care. Patients and families need to understand the nature of their disease and the treatment options available and documentation of the information provided, helps to involve patients in their care. Adequate communication between health care staff and patients can further be supported by using educational posters or leaflets.

6.4.2.1 - Designated, qualified staff members are responsible for conducting patient assessments.

6.4.2.2 - There are (national) clinical guidelines in each consultation room which guide staff in assessing and treating patients.

6.4.2.3 - Relevant information regarding the disease is given to patients and families in an understandable manner and is supported by educational aid/posters.

6.4.2.4 - Staff can explain how follow up instructions are provided.

SE06 - PRIMARY HEALTH CARE SERVICES

6.4 - Care processes and guiding documents

6.4.3 - Patients are educated on prevention of communicable and non-communicable diseases.

Standard intent

In order to provide adequate preventive care, health care staff needs to continuously inform and educate patients about prevention of disease. Non-communicable diseases such as diabetes and cardiovascular diseases are on the rise and managing risk factors before disease starts can decrease mortality rates. Screening of cancer is especially proven to be beneficial for cervix cancer and breast cancer, in certain age groups. Staff should be able to inform patients about screening in accordance with national guidelines. If screening is not provided in the facility patients should be adequately referred. Sexually transmitted infections (STI's) have a high prevalence but can be prevented with adequate information on protection and partner notification.

6.4.3.1 - There is a guideline for sexual transmitted infections (STI) screening, and staff educates patients on prevention, including partner notification.

6.4.3.2 - There is a guideline for prevention of cardiovascular disease and staff educates patients on lifestyle changes.

6.4.3.3 - There is a guideline for cancer screening and staff educates patients on when, how and what to screen.

6.4.3.4 - Evidence of patient education is observed .

SE06 - PRIMARY HEALTH CARE SERVICES

6.4 - Care processes and guiding documents

6.4.4 - Staff is guided in the appropriate use of rapid diagnostic tests (RDTs) and point of care devices.

Standard intent

RDTs are designed to obtain quick screening test result and are frequently used in point of care approaches. A range of rapid tests are available to screen for infectious diseases (e.g. HIV, Hepatitis, Malaria etc.), or for pregnancy (in urine), while other tests provide for example glucose and hemoglobin levels, using small portable devices. These tests can be used outside a laboratory setting, provided appropriate safety precautions are adhered to. (e.g. handling sharps and infectious waste, sufficient PPE, etc.) The facility needs to ensure that staff members performing the tests are adequately trained and are guided by standard operating procedures (SOPs). For example, for accurate screening of HIV, national testing algorithms have been developed and should be followed. Whichever test or device is used, reliability of results is essential, thus national MOH regulations with regard to approved tests must be taken into account where applicable. Storage conditions are important as not adhering to manufactures instructions can reduce shelf life considerably. Verification of test results (internal control) is required for all tests/devices used on regular basis. In order to provide effective point of care services, sufficient staff needs to be trained in performing and interpreting tests, as well as recording and reporting of test results.

6.4.4.1 - There are SOPs guiding staff in performing RDTs.

6.4.4.2 - The point of care tests are in accordance with the MOH regulations (e.g. national algorithm), and are correctly stored.

6.4.4.3 - Test kits are verified and test validated using appropriate internal controls, which are being recorded.

6.4.4.4 - Test results are recorded and authorized (signed and dated) in appropriate registers and patient's files.

SE06 - PRIMARY HEALTH CARE SERVICES

6.4 - Care processes and guiding documents

6.4.5 - There is a program for preventing and treating malaria.

Standard intent

Malaria poses an immense burden on mortality and on health care in general. Adequate measures need to be taken to prevent, detect and treat cases of malaria. Prevention starts with patient education which is especially relevant for pregnant women and mothers of children under five, and should be intensified during rainy seasons. For all non-emergency malaria suspected cases, each clinical diagnosis needs to be confirmed with a laboratory test in order to avoid unnecessary treatment (minimizing poly-pharmacy). Point of care (RDT) malaria tests are available that are easy to use and provide reliable results. Malaria treatment should be in accordance to current national guidelines in order to treat malaria effectively and to prevent emergence of resistant malaria strains. The facility should regularly monitor relevant medical personnel to ensure compliance to these guidelines.

6.4.5.1 - Malaria diagnostics are available through microscopy and/or RDT malaria tests.

6.4.5.2 - There is a document which guides staff in recognizing emergency cases or complications of malaria, including the required follow-up actions (e.g. referral).

6.4.5.3 - Malaria treatment in stock is in compliance with current national guidelines.

6.4.5.4 - Staff educates patients on malaria prevention and treatment.

SE06 - PRIMARY HEALTH CARE SERVICES

6.4 - Care processes and guiding documents

6.4.6 - There are adequate resources and guidelines to provide safe care in the treatment and minor surgery room.

Standard intent

The facility should determine which treatments are offered in the treatment and minor surgery room in order to ensure the required furniture, equipment and supplies are available to accommodate for this. In addition, staff qualifications need to match the treatments provided in order to avoid that staff members are operating outside their scope of practice. The facility should provide protocols on the most frequent treatments, how to ensure supplies are readily available inside the treatment and minor surgery room, and how to clean, disinfect and sterilize materials before re-use. Staff needs to be orientated to these to ensure a standardized approach for safe, efficient and effective care delivery.

6.4.6.1 - Appropriate equipment and materials for the services provided in the treatment room/minor surgery room are available.

6.4.6.2 - Designated qualified staff members are responsible for procedures in the treatment room/minor surgery room.

6.4.6.3 - The healthcare facility has identified what kind of procedures they offer and protocols/guidelines for specific procedures are available.

6.4.6.4 - Staff can explain relevant guidelines.

SE06 - PRIMARY HEALTH CARE SERVICES

6.4 - Care processes and guiding documents

6.4.7 - There are adequate resources to provide safe care for patients in observation.

Standard intent

When patients are under observation it must be clear at all times who is responsible for the nursing care of the patient and who is the treating clinician. Larger healthcare facilities will have duty rosters to ensure staff is allocated. Patients should be able to alert medical staff at all times while under observation and medical staff should respond to these signals timely and adequately. The facility needs to ensure that sufficient equipment to monitor vital signs is available for the staff responsible for patient care in observation, and that sufficient measures have been put in place for assuring privacy for patients.

6.4.7.1 - Sufficient equipment for monitoring vitals is available.

6.4.7.2 - It is clear who is responsible for patients under observation.

6.4.7.3 - Each patient has access to a nurse call system at all times.

6.4.7.4 - There is enough privacy for patients in observation.

SE06 - PRIMARY HEALTH CARE SERVICES

6.5 - Emergency Services

6.5.1 - Staff is guided in the provision of cardiopulmonary resuscitation.

Standard intent

When a cardiac or respiratory arrest occurs, the immediate initiation of chest compressions or respiratory support may mean the difference between life and death or, at the very least, may help avoid potentially serious brain damage. Essential to providing these critical interventions is the quick availability of standardized medical technology, medications for resuscitation, and staff properly trained in resuscitation. Monitoring the outcome of each resuscitated patient creates awareness of service provision and serves as a trigger to implement improvements when and where needed.

6.5.1.1 - Staff is trained in resuscitation and records are kept of their attendance of such training.

6.5.1.2 - The facility has a resuscitation guideline.

6.5.1.3 - All applicable cardiopulmonary resuscitation equipment is available and functioning.

6.5.1.4 - Outcomes of incidents of resuscitation are discussed and recorded in a logbook to improve service provision.

SE06 - PRIMARY HEALTH CARE SERVICES

6.5 - Emergency Services

6.5.2 - Staff is guided in the provision of other emergency services.

Standard intent

When the health care facility is not able to meet the needs of the patient with an emergency condition and the patient requires transfer to a higher level of care, the transferring facility must provide stabilizing treatment within its capacity prior to transport. The facility therefore needs to be aware which emergencies occur often, apart from CPR, like seizures, states of shock, severe asthma, an unconscious patient, etc. and determine the level of care that can be offered onsite prior to referral. Protocols need to be provided by the facility to guide staff in timely and appropriate identification and management of these cases. The interventions provided to patients and their response up till referral should be recorded, so that outcomes can be monitored and interventions altered or improved where needed.

6.5.2.1 - Guidelines are available to recognize and manage common or life threatening emergencies.

6.5.2.2 - The facility has listed which emergencies occur often and which level of care can be provided, or which pre-referral treatment can be given.

6.5.2.3 - Guidelines are available for pediatric emergency triage, assessment and treatment (ETAT).

6.5.2.4 - Implementation of guidelines and outcomes are discussed and reviewed.

SE06 - PRIMARY HEALTH CARE SERVICES

6.5 - Emergency Services

6.5.3 - Equipment, drugs and other supplies are readily available to manage emergencies.

Standard intent

In order to be prepared to deal with emergencies, the health care facility should have an emergency tray or trolley readily available in a central place. National guidelines can apply as to which drugs and equipment are needed or allowed on an emergency trolley. Relevant SOPs and checklists need to be available to guide the staff in emergency care processes and a staff member should be allocated to physically check that required supplies are adequately available on the tray or trolley at all times.

6.5.3.1 - There is a tray or trolley with appropriate supplies for intravenous therapy, insertion of naso-gastric tubing and drug administration (including pediatric sizes).

6.5.3.2 - The drugs available are in accordance with a specified list,and include those for coma, fits and states of shock (including pediatric doses), and plasma expanders.

6.5.3.3 - There is a document guiding staff in the usage of emergency equipment and drugs.

6.5.3.4 - Emergency materials and drugs are not expired

SE06 - PRIMARY HEALTH CARE SERVICES

6.5 - Emergency Services

6.5.4 - Staff is guided in the safe administration of oxygen.

Standard intent

If oxygen therapy is delivered, the health care facility needs to ensure it is done appropriately, including putting in place safety precautions for storage of oxygen. There are several ways of delivering oxygen (piped, by cylinder or by oxygen concentrator), and staff members administering oxygen to patients should be qualified and orientated on specific guidelines describing when and how to use oxygen. Pulse oximetry is recommended when considering oxygen therapy.

6.5.4.1 - Oxygen supplies (oxygen cylinders or air enrichers) meet the patient care needs and are stored in accordance with local safety standards.

6.5.4.2 - There are guidelines that guide staff on how to use and administer oxygen

6.5.4.3 - Cylinder pressures (i.e. contents) are constantly monitored while patients are receiving oxygen.

6.5.4.4 - Oxygen is administered by qualified staff who are trained on guidelines.

SE06 - PRIMARY HEALTH CARE SERVICES

6.5 - Emergency Services

6.5.5 - The health facility follows adequate referral processes for enabling continuity of patient care.

Standard intent

There are various referral options for the different types of patients. For example, up-referral to higher level facilities and down-referrals to lower level facilities. Protocols describing the lines of communication and which activities should take place when referring a patient should be provided to the staff for guidance. E.g. calling the referral facility to announce the patient, or ensuring referral forms are correct and completely filled out. It is important that the referral facility has all relevant information to ensure continuity of care and that a copy of the referral letter is available onsite for future reference.

6.5.5.1 - The facility has prepared a list of appropriate referral facilities for patients in need of (specialized) services not provided at the facility.

6.5.5.2 - There are protocols defining the situations in which patients are referred.

6.5.5.3 - There is an established process for referring patients for caesarian section when appropriate.

6.5.5.4 - A copy of the referral letter or a reference of referral is available in the patient's record.

SE06 - PRIMARY HEALTH CARE SERVICES

6.5 - Emergency Services

6.5.6 - The healthcare facility provides or has access to ambulance services for emergency referrals.

Standard intent

The healthcare facility needs to identify in what situations referral patients should be transported by ambulance. An effective system for facilitating communication between the personnel of the healthcare facility, the ambulance service, the drivers and the receiving organizations should be in place. In order to ensure timeliness, ambulance response time should be monitored. The ambulance need to be clean and properly stocked to deal with obstetric and cardiopulmonary emergencies, as well as trauma and the ambulance staff needs to be qualified for the job to ensure appropriate care can be provided at all times once on route.

6.5.6.1 - Medical transport/ ambulance vehicles that are used by the facility are clean, in good condition and are adequately equipped.

6.5.6.2 - The individuals who provide patient care in the ambulance service, have the required training and experience.

6.5.6.3 - There is a flowchart which guides staff in ambulance related communication steps.

6.5.6.4 - Ambulance related activities are recorded (logbook).

SE06 - PRIMARY HEALTH CARE SERVICES

6.6 - Mother and Child Care

6.6.1 - Where family planning services are provided, sufficient guidance and supplies are available for safe service delivery.

Standard intent

In order to provide a reliable family planning and reproductive health service, education of patients must be an integral component of the service. Different contraceptive methods should be available and stock outs of contraceptives should be prevented at all times. The service should be provided by qualified staff, with emphasis on training particularly on inserting intra-uterine devices (IUD's), if this is provided on site. The facility needs to provide guidance for staff in safe service provision, for example, clear indicators when and where to refer, templates to facilitate patient education, or standard checklists to facilitate correct record keeping.

6.6.1.1 - Frequently used contraceptive methods are available.

6.6.1.2 - Qualified staff members provide the contraceptive service.

6.6.1.3 - The chosen method for each patient is recorded.

6.6.1.4 - There is a document/checklist to guide staff in the provision of contraceptive services.

SE06 - PRIMARY HEALTH CARE SERVICES

6.6 - Mother and Child Care

6.6.2 - Where antenatal service is provided, sufficient guidance and supplies are available for safe service delivery.

Standard intent

Qualified staff is required to offers antenatal care services. A plan for each pregnant individual should be based on an assessment of needs. Measurements during follow-up need to be documented and should be easily retrievable from the patient's record. PMTCT must be supported for all patients that are ignorant about their status. Pregnant women should be informed on adequate nutrition during pregnancy and need to be prepared for delivery and breastfeeding. The frequency of follow-up visits should be clearly indicated. Country-specific clinical guidelines and protocols should be available to guide the staff in providing up-to-date treatment of complications during pregnancies and side effects of treatment with regard to the fetus.

6.6.2.1 - There is a document/checklist to guide staff in routine tests, observations and examinations to be conducted on pregnant women, and findings are recorded in the patient file.

6.6.2.2 - Qualified staff members provide the antenatal service.

6.6.2.3 - There is a document/checklist guiding staff in counselling pregnant women on adequate nutrition and selfcare during pregnancy, preparation for delivery, family planning and breastfeeding.

6.6.2.4 - There are guidelines for managing complicated pregnancies.

SE06 - PRIMARY HEALTH CARE SERVICES

6.6 - Mother and Child Care

6.6.3 - Where midwifery services are provided, adequate infrastructure and sufficient equipment for safe delivery are in place.

Standard intent

In order to provide safe obstetrical care, each delivery room requires adequate resources, such as a good delivery table and sufficient standard obstetric equipment. The delivery room should be adequate in terms of space, lightening, ventilation and privacy. Basic safety measures with regard to infection prevention should be in place for disposing of placenta's.

6.6.3.1 - The delivery room has adequate space and privacy and it's furnished with a suitably positioned delivery table, which allows for use in the Trendelenburg or lithotomy positions.

6.6.3.2 - The delivery room has adequate lighting, including an angle-poise lamp, and sufficient ventilation.

6.6.3.3 - Standard surgical/obstetric equipment is available, clean and in good condition

6.6.3.4 - There is a system for disposing safely of placentas.

SE06 - PRIMARY HEALTH CARE SERVICES

6.6 - Mother and Child Care

6.6.4 - Where midwifery services are provided, staff is adequately guided to ensure safe services for mother and child.

Standard intent

Maternal mortality is an important cause of death in many countries. Timely recording of observations during labor enables midwifery staff to intervene during prolonged labor and timely manage obstetric complications. Management includes timely referring patients who need higher-level care/caesarian sections. Midwifery services should be carried out by qualified midwifery staff and evidence-based guidelines need to be readily available for staff with the aim of reducing maternal and neonatal mortality and morbidity.

6.6.4.1 - Observations during labor are recorded (and signed) on a partograph.

6.6.4.2 - A registered professional with midwifery training is present at every birth.

6.6.4.3 - There is a document guiding staff in reducing the number of maternal deaths in the labor ward.

6.6.4.4 - Information on cases and the outcome of deliveries are discussed and recorded in a register/log book.

SE06 - PRIMARY HEALTH CARE SERVICES

6.6 - Mother and Child Care

6.6.5 - Where midwifery services are provided, there are adequate resources for neonatal care and resuscitation.

Standard intent

As many as 10% of all new-born infants need some intervention at birth. Although certain episodes of fetal asphyxia cannot be prevented, a prompt and skilled resuscitation may prevent lifelong adverse conditions. Adequate neonatal equipment should be readily available and staff needs to be trained in assessing neonates, recording and interpreting Apgar ratings and providing resuscitation.

6.6.5.1 - Neonatal resuscitation equipment and instruments are available and in a good condition.

6.6.5.2 - There is a guideline on neonatal resuscitation and staff is trained in neonatal resuscitation.

6.6.5.3 - There is a system to identify (tag) newborns and to protect them from unauthorized visitors to the maternity ward.

6.6.5.4 - An Apgar-rating is recorded (and signed) for each new-born baby and staff can explain the score.

SE06 - PRIMARY HEALTH CARE SERVICES

6.6 - Mother and Child Care

6.6.6. - Staff use guidelines to ensure appropriate postnatal services to mother and child.

Standard intent

Guidelines on postnatal and post-delivery care need to be provided by the facility to guide staff in the following important areas. Firstly, conducting routine follow-up of the mother and newborn after delivery, including adequate vaccinations. Secondly, infants born to HIV positive mothers should be followed up and education on breastfeeding should be provided to mothers. Thirdly, management of post-delivery and postnatal emergencies such as bleeding postpartum, jaundice and sepsis of the neonate. Lastly, staff needs to be guided on which information needs to be recorded, where and how. The use of templates is likely to increase the level of correct and complete record keeping. Routine follow-up usually takes place in mother and child clinics, or post-partum care clinics and focuses on counselling and preventive care. However, it is also possible that a woman or newborns presents with an acute post-partum complication at a facility that does not offer routine post-partum services. Every primary care facility needs to be able to recognize post-partum problems and either manage them or refer appropriately.

6.6.6.1 - Guidelines for post-natal care for mother and baby (including emergency care and vaccination) are available.

6.6.6.2 - There is a document which guides staff in providing information on breastfeeding (and options for HIV positive mothers).

6.6.6.3 - There is a document which guides staff in follow-up testing of infants born to mothers with HIV infection.

6.6.6.4 - All tests, results, observations, examinations and information regarding postnatal services provided are recorded and signed.

SE06 - PRIMARY HEALTH CARE SERVICES

6.6 - Mother and Child Care

6.6.7 - Where immunization services are provided, this is done in accordance with national guidelines.

Standard intent

Immunization is usually coordinated through country wide programs. Therefore, the country specific immunization programs and related requirements are leading in any immunization activities performed in the healthcare facility. In order to provide safe vaccine services, a continuous supply of vaccines and adequate equipment to keep vaccines under recommended storage temperatures should be available. Furthermore, national guidelines on vaccination (also for HIV+ children, if different) should be available to guide staff on how to handle vaccines effectively (easily destroyed by heat and rendered ineffective) and safely (appropriate disposal of used sharp syringes). In addition, staff needs guidance on record keeping vaccinations on tally sheets and on the Child-Health immunization cards, as well as how to educate mothers/child-caretakers about: A. possible side effects of each of the given vaccines, B. bringing the cards along with them when taking children to any health facility, C. returning the child for the next immunization date as indicated on the card, etc.

6.6.7.1 - Immunizations provided are recorded on child's vaccination card and next appointments are scheduled.

6.6.7.2 - There is a document which guides staff in providing immunizations.

6.6.7.3 - There is an uninterrupted supply of vaccines and cold-chain and expiry checks are recorded upon.

6.6.7.4 - There is a dedicated vaccine fridge and temperature logs are kept current.

SE06 - PRIMARY HEALTH CARE SERVICES

6.6 - Mother and Child Care

6.6.8 - Services are provided to promote the growth of children.

Standard intent

In order to provide adequate monitoring of pediatric growth and nutritional status, adequate equipment and guidelines for monitoring growth should be available. All children under 5 who are treated for illness must be evaluated for malnutrition as well. The fastest way is using MUAC, the most accurate way is doing a weight for height. There must be a guideline that includes when action is needed and what should be done. Mothers should be educated on adequate nutrition for their child and how to wean off breastfeeding.

6.6.8.1 - There are guidelines for monitoring child growth and the child health chart is completed and signed after each visit.

6.6.8.2 - Equipment for monitoring growth is available and operational.

6.6.8.3 - Children with nutritional deficiencies are identified, managed or appropriately referred.

6.6.8.4 - There are guidelines for educating mothers on weaning off breastfeeding and adequate under-5 nutrition.

SE06 - PRIMARY HEALTH CARE SERVICES

6.6 - Mother and Child Care

6.6.9 - Services are provided to promote the health of children.

Standard intent

Dehydration is an important cause of death in children under 5 years of age. It can be relatively easily treated using the ABC schedule for dehydration and oral or IV rehydration fluids. All health care facilities should therefore provide Oral Rehydration Service (ORS) by assuring sufficient resources are available and staff is guided in counseling and education care takers. Furthermore, guidelines on common childhood illnesses, including oral health should be available to guide staff for effective service provision.

6.6.9.1 - Health education about oral rehydration is provided to parents.

6.6.9.2 - There is a document which guides staff in integrated management of childhood illnesses (IMCI).

6.6.9.3 - Oral rehydration commodities are available to meet the patient needs.

6.6.9.4 - Guidelines for oral health for children are available.

SE06 - PRIMARY HEALTH CARE SERVICES

6.7 - TB and HIV services

6.7.1 - Where TB services are provided, staff is guided appropriately for effective service provision.

Standard intent

In-country regulations determine when health care facilities are allowed to provide TB treatment. For example, if the facility needs to be accredited by a National TB Program. In order to provide safe TB care, the facility needs an infection control plan which includes early detection of TB cases and prompt airborne precautions; sufficient space and ventilation; and adequate ways to collect sputum. Also, adequate treatment guidelines that are in line with approved TB regimes in the country, should be available. An uninterrupted supply of medicine is of utmost importance to maximize treatment effect for the individual patient, and to minimize development of resistant TB.

6.7.1.1 - TB treatment complies to (current) national guidelines.

6.7.1.2 - There is an uninterrupted supply of TB medicine in the facility.

6.7.1.3 - For each individual who is suspected to have TB, HIV diagnosis is also performed.

6.7.1.4 - The facility has a TB infection control plan, including a system for early detection (coughing) and collection of sputum.

SE06 - PRIMARY HEALTH CARE SERVICES

6.7 - TB and HIV services

6.7.2 - Where VCT/PITC services are provided, guidance and resources are appropriate for effective service provision.

Standard intent

Where VCT (Voluntary Counselling and Testing) and/or provider-initiated testing and counselling (PITC) is performed, national guidelines must be available to guide staff through national testing algorithm and counselling sessions. All staff conducting the tests and counselling sessions must be qualified to do so and trained on the procedures. The infrastructural requirements have to be sufficient in order to provide privacy and confidentiality and the required materials for VCT and PITC activities have to be available.

6.7.2.1 - Materials to provide VCT/PITC services are available.

6.7.2.2 - All staff performing HIV testing and counselling activities are qualified and properly trained.

6.7.2.3 - The set-up for VCT/PITC services allows for sufficient privacy/confidentiality for patients.

6.7.2.4 - There is a document which guides staff through national testing algorithm and counselling sessions.

SE06 - PRIMARY HEALTH CARE SERVICES

6.7 - TB and HIV services

6.7.3 - Where ART services are provided, staff is guided appropriately for effective service provision.

Standard intent

In-country regulations determine if health care facilities need to obtain permission from national bodies in order to provide ART treatment. To ensure safe service delivery, current national treatment guidelines that are in line with approved ART regimes in the country, should be available at the facility. In addition, PEP guidelines should be available in order to respond timely and correctly in case of occupational injuries (staff) or sexual assault (patients). It is important that assessments of patients and treatment provided is documented to ensure effective communication between health providers, especially when it comes to HIV+ obstetric patients.

6.7.3.1 - Antiretroviral therapy (ART) complies to (current) national guidelines.

6.7.3.2 - Guidelines for PEP (for patients AND staff) and appropriate ART are available.

6.7.3.3 - There are documents which guide staff in provision of appropriate care for HIV-positive obstetric patients.

6.7.3.4 - There is a process that ensures that patients, who are on ART, are monitored.

SE06 - PRIMARY HEALTH CARE SERVICES

6.8 - Mental Health

6.8.1 - Where mental health services are provided, this is done in a coordinated manner.

Standard intent

Despite the burden of mental and substance (drug) abuse disorders there is often a lack of awareness and adequate support for mental health services. Qualified staff members are required to manage the mental health service and should be able to consult mental health experts (psychiatrist or psychologist) when needed. Guidelines on mental health, including counseling should be provided by the facility to guide staff for effective service provision.

6.8.1.1 - There is access to mental health expertise, when required (psychiatrist or psychologist.)

6.8.1.2 - All examinations, tests and medications regarding mental health are recorded and signed in the patient file.

6.8.1.3 - Qualified staff manage the mental health service.

6.8.1.4 - There are documents to guide staff in the provision of mental health.

SE06 - PRIMARY HEALTH CARE SERVICES

6.9 - Dental Health

6.9.1 - There are adequate resources to provide effective dental services.

Standard intent

In country education systems determine which pre-service education contains the relevant training to offer dental care services. Even though dental services are often basic at primary care level, qualified staff is required to ensure safe practices. The facility should have an adequate lay-out and minimum equipment and medication for simple tooth filling and extractions, including adequate antibiotic prophylaxis when required. Guidelines for oral assessment and treatment, including appropriate record keeping should be available to guide staff in safe service provision.

6.9.1.1 - There is a qualified dental practitioner/oral hygienist.

6.9.1.2 - There is a designated dental area with sufficient dental equipment to meet the patinet needs.

6.9.1.3 - Sufficient medication and supplies for local anesthesia are available, and regular expiry checks are recorded.

6.9.1.4 - Assessment, treatment and patient education provided are recorded in the patient file.

SE06 - PRIMARY HEALTH CARE SERVICES

6.9 - Dental Health

6.9.2 - Staff is guided in measures to prevent infection for safe dental services.

Standard intent

To prevent infection transmission in the dental department, barrier techniques and adequate cleaning and disinfection procedures should be followed. Protocols should also be in place to ensure that equipment requiring sterilization are processed timely and correctly. The patient and staff should be protected to radiation in the case radiographic equipment is used within the dental department.

6.9.2.1 - There is a document which guides staff in cleaning and disinfection processes.

6.9.2.2 - There is a document which guides staff in sterilizing equipment.

6.9.2.3 - Sufficient and appropriate Personal Protective Equipment (PPE) is available.

6.9.2.4 - Appropriate shielding is present and appropriate protective clothing is worn when dental radiography services are provided.

SE06 - PRIMARY HEALTH CARE SERVICES

6.10 - Outreach and home based care services

6.10.1 - Where outreach and/or home based care services are provided, this is done in a coordinated manner.

Standard intent

Outreach is an activity of providing services to populations who might not otherwise have access to those services. Outreach has an educational role, e.g. raising the awareness of existing services, health promotion, education on malaria prevention, etc. Home based care service is offered to ensure continuation of care and the facility should plan accordingly to reach the required patients in the community.

6.10.1.1 - Home based care records are kept for each patient and include the type of care, medication and services provided.

6.10.1.2 - The facility has prepared a planning/schedule to ensure it reaches the whole community they serve during outreach activities.

6.10.1.3 - Staff, transport and resources are available to provide the outreach and/or home based care service.

6.10.1.4 - Health promotion and education are in line with the national objectives or policies and records are kept for topics and area covered for outreach.

SE07 - INPATIENT CARE

7.1 - Management and staffing

7.1.1 - The in-patient services are managed and staffed by qualified care providers.

Standard intent

It is important that the department defines staffing requirements (desired education, skills, knowledge and any other requirements for individual positions) to the needs of the patient. To perform well, a new staff member needs a general orientation to the health care facility and a specific orientation to the job, to understand his or her role in the health care facility. Training in infection control should be included in this orientation. Qualifications of the staff members need to match their responsibilities and a duty roster need to be available, which demonstrates adequate medical cover for the facility and shows which external experts can be called when needed after hours.

7.1.1.1 - A duty roster for the relevant caregivers, including Sundays, weekends and public holidays is available and known by the in-patient staff members.

7.1.1.2 - A designated qualified staff member is responsible for managing the in-patient services.

7.1.1.3 - The number and qualifications of the in-patient staff members correspond with the scope of practice for their day-to-day activities.

7.1.1.4 - New in-patient staff members are oriented to the job.

SE07 - INPATIENT CARE

7.1 - Management and staffing

7.1.2 - Routine care processes are performed in a coordinated manner.

Standard intent

Patient admissions, ward rounds and handovers and should be structured in a way that optimizes patient care. There should be a system to admit patients, which controls that (within 24hrs of admission) a patient has an individual plan of care. A plan of care consists of the medical status, nursing needs and social needs and needs to be updated during the ward round to facilitate adequate information sharing between healthcare workers. Handovers should be a standard practice at the start and end of each shift and should minimally include diagnosis, a summary of care, response to treatment and a future care plan.

7.1.2.1 - Regular ward rounds lead to an appropriate assessment of patients and an update of the nursing care plan, and both are documented.

7.1.2.2 - There is an organized system to screen and admit patients.

7.1.2.3 - Patient's assessments lead to an individual plan of care which is reviewed and documented.

7.1.2.4 - Relevant medical information of each patient is documented and exchanged during handovers at the start and end of each shift.

SE07 - INPATIENT CARE

7.1 - Management and staffing

7.1.3 - Patient and staff identification promotes effective communication.

Standard intent

It should be clear at all times who is responsible for the nursing care of a patient and who is the treating clinician. In order to be clearly recognizable, staff should wear appropriate uniforms and name badges for easy identification. Patient safety is enhanced by adequate communication measures such as a standard way to identify patients before medical procedures and an effective nurse call system.

7.1.3.1 - Identification of patients prior to medical procedures is standardized.

7.1.3.2 - All staff wear uniforms and has ID/name badges for easy identification.

7.1.3.3 - Nurses are allocated to patients and patients know who is allocated to them.

7.1.3.4 - Each patient confined to bed has access to an effective nurse call system at all times.

SE07 - INPATIENT CARE

7.2 - Infrastructure and supplies

7.2.1 - The infrastructure/layout is adequate for providing safe care to patients in the ward.

Standard intent

In order to provide safe patient care, each unit requires adequate space and resources, including measures to ensure privacy of patients in the wards. The physical facilities required include adequate office accommodation for the staff, designated areas for soiled materials and disposal of waste and adequate storage space for clean linen. In order to prevent infections, it should be possible to separate highly contagious patients from others.

7.2.1.1 - There is adequate space and privacy for patients in the wards.

7.2.1.2 - There is a separate area (scullery/sluice room) for patients' eliminations, waste and laundry.

7.2.1.3 - There is adequate space for staff (e.g. for handovers, administration).

7.2.1.4 - There's a designated area for highly contagious patients in order to isolate them from others.

SE07 - INPATIENT CARE

7.2 - Infrastructure and supplies

7.2.2 - There are adequate non-medical resources for providing safe care to patients in the ward.

Standard intent

The health care facility needs to provide sufficient number of beds, mattresses, bed linen and mosquito nets in order to deliver safe care in the wards. For patients confined to bed, the health care facility should provide hygiene materials such as washing bowls, kidney dishes, bed pans, etc. Patients and family should be adequately informed about with which personal hygiene materials are provided for by the facility and which items to bring themselves.

7.2.2.1 - Number of beds, matrasses and bed linen meets the patient needs.

7.2.2.2 - Patients are informed about which personal hygiene materials to bring themselves.

7.2.2.3 - Hygiene materials for patients confined to bed meet the patient needs.

7.2.2.4 - Number of bed nets are adequate to meet the patient needs.

SE07 - INPATIENT CARE

7.2 - Infrastructure and supplies

7.2.3 - There is adequate access to pharmaceuticals for providing safe care to patients in the ward.

Standard intent

Wards should have a system that ensures 24hr availability of pharmaceuticals for inpatients. If drugs are not kept in the ward, there should be a system to obtain pharmaceuticals from the pharmacy. If drugs are kept in a drug cabinet in the ward, adequate stock management should be in place and access should be limited to authorized staff only.

7.2.3.1 - There is 24-hour access for staff to pharmaceuticals within the facility.

7.2.3.2 - Drug cabinets in the ward are locked and only be accessible to authorized staff.

7.2.3.3 - Pharmaceuticals, vaccines and medical consumables stocked meet the patient care needs.

7.2.3.4 - Drug cabinets in the ward are routinely (re)stocked and expiry dates are checked.

SE07 - INPATIENT CARE

7.3 - Infection prevention and control (IPC)

7.3.1 - Staff and patients are guided in prevention of person to person transmission of infections.

Standard intent

Hand hygiene is fundamental for proper infection prevention and control and thus handwashing facilities need to be available in all areas where patients are assessed, in sanitary facilities and in all areas where staff manages contaminated material or infectious waste. Water, soap, disinfectants and hand drying facilities (e.g. paper towels) should be available in those areas. If no water and soap is available, a disinfectant agent (e.g. gel or sanitizer) should be used. Staff needs to be educated and reminded of proper hand-washing and hand-disinfection methods. Barrier techniques, such as the use of personal protective equipment are fundamental tools for proper infection prevention and control and thus need to be available at any site of care at which they could be needed. Sanitary and bathing facilities for the number of patients in the ward should be adequate.

7.3.1.1 - Hand washing facilities, including soap and (paper) towels, or alternatives e.g. gel or sanitizers, are available.

7.3.1.2 - Guidelines for hand hygiene are available and reminders (posters) are available at relevant sites.

7.3.1.3 - Adequate PPE is available for staff (gloves, aprons, masks, etc.).

7.3.1.4 - Sanitary and washing facilities are available in the ward for the patients.

SE07 - INPATIENT CARE

7.3 - Infection prevention and control (IPC)

7.3.2 - Staff is guided in management of contaminated equipment and infectious waste.

Standard intent

The proper management of sharps, waste, laundry and soiled equipment can result in reduced infection risk. An assessment will be made if adequate equipment and guidelines on disposal of waste/equipment are available and implemented. Cleaning, disinfection, and sterilization should take place in a sterilization area, which has adequate space to handle and store soiled, clean and sterile equipment.

7.3.2.1 - There is a guideline for the handling and processing of contaminated materials and infectious waste. .

7.3.2.2 - Adequate materials for proper handling of contaminated materials and disposal of infectious waste are available. (e.g. body fluids, contaminated linen)

7.3.2.3 - There is (access to) sterilization equipment (autoclave or equivalent) which is functional and sufficient for the workload.

7.3.2.4 - Staff is aware of correct wrapping, handling and checking sterility of packs.

SE07 - INPATIENT CARE

7.4 - Care processes and guiding documents

7.4.1 - Staff is guided in adequate monitoring of vital signs.

Standard intent

Monitoring vital signs is one of the core activities in the ward. There should be a written schedule for the routine monitoring of vital signs, the norms and what to do in case of vital signs outside the reference ranges. Often, a patient will exhibit early warning signs (for example, a worsening of vital signs or a subtle change in neurological status) shortly before experiencing significant clinical decline, resulting in a major event. When staff is able to identify these patients early and request additional assistance from specialized individuals, clinical outcomes are likely to improve.

7.4.1.1 - Vital signs are regularly monitored and registered and signed.

7.4.1.2 - Equipment for monitoring patients' vital signs is available.

7.4.1.3 - There is a document that guides staff in early recognition of deteriorating vital parameters.

7.4.1.4 - Staff can explain 'how to call for assistance'.

SE07 - INPATIENT CARE

7.4 - Care processes and guiding documents

7.4.2 - Staff is guided in identifying patients which need special care.

Standard intent

The health care facility needs to be aware of/has identified patients that need special care, such as patients in pain, patients with altered cognitive state (delirium), conditions that need psychology/psychiatric care and patients that need additional nutritional treatment. Patients in pain should be recognized, appropriately assessed and managed as unrelieved pain has adverse physical and psychological effects. A delirium, or acute confused state, should be recognized as it results from an underlying cause such as infection or medication. Patients with mental disorders should have access to psychological/psychiatric treatment. On initial assessment, patients are screened to identify those patients who may be at nutritional risk. When it is determined that a patient is at nutritional risk, a plan for nutrition therapy should be developed and carried out.

7.4.2.1 - There is a document that guides staff in the assessment and management of pain.

7.4.2.2 - Staff can explain how to recognize and manage altered cognitive state (e.g. delirium) and mental disorders.

7.4.2.3 - Staff can explain how to recognize patients at risk for nutritional problems.

7.4.2.4 - Staff is orientated on how to identify patients that require special care.

SE07 - INPATIENT CARE

7.4 - Care processes and guiding documents

7.4.3 - Staff is guided in the provision of complex procedures.

Standard intent

Protocols or checklists for complex procedures can lead to a higher quality of care provision. It is important that these are available for common procedures that could harm or damage the patient if executed wrongly. For example, nasogastric intubation, inserting an IV catheter or inserting urine catheters. Adequate equipment should be available to conduct these procedures safely and staff should be trained in performing these procedures as part of their professional development. (expanding skill set within their scope of practice).

7.4.3.1 - Nurses follow protocols/checklists for complex procedures.

7.4.3.2 - Equipment for the provision of complex procedures meet the patient care needs.

7.4.3.3 - The staff is trained in performing complex procedures and guidelines on professional development are available.

7.4.3.4 - Wound care standard operating procedures (SOPs) are available.

SE07 - INPATIENT CARE

7.4 - Care processes and guiding documents

7.4.4 - Staff is guided in resuscitation to provide safe patient care in the ward.

Standard intent

Essential to providing critical interventions in case of a cardiac or respiratory arrest is the quick availability of standardized medical technology, medications for resuscitation, and staff properly trained in resuscitation. The health care facility should describe the level of resuscitation offered (basic vs advanced life support) and ensure that the required equipment and supplies are readily available. Resuscitation guidelines should be provided to guide the staff and outcomes of resuscitation should be monitored and evaluated to improve processes where needed.

7.4.4.1 - Resuscitation equipment and supplies meets the patient care needs and is regularly checked.

7.4.4.2 - There is a document guiding staff in the usage of resuscitation equipment and when/how to alert trained staff.

7.4.4.3 - Staff is trained on the usage of resuscitation guidelines.

7.4.4.4 - Implementation of guidelines and outcomes is monitored and reviewed.

SE07 - INPATIENT CARE

7.4 - Care processes and guiding documents

7.4.5 - Staff is guided in safe administration of oxygen to patients in the ward.

Standard intent

In-country requirements may apply as to which facilities should have oxygen. Generally, all facilities with inpatients and/or delivery rooms should have oxygen available. If oxygen therapy is delivered, the health care facility needs to ensure it is done appropriately, including putting in place safety precautions for storage of oxygen. There are several ways of delivering oxygen (piped, by cylinder or by oxygen concentrator), and staff members administering oxygen to patients should be qualified and orientated on specific guidelines describing when and how to use oxygen. Pulse oximetry is recommended when considering oxygen therapy.

7.4.5.1 - There is a document guiding staff how to administer oxygen.

7.4.5.2 - Oxygen supplies in the ward meet the patient care needs and are stored in accordance with local safety standards.

7.4.5.3 - Cylinder pressures (i.e. contents) are constantly monitored while patients are receiving oxygen.

7.4.5.4 - Correct implementation of guidelines can be observed in the ward.

SE07 - INPATIENT CARE

7.4 - Care processes and guiding documents

7.4.6 - A system is used to ensure that medications are administered correctly to the right patient at the right time.

Standard intent

Administering medication to treat a patient requires specific knowledge and experience. Each healthcare facility is responsible for identifying those individuals with the appropriate knowledge and experience and who are also permitted by licensure, certification, laws, or regulations to administer medications. A healthcare facility may place limits on medication administration by an individual, such as for controlled substances or radioactive and investigational medications.

Before medications are administered, it is important to properly identify the patient and verify all aspects of the prescription to avoid medication errors.

7.4.6.1 - Patients are identified before the medications are administered.

7.4.6.2 - Only those permitted by the health facility and by relevant laws and regulations administer medications.

7.4.6.3 - Medications are verified against the prescription, (including name, dosage, route of administration).

7.4.6.4 - Adverse drug reactions are monitored and reported in the patient's record and in the healthcare facility according to the national requirements.

SE07 - INPATIENT CARE

7.4 - Care processes and guiding documents

7.4.7 - Patient care is guided by clinical practice guidelines.

Standard intent

In order to provide good clinical services, it is important that up to date (clinical) guidelines are present for all of the services that are offered in the healthcare facility. These can be National Guidelines, WHO guidelines or guidelines provided by a recognized health institute. The relevant guidelines can be used for care and treatment activities and can be used as reference and training materials for all the staff in the healthcare facility. The guidelines need to be available where they are needed and care is provided in order to enhance frequent and consistent usage. Staff need to be orientated on which clinical guidelines are present and how/when to use them effectively. Correct implementation of clinical guidelines should be monitored as part of continues quality improvement of the health care facility.

7.4.7.1 - Clinical practice guidelines, are present for the services provided.

7.4.7.2 - Staff is orientated and can explain how and when to use the current clinical guidelines.

7.4.7.3 - Guidelines are reviewed and kept up to date.

7.4.7.4 - Staff is informed about the release of new clinical guidelines.

SE07 - INPATIENT CARE

7.4 - Care processes and guiding documents

7.4.8 - Patients and their family are activily involved in their care and recovery process.

Standard intent

This standard sees to ensure that health education to patients and their family is a standardized subject during inpatient care. Patients who have to pay for treatment should be informed about financial consequences of staying in the inpatient department or starting treatment. Patients and families need to receive education about the safe use of medication and medical equipment, and medicine/food interactions. Furthermore, staff needs to explain the risks and benefits of the planned procedure; identification of potential complications; and alternatives to the treatment/procedure offered. The patient and family need to be taught in a language and format that they can understand, so that they are able to give informed consent for the planned procedure. To ensure continuity of care for the individual patients, it is important to keep record of all information and education provided to each patient for future reference.

7.4.8.1 - Patients and their families are educated about financial implications of their decisions.

7.4.8.2 - There is evidence in the patient health record that the patient is educated on the health implications of their decision.

7.4.8.3 - Information regarding the condition or relevant high health risk is given to the patient and family in an understandable manner.

7.4.8.4 - Information given to the patient and family is recorded and signed in the patient's record.

SE07 - INPATIENT CARE

7.4 - Care processes and guiding documents

7.4.9 - Safe mobility of the patient is facilitated where possible to enable a speedy recovery.

Standard intent

Immobility of patients can lead to slow recovery and further complications like stiffness or pressure (bed) sores. In addition, being able to change position in bed, or around the ward, independently increases the feeling of wellbeing of patients. Standard measurements to prevent patients from falling should thus be implemented by the health care facility and equipment for mobilization should be in place. Guidance for staff to promote patient mobility should be available, including clear processes for accessing professional physiotherapy services, if required.

7.4.9.1 - Number and availability of devices for facilitating patients' mobility meet the patient needs.

7.4.9.2 - Number and availability of devices to prevent patients' falling meet the patient needs.

7.4.9.3 - There is a guideline that describes how to promote mobility of patients in order to prevent complications.

7.4.9.4 - Patients receive professional physiotherapy care and assistance with rehabilitation if required.

SE07 - INPATIENT CARE

7.4 - Care processes and guiding documents

7.4.10 - There is an organized process for appropriately discharging patients.

Standard intent

Referring or discharging a patient outside the health care facility, either another care setting, or home/family, is based on the patient's health status and needs for continuing care or services. The patient's physician or individual responsible for his or her care must determine readiness for discharge or when to refer to another care setting. In order to ensure continuity of care, guidelines for referral and discharge processes need to be available to guide the staff. If the patient is being discharged, the patient's family should be included in the planning, and instructions for follow-up visits must be clearly communicated and provided in writing to the patient and family.

7.4.10.1 - Adequate follow-up instructions are recorded on the discharge note upon discharge by the medical practitioner.

7.4.10.2 - There is a documented process for appropriately discharging patients.

7.4.10.3 - There is a list of referral facilities and staff can explain how continuation of care is organized.

7.4.10.4 - The patient (and their families when appropriate) understand the follow-up instructions upon discharge.

SE07 - INPATIENT CARE

7.4 - Care processes and guiding documents

7.4.11 - Staff is guided in measures to deal with deceased patients.

Standard intent

The health care facility should have policy in place how to deal with deceased patients and should describe the roles and responsibilities of health care staff. The hospital morgue unit should serve as an area for the viewing and/or identification of a body and the temporary holding/storage of bodies prior to transfer to a mortuary. To meet the needs of hospital staff and relatives of deceased, the lay out of the unit should provide a safe and private environment. There should be direct access from the hospital for the delivery of the body and the unit should secure bodies and personal belongings of the deceased. Sufficient infection control measures should be in place, that ensures an adequate PPE, appropriate method of storage (i.e. refrigerated cabinets, cool room), and adequate facilities for hand hygiene, sterilization and disposal of infectious equipment/waste.

7.4.11.1 - There is a policy or guideline on how to deal with deceased patients.

7.4.11.2 - Where there is a morgue unit, it has enough body storage capacity, has direct access from the healthcare facility.

7.4.11.3 - Where there is a morgue unit, it has sufficient infection control measures.

7.4.11.4 - Where there is a morgue unit, it offers adequate security for bodies and personal belongings of the deceased.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.1 - Management and staffing

8.1.1 - The surgery and anesthetic services are managed and performed by qualified care providers.

Standard intent

Country-specific regulations determine who is allowed to administer sedation and anesthetics (e.g. anesthetists, nurse anesthetists or clinical officer anesthetists) and who is allowed to conduct surgery.

The operating theatre in-charge needs to define staffing requirements, and must ensure all staff has job descriptions which clearly define scope and limitations to the responsibilities and activities of each staff member.

8.1.1.1 - Anesthesia is administered by a qualified anaethetist, who operates within their in-country accepted scope of practice.

8.1.1.2 - The theatre and recovery area is managed by a designated professional, who is suitably qualified and/or experienced.

8.1.1.3 - Surgery is performed and assisted by qualified staff who operate within their in-country accepted scope of practice.

8.1.1.4 - Recovery room care is provided by authorized qualified staff who operate within their in-country accepted scope of practice.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.1 - Management and staffing

8.1.2 - Surgical services are planned and coordinated.

Standard intent

Staff rosters need to be in in place and match the needs of the elective and emergency surgeries scheduled. Registered nurses need to be present during all shifts, for theatre duties, anesthetic assistance, and for recovery room duties. The schedule for elective surgery should be available in time (e.g. 12 hours prior to surgery) to allow theatre staff for adequate planning of the operation. For emergency surgery there must be an on-call schedule. The facility needs to set a response time frame for the staff (the time between the call to the time the emergency surgery can start).

8.1.2.1 - Operating theatre rosters ensure that qualified staff is present for theatre duties and anesthetic assistance.

8.1.2.2 - Surgery is planned and communicated with the relevant caregivers.

8.1.2.3 - The recovery room nurses are allocated for the entire recovery period.

8.1.2.4 - There is an on-call roster for emergency surgery with set response time frame.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.2 - Pre-operative care

8.2.1 - Prior to surgery, all relevant information is recorded to ensure safe practices.

Standard intent

Because anesthesia carries a high level of risk, administration needs to be carefully planned. A medical assessment needs to be done by the surgeon in order to select the appropriate surgical procedure and identify which findings during monitoring may be significant. The surgical care planned for the patient must be documented in the patient's record, including a preoperative diagnosis. The surgeon also need to ensure that the informed consent is collected, which includes that patient and family are educated on the risks, benefits, potential complications, and alternatives related to the planned surgical procedure. An anesthesiologist or another qualified individual needs to conduct the pre-anesthesia assessment to identify any airway problems, to select the anesthesia and to plan anesthesia care based on the assessment and type of procedure.

8.2.1.1 - A medical assessment is done by the responsible surgeon prior to surgery.

8.2.1.2 - Informed consent is obtained prior to surgery and anesthesia.

8.2.1.3 - A standardized anesthetic assessment by the anesthetist is done prior to surgery.

8.2.1.4 - A standardized nursing assessment is done prior to surgery.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.2 - Pre-operative care

8.2.2 - Appropriate care is made for patients awaiting surgery.

Standard intent

Whether patients await surgery just outside theatre (ideal situation) or in the ward, adequate monitoring equipment needs to be in place in order to provide safe care (e.g. stethoscope, clock with second hand, pulse oximeter, BP machine, thermometer), and staff needs to be guided in appropriate pre-op monitoring of vitals.

8.2.2.1 - There is a pre-operative area (surgery preparation room) for patients awaiting surgery.

8.2.2.2 - The pre-operative area is suitably equipped.

8.2.2.3 - There's a document guiding staff in pre-operative monitoring of vitals.

8.2.2.4 - The pre-operative monitoring of vitals are recorded.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.2 - Pre-operative care

8.2.3 - Staff is guided through an appropriate verification process for all patients prior to sedation.

Standard intent

The provision of safe anesthesia depends on careful preparation, which is facilitated by a systematic approach to reviewing the patient, equipment and medications. Verification prior to sedation focuses on the physiological stability and readiness of the patient for anesthesia and occurs immediately prior to the induction of anesthesia. This is a crucial step prior to surgery as it has been proved that it minimizes adverse outcomes. In addition to the personnel involved in delivering anesthetic, the anesthesia system includes:

• any machine or apparatus that supplies gases, vapors, local anesthesia or intravenous anesthetic agents to induce and maintain anesthesia;

• any equipment necessary for securing the airway;

• any monitoring devices necessary for maintaining continuous evaluation of the patient; and

• the patient himself or herself, correctly identified, consensual and evaluated preoperatively (e.g. verification of allergies, last oral intake, any required pre-operative medication, management of hypertension, availability of blood products, etc.)

8.2.3.1 - There is a document guiding staff in identifying patients, checking informed consent, and verifying nature and site of operation prior to sedation.

8.2.3.2 - Any allergies and administration of pre-operative medication (e.g. prophylactic antibiotics 60 min prior to surgery) is verified.

8.2.3.3 - The last oral intake is verified prior to sedation.

8.2.3.4 - A designated nurse/nurse in charge completes a checklist to ensure all staff and equipment is ready for surgery.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.3 - Operative care

8.3.1 - There are adequate assets in the operating theatre for providing safe care.

Standard intent

The operating room should be of an appropriate size, well ventilated and well lit, conform relevant electrical safety codes. Electricity should always be supplied, and a back-up electrical generator should be immediately available. Temperature control is ideally done by a system that balances humidity and ensures that temperatures stay within appropriate range. When this is not available a van should be in place, as well as equipment to cool patients and minimize heat loss.

8.3.1.1 - There is a functional operating theatre table.

8.3.1.2 - There is a good theatre lamp with a system that ensures continuous power supply.

8.3.1.3 - There is adequate ventilation and temperature control in the operating theatre.

8.3.1.4 - Equipment to cool patients and minimize heat loss is available.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.3 - Operative care

8.3.2 - There is adequate access to medication and supplies in each theatre.

Standard intent

The facility needs to define which medication and supplies should be stored in the operating theatre. Medication and supplies listed should be readily available, stored properly and safely, and checked in terms of expiry dates in order to ensure safe and effective service provision.

8.3.2.1 - The healthcare facility has emergency trolley supplies for the exclusive use of the anesthetist in each theatre.

8.3.2.2 - There is safe and adequate storage space for pharmaceutical and surgical supplies in the operating theatre.

8.3.2.3 - Medication in the operating theatre is kept at the temperature as described by manufacturer.

8.3.2.4 - Expiry dates of medication and supplies are checked regularly.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.3 - Operative care

8.3.3 - Staff is guided in the provision of anesthetic drugs and mixtures.

Standard intent

Guidelines need to be present to describing the preparation of pre-operative medication for patients for anesthesia, and the drugs used during the operation. Various combinations of drugs are possible, depending on the patient, type of operation or the skills of the anesthetic professional. Anesthesia can be given intravenously, using agents such as ketamine, or as inhaled mixtures of volatile gases. Provision and use of anesthetic mixture components and other peri-operative medication must comply with the guidelines of a professional society or similar reputable professional body.

8.3.3.1 - There is a document which guides staff in the use of anesthetic mixtures and conscious sedation.

8.3.3.2 - The procedures used comply with the current guidelines of a professional society or similar reputable professional body.

8.3.3.3 - Staff is orientated/can explain the guidelines.

8.3.3.4 - An administration is available that shows how anesthetic mixtures are prepared.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.3 - Operative care

8.3.4 - Staff is guided in the use of anesthesia delivery systems and breathing circuits.

Standard intent

There must be an anesthesia delivery system that is capable of delivering oxygen and medical air (where this is clinically indicated) as well as other anesthetic agents commonly used. Whichever system is used, it has to be approved by a relevant national authority, and staff needs to be orientated and guided by clear instructions on how to operate the system correctly.

8.3.4.1 - A breathing system (oxygen) is available to meet the patient needs, and is clean and in good condition.

8.3.4.2 - There is a document/instructions which guides staff in appropriate usage of the equipment, including cleaning procedure.

8.3.4.3 - The breathing system is included in the general maintenance activities or program.

8.3.4.4 - Records of maintenance activities are available.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.3 - Operative care

8.3.5 - Staff is guided in the use of ancillary equipment.

Standard intent

In addition to the anesthesia apparatus, ancillary equipment is required to manage emergencies such as trauma, eclampsia and cardiac arrest. Units for the care of children should have special pediatric equipment. Ancillary equipment includes devices such as face masks, laryngoscopes etc. that must be available to ensure adequate breathing. Whichever equipment and devises are used, they to be approved by a relevant national authority, and staff needs to be guided how to operate the equipment and devices.

8.3.5.1 - Sufficient ancillary equipment is available to meet the patient needs, and is clean and in good condition.

8.3.5.2 - The ancillary equipment is in compliance with current national or international guidelines of a professional society.

8.3.5.3 - There are instructions which guides the staff in the appropriate usage of the equipment, including cleaning procedure.

8.3.5.4 - Staff is properly trained and can explain the guideline.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.3 - Operative care

8.3.6 - Staff is guided in the process of monitoring patients during surgery.

Standard intent

Physiological monitoring provides reliable information about the patient's status during anesthesia and the recovery period. Results of monitoring trigger key intraoperative decisions as well as postoperative decisions, such as return to surgery, transfer to another level of care, or discharge. Equipment for monitoring may be integrated within the anesthesia machine or be provided as separate modules. One monitor can display a number of parameters or have a single function. The most important component of monitoring is the continuous presence of a trained anesthetist, whose expertise is augmented by the physiological information displayed on the monitoring devices. In addition to monitoring, careful continuous clinical observation is required, because the equipment may not detect clinical deterioration as rapidly as a skilled professional. The overall monitoring during anesthesia and surgery should be consistent with professional practice and usage of equipment defined in guidelines/instructions. The results of monitoring and which anesthesia/sedation is used needs to be documented in the patient's record.

8.3.6.1 - The anesthesia/sedation used and the results of monitoring are entered in the patient's anesthetic record and signed

8.3.6.2 - A qualified individual monitors the patient during the entire period of sedation and anesthesia.

8.3.6.3 - Adequate monitoring equipment is available to meet the patient needs, and is clean and in good condition.

8.3.6.4 - There is a document/instructions which guides the staff in appropriate usage of the monitoring equipment, including cleaning procedure.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.3 - Operative care

8.3.7 - Routine procedures during and post-surgery are implemented and documented.

Standard intent

To support a continuum of postsurgical supportive care, the information about the surgery is recorded in the patient's record immediately after surgery, prior to the patient being transferred from the surgical or the post-anesthesia recovery area. A summary of the operation includes a surgical count, the amount of blood lost and blood administered, type and amount of specimens sent to the lab, any adverse events and a post-surgical diagnosis.

In addition, some patients may require care from other services, such as physical therapy or rehabilitation. Therefore, it is necessary to plan for that care, including the level of care, follow-up monitoring or treatment

8.3.7.1 - A surgical count of swabs, needles and sharps is performed before incision and prior to cavity closure.

8.3.7.2 - There is a system for obtaining blood from and sending specimens to the laboratory and timely receiving results.

8.3.7.3 - A summary of the operation recorded in the patient file.

8.3.7.4 - A summary of the post-surgical plan is recorded in the patient file.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.3 - Operative care

8.3.8 - Staff is guided in emergency situations and resuscitation.

Standard intent

Whether patients await surgery just outside theatre (ideal situation) or in the ward, adequate monitoring equipment needs to be in place in order to provide safe care (e.g. stethoscope, clock with second hand, pulse oximeter, BP machine, thermometer), and staff needs to be guided in appropriate pre-op monitoring of vitals.

8.3.8.1 - Emergency resuscitation equipment and supplies are available.

8.3.8.2 - Emergency and resuscitation equipment and supplies have clearly defined instructions for use and staff is trained.

8.3.8.3 - Emergency resuscitation equipment is in working order and regularly checked.

8.3.8.4 - There is a telephone/intercom to communicate with persons outside the anesthetizing location.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.3 - Operative care

8.3.9 - Adequate safety measures are in place where radiation is used in the operation theatre.

Standard intent

Staff and patients need to be protected from any hazards in the operating theatre. Protective gear should be available and a document needs to guide staff in adequate usage to protect themselves for radiation. There must be appropriate warning notices on display in every area in the operating theatre complex, where X-ray is used.

8.3.9.1 - Sufficient PPE is available to protect staff from radiation.

8.3.9.2 - There is a document guiding staff when and how to use PPE in the presence of radiographic equipment.

8.3.9.3 - Staff can explain the proper use of radiation related PPE.

8.3.9.4 - Hazard or warning notices are displayed.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.4 - Post-operative Care

8.4.1 - There are adequate equipment/resources in the recovery area for providing safe care.

Standard intent

Recovery from anesthesia should take place close to the operating theatre. In case of an emergency (threatened airway, unstable vital signs, bleeding etc., it should be possible to wheel the patient back into the operating theatre immediately. The number of recovery beds has to match the caseload and capacity of the operating theatres. Minimal recovery room equipment must be available in the recovery area and instructions for use, including cleaning procedures should be in place to guide staff in order to ensure safe service provision.

8.4.1.1 - Sufficient recovery room equipment is available to meet the patient needs, and appears clean and in good condition.

8.4.1.2 - There is an adequate number of recovery beds and sufficient bedlinen for the patients coming from the operating theatre.

8.4.1.3 - There is a document/instructions which guides staff in appropriate usage of the equipment, including cleaning procedure.

8.4.1.4 - Staff is oriented/can explain guideline.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.4 - Post-operative Care

8.4.2 - Patients are monitored during recovery and discharged when appropriate.

Standard intent

Ongoing, systematic collection and analysis of data on the patient's status in recovery support decisions about moving the patient to other settings and less-intensive services. This decision must be authorized by the anesthetist and should be based on established criteria. When the patient is transferred directly from the operating theatre to a receiving unit, (can also be the ward), monitoring and documentation requirements are the same as would be required in a recovery room.

8.4.2.1 - Monitoring findings during recovery period are recorded and signed.

8.4.2.2 - There is a document/standardized form which guides staff in monitoring patients during the recovery period.

8.4.2.3 - Established criteria are used to make decisions regarding the patient's discharge from the recovery room.

8.4.2.4 - The anesthetist igns the discharge forms for approval.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.5 - Infection prevention and control (IPC)

8.5.1 - The design and access control of the surgery units are adequate for preventing infections.

Standard intent

The design of the department and the flow of patients, staff and supplies is important in terms of prevention of infections, as well as patient safety. The recovery area should be adjacent to the operating rooms in case of complications during recovery. Access to the theatre facility should be controlled by clear signs demarcating the line between 'dirty' and 'clean' and signs that ensure access to authorized staff only. Changing rooms for personnel should allow for storage of personal and "dirty" clothes before entering the semi-sterile area. The lay out of the operating facility should allow for an adequate flow of patients, staff and equipment from "dirty" to "clean". An area to disinfect equipment that was used during operations and to dispose of waste needs to be located as close as possible to the operating theatre to minimize the need for transportation of infectious materials.

8.5.1.1 - The design of the operating theatre and surrounding/assisting spaces provides space for the reception, anesthesia, surgery and the recovery of patients.

8.5.1.2 - Access to the theatre facility is controlled.

8.5.1.3 - Changing rooms are provided with wash and shower facilities and personal belongings can be stored safely.

8.5.1.4 - There is a disinfection area, with stainless steel sinks, running water, and a sewage system.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.5 - Infection prevention and control (IPC)

8.5.2 - Staff is guided in adequate prevention of inter-personal transmission of infections.

Standard intent

It is essential to have clear guidelines on attire and hand hygiene; guiding documents must be available in changing rooms and scrubbing area to guide and remind staff on appropriate hand washing practices and correct usage of PPE. Staff should be orientated to them to ensure safe and consistent practices.

8.5.2.1 - Staff is guided in the use of theatre clothing and PPE for theatre staff are available.

8.5.2.2 - Clean theatre clothes are available and are in good condition.

8.5.2.3 - Hand hygiene and hand washing guidelines (including scrub) are available.

8.5.2.4 - Staff is orientated/can explain processes and there is proof of correct implementation.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.5 - Infection prevention and control (IPC)

8.5.3 - Staff is guided in adequate disinfection measures.

Standard intent

Between cases, the operating room should be cleaned and disinfected, instruments are re-sterilized and fresh linen should be provided. At the end of each day, the operating room has to be cleaned starting at the top and continuing to the floor ("top to down") and "out to in". A clean mop must be used in each theatre every day. Infectious and non-infectious waste should be managed properly. There should be appropriate facilities to disinfect equipment that was used during operations, and the waste water that is produced during disinfection needs to be safely disposed of. (Cleaning) staff needs to be orientated to the guidelines for safe service provision.

8.5.3.1 - There is a procedure that describes cleaning and disinfection practices for all equipment and surfaces in the operation theatre and related areas and staff is aware.

8.5.3.2 - A cleaning schedule is available and kept current.

8.5.3.3 - Sufficient cleaning materials (e.g. various colors of mops) are available and stored appropriately.

8.5.3.4 - Staff (including cleaning staff) is orientated and trained on the cleaning and disinfection procedures.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.5 - Infection prevention and control (IPC)

8.5.4 - The design and facilities of the sterilization area are adequate.

Standard intent

The operation theatre needs to have access to sterilization equipment which is in line with the size of the healthcare center and the services provided. Achieving sterility, particularly for reusable surgical instruments, requires a sequence of cleaning and mechanical removal of gross contamination, inspection and assembly, packaging, sterilization, storage, transport and delivery to the operating room, and certification of the sterilization process. The design of the sterilizing and disinfecting unit, must ensure flow of work from the soiled to the clean side of the unit. The status of a piece of equipment/linen must always be clear, and dirty, clean and sterile must never be mixed. After sterilization, the sterile packs need to be stored in a way that reduces any risks of contamination.

Moisture in the paper/linen that covers the packs, results in a very easy point of entry for bacteria, so this should always be avoided (by ensuring adequate circulation of air/ventilation).

8.5.4.1 - The sterilization area(s) enable a workflow from soiled to clean and areas for dirty, clean and sterile equipment/materials are clearly demarcated.

8.5.4.2 - There is access to sterilization equipment (autoclave or equivalent) which is functional and sufficient for the workload.

8.5.4.3 - There is sufficient storage capacity for sterilized materials.

8.5.4.4 - The area where sterilized materials are stored is well ventilated.

SE08 - OPERATING THEATRE AND ANAESTHETIC SERVICES

8.5 - Infection prevention and control (IPC)

8.5.5 - Staff is guided in sterilization procedures to prevent infections.

Standard intent

Despite the brief amount of time patients generally spend in an operating theatre, this is an environment that plays a great role in the onset and spread of infections. Materials such as surgical equipment, gowns, gauzes etc. need to be cleaned before packaged for autoclaving, and these clean, but not yet sterilized materials, need to be kept in a dedicated clean place, so there is no mix-up with dirty materials. Protocols should be provided by the facility to guide the staff in appropriate wrapping and handling of sterile packs and instructions should be to in place on how to operate the autoclave. This includes how to use autoclave tape for each individual pack, and how frequently autoclave sterility should be checked.

8.5.5.1 - Staff is aware of correct wrapping, handling and checking sterility of packs.

8.5.5.2 - The date of sterilization is recorded on the sterile pack.

8.5.5.3 - Autoclave sterility is tested daily and the results are recorded.

8.5.5.4 - All relevant staff is orientated and trained in disinfection and sterilization procedures.

SE09 - LABORATORY SERVICES

9.1 - Management and staffing

9.1.1 - The laboratory is managed by qualified care providers.

Standard intent

The laboratory service is under the direction of an individual who is qualified and has documented training, expertise and experience, in accordance with applicable laws and regulations. This individual has professional responsibility for the laboratory facility and for the services provided. The responsibilities of the laboratory director include:

• Developing service-related policies and procedures and ensuring that they are implemented and reviewed regularly.

• Managing relevant human resource functions, e.g. job descriptions, staff evaluation, staff training.

• Developing, coordinating, and monitoring the required quality control and improvement systems.

The laboratory staff is identified based upon their education, training, qualifications, and experience for laboratory staff members performing and interpreting laboratory tests, those who are approved to perform point-of-care screening tests at the bedside, and those who direct or supervise staff who perform testing. Supervisory staff and technical staff are oriented to their work. Technical staff are given work assignments consistent with their training and experience. Records of trainings are kept.

Specialty and subspecialty laboratory services are under the direction of appropriately qualified individuals.

9.1.1.1 - A designated qualified staff member is responsible for managing the laboratory.

9.1.1.2 - The qualifications of the laboratory staff members correspond with the scope of practice.

9.1.1.3 - New laboratory staff members are orientated on relevant topics.

9.1.1.4 - Records are kept of the training (CME) provided.

SE09 - LABORATORY SERVICES

9.1 - Management and staffing

9.1.2 - Laboratory services are managed and performed in a coordinated manner.

Standard intent

In order to provide effective and efficient laboratory services there are requirements that have to be addressed.

The number of staff needs to be matched with the patient load and utilization. The standards sees to ensure that sufficient staff is available to provide the required laboratory services, because understaffing could have a direct effect on the quality of the laboratory results.

Next to the regular laboratory services emergency services are available in order to ensure that the projected healthcare and related laboratory services is guaranteed.

Overviews of the number of tests performed and the related results can play an important role in decision making within a healthcare facility. It could provide information on the needs for the next period and could have an effect on stock and financial forecasting. The utilization figures in relation with the positivity rate could have implications on medical decision processes.

9.1.2.1 - There are sufficient laboratory staff members to meet the patient needs.

9.1.2.2 - Emergency laboratory services are available, including after-hours services.

9.1.2.3 - Weekly and/or monthly overviews are prepared with total number of tests performed, including positivity rates (HIV, STI, TB etc.).

9.1.2.4 - Weekly/monthly overviews are shared with appropriate staff members in the facility for review.

SE09 - LABORATORY SERVICES

9.2 - Infection prevention and control (IPC)

9.2.1 - The infrastructure of the laboratory is adequate for preventing infections.

Standard intent

The laboratory infrastructure has to comply to the (inter) national laws and regulations. In order to provide a safe environment to the laboratory staff and to ensure that the laboratory services are performed adequately the laboratory infrastructure has to comply the following requirements:

- The size of the laboratory is appropriate for the projected services and available staff
- The different laboratory services and activities are separated.
- The laboratory is constructed with proper materials and is in a good condition.
- Sufficient hand washing facilities are available.

9.2.1.1 - The lay-out of the laboratory service is in line with the in-country regulations

9.2.1.2 - The size and bench space of the laboratory is appropriate for the services provided.

9.2.1.3 - Materials used for floors, benches and sinks are in line with the in-country regulations (e.g. easy to clean, no cracks).

9.2.1.4 - Dedicated hand washing facilities including water are available in the laboratory.

SE09 - LABORATORY SERVICES

9.2 - Infection prevention and control (IPC)

9.2.2 - Adequate precautions are taken to prevent infections for staff and patients in the laboratory.

Standard intent

In a laboratory biological materials are processed and analyzed. The handling of biological specimens requires specific safety precautions that allows for the protection of the laboratory staff, including other healthcare facility staff and visitors.

In order to prevent infections the laboratory has to implement specific safety measures and precautions.

Safety measures that should be in place are:

- Ensure that the laboratory is only accessible for authorized staff.
- Ensure that the laboratory is well ventilated.
- Ensure that proper hand washing materials are available.
- Ensure that PPE [Personal Protective Equipment] is available (gloves, lab coats, etc.)

9.2.2.1 - Adequate PPE is available for the laboratory staff (gloves, lab coats, etc.).

9.2.2.2 - Access to the laboratory is controlled.

9.2.2.3 - The laboratory area is well ventilated, enabling safe laboratory practices.

9.2.2.4 - Soap and single use (paper) towels are available for hand washing.

SE09 - LABORATORY SERVICES

9.2 - Infection prevention and control (IPC)

9.2.3 - Staff is guided in procedures to prevent infection.

Standard intent

In order to guide the laboratory staff on infection prevention control (IPC) measures clear guidance and instructional documentation should be available. In order to ensure that IPC is effective and standardized it is essential that several laboratory processes are guided, and staff aware of these. The key processes for which guidance documentation should be available are:

- Guidance on the use of PPE (Protective and Preventive Equipment)
- Guidance on cleaning
- Guidance on (biological) waste management
- Guidance on how to act when staff is exposed to infectious agents (e.g. PEP procedure when a needle stich accident has occurred.

An assigned staff member that is responsible for the development of an infection prevention control (IPC) program, training and monitoring can ensure constant adherence.

9.2.3.1 - There is a document guiding staff in waste segregation and disposal.

9.2.3.2 - Staff can explain appropriate use of PPE.

9.2.3.3 - Staff can explain the cleaning and decontaminating processes.

9.2.3.4 - Staff can explain appropriate measures after expose to infectious agents.

SE09 - LABORATORY SERVICES

9.3 - Diagnostic processes and guiding documents

9.3.1 - Staff is guided in the process of safe specimen collection.

Standard intent

The healthcare facility needs to ensure that patient specimens can be collected at all times, can be collected and processed in a safe and organized manner and that the patient information and corresponding request forms are registered in an orderly manner. To this end, the following requirements apply:

- The supplies and materials are adequate to provide a safe and effective specimen collection
- There are guiding documents such as standard operating procedures for safe specimen collection and processing and specimen rejection and acceptance.
- Laboratory request forms are used on which patient specific information is available with the request for the specific assay(s).
- A dedicated administration should be available in which relevant patient information and requests are kept.

9.3.1.1 - Sufficient supplies are available in the specimen collection area to enable safe practices.

9.3.1.2 - There are guiding documents for safe handling of specimens.

9.3.1.3 - Specimens are appropriately processed (centrifuged and stored).

9.3.1.4 - Laboratory request forms are available and contain relevant information.

SE09 - LABORATORY SERVICES

9.3 - Diagnostic processes and guiding documents

9.3.2 - Staff is guided on proper patient and specimen identification processes.

Standard intent

It is essential that the correct results are reported for each patient in order to ensure that the diagnosis and subsequent treatment of the patient is correct. Proper identification of patients and laboratory specimens is very important in order to ensure that the correct specimens are processed and that the patient specific results are reported. There are several aspects that have a direct effect on the identification of patients and.

- Are the specimens appropriately labeled?
- Are the specimens appropriately checked before testing?
- Is there a patient identification process?
- Are the specimens, patient information and results registered in an organized manner?

9.3.2.1 - There are guiding documents for the labelling of specimens throughout the specimen processing activities and are followed.

9.3.2.2 - Patients are identified during the specimen collection and reporting process

9.3.2.3 - Specimens information and results are registered in an organized manner.

9.3.2.4 - Relevant patient information and results are registered in an organized manner.

SE09 - LABORATORY SERVICES

9.3 - Diagnostic processes and guiding documents

9.3.3 - Staff is guided to perform the laboratory tests provided .

Standard intent

In order to ensure that the laboratory tests provide quality results several requirements have to be in place. For each assay in the service package it is required that:

- SOPs are in place for each assay/test performed. In the SOP the specific steps are described that ensures that the test is performed consistently which results in a uniform and guaranteed quality. An SOP is also used as training documentation and should be used as a resource for the training of new staff. All available documentation is brought together in a laboratory manual.
- There are sufficient products, consumables and reagents available in order to provide the specific and projected number of laboratory tests provided.
- Quality control activities are in place (addressed in other standard)

9.3.3.1 - There is an SOP for each assay/test performed in the laboratory.

9.3.3.2 - There are sufficient kits, reagents and materials to perform the laboratory assays required to meet the patient needs.

9.3.3.3 - Staff can explain the procedures for the laboratory services provided.

9.3.3.4 - There is an organized laboratory manual in which SOPs and related documentation are filed and kept up to date.

SE09 - LABORATORY SERVICES

9.3 - Diagnostic processes and guiding documents

9.3.4 - Essential laboratory equipment is available and used appropriately.

Standard intent

The laboratory and laboratory staff needs to ensure that all equipment and medical technology, including medical devices used for (point-of-care) testing are available and functions at acceptable levels and in a manner that is safe to the operator(s). The laboratory leader is responsible to ensure that several requirements are in place in order to guarantee that the equipment is working appropriately. The next points need to be in place:

- The laboratory equipment and related medical technology is appropriate for the projected laboratory services in relation to the facility/patient needs;
- There is an inventory of laboratory equipment available;
- The instruments are kept in good/clean condition, maintenance is performed and controlled appropriately;
- Clear operating instructions are available and staff is appropriately trained

9.3.4.1 - Sufficient laboratory equipment is available to meet the patient needs, and are clean and in good condition.

9.3.4.2 - There is a document/instructions which guides the staff in appropriate usage of the equipment.

9.3.4.3 - There is a document/instructions which guides the staff in appropriate cleaning and/or maintenance of the equipment.

9.3.4.4 - Cleaning schedule, maintenance and control logs (where relevant) are kept current (incl. fridge).

SE09 - LABORATORY SERVICES

9.3 - Diagnostic processes and guiding documents

9.3.5 - A stock management system is in place that guarantees efficient and quality laboratory services.

Standard intent

This standard sees to ensure that laboratory products are kept in stock and quality is ensured. The quality and identification of laboratory products is essential for the provision of good laboratory services. Therefore the products have to be kept according the storage requirements, such as temperature and storage environment (e.g. dark), specified by the manufacturer's instructions, that the products are not used after the projected expiry date and that the laboratory products are appropriately labeled and dated. Processes have to be in place that guide the staff on these specific matters. A stock management system ensures the current assets (=inventory) for all individual laboratory tests is known at all times. An SOP should be in place that lists all laboratory items, including manufacturers and package sizes. The SOP should also define how often stock taking of current assets should take place, which information should be captured, and how this information is issued for procurement/stock keeping purposes. The following information should be captured and kept current:

- Product specifications (supplier, manufacturer, product name, catalog number, unit size
- Cost, date of purchase and expiry date of each item
- Quantity of each item in stock on a specific day (preferably specified as; non-expired, close to expired, expired)

9.3.5.1 - All reagents are stored and labelled according to manufacturers' instructions/directives or guiding document.

9.3.5.2 - The laboratory listed all reagents, chemicals, kits and other consumables that are required for the projected services.

9.3.5.3 - Staff keeps track of current stock in the laboratory.

9.3.5.4 - Records of regular expiry checks are kept current, and items expiring shortly are marked.

SE09 - LABORATORY SERVICES

9.3 - Diagnostic processes and guiding documents

9.3.6 - Quality control/assurance activities regarding assays/test are performed.

Standard intent

The quality of the laboratory services can be monitored using both internal and external quality control approaches. Designing and implementing internal and external quality control processes and activities is essential for assuring that the laboratory results are of good quality.

Quality control/assurance is ensured when

- test methods are validated for accuracy, precision and reportable range;
- daily surveillance of results is performed by qualified laboratory staff;
- there are deficiencies identified and that rapid corrective actions (CA) is performed and documented
- reagents used for laboratory tests are tested

There are different quality control /assurance processes. They can be divided into internal and external control processes. For both processes clear instructions, SOPs, should be available. In the SOPs details on the range and frequency of the internal controls, frequency of proficiency testing (confirmation) when mandatory by national law and regulations, or how participation in external quality control programs is organized are defined.

Proficiency testing determines how well an individual laboratory's results compare with other laboratories that use the same methodologies. Such testing can identify performance problems not recognized by internal mechanisms. Thus, the laboratory participates in an approved proficiency testing program when one is available. Alternatively, when approved programs are not available, the laboratory exchanges samples with a laboratory in another facility for peer comparison testing purposes. The laboratory maintains a cumulative record of participation in a proficiency testing process.

9.3.6.1 - Internal quality controls (IQC) are performed and recorded for each assay/test to verify reagent/kit quality.

9.3.6.2 - There is a documented quality control program in which all quality control aspects are defined.

9.3.6.3 - The laboratory participates in an external quality control (EQC), like a proficiency-testing program or an alternative, for all (specialized) laboratory tests.

9.3.6.4 - The laboratory keeps and maintains records of all the results of the IQA and EQA activities and the related corrective actions (CA).

SE09 - LABORATORY SERVICES

9.3 - Diagnostic processes and guiding documents

9.3.7 - Reporting of reliable results is performed appropriately and timely.

Standard intent

Laboratory test results need to be reliable and reported in a appropriate and timely manner.
Test results that are reported need to be reliable and therefore post examination instructions have to be available. Post-examination instructions should provide information on reporting the results, including the unit of measurement to be used, the normal (reference) range, ranges that are life-threatening (sometimes called “panic values”) and instructions for how to deal with an urgent report. They should also include references to the published sources of the procedures, including published evidence that the procedures are scientifically valid.
Test results have to be reported within a specific time frame in order to guarantee that the diagnosis can be performed as quickly as possible.
Several aspects are important to provide an appropriate and timely result. Such as:
- The results of the laboratory assays are registered in specific logbooks in an organized and orderly manner.
- The turnaround times (TAT) for laboratory tests (in-house and referral) are defined.
- The results are reviewed and validated as described in the specific assay SOPs.
- Reference and critical values are defined

9.3.7.1 - Results are being registered in a log-book in an orderly manner.

9.3.7.2 - Results are being reviewed and validated according to assay specific SOPs.

9.3.7.3 - The laboratory has established reference ranges and critical values for all relevant tests.

9.3.7.4 - Turn-a-round times for in-house laboratory tests,as well as those for referral services, are established.

SE09 - LABORATORY SERVICES

9.3 - Diagnostic processes and guiding documents

9.3.8 - Referral services are available and appropriately arranged.

Standard intent

A referral system needs to be in place in order to provide the laboratory services that cannot be performed within the health facility or when a specific test cannot be performed in case of unexpected shortage of staff (due to illness/absence), in case there is an unforeseen stock out of essential materials or in the case the specific instruments needed are out of order.

In order to provide a good referral process, some essential requirements have to be in place, such as:

- A list of referral services that is up to date and contains all relevant information from the referral laboratory (contact details, list of referral services/tests, turnaround times and related prices). The selection of referral laboratories can be guided by reviewing performance of the referral laboratories or by selecting a recognized laboratory (one that is accredited or in a certification program that has been reviewed and endorsed by a laboratory professional society or governmental or private agency).
- Guidance on how specimens are packaged and transported to the referral laboratory.
- A dedicated specimen register in which details are kept of which specimens are sent for referral, when they are sent, when the result was reported back etcetera.
- A system is in place in which the performance of the referral laboratory is monitored. Examples of a monitoring topics are response times, critical result reporting and problems with specimens such as missing identifiers or specimen rejection. The results of the monitoring process are used in order to define appropriate corrective or preventive actions.

9.3.8.1 - A referral register for the referred specimens is kept.

9.3.8.2 - Referral forms are available and used.

9.3.8.3 - There are guiding documents for packaging specimens and transporting them to the referral laboratories.

9.3.8.4 - A list of referral laboratories and laboratory services is available.

SE09 - LABORATORY SERVICES

9.3 - Diagnostic processes and guiding documents

9.3.9 - Staff is guided in providing safe blood transfusion services.

Standard intent

Blood banking and transfusion services need to be compliant to the applicable laws and regulations. Blood banking services and distribution is part of the responsibility of the local government but the healthcare facility is responsible for the storage and internal distribution process.

If and when the laboratory is the department that is assigned to store and distribute the blood products for blood transfusion, the following requirements need to be in place:

- a dedicated blood transfusion refrigerator for blood (product) storage with back-up, temperature control measures and current log;
- a dedicated blood transfusion administration is in place in which details about the transfusion products are recorded.
- a process for blood access and distribution in both planned and emergency situations;

Quality control processes for all transfusion services are established, implemented, and documented to ensure the safety of transfusion services.

9.3.9.1 - There is a dedicated and functioning refridgerator for blood products and back-up is arranged.

9.3.9.2 - Temperature control measures are in place and logs are kept current.

9.3.9.3 - There is a process in place for accessing blood in planned (and emergency) situations.

9.3.9.4 - There is a dedicated administration related to blood transfusion products.

SE10 - DIAGNOSTIC IMAGING SERVICE

10.1 - Ultrasound

10.1.1 - Staff and referral arrangements are adequate for safe provision of Ultrasound (US) services.

Standard intent

The healthcare facility identifies those staff members who may perform ultrasound procedures and those who may interpret and report the findings. These staff members have appropriate and adequate training, experience and skills, and are oriented to their work. There are enough staff members to provide the necessary staffing during all hours of operation and for emergencies and/or referral.

The healthcare facility is able to identify and contact emergency referral sources, when the need for such services arises.

10.1.1.1 - US procedures are performed only by individuals with proper and specific training.

10.1.1.2 - US services are available for the level of care provided at the helathcare facility.

10.1.1.3 - There is an adequate number of qualified/trained staff to meet the patient needs.

10.1.1.4 - Referral US services are available, also for services to be provided outside normal operating hours.

SE10 - DIAGNOSTIC IMAGING SERVICE

10.1 - Ultrasound

10.1.2 - Ultrasound system and supplies are adequate for safe Ultrasound (US) service delivery.

Standard intent

In order to provide safe and reliable ultrasound services, the required infrastructure and systemt needs to be available and maintained. Ultrasound personnel work to ensure that all equipment functions at acceptable levels and in a manner that is safe for the operator(s). A diagnostic imaging management program provides for:

• selecting and acquiring equipment and supplies

• an SOP for correct operation of the equipment

• monitoring equipment use through inspection, testing, calibration and maintenance

10.1.2.1 - US system (and supplies) are available and is sufficient to meet the patient needs.

10.1.2.2 - There is an SOP or checklist to guide staff in correctly operating the US equipment.

10.1.2.3 - US equipment is maintained in accordance with manufacturer's instructions.

10.1.2.4 - US equipment is tested and calibrated in accordance with manufacturer's instructions.

SE10 - DIAGNOSTIC IMAGING SERVICE

10.1 - Ultrasound

10.1.3 - Staff is guided for safe and efficient Ultrasound (US) service delivery.

Standard intent

The quality and performance of ultrasound services is dependent on adequate operational guidance. Procedural guidance should at least be available for:

- Requirements for a request form
- Requirements for operational processes (including safety)
- Requirements for reporting results
- Requirements for filing results

10.1.3.1 - US requests contain the required information.

10.1.3.2 - There is an SOP or checklist to guide staff in recording and reporting of US results.

10.1.3.3 - An US safety manual (describing potential safety risks and hazards) is available.

10.1.3.4 - Results of US findings are included in patient files and contain a clear conclusion.

SE10 - DIAGNOSTIC IMAGING SERVICE

10.2 - X-ray

10.2.1 - Staff and referral arrangements are adequate for safe provision of X-ray services.

Standard intent

Country specific requirements determine for which level of health care facility the provision of X-ray services is mandatory (e.g. district/tertiary/teaching hospital). In addition, in-country safety, staffing and license requirements regulate safe X-ray services if lower level health care facilities are offering the service. The organization identifies those staff members, who may perform procedures and those who may interpret X-ray films and report the findings. These staff members have appropriate and adequate training, experience and skills, and are oriented to their work. Radiographers are given assignments consistent with their training and experience. There are enough staff members to provide the necessary coverage during all hours of operation and for emergencies and/or referral. The healthcare facility is able to identify and contact emergency referral sources, when the need for such services arises.

10.2.1.1 - X-ray services are available for the level of care provided at the healthcare facility .

10.2.1.2 - The X-ray department is managed by a qualified individual with specific training.

10.2.1.3 - There is an adequate number of qualified/trained staff to meet the patient needs.

10.2.1.4 - Referral X-ray services are available, also for services to be provided outside normal operating hours.

SE10 - DIAGNOSTIC IMAGING SERVICE

10.2 - X-ray

10.2.2 - Infrastructure and equipment is adequate for safe X-ray service delivery.

Standard intent

In order to provide safe and reliable X-ray services, the required infrastructure and equipment needs to be available and maintained. X-ray personnel work to ensure that all equipment functions at acceptable levels and in a manner that is safe for the operator(s). The layout and available infrastructural precautions enable safe operations. A radiology equipment management program provides for:

• selecting and acquiring equipment;

• an SOP for correct operation of the equipment

• monitoring equipment use through inspection, testing, calibration and maintenance

10.2.2.1 - X-ray equipment is available and sufficient to meet the patient needs.

10.2.2.2 - The layout and available infrastructural safety precautions enable safe service provision.

10.2.2.3 - X-ray equipment is maintained in accordance with manufacturer's instructions.

10.2.2.4 - X-ray equipment is tested and calibrated in accordance with manufacturer's instructions

SE10 - DIAGNOSTIC IMAGING SERVICE

10.2 - X-ray

10.2.3 - X-Ray supplies are adequate for safe and efficient service delivery.

Standard intent

In order to provide the projected radiology services, essential supplies have to be available. The facility has to identify the quantities and products (e.g. such as x-ray films) necessary to provide a reliable radiology service to its patients. There is an effective process for ordering reagents and other supplies and all supplies are stored, labelled and dispensed in accordance with defined procedures. Periodic evaluation of (expiry of) reagents needs to be performed and logged in order to ensure that the products provide accurate and precise results.

10.2.3.1 - Adequate supplies (films, other reagents) are available to provide regular X-ray services.

10.2.3.2 - All reagents and solutions are properly stored and accurately labelled

10.2.3.3 - Expiry checks are performed on X-ray supplies and results recorded

10.2.3.4 - The facility has prepared a list with essential supplies for X-ray services.

SE10 - DIAGNOSTIC IMAGING SERVICE

10.2 - X-ray

10.2.4 - Radiation safety measures are in place.

Standard intent

The healthcare facility has an active radiation safety program that includes all components of the healthcare facility radiology services. The radiation safety program reflects the risks and hazards encountered. The program addresses safety practices and prevention measures for radiology staff, other staff and patients. The program is coordinated within the safety management program of the healthcare facility.

The radiation safety management program includes:

• Compliance with applicable standards, laws, and regulations;
• Compliance with standards addressing facility management and infection control programs;
• Availability of safety protective devices appropriate to the practices and hazards encountered;
• A radiation safety manual (describing potential safety risks and hazards, including waste)
A safety manual guides staff in daily routine practices, and can also be used for orientation purposes for new radiology staff.

10.2.4.1 - A copy of the local rules related to the Ionizing Radiation Regulations is available. and are followed.

10.2.4.2 - Appropriate PPE is available for staff to reduce safety risks (e.g. lead aprons, radiation badges).

10.2.4.3 - A radiation safety manual (describing potential safety risks and hazards, including waste disposal) is available

10.2.4.4 - A copy of the most recent radiation safety report is available.

SE10 - DIAGNOSTIC IMAGING SERVICE

10.2 - X-ray

10.2.5 - Staff is guided for safe and efficient service delivery.

Standard intent

The quality and performance of X-ray services is dependent on adequate operational guidance. The facility needs to have the relevant standard operation procedures (SOPs) in place in order to provide proper guidance and to orient all new X-ray staff on it. The X-ray department performs periodic quality and safety control checks and keeps records of outcomes. These are used for corrective and ultimately preventive actions in order to enable continuous quality improvement of the X-ray service provided.

10.2.5.1 - There is an SOP or checklist to guide staff in correctly operating the X-ray equipment.

10.2.5.2 - There is an SOP or checklist for quality and safety controls for the X-ray department and records of results are kept.

10.2.5.3 - Staff are oriented to all relevant procedures and practices and receive conitinuous medical education.

10.2.5.4 - Quality and safety control outcomes are used for corrective and preventive actions.

SE10 - DIAGNOSTIC IMAGING SERVICE

10.2 - X-ray

10.2.6 - Reporting, interpretation and storage of X-ray results is performed adequately.

Standard intent

The healthcare facility identifies those staff members who may perform X-ray procedures and those who may interpret and report the findings. The quality and performance of X-ray services is dependent on adequate operational guidance. Procedural guidance should at least be available for:

- Requirements for a request form
- Requirements for interpretation and reporting of results
- Requirements for filing results
- Requirements for operational processes, including a system to consult with external experts

10.2.6.1 - X-ray requests contain the required information.

10.2.6.2 - X-ray films are interpreted by qualified staff and result of findings are included in the patient files.

10.2.6.3 - X-ray reports contain a clear conclusion.

10.2.6.4 - The healthcare facility has a system to contact experts in specialized diagnostic imaging areas when needed.

SE11 - MEDICATION MANAGEMENT

11.1 - Management and staffing

11.1.1 - Medication use is managed and organized to enable safe service delivery to meet the patient needs, complies with applicable laws and regulations and is under the direction of a qualified individual.

Standard intent

Medications, as an important resource in patient care, must be organized effectively and efficiently. Medication management is not only the responsibility of the pharmaceutical service but also of managers and health care practitioners. How this responsibility is shared depends on the facility's structure and staffing. In those cases in which a pharmacy is not present, medications may be managed on each clinical unit according to facility policy. In other cases, where there is a central pharmacy, the pharmacy may organize and control medications throughout the facility.
Effective medication management includes all parts of the facility, inpatient, outpatient, and specialized units if applicable. In all case, a qualified individual directly supervises the activities of the pharmacy or medication service. The individual is trained and, if required, appropriately licensed and/or certified. Applicable laws and regulations are incorporated into the organizational structure and the operations of the medication management system used in the healthcare facility.
A healthcare facility should develop policies and procedures to guide processes regarding medication management:

- safe prescribing, ordering, transcribing and administering medications in the facility;
- scope and limitations to the responsibilities and activities of the staff who handle medication
- documentation requirements;
- the use of non-written medication orders;
- the availability and use of medication samples;
- documentation and management of any medications, brought into the facility for or by the patient;
- self-administration of medication by the patient;
- dispensing of medications at the time of the patient's discharge;
- preparing, handling, storing and distributing parenteral and enteral nutrition products;
- storing, handling, distributing and dispensing hazardous medications;
- the security of staff, equipment and stock.

11.1.1.1 - A designated, licensed individual directly supervises the activities of the pharmacy or pharmaceutical service.

11.1.1.2 - Job descriptions clearly define scope and limitations to the responsibilities and activities of the staff who manage medications.

11.1.1.3 - A written document identifies how medication use is organized and managed throughout the healthcare facility.

11.1.1.4 - Key members of staff regularly meet to discuss medication management.

SE11 - MEDICATION MANAGEMENT

11.2 - Stock selection and procurement

11.2.1 - An appropriate selection of medications are in continuous supply or readily accessible at all times.

Standard intent

Every healthcare facility must decide which medications to make available for prescribing and ordering by the health care practitioners. This decision is based on the facility's mission, patient needs, and types of services provided. The facility develops a list (often referred to as a formulary) of all the medications it stocks or that are readily available from outside sources. In some cases, laws and regulations may determine the medications on the list or the source of those medications. Medication selection is a collaborative process that includes patient need and safety as well as economics. Medications are occasionally out of stock due to delayed delivery, national shortages, or other reasons not anticipated through normal inventory control.

On occasion, medications are needed which are not stocked or readily available to the healthcare facility. The facility must have a process to approve and procure such medications. Also, there are occasions when medications are needed during the night or when the pharmacy is closed. Each facility needs to plan for these occurrences and educate staff on procedures to follow in the event they occur.

11.2.1.1 - Drugs for the top 10 (most common) diagnosis in the helathcare facility are available.

11.2.1.2 - There is an up to date list of medications that are kept in stock.

11.2.1.3 - There is a (manual or automated) stock management system to ensure that minimum and maximum stock levels are maintained.

11.2.1.4 - There is a process for healthcare workers to obtain medicines within the facility during the night or when the pharmacy is closed.

SE11 - MEDICATION MANAGEMENT

11.2 - Stock selection and procurement

11.2.2 - Medications are procured according to guidelines that ensure safety and effectiveness.

Standard intent

The medication procurement process must be carefully followed to ensure that medicines remain in good condition so that they will be most effective. In order to ensure that medications are not damaged or tampered with during procurement and transportation, a healthcare facility should work with a set of approved suppliers that understand the importance of maintaining medicine at the appropriate temperature. When medications or medical devices are recalled by the manufacturer (supplier), it is important to remove these materials from circulation as soon as possible.

11.2.2.1 - A procurement guideline is available conform to country-specific requirements, regarding specific agents and preferred/approved suppliers.

11.2.2.2 - Where facility staff transports procured medications themselves, they are guided to ensure this is done according to manufacturers' instructions.

11.2.2.3 - There is a system which allows for effective recalling of drugs and medical devices (e.g. laboratory kits) distributed in the facility when required.

11.2.2.4 - There is evidence that the medication is procured at preferred suppliers only.

SE11 - MEDICATION MANAGEMENT

11.3 - Control and storage of medication

11.3.1 - Adequate storage area(s) and equipment are available for the safe and effective storage of medications (including medical consumables).

Standard intent

Medications may be stored within a storage area, in a pharmacy or pharmaceutical service, or on the patient care units in unit pharmacies or the nursing station in the clinical unit. In all locations where medications are stored, the facilities must ensure that stored medications everywhere:

- can be accessed efficiently;
- are protected from loss, misuse or theft;
- are stored under conditions suitable for product stability;

11.3.1.1 - The main storage area is protected from heat and light and the temperature is monitored and effectively regulated.

11.3.1.2 - Medications are stored in a lockable storage area or cabinet, which is accessible only to authorized staff.

11.3.1.3 - The size and layout of the storage area(s) is appropriate for the services provided and is well ventilated.

11.3.1.4 - Where necessary, a dedicated refrigerator for medication is available and the temperature is monitored.

SE11 - MEDICATION MANAGEMENT

11.3 - Control and storage of medication

11.3.2 - Medication in store in the dispensing area are properly labelled.

Standard intent

The healthcare facility needs to ensure that: - controlled substances are accurately accounted for according to applicable laws and regulations; - medications and chemicals used to prepare medications are accurately labeled with contents, expirations dates, and warnings; - expirations dates are regularly checked; - hazardous and flammable materials are stored in dedicated and clearly labelled storage areas according to specifications.

11.3.2.1 - Medications are labelled with essential information according to national regulations.

11.3.2.2 - Where DDA (dangerous drug act) medication is available these are clearly labelled and controlled.

11.3.2.3 - Hazardous and flammable materials are clearly labelled.

11.3.2.4 - All pharmaceuticals, vaccines or medical consumables are regularly checked for expiry dates and checks are recorded.

SE11 - MEDICATION MANAGEMENT

11.4 - Prescribing and dispensing of medication

11.4.1 - Medications are prescribed in a safe and controlled manner.

Standard intent

Selecting a medication to treat a patient requires specific knowledge and experience. The healthcare facility identifies those individuals with the appropriate knowledge and experience and who are also permitted by licensure, certification, laws or regulations to prescribe or order medications.

Safe prescribing and ordering of medication is guided by facility policies and procedures. To improve patient safety, the healthcare facility defines the required elements of a complete order or prescription (both written and verbal).

11.4.1.1 - Prescriptions contain all relevant information according to the national guidelines.

11.4.1.2 - The healthcare facility has identified those staff members that are authorized to prescribe medication.

11.4.1.3 - Prescription pads and order books are accessible to authorized persons only.

11.4.1.4 - When verbal/telephonic medication orders are used, they are verified.

SE11 - MEDICATION MANAGEMENT

11.4 - Prescribing and dispensing of medication

11.4.2 - The facility dispenses medications in a safe and controlled environment and according to patient needs.

Standard intent

The organization dispenses medications in a clean and safe environment and in a way that complies with laws, regulations and professional practice standards. The healthcare facility takes patient confidentiality and needs into account during the dispensing process. This includes adequate privacy in the dispensing area and secure storage of prescriptions. In the dispensing process staff informs the patient of available generic equivalents, if available.

11.4.2.1 - There is a designated area for preparing and dispensing medication.

11.4.2.2 - The dispensing area is adequately furnished and allows for privacy for patients.

11.4.2.3 - Prescriptions are securely stored to protect patient confidentiality and avoid abuse.

11.4.2.4 - Dispensing staff informs the patient of available generic equivalents.

SE11 - MEDICATION MANAGEMENT

11.4 - Prescribing and dispensing of medication

11.4.3 - A system is used to dispense medications in the right dose to the right patient in the right dose at the right time.

Standard intent

All medication distribution points throughout the healthcare facility use the same system for preparing and dispensing medications. The healthcare facility dispensed medications in the most ready to administer form possible to minimize opportunities for error during distribution and administration. When medication is removed from its original packaging and not immediately administered, the medication must be labeled with name, dosage, data of preparation and expiration. Instruction for use is provided. The system supports accurate dispensing of medications in a timely manner.

11.4.3.1 - Medication dispensed is sufficient labelled and instruction for use is provided to the patient.

11.4.3.2 - There is a uniform medication dispensing and distribution system in the healthcare facility that supports accurate and timely dispensing.

11.4.3.3 - A standard operating procedure (SOP) guides dispensing staff to check and review written instructions of a designated healthcare worker for drug dispensing.

11.4.3.4 - Dispensing staff has quick access to patient information to check for allergies or contra-indications for particular medications.

SE11 - MEDICATION MANAGEMENT

11.5 - Administration of medication

11.5.1 - There is a mechanism for facilitating communication between the doctor and pharmacy regarding drug reactions.

Standard intent

When medicines are administered within a healthcare facility, it is important that the staff monitors this process closely in order to ensure that the medicine is having a positive effect and not causing any allergic or adverse drug reactions. If the medication dosage needs adjustment, or if multiple medications are causing a drug-interaction, these must be documented in a timely manner. Documentation of adverse drug reactions and medication errors protects patients and also identify opportunities to make medication management safer for all patients in the facility.

11.5.1.1 - Staff is guided in recording and reporting of medication errors or adverse drug reactions.

11.5.1.4 - Adverse drug reactions are recorded and reported in accordance to facility policy.

11.5.1.2 - Adverse drug reactions and medication erros are discussed in medical meetings.

11.5.1.3 - There is evidence that active follow up is performed in relation to adverse drug reactions and medication errors.

SE12 - FACILITY MANAGEMENT SERVICE

12.1 - Buildings, equipment, and utility systems

12.1.1 - The health facility and compound are managed to ensure safe and effective services.

Standard intent

Buildings, grounds, plant and machinery are designed and laid out as appropriate for their use as a healthcare facility. Attention is given to adequate ventilation and temperature control to ensure safe service provision. The buildings and utility systems (electrical, water, sewer, and other utility systems) are maintained, and do not pose hazards to the occupants. The construction of the building in terms of walls, ceilings, floors, doors and window must be sound. The general appearance will be examined for neatness, condition of paintwork, signs of leakage, mold spots, etc.

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

12.1.1.2 - All areas where patients congregate are adequately ventilated to allow effective air flow.

12.1.1.3 - Temperature control mechanisms are provided and maintained in areas where this is critical.

12.1.1.4 - All relevant areas have mesh windows and doors.

SE12 - FACILITY MANAGEMENT SERVICE

12.1 - Buildings, equipment, and utility systems

12.1.2 - The healthcare facility has established maintenance and repair services to ensure safe and effective healthcare services.

Standard intent

A suitably qualified individual, with proven competence, is appointed to manage the maintenance service.

Management ensures that enough competent staff are available to manage routine and emergency technical functions and meet the needs of a safe and effective health service. Staff may be in the employ of the organization or be contracted out.

Besides a competent maintenance staff there are several maintenance and repair requirements which are important like:

1. Ensuring that the maintenance and repair services are available for 7 days and 24 hours.

2. Ensuring that all the basic maintenance equipment is available in order to perform priority repairs

3. Keeping records of all the maintenance activities performed in the facility.

12.1.2.1 - The facility ensures technical backup services, either through on-call staff or through contracted maintenance services.

12.1.2.2 - A designated, competent individual is responsible for supervising (preventive) maintenance and repairs of the facility buildings, equipment, and utility systems.

12.1.2.3 - Basic maintenance equipment, tools, and spare parts are available.

12.1.2.4 - Maintenance activities to the building, plant and installations are recorded in a maintenance record book.

SE12 - FACILITY MANAGEMENT SERVICE

12.1 - Buildings, equipment, and utility systems

12.1.3 - The facility implements a preventative maintenance program for infrastucture.

Standard intent

It is important to identify and correct maintenance issues in a healthcare facility on a regular basis to protect the safety of patients and staff. Routine building inspection and maintenance will include the monitoring of the following aspects:

- the general appearance of the inside and outside structure, which includes the construction of walls, floors, doors and windows;
- the condition of the paintwork;
- water leaks, mold spots;
- electrical wiring, e.g. exposed wires, switches, electrical sockets;
- Maintenance of the grounds (no litter, neat garden and grass kept short).

The (preventive) maintenance plan should indicate when the inspection and preventive maintenance procedures are due on each item and a record of maintenance activities.

12.1.3.1 - Inspections of the infrastructure are regularly conducted and documented.

12.1.3.2 - The organization plans and budgets for the refurbishing and/or upgrading of the infrastructure.

12.1.3.3 - There are site and floor plans that depict the locations and layout of the main ancillary services (e.g. water, sanitation, and electricity supply) and medical gas shut off valves.

12.1.3.4 - The facility has an established, documented, preventive maintenance plan for the infrastructure.

SE12 - FACILITY MANAGEMENT SERVICE

12.1 - Buildings, equipment, and utility systems

12.1.4 - The healthcare facility has an adequate electrical supply system.

Standard intent

An uninterrupted source of electricity, adequate lighting and sufficient electrical sockets are essential to meet patient care needs, both routine and urgent. Regular and alternate electricity sources can be used in a facility. Critical equipment that provides emergency services must be connected to an emergency power system. Critical equipment can be located in several different departments (e.g. refrigerators for medication storage in pharmacy or laboratory), and lights and equipment in the operating theatre and delivery room.

Due to the importance of electricity supply in case of emergency, these alternate electricity supply systems must be regularly inspected and tested on full load according to manufacturers' specifications.

12.1.4.1 - Electrical power is guaranteed for critical equipment from regular or back-up (emergency) sources.

12.1.4.2 - Sufficient light sources (natural or electrical) are available to provide adequate light.

12.1.4.3 - Sufficient electrical socket outlets are provided in all areas to avoid overloading of individual outlets and minimize fire risks.

12.1.4.4 - There is documented evidence that emergency power (backup) systems (generators, uninterrupted power) are regularly tested and maintained.

SE12 - FACILITY MANAGEMENT SERVICE

12.1 - Buildings, equipment, and utility systems

12.1.5 - The healthcare facility has an adequate water supply system for regular and emergency situations.

Standard intent

An uninterrupted source of clean water is essential to meet patient care needs, both routine and urgent. Drinkable water needs to be available in all essential areas. Regular and alternate water sources can be used, provided safety of the water supply is guaranteed. Storage areas such as a well, storage tanks or other backup systems must be safe from contamination. The healthcare facility should be adequately prepared for situations where water supply is interrupted or contaminated. Emergency supplies must be available in priority areas within the facility.

12.1.5.1 - Clean water supplies are guaranteed, from regular or emergency sources, in all essential areas.

12.1.5.2 - Where water is collected from natural water sources, water filters are available to remove mud and dust particles.

12.1.5.3 - The healthcare facility has identified which areas are to be prioritized when water is scarce.

12.1.5.4 - Water derived from natural sources, which is used for drinking, is tested and the results are documented.

SE12 - FACILITY MANAGEMENT SERVICE

12.1 - Buildings, equipment, and utility systems

12.1.6 - The healthcare facility has an adequate and effective sewerage system which is regularly inspected and maintained.

Standard intent

An appropriate and effective (closed) sewerage system must be available and maintained. This will include disposal of waste water, surface water and sewage. The infrastructure, including drainage points, pipes, pumps and mains, needs to be protected to prevent spillage and contamination of the environment.

12.1.6.1 - The health facility has an enclosed sewerage system.

12.1.6.2 - Where there is a septic tank(s), the system is properly functioning.

12.1.6.3 - All drains and manholes are appropriately covered.

12.1.6.4 - The sewerage system is well maintained.

SE12 - FACILITY MANAGEMENT SERVICE

12.1 - Buildings, equipment, and utility systems

12.1.7 - Functional and clean toilet facilities and washrooms are available for the patients and staff.

Standard intent

Clean and sufficient toilet and washroom facilities are essential for patient care services. There need to be sufficient toilet and washrooms for both staff and patients in all departments where care is provided. Separate toilets for males and females ensure privacy. It is essential that the toilets are in working order and are clean to comply to infection control guidelines and regular cleaning needs to be performed. In each toilet unit a handwashing units needs to be present with water, soap and towels.

12.1.7.1 - Toilet/washroom facilities are clean and in working order.

12.1.7.2 - There are sufficient toilet and washrooms available both for staff and patients

12.1.7.3 - There are handwashing facilities with water, soap and single use (paper) towels in the toilets.

12.1.7.4 - There are separate toilets for males and females to provide privacy.

SE12 - FACILITY MANAGEMENT SERVICE

12.2 - Equipment

12.2.1 - Medical equipment is inspected, tested, and maintained.

Standard intent

Healthcare facilities are responsible for ensuring that appropriate medical equipment is available and ready for use at all times. Policies and procedures ensure that cost-effective, safe and appropriate (medical) equipment is procured and available to meet the needs of the facility. A designated individual takes responsibility for ensuring that medical equipment is available and appropriately maintained and repaired.

12.2.1.1 - The healthcare facility keeps record of age, physical condition, and maintenance performed on all (medical) equipment.

12.2.1.2 - The medical equipment available is appropriate to meet the needs of the patients.

12.2.1.3 - A designated and qualified individual supervises the management of medical equipment in the facility.

12.2.1.4 - Policies and procedures guide the management of medical equipment including procurement, testing, preventive maintenance, and repair of defective equipment.

SE12 - FACILITY MANAGEMENT SERVICE

12.2 - Equipment

12.2.2 - The healthcare facility has adequate and safe medical gas equipment which is regularly inspected and maintained.

Standard intent

A facility should assess the amount of medical gas (including back-up supplies) needed to adequately satisfy the patient profile and/or load requirements as directed by in-country regulations. Where there is no piped gas, the facility should document the (type of) supplies and ancillary equipment necessary to meet the needs of the facility and ensure availability. Special attention needs to be given to emergency situations that may arise and necessitate back-up.

System maintenance and testing of equipment (and alarm systems) is ensured in facilities with piped gas. In case of use of gas cylinders, safe storage is provided at strategic positions for timely deployment.

12.2.2.1 - Adequate and safe medical gas supplies (oxygen, nitrous oxide and medical air) and ancillary equipment are available to meet the needs of the facility.

12.2.2.2 - Emergency supplies of medical gas are available to meet the needs of the facility and are strategically positioned to enable rapid acces.

12.2.2.3 - In facilities with piped gas, the facility ensures maintenance and cleaning of all elements of the system.

12.2.2.4 - In facilities with piped gas, the medical gas system is fitted with an alarm, low pressure alarms are tested, and corrective actions documented (if applicable).

SE12 - FACILITY MANAGEMENT SERVICE

12.2 - Equipment

12.2.3 - The healthcare facility has adequate and safe medical vacuum equipment which is regularly inspected, tested, and maintained.

Standard intent

A facility should assess the amount of vacuum supplies necessary to meet the needs of the patients served. Policies and procedures relating to the testing and safety of vacuum systems are available and implemented. In case of interruption of power, alternative suction devices are available and can be rapidly accessed in case of emergency. Where there is a piped vacuum system, it is externally ventilated and able to provide sufficient suction to all piped vacuum points in the healthcare facility.

12.2.3.1 - Vacuum/suction equipment and supplies are available to meet the needs of the patients.

12.2.3.2 - Alternative suction devices are available in case power cuts occur.

12.2.3.3 - Where a piped vacuum system is used, it provides sufficient suction to all piped vacuum points in the healthcare facility.

12.2.3.4 - Where piped vacuum systems are used, they are regularly tested, and all tests and corrective actions are documented.

SE12 - FACILITY MANAGEMENT SERVICE

12.3 - Equipment

12.2.4 - ICT equipment is adequate to meet the needs of the facility and is properly maintained.

Standard intent

Dependent on the size and the needs of a healthcare facility it is important to have an IT system. IT systems can play a role in many administration and data processing activities and is applicable on most of the services, medical and non-medical, performed in the healthcare facility.

There are several aspect important in relation to IT systems. some of these aspects are defined below.

1. Are the systems available sufficient for the operational needs and requirements.

2. Is there a designated person responsible for management of the IT system or appointed to liaise with an IT maintenance company.

3. Are the systems protected to power changes.

4. Is a back up regularly made.

12.2.4.1 - The supply of ICT equipment is adequate to meet the operational requirements of the facility.

12.2.4.2 - A designated individual is responsible for management of ICT equipment or appointed to liaise with an external ICT maintenance company.

12.2.4.3 - All desktop and server computers are attached to an uninterrupted power supply (UPS) with surge protection.

12.2.4.4 - Timely back-ups are performed to ensure that all relevant data are safeguarded.

SE13 - SUPPORT SERVICES

13.1 - Food Service management

13.1.1 - The food service is managed and staffed to ensure safe and effective provision of services.

Standard intent

The food service needs to be effective and safe. Those who are managing and preparing the food service in the healthcare facility need to be well instructed and informed. In order to ensure this the next facts are important.

1. The is a person who is suitably qualified to coordinate the in-house food services.

2. A manual is available in which the kitchen processes are described.

3. Kitchen staff receives training on food preparation and hygiene topics and about infection control and safety.

4. The food preparation areas are only accessible for food preparation staff.

13.1.1.1 - A qualified individual is responsible for the day-to-day operation of the food service.

13.1.1.2 - Access to the food preparation area is limited to individuals who are preparing or serving food.

13.1.1.3 - Kitchen staff is aware of general food hygiene, health, and safety precautions.

13.1.1.4 - A kitchen manual describes the overall processes to guide the staff in food service.

SE13 - SUPPORT SERVICES

13.1 - Food Service management

13.1.2 - The food service area allows for safe food preparation.

Standard intent

The service manager needs to work closely with the facility managers to ensure that food service facilities and equipment are adequate and are inspected and approved by the regulatory authority to ensure adherence to health and safety regulations. Important aspects are: 1. availability of separate handwashing facilities with soap, water and paper-/single use towels; 2. adequately ventilation; 3.windows with fly screens or fly control.

13.1.2.1 - There are separate hand-washing facilities in the food preparation area, with soap, water, single-use (paper) towels in the kitchen,

13.1.2.2 - The food preparation area is adequately ventilated and temperature is monitored.

13.1.2.3 - Windows in the food preparation area have fly screens or alternative measuresd for fly control is available.

13.1.2.4 - The food preparation area is inspected and approved by the regulatory authority to ensure adherence to health and safety regulations.

SE13 - SUPPORT SERVICES

13.1 - Food Service management

13.1.3 - Basic food service hygiene measures are in place.

Standard intent

It is important to maintain a clean food service environment to prevent food-borne illness and protect the health of patients and staff. This is ensured through daily cleaning, handwashing by staff and the availability of adequate changing rooms and washrooms for food handlers. Staff members who might be ill must not be allowed to participate in food preparation or service.

13.1.3.1 - Food service equipment, floors, and walls are cleaned on a daily basis.

13.1.3.2 - Staff are constantly reminded of the importance of effective hand-washing.

13.1.3.3 - There are adequate changing rooms and washrooms for food-handlers.

13.1.3.4 - There is a procedures that guides staff to report infectious diseases in the family.

SE13 - SUPPORT SERVICES

13.1 - Food Service management

13.1.4 - Food products and meals are hygienically prepared, and served.

Standard intent

During preparation, foods are handled in a safe and hygienic manner. The environment protects patients and staff against the risk of infection. High-risk foods which may be contaminated and which may contaminate other foods are kept separate from other foods (prepared and unprepared). This includes meat, poultry and fish.

13.1.4.1 - Potentially high risk food are kept separately.

13.1.4.2 - Separate cutting boards are used different food preparation processes and types of food..

13.1.4.3 - Food is kept for a minimal amount of time after cooking and before serving.

13.1.4.4 - Food waste is put in covered containers and removed without delay from places where food is prepared.

SE13 - SUPPORT SERVICES

13.1 - Food Service management

13.1.5 - Food is stored in an appropriate and safe manner.

Standard intent

Food supplies are stored under conditions that ensure security, hygiene and freshness. Important aspects are storage off the ground, at the proper temperature, separation of food types, and stock rotation.

13.1.5.1 - Foods are covered, and stored off the ground on shelves of impenetrable material.

13.1.5.2 - Food is stored at the proper temperature.

13.1.5.3 - Different types of food (supplies) are stored in separate and clearly marked areas.

13.1.5.4 - Stock is rotated using the “First Expiry, First Out” principle.

SE13 - SUPPORT SERVICES

13.2 - Linen service management

13.2.1 - The linen service is managed and staffed to ensure safe and effective services.

Standard intent

Linen management encompasses all aspects of the provision of clean linen for all patient care services. Linen includes bedding like sheets and blankets, pillow cases, examination bed covers, uniforms/protective clothing, surgical drapes, towels etc. In most facilities, some types of linen are in use (uniforms, for example), so it is unlikely that this section is non-applicable. Every facility should describe how they deal with soiled uniforms and other linen, irrespective of the place where linen is eventually washed and how/where clean linen is stored.

The laundry service may be provided on-site or off-site. Whatever system is used, the processes will be assessed in terms of the provision and distribution of linen, stock control, the collection of soiled and infected linen, laundering processes and the storage and redistribution of clean linen.

Staff must be adequately orientated and trained on the job to familiarize themselves with facility policies and know the importance of hygiene, health, infection control, and safety.

13.2.1.1 - Laundry staff is orientated and aware of general hygiene, infection control, and safety precautions.

13.2.1.2 - A qualified individual is responsible for the day-to-day operation of linen service.

13.2.1.3 - A linen manual describes the overall processes regarding linen management.

13.2.1.4 - Laundry staff training records are kept.

SE13 - SUPPORT SERVICES

13.2 - Linen service management

13.2.2 - The area(s) where laundry activities are performed support hygiene and infection control.

Standard intent

Adequate handling, washing and drying of soiled linen is important to maintain hygiene and prevent infection. The facilities for laundry services need to include adequate space and equipment fit for the current workload. Clean and soiled linen should be kept separated and clean linen should be stored in a separate lockable space to keep it clean and prevent theft.

13.2.2.1 - The laundry area(s) provides a clear flow of laundry with clearly demarcated areas for soiled and clean linen.

13.2.2.2 - There is a designated space for laundry which is adequate to deal with the work load.

13.2.2.3 - The washing equipment (e.g. machines, presses) is sufficient to meet the needs of the facility.

13.2.2.4 - The clean linen is securely stored to maintain hygiene.

SE13 - SUPPORT SERVICES

13.3 - Cleaning Service

13.3.1 - The cleaning service is staffed and managed to ensure safety and effectiveness of the services provided in the healthcare facility.

Standard intent

The cleaning service plays and important role in preventing the spread of infection within the healthcare facility. It is important to ensure that all staff members who participate in cleaning are working under responsibility of a qualified individual and oriented to their jobs and trained in the importance of hygiene, infection control, and safety. A housekeeping manual describes overall housekeeping processes (including waste management (especially disposal of sharps and biomedical waste), which is important for the safety of patients, visitors, and staff).

13.3.1.1 - Cleaning staff is aware of general hygiene, infection control, and safety precautions.

13.3.1.2 - A qualified individual is responsible for the day-to-day operation of cleaning/housekeeping service.

13.3.1.3 - A housekeeping manual describes the overall housekeeping processes.

13.3.1.4 - A cleaning roster is available and activities are logged.

SE13 - SUPPORT SERVICES

13.3 - Cleaning Service

13.3.2 - The cleaning area(s) within the healthcare facility support support hygiene and infection control.

Standard intent

Adequate handling and storage of cleaning supplies is important to facilitate the cleaning process and maintain hygiene, safety and prevent infection within the facility. Mops and brooms are cleaned and dried before being stored. The housekeeping facilities should include adequate, tidy, secured and well-ventilated storage space for equipment and supplies. Chemicals for cleaning should especially be safely stored out of reach of patients, children and visitors.

13.3.2.1 - Mops and brooms are cleaned and dried before being stored.

13.3.2.2 - Adequate storage space is available for cleaning equipment (e.g. mops, brooms).

13.3.2.3 - Chemicals for cleaning are safely stored out of reach for patients, children and visitors.

13.3.2.4 - Cleaning cupboards are ventilated.

SE13 - SUPPORT SERVICES

13.3 - Cleaning Service

13.3.3 - The waste disposal system supports infection control.

Standard intent

Healthcare facilities produce considerable waste every day. Frequently, that waste is or could be infectious. Thus, the proper disposal of waste reduces the risk of infection in the healthcare facility. An implemented system for segregating, collecting, secure storing and transporting waste is essential.

13.3.3.1 - The facility has, and has implemented , standard operating procedures for the safel segregation, collection and transportation of (medical) waste.

13.3.3.2 - Bags/containers are color-coded or clearly labeled to indicate the type of waste.

13.3.3.3 - Prior to incineration or collection, waste is stored in a dedicated and secure location.

13.3.3.4 - Waste is collected regularly, within the different departments within the facility, to prevent hazardous overfilling of containers.