Licensing and Regulation Standards for Ambulatory Health Care Facilities

December 2012
Forward

The National Health Regulatory Authority (NHRA) is dedicated to ensuring health services in the Kingdom of Bahrain meet the required standards. Our mission is to be a continuous driver for safer patient care and establish a culture of continuous improvement in each of our healthcare facilities.

This set of NHRA standards recognizes the significant role of Ambulatory Care Facilities in the Kingdom. These standards address the care of individuals in the ambulatory care facility environment and are designed to ensure the provision of safe and high quality care.

The intent of the Ambulatory Care Standards is to keep them relevant and adaptable to all types of clinics or centers providing services to patients that need short-term care such as free-standing specialist clinic settings, GP clinics, polyclinics, minor/day surgery facilities, fertility clinics/centers, dental clinics/centers, and other similar free-standing facilities.

The development of these standards was a collaborative effort of representatives from the NHRA, Government Primary Health Care Services, Quality Improvement Directorate of the Ministry of Health, Private GP clinics and other ambulatory care facilities in Bahrain. This process has been facilitated by members of the International Development Ireland Project Team.

The standards are specific to the Kingdom of Bahrain; however they have been drawn heavily on the CBAHI accreditation standards in Saudi Arabia, which have been accepted as reference standards across all GCC countries. The standards have also been compared to international licensing standards and found to meet the basic intent of all international licensing standards. It is expected that the standards will be a catalyst for change and improvement in both the culture and practice of health care in Bahrain.

The standards identify core elements that are applicable to all Ambulatory Care Facilities. In addition, support elements and facility specific elements have been developed. These separate elements can be built upon to create a comprehensive inspection/audit template which is relevant to the individual ambulatory care facilities that are licensed in the Kingdom of Bahrain. Therefore, all ambulatory health care facilities are assessed against all core elements of the standard. The support elements are assessed as being applicable or not applicable and assessed accordingly, and the facility specific elements are only assessed in the ambulatory care facilities that provide the service/s identified.

Our appreciation and gratitude goes to CBAHI in Saudi Arabia for allowing their ambulatory care and primary health care accreditation standards to be used as reference for the development of the NHRA licensing and regulation standards. We extend our appreciation to the healthcare professionals who were generous with their feedback and suggestions to ensure the fulfillment of our mission.

Dr. Wahid Ali Agab

NHRA Chairman
# Contents

Introduction .................................................................................................................................................. 4

The Licensing Standards Structure ............................................................................................................... 5

Element One – Governance, Management and Leadership ............................................................................. 8

  Introduction ................................................................................................................................................ 8

  Element 1: Governance, Management and Leadership - Minimum Criteria ................................................. 9

Element Two - Human Resources ................................................................................................................ 12

  Introduction .............................................................................................................................................. 12

  Element 2 - Human Resources Standards - Minimum Criteria ................................................................. 13

Element 3 - Patient and Family Rights ......................................................................................................... 17

  Introduction .............................................................................................................................................. 17

  Element 3 - Patient and Family Rights – Minimum Criteria ................................................................... 18

Element 4 - Quality Management and Patient Safety ................................................................................... 21

  Introduction .............................................................................................................................................. 21

  Element 4 – Quality Management and Patient Safety - Minimum Criteria ................................................. 22

Element 5 - Management of Information and Medical Records ................................................................... 26

  Introduction - Management of Information ............................................................................................... 26

  Introduction - Medical Records .................................................................................................................. 27

  Element 5 Management of Information and Medical Records - minimum standards ............................... 28

  Element 5 - Medical Record Standards – minimum criteria ..................................................................... 30

Element 6 - Infection Prevention and Control ............................................................................................. 33

  Introduction .............................................................................................................................................. 33

  Element 6 Infection Prevention and Control – Minimum Criteria Standards ............................................. 34

Element 7 - Facility Management and Safety ............................................................................................... 40

  Introduction .............................................................................................................................................. 40

  Element 7 – Facility Management and Safety – Minimum Criteria ......................................................... 41

Element 8 Patient and Family Education .................................................................................................... 44

  Introduction .............................................................................................................................................. 44

  Element 8 Patient and Family Education - Minimum Criteria Standards .................................................. 45

Element 9 Provision of Care .......................................................................................................................... 47

  Introduction .............................................................................................................................................. 47
Element 9 Provision of Care – Minimum Criteria ................................................................. 48
Element 10 - Radiology ........................................................................................................ 53
  Introduction ........................................................................................................................ 53
  Element 10 Radiology Services - Minimum Criteria .......................................................... 54
Element 11 - Laboratory ...................................................................................................... 56
  Introduction ........................................................................................................................ 56
  Element 11 – Laboratory - Minimum Criteria ................................................................... 57
Element 12 - Pharmacy ........................................................................................................ 61
  Introduction ........................................................................................................................ 61
  Element 12 Pharmacy – Minimum Criteria Standards ...................................................... 62
Element 13 Minor Surgery / Procedures ............................................................................ 70
  Introduction ........................................................................................................................ 70
  Element 13 Minor Procedure / Operating Room - Minimum criteria Standards ................. 71
Element 14 - Anaesthesia and Sedation .............................................................................. 74
  Introduction ........................................................................................................................ 74
  Element 14 – Anaesthesia and Sedation – minimum Criteria ............................................. 75
Element 15 – Radiology Centres ......................................................................................... 80
  Introduction ........................................................................................................................ 80
  Element 15 Radiology Centre - Minimum Criteria ............................................................ 81
Element 16 Fertility and Assisted Reproductive Technology Standards .............................. 85
  Introduction ........................................................................................................................ 85
  Element 16 Fertility and Assisted Reproductive Technology - minimum criteria ............... 86
Element 17 Dental Services Standards .............................................................................. 89
  Introduction ........................................................................................................................ 89
  Element 17 Dental Services Standards ........................................................................... 90
Element 18 Optician Practices ............................................................................................ 93
  Element 18 Optician Practices – Minimum Criteria ......................................................... 94
Element 19 - Haemodialysis Standards .............................................................................. 96
  Introduction ........................................................................................................................ 96
  Element 19 - Haemodialysis Standards – Minimum Criteria .............................................. 97
Glossary ................................................................................................................................ 102
Introduction

Objectives of Licensing

Licensing is a statutory mechanism in the Kingdom of Bahrain which grants permission to health care organizations and/or facilities to operate and deliver health care services. A fundamental role of the NHRA is to ensure that health care organizations / facilities meet minimum standards to protect public health and patient safety and ensure health care services are of a high quality.

The NHRA grants Health Care facilities a license on an annual basis. This time limited approach requires that the facility not only complies with the minimum standards to operate at the outset, but also maintains the standards over a sustained period of time to ensure re-licensure is achieved.

License Inspection Surveys

Each inspection survey is tailored to the type, size and range of services offered by the ambulatory care facility. Applicable standard elements are determined by the licensure inspectors based on the scope of services offered by the facility. The inspectors will also discuss and consider the specific applicability of individual elements of the standards throughout the onsite inspection process.

Standard Development

The NHRA licensing standards have been developed using a consensus process. The draft standards drew heavily on the CBAHI standards which are approved by the Gulf Cooperative Council for use as reference standards across all GCC countries. The initial draft standards were then subject to a comprehensive review of national and international health care standards. During the development the standards went through reviews by various stakeholders, recommendations for change were reviewed, considered and applied where appropriate. The standards have been piloted across a number of ambulatory care facilities already operating throughout the Kingdom to ensure applicability before being approved by the NHRA Board.
The Licensing Standards Structure

The NHRA Ambulatory Care Licensing Standards are assembled around key services and functions common to clinics and other health care facilities providing ambulatory care:

Core Elements – (applicable to all Ambulatory Care Facilities)

All ambulatory health care facilities are assessed against all core elements of the standard.

1. Governance, Management and Leadership
2. Human Resources
3. Patient and family rights
4. Quality Management & Patient Safety
5. Mgt of Information and Medical Records
6. Infection Prevention and Control (including CSSD)
7. Facility Management & Safety
8. Health Promotion and Education
9. Provision of Care/Patient Journey

Support Elements

The support elements are assessed as being applicable or not applicable and included accordingly.

10. Radiology Services
11. Laboratory Services
12. Pharmacy

Facility Specific Elements

The facility specific elements are only included in the ambulatory facilities that provide the service/s identified.

13. Minor Surgery
14. Anesthesia and Sedation
15. Radiology Centers
16. Fertility
17. Dental
18. Optometry/Opticians
19. Hemodialysis

Each element has an introduction which provides an explanation about the relevance and contribution to safety and high quality patient care. Each element has a statement and when required sub-standard elements are identified to clarify further requirements. Each element has identified Evidence of Compliance (EoC).
Core Elements

All ambulatory health care facilities are assessed against all core elements of the standard.
Element One – Governance, Management and Leadership

Introduction

For any health care facility providing ambulatory care services, quality and patient safety depend on effective leadership and good organization.

It is important for all ambulatory health care facilities to have a clearly stated mission. It is the responsibility of the leadership of the facility to develop the mission and provide adequate resources to fulfill this mission.

Clinics, polyclinics, centers and other facilities which provide ambulatory care in the Kingdom of Bahrain vary in size, type of ownership, and complexity of service.

Each facility, regardless of its complexity should have an accountable body or person that provides leadership and direction. A large clinic or facility may have a governing body ultimately accountable for the operation and performance of the facility. In smaller facilities, these responsibilities may be handled by just one or two individuals.

This element addresses the roles and responsibilities of the leadership group that are responsible for the governance processes required, including:

- Development of a mission statement
- Development of an organizational structure and accountability chart for all levels of the organization
- Development and promotion of professional ethical conduct
- Formulation and construction of a strategic plan
- Planning and designing services and structures which includes patient and stakeholder engagement
- Processes for collaboration, coordination, and communication internally and externally
- Financial management
Element 1: Governance, Management and Leadership - Minimum Criteria

Governance elements 1.1 to 1.3 only apply to facilities and organizations that have a governing body in place:

1.1 The governing body responsibilities are defined in written documents such as bylaws, policies and procedures and reflect the legal responsibilities and accountability it has to the patients and public.

EoC: Governance responsibilities and accountabilities are described in documents. This should include responsibility for the quality of care provided and patients’ safety.

1.2 The governing body fosters communication and coordination between the facilities governance function and management.

EoC: There is evidence of communication and coordination between the facilities governance function and management. The governance body approves the mission statement, scope of services, strategic and management plans implemented through the management and leadership function.

1.3 The governing body performs periodic evaluation on both its own effectiveness and that of the leadership and management team, including review of plans, budgets, policies and procedures.

EoC: There is evidence of periodic evaluation of the governing body effectiveness and that of the management and leadership function within the facility which includes plans, budget, policies and procedures.

1.4 The facility leadership and management ensure that the facility complies with the laws and Regulations in the Kingdom of Bahrain.

EoC: The facility has a current NHRA License and adheres to the current Kingdom of Bahrain laws.

1.5 The management structure is defined with a clear, current organizational and accountability chart identifying names and lines of authority and responsibility of those leading, including the governing board /person(s) where appropriate.

EoC: The management structure is defined, updated, and circulated throughout the facility: It shows the names and titles of those responsible for management and leadership, clear lines of authority and accountability.

1.6 The facility should have a clear mission statement which is regularly reviewed and is communicated to all staff, patients and visitors.

EoC: There is a written mission statement publicly posted within the facility and staffs are aware of the mission statement.

1.7 The facility should have a documented scope of services and practices provided.
EoC: The facility has an approved and documented scope of services and practices provided including the Preventative, Promotion, Curative and Rehabilitative services provided.

1.8 The facility should have a 3 to 5 year strategy for providing the identified scope of services / practices which includes the provision of adequate resources (manpower, consumables, and capital assets).

EoC: Adequate resources are available for the facility to provide the approved scope of services, including adequate manpower, adequate consumables, adequate equipment and adequate contracted services where required.

1.9 The facility should have documented evidence of the budget control for both operating and capital expenditure.

EoC: There is documented evidence that the facility is managed and the leadership ensures the efficient use of the available resources. There is evidence of budget management to ensure the facility fulfills its objectives.

1.10 A suitably qualified person should be assigned to manage the facility on a full time basis in accordance with applicable laws and regulations. This person should have a clear written job description covering all aspects of their role.

EoC: A suitably qualified person is assigned and held accountable for the overall facility management and there is evidence of his/her performance being managed.

1.11 The facility fosters open and transparent communication and coordination between its management and leaders and the staff.

EoC: There is evidence of communication between management and staff through newsletters, meetings, training and education, notice boards, staff initiatives etc.

1.12 The facility leadership group meets regularly (at least monthly) in formal meetings to discuss all aspects of health care, achievement reports, regulatory reports and services provided to patients.

EoC: There is an identified leadership group who each has identified roles; there is evidence of this group meeting at least on a monthly basis to discuss all aspects of health care provision within the facility, achievement reports, regulatory reports and areas for improvement.

1.13 The facility can provide annual reporting information regarding:

1.13.1 The range of services (i.e. Preventive, Promotive, Curative and Rehabilitative).
1.13.2 The age groups who receive care.
1.13.3 The number of patients seen annually.
1.13.4 The major diagnostics or therapeutic methods used.
1.13.5 Number of complaints received
1.13.6 Number of incidents occurred

**EoC:** Annual reporting information is available for elements 1.17.1 to 1.17.6

1.14 The leaders develop a staffing plan for the organization to ensure that services meet the needs of the population(s) served.

**EoC:** There is a written staffing plan developed by the leadership group. The staffing plan defines the number, type and qualifications of staff required and their role in the facility.

1.15 There is a written policy for controlling the development and maintenance of policies and procedures for key functions and processes. Policy development should include:

1.15.1 A unique identification for each policy with title, number, and dates of issue and updates.
1.15.2 Policies being developed, approved, revised, and terminated by authorized individuals.
1.15.3 Policies being revised according to a defined revision due date that does not exceed (4) years or when required.
1.15.4 All Policies are dated and current.
1.15.5 Policies being communicated to staff and training provided where applicable.
1.15.6 Staff sign off on polices being implemented, ensuring staff understand their role in implementation.

**EoC:** There is a policy on policies and procedures, how the policies are developed, approved, revised, tracked, communicated, monitored and terminated. There is staff understanding on the policy on policies and procedures.

1.16 The organization has a written transfer agreement with a predetermined hospital(s) for the safe and timely transfer of patients to an alternate care facility when the need arises (e.g., extended or emergency services are needed to protect the health or well-being of the patient).

**EoC:** there is a written transfer agreement with a predetermined hospital(s).

1.17 There is oversight regarding all contracts for clinical or operational services, ensuring the services to be provided are clearly identified and the services meet the applicable laws and regulations and are consistent with the standards required.

**EoC:** There is evidence of a contract oversight process which ensures that services to be provided are clearly identified and they are provided in a way that is consistent with the standards required for regulation and licensing.
Element Two - Human Resources

Introduction

Each Ambulatory Care Facilities must have qualified staff with the right numbers and mix to meet its purpose. The roles and responsibilities of each staff must be clearly defined in a current job description. Staff must be oriented to the facility, their department, and job. Their knowledge, skills and abilities must be continually upgraded and their performance assessed regularly. An ongoing education program must be in place. Additionally, when gaps in knowledge, skills, or abilities are identified, the staff must receive appropriate training. A current, updated personnel file must exist for each employee and should contain all relevant personal details.

The requirements to perform the following human resources processes must be in place:

- Staffing plans
- Staff qualifications
- Job descriptions for all types of employees
- Credentialing and privileging
- Staff orientation and education
- Employees personnel files
- Staff performance evaluation
Element 2 - Human Resources Standards - Minimum Criteria

2.1 The ambulatory care facility maintains a personnel file for each employee, which is complete, up to date and maintained in a confidential manner.

EoC: There is a personnel file for each employee and there is a written policy which is implemented for maintaining confidentiality.

2.2 All new employees receive a comprehensive facility and departmental induction and orientation program which includes but is not, limited to:
   2.2.1 The facilities mission and organizational chart.
   2.2.2 Staff role in disasters and emergencies. (i.e., Fire, evacuation)
   2.2.3 General information about hazardous materials including Material Safety Data Sheets (MSDS)
   2.2.4 General information on standard infection control measures and sharps disposal.
   2.2.5 Electrical safety.
   2.2.6 General information on communication: paging, telephone system, bleeps, fax, patient communication, filing etc.
   2.2.7 General information on staff performance evaluation processes.
   2.2.8 The definition of Incidents, adverse events and sentinel events along with the process of reporting including Who should report, When to report, How to report, and to Whom the report is routed.
   2.2.9 Information on dealing with patient complaints.
   2.2.10 Overview of Credentialing, Privileging and Competency policies.
   2.2.11 General information about the quality improvement and patient safety processes of the organization and the importance of involvement of every member of staff.
   2.2.12 Information on the expected ethical conduct of the staff and the expected professional communication in his/her interactions with others.
   2.2.13 Information on protection of patients’ rights, privacy and confidentiality.
   2.2.14 All policies are provided and are signed that they have been read and understood.

EoC: Attendance records show that all new employees attended a mandatory general orientation and are documented in each employees personnel file. The orientation includes points 2.11 to 2.1.15 and is documented and signed off in the individuals personnel file.

2.3 The facility has a policy that addresses methods for dealing with staff complaints and managing resolution of conflicts between staff.

EoC: The facility has a policy for handling staff complaints and staffs are aware of this policy.

2.4 All staff positions in the facility have a clearly written job description that is reviewed and revised at least every (3) years and as needed and:
   2.4.1 Is used when selecting employees for hire, internal promotions, and transfer.
2.4.2 Outlines the necessary knowledge, skills, and attitude to perform the role.

2.4.3 Is provided to every employee on hiring and is located in every employees personnel file.

**EoC:** There is a job description policy which ensures all job descriptions follow a described format that outlines the necessary knowledge, skills and attitude required to perform the role and is reviewed every three years. All staff has a copy of their job description.

2.5 Staff are educated and trained on the safe operation of equipment, including medical devices, and there is a clear process to ensure that only trained and competent staff operates specialized equipment.

**EoC:** There is evidence of staff education on the safe operation of equipment together with tools to ensure competency of staff.

2.6 Department heads/management recommend, implement and evaluate the necessary courses and skills to update and maintain staff competence to provide care. This process is linked to performance review, assessment and improvement and is documented in each employee file.

**EoC:** There is evidence of recommendations being made from departmental heads / management of educational needs for each employee based on their individual performance assessment.

2.7 All staff members who provide direct patient care (medical staff, nursing staff and other health professionals) have received training in basic cardiopulmonary resuscitation, updated as required.

**EoC:** The basic cardiopulmonary resuscitation training for staff members who provide direct patient care is valid and repeated every 2 years.

2.8 The facility has processes in place to address the health and safety of staff: based on assessment, and where necessary, reduction of occupational health and safety risks. The facility has an employee health program which includes, but is not limited to:

2.8.1 Pre-employment medical evaluation of new employees including preventative immunizations.

2.8.2 Response to the health problems of the employees through direct treatment or referral.

2.8.3 Periodic medical evaluation of staff (at least once annually).

2.8.4 Screening for exposure and/or immunity to infectious diseases.

2.8.5 Management of exposure to blood borne pathogens and other work-related conditions.
2.8.6 Measures to reduce occupational exposures and hazards, including use of protective equipment and clothing, stress management, and ergonomic positioning.

2.8.7 Staff education on the risks within the environment as well as on their specific job-related hazards, e.g., lifting techniques, using equipment safely, and detecting, assessing, and reporting risks. Management and documentation of staff incidents, e.g., injuries or illnesses, taking corrective actions, setting measures in place to prevent recurrences.

EoC: The facility has policies which address points 2.8.1 to 2.8.1 in the standard. All issues related to staff medical fitness and wellness are documented in their personnel file.

2.9 The facility has an effective process for gathering, verifying, and evaluating the credentials (license, education, training, and experience) of those medical staff, nursing staff and other health professionals licensed to provide patient care.

EoC: There is an implemented process for gathering, verifying, and evaluating the credentials for medical, nursing, and other licensed professionals. This should include: professional license, certificates for training and education, work experience and relevant references.

2.10 The facility has a clearly defined and documented process used to appoint and grant privileges to the medical staff. The medical staff includes licensed physicians, dentists, and other licensed individuals permitted by law to provide patient care services independently in the organization. These privileges are reviewed and updated every (2) years, and as needed.

EoC: There are documented processes for medical staff appointment and granting clinical privileges. The processes are preceded by verification and evaluation of credentials. Medical appointments are approved by the governing body or those person/s accountable within the facility.

2.11 The facility ensures that all healthcare professionals (, full time, part time, locum, etc.) are licensed with the NHRA, and maintains a register of the current professional licenses.

EoC: There is evidence that all professional staff are currently licensed to work in the Kingdom of Bahrain by the NHRA.

2.12 The performance of each medical staff member is reviewed at least annually and when indicated by findings of the performance improvement activities. The performance evaluation includes, but is not limited to, the following:

2.12.1 Mortality and morbidity.
2.12.2 Outcomes of surgeries or procedures.
2.12.3 Utilization such as appropriateness of tests and interventions
2.12.4 Medication usage.
2.12.5 Medical records review for completeness and timeliness.

EoC: There is evidence of an annual performance appraisal for all physicians within the facility. This should include standards elements 2.12.1 to 2.12.5 as a minimum.
Element 3 - Patient and Family Rights

Introduction

Every patient is unique with his/her own needs, values and spiritual beliefs. In alignment with these issues, the ambulatory care facility is responsible for ensuring that patient and family rights are defined and respected within the facility.

The healthcare providers need to establish confidence, trust and clear communication with patients and to understand and protect each patient’s cultural, psychosocial and spiritual beliefs. Outcomes of patient care are much improved when patients, and where appropriate, their families or others who make decisions on their behalf, participate in their care decisions and plans.

This element in the standards addresses:

- Defining and supporting patient and family rights
- Defining treatments/procedures requiring informed consent and obtaining informed consent when indicated
- Protection of vulnerable patients
- Protection of patient belongings
- Regular conduction of patient and family satisfaction surveys and making improvements accordingly
- Establishing a process for resolution of patient complaints
- Making sure that patients and their families are fully informed.
Element 3 - Patient and Family Rights – Minimum Criteria

3.1 The Ambulatory Care facility supports and protects patient and family rights by:
   3.1.1 Developing and maintaining a Patient Rights and Responsibilities statement and policy to outline and support patient rights. These should include aspects such as:
      3.1.1.1 Treating patient with respect and dignity at all times.
      3.1.1.2 Respecting patients’ cultural, psychosocial, spiritual and personal values and beliefs.
      3.1.1.3 Providing all the information regarding the identity and the professional status of his/her treating physician and how to contact him/her.
      3.1.1.4 Respecting the patients’ need for privacy and not exposing any private parts unnecessarily during the treatment.
      3.1.1.5 Respecting patients’ right for pain assessment and management.
      3.1.1.6 Ensuring complete patient confidentiality of all patient’s treatment by never discussing the patient in public, never revealing the patient name or any information about his illness, and not publicizing any information.
      3.1.1.7 Not neglecting patients’ demands and/or needs, and respecting their right to complain.
      3.1.1.8 Allowing patients to submit verbal or written complaints or proposals with no effect on access to care or the quality of care provided.
      3.1.1.9 Protecting patients from verbal abuse by physicians, nurses, or any other staff.
      3.1.1.10 Providing the patient with a complete medical report and accurate check-up results when / if requested
   3.1.2 Discussing aspects of patient’s rights in selected meetings
   3.1.3 Ensuring patients are informed about their rights and responsibilities in a manner they can understand
   3.1.4 Clarifying and helping resolve issues that involve patient’s rights.
   3.1.5 Making patient rights and responsibilities available to patients and families.
   3.1.6 Providing staff training and education on patient and family rights and responsibilities.

EoC: There is a written patient’s rights and responsibility statement and policy that include identified areas. Staff and patients are aware of the statement and policy in place. There is evidence of patients’ rights being discussed at senior management level and staff receives training on this area.

3.1 An administrative policy is developed and implemented regarding everyone’s roles and responsibilities in supporting patient and family rights.

EoC: There is an administrative policy that outlines staff roles and responsibilities in implementing patient and family rights.
3.2 The patient is truthfully informed when his/her needs exceed the facilities capability for care.

EoC: Staff are knowledgeable on how to handle patients when services needed are not available.

3.3 The facility offers equal treatment to patients and the patient knows the estimated cost of treatment in advance.

EoC: There are standardised processes for patient care and treatments. Cost of treatment is published and displayed for all patients.

3.4 The facility staff allow patients and, when appropriate, their families to fully participate in decisions about their care, treatment, and services, including requests for a second opinion. Patients are informed about their diagnosis, options for care, treatment, and services (in simple layman’s terms) and how they can participate in care decisions.

EoC: The facility has a consent policy and instructs all staff to discuss with patients/family their plan of care, diagnosis, condition and treatment and support their rights in care planning and decision making.

3.5 The facility provides appropriate protection for vulnerable patients such as infants, children, disabled individuals, and the elderly. The facility should give consideration to the following security, unauthorized access, identification badges and protecting from physical abuse or abduction.

EoC: There is a written policy that addresses protection of vulnerable patients that includes as infants, children, disabled individuals, and the elderly.

3.6 The facility assists disabled patients by offering the necessary assistance to patients with special needs where needed (e.g. identified parking spaces near the entrance)

EoC: The facility is friendly for disabled and elderly patients (e.g. parking spaces near the entrance, ramps where necessary)

3.7 There is a policy that identifies an up-to-date list of high risk treatments and procedures that require informed consent as well as sedation or anaesthesia.

EoC: There is a written policy for high risk treatments and procedures requiring informed consent in addition to anaesthesia/sedation.

3.9 The informed consent process is done by fully informing the patient about the risks, benefits, and alternatives.

EoC: Informed consent is obtained and documented in accordance with the facilities policy, prior to surgical or invasive procedures, anaesthesia, or other high risk treatments and procedures with exception of trauma or emergency care.
3.10 The ambulatory care facility has an effective structure to handle patient complaints and can show satisfactory resolution for the complainant (including referral of unresolved matters to other bodies.).

**EoC:** There is a designated person within the facility who is responsible for complaint management. There is a complaint management policy that is implemented and there is oversight of the patient complaint process and outcomes.

3.11 All patient complaints are trended, aggregated and analysed on a quarterly basis and a summary report is presented to the management and leaders in the facility for discussion and action as appropriate.

**EoC:** There are trended reports concerning patient complaints which allow the facility to identify problem areas for improvement.

3.12 The facility has a system including policy, forms and process to conduct on-going patient satisfaction surveys and makes improvements based on the trended survey results.

**EoC:** There is a policy and form for on-going patient satisfaction survey which is trended and provides reports for improvement actions to be taken.

3.13 The Ambulatory Care facility adopts an ethical approach to advertising and marketing, honestly portraying its services to patients.

**EoC:** The facility has a code of ethics and markets its services honestly.

3.14 The facility has a defined process for informing patients and, when appropriate, families of the outcome of care including significant adverse medical events and unanticipated negative outcomes.

**EoC:** There is a policy outlining the process for patients and family members to be informed when they have been involved in a significant adverse clinical event.
Element 4 - Quality Management and Patient Safety

Introduction

This element addresses everyone's responsibility towards implementing a program that effectively improves quality and safety and reduces risks. The role of leadership is key to establishing quality management initiatives and a positive approach from all staff in achieving high quality care and reducing risk. Leadership, therefore, has to set up a planned and on-going program where processes and systems are the focus.

To be able to effectively improve quality of care and safety, and reduce risks, the facility must identify and use indicators to measure its performance. This information is then used to identify processes which can be improved. The facility must also be able to identify significant unexpected or adverse events and intensively analyse them to understand their underlying causes and make the necessary changes to prevent the same issue occurring again.

This chapter defines the processes required to improve quality and safety and reduce risks:

- A planned and organization-wide approach
- A required structure (committee)
- Staff training and education relating to quality management
- Data collection
- Prioritization and implementation of appropriate improvements
- Risk management
- Identification and analysis of significant events
- Patient safety
- Defining and adopting International Patient Safety Goals
Element 4 – Quality Management and Patient Safety - Minimum Criteria

4.1 There is a person identified who coordinates and leads quality concepts and principles within the facility.

EoC: There is a named person within the organisation who coordinates and leads quality concepts and principles.

4.2 The ambulatory care facility develops and implements a quality improvement plan that is systematic, continuous, facility-wide, supports innovation, and covers all aspects of performance. The plan should include, but is not limited to, the following:

   4.2.1 Identifying goals and objectives.
   4.2.2 Defining the scope of activities.
   4.2.3 Identifying all levels of staff roles and responsibilities.
   4.2.4 Outlining the educational activities about quality concepts.
   4.2.5 Describing the criteria used for selection of indicators, collection of data, data analysis, and implementation and evaluation of improvements.
   4.2.6 Identifying monitoring indicators (including high risk processes).
   4.2.7 Describing how problem identification, information gathering, implementing actions, and evaluation of actions taken will occur (models like FOCUS – PDSA or other).
   4.2.8 Outline how improvement projects are identified and prioritized by the facility leadership
   4.2.9 Describing how improvement activities will be communicated to everyone in the organization (flow of information).
   4.2.10 Reviewing the plan on an annual basis and making revisions as necessary.

EoC: There is a facility wide quality improvement plan that includes elements 4.2.1 to 4.2.10.

4.3 Quality Improvement is considered in senior management meetings, either as a standalone concept or within the leadership management committees.

EoC: There is evidence that the leaders participate in quality improvement discussions and implement actions identified from discussions. There should be minutes available for inspection.

4.4 The ambulatory care facility also has a risk management plan that addresses all potential operational, financial, and clinical and safety risks faced by the facility and includes:

   4.4.1 Scope and objectives of the plan.
   4.4.2 Staff responsible for the plan.
   4.4.3 A systematic process to identify and analyse potential risks for severity and likelihood of occurrence.
   4.4.4 Development of interventions to manage potential risks (e.g., reduction, prevention).
   4.4.5 Documentation of risk management activities.
4.4.6 Staff education on their roles and responsibilities related to the plan.
4.4.7 Regular review of the plan to ensure that the plan is effective:
4.4.8 Regular measurement of performance compared with required performance.
4.4.9 Using monitoring information to make improvements.
4.4.10 Strategies for communicating risk management activities to different groups.

EoC: There is evidence that the leaders use a planned approach to identify, analyse potential risk processes and implement interventions to eliminate or minimise the potential risks.

4.5 The ambulatory care facility has an incident (occurrence/variance/accident) reporting system (policy and form) that staff follows and use when reporting adverse events and near misses.
4.5.1 Reportable incidents are identified.
4.5.2 An identified staff member is responsible for managing the incident reporting system.
4.5.3 All incidents are reported and investigated in a timely way.
4.5.4 Immediate actions are taken as well as actions to prevent recurrence of incidents.
4.5.5 Patients are informed when involved in incidents with documentation in the medical records.
4.5.6 Incidents are monitored over time and trended information is used for improvements.
4.5.7 All staff are educated on the incident reporting system used within the facility.

EoC: The facility has processes and systems in place for reporting incidents and near misses. Aggregated incident reports can be produced to show trending of incidents and near misses.

4.6 The ambulatory care facility has a policy and process to handle incidents, near misses and sentinel events and it includes:
4.6.1 Identifying when further investigation is required.
4.6.2 The formation of a team for studying the causes of the event (root cause analysis).
4.6.3 Root cause analysis should be performed within 10 working days.
4.6.4 Developing an action plan and review systems for improvement.

EoC: The facility has a policy for handling incidents, near misses and sentinel events which require further investigation. There is evidence of a route cause analysis approach being taken and training provided.

4.7 The ambulatory care facility supports patient safety by:

4.7.1 Defining and adopting selected International Patient Safety Goals in the Quality Improvement and Patient Safety Plan.
4.7.2 Assigning staff or establishing a Patient Safety Team with representation from medical, nursing, and pharmacy and safety departments.
4.7.3 Charging the assigned staff or the Patient Safety Team with implementing and monitoring the patient safety goals and recommending actions for improvement.

**EoC:** The facility has a quality improvement and patient safety plan. There are documents which reflect staff assignment for implementation of patient safety goals and recommending actions for improvement. There is evidence of monitoring of patient safety issues in reports, minutes and action plans for improvement.

4.8 The ambulatory care facility adopts a process that requires two patient identifiers whenever administering controlled medications or performing an invasive procedure.

**EoC:** The facility has a policy for using two patient identifiers when administering controlled medications or performing an invasive procedure.

4.9 There is a process for preventing wrong site, wrong procedure, and wrong person procedure/surgery that includes:

4.9.1 Documentation of the verification process pre-surgical/pre-procedure of the correct person, procedure, and site.

4.9.2 A process to mark the site in a standardized method and symbol with permanent ink by the person performing the surgical/invasive procedure.

4.9.3 A documented “time out” conducted in the location where the procedure will be done, just before starting the surgery/procedure, and involves the entire staff involved using speech to verify correct patient identity, correct site, and agreement on the procedure.

**EoC:** The process of verification, marking and time out is documented in the medical records in a checklist or other format when minor surgery/procedures are being carried out. The surgical/procedure site is marked in standardized way throughout the facility.

4.10 The ambulatory care facility has a process for the safe storage and handling of medications, medicated creams, IV fluids and other medicinal preparations.

**EoC:** There is a policy and process for the safe storage and handling of all medications, medicated creams, IV fluids and other medicinal preparations.

4.11 There is coordinated, comprehensive, and continuous training and educational activities available for all staff on quality concepts and tools including:

4.11.1 Concepts of Quality Management.

4.11.2 How to work in teams.

4.11.3 Use of data, display of data.

4.11.4 Quality Improvement tools.

4.11.5 Quality learning and improvement cycle model like FOCUS –PDSA or other.

4.11.6 Decision-making tools.

**EoC:** There is coordinated, comprehensive, and continuous quality management education programme that includes working in teams, data usage, quality tools, PDCA and decision making tools.
4.12 The ambulatory care facility develops and implements a set of indicators that are collected and aggregated on a regular basis and are used for quality improvement as well as strategic and operational planning. These may include:

4.12.1 Mortality rates.
4.12.2 Health care associated-infection rates.
4.12.3 Staff satisfaction.
4.12.4 Patient satisfaction.
4.12.5 Unplanned returns to operating room.
4.12.6 Unplanned transfer to critical care area.
4.12.7 Resuscitation of patients (Cardiac/respiratory arrest).
4.12.8 Readmission to the organization within 3 days of discharge.
4.12.9 Adverse events (falls, injuries, pressure ulcers).
4.12.10 Sentinel events.
4.12.11 Patient complaints.
4.12.14 All invasive and high-risk procedures.
4.12.15 Increased length of stay.

**EoC:** Quality indicators as suggested are identified and set by the leaders in the facility. These indicators are monitored and reviewed to inform quality improvement activity.

4.13 There are quality control results from the laboratory and radiology.

**EoC:** Lab and Radiology quality control data is aggregated and analysed. There is evidence of these results being reviewed and acted upon.
Element 5 - Management of Information and Medical Records

Introduction - Management of Information

One of the most valuable resources for any organisation is information. Accurate information is necessary to support decision making. Information that is trended over time can be evaluated to see if any improvements need to be made or to evaluate the effectiveness of an improvement that has been done. The ambulatory care facility should have a process to meet the information needs of its clinical and managerial leaders and to compare its performance with other databases when relevant.

Among the main requirements of this function are:

- Information needs assessment
- Information planning
- Data collection and analysis
- Information flow and reporting requirements
- Security, integrity, and confidentiality
Introduction - Medical Records

Medical Records are the backbone of all health care provision and considered one of the important elements in a quality program. The quality of the medical records is essential. Health care providers must be able to have access to information in the medical record in order to provide safe care. Also, this is vital for continuity of care and communication between care providers so that health care providers can find the necessary information for every patient encounter. To ensure appropriate management of medical records, the facility should have processes for access to records, entries into the record, and use of medical records information.

The medical records standards in this chapter address the following processes and activities:

- Staff responsible
- Initiation, construction and contents of medical records
- Criteria for medical records documentation
- Availability of medical records
- Storage and retention
- Security, safety, and confidentiality of medical records
Element 5 Management of Information and Medical Records - minimum standards

5.1 The facility develops and implements information management processes to meet the information needs of all those who provide clinical services and for those who manage the facility, this should include:

5.1.1 A definition of data, information, security, confidentiality and integrity.
5.1.2 A categorization of data available (both manual and electronic)
5.1.3 An assessment of information needs by both clinical and managerial staff within the organization.
5.1.4 A description of how confidentiality, security, and integrity of the data and information will be maintained.
5.1.5 A description of the various kinds of reports, the frequency of the reports, and who will receive them.
5.1.6 An educational/training schedule for decision makers and other appropriate staff on the principles of data management for decision-making.
5.1.7 A description of the roles and responsibilities of the leadership and department heads in relation to implementation and evaluation.

EoC: There are comprehensive information management processes developed by the leadership including 5.1.1 to 5.1.7.

5.2 The facility leadership determines the roles and responsibilities for data entry (completion of forms), data collection, data analysis, and reports generation and this includes:

5.2.1 Data elements being defined and forms developed for designated staff to enter the necessary data.
5.2.2 Establishing time frames for collecting data.
5.2.3 Displaying and analysing data using software programs (e.g., excel, access, DATIX etc.)
5.2.4 The leadership deciding the routing of the reports.

EoC: There is policy and process for all data management; this includes data elements being defined and process for collation being defined.

5.3 The facility has a policy on how confidentiality of data and information will be maintained and includes:

5.3.1 Who will have access to all different types and categories of information, and describes the penalties for the staff that violate the security and confidentiality of data and information.
5.3.2 The policy includes levels of access to patient information on a need to know basis.
5.3.3 The policy includes access to patient information by parental and family members.
EoC: There is written policy on maintenance of data and information confidentiality including levels of access on a need to know basis and disciplinary actions when the policy is not adhered to.

5.4 The ambulatory care facility contributes to external databases in accordance with Bahraini laws and regulations.

EoC: There is contribution to external databases in accordance with Bahraini laws and regulations. (E.g. Infectious diseases)

5.5 When there is automation of data, there is a planned, documented recovery system in case of computer malfunction to include system linked and standalone computers.

EoC: There is documented recovery system for automated data on all computers.
Element 5 - Medical Record Standards – minimum criteria

5.6 A record is initiated for every patient assessed and/or provided care or services by the facility.

EoC: A medical record is initiated for every patient assessed and/or provided care or services by the facility

5.7 The patient record initiated is easily identified by a unique patient identifier and can be easily tracked within the facility.

EoC: The patient record is easily identified by a unique identifier number and there is a medical record system in place for retrieving and tracking records.

5.8 All medical records must contain the following information at a minimum:
   5.8.1 The patient’s CPR, name, address, date of birth, and next of kin. The name must include: family name, first name, middle name.
   5.8.2 The medical history of the patient including:
      5.8.2.1 Details of the present illness, including, when appropriate, assessment of the patient’s emotional, behavioural, and social status.
      5.8.2.2 Relevant past, social, and family histories appropriate to the age of the patient.
      5.8.2.3 A clinical review by body systems.
   5.8.3 As appropriate to the age of the patient, a summary of the patient’s psycho/social needs.
   5.8.4 Reports of relevant physical examinations.
   5.8.5 Diagnostic and therapeutic orders.
   5.8.6 Evidence of informed consent.
   5.8.7 Clinical observations, including the result of therapy.
   5.8.8 Reports of procedures, tests, and their results.
   5.8.9 Physician’s documentation includes his/her assessment, diagnosis, impression, and plan of care revisions when indicated and therapeutic intervention.
   5.8.10 Conclusions at termination of evaluation/treatment.
   5.8.11 Follow up and discharge information.

EoC: There is a complete and unified record that contains elements 5.8.1 to 5.8.11

5.9 Only authorized staff members are allowed to make entries in patient records and:
   5.9.1 There is a unique identifier (name and/or license number) for each staff member that he/she uses when making entries in the records.
   5.9.2 The staff dates and times each entry into the medical record.
   5.9.3 The staff signs each entry.
   5.9.4 The staff identifies their designation within the facility
   5.9.5 Staff date and sign any changes made within the record
   5.9.6 All entries should be clear and legible
EoC: There is a written policy to identify staff authorised to make entries in the medical records. All entries are dated, timed, signed with designation printed.

5.10 The ambulatory care organization has a policy on the storage and retention of records, data and information and:
   5.10.1 The policy is consistent with Bahraini laws and regulations.
   5.10.2 The policy defines the length of time required to retain the records including x-rays (minimum 5 years).
   5.10.3 The policy addresses how confidentiality, integrity, and security of the records will be maintained.

EoC: There is a written policy on the storage and retention of records, data and information. This policy should address confidentiality, integrity and security of medical records.

5.11 The following issues are included in the ambulatory care organization policy for the completions of medical records:
   5.11.1 Medical record completion is a requirement on the same day and must contain: All relevant diagnoses established by the time of discharge, as well as all operative procedures performed.
   5.11.2 When required, a typewritten summary concisely restating the significant findings and diagnosis, treatments, current medications and follow up instructions is provided to the patient and, as appropriate to the practitioner responsible for the patient's continuing or follow-up care.
   5.11.3 The attending physician is responsible for the completion of his own record.
   5.11.4 Physicians, who do not complete their records in a timely manner, receive disciplinary actions as outlined in the organization's policy.

EoC: There is a written policy on maintaining and completing medical records in the facility which includes 5.11.1 to 5.11.5

5.12 Essential information about the patient is legible and located in the face sheet along with the information such as allergies and code status.

EoC: there is an area of the face sheet to document essential patient information related to allergies, and code status.

5.13 All laboratory/radiology results are seen and signed by a physician before being filed in the patient’s record.

EoC: the facility has a process in place and can provide evidence that all lab/radiology results are signed by a physician before being filed in patients records.

5.14 The facility has a list of approved and prohibited abbreviations to be used within the facility and all staff area aware of these.
EoC: There is a written list of approved and prohibited abbreviations that are approved for use throughout the facility. There is evidence within the medical records that there is compliance with the approved and prohibited abbreviations.
Element 6 - Infection Prevention and Control

Introduction

The ambulatory care facility requires processes in place to support the prevention and control of infection that might be acquired or transmitted by patients, staff, and visitors. These processes should reduce spread of infection, and ensure that care is provided in a clean, or where appropriate, sterile environment. There needs to be an effective facility-wide infection prevention and control program that identifies, reduces and eliminates infection risks.

This chapter outlines the requirements for the following processes and activities related to infection prevention and control:

- Infection control program
- Staff education
- Personal protective equipment
- Hand hygiene
- Sharps safety
- Cleaning, decontamination, disinfection, and sterilization
- Healthcare-associated infection
- Blood exposure
- Communicable diseases
- Waste management
- Laundry
- IPC precautions for renovations and constructions
Element 6 Infection Prevention and Control – Minimum Criteria Standards

6.1 The ambulatory care facility has developed and implemented a coordinated IPC program, which is referenced by the approved GCC Infection Prevention and Control Manual, to ensure patients safety and reduce the risk of healthcare-associated infections (HAIs) which is enforced through clear leadership.

EoC: There is evidence of a comprehensive coordinated infection control programme which is based on scientific knowledge and is led through clear leadership.

6.2 There is a qualified individual, acting on full-time or part-time basis, responsible for the infection control program.

EoC: There is an assigned individual responsible for infection, prevention and control who has received training and has experience in Infection Prevention and Control issues.

6.3 The infection control program should be combined in a manual that includes all administrative and practical guidelines:
   6.3.1 Written statement of authority.
   6.3.2 Written policies and procedures for:
   6.3.3 Disinfection and sterilization.
   6.3.4 Handling sharps.
   6.3.5 Infectious materials and waste disposals.
   6.3.6 Prevention of patients and workers exposure to healthcare-associated infections.
   6.3.7 Mechanism for monitoring the implementation of infection control policies and procedures.

EoC: The infection control manual is relevant to the facilities scope of services; elements 6.3.1 to 6.3.7 are included as a minimum requirement. Policy and procedure implementation is monitored on an on-going basis. The IPC manual is reviewed every two years or as required.

6.4 The infection control policies and procedures are available for all employees.

EoC: The infection control program is part of the induction program for all new staff and all IPC policies and procedures are available for all staff, updates provided when necessary.

6.5 Infection control tools and supplies: disinfectants and personal protective equipment (gown, gloves, masks, and protective eyewear) are readily accessible and available and are used correctly by staff in all patient care areas.
   6.5.1 Written policies and procedures are available on the appropriate use of gloves, gowns, facemasks, protective eye wear.
   6.5.2 Gloves are properly used.
   6.5.3 Gloves are worn when there is a potential for contact with blood/body fluid.
   6.5.4 Gloves are removed and discarded after use.
6.5.5 Gloves are removed as soon as work on the patient is done, and before leaving room.
6.5.6 Contaminated gloves are not used to touch uncontaminated surfaces (telephone, pens, paper, and files).
6.5.7 Gowns or other protective clothes are worn during all procedures which are likely to generate splashes or soiling from blood or other body fluids.
6.5.8 Masks and protective eyewear or face shields are worn during all the procedures which are likely to generate droplets of blood or body fluids.

EoC: The IPC manual includes policies on the use of personal protective equipment and disinfectants.

6.6 The organization designs and implements an effective hand hygiene program.
6.6.1 Written policies and procedures on appropriate hand hygiene are available.
6.6.2 Hand hygiene is strictly observed in the facility.
6.6.3 The facility provides sufficient hand hygiene facilities such as sinks and alcohol hand rubs.
6.6.4 Toilets and hand washing facilities meet the needs of the facility and are clean and in good repair.
6.6.5 Hand washing sinks are available in all patient care area (e.g., clinics, dressing room and nursing stations).
6.6.6 Hand washing sinks facilities are supplied with hot and cold water under pressure.
6.6.7 Hand washing sinks are easily accessible to staff.
6.6.8 Plain and antiseptic soap and paper towels (not cloth towels) are available for hand washing.
6.6.9 Hand disinfectants are available in adequate number (one dispenser per clinic, dressing room and one in every nursing station).
6.6.10 There is a documented staff education program on infection control practices.

EoC: There is a written policy on Hand hygiene practices which are adhered to across the facility by all staff. The facility provides the necessary resources to ensure implementation of hand hygiene practices. (Toilets, hand washing facilities, hot and cold water, antiseptic soap, paper towels and hand disinfectant with dispensers.)

6.7 The organization defines in policy the cleaning, decontamination and disinfection processes in all patient care areas.
6.7.1 List of appropriate detergents and disinfectants are defined and approved
6.7.2 Detergents and disinfectants are available in all patient care areas.
6.7.3 Patient care areas are clean and equipment is disinfected properly.

EoC: There is a written policy and procedure for cleaning, decontamination and disinfection processes, which includes a list of approved disinfectants and detergents to be used within the facility.
6.8 The organization defines in policy the safe procedures for waste collection, storage and disposal to ensure the safety of internal and external environment.

6.8.1 The policy differentiates between regular waste and infectious waste.

6.8.2 The infectious waste is treated according to the national medical waste management system.

EoC: There is a written policy and procedure on waste management. This should include the implementation of safe waste collection, storage and disposal, using the required resources in a way that protect patients, staff and the environment. There is evidence of proper disposal of waste through contracted company.

6.9 A comprehensive program for preventing sharp injuries is implemented:

6.9.1 There are written policies and procedures that address handling sharps.

6.9.2 Needles are not bent, broken or recapped except in special and approved circumstances.

6.9.3 If recapping is necessary the "scoop method" is used.

6.9.4 Performing the necessary investigations following needle stick or sharps injury and this data is collected for trending and reporting.

EoC: There are written and implemented policies and procedures for handling sharps, use and disposal. Staff are aware and have the knowledge and skills to prevent sharps injuries. There is evidence of follow up after sharps exposure as per IPC guidelines.

6.10 Sharps are discarded in appropriate containers:

6.10.1 The type of sharp container used is puncture-proof and leak-proof and presents no risk to staff or patients.

6.10.2 There is a sufficient number of sharp containers (at least one sharp container in every patient care area), and should be appropriately located away from traffic and preferably wall mounted.

6.10.3 Sharp containers are properly used: not overfilled, not opened to transfer sharps into other containers, and at or below eye level.

6.10.4 Sharp containers are disposed through the nationally approved system for medical waste management when their contents are 3/4 of their sizes.

EoC: the facility has sufficient number of puncture and leak proof sharps containers. The sharps containers are properly located and used. There is evidence that the sharps containers are not overfilled and are sent for incineration when ¾ filled.

6.11 Housekeeping has policies and procedures describing their function in keeping the facility clean and safe and include:

6.11.1 All units have a cleaning/disinfection schedule which lists all environmental surfaces and items to be cleaned.

6.11.2 There is a review of cleaning procedures, schedules and agents by infection control staff.
EoC: There are written and implemented housekeeping policies and procedures that are reviewed and approved by IPC link personnel. Cleaning schedules are prepared and implemented by housekeeping staff and there is an identified list indicating chemicals concentration and method of use in the facility.

6.12 There is a system to handle blood/ body fluids spills and wastes:
   6.12.1 Staff working in patient care areas are proficient in cleaning of blood/body fluids spills.
   6.12.2 There is a blood spill kit in every patient care unit that includes all necessary equipment. Policies on spill kit use should be written.

EoC: there are written and implemented policies and procedures on handling blood/body fluid spills. There are blood/body fluid spill kits available for staff.

6.13 The facility should use single use instruments where appropriate and should have identified justification when single use is available and not utilised.

EoC: single use instruments should be used as preference and should never be sterilised or re-used under any circumstances. If reusable instruments are used and sterilised, proper procedures should be in place and proper justification for their use as opposed to single use should be given.

6.14 When required, sterilization services must be available with the following structural and functional specifications:

   6.14.1 Personal protective equipment is available and used during decontamination: heavy-duty gloves, waterproof aprons, facemask, goggles or face shield.
   6.14.2 Staff carrying out the sterilisation procedure need to have adequate knowledge and training.
   6.14.3 Cleaning, disinfection and sterilization of medical equipment/instruments should be done in a separate sterilization unit/area. This should not be carried out in an area where patients are seen/treated.
   6.14.4 There is a uni-directional flow of traffic from dirty to clean areas. I.e. decontamination area > packing > sterilization > storage areas.
   6.14.5 Proper sterilization parameters are recorded.
   6.14.6 Sterilization records are kept for one year to allow inspection.
   6.14.7 Sterilizers are maintained and in good working order and operational instructions are available. Chemical indicators are used in every package. Biological indicators are used at least weekly. Records of results are kept for one year for inspection

EoC: There are written and implemented policies and procedures for decontamination, disinfection, storage and sterilisation processes. There should be a designated area for sterilising equipment when required. There should be a uni directional flow of traffic from dirty to clean areas I.e. decontamination>disinfection>packing>sterilising>storage.
There is a complete and comprehensive monitoring and recording of the sterilisation process that can be presented showing, sterilisation records, spore results, biological indicator results, and other records.

6.15 Communicable diseases are tabulated and reported as required by Ministry of Health.

**EoC:** There is a written policy and procedure for reporting communicable disease as required by MoH.

6.16 Laundry functions are overseen by a person with infection control training.
   6.16.1 There is a written policy and procedure on linen management.
   6.16.2 Clean linen is transported, handled and stored in a way that keeps it protected from contamination and dust.
   6.16.3 There is functional separation of clean and used linen during storage and transport.
   6.16.4 Linen carts used for clean and used linen are clearly identified.
   6.16.5 Dirty laundry must be enclosed at all times.
   6.16.6 Contaminated laundry with patients’ blood, excreta, or other body fluids are contained and transported in accordance with the following standards:
   6.16.7 Linen is handled as little as possible and with minimum agitation.
   6.16.8 Linen is bagged at the location where it is used, and is not stored or pre-rinsed in patient's care areas.

**EoC:** There is a written policy and procedure on linen management that protects patients and health care workers from infectious hazards. Proper linen handling, transportation and storage processes are followed according to 6.16.1 to 6.16.8.

6.17 When food is provided in the facility, kitchen environment and functions are overseen by a person with infection control training. If food services are contracted the facility must ensure that the following requirements are still met:
   6.17.1 Food containers are properly labelled and expiry dates noted.
   6.17.2 Temperature requirements are met during storage, preparation and transportation.
   6.17.3 Food is protected from environment during storage, preparation, display and transportation.
   6.17.4 Fruits and vegetable are washed and disinfected thoroughly.
   6.17.5 Garbage containers or receptacles are adequate in number, and are insect and rodent proof and are covered.
   6.17.6 Food containers are washed immediately after being emptied from food.
   6.17.7 Boards to cut meat, poultry, chicken, or vegetables should be separate and should be immediately washed after use.
   6.17.8 Refrigerator temperatures are checked daily and documented on log sheets.
   6.17.9 Kitchen environment is clean without areas of stagnant water on floors.

**EoC:** Food containers are properly labeled and expiry dates are noted. Food is protected from the environment through proper storage, preparation and transportation (including proper temperature, washing disinfection and cutting). Comprehensive hygiene for all
steps of food preparation is followed. There are adequate resources that ensure clean kitchen environment (including adequate and proper garbage containers, no stagnant water on floors).

6.18 There are written policies and procedures that address all hygiene and health issues in the kitchen: these should include

6.18.1 Hands are washed and cleaned on start of shift, and every time when non-food item is touched.
6.18.2 Hair is covered when handling food.
6.18.3 Gloves are worn while handling raw meat, or vegetables, or fruits.
6.18.4 There are enough hand washing facilities with liquid soap and paper towels in the kitchen.
6.18.5 Personnel with respiratory infections or gastroenteritis are restricted from handling food.

EoC: There are written policies and procedures in the kitchen area and kitchen staff hygiene is practiced properly utilizing the required resources (hand washing, hair covering, wearing gloves, others).

The kitchen staff health is monitored as required and is supported through records and documentation.
Element 7 - Facility Management and Safety

Introduction

A safe, functional and effective environment for patients, staff and other individuals is crucial to prevent or minimize risks in the environment of care. The facility leadership has to provide all necessary support and resources to improve safety in the work place in alignment with regulatory requirements.

The facility must have plans for managing the safety of the environment and must implement these plans. The facility must collect and analyse data to determine the effectiveness of the plans and facilitate continuous improvement in safety.

Staff must also be educated on their responsibilities. Education must commence at orientation and continue on a regular basis thereafter.

Important aspects of the facility management and safety addressed in this chapter include the following:

- Safety
- Security
- Fire safety
- Emergency
- Hazardous materials
- Medical equipment
- Utilities
Element 7 – Facility Management and Safety – Minimum Criteria

7.1 There is an appropriately qualified person appointed in a full time or part time capacity, who is responsible for the facility management and safety program.
   7.1.1 In small facilities: if the safety officer (however named) is appointed/contracted on a part time capacity, the facility should demonstrate dedicated hours of service and frequency of attendance to be appropriate with workload.

EoC: There is an assigned, appropriately qualified management and safety officer for the facility. In a small facilities: if the safety officer is in a part time capacity, the job description or other document demonstrates dedicated hours of service and frequency of attendance to be appropriate with workload.

The safety officer should be qualified by education, training, experience, or certification.

7.2 The facility environment is safe for patients, visitors, and staff.
   7.2.1 The facility has plans that include emergency management, utility systems, hazardous materials, fire safety, medical equipment, building and environmental safety, and security.
   7.2.2 The building and the surroundings are free from hazards.
   7.2.3 Periodic preventive maintenance (PPM) and corrective maintenance are done in all electrical and mechanical systems.
   7.2.4 All staff are trained in health and safety.

EoC: The facilities plans detail how to respond to different emergencies/disasters and how to minimize risks. No hazards such as falling objects, exposed outlet or wiring, slippery floor, sharp ends, holes are in the ground are evident.

PPM records are kept for all electrical and mechanical systems i.e. A/C, Power, and equipment.

Staff are trained in evacuation, RACE/PASS for fire response, hygiene, and sterilization.

7.3 The facilities building and environment is user friendly.
   7.3.1 The building and surroundings are built as per Bahrain laws and regulations, taking account of municipality and MOIC requirements.
   7.3.2 The organization is equipped for people with special needs, e.g., disabled, elderly, children.
   7.3.3 The organization has adequate amenities, e.g., parking, waiting/rest areas, prayer rooms and male and female toilets.
   7.3.4 The organization has directional signs.

EoC: The building and its services comply with the NHRA minimum design standards, and the Kingdom of Bahrain laws & regulations. The facility waiting areas and parking areas are adequate for its users, and there is adequate toilets, wash rooms and baby changing areas if required. There are wheel chairs ramps in all elevated areas. There are
handrails in the corridors and stairs. The facility is child safe in the public areas, e.g., tamper free outlets, no small objects, and no sharp ends.

Directional signs are posted in proper places and fire exits are clearly signposted.

7.4 Regular multidisciplinary rounds are scheduled and conducted to ensure safety and include the following:
   7.4.1 Environmental audit rounds to check staff knowledge and implementation regarding the FMS plans (quarterly).
   7.4.2 Facility Tours to check the facility/physical plant (quarterly).
   7.4.3 The resulting information is used for corrective actions and planning and budgeting long-term facility upgrading and replacement.

EoC: There are regular documented environmental rounds describing findings and actions taken

7.5 The facility has a fire prevention program.
   7.5.1 Staff are trained on the fire evacuation plan.
   7.5.2 Escape routes are free from obstacles.
   7.5.3 Storage is appropriate and carried out properly.
   7.5.4 Fire systems including fire alarm and fire equipment are in place and functioning.

EoC: Each employee attends fire drills annually and attendance is logged. Escape routes plans are posted in the corridors. The fire drills and the evacuation plan are continuously improved and updated. Corridors and fire escapes are marked and free from obstacles, e.g., locks, boxes. Boxes are stored in a proper way and in the right place. Fire extinguishers are functioning, tested and distributed within the facility. Fire alarms are maintained and tested, and its PPM records are kept.

7.6 The facility is secured and protects its users.
   7.6.1 Security personnel are available if appropriate.
   7.6.2 The facilities equipment and data are secured.
   7.6.3 The patients’ privacy is respected.
   7.6.4 No smoking policy is enforced.
   7.6.5 Staff accommodation is located separate from the facility and is not accessed through the facility.

EoC: There are trained security personnel available if appropriate, the facility has an alarm system installed and the main doors are locked after hours. Patients and staff files are accessible for authorized persons only. Patients’ privacy is protected, e.g., curtains or segregation when appropriate, there is approved no smoking policy which is implemented, and smoking signs are posted in all entrances.

7.7 There is a plan and implemented program for inspecting, testing and maintaining medical equipment.
   7.7.1 There is an inventory list of all medical equipment.
7.7.2 The medical equipment is subjected to regular “predictive and preventative maintenance” (PPM) and is tagged accordingly.
7.7.3 All defective medical equipment is removed labelled accordingly.
7.7.4 No obsolete equipment is kept in the facility premises.
7.7.5 There are temperature chart recorders in all pharmacy and lab fridges and freezers.

EoC: There is an Inventory list and maintenance program of all medical equipment and records are kept. Functional/defective tagging is implemented. All obsolete medical equipment are removed from the facility. Temperature chart records are available in all pharmacy and lab fridges and freezers.

7.8 The facility has an emergency plan and staff are trained on it.
    7.8.1 The emergency plan defines the staff roles.
    7.8.2 The emergency plan identifies the nearest healthcare facilities for transferring patients if required.
    7.8.3 Staff are competent in completing the emergency drills.

EoC: The emergency plan is documented, evaluated annually and updated as needed. The staff roles are defined in the plan and the staff know where to refer patients during emergencies. The staff are trained in emergency drills annually. The emergency plan includes contact persons and authorities. The facility has an alternative power and water sources for emergencies.

7.9 The facility has a hazardous materials (hazmat) and waste disposal plan.
    7.9.1 The facility keeps a register of all Hazardous materials in the facility.
    7.9.2 Staffs are trained in dealing with Hazardous materials and waste.
    7.9.3 The Hazardous materials and waste are controlled.
    7.9.4 Emergency shower and eye washer are available in the lab if required.

EoC: The facility keeps an updated Hazmat register. Hazmats are stored, handled, transported, used, and disposed as per their Material Safety Data Sheets. All staff are trained in dealing with available Hazmats. The facility exerts effort to reduce Hazmats that are in use in the facility. Functioning emergency showers and eye washer are available in the lab. Fire rated cabinets are used for any flammable Hazmat that may be in use.
Element 8 Patient and Family Education

Introduction

Patients have a right to receive appropriate education, so they can utilize their knowledge to participate in their care and make informed care decisions. Additionally, patient education improves health by encouraging compliance with medical treatment. To ensure appropriate patient and family education, facilities should provide adequate resources, identify patient/family educational needs, develop individualized education plans and provide education accordingly, and evaluate the effectiveness of the education process.

This chapter outlines the following processes and activities:

- Educational resources
- Assessment of educational needs
- Education plan
- Effectiveness of education
Element 8 Patient and Family Education - Minimum Criteria Standards

8.1 There is an appropriate standardised approach, structure or mechanism of patient/family education throughout the facility:

8.1.1 There are efficient resources for patient/family education according to the facility needs. Based on patient/family needs, the facility provides appropriate teaching methods such as pamphlets, diagrams, models to practice on, pictures, and one-to-one presentations.

8.1.2 The job description of the healthcare professionals reflects their role in patient/family education.

8.1.3 Healthcare professionals (nurses, physicians, dieticians, etc.) and health educators, when employed and assigned by the facility, are knowledgeable about their essential role in patient education.

8.1.4 There are discussions of patient education efforts in staff meetings as an integral part of the care process.

EoC: The facility provides adequate resources to carry out the patient education function. All healthcare providers know their role in patient/family education is included in their job descriptions.

8.2 There are guidelines for health educators on how to teach the patient/family this includes but is not limited to:

8.2.1 How to deal with language barriers and teach the patient in a suitable language so the patient/family can understand.

8.2.2 How to provide sufficient time to allow the patient to absorb the information given to him.

8.2.3 How to provide enough time to interact with the patient/family.

8.2.4 How to use pamphlets, diagrams, models to practice on, visual aids or other teaching methods.

8.2.5 How to obtain feedback from the patient/family to ensure he/she/they understand by repeating or demonstrating.

EoC: A Policy and procedure is in place for the patient education function which includes elements 8.2.1 to 8.2.5.

8.3 The patient and/or his family are given the following necessary education and information by healthcare professionals as appropriate:

8.3.1 Giving the patient appropriate information about their illness and complications that might happen.

8.3.2 Teaching the patient infection control practices, especially basic hand washing.

8.3.3 Explaining the necessary treatments and procedures and providing pamphlets or diagrams if available.

8.3.4 Explaining and teaching the appropriate and safe use of the medical equipment or appliances with return demonstration.

8.3.5 Any surgical/minor op procedure needed and its benefits and potential risks involved with the procedure.
8.3.6 The pre-preparations needed and their importance.
8.3.7 Postoperative/post procedure care, i.e., breathing exercises, diet and wound care.
8.3.8 The necessary medications that are needed to be given pre and post-procedure, the medication’s potential side effects, and food/drug interactions.
8.3.9 The medications used to treat an illness, the frequency of taking the medication, the side effects, and precautions.
8.3.10 X-ray procedures; their benefits and the potential risks involved.
8.3.11 Explaining the conditions in which the patient needs to seek medical assistance and how to access it if necessary.
8.3.12 Ensuring that patients attend his/her follow up clinic appointment.
8.3.13 Informing the patient about community resources for additional care and how to access emergency services if necessary.

EoC: There is evidence that the care givers provide adequate education and information as appropriate to the patient’s needs.

8.4 All patient education activities provided by healthcare professionals including the patient’s response are documented in the patient’s medical record (preferably using a form designed for patient teaching).
8.4.1 There is documentation about the patient’s response to education in the patient medical record.

EoC: There is evidence of documentation of the education process in the medical record. The evaluation of the effectiveness of the education process is documented in the medical record.
Element 9 Provision of Care

Introduction

Ambulatory Care Facilities vary in the scope of services they provide and thus the types of patients they may effectively serve. The facility should accept patients for services according to its capability to provide the services that meet the identified patient’s needs. Providing optimum care requires careful planning, coordination, and communication. The ambulatory care facility must provide an appropriate and thorough assessment of each patient, and patient care must be planned and implemented to ensure the best possible outcome for the patient. To support continuity of care, patient assessment and care must be documented in a complete medical record for the patient. As the care process may need to occur between multiple providers, a collaborative process should be in place to promote continuity and coordination of care when the patient is referred, transferred, or discharged.

Important processes and activities addressed in this chapter include the following:

- Access to care
- Scope and content of patient assessment
- Medical assessment
- Nursing assessment
- Plan of care
- Reassessment
- Patient discharge, transfer and referral within or outside the facility
Element 9 Provision of Care – Minimum Criteria

9.1 The ambulatory care facility should define and display the services that it provides.

EoC: There is evidence that the facility defines its services and communicates them to the patients, families and the community at large. Staff are aware and familiar with the services provided.

9.2 The facility should provide facilities that ensure patients privacy and dignity are maintained.

EoC: The facilities are designed to ensure that privacy and dignity are maintained, either through separate rooms, or areas that are curtained off to ensure privacy.

9.3 The facility has a process to provide access to advice that meets the needs of different cultural beliefs, values and needs of the populations it serves.

EoC: The facility provides training to their staff and can provide health education material that addresses cultural beliefs, values, and needs of different populations being served.

9.4 There is an appointment system in operation which provides fair and open access and a standardised process for registering patients.

EoC: There is an appointment system and registration process in place.

9.5 Clinical practice guidelines are used to guide clinical care for patients as appropriate to the facilities mission statement and objectives.

9.5.1 Clinical practice guidelines are informed or adopted from best international practice and evidence based medicine and are followed by all staff

9.5.2 The clinical practice guidelines are updated at least every 2 years or when needed.

EoC: There are clinical practice guidelines, which are reviewed at least every 2 years or when needed and staff follow the clinical practice guidelines.

9.6 The ambulatory care facility identifies the health care needs of its patients through an established assessment process. This should include:

9.6.1 Which healthcare provider is responsible for screening and assessment of patients in accordance with laws, regulations, and licensure.

9.6.2 The scope and content of assessment by each discipline.

9.6.3 The scope and content of assessment in different care settings.

9.6.4 The time frame for completion of assessment by each discipline.

9.6.5 The frequency of reassessment of patients.

9.6.6 Each patient is screened for nutritional status, functional status, psychosocial needs, and potential abuse or neglect.

9.6.7 Terminally ill patients receive spiritual and cultural assessment.
EoC: There is a written policy to define the scope and content of assessment by each discipline and time frame for completion of the assessment process. There is evidence of documented complete assessment of patients.

9.7 Patients are assessed, reassessed and managed for pain (acute/chronic) which includes:
   9.7.1 The assessment and reassessment is appropriate to the patient’s condition.
   9.7.2 The assessment of pain includes the pain intensity, frequency, location, duration, and type experienced by the patient (e.g. sharp/dull.)
   9.7.3 The process of pain assessment and management is documented in the medical record.
EoC: There is evidence of pain assessment and management as appropriate to the patient’s condition.

9.8 Patient allergies or prior adverse reactions are noted, documented and prominently and consistently displayed in a specified area of the patient’s record.

EoC: There is evidence of documentation of patient allergy or prior adverse reactions in the medical record.

9.9 On the first visit, a comprehensive medical assessment including medical history and physical examination is carried out.
   9.9.1 Updates to the patient’s condition are documented at each patient’s visit.

EoC: There is a documented comprehensive history and physical examination performed on the first visit. There is a documented update at each visit.

9.10 The necessary diagnostic tests (laboratory and radiology) are performed in a timely manner to determine diagnosis.

EoC: Laboratory tests and radiological procedures results and follow up are documented in the medical record as appropriate.

9.11 All patients are reassessed at appropriate intervals to determine:
   9.11.1 Response to treatment.
   9.11.2 Compliance to treatment.
   9.11.3 Complications and side effects.
   9.11.4 Plan for continued treatment or completion of treatment.

EoC: There is documentation in the medical records of reassessment findings including elements 9.11.1 through 9.11.4

9.12 A care plan is developed to meet the needs of each patient.
   9.12.1 The care plan is developed by the attending physician, nurse, and other disciplines participating in care and is based on the assessments and reassessments.
9.12.2 The plan of care is revised every visit, when any significant changes in the patient’s condition occur, and new treatments are added or discontinued.

EoC: Plan of care is documented in the patient’s medical record. There is evidence of plan of care revision during subsequent visits.

9.13 The facility has a written policy and procedure regarding the acceptance and transfer of patients from and to other organizations/facilities. This should include safe travel arrangements and the transfer of care from physician to physician.

EoC: There is a written policy and procedure regarding transfer /acceptance of patients from/to other facilities/organizations. The policy includes the transfer process, documented in medical records and the transportation needs as per the patient’s condition.

The following two standards should be assessed if the facility “scope of services” includes minor operations, invasive procedures or IV administration.

9.14 The facility should have policies and procedures to guide the handling, use, and administration of blood and blood products if the scope of services require and include:

9.14.1 Only physicians order blood and/or blood products in accordance with a policy clarifying when blood and blood products may be ordered.

9.14.2 Informed consent is obtained for transfusion of blood and blood products: the physician provides information and education to the patient about the need for blood and/or blood products, and the benefits and the associated risks involved in receiving blood or blood products.

9.14.3 Two staff members verify the patient’s identity prior to the administration of blood or blood products.

9.14.4 Policy and procedure guides the administration and monitoring of blood and/or blood product transfusions.

9.14.5 Transfusion reactions are reported and analysed for preventive and corrective actions.

EoC: There are written criteria for ordering blood and blood products. There is a policy and procedure for the administration and monitoring of blood transfusions. There is an informed consent in the medical record for any blood transfusion procedure.

9.15 The facility has policies and procedures and an effective system to safely provide care to patients who require Cardio Pulmonary Resuscitation (CPR) and includes:

9.15.1 Standard emergency medications, intubation equipment and, venous access and airway access equipment, IV fluids that are appropriate and age specific (e.g. neonate, infant, child, adult).
9.15.2 A simple defibrillator/heart start monitor that is in good working order, maintained, and charged at all times.

9.15.3 Oxygen cylinder and oxygen administration set and mask.

9.15.4 Portable suction machine.

9.15.5 A recorded process for checking the emergency medications and equipment every shift by qualified staff.

9.15.6 A simple number such as 999 or other mechanism to call when summoning help.

9.15.7 Training for all clinical staff on how to use the alarm system and the CPR process.

9.15.8 A policy and procedure outlines the roles and responsibilities of staff handling CPR.

9.15.9 Documentation for performed CPR is standardized by using a “CPR form” which ensures proper documentation of the events, including informing patients’ relatives/family.

EoC: There is a policy and procedures defining the CPR response system and roles and responsibilities of individuals on duty. There is emergency medication and equipment available on the facility premise which is easily accessible.
Support Elements
The support elements are assessed as being applicable or not applicable and assessed accordingly.
Element 10 - Radiology

Introduction

The assessment/reassessment of patients to determine the proper diagnosis, the course of treatment, and evaluation of treatment plan for future decisions may require radiology services.

To meet patient needs, the ambulatory health care facility may offer basic radiology services required by its patient population, clinical services offered, and healthcare provider needs. The department, from a building perspective is expected to meet the necessary national guidelines on radiation safety.

This chapter addresses the following:

- Physical structure
- Staffing
- Safety program
- Results reporting (including panic findings)
Element 10 Radiology Services - Minimum Criteria

10.1 The primary healthcare center has a Radiology Services manual that is updated, available, and well known to concerned staff.

   10.1.1 Includes the scope of radiological services.
   10.1.2 Includes policies and procedures for radiological services.
   10.1.3 Identifies roles and responsibilities of the concerned staff.
   10.1.4 Includes forms and registries required for the radiological services.
   10.1.5 Includes quality control program.
   10.1.6 Includes radiation safety program.
   10.1.7 Includes indicators for performance monitoring, evaluation, and improvement.

EoC: There is a written, updated manual for the Radiology services that includes elements 10.1 through to 10.7. The manual is available and known to all staff.

10.2 Radiology services are provided and operated by qualified and adequate staff.

EoC: Radiology services staff are adequate and are licensed by the NHRA in the Kingdom of Bahrain.

10.3 The necessary equipment and supplies are available to provide the RS.

EoC: All necessary equipment and supplies are available in adequate amounts to provide the required radiology services.

10.4 The radiology space is in accordance with Bahraini law and is adequate for its function, well-maintained, free of clutter, and does not compromise the quality of work and personnel safety. The designated radiology space must have:

   10.4.1 Space that is adequate and appropriate for the work.
   10.4.2 A waiting area that provides toilets for the radiology unit that is comfortable and ensures privacy of patients.
   10.4.3 Appropriate storage area for x-ray films and dark room materials or CR digital storage.
   10.4.4 Changing area for patients

EoC: The space available is adequate and appropriate for the work. There is a comfortable waiting area that ensures privacy of patients. There is an appropriate storage area for x-ray films and dark room materials if required or evidence of appropriate storage for CR digital.

10.5 There is a radiation safety protocol or plan in place to protect staff, patients, and the environment that includes at least the following:

   10.5.1 All equipment is maintained in accordance with manufacturer’s instructions, meeting regulation requirements and are inspected and checked regularly with an experienced person.
   10.5.2 All radioactive materials are used according to the guidelines.
10.5.3 Safety warnings are posted on doors in clear and appropriate locations. There is a light outside that indicates when radiation is in use.
10.5.4 Women are checked for the possibility of being pregnant prior to having X-ray tests and the X-ray form demands that personnel ask the patient.
10.5.5 Personnel are monitored for radiation exposure:
   10.5.5.1 Thermo luminescence Dosimeter (TLD) is regularly checked for all radiology staff.
   10.5.5.2 Checking white blood cells periodically for all employees in Radiology Department.
   10.5.5.3 Radiation personal protective measures are available for employees and patients.

EoC: There is a written, comprehensive radiation safety program. Safety warning signs are posted as necessary. There is evidence that 10.5.1 through 10.5.8 are in place.

10.6 Physicians requesting x-ray procedures write all necessary information on the radiology X-ray request form.

EoC: All necessary information is written on the x-ray request form by the requesting physician.

10.7 Radiology reports are available by a defined reporting time according to patient needs.

EoC: There is evidence of availability of all radiologic studies within a defined reporting time.

10.8 There is a master X-ray folder or access to all archived previous radiological studies for every patient.

EoC: All archived patient radiology studies are accessible in a master x-ray jacket.

10.9 All diagnostic imaging examinations are reported by licensed medical specialists.

EoC: There is evidence that registered staff report all radiological studies.

10.10 There is a policy that "urgent" findings on the X-ray films are reported immediately to the person requesting the examination: e.g., air under the diaphragm.

EoC: There is a written policy for immediate reporting of "panic findings" to the requesting physician. There is evidence of implementation of the panic finding policy.
Element 11 - Laboratory

Introduction

The assessment/reassessment of patients to determine the proper diagnosis, the course of treatment, and evaluation of treatment plan for future decisions may require laboratory services. To meet the patient needs, the facility may provide basic laboratory services required by its patient population, clinical services offered, and healthcare provider needs.

This chapter addresses the following:

- Physical structure
- Staffing
- Safety program
- Specimen collection
- Equipment management program
- Labelling
- Results reporting
- Quality management program
- Point of care testing
**Element 11 – Laboratory - Minimum Criteria**

11.1 Laboratory services are available to meet patient needs and in accordance with applicable national standards.
   11.1.1 A list of available laboratory services is published.
   11.1.2 The laboratory has access to referral and consultation services in the form of agreement.
   11.1.3 When the laboratory services are provided through a contract, the organization is responsible to provide oversight of contracts and:
      11.1.3.1 Ensure relevant leaders’ recommendations and approval.
      11.1.3.2 Ensure that the provider meets applicable laws and regulations.
      11.1.3.3 Regularly monitor the provider’s compliance with accreditation standards, and other components of the contract as specified by the organization.

**EoC:** The available laboratory services meet the patients’ needs and applicable standards.

There is a written agreement with a licensed laboratory for the provision of special procedures and consultations. When there are contracts with outside sources for provision of laboratory services, elements 11.1.3.1 to 11.1.3.3 must be met.

11.2 A current laboratory policies and procedures manual is readily available to staff. The policies and procedures manual should be well structured and:
   11.2.1 Reviewed every two years.
   11.2.2 Laboratory personnel are knowledgeable about the contents of policies and procedures manual relevant to the scope of their testing activities.

**EoC:** There is a comprehensive, approved and current policies and procedures manual and there is evidence of that all staff are aware of the contents of the manual.

11.3 The laboratory facility structure is defined and available.
   11.3.1 A qualified individual(s) is responsible for managing the laboratory services.
   11.3.2 Appropriately qualified individuals staff the laboratory and are included in the structure.
   11.3.3 All laboratory sections are identified and they are under the responsible person’s supervision.
   11.3.4 Chain of command and reporting functions must be clear.

**EoC:** there is a suitably qualified clinician who is accountable within the laboratory. There is an updated and approved laboratory organizational structure which identifies all staff categories under supervision.

11.4 The laboratory space is adequate for its function, well-maintained, free of clutter and does not compromise the quality of work and personnel safety. The designated laboratory space must have:
   11.4.1 Adequate water taps, sinks and drains.
   11.4.2 Adequate electrical outlets and emergency power.
   11.4.3 Adequate ventilation, temperature and humidity control.
   11.4.4 Adequate lighting.
EoC: There is adequate space for Lab administrative and technical work. There are at least 2 sinks with one sink used exclusively for hand washing. Critical machines should be attached to emergency socket and/or have generator back up. All machines are attached directly to wall socket without extension cables and splitters. There is evidence of adequate control of temperature and humidity. There is a telephone in the laboratory.

11.5 The laboratory establishes a documented safety program under the supervision of the laboratory management and consistent with the facility’s safety guidelines. The laboratory safety program must include:
   11.5.1 Comprehensive current and approved laboratory safety manual readily available to laboratory personnel.
   11.5.2 Fire safety is implemented according to the facility’s plan.
   11.5.3 All doors leading to the laboratory are marked to indicate hazard.
   11.5.4 All sharp wastes (needle, syringes, blades, lancets) are discarded in a puncture proof rigid labelled container.
   11.5.5 Eye wash stations and emergency showers are available.
   11.5.6 Fume hoods and biological safety cabinets are inspected and certified when in situ.
   11.5.7 Reporting system of all occupational injuries or illnesses that require medical treatment and maintaining related records.
   11.5.8 Effective chemical management plan.

EoC: There is comprehensive, approved and current safety manual which includes, but not limited to, handling of chemical hazards, chemical spills, accident documentation, reporting injuries, fire prevention and control, safe handling of electrical equipment and wastage handling and disposal. There is evidence that all staff are aware of the safety manual contents. There are fire and safety training records. There are sufficient safety signs posted where appropriate. Eye wash stations and emergency showers are available and checked at regular intervals. Fume hoods and biological safety cabinet are inspected and certified at regular intervals. There is effective system for reporting and investigating occupational injuries and accidents.

11.6 The laboratory implements all the rules and guidelines of infection control and:
   11.6.1 Personal protective equipment (gloves, masks, and eye/ face shield, gowns, and lab coats) are available and worn as appropriate.
   11.6.2 Eating and drinking is prohibited in the laboratory.
   11.6.3 Universal precautions are implemented.
   11.6.4 All specimens of blood and body fluids are transported in leak-proof containers.
   11.6.5 Clean and contaminated working areas are marked.
   11.6.6 All employees are vaccinated with Hepatitis B Vaccine.
   11.6.7 Negative pressure is maintained in laboratory when dealing with high infectious material.

EoC: Personal protective equipment are available and used when appropriate. Observation, There is evidence for the implementation of policies on universal precaution and prohibition of eating and drinking in the lab. Leak-proof containers for sample transport are available and used. There is evidence of negative pressure monitoring in microbiology. There are evidences of clear designation of clean and
contaminated areas. There are records in support of the immune status or vaccination for all lab personnel.

11.7 The laboratory publishes and distributes clear written instructions for proper collection, handling, transportation, and preparation of specimens and include:
  11.7.1 Patient identification.
  11.7.2 Patient preparation.
  11.7.3 Specimen collection and labelling.
  11.7.4 Specimen preservation.
  11.7.5 Specimen storage.
  11.7.6 Conditions for transportation.
  11.7.7 Specimen receipt in the laboratory.

EoC: There are clear written instructions for proper collection, handling, transportation, and preparation of specimens including all of the above elements. There is a laboratory specimen guide distributed throughout the facility.

11.8 The laboratory keeps instrument and equipment in proper functional condition through the establishment of a system by which all equipment are properly operated, cleaned, quality controlled, monitored and maintained. This system must include but not limited to:
  11.8.1 Operation and service manual.
  11.8.2 Maintenance schedule.
  11.8.3 Maintenance records.

EoC: There are written policies and procedures for monitoring of instrument and equipment function in addition to preventive maintenance. Maintenance records for all laboratory equipment are maintained.

11.9 Reagents and solutions are properly labelled, as applicable and appropriate, with the following elements:
  11.9.1 Content, quantity, concentration and/or titre.
  11.9.2 Storage requirements.
  11.9.3 Date prepared or reconstituted by laboratory.
  11.9.4 Expiration date.
  11.9.5 All reagents are used and stored as recommended by the manufacturer.
  11.9.6 All reagents used must be within their indicated expiration date.
  11.9.7 If there are multiple components of a reagent kit, the laboratory uses components of reagent kits only within the kit lot unless otherwise specified by the manufacturer.
  11.9.8 New reagent lots are checked against old reagent lots or with suitable QC material before or concurrently with

EoC: There are written policies and procedures for reagent preparation, labelling, storage and expiration. There are package inserts of commercial reagents and kits. Reagents are labelled in accordance with the laboratory policy.

11.10 The laboratory has clear system for results reporting including:
  11.10.1 Defined Turn Around Time (TAT) for all laboratory services.
  11.10.2 Definition of Critical Results and their reporting method.
EoC: There is evidence of Turn Around Times for all laboratory services are defined, communicated and agreed upon by clinical departments. There are written policies and procedures for reporting panic values (critical results). There are records in support of proper reporting panic values.

11.11 The laboratory must have a quality management program approved by the management and available for all laboratory personnel. The laboratory quality management program is integrated with the organization wide quality improvement program and includes:

   11.11.1 Key quality indicators are selected, monitored and evaluated to detect potential problems.
   11.11.2 Incident, adverse events and accident reporting system to avoid reoccurrence.
   11.11.3 A Proficiency Testing (PT) system for each analyte reported either by participating in external PT or performing in-house alternative PT.
   11.11.4 Corrective and/or preventive actions taken, where appropriate, when expected results are not achieved.

EoC: There is written quality management program satisfying all of the elements above. There is evidence of defining the laboratory key quality indicators. There is evidence of participation in external and/or internal proficiency testing program that includes all laboratory analytes. There is evidence of employing efficient accident and adverse event reporting and investigating system. There is evidence of corrective and/or preventive measures taken when expected quality monitoring outcomes are not achieved.

11.12 There is documented evidence of on-going evaluation by the management of point of care testing (POCT) and:

   11.12.1 A point of care testing has a written QC/QM program.
   11.12.2 A list of all point of care testing equipment in the facility is available.
   11.12.3 A documented procedure manual for POCT is available in the areas where POCT is performed.
   11.12.4 A policy is in place to detect and correct significant clerical and analytical errors and unusual or unexpected test results.
   11.12.5 There is an appropriate person available on all shifts to assist with trouble shooting or other unusual POCT situations.
   11.12.6 There is a documented orientation, training, and competency assessment for POCT users.

EoC: There is a list of all POCT points in the facility. Point of care testing QC/QM program is available and documented. Corrective actions are documented and there is a training and competency assessment for staff performing POCT.
Element 12 - Pharmacy

Introduction

The use of medication is an important component in the treatment of many diseases and conditions. However, the improper management or use of medications may cause great harm to patients. Therefore, the ambulatory care facility needs to ensure that the pharmaceutical services are organized and administered appropriately to provide effective, efficient, and safe pharmacy services. In essence, a well-managed medication administration system promotes patient safety and quality of care.

The pharmacy standards comprise the following processes and activities:

- Ordering
- Medication security and safety
- Formulary system
- Labelling
- Dispensing
- Administration
- Storage
- Emergency medications
- Monitoring medications effects
- Medication error identification and reporting
- Adverse drug events identification, reporting, and response
- Retrieving and managing recalled medications
- Controlled drugs management
Element 12 Pharmacy – Minimum Criteria Standards

12.1 The ambulatory care facility has a pharmacy department which is managed by a qualified pharmacist. When a qualified pharmacist is not available, such as in a small facility, pharmaceutical services should be managed by a pharmacy technician.

12.1.1 The pharmacy manager is a certified and registered pharmacist (holds bachelor degree in pharmacy). When the pharmaceutical services are managed by a qualified assistant pharmacist, his/her competency should be assessed at least bi-annually by a qualified pharmacist and documented supervision maintained.

12.1.2 The pharmacy/assistant manager has a signed and updated job description.

12.1.3 The pharmacy/assistant manager has valid Bahraini NHRA license to work.

12.1.4 The pharmacy/assistant manager has work experience commensurate to the position held.

EoC: The pharmacy/assistant manager is licensed by the NHRA in Bahrain. They are a qualified and trained pharmacist (Bachelor of pharmacy or higher degree and work experience), or evidence of annual competency assessment of assistant pharmacist if he/she managing the pharmacy. There is a current signed job description of the person in charge of the Pharmacy.

12.2 The pharmacy has qualified and licensed staffing.

12.2.1 All pharmacy staff have evidence of valid NHRA license to practice in Bahrain.

12.2.2 All pharmacy staff have signed an updated job description.

EoC: All pharmacy staff are qualified and licensed by the NHRA in the Kingdom of Bahrain. All pharmacy staff have current and signed job descriptions.

12.3 The facility has established, updated policies and procedures which identify the mechanisms for overseeing and monitoring the medication management processes and dispensing pathway, including:

12.3.1 Ordering
12.3.2 Medication security and safety
12.3.3 Labelling
12.3.4 Dispensing and patient education
12.3.5 Storage
12.3.6 Emergency medications
12.3.7 Medication error identification and reporting
12.3.8 Adverse drug events identification, reporting, and response
12.3.9 Retrieving and managing recalled medications
12.3.10 Controlled drugs management

EoC: There are policies and procedures established which provide the mechanism for overseeing and monitoring the medication management processes.
12.4 The pharmacy has an orientation process for new staff and a continuing education and staff training program.

EoC: There is a written policy on pharmacy orientation and continuing education program. There is evidence of staff completion of pharmacy orientation and continuing education program. All necessary manuals (pharmacy, infection control, equipment operation, and MSDS manual) are available in the pharmacy.

12.5 There is a list of medical staff signatures who are authorized to prescribe medications and their prescribing privileges.

12.5.1 Clear copy of the signature list is available to pharmacy staff in drug dispensing area(s).

12.5.2 Only authorized staffs, with identified privileges are allowed to prescribe medications.

EoC: Comprehensive and updated records of all prescribers’ signatures are readily available in the pharmacy. There is pharmacy staff awareness of prescribers’ signature and privilege records.

12.6 Pharmacy areas should have adequate drug information resources including but not limited to:

12.6.1 Kingdom of Bahrain National Formulary.
12.6.2 Middle East Medical Index.
12.6.3 Posting and making available telephone number for the nearest poison control centre.

EoC: There are adequate drug information resources. Telephone number for the nearest poison control centre is posted.

12.7 The pharmacy space is adequate for a clear dispensing pathway to be followed. Hours of operation are determined, announced and followed.

12.7.1 The space provided for pharmacy services allows the principal functions to be carried out in efficient and effective manner following a clear dispensing pathway.

12.7.2 Hours of operation of the pharmacy are clearly defined in a policy and procedure, announced and posted at the pharmacy entrance.

EoC: Pharmacy has adequate space to efficiently operate a clear dispensing pathway. Pharmacy monthly work schedule is available and posted; pharmacy operation hours are known and posted.

12.8 Security measures are in place and include:

12.8.1 Limited access to clinical pharmacy.
12.8.2 Visible name tags for all personnel.
12.8.3 Proper locking procedures for the pharmacy after working hours.
12.8.4 The pharmacy doors and windows being locked during operation.
12.8.5 Identification of which pharmacy personnel have keys to pharmacy.
12.8.6 Having a policy for non-pharmacy staff accessing pharmacy after hours in case of emergency (fire, flood, etc.).

EoC: There are appropriate pharmacy security measures (visible name tags, limited access, doors and windows are closed during operation, key holding, etc.) There is a written policy and procedure on emergency opening of the pharmacy after working hours.

12.9 Safety measures are in place and include but not limited to:
12.9.1 Keeping a list of hazardous materials readily available in areas where they are stored or used.
12.9.2 Keeping material safety data sheets (MSDS) available in areas where hazardous materials are stored or used.
12.9.3 Keeping spill kits available in areas where hazardous materials are stored or used.
12.9.4 Training all staff on how to handle spills.

EoC: There is a written policy and procedure on identification, safe handling, stocking, and transportation of hazardous materials (chemicals, chemotherapy, flammables, etc.) Hazardous materials are stored safely (Hazardous list, safety cabinets, good ventilation, low shelves, original labelled container). The personal protective equipment, eye wash station, MSDS, and spill kits are available. The staffs are trained on handling of spills and waste disposal.

12.10 The ambulatory care organization has an updated formulary system.
12.10.1 The drug formulary contains all the essential drugs and updated annually.
12.10.2 The drug formulary is available to the healthcare team.
12.10.3 All newly hired physicians should be oriented to the drug formulary.
12.10.4 The physicians follow the formulary system as appropriate.

EoC: The organization has an annually updated drug formulary containing all essential drugs. Drug formulary is available to all staff in the pharmacy. The drug formulary is part of the general orientation program.

12.11 The pharmacy has a system developed for handling outpatient prescriptions which includes:
12.11.1 A policy for filling prescriptions and repeat prescriptions.
12.11.2 Confirming the completion of the basic data of the prescription: patient’s name, medical record number, age, sex, (body weight for paediatrics or when indicated), diagnosis, allergies, prescriber’s name, signature and stamp, clinic number and date.
12.11.3 Verifying all physician orders for diagnosis, dosing, frequency, route, duration, and interactions.

12.11.4 Double-checking mechanism and process.

**EoC:** There is a written policy on handling outpatient prescriptions. All prescriptions checked have the patient's name, medical record number, age, sex, diagnosis, allergy, prescriber's name/stamp, signature, clinic number and date. Evidence of double checking is available.

12.12 The pharmacy evaluates and monitors for drug indications, correct route of administration, drug interactions, and administration time.

12.12.1 There is a procedure for pharmacy intervention/clarification of physician orders.

12.12.2 The pharmacy notifies the prescribing physician if a prescribed drug is not available.

12.12.3 There is evaluation, monitoring, and documentation of drug-drug and drug-food interactions.

12.12.4 Drugs are prescribed and dispensed for their approved indications as evidenced by the given diagnosis.

12.12.5 Standard administration time is announced and adopted by pharmacy and nursing staff.

**EoC:** there is a written policy for monitoring prescribed medication including, indication, dosing, administration and interactions.

12.13 The pharmacy has a system developed for proper labelling of drugs which includes:

12.13.1 All dispensed drugs are labelled in Arabic and/or English according to patient preference.

12.13.2 Outpatient labels reflect the organization's name, patient name, medical record number, generic drug name, strength, dosage, directions and expiry date of the drug.

12.13.3 Coloured auxiliary labels that stick out are used whenever applicable (e.g. refrigerate, do not refrigerate, shake before use, external use only, etc.).

**EoC:** Dispensed drugs have safe labelling that includes patients name, medical record number, generic drug name, formulation, strength, dosage, directions and expiry date of the drug. Main label and all necessary coloured auxiliary labels are affixed to the immediate container after removal of outside carton.

12.14 The pharmacy has a system for storage of regular medications (pharmacy, store, patient care areas) and includes:

12.14.1 Appropriate storage area for regular medications with controlled temperature monitoring between 18 and 25 degree centigrade around the clock.
12.14.2 Medications are stored in an organized way to avoid mixing and with label showing drug name and expiry date. No medication is located on the floor or stacked over top shelves. Allow 45 centimetres from the ceiling.

12.14.3 Storing antiseptics, disinfectants and drugs for external use separately from internal and injectable medications.

**EoC:** There is a written policy on storage of regular medications. Drugs are stored in an organized way to avoid mixing with label showing drug name and expiry date. No medication is located on the floor or stacked over top shelves (allow 45 centimetres from the ceiling). Medications are stored in appropriate storage area: clean, dry, organized and with light protection. Temperature is controlled between 18 and 25 degrees centigrade around the clock. Antiseptics, disinfectants and external agents are stored separately.

12.15 The pharmacy has a system for storage of cold medications and vaccines in the pharmacy, store, and patient care areas and includes:

12.15.1 The pharmacy has refrigerators for storing vaccines and cold medications.

12.15.2 A list of the refrigerator’s contents (medications and pharmaceutical products) with expiration dates is posted on the refrigerator.

12.15.3 The refrigerators temperature is recorded daily. Appropriate refrigerator temperature is maintained between 2 and 8 degree centigrade. Appropriate freezer temperature is maintained between minus 10 to minus 25 degrees centigrade.

12.15.4 All medication refrigerators and freezers are equipped with appropriate thermometers or equivalent device for temperature recording and temperature log sheets.

12.15.5 There are written and implemented policies and procedures for handling medications in case of failure of electric power or whenever temperature is out of range.

12.15.6 Food, drinks, biological samples, culture media are not allowed inside medication refrigerators.

**EoC:** There is a written policy on storage of cold medications and vaccines, handling drug and pharmaceuticals in case of electric power failure. There is at least daily monitoring and recording of the temperature of refrigerators (2-8 degrees centigrade) and freezers (-10 degrees centigrade to -25 degrees centigrade). The vaccine refrigerator(s) is connected to emergency power supply and its temperature is recorded around the clock.

A list of refrigerator’s contents with expiration dates is attached to the refrigerator.

12.16 The pharmacy has a system for ensuring stability of medication available in multi-dose containers.

12.16.1 Developing and maintaining a set of guidelines for ensuring stability of multi-dose vials, vaccines, multi-dose oral liquid, and other multi-dose medications (e.g., eye, ear, and nose drops, creams, ointments, nebulization solution, etc.).
12.16.2 Ensuring that all open multi-dose containers carry open date, expiry date, initials, and time (if necessary).
12.16.3 Ensuring that no expired open or unlabelled open multi-dose containers are available in patient care areas.

EoC: The pharmacy has guidelines for stability of multi-dose vials and containers in all patient care units. There is proper labelling of vials and multi-dose containers after the first use.

12.17 The pharmacy has a system for ensuring preparedness of crash cart, emergency bags and emergency medications and this includes:
   12.17.1 Developing and maintaining a set of guidelines for crash cart medication.
   12.17.2 Protecting emergency medications from loss or theft using safety plastic seal.
   12.17.3 Keeping plastic seals stocked in a safe place under supervision of pharmacy or nursing.
   12.17.4 Monitoring emergency medications, crash cart medication and replacing them in a timely manner after use or when expired or damaged.
   12.17.5 Performing documented monthly inspection of crash cart and emergency bag medications and maintaining records in the pharmacy.

EoC: There are crash carts, emergency bags, and plastic seals. The pharmacy has guidelines for standardizing crash cart medication in accordance with international best practice. There are monthly inspection records of crash cart, emergency bags, and emergency medications.

12.18 There is a system to monitor drug allergies and includes the following:
   12.18.1 There is a written mechanism to ensure allergies are identified by the attending physician and immediately communicated to the pharmacy in writing.
   12.18.2 Allergies are documented in each patient drug profile before dispensing any medication.
   12.18.3 There is a written mechanism in place that allows for pharmacy intervention including stop dispensing when patient is identified as being allergic to prescribed drug(s).

EoC: There is a written mechanism for monitoring drug allergies (identification, documentation and communication, and pharmacy intervention). The patient's medical record is flagged for drug allergies.

12.19 There is a process for detecting, monitoring, and reporting adverse drug/vaccine reactions (ADRs) and includes:
   12.19.1 Written policy and procedure for ADR.
   12.19.2 Definition of a significant ADR and time frame for reporting.
   12.19.3 ADR reporting forms are available.
   12.19.4 Intensive analysis is performed for all significant ADRs.
12.19.5 Notification of treating physician.
12.19.6 There is evidence that the patient receives appropriate care for the ADR.
12.19.7 There is evidence that the medical record has been flagged for significant ADRs.
12.19.8 Process for improving ADR reporting.
12.19.9 Reporting any significant or unexpected ADR to the MOH or related authorities when required by rules and regulations.

**EoC:** There is a comprehensive policy on adverse drug reactions (ADRs) reporting including definition of serious/significant ADR, time frame and reporting format. There is an active reporting, analysing, and proper medical record flagging system. There is an interdisciplinary mechanism for review and utilization of the reported data to improve ADR reporting and medication use processes.

12.20 There is a process for identifying, monitoring, and reporting significant medication errors and includes:

- 12.20.1 Written policy and procedure for medication error reporting.
- 12.20.2 Definition of a significant medication error, time frame for reporting, and reporting format.
- 12.20.3 Root-cause analysis is performed for all significant medication errors.
- 12.20.4 Using reported data to improve medication use process and reduce error rate.

**EoC:** There is a policy on medication errors reporting including definition of significant errors, time frame and reporting format. There is an active reporting and root cause analysis of significant errors. There is an interdisciplinary mechanism for review and utilization of the reported data to improve medication safety.

12.21 The pharmacy has a system for identifying and handling expired medications.

**EoC:** There is a written policy on identification and proper handling of expired and nearly expired drugs. There is a system for labelling, isolation, destruction, and/or return of expired drugs.

12.22 The pharmacy has a system for handling drug recalls.

**EoC:** There is a written policy and procedure on handling drug recall.

12.23 There is a system for prescribing, handling and dispensing of narcotics, psychotropic and other controlled drugs in accordance with laws and regulations.

**EoC:** There is a written policy and procedure on handling narcotics, psychotropic and other controlled drugs. There are tight security measures for controlled drugs controlled by pharmacy, stored behind steel doors. Daily auditing is carried out and proper documentation is maintained. Proper disposal of unused portion is carried out. Approved prescriptions are used at all times.
Facility Specific Elements
The facility specific elements are assessed as being applicable only when the relevant services/services are provided within the facility.
Element 13 Minor Surgery / Procedures

Introduction
The quality and standard of surgical/minor procedure care in ambulatory care facilities is an important issue. It is important to address the fact that patient safety should not change based on facility size. Surgeries/minor procedures should be performed in a safe environment by qualified physicians who have been granted privileges to perform those surgeries/minor procedures and in accordance with the facilities license and scope of services.

This chapter addresses the following:

- Staffing
- Requirements prior to surgery
- Documentation
- Post-operative care
Element 13 Minor Procedure / Operating Room - Minimum criteria Standards

13.1. The minor procedure/operating room has an appropriately qualified physician in charge of its operation.

**EoC:** The physician in charge is a qualified in either Surgery or Anaesthetics.

13.2. There is a qualified nurse with appropriate training in operative care working in the operating/minor procedures room.

**EoC:** The nurse working in the minor procedures/operating room is appropriately qualified.

13.3. There are policies and procedures outlining the care and responsibilities in the unit that includes but is not limited to:

13.3.1. Checking the patient’s identity, procedure and site with at least two people. (correct patient, correct site, correct surgery)

13.3.2. Infection control guidelines.

13.3.3. Sterilization of equipment, tools, surgical instrument.

13.3.4. Sponge and instrument counts and their required documentation.

**EoC:** There are written policies and procedures defining the care provided, covering elements 13.3.1 to 13.3.4.

13.4. The patient is accepted into the OR only after:

13.4.1. Identification of the patient by name, CPR and medical record number is checked by patient ID band and asking the patient to state his/her name and procedure being carried out.

13.4.2. The consent form is checked for completion.

13.4.3. The operation procedure and the surgeon’s name is checked.

13.4.4. The site of surgery and its preparation and whether it is marked or not is checked.

13.4.5. The x-ray file is checked to see if it accompanies the patient as required.

13.4.6. All lab results, allergies and pregnancy test as appropriate are checked to see if they are in the medial record.

13.4.7. The pre-anaesthesia sheet is checked for completion.

13.4.8. The history and physical examination is checked for documentation in the medical record.

13.4.9. The requisition for blood is verified to ensure blood is reserved in the blood bank, if required.

**EoC:** All patients are accepted into the Operating/Minor procedures room after checking elements 13.4.1 though to 13.4.9.

13.5. There is continuous training for relevant clinical staff with competency assessment (e.g. written test, return demonstration, etc.) for, but not limited to, the following:

13.5.1. Use of equipment.
13.5.2 Use of defibrillator.
13.5.3 Use of pulse oximetry.
13.5.4 Use of diathermy.
13.5.5 CSSD policy.
13.5.6 Maintain a sterile field.
13.5.7 Safety issues including electrical, fire plan, etc.

**EoC: All relevant clinical staff have received training on 13.5.1 to 13.5.7**

13.6 Surgeons, anaesthetists, anaesthesia technicians, and nurses check the availability and functionality of all tools and equipment needed for the operation before induction of anaesthesia.

**EoC: Evidence is provided that all equipment and tools used in the procedure are checked prior to induction of the patient.**

13.7 There is a policy for handling patients with infectious diseases that include but not limited to: TB, HIV, Viral Hepatitis B & C

**EoC: there is a policy for the management of patient with infectious diseases who are undergoing invasive procedures.**

13.8 Surgical procedures performed in the ambulatory care facility are limited to those procedures performed as “Day Surgery”.

13.8.1 The facility defines patients who are not candidates for day surgery such as sickle cell patients and patients who require greater than (2) hours of anaesthesia.

**EoC: There is a policy that defines the procedures that can be performed as day surgery.**

13.9 Patients who are admitted for surgery/minor procedures have the following performed and documented in the medical record by the responsible physician prior to surgery:

13.9.1 History and physical examination (H & P) performed not more than (30) days. If the H & P is performed within 30 days, it must be updated with documentation in the medical record.

13.9.2 Preoperative diagnosis.

13.9.3 Laboratory and X-ray results if applicable.

13.9.4 Signed informed consent.

13.9.5 Planned procedure

**EoC: All patients undergoing minor surgery have a preoperative assessment which includes: history and physical examination, the preoperative diagnosis, Laboratory and X-ray results if applicable, signed consent. Appropriate documentation is maintained in the medical records.**
13.10 Tissues and / or fluid removed during surgery are sent for pathologic examination unless exempted by the medical staff from examination. The report of the examination, signed by the pathologist, is made part of the medical record.

EoC: There is evidence in the medical records that any specimen tissues and/or fluid removed during surgeries had pathologic examination, have been followed up as necessary and kept as part of the medical records.

13.11 An operative report is documented immediately after the surgery/procedure (before the patient leaves the recovery room) to support the continuity of patient care. The report is signed by the surgeon and includes:
   13.11.1 Pre and post-operative diagnosis.
   13.11.2 The names of all staff involved. (Surgeon, nurses, anaesthetist etc.)
   13.11.3 The operation/procedure performed.
   13.11.4 Description of the surgery/procedure, findings, and complications, if any.
   13.11.5 Specimen removed
   13.11.6 Amount of blood loss

EoC: An operative report containing elements 13.11.1 through OR.13.11.6 is available in the medical records of patients who had surgical procedures.

13.12 Each patient is assessed immediately after surgery and reassessed at intervals appropriate to the patient’s condition.
   13.12.1 Medical, nursing, and other care plans are documented in the medical record.

EoC: There is postoperative assessment and reassessment documented in the medical record. Postoperative plans are documented in the medical record and followed.
Element 14 - Anaesthesia and Sedation

Introduction

Although anaesthesia/sedation is necessary for many procedures, it is important to acknowledge that undergoing anaesthesia/sedation is not always a simple procedure. Patients can have adverse reactions to the anaesthesia drugs administered before, during and after surgery/minor procedures. Despite the potential hazards, anaesthesia/sedation can be relatively safe if proper standards are followed. To decrease the likelihood of anaesthesia/sedation related complications, the standards address pre-anaesthetic/sedation assessment performed prior to the administration of sedation or anaesthetic; patient monitoring during and after surgery/procedure until appropriate recovery; and anaesthetic/sedation supplies and equipment. Additionally, the standards require that staff be trained in cardiopulmonary resuscitation (CPR) to ensure the availability of a trained staff during normal hours of operation.

This chapter addresses the following processes:

- Anaesthesia Staff
- Equipment
- Pre-anaesthesia assessment
- Monitoring of patients receiving anaesthesia/sedation
- Moderate and deep sedation
- Recovery room
Element 14 – Anaesthesia and Sedation – minimum Criteria

14.1 A qualified anaesthetist administers all general anaesthesia.

EoC: General anaesthesia is administered only by a qualified anaesthesiologist (education, training, who are licensed with the NHRA as a specialist in accordance with laws and regulations.

14.2 One anaesthesiologist is physically present inside the operating room throughout the operation/ minor procedure.

EoC: Staffing plans show that one anaesthesiologist is physically present throughout the operation/procedure when general anaesthesia is being administered.

14.3 Appropriately qualified staff in cardiac life support are present on site for a patient who receives moderate or deep sedation or anaesthesia until the patient has been physically discharged from the facility.

EoC: Staff administering anaesthesia/moderate or deep sedation should have appropriate cardiac life support training and is recorded in personnel file.

14.4 There is a policy on the proper storage and handling of anaesthetic agents.

EoC: A policy for proper storage and handling of anaesthetic agents is available.

14.5 The anaesthesia machine and the operating room have the following equipment to meet the needs of the patient’s condition:
  14.5.1 Oxygen analyser.
  14.5.2 Pressure and disconnect alarm.
  14.5.3 Pin index safety system.
  14.5.4 Gas scavenger system.
  14.5.5 Oxygen pressure system.
  14.5.6 Oximetry.
  14.5.7 Capnography.
  14.5.8 On line Gas analyzer.
  14.5.9 Agent analyzer.
  14.5.10 ECG machine.
  14.5.11 Cardiac defibrillator.
  14.5.12 Ventilators.
  14.5.13 Suction equipment.

EoC: The anaesthesia machine and the operating room have the equipment specified in elements 14.5.1 through to 14.5.13.
14.6 The following equipment is available for difficult intubations.
   14.6.1 Laryngeal mask.
   14.6.2 Gum elastic bogie.
   14.6.3 Lighted stylet.
   14.6.4 Cricothyroidotomy kit.
   14.6.5 Fiber optic intubations scope.

EoC: Equipment required for difficult intubations specified in 14.6.1 to 14.6.5 are available in different sizes.

14.7 All anaesthesia machines are regularly checked and maintained and there is a record of preventive maintenance (PPM) and checking for every machine.

EoC: All PPM records are available for the anaesthesia machine/s and show regular maintenance and checking.

14.8 The head of anaesthesia implements the infection control guidelines inside the operating room including proper sterilization of the anaesthesia machines.

EoC: Infection control policies are available and implemented. The infection control policies cover the anaesthesia machines.

14.9 Pre-anaesthesia assessment is performed prior to the surgery by the anaesthetist and the type of anaesthesia to be used is decided based on this assessment.

EoC: Pre anaesthesia assessment includes risk category, any consultations needed, and anaesthesia plan which are documented in the pre anaesthesia assessment form. There is a signed anaesthesia/surgery informed consent.

14.10 The pre anaesthesia assessment is performed not more than 72 hours prior to the surgery / minor procedure date. If the pre anaesthesia assessment is performed more than 72 hours prior, the pre anaesthesia assessment must be updated with documentation in the medical record.

EoC: Pre anaesthesia assessment includes risk category, any consultations needed, anaesthesia plan which are documented in the pre anaesthesia assessment form. The pre anaesthesia assessment is performed within the time frame specified. There is a signed anaesthesia informed consent. Pre induction assessment is performed and documented immediately before induction.

14.11 The potential complications and risks are communicated to the patient and his/her family for obtaining informed consent.

EoC: There is a signed anaesthesia informed consent form which identifies all areas discussed with the patient and family.

14.12 There is an anaesthesia form in the medical record and the following essential information is recorded:
14.12.1 The anaesthetic agent.
14.12.2 The dosage of all of the medications and agents used.
14.12.3 The techniques used to administer the anaesthesia.
14.12.4 If blood is used, the amount of blood and the time given.
14.12.5 Any unusual events.
14.12.6 Any investigations carried out e.g. blood glucose, blood gases.
14.12.7 The status of patient at the end of the procedure.
14.12.8 The amount and type of IV fluids given.

**EoC:** A complete anaesthesia form is available in the medical record with elements 14.12.1 to 14.12.8.

14.13 The patient’s condition is continuously monitored during anaesthesia, and the following are documented on the anaesthesia sheet:
14.13.1 The patient’s vital signs.
14.13.2 The patient’s end tidal CO2.
14.13.3 The patient’s oxygen saturation.
14.13.4 The patient’s ECG.

**EoC:** There is evidence of continuous monitoring during anaesthesia with documentation on the anaesthesia sheet. Monitoring includes elements specified in 14.13.1 to 14.13.4.

14.14 A qualified anaesthesiologist is in charge of the recovery room at all times.

**EoC:** At all times, there is a qualified anaesthesiologist in charge of the recovery room.

14.15 Each staff member receives ongoing in-service and other education and training to maintain or advance his or her skills and knowledge.
14.15.1 Observing and recognizing any arrhythmias.
14.15.2 Reading from the Oximetry.
14.15.3 Administering blood and blood products.
14.15.4 The dosage and use of narcotics.
14.15.5 Recognition of critical findings from physical assessment, assessments from monitoring equipment, or diagnostic tests and the appropriate interventions.
14.15.6 The maintenance and preparedness of emergency equipment and drug supply.

**EoC:** Staff in recovery room receives training and competency assessment on elements specified in 14.15.1 to 14.15.6

14.16 The recovery room has a method to call for help quickly through an alarm system or paging system without leaving the patient’s bedside.

**EoC:** A process is in place for calling for help without leaving the patient’s bedside.

14.17 Patients who have infectious conditions are separated appropriately in the recovery room.
EoC: A process is in place for separating patients who have infectious conditions

14.18 The recovery room has the following equipment to meet the needs of the patient’s condition:
   14.18.1 Pulse Oximetry
   14.18.2 Automated blood pressure monitor
   14.18.3 ECG machine
   14.18.4 Crash cart with defibrillator
   14.18.5 Wall suction or suction equipment
   14.18.6 Oxygen

EoC: The recovery room is properly equipped with elements specified in 14.18.1 through 14.18.6

14.19 Each patient’s post anaesthesia physiological status is continuously monitored and documented in medical record.
   14.19.1 The time of admission and the time of discharge.
   14.19.2 The patient’s vital signs,
   14.19.3 Pain management
   14.19.4 The patient’s level of consciousness.
   14.19.5 Any unusual events.
   14.19.6 Oxygen saturation.
   14.19.7 ECG.
   14.19.8 Fluids tolerance.
   14.19.9 Voiding.

EoC: Post anaesthesia physiological status is continuously monitored in the recovery room for elements 14.19.1 through 14.19.8. Findings are documented in the medical records.

14.20 The patient is discharged from the recovery room by qualified anaesthesiologist or another qualified individual (e.g. Nurse) using written discharge criteria/guidance given by the anaesthesiologist.

EoC: There is a written order for discharging patients from the recovery room by qualified anaesthesiologist using the established discharge criteria.

14.21 There are policies and procedures for moderate and deep sedation in the organization approved by the Head of Anaesthesia, the nurse manager, and the appropriate department heads.

EoC: There are interdisciplinary policies for moderate and deep sedation.

14.22 Sedation is performed only in areas identified in policy and the following equipment is available to provide safe care:
   14.22.1 Wall suction or suction equipment.
14.22.2 Oxygen
14.22.3 Pulse Oximetry.
14.22.4 Automated blood pressure monitor or means of taking blood pressure.
14.22.5 ECG Monitor

EoC: There is a policy that identifies areas where sedation may be administered and in accordance with availability of elements 14.22.1 to 14.22.5

14.23 There is a crash cart with defibrillator, medications, IV access, and intubation equipment that is appropriate to the age of the patient available where sedation is being performed.

EoC: Emergency Medication and equipment is available where anaesthesia / sedation is administered.

14.24 There is a list of all medications used in sedation and includes the route administered along with dosage appropriate to the age groups available where sedation is performed.

EoC: Medications used for sedation are identified together with appropriate use.

14.25 Physicians who perform moderate and deep sedation have privileges granted to perform moderate and deep sedation.

EoC: Privileges forms of physicians performing sedation include administration of sedation.

14.26 Moderate and deep sedation is only used for patients having short diagnostic or therapeutic procedures.

EoC: The facility restricts moderate and deep sedation only for patients having short diagnostic or therapeutic procedures.
Element 15 – Radiology Centres

Introduction

The assessment/reassessment of patients to determine the proper diagnosis, the course of treatment, and evaluation of treatment plan for future decisions may require a variety of radiology services.

To meet the patient needs, the ambulatory care facility may offer radiology services as required by its patient population, clinical services offered, and healthcare provider needs. The department, from a building perspective is expected to meet the necessary national guidelines on radiation safety.

This chapter addresses the following:

- Physical structure
- Staffing
- Safety program
- Results reporting (including panic findings)
Element 15 Radiology Centre - Minimum Criteria

15.1 Radiology services are available to meet patient needs and in accordance with applicable national standards, laws and regulations.
   15.1.1 The radiology services have access to referral and consultation services in the form of agreement.
   15.1.2 When additional radiology services are provided through a contract, the facility is responsible to provide oversight of the contract and ensure the provider complies with standards, and other components of the contract as specified by the facility.

EoC: The available radiology services meet the patients’ needs in accordance with the facilities available scope of services. There is a written agreement with a licensed facility for the provision of other special procedures and consultations when required. When there are contracts with outside sources for provision of other radiology services, oversight needs to be evidenced.

15.2 A current radiology policies and procedures manual is readily available to staff. The policies and procedures manual should be well structured and:
   15.2.1 Adhere to current laws and regulations.
   15.2.2 Approved by the radiology centres management.
   15.2.3 Reviewed every two years.
   15.2.4 Radiology personnel are knowledgeable about the contents of policies and procedures manual relevant to the scope of their testing activities.

EoC: There is comprehensive, approved and current Radiology policy and procedure manual. There is evidence of that all staff are aware of the Radiology policy and procedure manual contents.

15.3 The radiology centres organizational structure is defined and available.
   15.3.1 There is a qualified physician radiologist available on site.
   15.3.2 All radiology services are identified and they are under supervision of a qualified individual.
   15.3.3 Shows all staff and their professions/roles.
   15.3.4 Chain of command must be clear.

EoC: The radiology department has a qualified physician radiologist assigned as being in charge. There is an updated and approved radiology department organizational structure with radiology services and staff professions and roles identified.

15.4 The radiology centre areas meet the required dimensions stated in the law and are adequate space for its function, are well-maintained, free of clutter and do not compromise the quality of work and personnel safety. The designated radiology space must have:
   15.4.1 The space and dimensions stipulated in the law.
   15.4.2 Space that is adequate and appropriate for the work.
   15.4.3 The waiting area is comfortable and ensures privacy of patients.
   15.4.4 There is appropriate storage area for x-ray films and dark room materials.
15.4.5 Ready access to toilets and private changing facilities for patients.

**EoC:** The space available for the radiology services is adequate and appropriate for the work. There is a comfortable waiting area that ensures privacy of patients in addition to a changing place, and toilets. There is appropriate storage area for x-ray films and dark room materials.

15.5 There is a radiation safety protocol or plan in place to protect staff, patients and environment that includes at least the following:

15.5.1 The program must cover all areas where ionizing radiation is used.
15.5.2 All radioactive materials are used according to professional guidelines and overseen by qualified personnel.
15.5.3 Safety warnings are posted in clear and appropriate locations on the doors, including a warning light outside the door when radioactive process is used.
15.5.4 Women are checked for the possibility of being pregnant prior to having X-ray tests and the X-ray form demands that the physicians check this point.
15.5.5 Personnel are protected from radiation exposure
   15.5.5.1 There is provision of a safe patient viewing area behind leaded glass.
15.5.6 Personnel are monitored for radiation exposure.
   15.5.6.1 Thermo luminescence Dosimeter (TLD) is regularly checked for all radiology staff.
   15.5.6.2 Checking white blood cells periodically for all employees in Radiology Department.
15.5.7 Radiation personal protective measures are available for employees and patients. Such as lead aprons in various sizes and gonadal protection,

**EoC:** There is a written comprehensive radiation safety program. Safety warning signs/lights are available as necessary, and there is evidence of those elements in 15.5.1 to 15.5.6 are in place.

15.6 Radiology services are carried out by adequate, qualified and properly trained staff.

15.6.1 Staff have the necessary knowledge, skills, and experience and evidenced in their job descriptions.
15.6.2 Each staff member has a valid license.
15.6.3 New staff are oriented to the department and services.
15.6.4 Staff receive continuing education relevant to their jobs.
15.6.5 Staff performance is evaluated annually.
15.6.6 Current competency is regularly tested.

**EoC:** Personnel records shows evidence for elements 15.6.1 to 15.6.6

15.7 The radiology department keeps equipment in proper functional condition in keeping with national laws and regulations, through the establishment of a system by which all equipment are periodically inspected, maintained, and calibrated. This system must include but not limited to:
15.7.1 Operation and service manual.
15.7.2 Qualified personnel maintain the equipment.
15.7.3 Records are properly maintained including corrective actions.
15.7.4 Equipment are periodically inspected and calibrated for their proper functioning.
15.7.5 There is a replacement policy in place to ensure equipment is up to date.

**EoC:** Operation and service manuals are available, and the facility maintains records showing that planned activities actually occurred by qualified personnel together with corrective actions documentation.

15.8 The radiology department has clear system for results reporting including:
15.8.1 Defined Turn Around Time (TAT) for all radiology services.
15.8.2 Definition of Critical Results and their reporting method.
15.8.3 There are records in support of proper reporting of critical values.

**EoC:** There is evidence of that Turn Around Times for each radiology service is defined, communicated and agreed upon. There are written policies and procedures for reporting panic values (critical results). There are records in support of proper reporting of panic values.

15.9 There is a master X-ray jacket or an access to all archived previous radiological studies for every patient.

**EoC:** All archived radiology studies in master x-ray jacket for every patient are accessible.

15.10 Physicians requesting the x-ray procedures write all the necessary information on the radiology X ray request Such as patient name, address, CPR, examination requested, past history if relevant, requesting physicians contact details

**EoC:** All necessary information is written on the x-ray request by the requesting physician.

15.11 All ultrasound examinations are read by qualified staff.

**EoC:** There is evidence of that qualified licensed medical specialists reads and reports all ultrasound studies.

15.12 There are policies and procedures that cover the following:
15.12.1 Angiogram.
15.12.2 Cat Scan.
15.12.3 MRI.
15.12.4 Interventional procedure.
15.12.5 Fluoroscopy.
15.12.6 Contrast agent reaction.
EoC: There is a written protocol for the elements in 10.12.1 through to 10.12.6 and they are available as appropriate to scope of services offered in the facility.

15.13 The radiologist documents all the details of any interventional procedure in the patient file before and after the procedure and informs the patient about the potential benefits and risks of the procedure.

15.13.1 The physician explains the risks and the benefits of the procedure to the patient.
15.13.2 The consent form is signed by the patient.
15.13.3 The patient’s coagulation parameters are checked: e.g. PT, PTT, platelets.
15.13.4 Any history of previous allergic reactions are included as part of the history.
15.13.5 The requesting physician writes include the necessary detail (Patient history, reason for the procedure) in the request for the procedure.

EoC: There is a written policy on interventional procedures that covers elements 10.13.1 to 10.13.5

15.14 A crash cart is available in the vicinity of the radiology department and staff are trained in CPR.

EoC: A fully equipped and accessible crash cart is available to the department and staff are trained in CPR and able to sue the equipment available.
Element 16 Fertility and Assisted Reproductive Technology Standards

Introduction

It is fundamental that in delivering Fertility and Assisted Reproductive Technology (ART) services, the patients and their offspring remain the most important consideration in all decisions. All facilities providing fertility and ART should aspire to deliver services in a manner that recognizes patients’ cultural and individual values and beliefs, upholds their dignity and privacy. Fertility and ART services involves clinical treatments; counseling services; and laboratory procedures for the assessment and preparation of human gametes and/or embryos.

The facilities are equipped with a laboratory that assesses and prepares human gametes and/or embryos for therapeutic service.

The purpose of the fertility and ART standards is to:

- Promote safety and continuous improvement in the quality of care offered to people accessing fertility treatment in the Kingdom of Bahrain.
- Provide a framework and set criteria for the inspection process that leads to licensing of the facilities that deliver fertility services.
- Ensure the inspection process can be carried out in a constructive manner.
Element 16 Fertility and Assisted Reproductive Technology - minimum criteria

16.1 There is appropriately qualified, trained and experienced staff for the safe delivery of appropriate fertility treatment. All professional staff must be licensed through the NHRA to practice in Bahrain.
   16.1.1 Medical director who is a specialist gynecologist or physician with qualifications and training in the field of reproductive endocrinology and infertility.
   16.1.2 Nurse manager, with experience in a related area.
   16.1.3 Senior counselor.
   16.1.4 Nursing staff qualified by experience and education.
   16.1.5 Laboratory staff who are appropriately qualified by experience and education, including a bachelor’s degree in chemical, biological, physical, medical technology, clinical or reproductive technology science.

EoC: All staff working in the facility are appropriately qualified and are licensed to practice by the NHRA in Bahrain. The facility is led by an appropriately qualified physician who has specialist training and experience in the field of reproductive endocrinology and infertility. The nurse management also is experienced and suitably qualified.

16.2 There is evidence demonstrating that the doctors, nurses and laboratory staff receive continuous education and training on the clinic’s policies and on fertility practice.

EoC: clear evidence that all staff receiving ongoing education and training in the most up to date methods and research in relation to fertility practice.

16.3 There is evidence demonstrating that all staff has been trained in the use of all equipment including identifying malfunctions and escalating issues for immediate repair.

EoC: All staff has been trained in the use of all equipment used in the facility. This evidence is recorded in individual personnel files.

16.4 There is an identified head of the laboratory and up to date procedure manuals are available for all procedures performed in the laboratory

EoC: There is an identified head of the laboratory function who is appropriately qualified to do so. Up to date procedure manuals are available for inspection and Interviews with staff verify that staff are familiar with and adhere to procedures as documented.

16.5 There are policies and systems in place to ensure that gametes, embryos and patients are correctly identified and matched at all times.
   16.5.1 There are clear written procedures to identify when, how and by whom for matching and verification is recorded for gametes, embryos and patients at all stages of the treatment process.
16.5.2 There is a clear written policy requiring staff to check the unique identifier against paperwork and sign it off each time the sample is moved. Documentation shows that staff are aware of and comply with this policy.

16.5.3 There is a clear written policy forbidding the handling of more than one cohort of oocytes, sperm or embryos at any given time.

16.5.4 All equipment is used once only before disposal or sterilization.

16.5.5 There is an audit trail to show that regular (at least annual) audit of the identification process takes place.

EoC: There are policies and systems in place that cover as a minimum element 16.6.1 to 16.6.5. There is evidence of these policies, procedures and systems being implemented.

16.6 The clinic ensures that cryopreserved gametes, embryos and tissues are appropriately managed.

16.6.1 An audit trail demonstrates that cryogenic storage units are cleaned, monitored and maintained in accordance with the manufacturer's manual.

16.6.2 There is a system to alert when the cryogenic storage units malfunction.

16.6.3 There is a documented system to identify, locate, retrieve and maintain cryopreserved material. An audit of randomly selected records shows that staff are aware of and comply with this system.

16.6.4 The clinic has a clear written policy for time limits (if any) on cryopreserved gametes, embryos and tissues and an audit trail showing the details of each specimen that has been disposed.

16.6.5 There is a clear written policy on the safe disposal of cryopreserved material, which takes into account the special status of the embryo as potential human life. There are consent forms which allow the couple to choose their preferred method of disposal, which may include the following:

- Incineration as biological waste
- Cremation or interment
- The couple is given the embryo(s) to take home and dispose of as they wish
- Donation to scientific research
- Indefinite cryogenic freezing

EoC: There is a clear written policy which addresses the management of the gametes, embryos and tissues, which includes instructions on their formation, storage and destruction.

16.7 The laboratory is appropriately prepared and maintained for safe handling, preparation and transfer of embryos.

16.7.1 There is a laboratory for preparation of embryos that meets all standard laboratory requirements for sterility, handling and storage of specimens and equipment
16.7.2 In addition to 5.1 the laboratory is appropriately equipped for embryology procedures, including:
16.7.3 Incubators have alarm systems with a backup generator for continuous power supply. Records show that there is daily monitoring of temperature and gas content.
16.7.4 The “wet area” for sterilization etc. is kept separate from the area in which oocytes and embryos are handled.
16.7.5 There are microscopes suitable for oocyte recovery, determination of fertilization, sperm analysis, manipulation and micro-manipulation of oocytes and embryos.
16.7.6 An audit trail demonstrates that all machinery and equipment is cleaned, maintained and calibrated in accordance with manufacturers’ manuals.
16.7.7 The laboratory has a process for ensuring appropriate consent is documented before it performs any embryology procedures.
16.7.8 The laboratory is within proximity of procedure rooms, or there is a documented system to ensure that embryo viability is not compromised during transfer to procedure rooms.
16.7.9 Walls and floors are composed of materials easily washed and disinfected. The floors are not carpeted.
16.7.10 Toxic chemicals and radioisotopes, including cleaning products, are not used in the laboratory.

EoC: There is documented evidence and audit trail for all elements in 16.8.1 through to 16.8.10.

16.8 In accordance with Bahraini Law:
16.8.1 All assisted conception techniques should only be performed for married couples in the Kingdom of Bahrain.
16.8.2 No sperm, egg or embryos are allowed to be donated.
16.8.3 No research studies to be carried out on embryos or gametes without prior written consent from the concerned couple and the concerned authorities.

EoC: There is evidence on file that all patients are in a martial relationship, that no donation is carried out and any research is carried out with the required consents.
Element 17 Dental Services Standards

Introduction

The quality and standard of dentistry care in ambulatory dental clinic facility is an important issue. It is important to address the fact that patient safety should not change based on facility size. Dentistry procedures should be performed in a safe environment by qualified dentists who have been granted privileges to perform procedures and in accordance with the facilities license and scope of services.

This chapter addresses the following:

• Staffing
• Requirements of the dental clinic
• Documentation
• Dentistry care
Element 17 Dental Services Standards

17.1 A qualified and licensed dentist is in-charge of the dental services.

EoC: The dentist in-charge of the dental unit has a valid license and registration with the NHRA in Bahrain.

17.2 All dental staff have privileges granted to perform the different types of dental procedures.

EoC: Procedures performed by dental staff are approved in accordance with the organization’s credentialing and privileging process.

17.3 Qualified dental technicians/nurse are available in the dental services.

EoC: Dental technicians/nurse have valid licenses and registration with the NHRA in Bahrain

17.4 There is a written scope of services for the dental unit.

EoC: A written scope of services for the dental unit is available.

17.5 Patients are educated and informed about:
   17.5.1 The nature of problem.
   17.5.2 Treatment and procedures needed.
   17.5.3 Time needed to finish the course of treatment.
   17.5.4 Cost attached.

EoC: The facility educates the patient about topics in elements 18.5.1 to 18.5.4

17.6 Each patient has a dental record written that includes:
   17.6.1 History of allergic reactions.
   17.6.2 Any chronic illnesses, e.g., Congenital Heart Disease, Rheumatic Heart Diseases and Diabetes.
   17.6.3 Any hematological illnesses, e.g., hemophilia.
   17.6.4 Chief complaints of patients.
   17.6.5 Physical examination findings.
   17.6.6 Treatment plan.
   17.6.7 X-rays taken including their interpretation.
   17.6.8 Treatment or planned procedure to be performed.
   17.6.9 Dose of local anesthesia, the tooth treated and the material used.
EoC: The patient dental record includes detailed medical history, allergy history, chronic illnesses/ blood disorders, chief complaints, examination findings, treatment plan, x-rays needed, anesthesia dose, tooth treated and material used.

17.7 Consent is obtained for all high-risk procedures.

EoC: A signed informed consent is available in the medical records of patients who had high risk dental procedures.

17.8 Treatment notes are documented and include:
   17.8.1 Type, location and amount of anesthesia.
   17.8.2 Teeth treated (using an accepted an accepted numbering system) and surfaces treated.
   17.8.3 All materials utilized are identified by name.
   17.8.4 Complications.
   17.8.5 Recommendations for follow up treatment or instructions.

EoC: Treatment notes are documented and include elements specified in 18.8.1 to 18.8.5

17.9 There is a policy on the sedation/general anesthesia which includes I.V. sedation and/or nitrous oxide and only privileged dentists are allowed to administer it.

EoC: There is a policy on sedation which includes IV sedation and nitrous oxide and outlines the privileges required for any dentist operating with the facility

17.10 Infection Control guidelines are strictly enforced. The guidelines include but are not limited to:
   17.10.1 Using gloves and masks for each case.
   17.10.2 Wearing protective eyewear.
   17.10.3 Providing eye protection for patients.
   17.10.4 Wearing protective clothing/gowns in the dental suite.
   17.10.5 Sterilizing all reusable instruments after each patient according to a written protocol, which indicates the time and method of sterilizing.
   17.10.6 Cleaning surfaces of working area between patients.

EoC: Infection control guidelines are available and implemented for elements 18.10.1 to 18.10.6

17.11 Safety rules are applied in the dental lab, and includes but is not limited to:
   17.11.1 Wearing of protective eye wear.
   17.11.2 Fire extinguishers
   17.11.3 Cautionary signs posted.
   17.11.4 A hooded exhaust in the casting area.
   17.11.5 Oxygen cylinders safely stored away from patient area.
   17.11.6 Safe evacuation of fumes exists.
17.11.7 Fire blanket is available.
17.11.8 Eye washing station/sink is available.
17.11.9 Emergency gas is available.

EoC: Safety measures specified in elements 18.11.1 through 18.11.9 are available and in place.

17.12 Emergency drugs and equipment are available in the vicinity to respond to patient who, have an allergic response or possible heart attack, and is checked and maintained regularly. Staff are trained in CPR and are able to use the equipment provided.

EoC: Appropriately emergency medication and equipment are available in the vicinity of the dental unit and staff are trained in CPR and the equipment available.

17.13 The need for antibiotic prophylaxis is assessed for each patient.

EoC: Assessment of the need for prophylactic antibiotics for each patient is evident.
**Element 18 Optician Practices**

The main focus of the NHRA licensing standards is to provide assurances that the premises from which optometric services are delivered in Bahrain are fit for purpose, in that their location and level of amenity provides the best customer care and service. The practice premises must be signposted and physically accessible. The facility must also have access to appropriate equipment to effectively practice all aspects of Optometry safely. The equipment must also be maintained in good working order and finally the facility must have an appropriately qualified person in charge and providing the optometry services to ensure patients are not misled and are given a correct diagnosis and the follow up ensure they have the appropriate glasses/lenses for their condition.
Element 18 Optician Practices – Minimum Criteria

18.1 The facility has all of the basic equipment necessary to perform eye examinations and dispense optical appliances. Including:
   18.1.1 Illuminated test chart, projector chart or other visual acuity charts
   18.1.2 Near vision tests
   18.1.3 Trial lenses and trial frame or phoropter *
   18.1.4 Retinoscope*
   18.1.5 Direct ophthalmoscope
   18.1.6 BIO (binocular indirect ophthalmoscope)
   18.1.7 Accommodation rule
   18.1.8 Colour vision test
   18.1.9 Distance and near oculomotor balance tests
   18.1.10 Test for stereopsis
   18.1.11 Applanation tonometer (non-contact and contact)
   18.1.12 Threshold controlled visual field equipment
   18.1.13 Peripheral visual field equipment
   18.1.14 Gonioscope
   18.1.15 Amslers charts
   18.1.16 Slit lamp*
   18.1.17 Condensing lens for indirect ophthalmoscopy with the slit lamp
   18.1.18 Keratometer
   18.1.19 Pen torch
   18.1.20 Contrast sensitivity test chart
   18.1.21 Foci meter
   18.1.22 Auto-refractor

EoC: All basic equipment necessary to perform eye examinations and dispense optical appliances as listed in 18.1.1 to 18.1.22 is available within the facility.

18.2 Basic equipment for dispensing optical appliances:
   18.2.1 Pupilometer or pupillary rule
   18.2.2 Vertometer or lensometer
   18.2.3 Calipers
   18.2.4 Lens measure
   18.2.5 Frame heater

EoC: basic equipment for dispensing optical appliances is available 18.2.1 to 18.2.5

18.3 The facility maintains basic optometric equipment to an appropriate standard.

EoC: There is evidence that all equipment is maintained and in proper working order
18.4 The facility has a documented audit trail and reminder system to monitor servicing and calibration of the following optometric equipment according to maintenance guides and operating instructions:

18.4.1 Slit lamp
18.4.2 Phoropter
18.4.3 Auto-refractor
18.4.4 Keratometer.

EoC: There is a documented audit trail and reminder system to monitor servicing and calibration of the equipment in 18.4.1 to 18.4.4

18.5 The facility premises are appropriate for the professional delivery of optometric services.

18.5.1 The practice and consulting rooms are accessible to the disabled.
18.5.2 There is adequate space in the consulting room for the discreet provision of eye examinations and contact lens fittings, with additional space for a support person/chaperon for the patient, if desired.
18.5.3 The practice has railings, ramps, step highlighters and other relevant safety features to assist people with disabilities (including low vision).
18.5.4 There is an area for dispensing of optical appliances, with seating for patients and easy access to all basic dispensing equipment.

EoC: The premises are appropriate for the delivery of optometric services and provide for 18.5.1 to 18.5.4

18.6 The facility is appropriately equipped to ensure hygienic practice is maintained.

18.6.1 Each consulting room has a washbasin, sterilizing wash solution and paper towels for clinically hygienic practice.
18.6.2 There is provision in consulting rooms for immediate hygienic disposal of used consumables.
18.6.3 The practice has a documented audit trail showing that cleaning of all equipment occurs at appropriate intervals and in line with manufacturer’s specifications.

EoC: The facility adheres to the requirements for hygienic practice outlined in 18.6.1 to 18.6.3
Element 19 - Haemodialysis Standards

Introduction

Haemodialysis is an integral management therapy for advanced chronic kidney disease. Recent research has identified that dialysis needs to be carried using a patient-centred approach, where the planning and provision of haemodialysis is accompanied with counselling, patient education and choice as well as the provision of adequate resources and appropriately trained staff.
Element 19 - Haemodialysis Standards – Minimum Criteria

19.1 The department head is a qualified, licensed Nephrologist.

EoC: The Nephrologist in-charge of the haemodialysis unit has a valid license with the NHRA in Bahrain

19.2 Haemodialysis procedures are ordered by a Nephrologist.

EoC: There is a Nephrologists’ order for dialysis documented in the medical record of each patient.

19.3 The Nephrologist in charge of the management of patients ensures, but not limited to, the following:
   19.3.1 The need for dialysis and choice of modality are based on sound clinical principles and a thorough clinical evaluation of medical condition and co-morbid.
   19.3.2 Recommending to the patient the modality that is best suited to him/her.
   19.3.3 Obtaining an informed consent for all dialysis patients after providing adequate information about the different modalities and modality that is most appropriate for the patient’s need. The consent is updated regularly (e.g., yearly) and when the risk to patient changes.
   19.3.4 Development of an interdisciplinary plan of care for each patient in consultation and coordination with other health professionals (e.g., physician, nurse, dietician, pharmacist, and social worker).
   19.3.5 Development of an appropriate interdisciplinary patient education plan.
   19.3.6 Adequate monitoring of patients during dialysis and subsequent after care.
   19.3.7 Rendering emergency medical care when needs arise and arranging emergency transfer when needed.

EoC: The facility has criteria for patients’ selection for dialysis. An appropriate informed consent is available in the medical record. An interdisciplinary plan is documented in the medical record in addition to a patient’s education plan. There is evidence in the medical records of patient monitoring during dialysis. The facility has a process for emergency care when the need arises.

19.4 A qualified licensed nurse with training in haemodialysis is the nurse manager.
   19.4.1 All nursing staff are registered nurses, qualified by experience and education.
   19.4.2 The nurses working in haemodialysis receive continuous education and training on the unit’s policies by qualified professionals with competency assessment (e.g., written test, return demonstration, etc.).

EoC: The nurse manager in-charge of the haemodialysis unit has a valid license with the NHRA in Bahrain. All nurses in the unit are qualified by training and experience. There is evidence of nursing education provided by qualified professionals with competency assessment.
19.5 All physicians, nurses and other appropriate health professionals working in haemodialysis are certified in BCLS and preferably ACLS

**EoC: All clinical staff have valid cardiac life support certificates.**

19.6 A crash cart(s) with defibrillator must be available at (or in the vicinity of) the dialysis unit

**EoC: A crash cart is readily accessible.**

19.7 A comprehensive policy and procedure manual related to the safe conduct of all patient care activities exists. The manual should include, but not limited to, the following:

- 19.7.1 Admission and discharge criteria.
- 19.7.2 Admission and discharge process.
- 19.7.3 Assessment and reassessment of patients.
- 19.7.4 Assessment of volume status.
- 19.7.5 Provision of appropriate access care and surveillance with access monitoring.
- 19.7.6 Care of patients with AV fistula/AV graft.
- 19.7.7 Care of tunnelled/non-tunnelled catheters.
- 19.7.8 Management of clotted access.
- 19.7.9 Preparation of haemodialysis machines.
- 19.7.10 Dialysis procedures
- 19.7.11 Peritoneal dialysis.
- 19.7.12 Management of anticoagulation.
- 19.7.13 Management of electrolyte imbalance.
- 19.7.14 Management of complications arising from dialysis.
- 19.7.15 Management of cardiopulmonary collapse and urgent medical conditions.
- 19.7.16 Emergency transfer of patients.

**EoC: There are written policies and procedures for elements 19.7.1 to 19.7.16**

19.8 All equipment and machines in the unit are operated within manufacturer’s specifications, and maintained free of defects.

- 19.8.1 Preventive maintenance (PM) program for equipment related to patient care is developed in accordance with manufacturer’s instructions and enforced.
- 19.8.2 The PM program is performed by qualified staff or authorities.
- 19.8.3 All maintenance and repair record is kept on file for future reference and inspection.
- 19.8.4 All staff are oriented to equipment used.
- 19.8.5 Staff are trained to identify malfunctioning of equipment and to report to appropriate staff for immediate repair.
- 19.8.6 Each dialysis machine is equipped with monitors and an alarm system.
- 19.8.7 The PM program includes the water treatment and distribution system.
EoC: The facility has processes in place for appropriate management of equipment and machines specified in 19.8.1 to 19.8.7

19.9 Infection prevention and control practices, specific to the dialysis services, are adopted from authoritative sources or other professional organizations and strictly supervised:

19.9.1 There is sufficient space (1.2 -1.5 meters) between patients to prevent transmission of infection.

19.9.2 There is a clear separation between patient care (contaminated) and office / supply areas (clean).

19.9.3 Standard precautions are strictly implemented in the unit with special emphasis on hand hygiene and the appropriate use of gloves, gowns, masks, and other barriers.

19.9.4 An adequate supply of personal protective equipment is available and readily accessible.

19.9.5 Hand disinfectants for waterless hand hygiene should be available at every chair/bed. Hands are washed before and after contact with each patient.

19.9.6 Sinks are available in adequate number (preferably one for every 2-4 chair/beds) and are conveniently located.

19.9.7 Staff has thorough knowledge about avoiding cross contamination.

19.9.8 Staff practice related to cross contamination is satisfactory.

19.9.9 Sharp disposal containers are located at each chair/bed and elsewhere as needed within the unit. Needles and sharps are disposed appropriately.

19.9.10 Infectious wastes are disposed of according to the organization’s waste disposal policies.

19.9.11 The surfaces of machines, including the control panels, and chairs/beds are disinfected after use with an approved disinfectant.

19.9.12 All machine manufacturers’ instructions on cleaning the machine are available and adhered to.

19.9.13 Blood spills are cleaned properly.

19.9.14 Equipment such as blood pressure cuffs, stethoscopes, clamps, scissors and thermometers are allocated to a single patient and are disinfected at the conclusion of each patient treatment.

19.9.15 There is a system in place that ensures that multi-dose vials are adequately labelled and used for one patient only.

19.9.16 There is a process in place for infection control procedures for dialysis machines between patients.

19.9.17 There is a process in place for appropriate cleaning and disinfection of the water treatment and distribution system.

EoC: The facilities have scientific-based infection control policies that cover the areas specified in 19.9.1 to 19.9.11. Staff are aware and implement the policies.

19.10 There is a system that protects patients and staff from blood borne pathogens during haemodialysis.
19.10.1 All patients are screened for Hepatitis B and Hepatitis C and HIV at the beginning of dialysis.
19.10.2 Patients whose laboratory tests for HBsAg, anti HBs, HCV, and/or HIV is/are negative should be re-screened every 3-6 months.
19.10.3 All patients susceptible to hepatitis B (negative for HBsAg and anti HBs) are immunized with Hepatitis B vaccine.
19.10.4 All patients infected with Hepatitis B are strictly segregated in a separate room and treated on a separate machine used exclusively for Hepatitis B (not for patients with Hepatitis C or HIV).
19.10.5 All haemodialysis unit employees are screened for Hepatitis B, Hepatitis C, and HIV/AIDS upon hiring and annually.
19.10.6 All haemodialysis unit employees susceptible to Hepatitis B are immunized with Hepatitis B vaccine.
19.10.7 All vaccinated personnel are tested for antibodies to evaluate response, and all non-responders are given a second series of the HBV vaccine.
19.10.8 Records for staff screening and hepatitis immunization are kept in database (cards, sheet or computerized) to allow a rapid evaluation of the information.

EoC: The patients' medical records show evidence of screening/rescreening and immunization in accordance with 19.10.1 to 19.10.8. The employees' medical records (or other files) show evidence of screening/rescreening and immunization in accordance with 19.10.1 to 19.10.8.

19.11 Water quality is periodically checked according to a written policy based upon manufacturer’s recommendations, regulations, and local experience.
19.11.1 Hardness and chlorine content of feeding water are monitored on a regular basis by designated staff or authorities.
19.11.2 Microbiologic monitoring of treated water and dialysate should be performed at least monthly and more frequently if a problem is identified. Water is collected from deionized water outlet before each haemodialysis machine, and from dialysate just existing from each haemodialysis machine.
19.11.3 Bacteriology testing of RO water as well as endotoxin assay should be done and documented at least once a month. Endotoxin assay is mandatory if Online HDF is used.
19.11.4 Chemical testing of water is done at least once a year (preferably once every 6 months).
19.11.5 Reverse osmosis (RO) system including the feeding pipelines into the centre is disinfected at least once a month preferably by heat as well as by chemical disinfection.
19.11.6 All physical and monitoring checks are verified and signed off by the Nephrologist with recording of any corrective action taken, e.g., out of range results for tests of water or dialysate (bacteria, endotoxin or chemical analysis).
19.11.7 Written record and results of microbiological and chemical testing of water are in place and reviewed.
EoC: There is a written policy for periodic checking of water quality based on manufacturer’s recommendations, regulations, and local experience and in accordance with the elements 19.11.1 to 19.11.7. There is evidence of implementation of the policy, e.g., Keeping appropriate records.

19.12 There is a documented departmental quality improvement plan to ensure safety and quality patient care. The plan should be consistent with the organization wide quality improvement plan and:
   19.12.2 Identify opportunities to improve care, develop quality improvement interventions, and measure their effectiveness.

EoC: There are reports about indicators used to measure the unit’s performance. There is evidence of improvement interventions based on available data.
Glossary

Access A person's ability to get necessary medical care and services when needed. The ease of access is determined by components such as the availability of medical services and their acceptability to the individual and community, the locale of health care facilities, transportation, and hours of operation.

Accountability The ability of a system to track an individual’s actions.

Accreditation A formal process by which a recognized body ("accrediting body") assesses and recognizes that a healthcare organization meets applicable, pre-determined standards.

Aggregate To combine standardized data/information.

Appropriateness Extent to which a particular procedure, treatment, test or service is effective, clearly indicated, not excessive, adequate in quantity, and provided in the setting best suited to the client needs.

Availability The degree to which appropriate care is available to meet the individual patient needs.

Benchmarking A continuous process of measuring products, services, and/or practices against the competition in order to find and implement best practices.

Clinical Practice Guidelines Statements that help practitioners and patients choose appropriate health care for specific clinical conditions.

Code of Conduct A set of principles and expected behaviours that are expectations of employee performance within a health care setting or as defined by the leadership group.

Collaborative An organizational culture characterized by a shared vision, shared leadership, empowered workers, and cooperation among organizational units as they work to improve process.

Competence Job knowledge, skills, and attitude required to perform the job. Knowledge is the understanding of facts and procedures. Skill is the ability to perform specific actions.

Committee A multidisciplinary body of persons officially delegated to consider, investigate, take action on, or report on some matter or perform a specified function.

Confidentiality The restricted access to data and information to individuals who have a need, a reason, and permission for such access. An individual’s right to personal and informational privacy, including his or her health care records.

Continuity of Care A performance dimension addressing the degree to which the care for a patient is coordinated among practitioners and organizations and over time, without interruption, cessation, or unnecessary repetition of diagnosis or treatment.
Continuous Quality Improvement (CQI) The culture, strategies and methods necessary for continual improvement in meeting and exceeding customer expectations.

Continuous Quality Improvement Tools CQI tools focus on process rather than the individual, and promote the need to analyze and improve process.

Credentialed The process of obtaining, verifying and assessing the qualifications of a health care professional to determine if an individual can provide patient care services in or for a health care organization.

Criteria Expected level(s) of achievement or specifications against which performance can be assessed.

Data Raw facts and figures from which information can be generated.

Database An organized, comprehensive collection of stored data.

Dosimeter Is any device used to measure an individual’s exposure to a hazardous environment, particularly when the hazard is cumulative over long intervals of time, or one’s lifetime.

Effectiveness The degree to which care is provided in the correct manner, given the current state of knowledge, to achieve the desired or projected outcome for the patient.

Efficacy The power to produce an effect, for example: Clinical trials in Medicine provide evidence or efficacy.

Evidence based Medicine The practice of medicine or the use of healthcare interventions guided by or based on supportive scientific evidence.

Facilitate To make easier.

Family or Responsible Person The person(s) with a significant role in the patient’s life. This may include a person(s) not legally related to the patient. This person(s) is often referred to as a surrogate decision maker if authorized to make care decisions for a patient if the patient loses decision-making ability.

Functional Status The ability of individuals to take care of themselves physically and psychologically.

Formulary An approved list of medications and associated information related to medication use. The list is subject to periodic review and modification.

Goal A broadly stated or long-term outcome written as an overall statement relating to a philosophy, purpose, or desired outcome.

Governance The function of determining the organization’s direction, setting objectives, and developing policy to guide the organization in achieving its mission.
**Governing Body** Collectively the individual(s), group, or agency that has ultimate authority, responsibility, and accountability for the overall strategic direction, methods of operations (management and planning), establishment of policies, maintenance of safety and quality of care of the organization.

**Guidelines** Principles guiding or directing action.

**Hazardous Materials** Substances, such as chemicals, that are dangerous to humans and other living organisms.

**Hazardous Waste** Waste materials dangerous to humans and other living organisms. Such materials require special precautions for disposal.

**Healthcare-Associated Infections (HAIs)** Infections that patients acquire during the course of receiving treatment for other conditions or that healthcare workers acquire while performing their duties within a healthcare setting. Specific criteria must be met in order to define an infection as healthcare-associated.

**Health Care Professional** Any person who has completed a course of study and is skilled in a field of health. This includes a physician, dentist, nurse, or other healthcare professionals. Healthcare professionals are often licensed by a government agency or certified by a professional organization.

**Medical Record** A record that contains patient health information generated by one or encounters. Included in this information are patient demographics, assessment findings, problems, medications, immunizations, diagnostic reports, provided education, and any other relevant patient-specific information.

**High Risk** High probability that severe injury will occur.

**Incident** Events that are unusual, unexpected, may have an element of risk, or that may have a negative effect on patients, staff, or the organization.

**Indicator** Performance measurement tool which is used as a guide to monitor, evaluate and improve the quality of patient care and service.

**Information** An interpreted set of data; organized data that provides a basis for decision-making.

**Information Management** The creation, use, sharing, and disposal of data or information across an organization. This practice is critical to the effective and efficient operation of organization activities.

**Informed Consent** Person’s voluntary agreement of one who has sufficient mental capacity with full knowledge of the risks involved, probable consequences, and the alternatives to make an informed decision. It allows a patient to balance the probable risks against the probable benefits of any potential care.
**Job Description** A written statements that describe the duties, responsibilities, required qualifications of candidates, and reporting relationship and co-workers of a particular job.

**Leaders** The identified and designated individuals who have the responsibility to oversee effective functioning of processes within a defined scope of services.

**Management** Setting targets or goals for the future through planning and budgeting, establishing processes for achieving those targets, and allocating resources to accomplish those plans.

**Mission** The reason or purpose for the existence of an organization or one of its components.

**Mission statement** A written expression that states the purpose of an organization or one of its components.

**Monitoring** A planned, systemic, ongoing process to gather, organize, and review data/information on a regular basis with the purpose of identifying changes in a situation.

**MSDS (Material Safety Data Sheet)** A form containing data regarding the hazardous properties of chemicals and other hazardous agents.

**Objectives** Concrete, measurable steps taken to achieve goals. Tampering

**Organizational Chart** A diagram representing the structure of the organization and reporting relationship. It shows employee positions, reporting relationship, and lines of authority.

**Orientation** The act of being oriented. The introductory process by which staff become familiar with all aspects of the work environment and their responsibilities.

**Outcome** A broad term that is used to describe the end result of a service, practice, procedure, or intervention.

**Patient** A patient is a person for whom the organization accepts responsibility for treatment, care and/or service. For CBAHI standards, a patient includes such designations as client, resident, and individual served.

**Patient Assessment** The gathering of information in order to evaluate a person's health and health-care needs.

**Patient Satisfaction** A measurement that obtains reports or ratings from patients about services received from an organization, hospital, physician, or healthcare provider.

**PDCA** It is a scientific method utilized to improve processes. Acronym meaning: PLAN the improvement, DO the improvement, collect data and analyze data, CHECK and study the results, ACT to improve the process and hold gains. Also known as the Shewart cycle, Deming cycle, or learning cycle of change.

**Personnel File** Collection of information about a staff member covering personnel issues such as licensure, certifications, leaves, appraisal reviews, and job description.
**Plan** To formulate or describe the approach to achieving the goals related to improving the performance of the organization.

**Plan of care (Care Plan)** A treatment plan especially designed for each patient, based on individual strengths and needs. The caregiver(s) develop(s) the plan with input from the family and communication with each others. The plan establishes goals and details appropriate treatment and services to meet the special needs of the patient. The planning is an interdisciplinary process.

**Policy** A policy is a written document which outlines the rules and expected performance of staff within the organization. Policies are dynamic and reflect current knowledge and practice and need to be reviewed on a regular basis.

**Privileging** The process of reviewing an individual's credentials through credentials body to determine the authority and responsibility to be granted to a practitioner for making independent decisions to diagnose, initiate, alter, or terminate a regimen of medical or dental care. Privileging determines the physician's scope of practice in the organization determined by his/her competencies.

**Procedure** A written set of instructions that describe the approved and recommended steps for a particular act or sequence of acts.

**Process** A set of interrelated steps directed at one particular outcome.

**Process Improvement** Mechanisms utilized to make improvements to a process through the use of continuous quality improvement methods.

**Probationary period** The time period identified by the organization for determining if the employee is competent to perform his/her duties and continue employment with the organization. Generally, the time period of probation is 3 months.

**Protocols** A plan, or set of steps, to be followed in a study, an investigation, or an intervention.

**Psychosocial** Refers to one's psychological development in the context of a social environment. It is simply the individual's interaction with the environment which he finds himself and the dynamics or factors which influence the individual's "psyche".

**Quality** The degree to which health services for individuals and population increases the likelihood of desired outcome and are consistent with current professional knowledge.

**Quality Control** A management process through which performance is measured against expectations and corrective actions are taken.

**Quality Improvement** Team Individuals (cross-department functions/services) knowledgeable about a particular aspect of care or service and commissioned to improve a process that has been identified as requiring attention.
**Referral** The process by which a patient is sent (1) from one clinician to another clinician or specialist; or (2) from one setting or service to another or other resource, either for consultation or care that the referring source is not prepared or qualified to provide.

**Rehabilitation** Programs and activities designed to help individuals maximize their independence.

**Risk** The combination of the assessment of magnitude of injury, or potential injury, with the probability that certain actions/events will occur.

**Root Cause** The underlying reason for the occurrence of a problem.

**Safe Care** The degree to which the risk of an intervention and the risk in the care environment are reduced for a patient and others, including the health care practitioners.

**Scope of Service** The range of activities provided to the patients and/or other customers by the leadership, clinical, and support personnel. This describes the full range of services, the demographics (age groups, types of patients) diagnostics provided, therapeutic interventions provided, and the number of patients who are provided each service annually. All of the resource and competency requirements flow from the organization’s scope of service.

**Screening** A system for examining and separating into different groups.

**Screening Criteria** A set of standardized rules or tests applied to patient groups on which to use a preliminary judgment that further evaluation is warranted.

**Sentinel Event** An event that, when noted, requires intensive assessment.

**Standard Statement** of structure and process expectations necessary to enhance quality care.

**Standardization** To confirm with a predetermined set of expectations.

**Strategic Planning** A management tool to help an organization do a better job. It is disciplined effort to produce fundamental decisions and actions that shape what an organization is, what it does, and why it does it, with a focus on the future.

**Structure** Environmental features which shape process and outcome: resources, money, equipment, supplies, staff, policies.

**System** A group of related processes.

**Team** A group of five to eight people consisting of a leader, facilitator, and members who are addressing an issue that impacts the operations of a process.

**Terms of reference** A formal document approved by the leadership that outlines the roles/responsibilities of a committee. This document describes the expected performance of the committee, how often the committee is expected to meet, and also includes a list of the membership and alternates if needed.
**Timely** The degree to which care is provided to the patient at the most beneficial or necessary time.

**Transfer** The formal shifting of responsibility for the care of a patient from one care unit to another, one clinical service to another, one qualified practitioner to another, or one organization to another organization.

**Trending** The evaluation of data collected over a period of time for the purpose of identifying patterns or changes.

**Triage** A system of establishing the order in which acts are to be carried out in an emergency, prioritize patients by their problems, symptoms determining the order of being managed.

**Turn Around Time** Initial time from the starting point to the end point. For example: For a stat order, the time the doctor's order was written, or stated, to the time it is carried out.

**Utilization** The use, patterns of use, or rates of use of a specified health care service.

**Values** The beliefs and philosophy within an organization that establish the basis for the operation and provides guidelines for daily behaviour.

**Vision** Description of what the organization would like to be.

Further modifications will be communicated to the Ambulatory Care Facilities through later editions and amendments. If you have any comments or queries about the Licensing standards please contact:

**NHRA – National Health Regulatory Authority**

Phone: 973 17113333

E-mail: admin@nhra.bh

Website: [www.nhra.org](http://www.nhra.org)