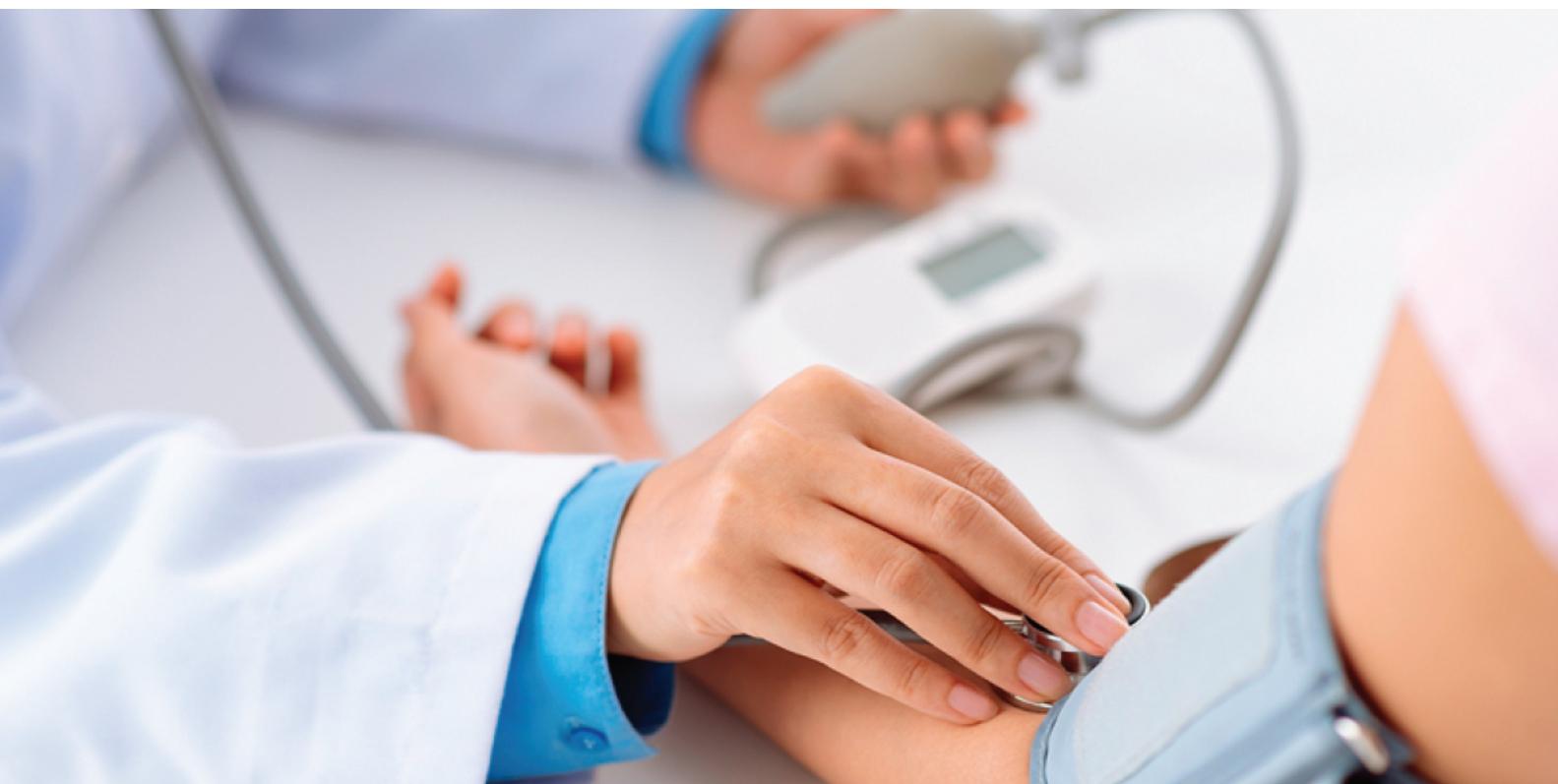




CBAHI

المركز السعودي لاعتماد المنشآت الصحية
Saudi Central Board for Accreditation
of Healthcare Institutions



المعايير الوطنية
لمراكز الرعاية الصحية الاولية

NATIONAL Primary Healthcare STANDARDS

1.1 Edition

SAUDI CENTRAL BOARD FOR ACCREDITATION OF HEALTHCARE INSTITUTIONS

**Effective
Feb. 2017**

The mission of the Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) is to continuously improve the safety and quality of healthcare services in the Kingdom of Saudi Arabia by supporting the healthcare facilities to continuously comply with the accreditation standards. CBAHI does this through the provision of preparation, on-site assessment, monitoring, education, publications and consultation services.

CBAHI is making every possible effort to separate its consultative and educational programs as well as all publications it produces from its accreditation activities. This manual is produced for the sole use of the individual healthcare facilities and healthcare professionals in Saudi Arabia. CBAHI provides supplementary educational sessions to explain the intent of this manual and its contents, and therefore, attendance at these activities is helpful in achieving compliance with the quality and safety standards followed by accreditation. Attendees at CBAHI training, orientation and educational programs and purchasers of its publications will not have a distinctive treatment by any CBAHI associates including CBAHI surveyors, nor receive any privilege regarding assessment scoring results or outcome.

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Foreword

The healthcare industry in Saudi Arabia is experiencing an evolution associated mainly with one of the fastest growing rates of population in the world and a remarkable economic prosperity. This has been paralleled by a significant and steady improvement in the overall performance of the Saudi health sector secondary to the never-ending government support and the several quality programs and initiatives, at the forefront of which are the accreditation programs implemented by the Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI), the national body responsible for setting the quality and patient safety standards and accreditation of all types of healthcare facilities working today in Saudi Arabia.

Healthcare accreditation is gaining more reputation as a proven system for enhancing the quality and safety of care provided to patients and their families. It also provides for a common language among healthcare professionals especially in a country like ours where dozens of nationalities are sometimes working in one hospital, each with a different educational and cultural background.

These benefits have encouraged most developed countries to establish their accreditation bodies, followed by any other less developed countries. Saudi Arabia has been among the first countries to take the initiative of establishing its own capabilities in the field of healthcare accreditation. This impetus resulted in the creation of CBAHI several years ago. Today, CBAHI is still committed to its original mission and is currently responsible for the assessment and accreditation of all the hospitals, primary healthcare centers, ambulatory healthcare centers, and medical laboratories across the country. It has become evident that CBAHI is an essential guarantor of the future of patient safety in the Kingdom of Saudi Arabia. CBAHI is backed by its cumulative experience and resources and before that, by the country's sincere and committed leadership towards fulfilling the healthcare needs of the Saudi citizens to the highest achievable quality levels.

H.E. Khalid AlFalih
Minister of Health
Chairman of Saudi Health Council

Standards Development Committee/ Advisory Committees and Experts Panel

Experts including physicians, nurses, pharmacists, laboratory specialists, infection control practitioners, biomedical engineers, administrators and public policy makers representing all health sectors in Saudi Arabia have actively guided the development of this 1.1 edition of the Primary Healthcare Standards. Several professional bodies have assisted as well with the development and refinement of the standards. CBAHI would like to extend thanks and appreciation to all health authorities, organizations and individuals who participated in or provided external commentaries to this important national initiative. The following is a list of participants in alphabetical order.

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Preface

The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) is proud to present the 1.1 Edition of the National Primary Healthcare Standards (PHC). Over the last few years, the health sector in Saudi Arabia has witnessed a major advancement at all levels. One remarkable area was the great expansion in the number of PCHs and the health care services they provide to more than thirty-one million population scattered over more than two million square kilometers area. This comes along with a great advancement in the medical field around the globe, with more focus on the need for PHC environments that support performance measurement and continuous quality improvement. Here comes the rationale for national, evidence-based standards that would support PHCs in Saudi Arabia in improving the quality and safety of patient care and cure.

The PHC Standards were developed to recognize the significant role PHCs play in rural and urban settings regardless of the ownership and operation of the entities. These standards address the delivery of care to individuals in the PHC environment and are designed to ensure the provision of safe and high-quality care. During the development of this 1.1 Edition of the PHC standards, one of the most important challenges we faced was to develop standards that would apply to all PHCs, considering the variation in the different levels and purpose of design across the continuum of care.

As with this edition, the development of the PHC standards aims to facilitate the process of PHC's self-assessment against preset requirements and performance expectations, ensure patient and public safety, encourage the PHC leadership to measure the PHC's performance through the use of measures and indicators, and put emphasis on the ever-lasting concept of continuous quality improvement. This should translate ultimately into a successful survey preparation and winning of accreditation.

Upon going through the manual, it provides important information about CBAHI, the eligibility for accreditation, the scheduling of accreditation surveys, the survey preparation, the on-site survey, and the accreditation decision rules. In the remaining part, one can find all the standards distributed over the twenty-three chapters.

Our appreciation and gratitude go to the committees, teams, and task forces that contributed to the development, compilation, design, review, revision, and production of this manual. We extend our appreciation to the healthcare professionals who were generous with their feedback and constructive comments and suggestions.

For more information on the PHC and other accreditation programs of CBAHI, as well as for all comments and suggestions for improvement, please contact us at cbahi@cbahi.gov.sa.

Dr. Salem Al Wahabi

Director General

Saudi Central Board for Accreditation of Healthcare Institutions - CBAHI

PART I

INTRODUCTION & EXPLANATORY NOTES



CBAHI at a Glance

The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) is the official agency authorized to grant healthcare accreditation to all governmental and private healthcare facilities operating today in the Kingdom of Saudi Arabia.

Originally emerged from the Saudi Health Council as a non-profit organization, CBAHI is primarily responsible for setting the quality and safety standards to ensure a better and safer healthcare. Its initial official inauguration was due after the Ministerial Decree number 144187/11 on October 2005, which called for the formation of the Central Board for Accreditation of Healthcare Institutions that shall be responsible for the initiation of a national voluntary healthcare accreditation program. In 1434/2013, the Council of Ministers mandated accreditation by CBAHI and gave it its current name.

The mission of the Saudi Central Board is to promote healthcare quality and patient safety by supporting healthcare facilities to continually comply with accreditation standards.

The vision of the Saudi Central Board is to be the regional leader in improving healthcare quality and patient safety.

Driven by its core values and the dedicated team of surveyors and staff at the central office, CBAHI is determined to be a major driving force and a recognized standard for the provision of safe and high-quality healthcare. CBAHI is proud to be amongst few healthcare accreditation agencies around the world that are accredited by the International Society for Quality in Healthcare (ISQua), for hospital standards and organization.

Healthcare accreditation: Definition and importance

Healthcare accreditation is an assessment process that involves a rigorous, transparent, and comprehensive evaluation by an external independent accreditation body. The health care facility undergoes an examination of its systems, processes, and performance by peer reviewers or surveyors to ensure that all is conducted in a manner that meets applicable predetermined and published national standards. Before the external evaluation, i.e., the survey visit, the healthcare facility is expected to conduct a comprehensive self-assessment to decide on the level of its preparedness and how far or how close it is from achieving full compliance with the standards. Accreditation therefore, represents a public recognition by the health care accreditation body of the achievement of accreditation standards by a health care facility. Standards set out a common framework to support healthcare facilities to provide effective, timely and quality services. They are designed to deliver improved levels of care and treatment to the citizens and residents of Saudi Arabia. There is good evidence from scientific research that shows that engaging in a robust healthcare accreditation program improves the structure, process and outcome of care provided by

healthcare facilities. Accreditation is not simply a certificate to obtain and hang on the wall. If utilized properly, accreditation can provide the following benefits:

- Accreditation provides a framework for the organizational structure and management: almost all accreditation standards focus on the governance and leadership structures and functions within a healthcare facility and the appropriate management of its business and day to day activities.
- Accreditation helps improve patient safety and minimize the risk of near misses, adverse outcomes, and medical errors: ensuring patient safety through risk management and risk reduction is at the heart of all accreditation standards and is the ultimate goal of the self-assessment and the survey activities.
- Accreditation enhances community confidence in the quality and safety of care provided: when a healthcare facility achieves accreditation, the message is clear; its leaders are committed to providing a nationally accepted standard of care in health services delivery.
- Surveyed healthcare facilities have found that seeing their own operation through the eyes of experienced surveyors provided them with a useful, more objective assessment of their internal administrative and clinical processes and effective proposals for further improving their processes and services to the community.
- Accreditation -on the long run- proves to increase the efficiency and enhance the lean practices, which translates into decreasing waste and more optimal results with less consumption of resources.
- Achieving accreditation helps improve the competitiveness of a healthcare facility: rising public confidence in an accredited facility will eventually encourage more patients to seek care and treatments in that facility which will positively impact its competitiveness in the healthcare sector and increase its market share.
- Achieving accreditation will satisfy the regulations of the Ministry of Health, being the legislative health authority, which is now considering linking the national accreditation by CBAHI with the licensing of the private healthcare facilities. Registration with CBAHI and enrollment in its national accreditation program is accepted by the Ministry of Health -at this stage- as a satisfactory evidence for the purpose of license renewal. Eventually however, all healthcare facilities operating in Saudi Arabia are required to achieve accreditation by CBAHI.
- Reimbursement by insurers and other third parties: there is a growing tendency, nationally and internationally, to link achieving accreditation with eligibility for insurance reimbursement.
- Accreditation provides a robust tool for the continuous quality improvement efforts in the healthcare facilities: striving relentlessly to comply with accreditation standards helps the leadership of the facility to ensure the sustainability of the quality improvement projects and initiatives.
- Accreditation provides for a great learning and educational opportunity: through staff education on the best practices and by adding emphasis on the importance of patient education and patient rights.

Standards development process

A standard is a statement of excellence, or an explicit predetermined expectation that defines the key functions, activities, processes and structures required for healthcare facilities to assure the provision of safe and quality care and services.

Standards are developed by peer experts in the field and it's against the standards that conformity of the healthcare facility is evaluated. Simply stated, the standard describes a healthcare facility's acceptable performance level. Within this context, there should be no confusion between accreditation standards and licensure standards. When applied to licensure of an individual practitioner or organization, the standard is usually set at a minimal level designed to protect public health and safety. Accreditation standards, on the other hand, are designed as optimal and achievable which, when met, would lead to a high-quality level in a system. Broadly speaking, CBAHI standards -as well as all other relevant accrediting agencies- are of three major types depending on which area they are addressing. Structure standards address the system's inputs, such as the PHC clinics' availability, the manpower, the design of the PHC building, the availability of personal protective equipment for health workers, such as gloves and masks, and the availability of equipment and supplies, such as microscopes and laboratory reagents. Process standards address the clinical and administrative activities or interventions carried out within the PHC in the care of patients or in the management of the PHC or its staff. Examples include patient assessment, patient education, medication administration, and alike. Outcome standards look at the assessment of the benefits of an intervention and whether the expected purpose of the activity was achieved. They provide information about whether predicted outcomes are being realized. Examples of outcome indicators include mortality rates, foreign object retained after suturing, patients' satisfaction, medication errors, falls, and manifestations of poor glycemic control.

CBAHI standards set expectations for PHC performance that are reasonable, attainable, measurable and therefore, survey-able. Standards were built to serve as the basis of an objective evaluation process that can help health care facilities measure, assess and improve performance. CBAHI is striving to be a nationally recognized symbol of excellence, respected throughout the industry and by other relevant authorities as an assurance that accredited healthcare facilities meet rigorous standards of quality and operational integrity that emphasize consumer protection and patient engagement. To this end, the process of standards development at CBAHI follows a long and robust methodology to ensure that our standards are correct, evidence-based, relevant and clear. As with previous editions, this current manual contains standards of quality and patient safety that were constructed to be descriptive in nature and department-oriented. The first draft of CBAHI standards are developed by specialized task forces, focus groups, and standards development committees that utilize input from a variety of sources, including:

- The standards set by the professional scientific societies, locally and internationally.
- Scientific literature review and research studies.
- Relevant laws, rules, and regulations.
- National (or international) emerging issues related to healthcare quality and patient safety.

- Input from health care professionals, providers, and patients.
- Panels of experts and consensus on the so-called “best practices”, given the current state of knowledge and technology.

The process of standards development can last up to 18 months or more before an initial draft is produced. The draft standards are then distributed nationally for review and made available for comment on the standards Field Review page of the CBAHI website. Based on the feedback received from the field review, the draft standards may be revised and again reviewed by the relevant experts and technical committees. The draft standards are finally approved by the Standards Development Committee and provided to the Board for comments and remarks before submission to the Saudi Health Council for approval. Thereafter, standards are provided in paper and electronic formats and distributed to all PHC centers and e-version is made available on CBAHI website. To comply with the guidelines of the International Society for Quality in Healthcare (ISQua), six months period is allowed for publishing the standards before they are effective. Once the standards are in effect, ongoing feedback is sought for the purpose of continuous improvement. The survey process is then tailored as needed to address the new standards, and surveyors are educated about how to assess compliance with the standards.

Accreditation Survey

CBAHI Surveyors typically employ a variety of evaluation techniques and strategies to objectively decide if the PHC meets standards related to key systems and functions, such as governance and leadership, human resources management, patient care processes, medication management, infection control, management and safety of the PHC environment, and quality assurance. For example, the survey team may review written documents (e.g., organizational bylaws, strategic and operational plans and budgets, or clinical policies and procedures). In addition to a review of documents, surveyors will interview the PHC leaders, physicians, nurses, employees, and patients in order to determine the PHC's performance and compliance with standards. For example, the surveyor might choose to interview a staff member to check on the process he or she should go through to report a medical error that has caused harm to one of the patients receiving care in that PHC. Similarly, a surveyor might choose to interview a patient about his or her level of satisfaction with the care provided by the PHC. The PHC leaders, including the members of the governing body, may be interviewed regarding the PHC's processes and how they are designed to meet standards related to planning, budgeting, quality assurance activities, and human resource management. Surveyors will tour the PCH's buildings and patient care areas in order to evaluate standards related to overall cleanliness, building safety, fire safety, waste management, equipment and supply management, infection control, and emergency preparedness. Other diagnostic and support services such as laboratory, radiology department, pharmacy, and central sterile services department are also assessed with respect to safety, effectiveness, quality control, and equipment management. In summary, surveyors use a variety of evaluation approaches during the on-site survey in order to determine the PHC's compliance or performance with applicable structure, process, and outcome standards. These methods might include any combination of the following:

- Interviews with PHC Leadership, clinical and support staff, patient and family.

- Observation of patient care and services provided.
- Building tour and observation of patient care areas, building facilities, equipment management, and diagnostic testing services.
- Review of written documents such as policies and procedures, orientation and training plans and documents, budgets, and quality assurance plans.
- Review of personnel files.
- Review of patients' medical records.
- Evaluation of the PHC's achievement of specific outcome measures (e.g., medication errors, patient satisfaction) through a review and discussion of monitoring and improvement activities.

CBAHI team conducts a one-day survey unless required to be more depending on the volume and complexity of services provided by the PHC, the number of locations or care settings included in the survey, and the type of survey (focused or full). The scope of the survey visit includes all standards-related functions in the PHC to be surveyed. This implies that any service/function/area that is not covered by the CBAHI PHC standards will not be assessed during the survey visit. Applicable standards from this manual are determined by CBAHI based on the scope of services and the decision of the onsite survey team on the specific applicability of individual standards.

The Structure of the National PHC Standards Manual – 1.1 Edition

The standards are assembled into (23) chapters around key services and functions provided by PHC in Saudi Arabia. The chapters included in this PHC standards manual are:

1. Leadership (LD)
2. Quality Management and Patient Safety (QM)
3. Manpower (MP)
4. Management of Information (MOI)
5. Health Record (HR)
6. Patient and Family Rights (PFR)
7. General Clinics (GC)
8. Referral (RF)
9. Community Participation (CP)
10. Health Promotion and Education (HPE)
11. Maternity and Child Health (MCH)
12. Immunization (IM)
13. Non-Communicable Diseases (NCD)
14. Geriatric Care (GRC)
15. Communicable Diseases (CD)
16. Dental and Oral Health (DOH)
17. Emergency Services (ES)
18. Environmental Health (EH)
19. Laboratory Services (LB)
20. Radiological Services (RS)

21. Pharmaceutical Services (PH)
22. Facility Management and Safety (FMS)
23. Prevention and Control of Infection (PCI)

Each chapter has a brief introduction that explains the chapter's relevance and contribution to safety and quality of patient care. Each standard is composed of a stem represented by a concise statement, followed by one or more sub-standards to clarify further the requirements of the standard.

Broadcast on changes in this 1.1 edition of PHC standards - Essential Safety requirements (ESR), and the survey process

The CBAHI accreditation standards for PHC underwent an extensive review based on the experience gained over the past years. The changes in this new edition include the identification of Essential Safety requirements (ESR) and the survey process.

Essential Safety Requirements

Adverse events often result in a medication errors, higher costs, poorer outcomes, or even death. Patient safety has been conceptualized as the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the processes of health care. Adverse events and medical errors are becoming major challenges facing health authorities and accreditation agencies almost everywhere in the world. The occurrence of several serious incidents in PHC centers made it clear to CBAHI that compliance with the standards did not guarantee a safe patient environment. Different strategies and tools have been introduced in this manual to enhance patient safety and minimize the risk of adverse events. Having a patient safety program and a system for incidents reporting are just few examples, but also the concept of Essential Safety Requirements (ESRs) that is included in this manual.

A selected group of standards have been assigned as Essential Safety Requirements indicated in this manual with the icon ESR.

Essential Safety Requirements are selected based on their level of risk on patients: proximity of risk, probability of harm, severity of harm, and number of patients at risk. As the name indicates, Essential Safety Requirements are defined as essential structures and practices -represented in this manual by a selected group of standards- that the PHCs undergoing CBAHI accreditation must have in place and be in full compliance with, to minimize the risk of serious harm and/or death of a patient or a staff member. The list was not meant to be all-inclusive of essential safety requirements but rather, a focus on some areas that are relevant to our national context. ESRs are scored similar to

the other PHC standards depending on the level of compliance as evidenced by documentation/interview/or observation of the surveyor.

There are (14) Essential Safety Requirements distributed in the different chapters of this manual as follows:

Essential Safety requirements (ESR)

- 1. GC.13** Patient allergies or prior adverse reactions are noted, documented, prominently, and consistently displayed in a specified area of the patient's record.
- 2. GC.19**
 - GC.19.1 A care plan is developed to meet the needs of each patient. The care plan is developed by the attending physician, nurse, and other disciplines participating in care.
 - GC.19.2 The care plan is based on the data from assessments and reassessments.
 - GC.19.3 The care plan contains measurable goals (desired outcomes) and is documented in the patient's record.
 - GC.19.4 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.
 - GC.19.5 Care or treatment is provided in accordance with the plan.
 - GC.19.6 The care provided for each patient is documented in the patient's record.
- 3. LB.10** The laboratory has a clear system for results reporting including:
 - LB.10.1 Defined turnaround time (TAT) for all laboratory services.
 - LB.10.2 Definition of panic values (critical results) and their reporting method.
- 4. RS.5** There is a radiation safety protocol or plan in place to protect staff, patients, and the environment that includes at least the following:
 - RS.5.1 All equipment are inspected and checked regularly with an experienced Safety Officer.
 - RS.5.2 All radioactive materials are used according to the guidelines and the Safety Officer oversees the activity in the unit.
 - RS.5.3 Safety warnings are posted on doors in clear and appropriate locations.
 - RS.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 ask the patient.
 - RS.5.5** Personnel are monitored for radiation exposure:
 - RS.5.5.1 Thermo luminescence Dosimeter (TLD) is regularly checked for all radiology staff.
 - RS.5.5.2 Checking white blood cells periodically for all employees in Radiology Department.
 - RS.5.6 Radiation personal protective measures are available for employees and patients.
- 5. PH.14** The primary healthcare center pharmacy has a system developed for handling prescriptions that includes:
 - PH.14.1 Pharmacist confirms the completion of the basic data of the prescription: patient's name, health record number, age, sex, body weight (for pediatrics or when indicated), diagnosis, allergies prescriber's name, signature and stamp, clinic number, and date.

- PH.14.2 A pharmacist verifies all physician orders for diagnosis, dosing, frequency, route, duration, and interactions.
 - PH.14.3 Drugs are prescribed and dispensed for their approved indications as evidenced by the given diagnosis.
 - PH.14.4 There is a procedure for pharmacy intervention/clarification of physician orders.
 - PH.14.5 There is a policy for filling and refilling prescriptions.
 - PH.14.6 The pharmacy notifies the prescribing physician if a prescribed drug is not available.
 - PH.14.7 There is evaluation, monitoring, and documentation of drug-drug and drug-food interactions.
 - PH.14.8 All prescriptions are double-checked by another qualified professional before dispensing.
- 6. QM.11** **The primary healthcare center supports patient safety by:**
- QM.11.1 Defining and adopting selected International Patient Safety Goals in the Quality Improvement and Patient Safety Plan.
 - QM.11.2 Assigning staff or establishing a Patient Safety Team with representation from medical, nursing, pharmacy, and safety departments.
 - QM.11.3 Charging the assigned staff or the Patient Safety Team with implementing and monitoring the patient safety goals and recommending actions for improvement.
- 7. HR.2.** **The health record is easily identified by a unique patient identifier**
- 8. ES.12** The crash cart is regularly monitored and checked for the following:
- ES.12.1 Functioning of cardio respiratory equipment.
 - ES.12.2 Defibrillator battery, full oxygen tank, suction machine, medications, ambu bags with reservoirs, drug calculation charts, ET tube (for neonates, pediatrics, and adults), sharp box. Crash cart is locked with lock number tag.
 - ES.12.3 Routine (minimum monthly) checking of all medications and equipment in the crash cart.
- 9. FMS.6** **Interdisciplinary rounds are scheduled and conducted to ensure safety, and include the following:**
- FMS.6.1 Environmental rounds to check staff knowledge and implementation regarding the FMS plans (quarterly).
 - FMS.6.2 Facility Tours to check the facility/physical plant (quarterly).
 - FMS.6.3 The resulting information is used for corrective actions, planning, and budgeting long-term facility upgrading and replacement.
- 10. FMS.8** **The primary healthcare center has a fire prevention program.**
- FMS.8.1 The staff are trained on the fire evacuation plan.
 - FMS.8.2 Egress routes are free from obstacles
 - FMS.8.3 Proper storage.
 - FMS.8.4 Fire systems, fire alarms, and fire equipment are in place and functioning.
- FMS.8.EC1** **Fire alarms are maintained and tested, and PPM records are kept**
- 11. FMS.8** **The primary healthcare center has a fire prevention program.**
- FMS.8.1 The staff are trained on the fire evacuation plan.
 - FMS.8.2 Egress routes are free from obstacles.
 - FMS.8.3 Proper storage.
 - FMS.8.4 Fire systems, fire alarms, and fire equipment are in place and functioning

- FMS.8.EC.6** Fire extinguishers are functioning, tested, and distributed in the center.
- 12. IPC.14** The primary healthcare center defines in policy the safe procedures for waste collection, storage, and disposal to ensure the safety of internal and external environment.
- IPC.14.1 The policy differentiates between regular waste and infectious waste.
- IPC.14.2 The infectious waste is treated according to the national medical waste management system.
- 13. IPC.22** A sterilization room (unit) must be available with the following structural and functional specifications:
- IPC.22.1 Personal protective equipment is available and used during decontamination: heavy-duty gloves, waterproof aprons, facemask, goggles, or face shield.
- IPC.22.2 Sterilization service staff have adequate knowledge and training.
- IPC.22.3 Cleaning, disinfection, and sterilization of medical equipment should be done in sterilization unit and not in the respective departments.
- IPC.22.4 There is a uni-directional flow of traffic from dirty to clean areas, i.e. decontamination area > packing > sterilization > storage areas.
- IPC.22.5 Proper sterilization parameters are recorded.
- IPC.22.6 Sterilization records are kept for one year to allow inspection.
- IPC.22.7 Sterilizers are in good working order and instructions are available for sterilizers.
- IPC.22.8 Chemical indicators are used in every package. Biological indicators are used at least weekly. Records of results are kept for one year.
- IPC.22.EC.3** All cleaning and sterilization of medical equipment is performed in the sterilization unit
- IPC.22** A sterilization room (unit) must be available with the following structural and functional specifications:
- IPC.22.1 Personal protective equipment is available and used during decontamination: heavy-duty gloves, waterproof aprons, facemask, goggles, or face shield.
- IPC.22.2 Sterilization service staff have adequate knowledge and training
- IPC.22.3 Cleaning, disinfection, and sterilization of medical equipment should be done in sterilization unit and not in the respective departments.
- 14. IPC.22.4** There is a uni-directional flow of traffic from dirty to clean areas, i.e. decontamination area > packing > sterilization > storage areas.
- IPC.22.5 Proper sterilization parameters are recorded.
- IPC.22.6 Sterilization records are kept for one year to allow inspection.
- IPC.22.7 Sterilizers are in good working order and instructions are available for sterilizers.
- IPC.22.8 Chemical indicators are used in every package. Biological indicators are used at least weekly. Records of results are kept for one year.
- IPC.22.EC.5** Chemical and biological indicators are used in the sterile packages.

Survey Process Changes

Most of the survey activities have been revised to focus on assessment of performance and implementation of the standards rather than reviewing documents. The goal is to ensure that the CBAHI standards are integrated into the daily practices of the PHC. Beside conferences, interviews, and review of documents, the major part of the survey visit will be allocated for the evaluation of implementation of standards and the performance of the different processes within the PHC.

No matter how robust was the methodology used in building the standards and the survey process, there will be always a room for improvement. Therefore, for all comments and remarks on a standard, CBAHI website includes an electronic form that allows PHC, experts, and other interested parties to comment on current standards. The form allows for constant stakeholder feedback on the standards. This is part of several other CBAHI's initiatives to improve the efficiency and effectiveness of its internal processes, including standards development, so as to better meet needs and expectations of our partners.

Eligibility for Accreditation

All PHCs licensed to practice in the Kingdom of Saudi Arabia are eligible for CBAHI accreditation. However, eligibility for conduction of a survey visit is contingent upon fulfilling all of the following requirements:

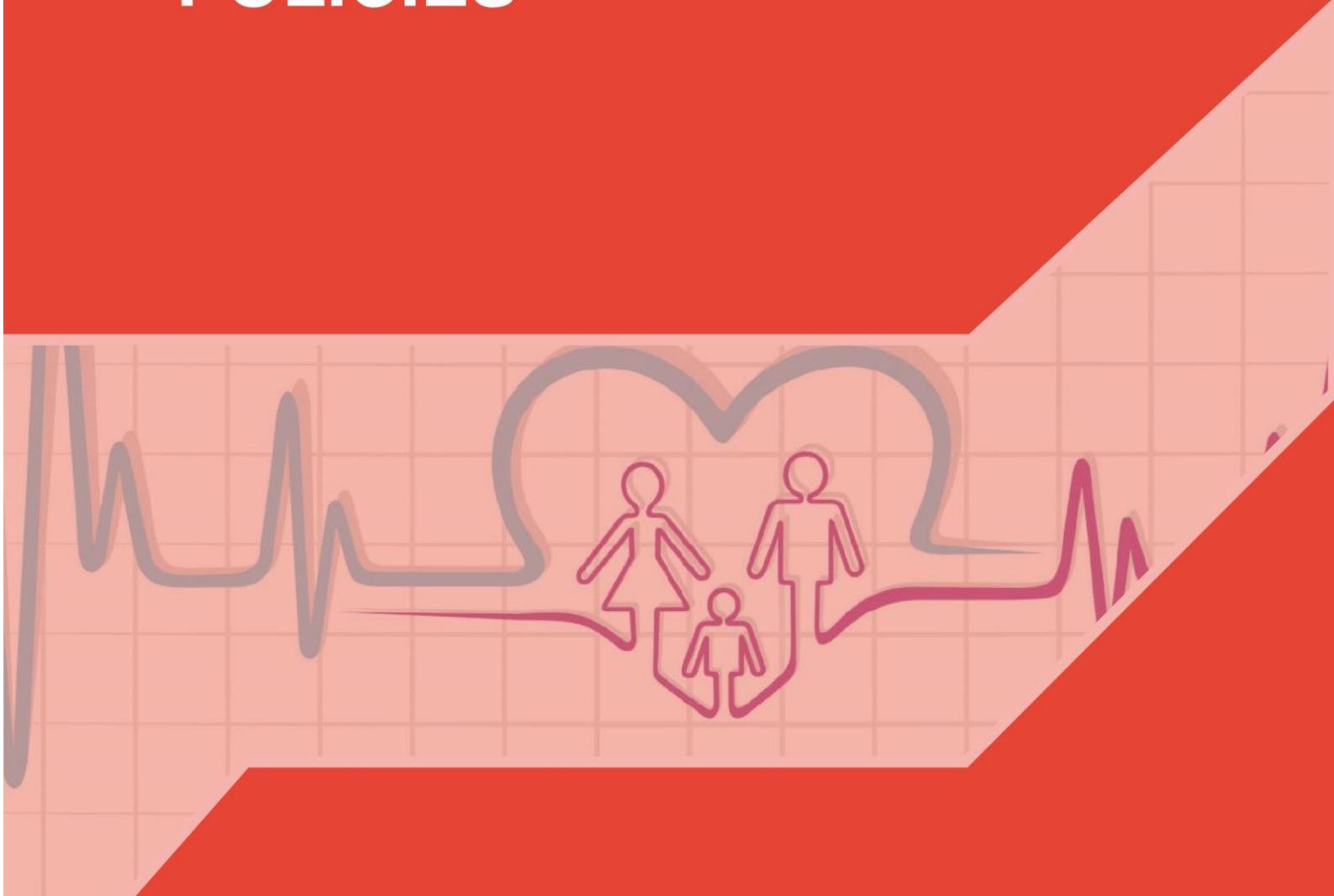
- The PHC meets all licensing requirements to operate (and therefore, has a valid license when applicable), as indicated by the statutes and regulations of the Ministry of Health.
- The PHC meets any additional licensing requirements as indicated by other relevant authorities (Most notably, valid certificate from the Civil Defense).
- The PHC meets the legal definition of a PHC as per the regulations of the Ministry of Health and the international guidelines in this regard:
 - Licensed as a PHC under the law governing healthcare institutions in Saudi Arabia.
 - Has an organized medical staff and continuous nursing services under the supervision of registered nurses.
 - Maintains permanent and full-time facilities that include outpatient primary health care services.
 - Provides diagnosis (has laboratory and radiology services directly or through a third party) and medical or surgical treatment primarily for, but not limited to, acutely sick and injured patients.
 - Provides emergency care services.
- The PHC provides healthcare services addressed by the CBAHI's National PHC Standards.
- The PHC has been in operation for at least (12) months before the on-site survey.

Effective Date of the National PHC Standards Manual- 1.1 Edition

The effective date of this edition of the National PHC Standards (NPH 1.1) is the first of February 2017. This is the date after which all surveys and accreditation decisions will be based on this 1.1 edition of the National PHC Standards. This applies to PHCs seeking accreditation by CBAHI for the first time as well as PHCs already accredited by CBAHI based on older editions of the PHC standards.

PART II

ACCREDITATION POLICIES



Registration with CBAHI

Registration with CBAHI for the purpose of accreditation is required for all eligible healthcare facilities and is the first step towards attaining accreditation whether for PHC or for all other accreditation programs offered by CBAHI.

PHC centers are required to register by completing the [Healthcare Facility Registration Form](#) located on CBAHI's portal. Registration is a quick, yet an important step that provides the Healthcare Accreditation Department at CBAHI with the basic information about the registering facility. A system generated auto-reply with a code number will be provided to the registering facility upon successful registration. The code number will be used for all future communication with CBAHI.

Accreditation Pathway

CBAHI is committed to its mission of promoting healthcare quality and patient safety by supporting healthcare facilities to continually comply with accreditation standards. There are several activities a healthcare facility will go through to obtain CBAHI accreditation.

Upon successful registration, the following resources will be provided to PHC centers seeking CBAHI accreditation:

- National PHC Standards
- PHC Accreditation Guide

PHC Accreditation Guide provides all required information to help the PHC prepare for the survey visits. It contains an abstract of each survey activity that includes logistical needs, session objectives and suggested participants.

Each year, CBAHI decides -in accordance with its yearly operational plan- which healthcare facilities are to be enrolled in its accreditation program for that particular year. CBAHI will notify the PHC included in its yearly accreditation program by a letter of enrollment.

CBAHI provides ongoing Health Care Facilities Orientation Programs (HOPs) in different locations throughout the year. PHC are highly encouraged to attend at one of HOPs offered by CBAHI, although any PHC can attend, the priority goes for PHC centers selected for the current year accreditation program. During these orientation sessions, standards, accreditation policies, and survey process are all explained in detail. This is a good opportunity for the PHC representatives to enquire about the intent of a standard and how it will be implemented. Dates and venues of the orientation programs will be communicated to the PHC in a timely manner.

All PHC centers enrolled in accreditation are required to conduct a comprehensive self-assessment using the Self-Assessment Tool (SAT) provided by CBAHI. This tool is intended to support the PHC in assessing how close it is to a satisfactory compliance with the standards and requirements. It also gives an idea of how much preparation and time the PHC needs before it can request a survey visit.

Usually, SAT is for the internal use of the healthcare facility, but it might be required by CBAHI to help deciding on the preparedness of the facility prior to conducting a survey.

Self-assessment is utilized by several other accreditation organizations to help them –if properly and objectively conducted- to have a better insight on the baseline situation of each PHC and provides for a common communication tool between the PHC seeking accreditation and the accrediting body. When both parties reach a compromise about the level of preparedness for a survey visit based on the self-assessment findings, a survey can be scheduled at a tentative date suitable for both.

Some PHC (especially those with no prior experience in accreditation) might opt to go for A Pre-Assessment Visit. This visit is offered by CBAHI (subject to the availability of resources) mainly to clarify more the accreditation policies, the standards and their intent, the survey process, the applicability of the different chapters of the standards manual, and to assess more the position of the PHC by verifying the findings of the self-assessment.

Upon reaching a satisfactory level of compliance with all applicable standards, a mutual agreement is made concerning the exact date of the onsite survey. Some PHC centers will prefer to go for a Mock Survey but this is subject to the availability of adequate resources at CBAHI and the requirement of its operational plans. CBAHI therefore is not obliged to respond to all incoming mock survey requests. Other PHC centers however may choose to go for an upfront Real Survey.

Once a PHC has applied for a real survey visit and completed all the pre-survey requirements as mentioned below, the date of the visit will depend on the scheduling availability as decided by the Healthcare Accreditation Department at CBAHI. The date of the survey will be shared with the PHC. As a general rule, a minimum of seven days will be allowed for PHC notification before the survey is actually conducted. When a short notice survey is to be conducted, the PHC leadership is expected to receive the survey team and facilitate its work. Failing to do so will subject the PHC to denial of accreditation as will be explained later.

In all cases, the following requirements are to be completed before CBAHI conducts a survey visit:

- The PHC has to submit successfully a completed Survey Application Form, located on CBAHI's portal.
- Service Agreement has to be acknowledged and duly signed by the PHC and a copy is returned back to CBAHI.
- Evidence of payment of the required accreditation fees.

The maximum number of real surveys a PHC is allowed to have for achieving accreditation is two (2) attempts, within two years timeframe. Six months is the minimal time interval between two consecutive real surveys. This, however, should not be misinterpreted as an “open-ended” exercise. For the majority of PHC previously accredited by CBAHI, the time interval between registration and achieving accreditation was 6-18 months on average. Therefore, PHC that will eventually prove to be incapable of achieving accreditation as reasonably persuaded by CBAHI (exceeded the two years’

timeframe from the date of the first real survey without achieving accreditation or underwent two real surveys but denied accreditation) will be suspended from participating in the national accreditation program for 12-18 months and referred to the relevant authorities for further action.

Survey Visit / Survey Team

To earn and maintain accreditation, a PHC must undergo an on-site survey by the CBAHI survey team. The Healthcare Accreditation Department at the central office handles all scheduling arrangements for surveys in coordination with the healthcare facility. The date of the survey visit will be determined through a mutual agreement, based on the capacity of CBAHI's yearly operational plan and the satisfactory level of preparedness as evidenced by the findings of the self-assessment.

PHC centers enrolled in the accreditation program will be notified by CBAHI to complete and submit the Survey Application Form (SAF) available on CBAHI's portal, indicating the type of survey requested (e.g. mock or real survey). A survey notification letter will be sent to the PHC indicating the date of the survey and other relevant information. The size and the specialties of the PHC survey team members are usually fixed but this might change according to the size of the PHC and its scope of services. As mentioned before, assessing compliance is accomplished through various survey activities and methods, such as review of documents, review of medical records and personnel files, staff or patient interviews, and the findings observed during facility tour and units' visits. Whatever the methodology used, CBAHI survey is structured to be an intelligent search for areas of nonconformance to the standards, rather than a check-list exercise. As a general rule, the PHC survey team is composed of seven (2) healthcare professionals:

- The PHC surveyor-1; who is also the visit's team leader: must be a physician.
- The PHC surveyor-2; must be a physician or a nurse.

The survey is conducted under the leadership of a Survey Team Leader (Lead Surveyor) that has been designated by CBAHI. The team leader is responsible for assuring that all survey activities are completed within the specified time frames and according to CBAHI's policies and survey protocols. The PHC under surveying is required to facilitate the work of the survey team members and to allow the survey team leader to practice his role and responsibilities which include:

Preparation and communication of the survey plan to the PHC;

- Chairing the opening and closing meetings;
- Communicating with PHC leadership regarding survey progress and initial findings;
- Evaluating team progress and adjusting survey plans as needed;
- Coordination and preparation of the survey report and submission of report to CBAHI central office.

Further details about the survey team and dynamics of the survey visit can be found in the PHC Accreditation Guide provided to all PHC centers upon successful registration.

Rescheduling / Postponement of Surveys

PHC centers scheduled for surveys are strongly encouraged to adhere to the survey date proposed by the Healthcare Accreditation Department at CBAHI. However, rescheduling or postponement may be considered for review, at the discretion of CBAHI and on a case by case basis, only upon:

- A rationale for postponement that is acceptable to CBAHI (e.g. events that will hinder the flow of the survey process such as changes in the management team/leadership of the PHC, natural or other disasters, or relocation of the PHC to another building).
- At least (30) days advance notice (an official letter from the PHC chief executive officer indicating the reason(s) for postponement).

Occasionally, requests for postponement (or cancellation of the survey visit) that meet the above conditions are accepted with no penalties, and another more realistic date is selected and agreed on with the PHC, provided this does not happen more than once during one accreditation cycle. However, requests for postponement or cancellation that do not meet the above conditions are subject to rejection (and the survey is to be conducted) or a “penalty charge” equal to (25%) of the required survey fee.

Accreditation Decision Rules

As a general rule, the PHC has to meet all applicable standards at an acceptable level to become accredited. CBAHI utilizes a multilevel process for making accreditation and reaccreditation decisions. This is to ensure fairness, consistency, objectivity, and accuracy. Towards this goal, CBAHI benefits from any relevant report and/ or significant findings or issues of concern related to the surveyed facility that were brought to attention from relevant health authorities, past accreditation surveys, and other credible sources.

Accreditation decisions are released and communicated to the PHC within (30) days after the conclusion of the survey visit. Accreditation decision making process is basically based on:

- The findings of the survey team members as recorded in the survey report.
- Discussions regarding the survey findings between the surveyor and the specialty team leader (STL).
- Review of the draft report by the participating PHC for feedback or correction of any issues of fact before making the accreditation decision.
- Review/discussion during the meeting of the Accreditation Decision Committee (ADC). This committee may request additional evidence(s) before it can make a final recommendation for an accreditation decision. All accreditation decisions are then ratified by CBAHI Director General.

It is important to note here that the decision to grant accreditation or not is primarily based on the findings of the on-site survey as recorded by the surveyors in the survey report. However, the numerical overall score that the PHC attains is one important factor among others upon which the

members of the Accreditation Decision Committee rely for making their recommendation. Other factors are:

- Criticality of the non-compliant standard(s), i.e. the degree of severity and immediacy of risk to patients, visitors or staff safety.
- Any concerns regarding the compliance of the PHC with the Essential Safety Requirements (ESRs) as specified in this manual.
- Criticality has several levels. The most serious of which is when the surveyor notices an immediate threat to safety or quality of care, e.g. bare electrical wire is hanging down without any protection.

When CBAHI surveyor notices an immediate threat whether linked or not linked to the standards or the ESRs, the survey team leader will notify the PHC director and will include the findings in the survey report. Consequently, the PHC will receive a preliminary denial of accreditation until the issue is resolved through a Corrective Action Plan, and possibly a follow up focused survey for verification.

It was stated before that each standard is composed of a stem statement and sub-standard(s). There are evidences of compliance to be scored by the surveyor during the on-site survey. Each evidence of compliance (EC) has an equal weight and is scored on a four-point scale as follows:

“3” = Fully Met when $\geq 75\%$ compliance with the EC for four months prior to the initial survey or one year for the triennial survey.

“2” = Partially Met when ≥ 50 to $< 75\%$ compliances with the EC or compliance is for three months prior to the initial survey or nine months for the triennial survey.

“1” = Minimally Met when ≥ 25 to $< 50\%$ compliances with the EC or compliance is for two months prior to the initial survey or six months for the triennial survey.

“0” = Not Met when $< 25\%$ compliance with the EC or compliance is less than two months to the initial survey or less than three months for the triennial survey.

“NA” = Not Applicable indicates that the standard/EC does not apply to the PHC

The overall score of the PHC is calculated using the average (arithmetic mean) score of all applicable evidences of compliance, i.e. as the sum of all values divided by the number of values added.

When one or more chapters of this manual are not applicable in a particular PHC, they are indicated by “N/A.” Non-applicable chapters are not scored and are not included in either the numerator or denominator of the overall score. Full details about scoring guidelines are available in the PHC Accreditation Guide.

The Accreditation Decision Committee shall recommend one of the following accreditation decisions:

Accredited:

Accreditation will be awarded when the surveyed PHC demonstrates an overall acceptable compliance with all applicable standards at the time of the initial (or reaccreditation) on-site survey, and there are no issues of concern related to the safety of patients, staff or visitors.

Accreditation will also be recommended when the healthcare facility has successfully addressed all requirements following a conditional accreditation and does not meet any rules for other accreditation decisions. The decision to grant accreditation is not always straightforward. In some cases though, the Accreditation Decision Committee may consider the need for more clarification and/or a follow up focused survey of specific standards/areas of concern or noncompliance before a consensus decision to grant accreditation can be reached. This will also give the PHC a period of time to come into acceptable compliance.

Scoring Guidelines:

- Overall score 85% or above and
- Essential safety requirements score 85% or above and
- No Essential safety requirements scored as "Not met"
- No other issues of concern related to the safety of patients, visitors or staff.

Conditional Accreditation:

Conditional Accreditation is granted when the PHC demonstrates a tangible compliance with all applicable standards at the time of the on-site survey but still has not met requirements for accredited status. The PHC is required then to develop a "Standards Compliance Progress Report", followed by a "follow up Focused Survey" if required before changing the accreditation status. The non-compliant standards may include essential safety requirements and/or other standards/issues of concern related to the safety of patients, staff or visitors.

Scoring Guidelines:

- Overall score 75% or above and less than 85% and/or
- Essential safety requirements score 75% or above and less than 85% and/or
- One to five Essential safety requirements scored as "Not met"

Preliminary Denial of Accreditation (PDA):

Preliminary Denial of Accreditation (PDA) is a stage -rather than a final accreditation decision- that precedes denial of accreditation. The aim of allowing this stage is to give some additional time for review and/or appeal before the determination to deny accreditation. It results when there is one or more of the following reasons to justify denying accreditation:

Presence of an immediate threat to the safety of patients, visitors or staff that is observed by CBAHI surveyors during the on-site survey.

- Presence of an immediate threat to the safety of patients, visitors or staff that is observed by CBAHI surveyors during the on-site survey.
- Significant noncompliance with the accreditation standards at the time of the on-site survey.
- Failure of timely submission of the post survey requirements after conditional accreditation.
- The PHC has received conditional accreditation and was subjected to a follow up focused survey but still could not meet the requirements for accreditation.
- Reasonable evidence exists of fraud, plagiarism, or falsified information related to the accreditation process. Falsification is defined as the fabrication of any information (given by verbal communication, or paper/electronic document) provided to CBAHI by an applicant or accredited healthcare facility through redrafting, additions, or deletions of a document content without proper attribution. Plagiarism is perceived by CBAHI as the deliberate use of other healthcare facility original (not common-knowledge) material without acknowledging its source. In this case, the PHC is required to respond to CBAHI by sending an official clarification letter within five working days of the communication.
- Refusal by the PHC to receive the survey team and conduct a survey. In this case, the PHC will receive upfront denial of accreditation and will be subject for exclusion from the national accreditation program.

Denial of Accreditation:

Results when a health care facility shows a significant noncompliance with the accreditation standards at the time of the on-site survey. It also results if one or more of the other reasons leading to preliminary denial of accreditation have not been resolved. When the PHC is denied accreditation, it is prohibited from participating in the accreditation program for a period of six months, unless the Director General of CBAHI, for good reason, waives all or a portion of the waiting period.

Scoring Guidelines:

- Overall score less than 75% and/or
- Essential safety requirements score less than 75% and/or
- More than five of the essential safety requirements scored as not met.

Appeal against Accreditation Decision:

A surveyed healthcare facility can appeal against the following accreditation outcomes:

- Preliminary Denial of Accreditation (provided it is not due to failure of timely submission of the post survey requirements after granting accreditation or after conditional accreditation, or due to the facility remains conditionally accredited after a follow up focused survey).
- Suspension/Revocation of Accreditation.

All appeals shall be made within maximum of (15) calendar days from receiving the official survey report, through a covering letter sent from the chief executive officer to the CBAHI Director General via registered mail/fast courier along with documentation to support argument for the appeal, and a completed Appeal Request Form (ARF) located on CBAHI's portal. Letters sent via electronic mail or facsimile will not be considered.

Grounds for appeals

The PHC is entitled for an appeal if it is based on one or more of the following grounds:

- Relevant and significant information which was available to the survey team was not considered in the making of the accreditation decision.
- The report of the surveyors(s) was inconsistent with the information presented to the survey team.
- Perceived bias of a surveyor(s).
- Information provided by the survey team was not duly considered in the survey report.
- The outcome of the appeal –if comes in favor of the appealed- will result in changing the accreditation status. Appeals that will not result in changing the status of accreditation will not be considered by CBAHI.

Upon the initial acceptance of the appeal request (only when it is shown with clear and convincing evidence that the PHC sustained one of the grounds for appeal), the prior status of the PHC, if any, shall be restored pending disposition of the appeal. The appeal request shall set forth the specific grounds for the request and shall include a statement of the reasons for each ground, along with any other relevant statements or documents the healthcare facility desires to include. PHC centers applying for an appeal must identify the specific alleged procedural failures or the specific manner in which the decision was arbitrary or unreasonable and not based on, or consistent with, CBAHI standards and policies. After studying all relevant reports and evidences, one of the following decisions shall be made and communicated to the appealed in a timely manner:

- The adverse decision is upheld, in which case the entire cost of the appeal shall be borne by the appealing facility.
- The healthcare facility's appeal is upheld, and denial of accreditation is modified or reversed. In this condition a full or focused re-survey may be decided. In this case, the cost of the appeal shall be borne equally by the healthcare facility and CBAHI.

Accreditation Maintenance (Post Survey Requirements)

CBAHI has redesigned its accreditation to represent a continuous process versus a once-every-three-years evaluation. Accredited healthcare facilities are required to maintain their accreditation status by showing their continued compliance with the standards and requirements of CBAHI

throughout the accreditation cycle and in accordance with the specified time frames. This translates into standing and Ad Hoc requirements.

Standing Requirements for Accreditation Maintenance

1 Corrective Action Plan (CAP)

When accreditation is awarded to a PHC, a Corrective Action Plan (CAP) addressing all standards that were not in satisfactory compliance during the on-site survey should be received for review and acceptance within (120) days from the date of the accreditation decision. The CAP ideally focuses on demonstrating what has been done rather than what will be done. The CAP should identify all non-compliant standards, the requirements for improvement, the corrective actions that have been taken or will be taken with dates and responsible individuals and as applicable, and the monitoring measures to ensure sustainability of the actions taken. A delay in the submission of the CAP that exceeds (30) days beyond the due date without justification might result in temporary suspension of the accreditation certificate.

2 Standards Compliance Progress Report (SPR)

When a PHC is conditionally accredited, it is expected to maintain this “transitional” status until fulfilling the requirements for an accredited status. Therefore, the PHC is required to address all ESRs and other standards and issues of concern that were not in satisfactory compliance during the on-site survey in a Standards Compliance Progress Report (SPR). The SPR should be received for review and acceptance by the relevant department at CBAHI within (60) days from the date of the accreditation decision. There are cases where the SPR is going to be reviewed and accreditation decision made on that basis. In other cases, the PHC compliance is going to be validated through a follow up focused survey within (30) days from the date of receiving the SPR. Successful compliance with the standards after the follow up focused survey will result in changing the conditional accreditation to accredited status. When the PHC fails to submit the SPR as required or still does not meet the conditions for accreditation after the follow up focused survey, it will enter into a Preliminary Denial stage.

3 Midterm Self-Assessment

Accredited PHC centers are required to participate in a mid-cycle self-evaluation of standards compliance (Midterm Self-Assessment). Fifteen months from the date of accreditation awarding, the PHC should start utilizing the self-assessment tool to assist in the periodic review of its performance against the standards. The PHC then has (3) months to complete the assessment.

Completion of the midterm assessment will allow the PHC to identify areas of non-compliance with the standards and therefore, to set a plan for correction of deficient areas and come into compliance before the next on-site survey.

For those areas self-identified as non-compliant with CBAHI standards, the PHC will submit a Corrective Action Plan to CBAHI that includes evidence(s) to substantiate that the standard has been

brought into compliance. The relevant department at CBAHI will review each PHC's plan of action via a telephone interview and will indicate whether the action plan and timetables are acceptable to bring the standard into compliance.

During the next on-site visit following submission of the mid-term assessment, the surveyor will look for the evidences of compliance/correction that the PHC provided as part of the plan of action.

When there is a legitimate concern about the safety and quality of services provided by an accredited PHC at the time of the mid-term assessment, CBAHI may require the PHC to undergo a mid-cycle survey, (a fee will be charged to cover costs) and to submit a plan of action for areas of non-compliance.

A delay in submitting the mid-term assessment by more than (60) days from the due date without a justification acceptable to CBAHI may result in temporary suspension of accreditation, followed by revocation of accreditation if the total delay exceeds (90) days.

Ad Hoc Requirements for Accreditation Maintenance

1 Reporting of a sentinel event

It is not rare to see a sentinel event occurring in an accredited facility. When it occurs, it must be reported to CBAHI within (5) working days of the internal notification of the event. Root Cause Analysis (RCA) with a risk reduction action plan must then be submitted to CBAHI within (30) working days (see more about how and why to report a sentinel event in the Policy on Sentinel Events).

2 Notification of significant changes

Accredited PHC centers must notify CBAHI in writing about any significant structural/functional/regulatory changes that took place after the accreditation survey, no more than (30) days of the initiation/occurrence of such changes, which include, but are not limited to, the following:

- The Ministry of Health has revoked the operating license and/or has mandated closure for all or part of the PHC.
- The PHC is not in compliance anymore with other relevant rules and regulations (e.g., Civil Defense license or license related to radiation handling and safety have been withdrawn).
- PHC accreditation by other international accrediting organizations has been suspended or revoked.
- A new service is initiated for which CBAHI has standards and was not included in the last survey.
- The PHC has a new location or a new branch.
- Major construction/destruction/renovation work.
- Significant increase (or decrease) in the volume of services/bed capacity.
- Merge with or acquisition of an unaccredited facility.
- Significant change in the governance or ownership.

The impact of these changes will be evaluated by relevant departments in CBAHI and a decision for conducting a For-Purpose Survey may be warranted accordingly.

A delay in notifying CBAHI of such significant changes occurring in an accredited facility by more than (60) days from the due date without a justification acceptable to CBAHI may result in temporary suspension of accreditation, followed by revocation of accreditation if the total delay exceeds (90) days.

Sentinel Events

Thousands of patients all over the world die every year because of serious incidents happening to them while receiving care inside healthcare facilities. CBAHI and all other healthcare accreditation organizations have one purpose in common: contribute to improved quality, safety and experience of healthcare services through systems that are patient/family-centered, provide for early identification and review of near misses and reportable events, and ensure lessons are learnt so preventable adverse events are not repeated.

Sentinel Events (SE) are relatively infrequent but they do occur. Simply defined, a sentinel event is any event leading to serious patient harm or death and is caused by healthcare rather than the patient's underlying illness. By investigating sentinel events, we can identify deficiencies in healthcare systems and processes, and put actions in place to prevent recurrence.

The Ministry of Health has identified the following events as must-to report events:

- Unexpected death
- Maternal death
- Wrong patient, wrong procedure or wrong site.
- Retained instrument or sponge
- Medication error leading to death or major morbidity
- Infant abduction or infant discharged to the wrong family
- Unexpected loss of a limb or a function
- Hemolytic blood transfusion reaction
- Inpatient suicide
- Gas embolism

The policy of CBAHI on sentinel events calls for the following:

- Open disclosure/open communication: patients and their families are entitled at all times to truthful and transparent communication and explanation of any sentinel events happening to them.
- A distinction has to be made, both at the healthcare facility and the national level, between a sentinel event occurring because of a pure negligence from the healthcare practitioner or

a criminal act or a deliberate unsafe act, and another sentinel event occurring because of an underlying system failure. The former is dealt with by a special process that may involve the relevant authorities. However, for sentinel events occurring due to a system failure, individual healthcare practitioners are not held accountable for system failures and a just culture prevails. CBAHI always encourages blame free non -punitive environment and it is the prime responsibility of the PHC leadership and the heads of the departments to establish this culture of openness and disclosure in their work place, otherwise “you cannot fix that which you are unaware of!”.

- When a reportable sentinel event occurs in a PHC accredited by CBAHI, it must be reported to CBAHI as indicated in the timeframe below. PHC centers and other healthcare facilities that are not accredited by CBAHI are encouraged -but not required- to report. Besides reporting, CBAHI may become aware of the occurrence of a sentinel event by one of CBAHI's surveyors, from the media, from a patient or a relative, from the healthcare facility's employee or through other means of communication.
- CBAHI is interested to know about reportable sentinel events when they occur in accredited facilities for the purpose of learning and dissemination of lessons learnt to the medical community so that to avoid any recurrence of such events in the future. Medical errors and adverse events are opportunities for education and quality improvements (educate the young and regulate the old).
- Reporting must be safe. Patients, families and staff are encouraged -and should be empowered by the PHC leadership- to report any sentinel event without fear of retribution. CBAHI has zero tolerance for accredited PHC centers taking disciplinary actions against a staff member who reported a sentinel event. If the disciplinary action proves to be related to reporting, this might negatively impact the accreditation status of the PHC.
- Starting from January 2016, healthcare facilities accredited by CBAHI must report to CBAHI all sentinel events by filling up and submitting the Sentinel Event Reporting Form (SERF) found on CBAHI portal, within (5) working days of the internal notification of the sentinel event (the date when the relevant authority in the PHC was notified of the incident). This should be followed by a Root Cause Analysis (RCA) and Risk Reduction Action Plan within (30) working days from the date of notification of the sentinel event. Root Cause Analysis is a formal process of investigation designed to identify the root causes of adverse events.
- CBAHI will study the sentinel event report for further action as appropriate. This includes the submission of a progress report to show the progress made in implementing the risk reduction plan and eliminating the chance of recurrence, but it might also include a validating focused survey-scheduled or unannounced- at the discretion of the relevant department at CBAHI.
- The final outcome of a reported sentinel event is dependent on the level of commitment demonstrated by the healthcare facility towards studying the root cause(s) of the incident and re-designing its processes and systems to prevent future recurrence. When CBAHI is

persuaded of this constructive approach of the concerned PHC in dealing with sentinel events, accreditation is usually maintained. When this is not the case, CBAHI will pursue this further to decide on the eligibility of the PHC to maintain versus suspend its accreditation until the required corrections are made. In some other situations when the validity of the accreditation certificate is less than (6) months and CBAHI is not enough persuaded of the corrections made, an early full re-accreditation survey might be warranted.

Accreditation Suspension and Revocation

CBAHI expects nothing but truth, honesty, and sincere intentions in all dealings and propositions from healthcare facilities engaged in its accreditation program. This "good faith" engagement applies continuously throughout the accreditation cycle, and the healthcare facility must ensure that it is not violated at all times. In addition, accredited PHC centers are expected to keep the same momentum before and after granted accreditation. Some might argue that it is a natural tendency to "relax" after a survey visit, but it is not acceptable that the compliance with the standards drops simply because the survey is over, and accreditation is awarded. If CBAHI became aware by any mean of an accredited PHC that is not in compliance with the standards, this will be verified, and an appropriate action will be taken accordingly.

CBAHI may receive information regarding possible violations from accredited healthcare facilities through several channels; most importantly reports of related government agencies, written or verbal complaints and media. Types of violation include, but are not limited to, the following:

- CBAHI becomes aware of the presence of an immediate threat to the safety of patients or staff in an accredited PHC.
- The PHC is not committed to the specified timeframes for accreditation maintenance (e.g., timely submission of corrective action plan after granting accreditation or timely submission of midterm self-assessment).
- The PHC failed to report a sentinel event as per the relevant policy without an acceptable justification.
- The PHC is committing an act of misuse (see the policy on accreditation certificate and seal), deception, or any deliberate misrepresentation of the truth (see the policy on truthfulness and ethics clause).
- The PHC is discouraging communication or taking disciplinary action/reprisal against patients or staff members trying to communicate directly with CBAHI for concerns about safety or quality of care.
- The PHC is intentionally lacking commitment towards the continuous compliance with CBAHI standards. This might represent an overweening behavior and is a strong violation of the CBAHI accreditation process.
- The PHC is deliberately violating any of the other accreditation policies mentioned in this manual or in other supporting documents and manuals provided by CBAHI for the purpose of accreditation.

Once CBAHI is persuaded about one or more of the aforementioned violations in an accredited PHC, it usually responds by taking one of the following actions in any order:

- Issuing a letter of "At Risk of Suspension of Accreditation".
- Suspension of Accreditation
- Revocation of Accreditation.

CBAHI decides the level of response to a certain violation based on several factors including the severity of the violation, its frequency, the previous accreditation history, the source of information regarding the violation, and findings and conclusion of CBAHI's enquiry. Whenever deemed necessary, a focused or a full survey might be conducted for validation before a response or action can be made. This kind of "Discretionary surveys" is always for one or more of the above causes (e.g., when concerns have been raised about an accredited PHC's continued compliance with CBAHI Standards). An accredited PHC may undergo a discretionary survey at any time, at the discretion of CBAHI, and the survey is usually unscheduled (the PHC receives 48 hours' notice before it is conducted) or unannounced (without advance notice) depending on the seriousness and type of the violation. Again, surveys can include either all of a PHC's services or only those areas where a serious concern may exist. PHC centers are usually charged for these surveys, regardless of the outcome, and results can affect the PHC accreditation status. If the PHC does not allow CBAHI surveyors to conduct the survey, CBAHI may change the PHC's status to Revocation of Accreditation.

It should be noted that when the PHC accreditation is suspended, the PHC can regain accreditation once the causative violation has been rectified, but suspension will not be lifted before a prohibition period of (12) months from the date of suspension.

The revocation of accreditation is a more serious complication that prohibits participation in CBAHI accreditation program for minimum of (18) months from the date of revoke. In both suspension and revocation of accreditation, CBAHI will communicate the new accreditation decision with the relevant authorities and will display it on its website. The Director General of CBAHI, for good reason, can waive all or a portion of the prohibition period.

Random Surveys

To support CBAHI's ongoing quality assurance initiatives, an accredited PHC may be selected for a random survey from (9) to (30) months after an accreditation survey. Random surveys are unannounced. Five per cent sample of all accredited PHC centers is randomly selected each year for this activity. These unannounced surveys, which are usually conducted by 2-3 surveyors but could be full surveys, are a means by which CBAHI can evaluate the consistency and quality of its program, while also demonstrating to the public and regulators that accredited PHC centers remain committed to CBAHI standards throughout the accreditation cycle. Random surveys also provide CBAHI and its surveyors with opportunities to further consult with accredited PHC centers in the interval between regular surveys. No fee shall be charged to the PHC when a random survey is conducted.

Accreditation Certificate and Seal

Once accreditation is granted, healthcare facilities are encouraged to display CBAHI logo, accreditation certificate and seal on the facility bulletin boards, banners, website, newsletters, brochures, and headed stationery denoting their accreditation status.

CBAHI requires all accredited healthcare facilities to follow the guidelines and conditions for the appropriate use of the CBAHI logo, accreditation certificate and seal. Specifically, CBAHI works to ensure that no accreditation material be used in a way which may mislead the public or others or provide false information related to the accreditation status of a healthcare facility.

Upon receiving the certificate package, accredited PHC centers are required to sign and return back a disclaimer/ guidelines form related to the conditions of display and publication of CBAHI logo, accreditation certificate and seal, which include:

- Ensuring that printing of the accreditation seal is accurate and legible with no degradation or distortion.
- The size of CBAHI logo and its accreditation seal should remain in the same permitted proportion as provided.
- The CBAHI logo, certificate, and seal should be used in the same format, with avoidance of adding any extra graphics or words.
- The PHC abides by the same colors used in CBAHI logo or black and white, when being used for certain printed materials such as newspaper advertisements, newsletters, brochures, flyers and posters.
- The PHC is prohibited from the use of CBAHI logo or accreditation seal on business cards.
- Upon expiry of the certificate validity period, or suspension/revocation of the accreditation, the PHC shall immediately take actions within maximum of (30) days to refrain from using the CBAHI logo, accreditation certificate and seal. Failure to comply with the specified time frame might subject the PHC to the appropriate decision according to the policy on accreditation suspension and revocation.

Release of Accreditation - Related Confidential Information

CBAHI acknowledges that PHC centers undergoing its accreditation survey are expected to provide access to information related to the evaluation of their conformance to the CBAHI standards.

As a guiding policy, CBAHI commits to healthcare facilities engaged in its different accreditation programs that all information obtained or received during the accreditation process will be kept confidential, including all survey data and information that surveyors come across during the survey process.

For a PHC that is a participating member of the CBAHI accreditation program, some information is subject to public release, which includes:

- The PHC accreditation status being posted on CBAHI website.
- The areas of the PHC which were included in the accreditation survey.
- The standards under which the accreditation survey was conducted.

Other accreditation-related information is not subject to public release except to the PHC on question. The exception to this rule is when CBAHI receives an official request for clarification from relevant health authorities or public health agencies. Information includes:

- The mock and final accreditation survey reports.
- Accreditation Committee minutes and agenda materials.
- The notification letter of the survey report to the PHC director.
- The accreditation certificates
- The post-survey requirements including any CAPs or SPRs.
- The result of investigations related to a sentinel event including the root cause analysis prepared in response to that event.
- The result of investigations involving any falsified information provided to CBAHI by the PHC.
- Any other information related to compliance with CBAHI standards that is obtained from the PHC before, during, or following the accreditation survey.

Complaints against Accredited PHC

CBAHI is interested to collect information from a variety of sources to improve the quality and safety in all accredited PHC centers. One of these sources is complaints from patients, their families, the PHC staff, government agencies, media and the public. In particular, staff members at any given PHC accredited by CBAHI must be informed that they may make a complaint directly to CBAHI without fear of retaliatory actions from their PHC.

CBAHI addresses all complaints that would help identify possible noncompliance with its accreditation standards, and consequently, a possible threat to the safety of patients, staff, or public. To be more precise, CBAHI can only evaluate complaint information in terms of its relevance to compliance with its standards. Issues of personal nature or individual disputes should be dealt with by the concerned facility or the regional health authority. CBAHI also cannot follow up on complaints about PHC centers that it does not accredit.

When a complaint against accredited PHC is received by CBAHI, it will undergo an initial screening to decide on its relation to standards and its impact on patient safety. If it does not relate to compliance with CBAHI standards, a response of “non-relevance” will be forwarded to the complainant and will be advised to forward the complaint to the PHC leadership or the regional health authority. If the complaint relates to compliance with one or more of CBAHI standards, a specific response shall be taken accordingly. The response will depend on a risk assessment matrix

to decide on the probability and severity components. We also check for other complaints about the same PHC. Broadly speaking, CBAHI will take one or both of the following responses:

- CBAHI may write to the PHC about the complaint received and the PHC is required to make available, when requested, its records of complaints and subsequent action taken.
- CBAHI may decide to visit the PHC to verify if there is a problem in meeting the standards that deal with the complainant's concern. Such visits are usually unannounced, and the outcome may change the accreditation decision.

It is the policy of CBAHI not to disclose any information related to patients or complainants unless authorized to do so. Besides the information given to the complainant about the relevance of the complaint to CBAHI standards, the complainant will be provided with the following information:

- The course of action taken by CBAHI regarding the complaint.
- Whether CBAHI has decided to take action regarding PHC's accreditation decision following completion of the complaint investigation.

To file a complaint against a PHC accredited by CBAHI, an individual can send his concern via the contact form on CBAHI website. The other way is to file the complaint directly by calling the Universal Access Number 920012512.

CBAHI requires the identity of the complainer. Therefore, anonymous complaints will not be considered.

Conflict of Interest

CBAHI works to ensure the integrity and fairness of all businesses run by the employees working in the central office as well as the surveyors.

In addition, all healthcare facilities engaged in CBAHI accreditation process are required to refrain from any actual or potential act or behavior that might create a conflict of interest including:

- Proposing any fee, remuneration, gift, or gratuity of any value to CBAHI employees or surveyors for performance of their duties or survey-related activities.
- Employing or contracting or having any financial relationship with CBAHI employees or surveyors for the purpose of the provision of consulting or related services in any capacity, either directly or through another party. This includes services provided in preparation for the survey, assisting in preparation of the self-assessment, conducting mock surveys, helping in the interpretation of the standards, and alike. All requests for consulting services utilizing one of CBAHI associates shall be directed to CBAHI central office.
- Not declaring to CBAHI any business (including consulting) or recruiting relationship with one or more of CBAHI surveyors either directly or through another party with whom he or she is affiliated, at any time during the preceding three (3) years.

Truthfulness and Ethics Clause

CBAHI strives to maintain the highest ethical and legal standards in the conduct of its business. This includes being honest, transparent, and truthful in all its dealings, with avoidance of all situations that might give even the impression of being unethical or illegal. The same is expected from the PHC centers going for accreditation by CBAHI. CBAHI employees are committed to politely declining any gifts or gratuities offered to them or to a member of their family including spouses, children, and parents when the donor expects something in return, may be attempting to gain an unfair advantage, or influence the manner in which the associate performs his/her job duties. Gifts of nominal value may be accepted as tokens of appreciation or goodwill providing that they are given as a gesture of a professional relationship and do not involve or create the appearance of any commitment towards the survey results or accreditation decisions.

Business lunch, tea, coffee, and snacks during the survey are permitted. Other social gatherings are prohibited, and PHC centers are encouraged not to offer such to the survey team. Transporting the survey team by the PHC vehicle to and from the survey site is acceptable.

CBAHI's confidential and proprietary business information are safeguarded and utilized only in keeping with the best interests of CBAHI, its obligations to third parties, and the highest ethical and legal standards. Such information is not to be disclosed to a third party without prior approval of a duly authorized member of CBAHI management upon an acceptable reason.

CBAHI maintains the confidentiality of all data and information of both CBAHI and healthcare facilities in accordance with CBAHI's core values and relevant policies.

CBAHI is also committed to resolve complaints and ethical issues raised by CBAHI employees or client PHC centers in order to ensure justice, confidentiality, impartiality, timeliness, and feedback to the complainant.

PART III

STANDARDS



LEADERSHIP (LD)

Introduction

For any Primary Healthcare Center (PHC), quality and patient safety depend on effective leadership. It is important for all centers to have a clearly stated mission. It is the responsibility of the leadership of the center to develop the mission and provide adequate resources to fulfill this mission. That leadership must come from the governing body that oversee the center and center executive management including the center director, medical director, nursing director, administrator, and department heads. To ensure quality and safety of healthcare services, the members of the leadership group must work collaboratively, communicate effectively through clear lines of authority, and coordinate and integrate services provided.

This chapter addresses the roles and responsibilities of the leadership group for the following processes:

- Development of mission, vision, and values
- Organizational structure
- Development and promotion of professional ethical conduct
- Formulation and construction of a strategic plan
- Planning and designing services and structures
- Processes for collaboration, coordination, and communication
- Financial management
- Contract oversight
- The responsibility of the governing body
- The responsibility of the center director
- The responsibility of department heads

STANDARDS

LD.1 The primary healthcare center governing structure is defined.

Evidence of Compliance

LD.1.EC.1 The governing structure is identified in PHC documents.

Document Review

LD.2 The primary healthcare center governance and management has a defined, current, and clear organization structure that is known to all staff.

LD.2.1 The organization structure identifies the names, titles and lines of authority and responsibility of the PHC leaders.

Evidence of Compliance

LD.2.EC.1 The PHC has a current organizational chart that has names and titles of PHC governance, leaders, and department heads with identified lines authority and responsibility.

Document Review

LD.2.EC.2 The PHC organization chart is known to all staff.

Interview

LD.3 The primary healthcare center governing body responsibilities are defined in written documents such as bylaws, policies and procedures.

LD.3.1 The PHC governing body responsibilities reflect its responsibility and accountability to the patients and its obligation to the community it is established to serve.

LD.3.2 The governing body responsibilities reflect its ultimate accountability and responsibility for the quality of care and patient safety.

Evidence of Compliance

LD.3.EC.1 Governance responsibilities and accountabilities include quality of care and patient safety.

Document Review

LD.4 The governing body approves (or develops) the primary healthcare center mission, vision, and values statement.

LD.4.1 The governing body ensures the regular review of the PHC mission.

LD.4.2 The governing body ensures communication of the PHC mission, vision, and values to all staff and customers.

Evidence of Compliance

LD.4.EC.1 PHC mission, vision and values statement is approved and regularly reviewed by the governing body.

Document Review

LD.4.EC.2 The PHC mission, vision, and values statement is publicly posted.

Observation

LD.5 The governing body approves the primary healthcare center scope of services.

Evidence of Compliance

- LD.5.EC.1** The PHC scope of services is approved by the PHC governing body. Document Review

LD.6 **The governing body approves the primary healthcare center strategic and management plans and policies and procedures.**

- LD.6.1 The governing body defines the approval authority delegation.

Evidence of Compliance

- LD.6.EC.1** The PHC strategic and management plans, policies and procedures, and authority delegation are approved by the governing body. Document Review

LD.7 **The governing body ensures provision of adequate resources (manpower, consumables, and capital assets) based on scope of services and to fulfill the primary healthcare center mission.**

- LD.7.1 The governing body approves the operating and capital budgets of the PHC.

Evidence of Compliance

- LD.7.EC.1** Adequate manpower is available in the PHC according to its scope of services. Document Review

- LD.7.EC.2** Adequate consumables and capital assets are available in the PHC according to its scope of services. Observation

LD.8 **The governing body appoints a qualified director who is responsible for the management of the primary healthcare center.**

- LD.8.2 The governing body assures the director's effective performance through ongoing performance evaluation.

- LD.8.1 The governing body uses selected criteria for appointment and reappointment of the PHC director.

Evidence of Compliance

- LD.8.EC.1** The PHC director is appointed and reappointed by the governing body according to selected criteria. Document Review

- LD.8.EC.2** There is evidence of ongoing director's performance evaluation by the governing body. Personnel File

LD.9 **The governing body fosters communication and coordination between the primary healthcare center governance and management.**

Evidence of Compliance

- LD.9.EC.1** There is evidence of communication and coordination between the PHC governance and management. Document Review

LD.10 **The governing body approves and promotes performance improvement, patient safety, and a risk management program.**

LD.10.1. The governing body regularly receives, reviews and acts upon the reports of performance improvement, patient safety, and the risk management program

Evidence of Compliance

LD.10.EC.1 There is regular reporting of performance improvement, patient safety, and risk management activities.

Document Review
Document Review

LD.10.EC.2 There is evidence of the reports' review and actions taken by the governing body.

LD.11 The governing body performs periodic evaluation to ensure its own effectiveness.

Evidence of Compliance

LD.11.EC.1 There is evidence of periodic evaluation of governing body effectiveness.

LD.12 The primary healthcare center director exercises the authority delegated by the governing body to manage the center.

Evidence of Compliance

LD.12.EC.1 The PHC director exercises the authority delegated by the Leadership Interview governing body to manage the center.

LD.13 The primary healthcare center director has a job description, developed by the governing body that states the responsibilities and qualifications.

Evidence of Compliance

LD.13.EC.1 The PHC director's job description is developed by the governing body and states the responsibilities and qualifications.

LD.14 The primary healthcare center director ensures the primary healthcare center's compliance with the Kingdom law and regulations.

Evidence of Compliance

LD.14.EC.1 The center adheres to Saudi Arabian laws: having a current MOH License and building safety certificate from Civil Defense.

LD.15 The primary healthcare center director provides oversight of the center's day to day operations.

Evidence of Compliance

LD.15.EC.1 There is evidence of managing the center's day to day operations by the director.

LD.16 The primary healthcare center director recommends and ensures that necessary policies and procedures are developed and implemented.

- LD.16.1 The director ensures compliance with approved policies.
- LD.16.2 The director recommends required new policies for approval to the governing body.

Evidence of Compliance

- | | |
|--|---|
| <ul style="list-style-type: none"> LD.16.EC.1 The director recommends required new policies for approval to the governing body. LD.16.EC.2 The PHC director establishes processes that ensure the compliance with approved policies. | Document Review
Leadership Interview |
|--|---|

LD.17 The primary healthcare center director ensures appropriate response to reports from any inspecting or regulatory agencies, including accreditation.

Evidence of Compliance

- LD.17.EC.1 There is evidence of response to reports from inspecting or regulatory agencies.

LD.18 The primary healthcare center director provides oversight of human, financial, physical, and other resources.

- LD.18.1 The director ensures that all physical properties are kept in a good state of repair and operating condition.
- LD.18.2 The director ensures availability of adequate and proper resources such as human resources, equipment, supplies and medications required for the planned services.
- LD.18.3 The director manages the PHC's financial resources adequately.

Evidence of Compliance

- | | |
|---|-------------------------------------|
| <ul style="list-style-type: none"> LD.18.EC.1 The PHC director manages human, financial, physical, and other resources. LD.18.EC.2 There is evidence of availability of adequate resources in good working condition. | Leadership Interview
Observation |
|---|-------------------------------------|

LD.19 The primary healthcare center leadership group is identified (as executive management committee or however named).

- LD.19.1 The leadership group should include the director, the medical director, the nursing director, the quality coordinator, and department heads.
- LD.19.2 Each member in the leadership group has a defined scope of responsibility as outlined in a current job description.
- LD.19.3 The leadership group meets regularly (at least monthly) in formal meetings to discuss all aspects of health care, achievement reports, and services provided to patients.

Evidence of Compliance

- | | |
|--|-----------------|
| <ul style="list-style-type: none"> LD.19.EC.1 The PHC leadership group is identified to include at least the PHC director, the medical director, the nursing director, and the quality coordinator. | Document Review |
|--|-----------------|

LD.19.EC.2 There are regular meetings of the PHC leadership group, and the meeting minutes reflect discussion of all aspects of health care, achievement reports, and services provided to patients. Document Review

LD.19.EC.3 There is job description for each member in the leadership group. Personnel File

LD.20 **The primary healthcare center leadership group develops (or adopts from the governing body) the center's mission, vision, and values and submits to the governing body for approval.**

LD.20.1 The leadership group communicates the mission, vision, and values to all staff and customers.

Evidence of Compliance

LD.20.EC.1 The PHC's mission, vision, and values statement is developed by the leadership group (or adopted from the governing body). Document Review

LD.21 **The leadership group collaboratively develops and carries out plans, budgets, policies and procedures to fulfill the mission.**

Evidence of Compliance

LD.21.EC.1 The leadership group develops collaboratively plans, budgets, policies and procedures to fulfill the PHC mission. Leadership Interview

LD.22 **The leadership group uses research, evidence, and best practice information to develop and improve the center's services.**

Evidence of Compliance

LD.22.EC.1 The leaders while designing and improving services use and encourage staff to use research and best practice information. Interview

LD.23 **The leadership group allocates resources for a safe and effective facility, and this includes:**

LD.23.1 Planning and budgeting to meet applicable laws, regulations, and other requirements.

LD.23.2 Ensuring efficient use of different resources through regular review and evaluation against plans and budgets.

LD.23.3 Planning and budgeting to upgrade or replace buildings, equipment, or other resources.

Evidence of Compliance

LD.23.EC.1 There is evidence that the center's leaders ensure the efficient use of the center's resources. Interview

LD.24 **The leadership group plans with the community leaders and other identified customers to meet the current and future needs of the population(s) it serves.**

- LD.24.1 The leadership group works with the community and other organizations to regularly assess the community's health needs.
- LD.24.2 Planning includes soliciting inputs from staff, patients and families.
- LD.24.3 Planning considers environmental and financial factors and is consistent with the center's mission and strategic direction.
- LD.24.4 Planning considers cultural and spiritual needs of the populations served.
- LD.24.5 Planning ensures coordination and integration of services throughout the center as well as with relevant external services.

Evidence of Compliance

LD.24.EC.1 There is evidence that the PHC's leaders collaborate with Interview community leaders and other customers including patients to plan services required for the community considering elements LD.24.1 through LD.24.5.

LD.25 The primary healthcare center leadership has a three to five (3-5) year strategic plan for the center that is updated every year and has the following components:

- LD.25.1 Guided by the mission and vision of the PHC.
- LD.25.2 Based on the Strength (S), Weakness (W), Opportunity (O), Threat (T), (environmental) (SWOT) analysis and financial factors.
- LD.25.3 Defining the organization's vision.
- LD.25.4 Identified by at least five (5) goals (customer/community, employee, education, continuous improvement, and financial).
- LD.25.5 Translated to objectives, actions, and timelines for implementation with identified staff responsibilities.
- LD.25.6 A process is in place for the annual review of the strategic objectives' achievement and to determine needs for the next annual operational plan.
- LD.25.7 Department heads develop an annual departmental plan in line with PHC strategic plan.

Evidence of Compliance

LD.25.EC.1 The leadership has an annually reviewed (3-5 year) strategic plan, and identified by at least 5 strategic directions. Document Review

LD.25.EC.2 All department heads have an annual plan based on the PHC strategic plan. Document Review

LD.26 The leadership group collaboratively develops the primary healthcare center scope of services and includes:

- LD.26.1 The range of services (i.e. preventive, promotive, curative, and rehabilitative).
- LD.26.2 The age groups who receive care.

- LD.26.3 The number of patients seen annually.
- LD.26.4 The major diagnostics or therapeutic methods used.

Evidence of Compliance

LD.26.EC.1 The leadership group collaboratively developed scope of services that includes items in LD26.1 through LD26.4. Document Review

LD.27 **The leadership group provides patients with information on care and services available as well as how to access these services, and this includes:**

- LD.27.1 Providing the information in different formats (for example, brochures, handouts, signage, etc.)
- LD.27.2 Carrying out activities to ensure that the public are aware of the information provided.

Evidence of Compliance

LD.27.EC.1 Patients are provided information on how to access services in the PHC. Leadership Interview

LD.28 **The leadership group develops the staffing plan to ensure that services meet the needs of the population(s) served.**

- LD.28.1 The staffing plan defines the number, type, and qualifications of staff required and their roles.

Evidence of Compliance

LD.28.EC.1 A collaboratively developed staffing plan defines the number, type, and qualifications of staff required and their role. Document Review

LD.29 **There is a written policy for controlling the development and maintenance of policies and procedures for key functions and processes.**

- LD.29.1 There is a unique identifier system for each policy with title, number, and dates of issue and review.
- LD.29.2 Policies are developed, approved, revised, and terminated by authorized individuals.
- LD.29.3 Policies are revised according to a defined revision due date that does not exceed two (3) years or when required.
- LD.29.4 Policies are dated and current.
- LD.29.5 Policies are communicated and available to staff.
- LD.29.6 A process is in place to ensure that staff implements the policies.
- LD.29.7 A process is in place to ensure that only current versions of policies are available for use in the center.

- LD.29.8 A similar process exists for the development and maintenance of other important documents (e.g., organizational plans).

Evidence of Compliance

- LD.29.EC.1 There is a policy on policies and procedures, and other documents (e.g. plans): how documents are created, approved, revised, composed, kept current, tracked, communicated, monitored, and terminated.

LD.30 The primary healthcare center leaders oversee any contracts for clinical or operational services and:

- LD.30.1 Ensure that the contracts clearly state the services to be provided by the contracted entity.
- LD.30.2 Ensure relevant leaders recommendations and approval.
- LD.30.3 Ensure that the contracted entity and services provided meet applicable laws and regulations.
- LD.30.4 Ensure that the services provided are consistent with the center's standards for accreditation, quality, and safety that would be required if such services are provided by the center.
- LD.30.5 Monitor compliance with the appropriate standards on a regular basis and take corrective actions for improvement when standards are not met.
- LD.30.6 Document the contract oversight process.

Evidence of Compliance

- LD.30.EC.1 There is evidence of leadership documentation of the contract oversight process including LD.30.1 through LD.30.5.

LD.31 The primary healthcare center leaders have basic knowledge of Quality Management concepts and this includes:

- LD.31.1 Data analysis.
- LD.31.2 Quality improvement cycle (e.g., PDCA) or other method to make improvements.
- LD.31.3 Team working.
- LD.31.4 Root causes analysis (RCA).

Evidence of Compliance

- LD.31.EC.1 There is evidence of a leadership educational program on quality management concepts, data analysis, PDCA, RCA, and team work.
- LD.31.EC.2 There is evidence of PHC leaders' participation in quality improvement.

LD.32 There is a designated interdisciplinary committee(s) to provide oversight for, but not limited to, medication management, safety, morbidity and mortality, cardio pulmonary resuscitation, health record review, utilization review, credentialing and privileging.

- LD.32.1 The committee(s) has terms of reference that include committee functions, membership, quorum, frequency of meetings, approval, and distribution of minutes.
- LD.32.2 The committee(s) meets as outlined in the terms of reference (at least quarterly).
- LD.32.3 The committee(s) submits an annual report of accomplishments to the reporting authority.

Evidence of Compliance

- LD.32.EC.1 Regular meeting minutes of the PHC interdisciplinary Document Review committee(s) reflects discussion of medication management, safety, morbidity and mortality, cardio pulmonary resuscitation, health record review, utilization review, credentialing and privileging.
- LD.32.EC.2 There is evidence of annual review of each committee's Document Review accomplishments.

LD.33 Each administrative or clinical department is directed by an appropriately qualified individual.

Evidence of Compliance

- LD.33.EC.1 The department heads have proper qualifications and Personnel File experience.

LD.34 The responsibilities of the head of each department include, but not limited to, the following:

- LD.34.1 Providing a written scope of services provided by the department.
- LD.34.2 Ensuring coordination and integration of services within the department and with other departments.
- LD.34.3 Defining and requesting space, equipment, supplies, staffing, and other resources.
- LD.34.4 Ensuring that sufficient resources and staffing levels are available at all times to carry out safe medical practice.
- LD.34.5 Developing departmental policies and procedures and ensuring appropriate communication to relevant staff and implementation.
- LD.34.6 Determining the necessary qualifications required by all categories of staff in the department: education, skills, training, experience, and license, certification, or registration.
- LD.34.7 Providing a written departmental staffing plan that defines the number, type, and qualifications required for each position to fulfill the department's responsibilities.

- LD.34.8 Providing orientation, training, and continuing education for all persons in the department.
- LD.34.9 Managing processes to systematically measure and improve the performance of important processes of the department as well as staff performance. These processes are consistent with the PHC wide quality improvement and patient safety plan, and:
 - LD.34.9.1 Based on department important activities and priorities.
 - LD.34.9.2 Include regular data collection and analysis about department performance and staff performance.
 - LD.34.9.3 The performance monitoring is reported periodically to leadership.

Evidence of Compliance

LD.34.EC.1	There is written scope of services for each department and signed by the department head.	Document Review
LD.34.EC.2	There is evidence that the department heads define and request space, equipment, supplies, staffing, and other resources.	Document Review
LD.34.EC.3	There are periodic reports of department's performance monitoring.	Document Review
LD.34.EC.4	The job description of the department heads includes the above responsibilities (LD.34.1 - LD.34.9).	Personnel File
LD.34.EC.5	There is evidence that the department heads determine the necessary orientation, education, training, experience, and license to practice.	Leadership Interview

QUALITY MANAGEMENT AND PATIENT SAFETY

Introduction

This chapter addresses the senior leaders and everyone's responsibility towards implementing a program that effectively improve quality and safety and reduce risks. The center's leadership has an essential role in ensuring the structure and the direction towards achieving these goals. When the center's leaders are personally involved and encourage and support everyone in the center to be involved in the quality management initiative, a general atmosphere of confidence and inspiration to work harder and to achieve high quality care and a maximum degree of safety is established. Leadership, therefore, has to establish a planned and ongoing program where processes and systems are the focus of the operation.

To be able to effectively improve quality of care, safety, and reduce risks, the center must constantly use indicators to measure its performance and use that information to identify processes that can be improved. The center must also be able to identify significant unexpected or adverse events and intensively analyze them to understand their underlying causes and, as a result, make the necessary improvement changes.

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

- A planned and center- wide approach
- The required structure(s) (committee(s))
- Leadership and staff quality concepts education
- Data collection for structure, process, and outcome indicators of quality
- Prioritization and implementation of appropriate improvements
- Risk management
- Identification and analysis of significant events
- Patient safety
- Defining and adopting International Patient Safety Goals

Standards

QM.1 There is a qualified Quality Management (QM) Coordinator/leader who can apply quality concepts and principles.

QM.1.1 The quality management coordinator or leader reports to the PHC Director.

Evidence of Compliance

QM.1.EC.1 The quality management coordinator/leader is qualified by Personnel File education and/or experience.

QM.2 The QM coordinator has the following resources (and others as needed) to carry out the scope of services.

QM.2.1. Sufficient working and meeting space

QM.2.2 Computer, photocopier, printer, phone, fax, in sufficient quantity.

QM.2.3 Internet access.

QM.2.4 Appropriate software.

Evidence of Compliance

QM.2.EC.1 The QM coordinator has sufficient space, computers, printers, Observation phones, access to internet, software, and photocopier that is adequate to carry out the scope of services.

QM.3 The primary healthcare center develops and implements a quality improvement plan that is systematic, continuous, organization wide, supports innovation, and covers all aspects of performance. The plan includes, but is not limited to, the following:

QM.3.1 Identifying goals and objectives.

QM.3.2 Defining the scope of activities.

QM.3.3 Identifying all levels of staff roles and responsibilities.

QM.3.4 Outlining the educational activities about quality concepts.

QM.3.5 Describing the criteria used for selection of indicators, collection of data, data analysis, implementation, and evaluation of improvements.

QM.3.6 Identifying indicators for monitoring (including high risk processes).

QM.3.7 Describing how problem identification, information gathering, implementing actions, and evaluation of actions taken will occur (models like FOCUS – PDCA or other).

QM.3.8 Outlining how improvement projects are identified and prioritized by the leadership

QM.3.9 Outlining that all improvement teams report to the quality improvement committee.

- QM.3.10 Describing how improvement activities will be communicated to everyone in the organization (flow of information).
- QM.3.11 Describing how the plan is approved by the committee and the center director.
- QM.3.12 Reviewing the plan on an annual basis and making revisions as necessary.

Evidence of Compliance

QM.3.EC.1 There is a PHC wide quality improvement plan that includes Document Review elements QM.3.1 through QM.3.12.

QM.4 **There is a Quality Improvement Committee that consists of at least the leadership group that implements the plan(s) and this includes at least the following:**

- QM.4.1 Approves all quality management initiatives and provides oversight for the quality management program.
- QM.4.2 Receives reports from all teams, heads of departments, and other members assigned for quality improvement projects.
- QM.4.2 Approves all center wide teams that are formed to solve a particular issue.
- QM.4.4 Provides feedback to their staff on quality improvement projects.

Evidence of Compliance

QM.4.EC.1 There is quality improvement committee terms of reference Document Review that reflect its membership and functions mentioned in QM.4.1 through QM.4.4, and the meeting minutes reflect discussion of the implementation of the plan(s).

QM.5 **The primary healthcare center leaders are actively involved in the quality campaign efforts and participate in:**

- QM.5.1 Quality management and patient safety educational activities.
- QM.5.2 Quality improvement teams.

Evidence of Compliance

QM.5.EC.1 There is evidence that the leaders participate in quality improvement teams. There is evidence that the leaders have good understanding of FOCUS-PDCA or other methodology.

QM.6 **The primary healthcare center leaders encourage staff to participate in:**

- QM.6.1 Quality management and patient safety educational activities

QM.6.2 Quality improvement teams.

Evidence of Compliance

QM.6.EC.1 Staff demonstrates participation in patient safety educational activities and quality improvement teams. Interview

QM.7 The primary healthcare center has a risk management plan that addresses all potential operational, financial, clinical, and safety risks faced by the center and includes:

- QM.7.1 Scope and objectives of the plan.
- QM.7.2 Staff responsible for the plan.
- QM.7.3 A systematic process to identify and analyze potential risks for severity and likelihood of occurrence.
- QM.7.4 Development of interventions to manage potential risks (e.g., reduction, prevention).
- QM.7.5 Documentation of risk management activities.
- QM.7.6 Staff education on their roles and responsibilities related to the plan.
- QM.7.7 Regular review of the plan to ensure that the plan is effective:
 - QM.7.7.1 Regular measurement of performance compared with required performance.
 - QM.7.7.2 Using monitoring information to make improvements.
- QM.7.8 Strategies for communicating risk management activities to different groups.

Evidence of Compliance

QM.7.EC.1 The leaders use a planned approach to identify, analyze potential risk process(s) and then implement interventions to eliminate or minimize such risk(s). Leadership Interview

QM.8 The primary healthcare center has an incident (occurrence/variance/accident) reporting system (policy and form) that staff follow and use when reporting adverse events and near misses.

- QM.8.1 Reportable incidents are identified.
- QM.8.2 An identified staff member is responsible for managing the incident reporting system.
- QM.8.3 All incidents are reported and investigated in a timely way.
- QM.8.4 Immediate actions are taken as well as actions to prevent recurrence of incidents.
- QM.8.5 Patients are informed when involved in incidents with documentation in the health records.

QM.8.6 Incidents are monitored over time and information is used for improvements.

QM.8.7 All staff are educated on the incident reporting system.

Evidence of Compliance

QM.8.EC.1 There is a PHC incident reporting system (policy and form), Document Review with an aggregated data from the incident reports.

QM.9 Sentinel events are identified in policy that includes but is not limited to:

QM.9.1 Unexpected deaths.

QM.9.2 Suicide of a patient.

QM.9.3 Child abduction or discharge to a wrong family.

QM.9.4 Procedures on the wrong patient or the wrong body part.

QM.9.5 Serious injury with loss of limb or function.

Evidence of Compliance

QM.9.EC.1 Sentinel events policy states a list of reportable sentinel events that includes at least events listed in QM.9.1 through QM.9.5.

QM.10 The primary healthcare center has a process to handle sentinel events and it includes:

QM.10.1 Reporting the sentinel event within 24 hours.

QM.10.2 Formation of a team for studying the causes of the event (root cause analysis).

QM.10.3 Root cause analysis is to be performed within ten (10) working days.

QM.10.4 Developing an action plan and review systems for improvement.

Evidence of Compliance

QM.10.EC.1 The process of handling sentinel events includes reporting the sentinel event within 24 hours, formation of a team for studying the causes of the event (root cause analysis) within 10 working days, and is documented in minutes, reports, or other documents.

QM.11 The primary healthcare center supports patient safety by:

QM.11.1 Defining and adopting selected International Patient Safety Goals in the Quality Improvement and Patient Safety Plan.

- QM.11.2 Assigning staff or establishing a Patient Safety Team with representation from medical, nursing, pharmacy, and safety departments.
- QM.11.3 Charging the assigned staff or the Patient Safety Team with implementing and monitoring the patient safety goals and recommending actions for improvement.

Evidence of Compliance

- QM.11.EC.1 There are patient safety team/committee terms of reference Document Review or other document that reflects membership and functions required.
- QM.11.EC.2 The International Patient Safety Goals (IPSGs) are defined in Document Review the Quality Improvement and Patient Safety Plan(s).
- QM.11.EC.3 There is monitoring of IPSGs evidenced in reports, meeting Interview minutes, and action plans for improvements.

QM.12 There is a written policy on verbal and telephone orders and includes:

- QM.12.1 The attending physician or his designee signs off on the entire verbal and telephone orders.

Evidence of Compliance

- QM.12.EC.1 There is timely authentication of verbal and telephone Health Record Review orders according to the policy.

QM.13 The primary healthcare center adopts a process that requires two (2) patient identifiers whenever taking blood samples, administering medications, or performing a procedure.

Evidence of Compliance

- QM.13.EC.1 PHC staff are aware about the two patient identifiers and Interview when to be used.

QM.14 There is a process for preventing wrong site, wrong procedure, and wrong person procedure/surgery that includes:

- QM.14.1 Documentation of the verification process pre-operatively of the correct person, procedure, and site.
- QM.14.2 A process to mark the operative site with a standardized method and symbol with permanent ink by the person performing the operation and/or procedure.
- QM.14.3 A documented “time out” conducted in the location where the procedure will be done.

Evidence of Compliance

- QM.14.EC.1 The process of verification, marking and time out is Health Record Review documented in the health records in a checklist or other form.
- QM.14.EC.2 There is a process to mark the operative site with a Health Record Review standardized method and symbol with permanent ink by the person performing the operation and/or procedure.

QM.15 The primary healthcare center has a process for effective identification, assessment, and interventions for patients who are at risk for falling

Evidence of Compliance

- QM.15.EC.1 There is a process for effective identification, assessment and interventions of patients who are at risk for falling. Interview

QM.16 The primary healthcare center has a policy that guides staff to practice proper hand hygiene techniques to reduce the risk of healthcare-associated infections.

Evidence of Compliance

- QM.16.EC.1 The hand hygiene policy is properly implemented. Observation

QM.17 The primary healthcare center has a process for the safe storage and handling of high alert medications.

- QM.17.1 Concentrated electrolytes are removed from patient care areas.
 QM.17.2 Concentrated medications have additional safety measures to prevent inadvertent use.

Evidence of Compliance

- QM.17.EC.1 There are additional safety measures to prevent inadvertent use of concentrated medications, and no concentrated electrolytes stocked in patient care areas. Observation

QM.18 There are coordinated, comprehensive, and continuous educational activities on quality concepts and tools taught by staff who are qualified in the field and educational activities include:

- QM.18.1 Concepts of quality management.
 QM.18.2 How to work in teams.
 QM.18.3 Use of data, display of data.
 QM.18.4 Quality improvement tools.
 QM.18.5 Quality learning and improvement cycle model like FOCUS – PDCA or other methodology.
 QM.18.6 Decision-making tools.

Evidence of Compliance

- QM.18.EC.1 There is a coordinated, comprehensive, and continuous quality management education program that is conducted by qualified staff in the field. Document Review

QM.19

The primary healthcare center leaders develop and implement 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.

QM.19.1 The indicators represent key care and service structures, processes, and outcomes.

QM.19.2 The indicators focus on important managerial and clinical areas.

QM.19.3 The clinical indicators are referenced to current evidence based practice.

QM.19.4 Data are gathered from qualitative and quantitative sources.

QM.19.5 Data are coordinated with other performance monitoring activities such as patient safety and risk management.

QM.19.6 Each indicator has a definition, sample size, data collection method, frequency, analysis, and expression (e.g., expressed as a ratio, with defined numerator and denominator).

Evidence of Compliance

QM.19.EC.1 The leaders set (approve) the list of indicators to be monitored Document in the center, including indicators for performance monitoring, Review evaluation, and improvement of all PHC Programs and Services.

QM.20

There are structure indicators based on the mission and scope of services that may include but is not limited to:

QM.20.1 Availability of essential supplies and equipment.

QM.20.2 Availability of health records.

QM.20.3 Availability of emergency medications.

QM.20.4 Vacancy rates in all departments.

Evidence of Compliance

QM.20.EC.1 There are structure indicators collected (aggregated, Document Review analyzed reports, and reflected in minutes of the PHC committees).

QM.21

There are process indicators based on the mission and scope of services that may include but not limited to:

QM.21.1. The timing and use of antibiotics

QM.21.2 Documentation in the health records.

QM.21.3 Delays of physician answering calls.

Evidence of Compliance

QM.21.EC.1 There are process indicators collected (aggregated, Document Review analyzed reports, and reflected in minutes of the PHC committees).

QM.22 There are outcome indicators based on the mission and scope of services that may include but is not limited to:

- QM.22.1 Staff satisfaction.
- QM.22.2 Patient satisfaction.
- QM.22.3 Unplanned returns to the PHC.
- QM.22.4 Resuscitation of patients (Cardiac/respiratory arrest).
- QM.22.5 Adverse events (falls, injuries).
- QM.22.6 Sentinel events.
- QM.22.7 Patient complaints.
- QM.22.8 Medication errors.
- QM.22.9 Common procedures.

Evidence of Compliance

QM.22.EC.1 There are outcome indicators collected (aggregated analyzed Document reports and reflected in minutes of the PHC committees). Review

QM.23 There are quality control results from the laboratory and radiology.

Evidence of Compliance

QM.23.EC.1 Radiology and Lab quality control data, or minutes of the concerned committee/department reviewing the results are available (data are aggregated and analyzed). Document Review

QM.24 Data are systematically aggregated and analyzed by qualified staff.

- QM.24.1 Data are analyzed into useful information for trends and variances on a regular basis.
- QM.24.2 Data are compared internally by historical trends and externally by benchmarks (when available).
- QM.24.3 Information are provided to the appropriate users in a way they can understand and use.
- QM.24.4 Information about the quality and performance of the services offered are provided to the public in an appropriate format.

Evidence of Compliance

QM.24.EC.1 There are minutes or other documents of committees that Document reflect trending of data over time for internal and external Review comparison.

QM.25

The Quality Improvement Committee identifies and prioritizes recommendations for quality improvement (QI) projects based on the organization's prioritization criteria and the analysis of trends.

QM.25.1 Sustained performance improvements (including accreditation status) are communicated to the staff, public, community, and other customers.

Evidence of Compliance

QM.25.EC.1 Review of documents such as quality improvement committee Document terms of reference and meetings minutes identify the Review responsibility and the use of analyzed data in prioritization and selection of QI projects.

QM.25.EC.2 There is evidence that performance improvements (including Observation accreditation status) are communicated to the public, community, and other customers.

QM.26

Quality Management teams are selected by the primary healthcare center leaders and these teams use quality tools to improve processes.

QM.26.1 Membership of the quality improvement teams is determined by the leadership

QM.26.2 The teams include a facilitator.

QM.26.3 The teams include a designated 'team leader' who is an identified leader within the PHC.

QM.26.4 The teams use the quality learning and improvement cycle.

QM.26.5 The teams use CQI tools (Pareto charts, brainstorming, affinity diagrams, fishbone charts, multivote, etc).

Evidence of Compliance

QM.26.EC.1 Staff and particularly leadership show proper selection Leadership Interview of team members, understanding and use of quality tools.

MANPOWER

Introduction

The Primary Healthcare Center must have qualified staff with the right number and mix to meet its mission. The roles and responsibilities of each staff must be clearly defined in a current job description. Staff must be oriented to the center, 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.

This chapter looks at the requirements to perform the following manpower processes:

- Staffing plans
- Staff qualifications
- Job descriptions for all categories of employees
- Credentialing and privileging
- Staff orientation and education
- Employees personnel files
- Staff performance evaluation

Standards

MP.1 There is qualified individual assigned for managing human resources activities.

Evidence of Compliance

MP.1.EC.1 The Human Resources director has proper qualification and Personnel File experience.

MP.2 The primary healthcare center has a Human Resource “Employee” Manual that is given to all new employees during primary healthcare center orientation.

Evidence of Compliance

MP.2.EC.1 The PHC has an employee manual.

Document Review

MP.3 The Human Resource “Employee” Manual has a policy for handling staff complaints and/or dissatisfaction.

Evidence of Compliance

MP.3.EC.1 Human Resource Employee Manual has a policy for handling staff complaints. Document Review

MP.4 The primary healthcare center has a policy that addresses methods for resolution of conflicts between staff.

Evidence of Compliance

MP.4.EC.1 There is a written policy for resolution of conflicts between staff. Document Review

MP.5 The primary healthcare center leaders develop and implement a program for recruitment, retention, development and continuing education for all staff members.

Evidence of Compliance

MP.5.EC.1 There is a written program for staff recruitment, retention, and staff development developed by the PHC leaders. Document Review

MP.6 The primary healthcare center has a policy that requires all categories of staff to have clearly written job descriptions that are reviewed and revised at least every three (3) years and as needed and:

MP.6.1 The job description is used when selecting staff for hire, internal promotions, and transfer.

MP.6.2 The job description outlines the necessary knowledge, skills, and attitude to perform the role.

MP.6.3 The job description is provided to every staff member at time of hire and is located in the employee’s personnel file and departmental manual.

MP.6.4 All job descriptions follow a prescribed format.

MP.6.5 All job descriptions are competency based.

Evidence of Compliance

MP.6.EC.1 There is a job description policy. Document Review

MP.6.EC.2 All job descriptions are competency based, used for staff credentialing, and follow a prescribed format. Personnel File

MP.7 The primary healthcare center ensures the completion and update of the personnel files of the staff.

MP.7.1 Ensuring the registration of healthcare workers in the Saudi Commission for Health Specialties.

MP.7.2 The PHC implements a policy to maintain the confidentiality of the files.

Evidence of Compliance

MP.7.EC.1 There is a written policy to maintain the confidentiality of the personnel files. Document Review

MP.7.EC.2 All healthcare workers are registered in the Saudi Council for Health Specialties. Personnel File

MP.8 The primary healthcare center has a comprehensive mandatory general orientation that all new employees attend, and the content includes, but is not limited to:

MP.8.1 The PHC mission, vision, values, and organizational chart.

MP.8.2 Staff role in disasters and emergencies. (i.e., fire).

MP.8.3 General information about hazardous materials including Material Safety Data Sheet (MSDS).

MP.8.4 General information on Infection control and sharps disposal.

MP.8.5 Electrical safety.

MP.8.6 General information on communication devices: paging, telephone system, and bleeps.

MP.8.7 General information on staff evaluation process.

MP.8.8 The definition of 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.

MP.8.9 The policy on abuse and neglect of children and adults.

MP.8.10 Overview of credentialing, privileging, and competency policies.

MP.8.11 General information about staff health program and its components.

MP.8.12 General information about the cultural and social issues in the Kingdom.

MP.8.13 General information about the quality improvement and patient safety processes of the PHC and the importance of all staff involvement.

MP.8.14 Information on the expected ethical conduct of the staff and the expected professional communication in his/her interactions with others.

MP.8.15 Information on protection of patient's rights, privacy, and confidentiality.

Evidence of Compliance

MP.8.EC.1 Attendance records show that all new employees attended a Document Review mandatory general orientation that includes MP.8.1 through MP.8.15.

MP. 9 The primary healthcare center ensures that staff are educated on the safe operation of equipment.

MP.9.1 Staff are trained on the safe operation of equipment, including medical devices.

MP.9.2 There is a process to ensure that only trained and competent staff operate specialized equipment.

Evidence of Compliance

MP.9.EC.1 There is evidence of staff education on the safe operation of Personnel File equipment together with tools to ensure competency of staff.

MP.10 The primary healthcare center general orientation is documented in each employee's personnel file.

Evidence of Compliance

MP.10.EC.1 The general orientation is documented in the employee's file. Personnel File

MP.11 All new staff receive a comprehensive departmental orientation provided by the head of department that includes, but is not limited to:

MP.11.1 All new employees read the appropriate departmental policies and sign that they have read and understood them.

MP.11.2 All new employees read their job description and sign that they have read and understood it.

MP.11.3 All new employees receive an assessment of the knowledge, skills, and attitude required of the employee to function successfully in his/her position.

MP.11.4 All new employees receive education on the proper use of equipment including troubleshooting and reporting malfunctions.

MP.11.5 All new employees receive more clarification as needed on all topics provided in the general orientation and this is signed by the employee and immediate supervisor.

MP.11.6 Orientation for new employees is located in the employee's personnel file.

Evidence of Compliance

- MP.11.EC.1 The departmental orientation is documented in the employee's personnel file. Personnel File
- MP.11.EC.2 There is departmental orientation that is provided by the head of department and includes elements in MP.11.1 through MP.11.5. Interview

MP.12 The leadership supports continuing education for all categories of staff to pursue professional development and learning.

- MP.12.1 The leadership grants financial support and/or time off for staff to attend educational activities.

Evidence of Compliance

- MP.12.EC.1 There is evidence of financial support and/or time off for staff Interview to attend educational activities.

MP.13 The primary healthcare center has an educational program (academic program) with an ongoing schedule of educational activities and training based on primary healthcare center needs.
Evidence of Compliance

- MP.13.EC.1 There is an educational plan/academic program schedule. Document Review

MP.14 Department heads recommend, implement, and evaluate the necessary courses and skills to update and maintain staff's competence to provide care. This process is linked to performance improvement and documented in each employee's file.
Evidence of Compliance

- MP.14.EC.1 There is a recommendation of educational needs based on Document Review performance evaluation by department head.
- MP.14.EC.2 Attendance to the educational program is documented in Personnel File personnel file.

MP.15 The needs identified for training and education are based on, as appropriate:

- MP.15.1 The PHC's mission, vision, and values.

- MP.15.2 The patient population served, the type and nature of care provided by the PHC, and the department/service.

- MP.15.3 Individual staff member's education and training needs.

- MP.15.4 Information from quality assessment and improvement activities.

- MP.15.5 Needs generated by advancements made in health care management and health care science and technology.

MP.15.6 Findings from department/service performance appraisals of individuals.

MP.15.7 Findings from review activities by peers, if appropriate.

MP.15.8 Findings from the PHC's plant, technology, and safety management programs.

MP.15.9 Findings from infection control activities.

Evidence of Compliance

MP.15.EC.1 The education and training program is focused on the PHC Document Review needs and based on elements in MP.15.1 through MP.15.9.

MP.16 All staff members who provide direct patient care (medical staff, nursing staff, and other health professionals) receive training in basic cardiopulmonary resuscitation (BLS) and the training is repeated every two (2) years.

Evidence of Compliance

MP.16.EC.1 The BLS training for each individual is validated and repeated Personnel File every 2 years.

MP.17 The primary healthcare center has processes in place to address the health and safety of all staff consistent with laws and regulations and coordinated with the center's quality, safety, risk management, and infection control programs:

MP.17.1 The program is based on assessment, and where necessary, reduction of occupational health and safety risks.

MP.17.2 The program includes, but not limited to, the following:

MP.17.2.1 Pre-employment medical evaluation of new staff.

MP.17.2.2 Response to the health problems of the staff through direct treatment or referral.

MP.17.2.3 Periodic medical evaluation of staff (at least annually).

MP.17.2.4 Screening for exposure and/or immunity to infectious diseases.

MP.17.2.5 Staff preventive immunizations.

MP.17.2.6 Management of exposure to blood borne pathogens and other work-related conditions.

MP.17.2.7 Measures to reduce occupational exposures and hazards, including use of protective equipment and clothing, stress management, and ergonomic.

MP.17.2.8 Staff education on the risks within the center environment as well as on their specific job-related hazards, e.g., lifting techniques, using equipment safely, and detecting, assessing, and reporting risks.

- MP.17.2.9 Management and documentation of staff incidents, e.g., injuries or illnesses, taking corrective actions, setting measures to prevent recurrences.
- MP.17.3 There is appropriate record keeping and management (employee health records that are filed separately).

Evidence of Compliance

- MP.17.EC.1 There are health files for all employees with contents that include MP.17.2.1 through MP.17.2.9. Document Review

MP.18 The primary healthcare center leaders has an effective process to evaluate staff within the probationary period of employment, and this includes:

- MP.18.1 A policy that outlines the roles and responsibilities for evaluating staff during their probationary period.
- MP.18.2 Documentation in the employee's personnel file.

Evidence of Compliance

- MP.18.EC.1 There is a probationary period staff evaluation policy. Document Review

- MP.18.EC.2 Probationary period staff evaluation is documented in the employee's personnel file. Personnel File

**STANDARDS
MANPOWER**

MP.19 The primary healthcare center leaders has an effective process to evaluate staff at least annually, and this includes:

- MP.19.1 A policy that outlines the roles and responsibilities for evaluating staff at least annually.
- MP.19.2 A comprehensive evaluation form that covers all aspects of expected performance levels as outlined in his/her job description (e.g. competence, attitude, etc).
- MP.19.3 Documentation in the employee's personnel file.
- MP.19.4 All staff reading and signing their evaluation.

Evidence of Compliance

- MP.19.EC.1 There is an annual evaluation policy and evaluation form that covers all expected performance levels. Document Review

- MP.19.EC.2 All employees' files contain the completed annual evaluation form (as appropriate) with staff signature. Personnel File

MP.20 The primary healthcare center 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.

- MP.20.1 To the extent possible, the credentials are verified from the original source.
- MP.20.2 Job responsibilities and clinical work assignments are based on evaluation of the verified credentials.
- MP.20.3 The center ensures the registration of healthcare professionals with the Saudi Commission for Health Specialties in accordance with laws and regulations.
- MP.20.4 The center maintains a record (a credentials or other file) of the current professional license, certificate, or registration, when required by law, regulation, or by the organization, of every medical staff, nursing staff, and other health professionals. This information is updated as appropriate.
- MP.20.5 The process applies to all medical staff categories (e.g., full time, part time, locum, etc).

Evidence of Compliance

MP.20.EC.1 The credentials are verified from the original source, to the Personnel File extent possible.

MP.21 There is a Nurse Leader (Nursing Director/Nurse Executive) who is a registered nurse qualified by appropriate education and experience.

- MP.21.1 The Nurse Leader/designee participates in the PHC interdisciplinary structures, e.g., relevant committee(s).
- MP.21.2 The Nurse Leader develops and maintains a current standard of practice for each nursing unit.
- MP.21.3 The Nurse Leader develops a staffing plan that maintains an adequate staffing level on all units.
- MP.21.4 The Nurse Leader allocates nursing staff according to:
 - MP.21.4.1 Skill level and appropriate qualifications based on laws and regulations.
 - MP.21.4.2 Patient type and acuity on units.

Evidence of Compliance

MP.21.EC.1 There is a nursing staffing plan. Document Review

MP.21.EC.2 There is evidence that the Nurse Leader/designee is Personnel File qualified and participates in relevant interdisciplinary structures (e.g., committee).

MP.21.EC.3 There is evidence that nurses' allocation to units is based on Leadership Interview elements specified in MP.21.4.

MP.22 The primary healthcare center has clearly defined, and documented processes 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 center.

- MP.22.1 Medical staff appointments and granting privileges are in accordance with law and legal requirements.
- MP.22.2 Medical staff appointments and granting privileges are based on evaluation of the verified credentials (license, education, training, and experience) as well as physical and mental health.
- MP.22.3 Medical staff appointments and granting privileges are recommended by the medical staff leaders, e.g., credentialing and privileging committee and medical executive committee, and approved by the governing body, either directly or by appropriate delegation.
- MP.22.4 The process applies to all medical staff categories (e.g., full time, part time, locum, etc).

Evidence of Compliance

- MP.22.EC.1 There are documented processes for medical staff appointment and granting of clinical privileges and approved by the governing body or by appropriately delegated authority. Document Review

MP.23 All medical staff members have current delineated clinical privileges:

- MP.23.1 The clinical privileges are determined based on documented competency.
- MP.23.2 The clinical privileges of the medical staff are recommended by the medical staff leaders and approved by the governing body, either directly or by appropriate delegation.
- MP.23.3 All department heads ensure that the physicians working within their area limit their scope of practice to the clinical privileges assigned to them.
- MP.23.4 The physician privileges are reviewed and updated every two (2) years, and as needed.

Evidence of Compliance

- MP.23.EC.1 All medical staff members have current (no more than two years), Personnel File delineated clinical privileges approved by the governing body or by appropriately delegated authority.
- MP.23.EC.2 Medical staff members work within the scope of practice Personnel File according to the clinical privileges.

MP.24 The Medical Director together with the department heads evaluate the performance of each medical staff member for the following:

- MP.24.1: The evaluation includes at a minimum

- MP.24.1.1 Mortality and morbidity.

- MP.24.1.2 Appropriateness of referrals.
 - MP.24.1.3 Outcomes of procedures.
 - MP.24.1.4 Utilization such as appropriateness of interventions, medications, and waiting time.
 - MP.24.1.5 Medication usage.
 - MP.24.1.6 Treatment according to the guidelines.
- MP.24.2 The performance is reviewed at least annually and when indicated by findings of the performance improvement activities.

Evidence of Compliance

- MP.24.EC.1 The medical staff evaluation is conducted at least annually Document Review and includes at a minimum elements MP.24.1.1 through MP.24.1.6.
- MP.24.EC.2 The Medical Director collaborates with the department Leadership Interview heads to evaluate the medical staff members.

MANAGEMENT OF INFORMATION

Introduction

One of the most valuable resources that the leadership can have is information. Accurate information is necessary for the leadership 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 center should have a plan 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:

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

Standards

MOI.1 The primary healthcare center leaders develop and implements information management processes to meet the information needs of all those who provide clinical services and for those who manage the primary healthcare center, and includes:

- MOI.1.1 A definition of data, information, security, confidentiality, and integrity.
- MOI.1.2 A categorization of data available (both manual and computerized).
- MOI.1.3 An assessment of information needs by both clinical and managerial staff within the PHC.
- MOI.1.4 A description of how confidentiality, security, and integrity of the data and information will be maintained.
- MOI.1.5 A description of the various kinds of reports, the frequency of the reports, and who will receive them.
- MOI.1.6 An educational/training schedule for decision makers and other appropriate staff on the principles of data management for decision-making.
- MOI.1.7 A description of the technology and other resources required for information management.
- MOI.1.8 A description of the roles and responsibilities of the leadership and department heads in relation to implementation and evaluation.

Evidence of Compliance

- MOI.1.EC.1 There are comprehensive information management Document Review processes developed by the leadership including MOI.1.1 through MOI.1.8.
- MOI.1.EC.2 There is evidence of implementation of the MOI processes. Leadership Interview

MOI.2 Appropriate clinical and managerial staff participate in selecting, integrating, and using information management technology.

Evidence of Compliance

- MOI.2.EC.1 There is evidence of participation of clinical and managerial Leadership Interview staff in selecting, integrating, and using information management technology.

MOI.3 There is a responsible person to prepare the required statistical reports in a timely manner.

Evidence of Compliance

- MOI.3.EC.1 There is evidence of preparation of the required statistical Document Review reports in a timely manner by an assigned person.

MOI.4 The primary healthcare center has sufficient resources including equipment and forms required for statistical reports.

Evidence of Compliance

MOI.4.EC.1 The equipment and forms required for any statistical Observation reports are available in adequate amounts.

MOI.5 **The primary healthcare center leaders work with all department heads to identify the necessary data that will be used for decision-making on a regular basis and this includes:**

MOI.5.1 The identification of necessary data based on the PHC scope of service and complexity of care.

Evidence of Compliance

MOI.5.EC.1 There is collaboration with department heads to assess the Interview information needs required for decision making.

MOI.6 **The primary healthcare center leaders determine the roles and responsibilities for data entry (completion of forms), data collection, data analysis, and reports generation and this includes:**

MOI.6.1 Data elements being defined and forms developed for designated staff to enter the necessary data.

MOI.6.2 Establishing time frames for collecting data.

MOI.6.3 Displaying and analyzing data using software programs.

MOI.6.4 The leadership deciding the routing of the reports.

Evidence of Compliance

MOI.6.EC.1 The PHC leaders determine the data management process Document Review involving (data element definition, establishing time frame, data analysis, and report routing).

MOI.7 **The primary healthcare center leaders analyze the information with the assistance of the Quality Coordinator.**

Evidence of Compliance

MOI.7.EC.1 The PHC leaders analyze information with the assistance of Document Review the quality coordinator (i.e. available reports).

MOI.8 **The primary healthcare center leaders use the information to make decisions, strategically plan, identify, and prioritize quality improvement projects.**

MOI.8.1 Planning is based on analysis of patient demographics and services required data.

Evidence of Compliance

MOI.8.EC.1 The PHC leaders use information to make decisions, Leadership Interview strategic planning, identifying, and prioritizing QI projects (aggregate reports are analyzed and used by leadership to make decisions).

MOI.9 **The primary healthcare center leaders receive education on data management appropriate to their roles and responsibilities within the center.**

Evidence of Compliance

MOI.9.EC.1 The PHC leaders and other staff, as appropriate, are knowledgeable about data management. Leadership Interview

MOI.10 The primary healthcare center maintains a master population index, updated regularly, and at each new and follow-up patient/family visit.

Evidence of Compliance

MOI.10.EC.1 There is a master population index, updated regularly, Document Review and at each new and follow-up patient/family visit.

MOI.11 The primary healthcare center has a policy on how confidentiality of data and information will be maintained, and includes:

MOI.11.1 Who will have access to different types and categories of information and describes the penalties for the staff that violate the security and confidentiality of data and information.

MOI.11.2. The policy includes levels of access to patient information on a need to know basis

Evidence of Compliance

MOI.11.EC.1 There is a written policy on maintenance of data and Document Review information confidentiality including levels of access on need to know basis, and disciplinary actions when the policy is violated.

MOI.12 The primary healthcare center contributes to external databases in accordance with Saudi laws and regulations.

Evidence of Compliance

MOI.12.EC.1 There is contribution to external databases in accordance Document Review with Saudi laws and regulations (infectious diseases reports, cancer registry, etc.).

MOI.13 There is internet access for staff to obtain information that supports safe patient care.

Evidence of Compliance

MOI.13.EC.1 There is internet access for staff to support safe patient care. Interview

MOI.14 When there is automation of data, there is a planned, documented recovery system in case of computer malfunction, to include system linked and stand-alone computers.

Evidence of Compliance

MOI.14.EC.1 There is a documented recovery system for automated data Interview on all computers.

HEALTH RECORDS

Introduction

A Health Records is the backbone of the Primary Healthcare Center and considered one of the important elements in the quality program. The quality of the health records is essential. Health care providers must be able to have access to information in the health record in order to provide safe care. Also, vital information in the health record is needed for patient continuity of care and communication between healthcare providers at every patient encounter. To ensure appropriate management of health records, the center should have processes for access to records, entries in the record, and use of health record information.

The health record standards in this chapter address the following processes and activities:

- Health records department staffing
- Initiation, construction, and contents of health records
- Criteria for health records documentation
- Coding
- Availability of health records
- Storage and retention
- Security, safety, and confidentiality of health records
- Health records quality improvement

Standards

HR.1 A health record is initiated for every patient assessed and/or provided care or services by the primary healthcare center.

Evidence of Compliance

HR.1.EC.1 A health record is initiated for every patient assessed and/or Interview provided care or services by the PHC.

HR.2 The health record is easily identified by a unique patient identifier.

Evidence of Compliance

HR.2.EC.1 An initiated patient health record is easily identified by a Health Record Review unique patient identifier.

HR.3 All health records must contain the following information, at a minimum:

HR.3.1 The patient's name, address, date of birth, and next of kin. The name must include: family name, first name, middle name.

HR.3.2 The medical history of the patient.

HR.3.2.1 Details of the present illness, including, when appropriate, assessment of the patient's emotional, behavioral, and social status.

HR.3.2.2 Relevant past, social, and family histories appropriate to the age of the patient.

HR.3.2.3 A clinical review by body systems.

HR.3.3 As appropriate to the age of the patient, a summary of the patient's psycho/social needs.

HR.3.4 Reports of relevant physical examinations.

HR.3.5 Diagnostic and therapeutic orders.

HR.3.6 Evidence of informed consent.

HR.3.7 Clinical observations, including the result of therapy.

HR.3.8 Reports of procedures, tests, and the results.

HR.3.9 Physician documentation includes his/her assessment, diagnosis, impression, and plan of care revisions when indicated and therapeutic intervention.

HR.3.10 Evidence of patient/family education and health promotion.

HR.3.11 Conclusions at termination of evaluation/treatment.

Evidence of Compliance

HR.3.EC.1 There is a completed and unified health record that includes Health Record Review HR.3.1 through HR.3.11.

HR.4 Only authorized staff members are allowed to make entries in the health records and:

- HR.4.1 There is a unique identifier (name and/or number) for each staff member that he/she uses when making entries in the records.
- HR.4.2 Staff date and time each entry into the health record.
- HR.4.3 Staff sign each entry.

Evidence of Compliance

- HR.4.EC.1 There is a written policy to identify staff authorized to make entries in the health records (using name, ID number or stamp, and signature).
- HR.4.EC.2 All entries are dated, timed, and signed. The identity of staff making the entry can be identified, e.g. by name or ID number.

HR.5 The primary healthcare center has essential administrative policies and procedures that include but are not limited to:

- HR.5.1 Initiation of a new health record
- HR.5.2 Transferring a health record to another PHC.
- HR.5.3 Receiving a health record from another PHC.
- HR.5.4 Archiving the responses to the patients' referrals.
- HR.5.5 Retrieving an individual file from a family record and replacing it.
- HR.5.6 Documentation and exchange of information related to treatment of visitors from outside the PHC's catchment area.

Evidence of Compliance

- HR.5.EC.1 There are written policies and procedures for topics in HR.5.1 through HR.5.6.

HR.6 The primary healthcare center uses standardized diagnosis codes (such as International Classification of Diseases 10th, International Classification of Primary Care (ICD-10.ICPC-2e), Current Procedure Terminology, or Diagnostic Related Groups), procedure codes, and definitions so that data can be aggregated and transformed into information by:

- HR.6.1 Using standardized diagnosis codes.
- HR.6.2 Using standardized procedure codes.
- HR.6.3 Using standardized symbols and definitions.

Evidence of Compliance

HR.6.EC.1 There are standardized diagnosis and procedure codes (ICD9 or ICD-10.ICPC-2e, CPT, or DRG), and standardized symbols and their definitions.

HR.7 **The primary healthcare center has a policy on the storage and retention of records, data, and information and:**

- HR.7.1 The policy is consistent with laws and regulations.
- HR.7.2 The policy defines the length of time required to retain the records including x-rays (minimum 5 years).
- HR.7.3 The policy addresses how confidentiality, integrity, and security of the records will be maintained.

Evidence of Compliance

HR.7.EC.1 There is a written policy on the storage and retention of records, data, and information that is consistent with laws and regulations (minimum of 5 years).

HR.7.EC.2 There is a written policy on the confidentiality, integrity, and security of health records.

HR.8 **There is a policy that outlines how records are protected from loss, theft, and/or deliberate alterations or tampering that includes, but is not limited to:**

- HR.8.1 Describing how records will be protected from loss.
- HR.8.2 Describing the disciplinary action to be taken if staff make any deliberate alterations (tampering).

Evidence of Compliance

HR.8.EC.1 There is a written policy on medical records protection from loss, theft and/or deliberate alterations, destruction or tampering, and disciplinary actions in case of violation by staff.

HR.9 **There is a health records tracking system that can identify the location of any record not in the health records department.**

Evidence of Compliance

HR.9.EC.1 There is a health record tracking system. Interview

HR.10 **Each patient visit or treatment is documented in the health record.**

Evidence of Compliance

HR.10.EC.1 There is documentation of each visit or treatment in the health record.

HR.11 The primary healthcare center has a policy for the Health Records Department that includes the content and the forms that are filed in the record. A complete health record is the one that contains the following:

- HR.11.1 Identity information of patients and next of kin.
- HR.11.2 History and physical examination.
- HR.11.3 Periodic health assessment.
- HR.11.4 All interventions of physicians.
- HR.11.5 All interventions of nurses.
- HR.11.6 All physician orders signed.
- HR.11.7 Problem list, care plan, and family pedigree.
- HR.11.8 Environmental status.
- HR.11.9 Health education sheet.

Evidence of Compliance

- HR.11.EC.1 There is a written policy for health records content. Document Review
- HR.11.EC.2 The complete health record is the one that contains Health Record Review elements in HR.11.1 through HR.11.9.

HR.12 The following issues are included in the primary healthcare center policy for the completion of health records:

- HR.12.1 All relevant diagnoses, as well as all procedures performed.
- HR.12.2 When required, a typewritten summary concisely restating the significant findings and diagnosis, treatments, current medications, and follow-up instructions provided to the patient and, as appropriate to the practitioner responsible for the patient's continuing or follow-up care.
- HR.12.3 The attending physician is responsible for the completion of his/her own record.
- HR.12.4 Physicians, who do not complete their records in a timely manner, receive disciplinary action as outlined in the PHC's delinquent record policy.

Evidence of Compliance

- HR.12.EC.1 There is a written policy on completion of health records Document Review describing documentation of all relevant diagnoses, as well as all procedures performed.

HR.13 The Head of Health Records Department works closely with the Health Records Review Committee to check the quality of the following documentation:

- HR.13.1 History and physical.

HR.13.2 Patient assessments.

HR.13.3 Lab results.

HR.13.4 Progress notes.

HR.13.5 Plan of care.

HR.13.6 Documentation of patient education and health promotion activities.

Evidence of Compliance

HR.13.EC.1 The health records review committee evaluates the quality Document Review of all health records documents, e.g. meeting minutes and reports.

HR.14 The Health Records Department has the following categories of staff and has clear job descriptions for the positions. (as per the scope of services and volume of work):

HR.14.1 Coders.

HR.14.2 Assemblers / analysts.

HR.14.3 Medical secretaries.

HR.14.4 File clerks.

Evidence of Compliance

HR.14.EC.1 The health record department has the following staff: coders, Document Review assemblers/analysts, transcribers/medical secretaries, and file clerks.

HR.15 The health records head is qualified by education, training, and experience.

Evidence of Compliance

HR.15.EC.1 There is qualified, trained, and experienced health record Personnel File director.

HR.16 The health records are available within 15 minutes of being requested.

Evidence of Compliance

HR.16.EC.1 The health record is available within 15 minutes of request. Interview

HR.17 The health records can be retrieved any time of the day.

Evidence of Compliance

HR.17.EC.1 The health records can be retrieved any time of the day including Interview after hours.

HR.18 Health records are only released out of Health Records Department according to a policy approved by primary healthcare center leaders, that includes:

- HR.18.1 Records can be released to the nurses in the general clinics.
- HR.18.2 Records can be released to the emergency room nurses for a patient in Emergency Room.
- HR.18.3 Records are released to chairperson of Morbidity and Mortality Committee and he/she signs for it.
- HR.18.4 Approval by the PHC director or medical director for all other requests for release of the health record.

Evidence of Compliance

HR.18.EC.1 There is a written policy on the release of health records from Document Review the health record department (general clinic nurse, emergency room nurse, morbidity and mortality chairperson, or cases exceptionally approved by medical/PHC director).

HR.19 Essential information about the patient is legible and located in the face sheet along with other information, such as allergies.
Evidence of Compliance

HR.19.EC.1 There is documentation on the face sheet of all essential patient information in addition to allergies and code status.

HR.20 All entries in the health record are clear and legible.

- HR.20.1 There are specific guidelines for correcting an error in the health record that does not include the use of correction fluid to erase any entry.

Evidence of Compliance

HR.20.EC.1 There is a written policy on legible and clear handwriting, Document Review and error correction.

HR.20.EC.2 All health record entries are clear and legible. Health Record Review

HR.21 All laboratory results are seen and signed by a physician before being filed in the patient's record.
Evidence of Compliance

HR.21.EC.1 All laboratory results are signed by a physician before filing Health Record Review in the patient's record.

HR.22 The primary healthcare center prepares a list of prohibited abbreviations not to be used and it is recommended and approved by related committees such as the pharmacy and therapeutic committee and health records review committee.
Evidence of Compliance

HR.22.EC.1 There is a written list of prohibited medical abbreviations Document Review approved by pharmacy and therapeutics committee and health record committee.

HR.22.EC.2 There is health records compliance with the prohibited Health Record abbreviation list.

HR.23 The primary healthcare center prepares a list of approved abbreviations as required by regulating agencies to be used in the institution and it is recommended by the health records review committee.

Evidence of Compliance

HR.23.EC.1 There is a written list of approved medical abbreviations that Document Review is approved by the health records review committee.

HR.23.EC.2 There is health record compliance with the approved Health Record Review medical abbreviation list.

HR.24 The health records department head participates in the quality management program.

Evidence of Compliance

HR.24.EC.1 There is evidence of participation of the health record Document Review department head in the quality management program (membership in QMC, meeting minutes, reports, etc.).

PATIENT AND FAMILY RIGHTS

Introduction

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

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 safer and 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 chapter addresses standards for:

- Defining and supporting patient and family rights
- Defining treatments/procedures requiring informed consent and obtaining informed consent when indicated
- Protection of vulnerable patients
- Pain management
- 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 patients and their families are fully informed and protected when they are involved in research projects

Standards

PFR.1 The primary healthcare center leaders are involved in supporting and protecting patient and family rights by:

- PFR.1.1 Developing and maintaining a patient rights and responsibilities statement and policies to outline and support patient rights.
- PFR.1.2 Discussing aspects of patient's rights in selected workshops and/or meetings.
- PFR.1.3 Assigning a committee to clarify and help resolve issues that involve patient's rights where needed.
- PFR.1.4 Ensuring patients are informed about their rights and responsibilities in a manner they can understand.
- PFR.1.5 Making patient rights and responsibilities available to patients and families
- PFR.1.6 Providing staff training and education on patient and family rights and responsibilities.

Evidence of Compliance

PFR.1.EC.1	There is a terms of reference for the Patient Rights/Advocacy Committee.	Document Review
PFR.1.EC.2	Staff receive training and education on patient and family rights	Interview

PFR.2 An administrative policy is developed and implemented regarding everyone's roles and responsibilities in supporting patient and family rights.

Evidence of Compliance

PFR.2.EC.1	There is an administrative policy that outlines roles and responsibilities in implementing patient and family rights.	Document Review
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PFR.3 The patient is truthfully informed when his/her needs exceed the primary healthcare center's capability for care.

Evidence of Compliance

PFR.3.EC.1	Staff are knowledgeable on how to handle patients when needed services are not available.	Interview
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PFR.4 The primary healthcare center offers equitable healthcare services to all patients.

Evidence of Compliance

PFR.4.EC.1	There are standardized processes for patients care.	Interview
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PFR.5 The center staff members allow patients and, when appropriate, their families to fully participate in decisions about their care, treatment, and services.

- PFR.5.1 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.

- PFR.5.2 Patients are supported to discuss their plan of care with the physician and have all their questions answered.
- PFR.5.3 Staff members respond appropriately to requests for a second consultation.
- PFR.5.4 Patients' preferences and choices are respected.

Evidence of Compliance

- PFR.5.EC.1 The patient is informed about his/her rights (consent policy or other document instructing staff to discuss with patients/families their plan of care, diagnosis, condition, treatment and support their rights in care planning and decision making) and this is documented in the patient's health record. Health Record Review

PFR.6 The primary healthcare center provides appropriate protection for vulnerable patients such as infants, children, disabled individuals, and the elderly.

- PFR.6.1 There is a written policy that addresses actions and responsibilities in the prevention of infant/child abduction.
- PFR.6.2 Having security available in sensitive and remote areas.
- PFR.6.3 Preventing unauthorized access to the sensitive areas.
- PFR.6.4 Providing visitors with identification badges issued by the PHC.
- PFR.6.5 Assigning a code such as "Code Pink" for child abduction.

Evidence of Compliance

- PFR.6.EC.1 There is a written policy that addresses actions and Document responsibilities in the prevention of infant/child abduction including "Code Pink". Review
- PFR.6.EC.2 There is security available in all sensitive areas to protect Observation patients, assist disabled patients, and control visitors' entrance (provision of temporary identification badges). Observation

PFR.7 The primary healthcare center assists disabled patients by offering the necessary assistance to patients with special needs where needed (e.g. identified parking spaces near the entrance)

Evidence of Compliance

- PFR.7.EC.1 The PHC is a friendly facility for disabled and elderly Observation patients (e.g. identified parking spaces near the entrance, etc.). Observation

PFR.8 The primary healthcare center implements general principles of patient and family rights which includes:

- PFR.8.1 Treating patients with respect and dignity at all times.
- PFR.8.2 Respecting patients' cultural, psychosocial, spiritual, and personal values and beliefs.

- PFR.8.3 Providing all the information regarding the identity and the professional status of his/her treating physician and how to contact him/her.
- PFR.8.4 Respecting the patients' need for privacy and not exposing any private parts unnecessarily during the treatment.
- PFR.8.5 Respecting patients' right for pain assessment and management.
- PFR.8.6 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.
- PFR.8.7 Not neglecting patients' demands and/or needs and respecting their right to complain.
- PFR.8.8 Allowing patients to submit verbal or written complaints or proposals with no effect on the quality of care provided.
- PFR.8.9 Allowing patients to refuse to talk to any individual that has no relationship to the care provided.
- PFR.8.10 Protecting patients from verbal abuse by physicians, nurses, or any other staff.
- PFR.8.11 Providing patients a complete medical report and accurate check-up results.

Evidence of Compliance

PFR.8.EC.1 Staff are aware of the general principles of patients' rights. Interview

PFR.9 There is a policy that identifies an up-to-date list of high risk treatments and procedures that require informed consent, such as surgery under local anesthesia.

Evidence of Compliance

PFR.9.EC.1 There is a written policy for high risk treatments and Document procedures requiring informed consent (surgeries under Review local anesthesia).

PFR.10 The consent process includes:

- PFR.10.1 Fully informing the patient about the risks, benefits, and alternatives.
- PFR.10.2 Signing the consent form prior to any surgical or invasive procedure, anesthesia, or other high risk treatments and procedures with exception to emergencies and trauma.
- PFR.10.3 Written consent is obtained prior to photography of patient (especially the face).

Evidence of Compliance

PFR.10.EC.1 Informed consent is obtained and documented in Health Record accordance with PHC policy: prior to any Review surgical/invasive procedure with exception of emergency /trauma. Consent is obtained for medical photography.

PFR.11 The informed consent is signed by the patient or his/her designee as defined by primary healthcare center policy and witnessed for all high risk procedures, and this includes:

- PFR.11.1 There is proper identification and a clearly written name when any other family member signs the consent on behalf of the patient.

Evidence of Compliance

- PFR.11.EC.1 The informed consent is signed by the patient or his/her designee as defined by PHC policy and witnessed for all high-risk procedures using a legible written name.

PFR.12 Staff respect and protect patient privacy and confidentiality throughout the provision of care.

Evidence of Compliance

- PFR.12.EC.1 Patients are provided with privacy and their information is kept confidential across the facility.

PFR.13 The primary healthcare center has an effective structure to handle patient complaints, that includes the following:

- PFR.13.1 There is a specific unit or person in the organization (e.g. Patient Relations, Social Worker, and Quality Department) responsible for complaint management.
- PFR.13.2 There is a committee that has oversight of the patient complaint process and outcomes and the membership includes at least medical, nursing, patient relations, and quality management.
- PFR.13.3 The unit or person responsible for patient complaints routes patient complaints that have a non medical implication to the concerned department/section leader who will investigate and help resolve the issues.
- PFR.13.4 The unit or person responsible for patient complaints routes patient complaints that have a medical implication to the medical director to handle the clinical review process of the case.
- PFR.13.5 The medical director routes all complaints that have been identified as mortality and/or morbidity cases by the clinical review process, to the mortality and morbidity committee.
- PFR.13.7 The PHC investigates immediately and finalizes the medical cases by no later than one month from receiving the complaint and gives feedback to the complainant.
- PFR.13.8 The committee with oversight of patient complaints receives a confidential summary report of the complaint cases reviewed from the Mortality/Morbidity Committee Chairperson with copies to the center's director, the medical director and the Quality Management Committee.
- PFR.13.10 The chairperson of the committee with oversight for patient complaints routes trended reports to department heads as needed and receives written feedback from them.

- PFR.13.11 The chairperson of the committee with oversight for patient complaints routes copies of the minutes to the center's director, medical director, and quality management coordinator.
- PFR.13.12 The center's leaders ensure taking quality improvement and strategic actions based on monthly, quarterly and annual trended report data.

Evidence of Compliance

- PFR.13.EC.1 There is a committee that has oversight of the patient complaint Document Review process and outcomes with trended reports.
- PFR.13.EC.2 There is a policy that guides the handling of patients' complaints. Document Review

PFR.14 The primary healthcare center has a system including policy, forms, and process to conduct ongoing patient satisfaction surveys and makes improvements based on the trended survey results.

Evidence of Compliance

- PFR.14.EC.1 There is policy and form for ongoing patient satisfaction surveys. Document Review
- PFR.14.EC.2 There are patient satisfaction trended reports that include improvement actions taken based on the trended survey results. Observation

PFR.15 The primary healthcare center develops and implements an administrative policy and procedure (APP) for protection of patient belongings, that includes but is not limited to:

- PFR.15.1 The location where the patient belongings are kept.
- PFR.15.2 The person(s) responsible for obtaining the required signatures on the form when receiving and handing over the patient's belongings.
- PFR.15.3 How the valuables of trauma and vulnerable patients (comatose, confused, elderly, and children) are handled.

Evidence of Compliance

- PFR.15.EC.1 There is a policy for protection of patient belongings that Document Review includes PFR.15.1 through PFR.15.3.
- PFR.15.EC.2 Implementation of patient belongings policy (location, safety, handling belongings of trauma and vulnerable patients). Observation

PFR.16 Physicians and nurses involve the patient/designee/family as appropriate, to assist the patient in making informed decisions about treatment offered, by giving them accurate and honest information for:

- PFR.16.1 Their illness.
- PFR.16.2 The proposed treatment.
- PFR.16.3 Potential benefits.

PFR.16.4 Potential complications.

PFR.16.5 Likelihood of success of treatment.

PFR.16.6 Their attending physician's name and other consultants' names involved in their care.

PFR.16.7 Change or transfer of the patient care from one physician to another.

Evidence of Compliance

PFR.16.EC.1 Patients and/or their designees are involved in making Health Record decisions and this is documented in the health records Review (signed consent forms).

PFR.17 There is a policy to deal with patients who refuse treatment or discontinue treatment and:

PFR.17.1 Patients have the right to refuse treatment offered.

PFR.17.2 The consequences of treatment refusal are explained to patients.

PFR.17.3 Patients are informed about available care and treatment alternatives.

PFR.17.4 Family members, when appropriate, are involved in the process.

PFR.17.5 Patient and family choices are respected.

PFR.17.6 The above discussion is documented in the patient's file.

Evidence of Compliance

PFR.17.EC.1 There is a policy to deal with patients who refuse treatment or discontinue treatment (right to refuse treatment, consequences of refusal, and respect for decisions made by the patient/family members). Document Review

PFR.17.EC.2 The discussion with the patient/family is documented in the health record. Health Record Review

PFR.18 The primary healthcare center cares for the patient in pain and this includes:

PFR.18.1 Assessing patient during visits.

PFR.18.2 Quick pain relief experienced by the patient.

PFR.18.3 Assessing the response of the patient to pain medications.

PFR.18.4 Dealing with side effects from pain medications administered.

PFR.18.5 Providing advice on how to deal with chronic pain.

PFR.18.6 Referring the patient to other healthcare settings, as appropriate.

PFR.18.7 Educating the patient regarding his/her pain and how to minimize it.

Evidence of Compliance

PFR.18.EC.1	There is pain management policy.	Document Review
PFR.18.EC.2	There is documentation of patient education for management of chronic pain and referrals to other healthcare settings.	Health Record Review

PFR.19 The primary healthcare center leaders develop and/or adopt the ethical standard in dealing with patients and their supporters and sponsors

PFR.19.1 Accurately billing for services. Availing the price list for patients and their sponsors.

PFR.19.2 Honestly portraying its services to patients.

PFR.19.3 Performing ethical marketing.

PFR.19.4 Ensuring that the provision of care is not affected by the patient's inability to pay.

Evidence of Compliance

PFR.19.EC.1 The PHC has a code of ethics that includes elements PFR.19.1 Document Review through PFR.19.4.

PFR.20 The leaders develop a set of values and professional code of conduct for all staff that describes the primary healthcare center's expectations of the staff regarding their behavior and communication with each other and with their patients.

Evidence of Compliance

PFR.20.EC.1 There is a written set of values and professional code of conduct. Document Review

PFR.21 The primary healthcare center 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.

Evidence of Compliance

PFR.21.EC.1 Patients are informed when they have significant adverse medical Interview events.

PFR.22 The primary healthcare center informs the staff and educates the patients and their families about the choices and procedures of organ donation and includes:

PFR.22.1 Providing the family with all the necessary information about the donation.

Evidence of Compliance

PFR.22.EC.1 Promotion of organ donation in cooperation with Saudi Center for Interview Organ Transplantation (SCOT).

PFR.23 The primary healthcare center has a Research Committee or a team that decides on research, new procedures, or new drugs that involves patients, to ensure that the research is appropriate and safe by the following actions:

- PFR.23.1 The team meets to discuss and evaluate the scientific evidence of the new research.
- PFR.23.2 The team studies the potential benefits and risks involved with the new drug, equipment, or procedure for the patient.
- PFR.23.3 The team has a process to explain the benefits and risks involved in the research protocol and the patient signs the research consent if willing to participate.
- PFR.23.4. Patient wishes are respected

Evidence of Compliance

PFR.23.EC.1 There is a research committee terms of reference, and meeting minutes reflect evaluation of the scientific evidence of any new research, and implementation of informed consent for involved patients. Document Review

PFR.24 Patients are informed of their responsibilities in the following:

- PFR.24.1 PHC policies and procedures (such as patient rights and responsibilities, working hours, smoking policy, use of electrical appliances, safety of belongings, etc) are communicated preferably by a patient information handbook or other appropriate tools.
- PFR.24.2 The plan of care communicated (preferably by patient education handout/form).

Evidence of Compliance

PFR.24.EC.1 Patient rights and responsibilities, working hours and smoking policy are appropriately communicated to patients. Observation

PFR.25 The primary healthcare center adopts the system of providing emergency medical care in the emergency room for all life-threatening cases.**Evidence of Compliance**

PFR.25.EC.1 There is a policy on providing emergency care for all life threatening cases regardless of patient ability to pay. Document Review

GENERAL CLINICS

Introduction

Providing optimum care requires careful planning, coordination, and communication. The Primary Healthcare Center 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/reassessment and care must be documented in a complete health record for the patient.

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

- General clinics staffing
- Appointment system
- Scope and content of patient assessment/reassessment
- Medical assessment/reassessment
- Nursing assessment/reassessment
- Plan of care
- Social services
- Patient and family education

Standards

GC.1 The primary healthcare center has a manual for General Clinics (GC) that:

- GC.1.1 Is updated, available, and well known to concerned staff.
- GC.1.2 Defines the scope of services.
- GC.1.3 Includes policies and procedures.
- GC.1.4. Includes forms and registries required
- GC.1.5 Includes a system for patient follow-up.
- GC.1.6 Identifies roles and responsibilities of the concerned staff.
- GC.1.7 Includes indicators for performance monitoring, evaluation, and improvement.

Evidence of Compliance

GC.1.EC.1 There is a written updated manual for GC that includes GC.1.2 Interview through GC.1.6 that is available and well known to the staff.

GC.2 Patient care is uniform when similar care is provided and is guided by the applicable laws and regulations.
Evidence of Compliance

GC.2.EC.1 Patients are provided with similar care in all settings across the Interview facility.

GC.3 Patient care is culturally and spiritually sensitive to the populations served and considers their special preferences.

- GC.3.1 The center provides staff training on the cultural beliefs, values, and needs of different populations served.
- GC.3.2 The center provides separate facilities for women, where appropriate.
- GC.3.3. The center has a process to provide access to spiritual care or advice that meets the needs of the different populations served

Evidence of Compliance

GC.3.EC.1 The center provides training on the cultural beliefs, values, and needs of different populations served with separate facilities for women, where appropriate.

GC.3.EC.2 Separate facilities are provided for women. Observation

GC.4 Patients have access to services based on their health needs and services available.

- GC.4.1 There is a standardized process for screening and assessing patients to ensure that required services are available and are appropriate to the needs of the patients.
- GC.4.2 There is a standardized registration and appointment system for patients.

- GC.4.3 Patients are accepted only when the organization can meet their healthcare needs.
- GC.4.4 There is a process to handle patients when resources are not available.

Evidence of Compliance

- GC.4.EC.1 There is an implemented process for screening and assessing patients. Health Review Record
- GC.4.EC.2 Patients are accepted for services only when their needs can be met, with a clear management process in place when resources are not available. Interview
- GC.4.EC.3 There is a functional registration and appointment system. Observation

GC.5 The primary healthcare center identifies and reduces physical, language, cultural, and other barriers that prevent patients from accessing services.

- GC.5.1 The center provides mechanisms that ensure effective communications between staff and patients with special communication needs (for example, sign language for the hearing impaired patients, translator services for non-Arabic speaking patients, and assistance modalities for sight impaired patients).

Evidence of Compliance

- GC.5.EC.1 There are mechanisms to identify and handle common barriers that compromise patients from accessing services. Interview

GC.6 The GC has all necessary equipment and resources.

Evidence of Compliance

- GC.6.EC.1 The GC has necessary equipment and resources available for care. Observation

GC.7 The GC has an equipped observation room.

Evidence of Compliance

- GC.7.EC.1 There is a well-equipped observation room in the General Clinics. Observation

GC.8 The GC has qualified medical and technical staff which include but not limited to:

- GC.8.1 A family physician and/or general practitioner trained in family medicine basics.
- GC.8.2 A nurse in charge of general clinics' services who handles administrative and clinical issues related to nursing.

Evidence of Compliance

- GC.8.EC.1 GC staff is properly qualified (family physician and/or a general practitioner trained in family medicine, nurse in charge of GC services). Personnel File

GC.9	There are sufficient medical and nursing staff at all times to meet patient needs and with no significant variation during holidays or weekend coverage.		
Evidence of Compliance			
GC.9.EC.1	There is a staffing plan guidelines/schedule to cover all GC Document Review hours.		
GC.10 Clinical practice guidelines and protocols are used to guide clinical care for patients as appropriate to the center's mission.			
GC.10.1	Clinical practice guidelines developed by the center are evidence based whenever possible.		
GC.10.2	The clinical practice guidelines are updated at least every two (2) years or when needed.		
GC.10.3	Staff follow the clinical practice guidelines and protocols.		
Evidence of Compliance			
GC.10.EC.1	There are updated evidence based clinical practice Document Review guidelines (reviewed at least every 2 years or when needed).		
GC.10.EC.2	The medical staff follows the clinical practice guidelines.		Health Record Review
GC.11	The primary healthcare center identifies the health care needs of its patients through an established assessment/reassessment process. The organization defines in policy and procedure the following:		
GC.11.1	Which healthcare provider is responsible for screening and assessment of patients in accordance with laws, regulations, and licensure.		
GC.11.2	The scope and content of assessment by each discipline.		
GC.11.3	The scope and content of assessment in different care settings.		
GC.11.4	The time frame for completion of assessment by each discipline.		
GC.11.5	The frequency of reassessment of patients.		
Evidence of Compliance			
GC.11.EC.1	There is a written policy to define the scope and content of assessment/reassessment by each discipline and time frame for completion of the assessment/reassessment process.		
GC.11.EC.2	There is evidence of documented complete assessment of patients.		Health Record Review
GC.12	Each patient is screened for pain, nutritional status, functional status, risk of fall, psychosocial needs, and abuse.		

GC.12.1 The patients are appropriately referred for assessment and treatment if needed.

Evidence of Compliance

GC.12.EC.1 There is evidence of complete screening for nutritional status, social and psychological needs, risk of fall, abuse, pain frequency, pain location, and the type of pain experienced by the patient (e.g. sharp/dull), with documented referral if needed.

GC.13 **Patient allergies or prior adverse reactions are noted, documented, prominently, and consistently displayed in a specified area of the patient's record.**

Evidence of Compliance

GC.13.EC.1 There is evidence of documentation of patient allergy and/or prior adverse reactions in the health record.

Health Record Review

GC.14 **Nursing assessment and care plan are performed and recorded in the health record.**

Evidence of Compliance

GC.14.EC.1 There is evidence of implementation of nursing assessment policy (patient history, drug allergies, patient condition, psychosocial status, pain assessment nutritional status).

Health Record Review

GC.15 **On the first visit, the attending physician performs a comprehensive history and physical examination.**

Evidence of Compliance

GC.15.EC.1 There is a documented comprehensive history and physical examination by the attending physician on the patient's first visit.

Health Record Review

GC.16 **The history and physical examination with preliminary or final diagnosis are documented in the health record, including the problem list.**

Evidence of Compliance

GC.16.EC.1 There is evidence of documentation of history, physical examination, diagnosis, and problem list in the health record.

Health Record Review

GC.17 **The necessary diagnostic tests (laboratory and radiology) are performed on time to determine the diagnosis.**

Evidence of Compliance

GC.17.EC.1 Laboratory tests and radiological procedures results are documented in health record as appropriate.

Health Record Review

GC.18 **All patients are reassessed at appropriate intervals to determine:**

- GC.18.1 Response to treatment.
- GC.18.2 Compliance to treatment.
- GC.18.3 Complications and side effects.
- GC.18.4 Plan for continued treatment or completion of treatment.

Evidence of Compliance

GC.18.EC.1 There is evidence of reassessment of response to Health Record Review treatment, compliance to treatment, complications, side effects, and plan.

GC.19

A care plan is developed to meet the needs of each patient.

- GC.19.1 The care plan is developed by the attending physician, nurse, and other disciplines participating in care.
- GC.19.2 The care plan is based on the data from assessments and reassessments.
- GC.19.3 The care plan contains measurable goals (desired outcomes) and is documented in the patient's record.
- GC.19.4 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.
- GC.19.5 Care or treatment is provided in accordance with the plan.
- GC.19.6 The care provided for each patient is documented in the patient's record.

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GENERAL CLINICS

Evidence of Compliance

GC.19.EC.1 Plan of care is documented in the patient's medical Health Record Review record.
 GC.19.EC.2 There is evidence of plan of care revisions during Health Record Review subsequent visits.

GC.20

If a procedure is planned, then:

- GC.20.1 Procedures are explained to the patient.
- GC.20.2 Informed consent is taken.
- GC.20.3 Clear follow-up instructions are given.
- GC.20.4 Follow-up appointment is given.

Evidence of Compliance

GC.20.EC.1 There is documented patient education, signed Health Record consent, and follow-up appointment/instructions after Review any outpatient procedures.

GC.21 If any local anesthetic will be used, the physicians are expected to document:

- GC.21.1 Dose of the local anesthesia to be used.
- GC.21.2 The type of local anesthesia and its suitability to the patient's condition.

Evidence of Compliance

- GC.21.EC.1 There is documentation of anesthesia administered Health Record Review (type, dose, and appropriateness).

GC.22 Social services are provided to patients when needed by experienced and qualified individual(s) and includes:

- GC.22.1 Assessment of psychological, spiritual, and social needs of the patient so he/she can help the physician develop a plan of care for the patient.
- GC.22.2 Education and referral of the agencies available that can provide assistance to the patient.
- GC.22.3 Assessment and assistance with the financial issues/status of the patient.
- GC.22.4 Assessment of the patient's home situation and the patient's non-compliance/adherence to treatment.
- GC.22.5 Evaluation of the disability of the patient and reducing its impact.
- GC.22.6 Assessment of patient's religion and spiritual needs.

Evidence of Compliance

- GC.22.EC.1 Patients' psycho-social and spiritual needs are determined in collaboration with physicians and nurses.
- GC.22.EC.2 The social workers assess and assist the patients' Health Record Review needs GC.22.3 through GC.22.6.

GC.23 The physician informs and educates the patient about:

- GC.23.1 The nature of his/her illness.
- GC.23.2 Diagnosis.
- GC.23.3 Treatment plan.
- GC.23.4 Medications used, their side effects, and response to therapy.

Evidence of Compliance

- GC.23.EC.1 The physician educates the patient about elements in Health Record Review GC.23.1 through GC.23.4.

GC.24 Each patient's educational needs are assessed and documented in his/her health record by:

- GC.24.1 Assessing who will provide care at home (caregiver and/or patient).
- GC.24.2 Assessing learning needs.

- GC.24.3 Assessing literacy skills.
- GC.24.4 Assessing caregiver/patient's readiness and ability to learn.
- GC.24.5 Providing the caregiver/patient with educational materials that meet their learning skills (written, verbal, pictures, demonstration, etc.)
- GC.24.6 Assessing understanding of education provided by observation and feedback (verbal/return demonstration) from the caregiver/patient.
- GC.24.7 Documenting the assessment in the health record.

Evidence of Compliance

- GC.24.EC.1 There is a comprehensive documented patient education Health Record needs assessment that includes elements GC.24.1 Review through GC.24.6.

GC.25	The patient and/or family are given the following necessary education and information by healthcare professionals, as appropriate:
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- GC.25.1 Giving the patient appropriate information about his/her illness and complications that might happen.
- GC.25.2 Teaching the patient infection control practices, especially basic hand washing.
- GC.25.3 Explaining the necessary treatments and procedures and providing pamphlets or diagrams if available.
- GC.25.4 Explaining and teaching the appropriate use of the medical equipment or appliances (e.g. ventolin inhaler) with return demonstration.
- GC.25.5 Any surgical procedure needed, and its benefits and potential risks involved.
- GC.25.6 The medications used to treat an illness, the frequency of taking the medication, the side effects, and precautions.
- GC.25.7 X-ray procedures; their benefits and the potential risks involved.
- GC.25.8 Any restrictions of the diet and the reasons why the restrictions are necessary.
- GC.25.9 Explaining the conditions in which the patient needs to seek medical assistance.
- GC.25.10 Ensuring that patient has his/her follow-up clinic appointment.

Evidence of Compliance

- GC.25.EC.1 Patient/family education is documented in the health Health Record record.

GC.26	All patient education activities provided by primary healthcare center staff including the patient's response are documented in the patient's health record.
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Evidence of Compliance

GC.27 **There are guidelines for primary healthcare center staff (nurses, physicians, dietitians, etc.) on how to teach the patient/family that includes, but is not limited to:**

- GC.27.1 How to teach the patient in an easy language so the patient/family understand.
- GC.27.2 How to provide sufficient time to allow the patient to understand the information given to him.
- GC.27.3 How to provide enough time to interact with the patient/family.
- GC.27.4 How to use pamphlets, diagrams, models to practice on, or other teaching methods.
- GC.27.5 How to obtain feedback (repeating or demonstrating) from the patient/family to ensure understanding.

Evidence of Compliance

GC.27.EC.1 There are comprehensive written guidelines for health Document Review educators i.e. nurses, physicians, dietitians on GC.27.1 through GC.27.5.

GC.28 **Each patient/family receives education to help him/her give informed consent, participate in care processes, and understand any financial implications of care choices.**

Evidence of Compliance

GC.28.EC.1 There is patient/family involvement in the care provided Health Record to him/her (informed consent, care decision, financial Review implications of care choices).

GC.29 **At the end of service, the primary healthcare center identifies the post-service needs and support continuity of care.**

Evidence of Compliance

GC.29.EC.1 There is evidence of identification of patient post-service Health Record needs and support of continuity of care. Review

REFERRAL

Introduction

The Primary Healthcare Center may need to refer patients to other providers when their needs require care beyond the center's scope of service. To ensure continuity of care, the center should establish a well-defined system for referrals.

The center should identify facilities to which patients may be referred by type of service. Practice guidelines or protocols should indicate conditions requiring referrals.

The center's leaders are required to have agreements with facilities to which patients may be referred. All information related to the referral system should be made available to relevant staff.

To ensure optimal, efficient, and continuous care of patients among the different providers and facilities, a well-defined two-way reporting system between the center and referral facilities should be in place. This includes communicating all the relevant clinical details to the receiving facility for the benefit of the team receiving the patient. Records and forms for the referral process should be properly completed and maintained.

This chapter defines the requirements for the following areas:

- Policies and procedures
- Arrangements with referral facilities
- Staff familiarity
- Records, forms, and registries
- Follow-up of referred patients
- Performance measurement and improvement

Standards

RF.1 There is a referral system to appropriate providers when patients assessed needs require care beyond the primary healthcare center scope of services. The system should ensure continuity of care in a timely manner, and includes the following:

- RF.1.1 Policies and procedures to guide referrals.
- RF.1.2 Staff roles and responsibilities.
- RF.1.3 Approved forms and registries required for referral.
- RF.1.4 Policies and procedures to receive the results of referrals and to document them in the patient's record.

Evidence of Compliance

RF.1.EC.1 There is a manual for referral system that includes RF.1.1 Document Review through RF.1.4.

RF.2 The primary healthcare center has informal or formal arrangements with other institutions to accept patients for referral :

- RF.2.1 There is a list of referral facilities that includes the type of services.
- RF.2.2 There is an effective communication process to coordinate the referrals with the referral facilities.

Evidence of Compliance

RF.1.EC.2 There is a job description of staff assigned for the referral Personnel File system

RF.3 Necessary equipment for referral are available.

Evidence of Compliance

RF.3.EC.1 All referral necessary equipment are available, such as Observation telephones and faxes.

RF.4 All records and forms of the referral system are properly completed.

Evidence of Compliance

RF.4.EC.1 All referred cases are recorded in the referral registries.

Document Review

RF.4.EC.2 There is evidence that all records and forms are completed for the referred patients.

Health Record Review

RF.5 The process to receive results from the referral facility is implemented and includes follow-up of referred patients.

Evidence of Compliance

RF.5.EC.1 There is evidence of receiving and filing the referral feedback, with follow-up from the feedback when required.

Health Record Review

RF.6 The emergency cases are referred to the appropriate facility in a timely manner.

Evidence of Compliance

RF.6.EC.1 There is evidence that emergency cases are referred to the Health Record appropriate facility in an appropriate time frame. Review

RF.7 Receiving institutions receive the necessary information to provide care to the patient and this includes the following:

- RF.7.1 Patient diagnosis.
- RF.7.2 Brief summary of interventions.
- RF.7.3 Medication list and time of last dose(s) given.
- RF.7.4 Condition at the time of transfer.
- RF.7.5 Reason for transfer.
- RF.7.6 Copy of the patient's laboratory investigation and X-rays are sent with the patient to avoid further delay in treatment.
- RF.7.7 Referred specialty.
- RF.7.8 Approval for referral.
- RF.7.9 Time of referral.

Evidence of Compliance

RF.7.EC.1 There is a completed PHC referral form including RF.7.1 through RF.7.9. Health Record Review

RF.8 Transfers are done quickly and safely especially in emergency cases (e.g. trauma, or cardiac emergency) and the medical staff ensure that the patient's needs are met by:

- RF.8.1 Assigning a qualified physician or paramedic (as appropriate) to accompany the patient and handle any emergency that might occur during transfer.
- RF.8.2 Assigning a physician certified in BCLS (preferably ACLS) to accompany all critically ill patients or intubated patients.
- RF.8.3 Having adequate equipment and supplies on the ambulance.
- RF.8.4 The patient is continuously monitored by qualified staff during the transfer.

Evidence of Compliance

RF.8.EC.1 Critically ill patients are accompanied by qualified physician or paramedic (certified in BCLS - preferably ACLS). Document Review

RF.9 The primary healthcare center leaders identify indicators to monitor the appropriateness and timeliness of referrals.

- RF.9.1 The results of monitoring are communicated to concerned staff and used for performance improvement.

Evidence of Compliance

RF.9.EC.1 There are written indicators to monitor the appropriateness and timeliness of referral.

Document Review

STANDARDS
REFERRAL

COMMUNITY PARTICIPATION

Introduction

In order to provide optimum efficient services for the community served by the center, the center should identify relevant community leaders and establish partnership with them. The center leaders should work together with the community representatives to assess the community needs. This group should collaboratively plan, implement, and evaluate the services provided to satisfy those needs. This strategy aims to use the available resources efficiently and benefit the community at large.

This chapter defines standards for community participation:

- The required structure (committee)
- Identification of community representatives
- Community needs assessment
- Planned and center-community approach

Standards

CP.1 The primary healthcare center leaders support and promote community participation by assessing and planning the community healthcare needs.

Evidence of Compliance

CP.1.EC.1 There is evidence of PHC leadership support of community Leadership participation, such as participation in community activities and Interview attendance of community health committee meetings.

CP.2 The primary healthcare center leaders identify community representatives and resources related to the primary healthcare center scope of services.

Evidence of Compliance

CP.2.EC.1 There is a written list of community representatives and resources related to the PHC scope of services. Document Review

CP.3 There is a designated committee(s) to coordinate community involvement.

Evidence of Compliance

CP.3.EC.1 There are terms of reference of Community Health Committee(s). Document Review

CP.4 The membership of the committee includes representatives from relevant sectors in the community as well as the primary healthcare center leaders.

Evidence of Compliance

CP.4.EC.1 Terms of reference of Community Health Committee(s) identify representatives from relevant sectors in the community and PHC leaders. Document Review

CP.5 The committee meets regularly in minuted formal meetings to discuss all aspects of community participation and services provided to the community.

Evidence of Compliance

CP.5.EC.1 The committee meets regularly. The meeting minutes reflect discussion of community participation and services provided to the community. Document Review

CP.6 Functions of the committee should include, but not limited to, the following:

CP.6.1 Identifies and prioritizes community health needs.

CP.6.2 Assesses environmental and health problems.

CP.6.3 Collaboratively designs and implements plans.

CP.6.4 Reviews and evaluates plans and meetings recommendations for progress.

CP.6.5 Facilitates community participation in conduction of immunization campaigns, health surveys, field studies, community education, and other health events such as Health Days.

Evidence of Compliance

CP.6.EC.1 The committee terms of reference reflect relevant functions from Document Review CP.6.1 to CP.6.5.

HEALTH PROMOTION AND EDUCATION

Introduction

The Primary Healthcare Center is responsible for ensuring that health promotion and education is not only provided to an individual patient and his/her family but also to the community at large. In this regard, the leaders are required to collaborate with representatives from relevant governmental and non-governmental organizations. This partnership should focus on identification of the health promotion and education needs and development of related plans. The plans should be directed towards the health priorities of the community. Together with community participation, the plans should be regularly updated to reflect current needs.

This chapter outlines the following processes and activities participation:

- Community participation
- Health promotion and education plan
- Relevant health promotion and education programs
- Staff competency
- Performance measurement and improvement

Standards

HPE.1 The primary healthcare center leadership supports the implementation of health promotion and education concepts.

Evidence of Compliance

HPE.1.EC.1 There is evidence of leadership support in health promotion and education concepts. Leadership Interview

HPE.2 The primary healthcare center leaders develop the health promotion and education plans and programs with assistance from professionals and effective community participation.

Evidence of Compliance

HPE.2.EC.1 There are written health promotion and education plans and programs. Document Review

HPE.3 The primary healthcare center has approved and implemented health promotion and education plans that:

- HPE.3.1 Identify the health needs and priorities of the individuals and community.
- HPE.3.2 Identify behaviors, social and environmental factors that positively or negatively affect the health of individual and community.
- HPE.3.3 Depend on the health priorities of the catchment area of the PHC and deal with habits, activities, and concerns of the target groups.
- HPE.3.4 Are updated and evidence based.
- HPE.3.5 Are culturally accepted by the community
- HPE.3.6 Identify roles and responsibilities of the following in health promotion and education activities:
 - HPE.3.6.1 PHC staff.
 - HPE.3.6.2 Governmental, private, and nongovernmental organizations.

Evidence of Compliance

HPE.3.EC.1 There are written health promotion and education plans that include elements in HPE 3.1 through HPE 3.6. Document Review

HPE.3.EC.2 All staff understand their role in health promotion and education Interview plans.

HPE.4 The primary healthcare center leaders and staff collaborate with relevant sectors to implement the health promotion and education programs, and this includes but not limited to:

- HPE.4.1 Healthy nutrition program that includes at least:
 - HPE.4.1.1 Encouraging healthy-balanced nutrition.
 - HPE.4.1.2 Discouraging the intake of soft drinks and foods that affect oral and dental health in schools.

HPE.4.1.3 Encouraging the introduction of milk as an essential component in the school nutrition.

HPE.4.1.4 Ensuring safe food provision.

HPE.4.1.5 Risks of obesity.

HPE.4.2 Encouraging safe driving practices.

HPE.4.3 Education about the importance of premarital counseling and examination.

HPE.4.4 Education about the importance of physical exercise.

HPE.4.5 Combating smoking and drugs.

HPE.4.6 Combating sexually transmitted infections.

Evidence of Compliance

HPE.4.EC.1 There is a written healthy nutrition program that includes at least: Document Review
HPE.4.1.1 through HPE.4.1.5.

HPE.4.EC.2 There is evidence of collaborative educational activities with Interview relevant sectors that include at least: safe driving practices, importance of premarital counseling and examination, physical exercise, combating smoking, drugs, and sexually transmitted infections (i.e. lectures, publications, brochures ...).

HPE.5 **The primary healthcare center leaders encourage the community participation in the implementation of health promotion and education programs, including at least:**

HPE.5.1 School teachers.

HPE.5.2 Food handlers.

HPE.5.3 Grocery owners.

Evidence of Compliance

HPE.5.EC.1 There is evidence of participation of teachers, food handlers, and grocery owners in the implementation of programs related to health promotion and education (meeting minutes, recommendations, and educational materials). Document Review

HPE.6 **Health promotion program includes periodic health assessment for age specific target population and:**

HPE.6.1 Based on updated scientific guidelines.

HPE.6.2 Documented in the health record.

Evidence of Compliance

HPE.6.EC.1 There is a written, updated, and evidence based periodic health assessment program. Document Review

HPE.6.EC.2 The periodic assessment activities are documented in the health record. Health Record Review

HPE.7 The primary healthcare center provides information on locations in its catchment area that support health promotion programs including at least the following:

- HPE.7.1 Places available for physical exercise and walking.
- HPE.7.2 Safe food places.

Evidence of Compliance

- HPE.7.EC.1 There is a list of locations/places that support health promotion Document Review programs (physical exercise and safe food).

HPE.8 The primary healthcare center leaders are working to update the knowledge and competencies of service providers in the field of health promotion and education, that includes at least:

- HPE.8.1 Facilitating access to international updates in health promotion and education field.
- HPE.8.2 Developing and communicating the training and education materials.

Evidence of Compliance

- HPE.8.EC.1 Health promotion service providers are competent and knowledgeable in the field. Interview

HPE.9 The primary healthcare center leaders identify indicators to monitor the effectiveness of the health promotion and education programs and use data for performance improvement.

Evidence of Compliance

- HPE.9.EC.1 The leaders identify performance indicators that are used for Document Review performance improvement.

HPE.10 The primary healthcare center has appropriate places to carry out group health education in line with community values and traditions.

Evidence of Compliance

- HPE.10.EC.1 There are appropriate places to carry out group health education. Observation

HPE.11 The primary healthcare center has the necessary audio-visual media and publications to implement the health education plan.

Evidence of Compliance

- HPE.11.EC.1 There are audio-visual media and publications available. Observation

MATERNAL AND CHILD HEALTH

Introduction

The standards in the Maternal and Child Health (MCH) chapter center on the health needs of women of child-bearing years and their infants. The center's leaders should establish preventive as well as curative care processes to effectively satisfy those needs. These care processes may occur before conception, during pregnancy, and after delivery. Additionally, achieving high quality MCH outcomes is highly dependent on effective education for those served, concerning healthy behaviors and preventive measures.

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

- Policies and procedures manual
- Documentation (e.g., forms and registries)
- Staffing and other required resources
- Patient education during pregnancy and after delivery
- Performance indicators and surveillance system

Standards

MCH.1

The primary healthcare center has a Maternal and Child Health (MCH) program manual that:

- MCH.1.1 Is updated, available and well known to concerned staff.
- MCH.1.2 Includes policies and procedure for MCH program.
- MCH.1.3 Includes roles and responsibilities of the concerned staff.
- MCH.1.4 Includes MCH cards, forms, and registries required.
- MCH.1.5 Includes a process to follow-up the patients.
- MCH.1.6 Includes a system for identification and management of high risk cases.
- MCH.1.7 Includes indicators for performance monitoring, evaluation, and improvement.

Evidence of Compliance

MCH.1.EC.1 The manual is available and well known to the staff. Interview

MCH.2

There is adequate and qualified staff to manage the program.

Evidence of Compliance

MCH.2.EC.1 MCH staff are properly qualified and adequate to manage Personnel File the program.

MCH.3

The necessary tools and equipment are available.

Evidence of Compliance

MCH.3.EC.1 All MCH necessary tools and equipment are available in Observation adequate amounts.

MCH.4

All MCH related medications and vaccines are available.

Evidence of Compliance

MCH.4.EC.1 All MCH related medications and vaccines are available in Observation adequate amounts.

MCH.5

There is a well structured education plan for the pregnant women, that includes at least:

- MCH.5.1 Healthy nutrition.
- MCH.5.2 Adherence to follow-up visits' schedule.
- MCH.5.3 Breast care and breastfeeding.
- MCH.5.4 Danger signs during pregnancy.
- MCH.5.5 Personal hygiene.
- MCH.5.6 Oral and dental care.
- MCH.5.7 Use of medications.
- MCH.5.8 Adherence to vaccination schedule.

- MCH.5.9 Postpartum follow-up care.
- MCH.5.10 Taking care of newborn babies.
- MCH.5.11 Abdominal and pelvic-floor exercise.

Evidence of Compliance

- MCH.5.EC.1 Pregnant women education that includes MCH.5.1 Health Record through MCH.5.11 is documented in the health record. Review

MCH.6 The mother receives proper education about:

- MCH.6.1 Proper child nutrition.
- MCH.6.2 The vaccination schedule of the child.
- MCH.6.3 The importance of growth monitoring.
- MCH.6.4 Child care.
- MCH.6.5 Breastfeeding.

Evidence of Compliance

- MCH.6.EC.1 The mother education that includes MCH 6.1 through MCH 6.5 is documented in the health record. Health Record
Review
- MCH.6.EC.2 Staff are aware about how to deal with breastfeeding problems. Interview

MCH.7 The MCH program is implemented in the primary healthcare center.

Evidence of Compliance

- MCH.7.EC.1 There is evidence of implementation of the MCH program. Interview

MCH.8 The primary healthcare center has a surveillance system for the MCH program.

Evidence of Compliance

- MCH.8.EC.1 There is a surveillance system for recording MCH related information. Document Review

IMMUNIZATION

Introduction

Immunization is considered one of the most powerful and cost-effective health interventions in Primary Healthcare. Immunizing populations is a proven program for controlling and even eradicating potentially serious infectious diseases. To reduce morbidity and mortality, the center should ensure a high coverage level of immunizations against target diseases. This is particularly important among infants, children, and other specific populations. How a center maintains a cold chain and has a response plan for cold chain break, determines the safety and effectiveness of the immunization program.

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

- Policies and procedures manual
- Documentation (e.g., forms and registries)
- Staffing and other required resources
- Mother and significant others education
- Performance indicators and surveillance system

Standards

IM.1 The primary healthcare center has an immunization program (IM) manual that:

- IM.1.1 Is updated, available, and well known to concerned staff.
- IM.1.2 Includes policies and procedure for the immunization program.
- IM.1.3 Includes the roles and responsibilities of the concerned staff.
- IM.1.4 Includes vaccination cards, forms and registries required for the immunization program.
- IM.1.5 Includes a process for patient follow-up.
- IM.1.6 Includes a mechanism for follow-up of the cold chain and cold chain break Response Plan.
- IM.1.7 Includes a system for Identification and management of high risk cases.
- IM.1.8 Includes indicators for performance monitoring, evaluation, and improvement.

Evidence of Compliance

- IM.1.EC.1 There is an available, updated manual for the IM program that Interview includes IM.1.2 through IM.1.8, and it is well known to the staff.

IM.2 There is adequate and qualified staff to manage the program.

Evidence of Compliance

- IM.2.EC.1 IM staff are properly qualified and adequate to manage the Personnel File program.

IM.3 The necessary tools and equipment are available.

Evidence of Compliance

- IM.3.EC.1 All IM necessary tools and equipment are available in adequate Observation amounts.

IM.4 All IM related medications and vaccines are available.

Evidence of Compliance

- IM.4.EC.1 All IM related medications and vaccines are available in adequate Observation amounts.

IM.5 The primary healthcare center identifies target populations for immunization that includes, but not limited to:

- IM.5.1 Travelers
- IM.5.2 Pregnant women
- IM.5.3 Elderly
- IM.5.4 Pilgrims

Evidence of Compliance

IM.5.EC.1 There is a written list of target populations for immunization that includes, but not limited IM.5.1 through IM.5.4. Document Review

IM.6 The mother or caregiver receives proper education about:

- IM.6.1 Adherence to immunization schedule
- IM.6.3 Child care post-immunization
- IM.6.2 Side effects of immunization

Evidence of Compliance

IM.6.EC.1 The mother education is documented in the health record. Health Record Review

IM.7 The IM program is implemented in the primary healthcare center.**Evidence of Compliance**

IM.7.EC.1 There is evidence of implementation of the IM program. Interview

IM.8 The primary healthcare center has a surveillance system for the IM program**Evidence of Compliance**

IM.8.EC.1 There is a surveillance system for recording IM related information. Document Review

NON COMMUNICABLE DISEASES

Introduction

Non communicable diseases are increasingly recognized as a major cause of morbidity and mortality. Primary care has a key role to play in chronic disease management. Chronic disease management has an impact prevent crises and deterioration, and enabling people living with chronic conditions to attain the best possible quality of life. This chapter aims at reducing the burden of non communicable diseases (NCDs) through a sound system of identification, management, education, as well as surveillance of these diseases.

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

- Policies and procedures manual
- Documentation (e.g., forms and registries)
- Staffing and other required resources
- Patient and family education
- Performance indicators and surveillance system

Standards

NCD.1 The primary healthcare center has a Non Communicable Diseases (NCD) program manual that:

- NCD.1.1 Is updated, available, and well known to concerned staff.
- NCD.1.2 Identifies a list of noncommunicable diseases that include at least (diabetes, hypertension, bronchial asthma, cardiovascular disease, cancer).
- NCD.1.3 Includes the policies and procedure for the NCD program.
- NCD.1.4 Includes the roles and responsibilities of the concerned staff.
- NCD.1.5 Includes the forms and registries required for the NCD program.
- NCD.1.6 Includes a system for patient follow-up.
- NCD.1.7 Includes a system for Identification and management of high risk cases.
- NCD.1.8 Includes indicators for performance monitoring, evaluation, and improvement.

Evidence of Compliance

- NCD.1.EC.1 There is an available manual for the NCD program that Interview includes NCD.1.2 through NCD.1.8, and it is well known to staff.

NCD.2 There is adequate and qualified staff to manage the NCD program who provide, not limited to, the following:

- NCD.2.1 Nutritional counseling.
- NCD.2.2 Health and diabetic education.
- NCD.2.3 Diabetic foot care.
- NCD.2.4 Social and psychological services.

STANDARDS
NON COMMUNICABLE DISEASE

Evidence of Compliance

- NCD.2.EC.1 The NCD staff are adequate and properly qualified by Personnel File education and/or training to provide NCD.2.1 through NCD.2.4.

NCD.3 The necessary tools and equipment are available.

Evidence of Compliance

- NCD.3.EC.1 All NCD necessary tools and equipment are available in Observation adequate amounts.

NCD.4 All NCD drugs are available.

Evidence of Compliance

- NCD.4.EC.1 All NCD drugs are available in adequate amounts. Observation

NCD.5 There is a well structured education plan for the patients and family that includes at least:

- NCD.5.1 Information about the diseases.
- NCD.5.2 Lifestyles modification.
- NCD.5.3 Periodic follow-up visits.
- NCD.5.4 Frequency of taking medication, the side effects, and precautions.
- NCD.5.5 Complications of the disease.

Evidence of Compliance

- NCD.5.EC.1 Patient and family education is documented in the health Health Record Review record.

NCD.6 The NCD program is implemented in the primary healthcare center.

- NCD.6.EC.1 There is evidence of implementation of the NCD program. Interview

NCD.7 The primary healthcare center has a surveillance system for the NCD program.

- NCD.7.EC.1 There is a surveillance system for recording NCD related Document Review information.

GERIATRIC CARE

Introduction

With rapid changes in the economic, social, and demographic situation, people are living longer. Ageing may be considered to be the loss of adaptability of an individual with time. Older people are the main users of health and social care services and their high morbidity rates, different patterns of disease presentation, slower response to treatment, and requirements for social support, call for special care processes. These care processes need to meet the health care needs of the geriatric population focusing on health promotion and the prevention and treatment of disease and disability in the elderly. Primary Healthcare Centers should design effective and safe care processes unique to this high risk patient population.

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

- Policies and procedures manual
- Documentation (e.g., forms and registries)
- Staffing and other required resources
- Patient and family education
- Performance indicators and surveillance system

Standards

GRC.1 The primary healthcare center has a Geriatric Care (GRC) program manual that:

- GRC.1.1 Is updated, available, and well known to concerned staff.
- GRC.1.2 Includes policies and procedures for geriatric care and home visits.
- GRC.1.3 Includes forms and registries required.
- GRC.1.4 Includes roles and responsibilities of the concerned staff.
- GRC.1.5 Includes a list of common geriatric health problems.
- GRC.1.6 Includes a process for patient follow-up.
- GRC.1.7 Includes policies for management of high risk cases.
- GRC.1.8 Includes indicators for performance monitoring, evaluation, and improvement.

Evidence of Compliance

GRC.1.EC.1 There is evidence of an updated manual for the GRC Interview program (GRC.1.2 through GRC.1.8) that is available and well known to the staff.

GRC.2 There is adequate and qualified staff to provide the following:

- GRC.2.1 Nutritional counseling.
- GRC.2.2 Health education.
- GRC.2.3 Psychosocial including spiritual services.
- GRC.2.4 Palliative services.

Evidence of Compliance

GRC.2.EC.1 The GRC staff are adequate and properly qualified by Personnel File education and/or training to provide GRC.2.1 through GRC.2.4.

GRC.3 The necessary tools and equipment are available.
Evidence of Compliance

GRC.3.EC.1 All GRC necessary tools and equipment are available in Observation adequate amounts.

GRC.4 All GRC related medications and vaccines are available.
Evidence of Compliance

GRC.4.EC.1 All GRC related medications and vaccines are available in Observation adequate amounts.

GRC.5 There is a well structured education plan for the patients and family that includes at least:

- GRC.5.1 Appropriate diet.
- GRC.5.2 Information about common diseases encountered in elderly.
- GRC.5.3 Adherence to follow-up visits.
- GRC.5.4 Frequency of taking medication, the side effects, and precautions.
- GRC.5.5 Physical activity.
- GRC.5.6 Follow-up instructions.
- GRC.5.7 Healthy behavior and avoiding harmful habits.
- GRC.5.8 Overcoming the problems related to memory, vision, hearing, mouth, and teeth problems.
- GRC.5.9 Home safety.

Evidence of Compliance

- GRC.5.EC.1 Patient and family education that includes GRC.5.1 Health Record through GRC.5.9 is documented in the health record. Review

GRC.6**The GRC program is implemented in the primary healthcare center.****STANDARDS**
GERIATRIC CARE**Evidence of Compliance**

- GRC.6.EC.1 There is evidence of implementation of the GRC Interview program.

GRC.7**The primary healthcare center has a surveillance system for GRC program.****Evidence of Compliance**

- GRC.7.EC.1 There is a surveillance system for recording GRC Document Review related information.

COMMUNICABLE DISEASES

Introduction

This chapter focuses on the obligation of center leaders to manage communicable diseases (CD) of the target population. The obligation is twofold, demanding that the center follows appropriate processes not only to control but also to prevent communicable diseases. Additionally, the center should have processes for identification, management, and follow-up of patients and contacts.

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

- Policies and procedures manual
- Documentation (e.g., forms and registries)
- Staffing and other required resources
- Patient and family education
- Performance indicators and surveillance system

Standards

CD.1 The primary healthcare center has a Communicable Disease (CD) program manual that:

- CD.1.1 Is updated, available, and well known to concerned staff.
- CD.1.2 Identifies a list of common communicable diseases, such as hepatitis, chicken pox, mumps, whooping cough.
- CD.1.3 Includes policies and procedures for CD.
- CD.1.4 Identifies roles and responsibilities of the concerned staff.
- CD.1.5 Includes forms and registries required for CD activities.
- CD.1.6 Includes a system for following up the cases and contacts during the period of epidemiological monitoring.
- CD.1.7 Includes identification and management of high risk cases.
- CD.1.8 Includes indicators for performance monitoring, evaluation and improvement.

Evidence of Compliance

- CD.1.EC.1 There is an available updated manual for the CD program that Interview includes CD.1.2 through CD.1.8, and it is well known to the staff.

CD.2 There is adequate and qualified staff to manage the program.

Evidence of Compliance

- CD.2.EC.1 CD staff are adequate and properly qualified by education and/or Personnel File training.

CD.3 The necessary tools and equipment are available.

Evidence of Compliance

- CD.3.EC.1 All CD necessary tools and equipment are available in adequate Observation amounts.

CD.4 All CD medications, vaccines, and immunoglobulin are available.

Evidence of Compliance

- CD.4.EC.1 All CD medications, vaccines, and immunoglobulin are available in Observation adequate amounts.

CD.5 There is a well-structured education plan for the patients and caregivers that includes at least:

- CD.5.1 Information about the disease.
- CD.5.2 Modes of transmission and methods of prevention.
- CD.5.3 Frequency of taking medication, the side effects, and precautions.

- CD.5.4 Healthy behavior.
- CD.5.5 Appropriate food and water handling.
- CD.5.6 Follow-up instructions.

Evidence of Compliance

CD.5.EC.1 Patient education is documented in the health record.

Health Record
Review

CD.6 The CD program is implemented in the primary healthcare center.**Evidence of Compliance**

CD.6.EC.1 There is evidence of implementation of the CD program.

Interview

CD.7 The primary healthcare center has a surveillance system for the CD program.**Evidence of Compliance**

CD.7.EC.1 There is a surveillance system for recording CD related information.

Document
Review

DENTAL AND ORAL HEALTH

Introduction

The primary function of the dental and oral health is both curative and prevention services. Policies and procedures must be clearly identified outlining both services. Patients presenting with dental conditions should have proper assessment and plan of care. Properly documented records should be maintained for all patients. The leaders should ensure having adequate equipment, supplies, and medications required for proper care. The center is required to have educational plans targeting vulnerable populations.

To support patient safety, the center should design and implement strict infection control practices. The center should provide curative care in addition to prevention services.

This chapter defines the requirements for the following areas:

- Policies and procedures
- Staffing
- Equipment, supplies, and medications
- Records, forms, and registries
- Population education
- Surveillance

Standards

DOH.1 The primary healthcare center has a Dental and Oral Health (DOH) program manual that:

- DOH.1.1 Identifies the scope and goals of service of the DOH program.
- DOH.1.2 Is updated, available, and well known to concerned staff.
- DOH.1.3 Includes policies and procedures for dental and oral health services.
- DOH.1.4 Identifies roles and responsibilities of the concerned staff.
- DOH.1.5 Identifies a list of most prevalent dental and oral health problems and diseases.
- DOH.1.6 Includes the forms and registries required for the dental and oral health activities.
- DOH.1.7 Includes a process for treatment and follow-up of patients.
- DOH.1.8 Includes identification and management of high risk cases.
- DOH.1.9 Includes indicators for performance monitoring, evaluation, and improvement.

Evidence of Compliance

DOH.1.EC.1 There is evidence of an updated manual for the DOH program Interview (DOH.1.3 through DOH.1.9) that is available and well known to the staff.

DOH.2 There is adequate and qualified staff to perform the required dental and oral health services including:

- DOH.2.1 Qualified dentist in-charge of the dental and oral primary healthcare services.
- DOH.2.2 Qualified dental assistant per dental and oral healthcare clinic.
- DOH.2.3 Qualified dental hygienist for every PHC where dental and oral health clinic(s) is available or in coordination with other facilities.

Evidence of Compliance

DOH.2.EC.1 DOH staff are adequate and properly qualified (dentist, dental Personnel File assistant, and dental hygienist).

DOH.3 The necessary tools, equipment, and materials are available.
Evidence of Compliance

DOH.3.EC.1 All DOH necessary tools, equipment, and materials are available in Observation adequate amounts.

DOH.4 All dental and oral health related medications are available.
Evidence of Compliance

DOH.4.EC.1 All dental and oral health related medications are available in Observation adequate amounts.

DOH.5 There is a well structured education plan for dental and oral health for target groups including at least:

- DOH.5.1 Dental prevention program for the pre-school children and school students.
- DOH.5.2 Dental prevention program for patients with non communicable diseases.
- DOH.5.3 Dental prevention program for pregnant women.
- DOH.5.4 An educational program for patients with special needs.

Evidence of Compliance

DOH.5.EC.1 Education of the target groups (DOH.5.1 to DOH.5.4) is Health Record documented in the health record.

DOH.6 The DOH program is implemented in the primary healthcare center and includes at least:

- DOH.6.1 Comprehensive history, extra/intra-oral examination, and preliminary investigations performed on the first visit for all patients registered in the dental clinic.
- DOH.6.2 Risk factors are listed for each patient.
- DOH.6.3 Medically compromised cases are clearly noted.
- DOH.6.4 Consent is obtained for all high risk dental procedures.
- DOH.6.5 The need for antibiotic prophylaxis is assessed for each patient in the dental clinic.
- DOH.6.6 Oral hygiene instructions.
- DOH.6.7 Management and control of dental caries, periodontal diseases, and oral soft/hard tissue diseases.

Evidence of Compliance

DOH.6.EC.1 There is evidence of program implementation that includes Health Record Review DOH.6.1 through DOH.6.7.

DOH.7 Each patient has a written dental record and this includes, but not limited to:

- DOH.7.1 History of allergic reactions.
- DOH.7.2 Any chronic illnesses, e.g., congenital heart disease, rheumatic heart diseases, and diabetes.
- DOH.7.3 Any hematological illnesses, e.g., hemophilia.
- DOH.7.4 Chief complaints of patients.
- DOH.7.5 Treatment plan.
- DOH.7.6 X-rays needed.
- DOH.7.7 Dose of local anesthesia, the tooth treated, and the material used.

Evidence of Compliance

DOH.7.EC.1 There is a comprehensive dental record for dental patients that include DOH.7.1 through DOH.7.7.

DOH.8 The primary healthcare center implements the infection control policies and guidelines in the dental clinic that includes, but not limited to:

- DOH.8.1 Using gloves and masks for each case.

- DOH.8.2 Wearing protective eyewear.
- DOH.8.3 Providing eye protection for patients.
- DOH.8.4 Wearing gowns in the dental suite.
- DOH.8.5 Sterilizing all reusable instruments after each patient according to a written protocol.
- DOH.8.6 Cleaning all items in the ultrasonic unit.
- DOH.8.7 Sterilizing all hand pieces, nose cones between patients.
- DOH.8.8 A written protocol for sterilizing the instrument that indicates time and method of sterilization.
- DOH.8.9 Cleaning surfaces of working area between patients.

Evidence of Compliance

- DOH.8.EC.1 There is a written protocol for sterilizing the instrument and Document Review indicates time and method of sterilization.
- DOH.8.EC.2 There is implementation of infection control guidelines that Observation includes DOH.8.1 through DOH.8.9.

DOH.9 The primary healthcare center has a surveillance system for dental and oral diseases.**Evidence of Compliance**

- DOH.9.EC.1 There is a surveillance system for recording DOH related Document information.

EMERGENCY SERVICES

Introduction

To meet the needs of the patient population being served, the Primary Healthcare Center may have to handle emergency cases that require immediate examination and treatment. The center must provide emergency services by establishing an emergency room. The Emergency Services (ES) should be organized to provide optimum care for patients in a safe, appropriate, efficient, effective, responsive, and caring manner and, directed and coordinated with other services in the community.

A reliable and consistent triage system performed by qualified staff should be established and used to assess all patients on arrival. It is essential that the patient's complaints are assessed and the appropriate treatment arranged, taking into account the degree of urgency and clinical condition of the patient. For all patients, documentation should be detailed, accurate, professional, and maintained.

Where the center does not have the facilities or medical skills to treat the emergency patient, arrangements must be made for safe transfer to an appropriate treatment facility after performing appropriate and basic resuscitation or stabilization. When arranging for the patient to be transferred, communication with the receiving facility should be established. The patient must be accompanied by an individual(s) with appropriate competencies. All relevant clinical details must be documented and communicated to the receiving facility for the benefit of the team receiving the patient.

This chapter addresses the following:

- Physical structure
- Staffing
- Equipment and supplies
- Triage
- Patient care
- Cardiopulmonary resuscitation
- Patient transfer
- Ambulance and transportation
- Community education

Standards

ES.1 The primary healthcare center has a manual for Emergency Services (ES) that:

- ES.1.1 Is updated, available, and well known to concerned staff
- ES.1.2 Identifies a list of common injuries, accidents, and emergency cases.
- ES.1.3 Includes forms and registries required for ES.
- ES.1.4 Identifies roles and responsibilities of the concerned staff.
- ES.1.5 Includes policies and procedures for ES.
- ES.1.6 Includes a system for following up the cases.
- ES.1.7 Includes identification and management of cases that need resuscitation.
- ES.1.8 Includes indicators for monitoring, evaluation, and improvement of performance.

Evidence of Compliance

- ES.1.EC.1 There is an available updated manual for the ES program that Interview includes ES.1.2 through ES.1.8, and it is well known to the staff.

ES.2 Emergency services cover twenty-four (24) hours.
Evidence of Compliance

- ES.2.EC.1 There is a process in place for covering emergency services outside Interview working hours.

ES.3 There is adequate and qualified/trained staff that include, but not limited to:

- ES.3.1 Availability of a qualified healthcare team.
- ES.3.2 A qualified physician is present with at least two (2) years experience.
- ES.3.3 All physicians and nurses are certified in Basic Cardiac Life Support (BCLS) and preferably Advanced Cardiac Life Support (ACLS), and Advanced Trauma Life Support (ATLS).

Evidence of Compliance

- ES.3.EC.1 ES staff are adequate and properly qualified, with a valid Personnel File certificate(s) of Basic Cardiac Life Support (BCLS) and preferably Advanced Cardiac Life Support (ACLS), and Advanced Trauma Life Support (ATLS).
- ES.3.EC.2 There is a qualified and experienced (at least 2 years) physician. Personnel File

ES.4 The primary healthcare center has an equipped room to manage common injuries, accidents, and emergency cases.
Evidence of Compliance

- ES.4.EC.1 There is an equipped room to deal with common injuries, Observation accidents, and emergency cases.

ES.5 The primary healthcare center has an established policy on how to triage patients and prioritize their needs.

Evidence of Compliance

ES.5.EC.1 There is a written policy and procedures on patient triage and Document prioritization. Review

ES.6 The emergency room (ER) has the following necessary equipment and drugs:

- ES.6.1 Crash cart.
- ES.6.2 ECG machine
- ES.6.3 Monitor.
- ES.6.4 Defibrillator.
- ES.6.5 Pulse oximetry.
- ES.6.6 Chest tubes of different sizes.
- ES.6.7 Intubation equipment for adult.
- ES.6.8 Intubation equipment for children.
- ES.6.9 Emergency and CPR drugs.

Evidence of Compliance

ES.6.EC.1 All essential emergency room equipment are available and includes Observation but not limited to ES.6.1 to ES.6.9.

ES.7 There is an emergency assessment sheet/form that is documented for every patient presenting for care in the ER and includes:

- ES.7.1 Time of arrival and means of arrival.
- ES.7.2 Vital signs.
- ES.7.3 History of illness.
- ES.7.4 Allergies to medications, environment, foods.
- ES.7.5 Physical assessment/reassessment.
- ES.7.6 Suspected diagnosis.
- ES.7.7 Any investigations requested.
- ES.7.8 Treatment given.
- ES.7.9 Time of referral and/or discharge from PHC.
- ES.7.10 Documentation of patient condition at time of discharge or referral to other facility.

Evidence of Compliance

ES.7.EC.1 There is full documentation of emergency assessment on a health record sheet/form that includes ES.7.1 through ES.7.10. Review

ES.8 Medical bags in the ER are updated and checked daily and after each use (the medical bags contain all of the essential medications).

Evidence of Compliance

ES.8.EC.1 There is evidence of regular checks of readiness of ER medical bags Observation (at least daily and after each use).

ES.9 The primary healthcare center has a health education plan on common accidents and emergencies and the importance of 1st aid measures.

Evidence of Compliance

ES.9.EC.1 There is a written health education plan about common accidents Document and emergencies and the importance of 1st aid measures. Review

ES.10 The primary healthcare center has the means for emergency transport (ambulance / Red Crescent).

Evidence of Compliance

ES.10.EC.1 There is ambulance / Red Crescent available. Observation

ES.11 Ambulances are checked daily and are equipped with the following:

- ES.11.1 Oxygen supply.
- ES.11.2 Intubation set.
- ES.11.3 C-spine cuff.
- ES.11.4 Spinal board.
- ES.11.5 Suction equipment.

Evidence of Compliance

ES.11.EC.1 There is evidence of daily checks of essential ambulance equipment Observation including, oxygen, intubation set, C-spine cuff, spinal board, and suction machine (log book).

ES.12 The crash cart is regularly monitored and checked for the following:

- ES.12.1 Functioning of cardio respiratory equipment.
- ES.12.2 Defibrillator battery, full oxygen tank, suction machine, medications, ambu bags with reservoirs, drug calculation charts, ET tube (for neonates, pediatrics, and adults), sharp box. Crash cart is locked with lock number tag.
- ES.12.3 Routine (minimum monthly) checking of all medications and equipment in the crash cart.

Evidence of Compliance

ES.12.EC.1 There are written, multidisciplinary policy and procedure of Document restocking of crash cart medications and equipment. Review

ES.12.EC.2 There are routine (minimum monthly) checking of all medications Observation and equipment in the crash cart.

ES.13 The roles and responsibilities of the following staff handling CPR are outlined in policy:

- ES.13.1 The staff who first discover the code.

ES.13.2 The code team leader.

ES.13.3 The code team members.

Evidence of Compliance

ES.13.EC.1 There is a CPR policy that outlines the roles and responsibilities of the staff during codes. Document Review

ES.14 The primary healthcare center has a surveillance system for ES.**Evidence of Compliance**

ES.14.EC.1 There is a surveillance system for recording ES related information. Document Review

ENVIRONMENTAL HEALTH

Introduction

Environmental health of the community positively impacts the health of the population served. The leaders should perform environmental risk assessment and design plans accordingly. The environmental risks should be integrated in a comprehensive database and updated health map. The primary healthcare center in collaboration with relevant community sectors is required to provide periodic environmental rounds and appropriate prevention measures for common conditions that, if not properly managed, may negatively affect the health of the population. This preventive approach is expected to support the general health of the community.

This chapter outlines the activities and processes required for environmental health:

- Policies and procedures
- Staffing
- Equipment and medication
- Periodic rounds
- Surveillance

Standards

EH.1 The primary healthcare center has a manual for Environmental Health (EH) program that:

- EH.1.1 Is updated, available, and well known to concerned staff.
- EH.1.2 Includes the EH cards, forms, and registries required for EH
- EH.1.3 Includes the roles and responsibilities of the concerned staff.
- EH.1.4 Includes the policies and procedure for EH program in the field of:
 - EH.1.4.1 Monitoring of food, restaurants, and food poisoning cases.
 - EH.1.4.2 Monitoring of drinking water.
 - EH.1.4.3 Monitoring of the workshops and factories.
 - EH.1.4.4 Disposal of garbage and waste.
 - EH.1.4.5 Monitoring of animal and bird yards.
 - EH.1.4.6 Filling up the ponds and marshes.
 - EH.1.4.7 Monitoring of labor housing and public places.
- EH.1.5 Includes a system for following up actions taken.
- EH.1.6 Includes a system for identification of the environmental risks.
- EH.1.7 Includes indicators for monitoring, evaluation, and improvement of performance.

Evidence of Compliance

EH.1.EC.1 To: There is an available updated manual for EH program that Interview includes EH.1.2 through EH.1.7, and it is well known to the staff.

EH.2 There is adequate and qualified staff to manage the EH program.
Evidence of Compliance

EH.2.EC.1 EH staff are adequate and properly qualified by education and/or Personnel File training.

EH.3 The necessary tools and equipment are available.
Evidence of Compliance

EH.3.EC.1 All EH necessary tools and equipment are available in adequate Observation amounts.

EH.4 All EH related medications and vaccines are available
Evidence of Compliance

EH.4.EC.1 All EH related medications and vaccines are available in adequate Observation amounts.

EH.5 The primary healthcare center conducts a health education program regarding the maintenance and importance of environmental health.

Evidence of Compliance

EH.5.EC.1 There is evidence of conducting an education program on the Interview importance and maintenance of environmental health.

EH.6 The primary healthcare center conducts periodic rounds for environmental health.**Evidence of Compliance**

EH.6.EC.1 There is evidence of the periodic environmental health rounds. Document Review

EH.6.EC.2 There is an appropriate mean of transportation for the team responsible for environmental health rounds. Observation

EH.7 The primary healthcare center cooperates with the relevant sectors to implement the activities of the EH program.**Evidence of Compliance**

EH.7.EC.1 There is evidence of cooperation between the PHC and the relevant agencies to implement the activities of the EH program. Interview

EH.8 The EH program is implemented in the primary healthcare center.**Evidence of Compliance**

EH.8.EC.1 There is evidence of implementation of the EH program. Interview

EH.9 There is a comprehensive database and updated health map determining the environmental risks.**Evidence of Compliance**

EH.9.EC.1 There is a comprehensive database and updated health map determining the environmental risks. Document Review

EH.10 The primary healthcare center has a surveillance system for EH program.**Evidence of Compliance**

EH.10.EC.1 There is a surveillance system for recording EH related information. Document Review

LABORATORY SERVICES

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 patient needs, the primary healthcare center should 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
- Labeling
- Results reporting
- Quality management program

Standards

LB.1 Laboratory services (LB) are available to meet patient needs, applicable to national standards and include:

- LB.1.1 Basic laboratory services are available (e.g. hematology, basic microbiology and biochemistry).
- LB.1.2 The laboratory has access to referral and consultation services in the form of agreements.
- LB.1.3 A list of available laboratory services is published and distributed to all departments.

Evidence of Compliance

- | | |
|--|-----------------|
| LB.1.EC.1 There is a laboratory service guide explaining available tests, specimen requirement, and turnaround time (TAT). | Document Review |
| LB.1.EC.2 There is a written agreement with an accredited lab for the provision of special procedures and consultations. | Document Review |

LB.2 A current laboratory policies and procedures manual is readily available to staff. Policy and procedure manual should be well structured and:

- LB.2.1 Approved by the laboratory director.
- LB.2.2 Reviewed every two years.
- LB.2.3 Laboratory personnel are knowledgeable about the contents of policies and procedures manuals relevant to the scope of their testing activities.

Evidence of Compliance

- | | |
|---|-----------|
| LB.2.EC.1 There is evidence of comprehensive, approved, and current policies and procedures manual that is available and well known to the staff. | Interview |
|---|-----------|

LB.3 Laboratory services (LB) are available to meet patient needs, applicable to national standards and include:

- LB.3.1 A qualified individual(s) is responsible for managing the clinical laboratory service.
- LB.3.2 All laboratory sections are identified and are under the director supervision.
- LB.3.3 All staff categories are included.
- LB.3.4 Chain of command must be clear.

Evidence of Compliance

- | | |
|--|-----------------|
| LB.3.EC.1 There is an updated and approved laboratory organization structure with sections and staff categories identified under the director supervision. | Document Review |
| LB.3.EC.2 Laboratory director is a qualified pathologist or a qualified clinical scientist. | Personnel File |

LB.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:

- LB.4.1 Adequate water taps, sinks, and drains.
- LB.4.2 Adequate electrical outlets and emergency power.
- LB.4.3 Adequate ventilation, temperature, and humidity control.
- LB.4.4 Adequate lighting.
- LB.4.5 Conveniently located telephones with option to transfer calls.

Evidence of Compliance

- LB.4.EC.1 There is adequate lab space, that must have: 2 sinks with one sink used exclusively for hand washing, machines attached directly to wall socket, critical machines attached to emergency socket, adequate control of temperature and humidity, and telephone facility. Observation

LB.4 The laboratory establishes a documented safety program under the supervision of the laboratory director and consistent with the facility's safety guidelines. The laboratory safety program must include:

- LB.5.1 Comprehensive, current, and approved laboratory safety manual readily available to laboratory personnel.
- LB.5.2 Fire safety is implemented according to the facility's plan.
- LB.5.3 Sufficient safety signs and phone numbers are posted.
- LB.5.4 All doors leading to the laboratory are marked to indicate hazard.
- LB.5.5 All sharp wastes (needle, syringes, blades, lancets) are discarded in a puncture proof, rigid, labeled container.
- LB.5.6 Eye wash stations and emergency showers are available.
- LB.5.7 Fume hoods are inspected and certified.
- LB.5.8 Reporting system of all occupational injuries or illnesses that require medical treatment and maintaining related records.
- LB.5.9 Effective chemical hygiene plan.

Evidence of Compliance

- | | | |
|-----------|--|-----------------|
| LB.5.EC.1 | There are fire and safety training records. | Document Review |
| LB.5.EC.2 | There is an effective system for reporting and investigating occupational injuries and accidents. | Document Review |
| LB.5.EC.3 | There is evidence of comprehensive, approved, and current safety manual that is available and well known to the staff. | Interview |
| LB.5.EC.4 | There are sufficient safety signs posted where appropriate. | Observation |
| LB.5.EC.5 | Eye wash stations and emergency showers are available and checked at regular intervals. | Observation |

LB.5.EC.6 Fume hoods and biological safety cabinet are inspected and Observation certified at regular intervals.

LB.6 The laboratory implements all the rules and guidelines of infection control and:

- LB.6.1 Personal protective equipment (gloves, masks, and eye/ face shield, gowns, and lab coats) are available and worn as appropriate.
- LB.6.2 Eating and drinking is prohibited in the laboratory.
- LB.6.3 Universal precautions are implemented.
- LB.6.4 All specimens of blood and body fluids are transported in leak-proof containers.
- LB.6.5 Clean and contaminated working areas are marked.
- LB.6.6 All employees are vaccinated with Hepatitis B Vaccine.
- LB.6.7 Negative pressure is maintained in laboratory dealing with high infectious material.

Evidence of Compliance

- LB.6.EC.1 There are records to support of the immune status or vaccination Personnel File for all lab personnel.
- LB.6.EC.2 Personnel protective equipment are available and used when Observation appropriate.
- LB.6.EC.3 There is evidence of the implementation of policies on universal Observation precautions and prohibition of eating and drinking in the lab.
- LB.6.EC.4 Leak-proof containers for sample transport are available and used. Observation
- LB.6.EC.5 There is evidence of negative pressure monitoring in Observation microbiology.
- LB.6.EC.6 There is evidence of clear designation of clean and contaminated Observation areas.

LB.7 The laboratory publishes and distributes clear written instructions for proper collection, handling, transportation, and preparation of specimens and include:

- LB.7.1 Patient identification (at least two identifiers).
- LB.7.2 Patient preparation.
- LB.7.3 Specimen collection and labeling.
- LB.7.4 Specimen preservation.
- LB.7.5 Specimen storage.
- LB.7.6 Conditions for transportation.
- LB.7.7 Specimen receipt in the laboratory.

Evidence of Compliance

- LB.7.EC.1 There is a laboratory specimen guide (LB.7.1-LB.7.7) distributed to Observation all clinical departments.

LB.8 The laboratory keeps instrument and equipment in proper functional condition through the establishment of a system where equipment are properly operated, cleaned, quality controlled, monitored and maintained. This system must include, but not limited to:

- LB.8.1 Operation and service manual.
- LB.8.2 Maintenance schedule.
- LB.8.3 Maintenance records.

Evidence of Compliance

LB.8.EC.1 Inspection and preventive maintenance records for all laboratory equipment are maintained. Document Review

LB.9 Reagents and solutions are properly labeled, as applicable and appropriate, with the following elements:

- LB.9.1 Content, quantity, concentration and / or titer.
- LB.9.2 Storage requirements.
- LB.9.3 Date prepared or reconstituted by laboratory.
- LB.9.4 Expiration date.
- LB.9.5 All reagents are used and stored as recommended by the manufacturer.
- LB.9.6 All reagents must be used within their indicated expiration date.
- LB.9.7 If there are multiple components of a reagent kit, the laboratory uses components only within the kit lot unless otherwise specified by the manufacturer.
- LB.9.8 New reagent lots are checked against old reagent lots or with suitable QC material before or concurrently being placed in service.
- LB.9.9 Current package inserts are available for all reagents used by the laboratory.

Evidence of Compliance

LB.9.EC.1 There are written policies and procedures for reagent preparation, labeling, storage, and expiration. Document Review
 LB.9.EC.2 Reagents are labeled in accordance with the laboratory policy. Observation

LB.10 The laboratory has a clear system for results reporting including:

- LB.10.1 Defined turnaround time (TAT) for all laboratory services.
- LB.10.2 Definition of panic values (critical results) and the reporting method.

Evidence of Compliance

LB.10.EC.1 There are written policies and procedures for reporting panic values (critical results). Document Review
 LB.10.EC.2 There is evidence of that TAT for all laboratory services is defined, communicated, and agreed upon by clinical departments. Interview
 LB.10.EC.3 There are records in support of proper reporting of panic values. Observation

LB.11 The laboratory must have a quality management program approved by the laboratory director and available for all laboratory personnel. The laboratory quality management program must be integrated with the center-wide quality program and includes:

- LB.11.1 Key quality indicators are selected, monitored, and evaluated to detect potential problems.
- LB.11.2 Incident, adverse events, and accident reporting system to avoid reoccurrence.
- LB.11.3 A Proficiency Testing (PT) system for each analyte reported either by participating in external PT or performing inhouse alternative PT.
- LB.11.4 Corrective and/or preventive action taken, where appropriate, when expected results are not achieved.

Evidence of Compliance

LB.11.EC.1	There is a written quality management program satisfying all of the elements above.	Document Review
LB.11.EC.2	There is evidence of participation in external and/or internal proficiency testing program covering all laboratory analytes.	Document Review
LB.11.EC.3	There is evidence of using an efficient accident and adverse event reporting and investigating system.	Document Review
LB.11.EC.4	There is evidence of corrective and/or preventive measures taken when expected quality monitoring outcomes are not achieved.	Document Review

RADIOLOGY SERVICES

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 primary healthcare center should offer basic radiology services (RS) 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)

Standards

RS.1 The primary healthcare center has a Radiology Services (RS) manual that:

- RS.1.1 Is updated, available, and well known to concerned staff.
- RS.1.2 Includes the scope of radiological services.
- RS.1.3 Includes policies and procedures for radiological services.
- RS.1.4 Identifies roles and responsibilities of the concerned staff.
- RS.1.5 Includes forms and registries required for the radiological services.
- RS.1.6 Includes quality control program.
- RS.1.7 Includes radiation safety program.
- RS.1.8 Includes indicators for performance monitoring, evaluation, and improvement.

Evidence of Compliance

- RS.1.EC.1 There is a written, updated manual for RS program (RS.1.2 through RS.1.8), that is available and well known to the staff.

RS.2 Radiology services are provided and operated by qualified and adequate staff.**Evidence of Compliance**

- RS.2.EC.1 RS staff are adequate and registered with Saudi Commission for Personnel File Healthcare Specialties.

RS.3 The necessary equipment and supplies are available to provide the RS.**Evidence of Compliance**

- RS.3.EC.1 All RS necessary equipment and supplies are available in adequate amounts.

RS.4 The radiology space 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:

- RS.4.1 Space that is adequate and appropriate for the work.
- RS.4.2 A waiting area for the radiology unit that is comfortable and ensures privacy of patients.
- RS.4.3 Appropriate storage area for x-ray films and dark room materials.

Evidence of Compliance

- RS.4.EC.1 There is adequate and appropriate RS space for the work and Observation storage.
- RS.4.EC.2 There is a comfortable waiting area for the radiology unit that ensures privacy of patients.

RS.5 There is a radiation safety protocol or plan in place to protect staff, patients, and the environment that includes at least the following:

- RS.5.1 All equipment are inspected and checked regularly with an experienced Safety Officer.
- RS.5.2 All radioactive materials are used according to the guidelines and the Safety Officer oversees the activity in the unit.
- RS.5.3 Safety warnings are posted on doors in clear and appropriate locations.
- RS.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 ask the patient.
- RS.5.5 Personnel are monitored for radiation exposure:
 - RS.5.5.1 Thermo luminescence Dosimeter (TLD) is regularly checked for all radiology staff
 - RS.5.5.2 Checking white blood cells periodically for all employees in Radiology Department.
- RS.5.6 Radiation personal protective measures are available for employees and patients.

Evidence of Compliance

- | | | |
|-----------|---|-----------------|
| RS.5.EC.1 | There is a written, comprehensive radiation safety program. | Document Review |
| RS.5.EC.2 | There is evidence that RS.5.1 through RS.5.6 are in place. | Observation |

RS.6 Physicians requesting x-ray procedures write all necessary information on the radiology X-ray request form.

Evidence of Compliance

- | | | |
|-----------|---|----------------------|
| RS.6.EC.1 | All necessary information is written on the x-ray request form by the requesting physician. | Health Record Review |
|-----------|---|----------------------|

RS.7 Radiology reports are available by a defined reporting time according to patient needs.

Evidence of Compliance

- | | | |
|-----------|--|----------------------|
| RS.7.EC.1 | There is evidence of availability of all radiologic studies within a defined reporting time. | Health Record Review |
|-----------|--|----------------------|

RS.8 There is a master X-ray jacket or access to all archived previous radiological studies for every patient.

Evidence of Compliance

- | | | |
|-----------|---|-------------|
| RS.8.EC.1 | All archived patient radiology studies are accessible in a master x-ray jacket. | Observation |
|-----------|---|-------------|

RS.9 All diagnostic imaging examinations are reported by registered staff.

Evidence of Compliance

- | | | |
|-----------|---|----------------|
| RS.9.EC.1 | There is evidence of that registered staff report all radiological studies. | Personnel File |
|-----------|---|----------------|

RS.10 There is a policy that “panic” findings on the X-ray films are reported immediately to the specialty requesting the examination: e.g., air under the diaphragm.

Evidence of Compliance

- | | | |
|------------|--|-----------------|
| RS.10.EC.1 | There is a written policy for immediate reporting of "panic findings" to the requesting physician. | Document Review |
| RS.10.EC.2 | There is evidence of implementation of the panic finding policy. | Interview |

PHARMACEUTICAL SERVICES

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 pharmaceutical services should be organized and administered to provide effective, efficient, and safe pharmacy services. In essence, a well-managed medication system promotes patient safety and quality of care.

The pharmaceutical services standards comprise the following processes and activities:

- Ordering
- Medication security and safety
- Formulary system
- Labeling
- Dispensing
- Administration
- Storage
- Emergency medications
- Monitoring medication effects
- Medication error identification and reporting
- Adverse drug events identification, reporting, and response
- Retrieving and managing recalled medications
- Controlled drugs management

Standards

PH.1 The primary healthcare center has a pharmacy department and headed by a qualified pharmacist.

- PH.1.1 The pharmacy head is certified and a registered pharmacist (holds bachelor's degree in pharmacy).
- PH.1.2 The pharmacy head has signed an updated job description.
- PH.1.3 The pharmacy head has a current Saudi Commission for Health Specialties license.
- PH.1.4 The pharmacy head has work experience of at least one year in healthcare setting.

Evidence of Compliance

- PH.1.EC.1 There is qualified and trained pharmacist (Bachelor of pharmacy Personnel File or higher degree, PHC work experience).

PH.2 The primary healthcare center pharmacy has qualified and licensed staff.

- PH.2.1 All pharmacy staff have evidence of valid Saudi Commission for Health Specialties license to practice in Saudi Arabia.
- PH.2.2 All pharmacy staff have signed an updated job description.

Evidence of Compliance

- PH.2.EC.1 All pharmacy staff are qualified and licensed by the Saudi Council Personnel File of Health Specialties.
- PH.2.EC.2 All pharmacy staff have current and signed job description. Personnel File

PH.3 The primary healthcare center establishes an interdisciplinary committee for overseeing and monitoring the medication management processes.**Evidence of Compliance**

- PH.3.EC.1 There are terms of reference for the medication management Document committee, with meeting minutes reflect its function. Review

PH.4 The primary healthcare center pharmacy has a process for continuing education and staff training by:

- PH.4.1 Written policy of a defined pharmacy orientation and continuing education program.
- PH.4.2 Pharmacy orientation for all newly hired pharmacy staff.
- PH.4.3 Continuing education activities (provision of attendance to lectures, in-services, conferences, symposia, and/or distant learning, e.g., internet or CE articles).
- PH.4.4 PHC pharmacy has the following reference manuals and/or policies (relevant policy and procedure manual, infection control manual, safety manual, operating manual of equipment, MSDS manual).

Evidence of Compliance

- PH.4.EC.1 There is a written policy on pharmacy orientation and continuing education program. Document Review
- PH.4.EC.2 There is evidence of staff completion of pharmacy orientation and continuing education programs. Personnel File
- PH.4.EC.3 All necessary manuals (pharmacy, infection control, equipment operation, and MSDS) are available in the pharmacy. Observation
- PH.4.EC.1 There is a written policy on pharmacy orientation and continuing education program. Document Review

PH.5 There is a list of medical staff signatures who are authorized to prescribe medication:

- PH.5.1 The list contains medical staff name, signature, ID number, specialty, and stamp or code (if available) and updated regularly.
- PH.5.2 Clear copy of the signature list is available to pharmacy staff in drug dispensing area(s).
- PH.5.3 Pharmacy staff are aware of the list.
- PH.5.4 Only authorized staff are allowed to prescribe medications.

Evidence of Compliance

- PH.5.EC.1 Comprehensive and updated records of all prescribers' signatures are readily available in the pharmacy. Observation

PH.6 There is an updated list of prescribers and their prescribing privileges:

- PH.6.1 The list contains medical staff specialties and their prescribing privileges.
- PH.6.2 The list clearly defines prescribing privileges especially for narcotics, controlled drugs, psychotropics, etc.
- PH.6.3 The list is updated every year and whenever a new medical staff joins.
- PH.6.4 Clear copy of the privilege list is available to pharmacy staff in each drug dispensing area.
- PH.6.5 PHC pharmacy staff are aware of the list.
- PH.6.6 There is clear evidence of proper implementation.

Evidence of Compliance

- PH.6.EC.1 Comprehensive, updated, and approved list of medical staff prescribing privileges is readily available in the pharmacy. Observation

PH.7 Pharmacy areas should have adequate drug information resources, such as:

- PH.7.1 Saudi National Formulary (SNF).
- PH.7.2 British National Formulary (BNF).
- PH.7.3 Middle East Medical Index.
- PH.7.4 Posting and making available telephone number for a poison control center.

Evidence of Compliance

PH.7.EC.1 There are adequate drug information resources, such as Drug Observation Formularies and contact details of Poison Control Center.

PH.8 The pharmacy space is adequate. Hours of operation are determined, announced, and followed:

- PH.8.1 The space provided for the pharmacy services allows the principal functions to be carried out in an efficient and effective manner.
- PH.8.2 Hours of operation of the pharmacy are clearly defined in a policy and procedure, announced, and posted at the pharmacy entrance.

Evidence of Compliance

- PH.8.EC.1 Pharmacy has adequate space to efficiently operate. Observation
- PH.8.EC.2 Pharmacy operating hours and monthly work schedule are available and posted. Observation

PH.9 Security measures are in place and include:

- PH.9.1 Limited access to pharmacy.
- PH.9.2 Visible name tags for all personnel.
- PH.9.3 Proper locking procedures for the pharmacy after working hours.
- PH.9.4 The pharmacy doors and windows locked during operation.
- PH.9.5 Identification of which pharmacy personnel have keys to pharmacy.
- PH.9.6 Having a policy for non-pharmacy staff accessing pharmacy after hours in case of emergency (fire, flood, etc.)

Evidence of Compliance

- PH.9.EC.1 There are written policy and procedures on emergency opening of the pharmacy after working hours. Document Review
- PH.9.EC.2 There are appropriate pharmacy security measures (visible name tags, limited access, doors and windows are closed during operation, key holding, etc.). Observation

PH.10 Safety measures are in place and include, but not limited to:

- PH.10.1 Keeping a list of readily available hazardous materials in areas where they are stored or used.
- PH.10.2 Keeping material safety data sheets (MSDS) available in areas where hazardous materials are stored or used.
- PH.10.3 Keeping spill kits available in areas where hazardous materials are stored or used.
- PH.10.4 Training all staff on how to handle spills.

Evidence of Compliance

- PH.10.EC.1 There are written policy and procedures on identification, safe handling, stocking, and transportation of hazardous materials (chemicals, chemotherapy, flammables, etc.). Document Review

- PH.10.EC.2 The staff are trained on handling of spills and waste disposal. Interview
- PH.10.EC.3 Hazardous materials are stored safely (hazardous list, safety cabinets, good ventilation, low shelves, original labeled container). Observation
- PH.10.EC.4 The personal protective equipment, eye wash station, MSDS, and spill kits are available. Observation

PH.11 The primary healthcare center pharmacy has an updated internal policies and procedures manual for all available services

- PH.11.1 All approved policies and procedures are written according to standard PHC format and updated every two-three (2-3) years.
- PH.11.2 Policies and procedures are made accessible to all pharmacy staff all the time and staff are familiar with it.

Evidence of Compliance

- PH.11.EC.1 Pharmacy internal policy and procedures are complete, updated (every 2-3 years), and approved. Document Review

PH.12 The primary healthcare center has an updated formulary system.

- PH.12.1 The drug formulary contains all essential drugs mandated by the Saudi Ministry of Health or other relevant regulatory agencies and updated annually.
- PH.12.2 The drug formulary is available to the healthcare team.
- PH.12.3 All newly hired physicians should be oriented to the drug formulary.
- PH.12.4 The physicians follow formulary system as appropriate.

Evidence of Compliance

- PH.12.EC.1 The drug formulary is part of the general orientation program. Interview
- PH.12.EC.2 Annually updated drug formulary is available to healthcare team. Observation

PH.13 The primary healthcare center drug formulary is very well structured and includes all essential drugs:

- PH.13.1 The drug formulary has at least generic name information, formulations, strength, therapeutic classification, and brief prescribing information.
- PH.13.2 The drug formulary is properly indexed using alphabetical indexing for available generic and brand name drugs.
- PH.13.3 Approved prescribing abbreviation and prohibited prescribing abbreviation lists are included in a separate section of the drug formulary and there is evidence of implementation.
- PH.13.4 Antibiotic use guidelines (prophylactic and therapeutic) are included in a separate section of the drug formulary and there is evidence of implementation.

Evidence of Compliance

- PH.13.EC.1 The drug formulary includes; generic name, formulation, strength, therapeutic class, prescribing information, approved prescribing abbreviations, antibiotic use guidelines, and alphabetical index. Document Review

PH.13.EC.2 There is evidence of implementation of the approved prescribing Observation abbreviations and antibiotic use guidelines.

PH.14 The primary healthcare center pharmacy has a system developed for handling prescriptions that includes:

- PH.14.1 Pharmacist confirms the completion of the basic data of the prescription: patient's name, health record number, age, sex, body weight (for pediatrics or when indicated), diagnosis, allergies, prescriber's name, signature and stamp, clinic number, and date.
- PH.14.2 A pharmacist verifies all physician orders for diagnosis, dosing, frequency, route, duration, and interactions.
- PH.14.3 Drugs are prescribed and dispensed for their approved indications as evidenced by the given diagnosis.
- PH.14.4 There is a procedure for pharmacy intervention/clarification of physician orders.
- PH.14.5 There is a policy for filling and refilling prescriptions.
- PH.14.6 The pharmacy notifies the prescribing physician if a prescribed drug is not available.
- PH.14.7 There is evaluation, monitoring, and documentation of drug-drug and drug-food interactions.
- PH.14.8 All prescriptions are double-checked by another qualified professional before dispensing.

Evidence of Compliance

- PH.14.EC.1 There is a written policy on handling prescriptions that includes Document Review PH.14.1 through PH.14.8.
- PH.14.EC.2 All prescriptions have the patient's name, health record number, Observation age, sex, diagnosis, allergy, prescriber's name/stamp, signature, clinic number and date.

PH.15 The primary healthcare center pharmacy has a system developed for proper labeling of drugs that includes:

- PH.15.1 All dispensed drugs are labeled in Arabic and/or English according to patient preference.
- PH.15.2 Medication labels reflect the PHC name, patient name, health record number, generic drug name, strength, dosage, directions, and expiry date of the drug.
- PH.15.3 Colored auxiliary labels that stick out are used whenever applicable (e.g., refrigerate, do not refrigerate, shake before use, external use only, etc).

Evidence of Compliance

- PH.15.EC.1 Dispensed drugs have safe labeling that includes PH.15.1-PH.15.3. Observation

PH.16 The primary healthcare center pharmacy has a system for storage of regular medications in the pharmacy, store, patient care areas, and includes:

- PH.16.1 There is an appropriate storage area for regular medications with controlled temperature between 18 and 25 degree centigrade around the clock.

- PH.16.2 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 centimeter from the ceiling.
- PH.16.3 Storing antiseptics, disinfectants, and drugs for external use separately from internal and injectable medications.

Evidence of Compliance

- | | | |
|------------|--|-----------------|
| PH.16.EC.1 | There is a written policy on storage of regular medications. | Document Review |
| PH.16.EC.2 | Medications are stored in appropriate storage area: organized, clean, dry, with light protection, and temperature is controlled between 18 and 25 degrees centigrade around the clock. | Observation |
| PH.16.EC.3 | Antiseptics, disinfectants, and external agents are stored separately. | Observation |

PH.17 The primary healthcare center pharmacy has a system for storage of cold medications and vaccines in the pharmacy, store, patient care areas, and includes:

- PH.17.1 The pharmacy has refrigerators for storing vaccines and cold medications.
- PH.17.2 A list of refrigerator's contents (medications and pharmaceutical products) with expiration dates is posted on the refrigerator.
- PH.17.3 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.
- PH.17.4 All medication refrigerators and freezers are equipped with appropriate thermometers or equivalent device for temperature recording and temperature log sheets.
- PH.17.5 The vaccine refrigerator is connected to emergency power source (electric outlets are marked) and the temperature is recorded daily or equivalent process is in place to monitor temperature around the clock.
- PH.17.6 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.
- PH.17.7 Food, drinks, biological samples, culture media are not allowed inside medication refrigerators.

Evidence of Compliance

- | | | |
|------------|---|-----------------|
| PH.17.EC.1 | There is a written policy on storage of cold medications and vaccines, handling drug and pharmaceuticals in case of electric power failure. | Document Review |
| PH.17.EC.2 | There is at least daily monitoring and recording of the temperature of refrigerators (2-8 degrees centigrade) and freezers (-10 degrees to -25 degrees centigrade). | Observation |
| PH.17.EC.3 | The vaccine refrigerator(s) is connected to emergency power supply and its temperature is recorded around the clock. | Observation |
| PH.17.EC.4 | A list of refrigerator's contents with expiration dates is attached to the refrigerator door. | Observation |

PH.18 The pharmacy has a system for ensuring stability of medications available in multi-dose containers.

- PH.18.1 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.).
- PH.18.2 Ensuring that all open multi-dose containers carry open date, expiry date, initials, and time (if necessary).
- PH.18.3 Ensuring that no expired and opened or unlabeled and opened multi-dose containers are available in patient care areas.

Evidence of Compliance

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|-------------------|---|-----------------|
| PH.18.EC.1 | The pharmacy has guidelines for stability of multi-dose vials and containers in all patient care units. | Document Review |
| PH.18.EC.2 | There is proper labeling of vials and multi-dose containers after the first use. | Observation |

PH.19 The primary healthcare center pharmacy has a system for ensuring preparedness of crash cart, emergency bags, and emergency medications, and this includes:

- PH.19.1 Developing and maintaining a set of guidelines for crash cart medication.
- PH.19.2 Updating the crash cart drug list in accordance with the Saudi Heart/American Heart Association recommendations.
- PH.19.3 Protecting emergency medications from loss or theft using safety plastic seal.
- PH.19.4 Keeping plastic seals stocked in a safe place under supervision of pharmacy or nursing.
- PH.19.5 Monitoring emergency medications, crash cart medication, and replacing them in a timely manner after use or when expired or damaged.
- PH.19.6 Performing documented monthly inspection of crash cart and emergency bag medications and maintaining records in the pharmacy.

Evidence of Compliance

- | | | |
|-------------------|---|-----------------|
| PH.19.EC.1 | The pharmacy has guidelines for standardizing crash cart medication contents (according to Saudi/American Heart Association recommendations). | Document Review |
| PH.19.EC.2 | There are monthly inspection records of crash cart, emergency bags, and emergency medications. | Observation |

PH.20 The primary healthcare center pharmacy has a system for ensuring preparedness of crash cart, emergency bags, and emergency medications, and this includes:

- PH.20.1 There is a written mechanism to ensure allergies are identified by the attending physician and immediately communicated to the pharmacy in writing.
- PH.20.2 Allergies are documented in each prescription before dispensing any medication.
- PH.20.3 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).

Evidence of Compliance

PH.20.EC.1 There is a written mechanism for monitoring drug allergies Document (identification, documentation, communication, and pharmacy Review intervention).

PH.20.EC.2 Patient's health record is flagged for drug allergies. Observation

PH.21 **There is a process for detecting, monitoring, and reporting adverse drug/vaccine reactions (ADRs), and includes:**

- PH.21.1 Written policy and procedure for ADR.
- PH.21.2 Definition of a significant ADR and time frame for reporting.
- PH.21.3 ADR reporting forms are available.
- PH.21.4 Intensive analysis is performed for all significant ADRs.
- PH.21.5 Notification of treating physician.
- PH.21.6 There is evidence that the patient receives appropriate care for the ADR.
- PH.21.7 There is evidence that the health record has been flagged for significant ADRs.
- PH.21.8 Process for improving ADR reporting.
- PH.21.9 Reporting any significant or unexpected ADR to the related authorities as per rules and regulation.

Evidence of Compliance

PH.21.EC.1 There is a comprehensive policy on adverse drug reaction (ADRs) Document reporting including definition of serious/significant ADR, time Review frame and reporting format.

PH.21.EC.2 There is an active reporting, analyzing, and proper utilization of Document data for quality improvement purpose (Pharmacy and Review Therapeutics Committee).

PH.22 **There is a process for identifying, monitoring, and reporting medication errors, and includes:**

- PH.22.1 Written policy and procedure for medication error reporting.
- PH.22.2 Definition of a significant medication error, time frame for reporting, and reporting format.
- PH.22.3 Active reporting.
- PH.22.4 Intensive root-cause analysis is performed for all significant medication errors.
- PH.22.5 Using reported data to improve medication use process and reduce error rate.

Evidence of Compliance

PH.22.EC.1 There is a policy on medication errors reporting including; Document definition of significant errors, time frame, and reporting format. Review

PH.22.EC.2 There is an active reporting, root-cause analysis of significant Document errors, and proper utilization of data for quality improvement Review purpose (Pharmacy and Therapeutics Committee). There is an active reporting and root-cause analysis of significant errors.

PH.23 The primary healthcare center pharmacy has a system for identifying and handling expired medications.

- PH.23.1 There is a written policy that clearly defines expiry date, expired medications, and proper procedures for handling expired drugs, and inspection form(s).
- PH.23.2 There is a written and implemented policy for detecting and returning the nearly expired medications before the expiration date.
- PH.23.3 No expired drugs are found in any patient care area.
- PH.23.4 Documents of returned expired drugs to supplier or manufacturer are maintained on file for evidence of proper destruction.
- PH.23.5 All expired and/or nearly expired medications are properly labeled and stored separately from other medications.

Evidence of Compliance

- PH.23.EC.1 There is a written policy on identification and proper handling of expired and nearly expired drugs. Document Review

PH.24 The primary healthcare center pharmacy has a system for handling drug recalls.

- PH.24.1 There is a clearly written policy and procedure that includes identification and handling drug recalls, time frame, and procedures for informing patients who received any recalled drug.
- PH.24.2 All drug recalls are properly documented (memos, recall forms, drug exit documents).
- PH.24.3 None of the recalled drugs are available in the pharmacy or patient care areas.

Evidence of Compliance

- PH.24.EC.1 There are written policy and procedures on handling drug recall. Document Review
- PH.24.EC.2 Drug recalls are monitored on a timely basis by the pharmacy and therapeutics committee. Interview

PH.25 The pharmacy has infection control guidelines that include:

- PH.25.1 Written policies and procedures.
- PH.25.2 Guidelines verbalized by pharmacy staff.
- PH.25.3 Guidelines adhered to by pharmacy staff.
- PH.25.4 No food, drink, or smoking is allowed in the pharmacy.
- PH.25.5 A sink, soap, and antiseptic hand scrub are available in the pharmacy.

Evidence of Compliance

- PH.25.EC.1 There is a written policy on pharmacy infection control. Document Review
- PH.25.EC.2 There is evidence of implementation of infection control guidelines by staff. Interview

- PH.25.EC.3 There is sink, soap, and antiseptic hand scrubs. No food, drink, or smoking is allowed in the pharmacy. Observation
- PH.25.EC.1 There is a written policy on pharmacy infection control. Document Review

PH.26 There is a system for handling narcotics, psychotropics, and other controlled drugs in accordance with laws and regulations, and includes but not limited to:

- PH.26.1 A written policy and procedure for handling narcotics, psychotropics, and other controlled drugs.
- PH.26.2 Receiving, storing, and dispensing narcotics, psychotropics, and other controlled drugs by the pharmacy.
- PH.26.3 Keeping controlled drugs behind steel doors with double locks.
- PH.26.4 Keeping limited floor stock supply.

Evidence of Compliance

- PH.26.EC.1 There are written policy and procedures on handling narcotics, psychotropics and other controlled drugs. Document Review
- PH.26.EC.2 There are tight security measures for controlled drugs (controlled by pharmacy, stored behind steel doors). Observation

PH.27 There is a system for handling narcotics, psychotropics, and other controlled drugs in accordance with laws and regulations, and includes but not limited to:

- PH.27.1 Daily auditing in the pharmacy.
- PH.27.2 Maintaining proper documentation of drug count and accountability in the pharmacy.
- PH.27.3 Maintaining proper documentation of empty containers of narcotics.
- PH.27.4 Proper disposal of unused portion of an ampoule or a tablet.

Evidence of Compliance

- PH.27.EC.1 There is an auditing system for narcotics and psychotropics (daily, full and empty ampoule, unused portion of an ampoule or a tablet). Observation

PH.28 There is a system for prescribing narcotics, psychotropics, and other controlled drugs in accordance with the laws and regulations and includes but not limited to:

- PH.28.1 Using the approved prescriptions.
- PH.28.2 Not allowing physicians to prescribe controlled drugs for self or family members.
- PH.28.3 Allowing only clinical privileged physicians to prescribe.
- PH.28.4 Not allowing injectable narcotics and controlled drugs outside the center.

Evidence of Compliance

PH.28.EC.1 There is full compliance with the laws and regulations: approved prescriptions, prescribing privileges, and dispensed quantities. Not allowing injectable narcotics and controlled drugs outside the center.

PH.29 **The pharmacy has a system developed for patient and family education before going home that includes:**

- PH.29.1 Patients and families are offered education for dispensed medications.
- PH.29.2 Written drug counseling materials are available in easy understandable language (Arabic and English).
- PH.29.3 The pharmacist explains to the patient how to use his/her medications (dose, route, frequency, and time in relation to meals), and side effects.

Evidence of Compliance

PH.29.EC.1 There is patient and family education system (written education materials in appropriate language/s). Document Review

PH.30 **The pharmacy shows evidence of Quality Improvement by:**

- PH.30.1 Having standards for all pharmaceutical care processes.
- PH.30.2 Subjecting current standards to evaluation.
- PH.30.3 Active participation in PHC-wide performance improvement program.
- PH.30.4 Continually determining areas for improvement.
- PH.30.5 Reporting any questionable drug quality to related health authority (e.g. ineffective medication, inconvenient size, shape, volume, color, package, or label, etc.).

Evidence of Compliance

PH.30.EC.1 There is a continuous performance improvement program, and reporting system for any questionable drug quality. Document Review

PH.31 **The pharmacy safely manages look-alike, sound-alike (LASA) medications:**

- PH.31.1 The pharmacy identifies, in writing, its LASA medications.
- PH.31.2 The pharmacy has a process for managing LASA medications.
- PH.31.3 The pharmacy implements its process for managing LASA medications.

Evidence of Compliance

PH.31.EC.1 There is a written list of look-alike, sound-alike (LASA) medications with clear guidelines for managing LASA medications. Document Review

PH.31.EC.2 There is clear evidence of implementing LASA medication guidelines. Interview

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 center leadership has to provide all necessary support and resources to improve safety in the work place in alignment with regulatory requirements.

The center must have plans for managing the safety of the environment and must implement these plans. The center must collect and analyze data to determine the effectiveness of the plans and facilitate continuous quality improvement.

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

Important aspects of the facility management and safety (FMS) addressed in this chapter includes the following:

- Safety
- Security
- Fire safety
- Emergency
- Hazardous materials
- Medical equipment
- Utilities

Standards

FMS.1 There is a qualified individual(s), at least part timer, responsible for the facility management and safety (FMS) program.

Evidence of Compliance

FMS.1.EC.1 There is an assigned Safety Officer (at least part timer) for the Personnel File PHC who is qualified by education, training, experience, and/or certification.

FMS.2 The primary healthcare center establishes an interdisciplinary committee for overseeing and monitoring the FMS program and includes, but not limited to:

- FMS.2.1 Regularly inspecting, testing, and maintenance of all operating components of the program.
- FMS.2.2 Reviewing, analyzing, and aggregating data related to safety issues.
- FMS.2.3 Recommending appropriate solutions (including education) when safety issues are identified.

Evidence of Compliance

- FMS.2.EC.1 The terms of reference for the FMS committee(s) includes; Document committee's functions, membership, quorum, frequency of Review meetings, and approval and distribution of minutes.
- FMS.2.EC.2 The meeting minutes of the committee(s) reflects discussion of Document FMS.2.1 through FMS.2.3.

FMS.3 The primary healthcare center environment is safe for patients, visitors, and staff.

- FMS.3.1 The center has an integrated plan that covers major disasters, utility failures, hazardous materials, fire safety, medical equipment, building safety, and security.
- FMS.3.2 The building and surroundings are free from hazards.
- FMS.3.3 Periodic Preventive Maintenance (PPM) and corrective maintenance are done in all electrical and mechanical systems.
- FMS.3.4 All staff are trained in safe practices.

Evidence of Compliance

- FMS.3.EC.2 PPM records are kept for all electrical and mechanical systems Document i.e., A/C, power, and equipment. Review
- FMS.3.EC.3 Staff are trained in evacuation, RACE/PASS, hygiene, and Interview sterilization.
- FMS.3.EC.4 No falling objects, exposed outlet or wiring, slippery floor, sharp Observation ends, holes in the ground, or any other hazards.

FMS.4 The primary healthcare center administration ensures that the building and its services comply with national standards, laws, and regulations and recommendations of professional organizations that relate to management of the physical environment.

Evidence of Compliance

FMS.4.EC.1 There is evidence of facility awareness and implementation of Interview standards, laws, and regulations related to safety of the building.

FMS.5 The primary healthcare center environment is user friendly.

- FMS.5.1 The center has adequate amenities, e.g., parking, waiting areas, and toilets.
- FMS.5.2 The center is equipped for people with special needs, e.g., disabled, elderly, and children.
- FMS.5.3 The center has directional signs.

Evidence of Compliance

- FMS.5.EC.1 There is adequate parking as per laws and regulations Observation requirements (Ministry of Municipal and Rural Affairs).
- FMS.5.EC.2 The adequate PHC waiting areas and toilets with diaper changing Observation stations for its users.
- FMS.5.EC.3 There are wheel chairs ramps in all elevated areas, and handrails Observation in the corridors and stairs.
- FMS.5.EC.4 Directional signs are posted in proper places. Observation

FMS.6 Interdisciplinary rounds are scheduled and conducted to ensure safety, and include the following:

- FMS.6.1 Environmental rounds to check staff knowledge and implementation regarding the FMS plans (quarterly).
- FMS.6.2 Facility Tours to check the facility/physical plant (quarterly).
- FMS.6.3 The resulting information is used for corrective actions, planning, and budgeting long-term facility upgrading and replacement.

Evidence of Compliance

- FMS.6.EC.1 There are documented environmental rounds describing findings Document and actions taken. Review

FMS.7 The primary healthcare center administration complies with applicable environmental protection standards, laws, and regulations (for example, discharges to drainage systems, safe disposal of waste, and the like).

Evidence of Compliance

- FMS.7.EC.1 There is evidence of facility awareness and implementation of Interview standards, laws, and regulations related to environmental protection.

FMS.8 The primary healthcare center has a fire prevention program.

- FMS.8.1 The staff are trained on the fire evacuation plan.
- FMS.8.2 Egress routes are free from obstacles.
- FMS.8.3 Proper storage.

FMS.8.4 Fire systems, fire alarms, and fire equipment are in place and functioning.

Evidence of Compliance

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|---|-----------------|
| FMS.8.EC.1 Fire alarms are maintained and tested, and PPM records are kept. | Document Review |
| FMS.8.EC.2 Each employee annually attends fire drills and attendance is logged. | Personnel File |
| FMS.8.EC.3 The fire drills and the evacuation plan are continuously improved and updated. | Interview |
| FMS.8.EC.4 Escape routes plans are posted in the corridors. | Observation |
| FMS.8.EC.5 Corridors and fire escapes are marked and free from obstacles, e.g., locks, boxes. | Observation |
| FMS.8.EC.6 Fire extinguishers are functioning, tested, and distributed in the center. | Observation |

FMS.9 The primary healthcare center is secured and protects its users.

- FMS.9.1 Security personnel are available.
- FMS.9.2 The center's equipment and data are secured.
- FMS.9.3 The patients' privacy is respected.
- FMS.9.4 No Smoking policy is enforced.

Evidence of Compliance

- | | |
|--|-----------------|
| FMS.9.EC.1 There is an approved 'no smoking' policy. | Document Review |
| FMS.9.EC.2 Trained security personnel are adequately available in the center. | Personnel File |
| FMS.9.EC.3 Patient and staff files are accessible for authorized persons only. | Interview |
| FMS.9.EC.4 Burglary alarm system is installed and the main doors are locked after hours. | Observation |
| FMS.9.EC.5 Patient privacy is protected, e.g., curtains or segregation. | Observation |
| FMS.9.EC.6 No smoking signs are posted in all entrances. | Observation |
| FMS.9.EC.7 All staff should have identification badges. | Observation |

FMS.10 There is a plan and implemented program for inspecting, testing and maintaining medical equipment.

- FMS.10.1 There are temperature chart logs in all pharmacy and lab refrigerators and freezers.
- FMS.10.2 There is an inventory list of all medical equipment.
- FMS.10.3 The medical equipment is PPM tagged.
- FMS.10.4 All defective medical equipment are labeled accordingly.
- FMS.10.5 No obsolete equipment is kept in the center.

Evidence of Compliance

- | | |
|---|-----------------|
| FMS.10.EC.1 Inventory list of all medical equipment is updated. | Document Review |
|---|-----------------|

- FMS.10.EC.2 All obsolete medical equipment are removed from the center. Interview
- FMS.10.EC.3 PPM program is implemented for all the medical equipment and records are kept. Observation
- FMS.10.EC.4 Functional/defective tagging is implemented. Observation
- FMS.10.EC.5 Temperature chart logs are available in all pharmacy and lab refrigerators and freezers. Observation

FMS.11 The primary healthcare center has an emergency plan and staff are trained on it.

- FMS.11.1 The emergency plan defines the staff roles.
- FMS.11.2 The emergency plan identifies the nearest healthcare facilities.
- FMS.11.3 Staff are certified in completing the emergency drills.

Evidence of Compliance

- FMS.11.EC.1 There is an emergency plan with the staff roles are defined, the plan must be evaluated annually and updated as needed. Document Review
- FMS.11.EC.2 Staff are trained in emergency drills annually and they know where to refer patients during emergencies. Interview
- FMS.11.EC.3 The center has an alternative power and water source for emergencies. Observation

FMS.12 The primary healthcare center has a hazardous materials (hazmat) and waste disposal plan.

- FMS.12.1 The PHC keeps a register of all hazardous materials in the center.
- FMS.12.2 Staff are trained in dealing with hazardous materials and waste.
- FMS.12.3 The hazardous materials and waste are controlled.
- FMS.12.4 Emergency shower and eye washers are available in the lab.

Evidence of Compliance

- FMS.12.EC.1 The center keeps an updated, hazardous materials registry and MSDS. Document Review
- FMS.12.EC.2 All staff are trained in dealing with available hazardous materials. Personnel File
- FMS.12.EC.3 Hazardous materials are stored, handled, transported, used, and disposed as per MSDS. Observation
- FMS.12.EC.4 Functioning emergency showers and eye washer are available in the lab. Observation
- FMS.12.EC.5 Fire rated cabinets are used for flammable hazardous materials. Observation

INFECTION PREVENTION AND CONTROL

Introduction

The Primary Healthcare Center requires processes to support the prevention and control of infection that might be acquired or transmitted by patients, staff, and visitors while in the center. These processes reduce risk or spread of infection, and ensure that care is provided in a clean environment. To ensure staff and patient safety, the infection prevention and control personnel requires effective center-wide infection prevention and control (IPC) program that identifies, reduces, and/or 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
- Protective personal equipment
- Hand hygiene
- Sharps safety
- Cleaning, decontamination, disinfection, and sterilization
- Healthcare-associated infection (HAI)
- Employee health
- Blood exposure
- Communicable diseases
- Waste management
- Laundry
- IPC precautions for renovations and construction

Standards

IPC.1 The primary healthcare center implements a coordinated program to reduce the risk of healthcare associated infections (HAIs):

- IPC.1.1 The program involves patients, visitors, staff, and volunteers.
- IPC.1.2 The program involves all patient care areas and support services such as laboratory, housekeeping, and pharmacy.

Evidence of Compliance

- IPC.1.EC.1 There is a comprehensive coordinated infection control program Document Review that includes IPC.1 through IPC.1.2.

IPC.2 The infection prevention and control program (IPC) is based on:

- IPC.2.1 Current scientific knowledge.
- IPC.2.2 Accepted practice guidelines.
- IPC.2.3 Applicable laws and regulations.

Evidence of Compliance

- IPC.2.EC.1 The IPC program is based on scientific knowledge, practice Document Review guidelines, and on local laws and regulations.

IPC.3 There is a qualified infection control practitioner(s), at least part timer, to manage the infection control program.**Evidence of Compliance**

- IPC.3.EC.1 There is an assigned qualified Infection Control (IC) Practitioner, Personnel File by education, training, experience, and/or certification for the center.

IPC.4 The primary healthcare center establishes a functioning infection control committee with representatives from all relevant disciplines to coordinate the program, and this includes at least the following:

- IPC.4.1 Review and approval of infection control policies developed by the infection control team.
- IPC.4.2 Evaluation and revision, on a continuous basis, of the procedures and the mechanisms developed by the infection control team to meet established standards and goals.
- IPC.4.3 Review and evaluation of the reports of healthcare-associated infections surveillance submitted regularly by the infection control team, and suggest appropriate actions to be taken with concerned departments.
- IPC.4.4 New infection control issues from various departments are brought to the attention of the infection control team with suggestions for resolution.
- IPC.4.5 Revision of the yearly plan submitted by infection control team and suggestions of additions/changes, if necessary.

Evidence of Compliance

- IPC.4.EC.1** There are terms of reference for the infection control Document committee(s) that includes; committee's functions, membership, Review quorum, frequency of meetings, approval, and distribution of minutes.
- IPC.4.EC.2** The meeting minutes of the committee(s) reflect discussion of the Document items IPC.4.1 through IPC.4.5.

IPC.5 The primary healthcare center leaders support and monitor the implementation of the IPC program.

Evidence of Compliance

- IPC.5.EC.1** There is evidence of leadership support for the IPC program.

Leadership Interview

IPC.6 The IPC program is combined in a manual that includes all administrative and practice guidelines:

- IPC.6.1** Written statement of authority.
- IPC.6.2** Written policies and procedures for:
- IPC.6.2.1** Disinfection and sterilization.
 - IPC.6.2.2** Handling sharps.
 - IPC.6.2.3** Infectious materials and waste disposals.
 - IPC.6.2.4** Prevention of patient and worker exposure to healthcare-associated infections.
- IPC.6.3** Mechanism for monitoring the implementation of IC policies and procedures.

Evidence of Compliance

- IPC.6.EC.1** The IC manual has a written statement of authority, policies and procedures for elements IPC.6.2.1 through IPC.6.2.4.

Document Review

- IPC.6.EC.2** There is a written mechanism for monitoring the implementation of IC policies and procedures.

Document Review

IPC.7 The infection control policies and procedures are available for all employees.

Evidence of Compliance

- IPC.7.EC.1** The IPC program is part of the general orientation program and available for all employees.

IPC.8 The infection control program is implemented in the primary healthcare center.

Evidence of Compliance

- IPC.8.EC.1** There is evidence of implementation of IPC program policies and procedures.

IPC.9 Infection control tools and supplies: disinfectants and personal protective equipment (gown, gloves, masks, and protective eyewear) are readily accessible, available, and are used correctly by staff in all patient care areas.

- IPC.9.1 Written policies and procedures are available on the appropriate use of gloves, gowns, facemasks, protective eye wear.
- IPC.9.2 Gloves are properly used.
- IPC.9.3 Gloves are worn when there is a potential risk for blood/body fluid contact.
- IPC.9.4 Gloves are removed and discarded after use.
- IPC.9.5 Gloves are removed as soon as healthcare professional duties are completed and before leaving room.
- IPC.9.6 Contaminated gloves are not used to touch uncontaminated surfaces (telephone, pens, paper, and files).
- IPC.9.7 Gowns or other protective clothes are worn during all procedures, that are likely to generate splashes or soiling from blood or other body fluids.
- IPC.9.8 Masks, protective eyewear, or face shields are worn during all procedures that are likely to generate droplets of blood or body fluids.

Evidence of Compliance

- IPC.9.EC.1 Infection control manual includes policies on the appropriate use of personal protective equipment (PPE). Document Review
- IPC.9.EC.2 Disinfectants and PPE are readily accessible in all areas where it is required. Observation

IPC.10 The primary healthcare center designs and implements an effective hand hygiene program:

- IPC.10.1 Written policies and procedures on appropriate hand hygiene are available.
- IPC.10.2 Hand hygiene is strictly observed in the center.
- IPC.10.3 The center provides sufficient hand hygiene facilities, such as sinks and alcohol hand rubs.
- IPC.10.4 Toilets and hand washing facilities meet the needs of the center and are clean and in good repair.
- IPC.10.5 Hand washing sinks should be available in all patient care areas (e. g clinics, dressing room, and nursing stations).
- IPC.10.6 Hand washing sinks facilities are supplied with hot and cold water under pressure.
- IPC.10.7 Hand washing sink are easily accessible to staff.
- IPC.10.8 Plain and antiseptic soap and paper towels (not cloth towels) are available for hand washing.
- IPC.10.9 Hand disinfectants is available in adequate number (one dispenser per clinic, dressing room, and one in every nursing station).

Evidence of Compliance

- IPC.10.EC.1 Proper hand hygiene technique is performed according to policies including IPC.10.1 through IPC.10.9. Interview
- IPC.10.EC.2 There is evidence that the center provides the necessary resources to ensure the implementation of hand hygiene practice (toilets, hand washing facilities, hot and cold water, plain and antiseptic soap, paper towels, and hand disinfectant with dispenser). Interview

IPC.10.EC.3 There are sufficient hand hygiene points.

Observation

IPC.11 There is a documented staff education program on infection control practices.

Evidence of Compliance

IPC.11.EC.1 All staff are well trained on a coordinated, comprehensive, and continuous infection control training program.

IPC.12 Appropriate procedures are taken to manage any cases of healthcare-associated infection in the primary healthcare center.

Evidence of Compliance

IPC.12.EC.1 There are written policy and procedures for managing cases of HAIs.

Document Review

IPC.12.EC.2 There is evidence of managing cases according to the written policy and procedure.

Interview

IPC.13 The primary healthcare center defines in policy the cleaning, decontamination and disinfection processes in all patient care areas.

IPC.13.1 List of appropriate detergents and disinfectants are defined and approved.

IPC.13.2 Detergents and disinfectants are available in all patient care areas.

IPC.13.3 Patient care areas are clean and equipment are disinfected according to policy.

Evidence of Compliance

IPC.13.EC.1 There is a written policy and procedure for cleaning, decontamination, and disinfection processes, with an available and approved list of disinfectant.

Document Review

IPC.13.EC.2 Detergents and disinfectants are available in all patient care areas and adhere to the approved disinfectant's list.

Observation

IPC.14 The primary healthcare center defines in policy the safe procedure for waste collection, storage, and disposal to ensure the safety of internal and external environment.

IPC.14.1 The policy differentiates between regular waste and infectious waste.

IPC.14.2 The infectious waste is treated according to the national medical waste management system.

Evidence of Compliance

IPC.14.EC.1 There is a written policy and procedures on waste management.

Document Review

IPC.14.EC.2 There is evidence of implementation of the proper procedures on waste management.

Interview

IPC.14.EC.3 There is proper waste collection, storage, and disposal using the required resources, in a way that protect staff and environment.

Observation

IPC.15 A comprehensive program for preventing sharp injuries is implemented:

- IPC.15.1 There is a written policy and procedure that addresses handling sharps.
- IPC.15.2 Needles are not bent, broken, or recapped except in special and approved circumstances.
- IPC.15.3 If recapping is necessary, the 'scoop method' is used.
- IPC.15.4 Performing the necessary investigations following needle stick or sharps injury. Needle stick/sharp injury data is collected for trending and reported at infection control committee.

Evidence of Compliance

- | | | |
|-------------|--|-----------------|
| IPC.15.EC.1 | There are written policies and procedures on handling sharps, use and disposal. | Document Review |
| IPC.15.EC.2 | There is evidence of follow-up after exposure of needle prick/sharps injury as per infection control guidelines. | Document Review |
| IPC.15.EC.3 | There is evidence of calculation of sero-conversion among staff. | Document Review |
| IPC.15.EC.4 | PHC staff have the knowledge and skills on handling sharps (needles are not bent or broken, scoop method for necessary recapping). | Interview |

IPC.16 Sharps are discarded in appropriate containers:

- IPC.16.1 The type of sharp container used is puncture-proof, leak-proof, and presents no risk to staff or patients.
- IPC.16.2 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.
- IPC.16.3 Sharp containers are properly used: not overfilled, not opened to transfer sharps into other containers, and at/or below eye level.
- IPC.16.4 Sharp containers are disposed through the nationally approved system for medical waste management when its contents are 3/4 full.

Evidence of Compliance

- | | | |
|-------------|--|-------------|
| IPC.16.EC.1 | There are sufficient numbers of sharp containers that are puncture and leak proof and presenting no risk to staff or patients. | Observation |
| IPC.16.EC.2 | Sharp containers are properly located, and sent for incineration when their contents are 3/4 full. | Observation |

IPC.17 Housekeeping has policies and procedures describing their functions and include:

- IPC.17.1 All units have a cleaning / disinfection schedule that lists all environmental surfaces and items to be cleaned.
- IPC.17.2 There is review of cleaning procedures, schedules, and agents by infection control staff.

Evidence of Compliance

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|-------------|---|-----------------|
| IPC.17.EC.1 | Cleaning schedules are prepared and implemented by housekeeping staff and monitored by infection control staff. | Document Review |
| IPC.17.EC.2 | There is a list indicating chemicals concentrations and method of use in the center. | Document Review |

IPC.18 The primary health care environment is kept clean and safe.**Evidence of Compliance**

- IPC.18.EC.1 There are separate dirty and clean utility rooms in the center. Observation
- IPC.18.EC.2 There is evidence of center-wide clean environment, lockers, and cabinets. Observation

IPC.19 There is a system to handle blood/ body fluid spills and wastes:

- IPC.19.1 PHC staff working in patient care areas are proficient in cleaning blood/body fluids spills.
- IPC.19.2 There is a spill kit in every patient care unit that includes all necessary equipment. Policies on spill kit use should be written.

Evidence of Compliance

- IPC.19.EC.1 There are written policies and procedures on handling spills. Document Review
- IPC.19.EC.2 There is accessible spill kit in areas where it may be needed for use. Observation

IPC.20 The primary healthcare center sterilization process is conducted by qualified staff.**Evidence of Compliance**

- IPC.20.EC.1 Central sterilization service staff is qualified as CSSD technician or a nurse who has adequate experience and training in sterilization. Personnel File

IPC.21 Equipment and supplies used for sterilization and disinfection stated in the IPC program are available.**Evidence of Compliance**

- IPC.21.EC.1 The infection control program includes a list of all equipment and supplies used for sterilization and disinfection. Document Review
- IPC.21.EC.2 Sterilization equipment and supplies are available. Observation

IPC.22 A sterilization room (unit) must be available with the following structural and functional specifications:

- IPC.22.1 Personal protective equipment is available and used during decontamination: heavy-duty gloves, waterproof aprons, facemask, goggles, or face shield.
- IPC.22.2 Sterilization service staff have adequate knowledge and training.
- IPC.22.3 Cleaning, disinfection, and sterilization of medical equipment should be done in sterilization unit and not in the respective departments.
- IPC.22.4 There is a uni-directional flow of traffic from dirty to clean areas, i.e. decontamination area > packing > sterilization > storage areas.
- IPC.22.5 Proper sterilization parameters are recorded.
- IPC.22.6 Sterilization records are kept for one year to allow inspection.
- IPC.22.7 Sterilizers are in good working order and instructions are available for sterilizers.

IPC.22.8 Chemical indicators are used in every package. Biological indicators are used at least weekly. Records of results are kept for one year.

Evidence of Compliance

- | | |
|--|-----------------|
| IPC.22.EC.1 There are written policies and procedures for disinfection and sterilization. | Document Review |
| IPC.22.EC.2 There is complete and comprehensive monitoring of the sterilization process that is documented and can be presented (sterilization records, spore results, biological indicator results, and other records). | Document Review |
| IPC.22.EC.3 All cleaning and sterilization of medical equipment is performed in the sterilization unit. | Observation |
| IPC.22.EC.4 There is a uni-directional flow of traffic from dirty to clean areas, i.e. decontamination area > packing > sterilization > storage areas. | Observation |
| IPC.22.EC.5 Chemical and biological indicators are used in the sterile packages. | Observation |

IPC.23 The primary healthcare center has an employee's health program in accordance with scientific recommendations and the institutional guidelines to assure employee protection against the following infectious agents; TB, Hepatitis B, C, HIV, Measles, mumps, rubella, and varicella.

- IPC.23.1 There is written policies and procedures that address employees' immunization and post exposure prophylaxis.
- IPC.23.2 Conducting pre-employment assessment on every staff member as required by laws and regulations.
- IPC.23.3 There is a process for referral of employees to staff health clinic for counseling and medical services related to screening, immunization, and post exposure management.
- IPC.23.4 The screening and immunization data are kept in staff health records.
- IPC.23.5 Baseline screening of all employees for hepatitis B, C, HIV, and PPD should be done.
- IPC.23.6 The immune status of employees against hepatitis B, measles, mumps, rubella, and varicella should be determined by serological testing and/or authenticated document proving the appropriate vaccine administration.
- IPC.23.7 Response to hepatitis B vaccination is monitored in vaccinated employees.
- IPC.23.8 Non-responders to hepatitis B vaccine are offered at least a second session of the vaccine.
- IPC.23.9 Employees are screened for TB upon contracting with PPD test, and the test repeated annually for those who are non-reactive.

Evidence of Compliance

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|---|-----------------|
| IPC.23.EC.1 Policies for staff health that include IPC.23.2 to IPC.23.9. | Document Review |
| IPC.23.EC.2 Response to hepatitis B vaccination is monitored in vaccinated employees, Non-responders are offered at least a second series of the vaccine. | Document Review |
| IPC.23.EC.3 Employees are screened for TB upon contracting with PPD test, and the test repeated annually for those who are non-reactive. | Document Review |
| IPC.23.EC.4 Employees' health records reflect required staff immunization. | Personnel File |

- IPC.23.EC.5 The immune status of employees against hepatitis B, measles, mumps, rubella, and varicella should be determined by serological testing.
- IPC.23.EC.6 The vaccine is available according to staff immunization policies. Observation

IPC.24 Infection control team monitors incidence of exposure of the staff to pathogens in the primary healthcare center:

- IPC.24.1 There is a system for reporting, follow-up, and management of exposure to open pulmonary TB.
- IPC.24.2 There is a system for reporting, follow-up, and management of needle stick and sharp injuries.
- IPC.24.3 There is a system for reporting, follow-up, and management of exposure to vaccine-preventable viruses (chickenpox, measles, mumps, and rubella).
- IPC.24.4 PPD conversion rate is calculated and sharp injuries aggregated data.

Evidence of Compliance

- IPC.24.EC.1 There are policies on identification of exposures to TB, varicella, and sharp injuries, with clear procedures for post exposure management. Document Review
- IPC.24.EC.2 Infection control staff report and monitors incidence of exposure of staff to: open pulmonary TB, needle prick and sharp injuries, chickenpox, measles, mumps, and rubella. Appropriate management is followed as indicated. Document Review
- IPC.24.EC.3 There is calculation of aggregated data on PPD conversion rate and sharp injuries. Document Review
- IPC.24.EC.1 There are policies on identification of exposures to TB, varicella, and sharp injuries, with clear procedures for post exposure management. Document Review

IPC.25 There is a system that separates patients with communicable diseases and those who are colonized or infected with epidemiologically important organisms from other patients, staff and visitors.

Evidence of Compliance

- IPC.25.EC.1 There are written policies and procedures on standard and transmission-based precautions. Document Review
- IPC.25.EC.2 There is evidence of compliance with standard and transmission-based precautions. Observation

IPC.26 Infection control practitioner implements the required guidelines for prevention of infections among patients, visitors, and staff when renovation projects occur at primary healthcare center.

Evidence of Compliance

- IPC.26.EC.1 There is a written policy and procedure on infection control during renovation. Document Review
- IPC.26.EC.2 There is evidence of providing negative pressure during a renovation process within construction areas, with environmental disinfection process for fungal sporing conducted after any renovation. Document Review

IPC.27 Communicable diseases are tabulated and reported, as required by law and regulation.**Evidence of Compliance**

IPC.27.EC.1 There is evidence of implementing a policy for reporting Document communicable diseases as required by laws and regulations. Review

IPC.28 Laundry functions are supervised by infection control.

IPC.28.1 There is a written policy and procedure on linen management.

IPC.28.2 Clean linen is transported, handled, and stored in a way that keeps it protected from contamination and dust.

IPC.28.3 There is functional separation of clean and used linen during storage and transport.

IPC.28.4 Linen carts used for clean and used linen are clearly identified.

IPC.28.5 Dirty laundry must be enclosed at all times.

IPC.28.6 Contaminated laundry with patient's blood, excreta, or other body fluids are contained and transported in accordance with the following standards:

IPC.28.6.1 Linen is handled as little as possible and with minimum agitation.

IPC.28.6.2 Linen is bagged at the location where it is used, and is not stored or pre-rinsed in patient care areas.

Evidence of Compliance

IPC.28.EC.1 There are written policy and procedures on linen management Document that protects patients and health care workers from infectious Review hazards.

IPC.28.EC.2 There is proper linen handling, transportation, and storage using Observation the required resources, in a way that protect staff and the environment.

Glossary

Access: A person's ability to obtain necessary medical care and services when needed. The ease of access is determined by components such as the availability of medical services, 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 patient's 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 behaviors 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 processes.

Competence: 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 for 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 a process.

Credentialing: 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: Describes the ability to do what is desired or to be effective at producing a result. For example, clinical trials in medicine provides evidence that a treatment/medication improves patient outcomes.

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 policies 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 center.

Guidelines: Principles guiding or directing action.

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

Hazardous Waste: Materials that are 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 Organization: A generic term used to describe many types of organizations that provide health care services.

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.

Health Record: A record that contains patient health information generated by one or more healthcare 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 center.

Indicator: Performance measurement tool that 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: Written statements that describe the duties, responsibilities, required qualifications, and reporting relationship for employee in his/her current job.

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

Management: Persons that set 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 safe handling and emergency procedures for hazardous properties of chemicals and other hazardous agents.

Objectives: Concrete, measurable steps taken to achieve goals.

Organizational Chart: A diagram representing the structure of the center 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 person for whom a center 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, or healthcare provider.

PDCA: Is a scientific method utilized to improve processes. The 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 or team.

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 other healthcare providers. 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 that 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.

Primary Care: Is the point when the patient first seeks assistance from the medical care system before referral elsewhere within the system. It is also basic, general, or essential health care. The primary care provider assumes ongoing responsibility for the patient in both health maintenance and treatment.

Privileging: The process of reviewing an individual's credentials through a committee 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 three (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/she finds himself/herself and the dynamics or factors which influence the individual's 'psyche'.

Quality: The degree to which health services for individuals and populations increase the likelihood of desired outcomes 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 setting for other resources, either for consultation or care that the referring source is not prepared or qualified to provide.

Rehabilitation: Treatment or treatments designed to facilitate the process of recovery from injury, illness, or disease to as normal a condition as possible.

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 and services provided to patients and/or other customers by the leadership, clinical, and support personnel. A documented scope of service describes the full range of services, the demographics (age groups, types of patients) diagnostics provided, therapeutic interventions provided, and the number of patients that received services annually. 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 patients that indicate further evaluation is warranted.

Sentinel Event: Is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.

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

Standardization: To conform with a predetermined set of expectations.

Strategic Planning: A management tool to help an organization define its direction and make decision on resource allocation in order to meet goals. It is a 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 that 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, and determining the order of being managed.

Turn Around Time: Initial time from the starting point to the end point. For example: when the physician writes an order for a patient laboratory test to the time results are reported to the doctor.

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 behavior.

Vision: Description of what the organization would like to be.