CBAHI

المركز السعودي لاعتماد المنشآت الصحية

Saudi Central Board for Accreditation of Healthcare Institutions

المعايير الوطنية للمستشفيات

NATIONAL HOSPITAL STANDARDS

THIRD EDITION 2015

SAUDI CENTRAL BOARD FOR ACCREDITATION OF HEALTHCARE INSTITUTIONS

Effective
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NATIONAL

HOSPITAL STANDARDS

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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.

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المركز السعودي
لاعتماد المنشآت الصحية (سباهي) هو:

الجهة الرسمية المخولة منح شهادات اعتماد الجودة لكافة المرافق الصحية الحكومية والخاصة التي تعمل في المملكة العربية السعودية. ينبثق المركز أساساً عن المجلس الصحي السعودي، ويعتبر جهة غير هادفة للربح، يتولى بشكل أساسي تقييم المنشآت الصحية بغرض تحديد مدى التزامها بتطبيق معايير الجودة وسلامة المرضى التي صممها المركز لهذا الغرض. بدأ المركز عمله تحت مسمى المجلس المركزي لاعتماد المنشآت الصحية بقرار معالي وزير الصحة رئيس مجلس الخدمات الصحية رقم (١٤٤١٨٧) وتاريخ ١-٩-١٤٢٦هـ ، واستمر في تأدية المهام المناطة به حتى صدور قرار مجلس الوزراء الموقر رقم (٣٧١) وتاريخ ٢٤-١١-١٤٣٤هـ ، القاضي بتحويله إلى المركز السعودي لاعتماد المنشآت الصحية ، واستمراره في وضع وتطبيق المعايير الوطنية للجودة وسلامة المرضى في كافة المرافق الصحية ومنح شهادات الاعتماد المتعلقة بذلك. يعتبر الحصول على الاعتماد الوطني من قبل المركز السعودي إلزامياً على كافة المرافق الصحية الحكومية والخاصة بموجب القرار سالف الذكر وبموجب قرار المجلس الصحي السعودي رقم (٨/ ٥٨) وتاريخ ٩-١-١٤٣٣هـ، كما تشترط وزارة الصحة السعودية تطبيق معايير الاعتماد الوطني الموضوعة من قبل المركز وإثبات ذلك بالحصول على شهادة الاعتماد كمتطلب مستقبلي من متطلبات الاستمرار في الترخيص للمنشآت الصحية الخاصة الخاضعة لإشرافها.

The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI)

is the official agency authorized to grant accreditation certificates to all governmental and private healthcare facilities operating today in Saudi Arabia. CBAHI has emerged from the Saudi Health Council as a non-profit organization. The principal mission of CBAHI is to set the healthcare quality and patient safety standards against which all healthcare facilities are evaluated for evidence of compliance. The foundation of CBAHI dated back to October 2005 as the Central Board for Accreditation of Healthcare Institutions, formed then by the Ministerial Order Number (144187). Since then, it continued pursuing its mission until 30-9-2013 when the Cabinet of Ministers Decree Number (371) called for changing the name to become the Saudi Central Board for Accreditation of Healthcare Institutions, and also mandated the national accreditation by CBAHI on all healthcare facilities. The Ministry of Health is planning to mandate CBAHI accreditation as a future prerequisite for renewal of the operating license, a step towards encouraging more participation in this ambitious national initiative.

Table of Contents

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 many 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 third edition of the National Hospital 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 this third edition of the National Hospital Standards. 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 hospitals and the complexity of health care services they provide to more than twenty eight 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 hospital environments that support performance measurement and continuous quality improvement. Here comes the rationale for national, evidence-based standards that would support acute care hospitals in Saudi Arabia in improving the quality and safety of patient care and treatment.

Since the official inception in the late 2005, accreditation by the "Central Board" was a voluntary program that showed a remarkable success over the years. Lately, this has changed into a national mandatory program that is intended to be linked with licensure in order to enhance its mission and encourage more participation of more than four hundred hospitals operating today across the country.

During the development of this current edition of the hospital standards, one of the most important challenges we faced was to develop standards that would apply to all acute care hospitals, considering the variation in the quality levels across the continuum of care as we move from small hospitals in the small peripheral cities and towns to the large tertiary medical centers in the major cities. Being departmental, detailed and prescriptive in design and nature, this third edition of the National Hospital Standards was built to be as relevant and applicable as possible once implemented in the relevant hospitals licensed to practice in the Kingdom of Saudi Arabia.

As with the previous editions, the development of hospital standards aims to facilitate the process of hospital self-assessment against preset requirements and performance expectations, ensure patient and public safety, encourage the hospital leadership to measure the hospital 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 goes 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 hospital and other accreditation programs of CBAHI, as well as for all comments and suggestions for improvement, please contact us at cbahi@cbahi.gov.sa

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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.
In addition to the hospital accreditation program, CBAHI now has two other accreditation programs (Primary Healthcare Centers and Ambulatory Healthcare Centers including Medical Laboratories). Additional certification program for blood banks and blood transfusion services is underway.

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), both 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 hospital beds available, the manpower, the design of the hospital 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 hospital in the care of patients or in the management of the hospital 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 surgery, air embolism, blood incompatibility, pressure ulcers, falls, vascular catheter-associated infection, catheter-associated urinary tract infection, and manifestations of poor glycemic control.

CBAHI standards set expectations for hospital performance that are reasonable, attainable, measurable and therefore, surveyable. 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 hospitals 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 hospital 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 hospital 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 hospital leaders, physicians, nurses, employees, and patients in order to determine the hospital'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 hospital. Similarly, a surveyor might choose to interview a patient about his or her level of satisfaction with the care provided by the hospital. Hospital leaders, including the members of the governing body, may be interviewed regarding the hospital'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 hospital'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, central sterile services department, dietary and rehabilitation 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 hospital's compliance or performance with applicable structure, process, and outcome standards. These methods might include any combination of the following:

- Interviews with hospital 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 hospital's achievement of specific outcome measures (e.g., hospital-acquired infection rates, patient satisfaction) through a review and discussion of monitoring and improvement activities.

CBAHI team conducts a three-day survey unless required to be more depending on the volume and complexity of services provided by the hospital, 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 hospital to be surveyed. This implies that any service/function/area that is not covered by the CBAHI hospital 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 Hospital Standards Manual – 3rd Edition

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

1. Leadership (LD)
2. Human Resources (HR)
3. Medical Staff (MS)
4. Provision of Care (PC)
5. Nursing Care (NR)
6. Quality Management and Patient Safety (QM)
7. Patient &Family Education and Rights
   - Patient &Family Education (PFE)
   - Patient &Family Rights (PFR)
8. Anesthesia Care (AN)
9. Operating Room (OR)
10. Critical Care
    - Adult Intensive Care Unit (ICU)
    - Pediatric Intensive Care Unit (PICU)

- Neonatal Intensive Care Unit (NICU)
- Coronary Care Unit (CCU)

11 Labor &Delivery (L&D)
12 Hemodialysis (HM)
13 Emergency Care (ER)
14 Radiology Services (RD)
15 Burn Care (BC)
16 Oncology &Radiotherapy (ORT)
17 Specialized Care Services
- Respiratory Care Services (RS)
- Dietary Services (DT)
- Social Care Services (SC)
- Physiotherapy Services (PT)

18 Dental Care (DN)
19 Management of Information and Medical Records
- Management of Information (MOI)
- Medical Records (MR)

20 Infection Prevention and Control (IPC)
21 Medication Management (MM)
22 Laboratory (LB)
23 Facility Management and Safety (FMS)

Each chapter has a brief introduction that explains the chapter's relevance and contribution to safety and quality 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. Unlike the older editions of the hospital standards, each substandard is now constructed in a way so that to serve by itself as the evidence of compliance that is going to be measured and scored during the on-site survey.

Broadcast on changes in this third edition of hospital standards - Chapters, Standards and Survey Process

The CBAHI accreditation standards for hospitals underwent an extensive review based on the experience gained over the past years. The changes in this new edition include the chapters, standards, and the survey process.

Chapter Changes

The standards related to human resources in the former "Leadership" chapter have been moved, modified, and updated in a new separate chapter "Human Resources". Additionally, the former chapter "Medical Staff and Provision of Care" has been divided into two chapters: "Medical Staff", which describes the structure and organization of the medical staff as an entity within the hospital and "Provision of Care" that addresses the quality and safety of the actual clinical care processes provided to patients. Moreover, the "Ambulatory Care" and the "Psychiatry" chapters of the previous editions have been merged with the "Provision of Care" chapter to emphasize the continuum of care from the beginning of the episode of care until patient is discharged.

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 hospital. 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 hospital.

Standards Changes

The 3rd edition of CBAHI hospital standards encompasses several new and revised standards for hospitals to advance quality care and patient safety. While the changes range from minimal adjustments in some areas to entirely new content in others, this edition maintains focus on quality care and patient safety. The standards were updated with four goals in mind:

- Develop new standards related to patient safety;
- Refine existing standards;
- Improve the clarity and applicability of standards; and
- Update the terminology to reflect current contexts.

No matter how robust was the methodology used in building the standards, 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 hospitals, 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.

Essential Safety Requirements

Adverse events often result in a longer hospital stay, 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 accredited hospitals, some of which had earned a high accreditation rating whether by CBAHI or other international accrediting organizations, 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 hospitals 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 old physiological principle ; the " All or None Law " , meaning that a standard that represents an Essential Safety Requirement is scored during the on-site survey as a full rate or zero, depending on the level of compliance as evidenced by documentation/interview/or observation of the surveyor. Partial compliance will not be acceptable for any ESR and accreditation award will not be granted unless all ESRs are in full compliance.

There are (16) Essential Safety Requirements distributed in the different chapters of this manual as follows:

HR.5	The hospital has a process for proper credentialing of staff members licensed to provide patient care.
MS.7	Medical staff members have current delineated clinical privileges.
PC.25	Policies and procedures guide the handling, use, and administration of blood and blood products.
PC.26	Patients at risk for developing venous thromboembolism are identified and managed.
QM.17	The hospital has a process to ensure correct identification of patients.
QM.18	The hospital has a process to prevent wrong patient, wrong site, and wrong surgery/procedure.
AN.2	Anesthesia staff members have the appropriate qualifications.
AN.15	Qualified staff perform moderate and deep sedation/analgesia.
IPC.4	There is a designated multidisciplinary committee that provides oversight of the infection prevention and control program.
IPC.15	Facility design and available supplies support isolation practices.
MM.5	The hospital has a system for the safety of high-alert medications.
MM.6	The hospital has a system for the safety of look-alike and sound-alike (LASA) medications.
MM.41	The hospital has a process for monitoring, identifying, and reporting significant medication errors, including near misses, hazardous conditions, and at-risk behaviors that have the potential to cause patient harm.
LB.51	The blood bank develops a process to prevent disease transmission by blood/platelet transfusion.
FMS.9	The hospital ensures that all its occupants are safe from radiation hazards.
FMS.32	The hospital ensures proper maintenance of the medical gas system.

Eligibility for Accreditation

All hospitals 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 hospital 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 hospital meets any additional licensing requirements as indicated by other relevant authorities (Most notably, valid certificate from the Civil Defense, and any radiation-related licensing requirements from King Abdul Aziz City for Science & Technology).

- The hospital meets the legal definition of a hospital as per the regulations of the Ministry of Health and the international guidelines in this regard :
  - Licensed as a hospital 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 inpatient beds for the care of overnight resident patients, i.e. bed and board.
  - Provides diagnosis (has laboratory and radiology services) and medical or surgical treatment primarily for, but not limited to, acutely sick and injured patients. (This manual is not for facilities providing treatment for patients with mental illness or providing treatment in special inpatient care facilities e.g. long term care facilities).
  - Provides emergency and intensive care services.

- The hospital provides healthcare services addressed by the CBAHI's National Hospital Standards.

- The hospital has been in operation for at least (12) months before the on-site survey.

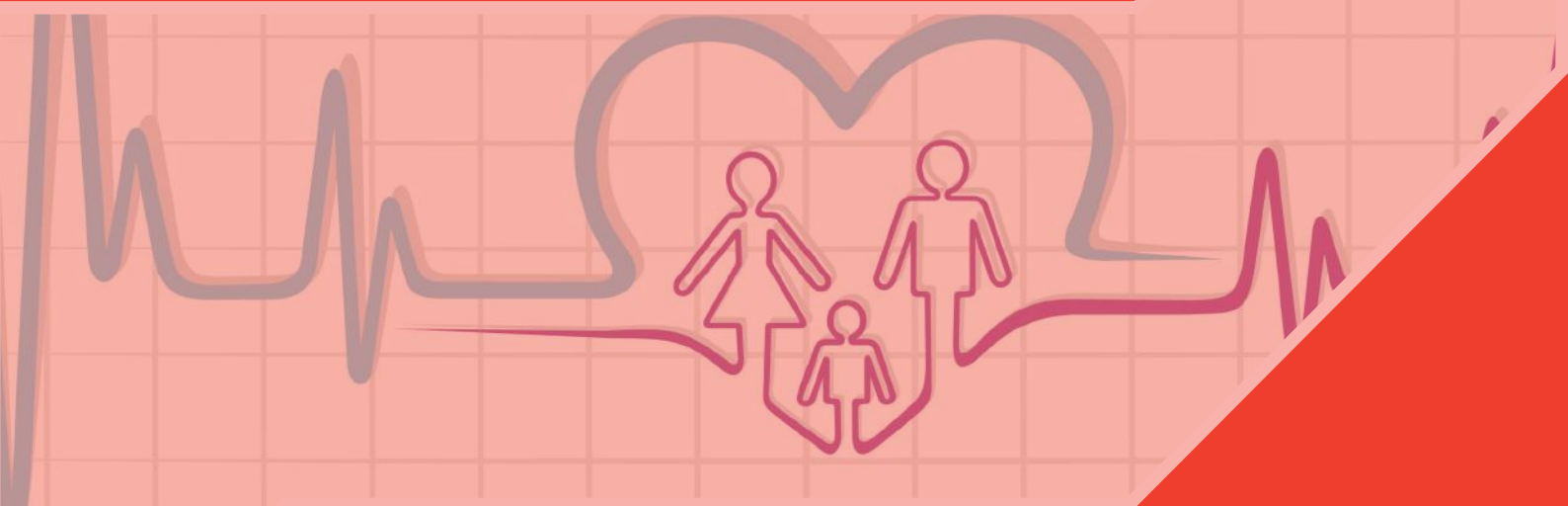
Effective Date of the National Hospital Standards Manual- 3rdEdition

The effective date of this third edition of the National Hospital Standards is the first of January 2016. This is the date after which all surveys and accreditation decisions will be based on this third edition of the National Hospital Standards. This applies to hospitals seeking accreditation by CBAHI for the first time as well as hospitals already accredited by CBAHI based on older editions of the hospital 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 hospitals or for all other accreditation programs offered by CBAHI.

Hospitals 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 hospitals seeking CBAHI accreditation:

- National Hospital Standards
- Hospital Accreditation Guide

Hospital Accreditation Guide provides all required information to help the hospital 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 hospital included in its yearly accreditation program by a letter of enrollment.

CBAHI provides ongoing Hospital Orientation Programs (HOPs) in different locations throughout the year. Hospitals are highly encouraged to attend at one of HOPs offered by CBAHI, Although any hospital can attend, the priority goes for hospitals 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 hospital 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 hospitals in a timely manner.

All hospitals 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 hospital 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 hospital 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 hospital and provides for a common communication tool between the hospital 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 hospitals (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 hospital 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 hospitals 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 hospitals however may choose to go for an upfront Real Survey.

Once a hospital 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 hospital. As a general rule, a minimum of seven days will be allowed for hospital notification before the survey is actually conducted. When a short notice survey is to be conducted, the hospital leadership is expected to receive the survey team and facilitate its work. Failing to do so will subject the hospital 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 hospital 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 hospital and a copy is returned back to CBAHI.
- Evidence of payment of the required accreditation fees.

The maximum number of real surveys a hospital 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 hospitals previously accredited by CBAHI, the time interval between registration and achieving accreditation was 6-18 months on average. Therefore, hospitals 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 hospital 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.

Hospitals 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 hospital indicating the date of the survey and other relevant information. The size and the specialties of the hospital survey team members are usually fixed but this might change according to the size of the hospital 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 hospital survey team is composed of seven (7) healthcare professionals:

- The Core team, composed of three surveyors: administrator, nurse, and physician.
- The Specialty Team, composed of four surveyors: Pharmacist, Infection Control specialist, Laboratory specialist, and facility management and safety specialist.

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 hospital 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 hospital;
- Chairing the opening and closing meetings;
- Communicating with hospital 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 Hospital Accreditation Guide provided to all hospitals upon successful registration.

Rescheduling / Postponement of Surveys

Hospitals scheduled for surveys are strongly encouraged to adhere to the survey date proposed by the Healthcare Accreditation Departmentat 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 hospital, natural or other disasters, or relocation of the hospital to another building).
- At least (30) days advance notice (an official letter from the hospital 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 hospital, 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 hospital 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 hospital 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 hospital 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 hospital 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 hospital 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. Examples include:

- Healthcare provider is entering a contact isolation room without proper Personal Protective Equipment (PPE).
- Expired catheter is being used during central line insertion or other invasive procedure.
- Bare electrical wire is hanging down without any protection.
- Incompatible blood sample is sent from the operating room while the operation is in progress.
- A new-born is not properly identified.

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 hospital director and will include the findings in the survey report. Consequently, the hospital 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). The sub-standard is the evidence of compliance to be scored by the surveyor during the on-site survey. Each sub-standard has an equal weight and is scored on a three point scale as follows:

0 = Insufficient Compliance (Less than 50% compliance with the standard).
1 = Partial Compliance (From 50% to less than 80% compliance with the standard).
2 = Satisfactory Compliance (80% and more compliance with the standard).
N/A = Not Applicable

The overall score of the hospital is calculated using the average (arithmetic mean) score of all applicable sub-standards, 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 hospital, 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 Hospital Accreditation Guide.

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

Accredited:

Accreditation will be awarded when the surveyed hospital 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 hospital a period of time to come into acceptable compliance.

Scoring Guidelines:

- Overall score 85% or above and
- All essential safety requirements are in satisfactory compliance and
- No other issues of concern related to the safety of patients, visitors or staff.

Conditional Accreditation:

Conditional Accreditation is granted when the hospital 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 hospital 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
- Some of the essential safety requirements (but not exceeding 25% of them) are not in satisfactory compliance.

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.
- 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 hospital 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 hospital is required to respond to CBAHI by sending an official clarification letter within five working days of the communication.
- Refusal by the hospital to receive the survey team and conduct a survey. In this case, the hospital 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 hospital 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
- More than 25% of the essential safety requirements are not in satisfactory compliance.

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 hospital 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 appealer- 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 hospital sustained one of the grounds for appeal), the prior status of the hospital, 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. Hospitals 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 appealer 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 hospital, 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,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 hospital is conditionally accredited, it is expected to maintain this "transitional" status until fulfilling the requirements for an accredited status. Therefore, the hospital 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 hospital 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 hospital 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 hospitals 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 hospital should start utilizing the self-assessment tool to assist in the periodic review of its performance against the standards. The hospital then has (3) months to complete the assessment.

Completion of the midterm assessment will allow the hospital 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 hospital 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 hospital'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 hospital 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 hospital at the time of the mid-term assessment, CBAHI may require the hospital 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 hospitals 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 hospital.
- The hospital 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).

- Hospital 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 hospital 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 hospitals. 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 hospital 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 hospital 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 hospital accredited by CBAHI, it must be reported to CBAHI as indicated in the timeframe below. Hospitals 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 hospital leadership- to report any sentinel event without fear of retribution. CBAHI has zero tolerance for accredited hospitals 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 hospital.

- Starting from January 2016, hospitals 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 hospital 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 hospital 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 hospital 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 hospital 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 hospitals 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 hospital 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 hospital.
- The hospital 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 hospital failed to report a sentinel event as per the relevant policy without an acceptable justification.
- The hospital 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 hospital 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 hospital 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 hospital 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 hospital, 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 hospital's continued compliance with CBAHI Standards). An accredited hospital may undergo a discretionary survey at any time, at the discretion of CBAHI, and the survey is usually unscheduled (the hospital 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 hospital's services or only those areas where a serious concern may exist. Hospitals are usually charged for these surveys, regardless of the outcome, and results can affect the hospital accreditation status. If the hospital does not allow CBAHI surveyors to conduct the survey, CBAHI may change the hospital's status to Revocation of Accreditation.

It should be noted that when the hospital accreditation is suspended, the hospital 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 hospital 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 hospitals 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 hospitals remain committed to CBAHI standards throughout the accreditation cycle. Random surveys also provide CBAHI and its surveyors with opportunities to further consult with accredited hospitals in the interval between regular surveys. No fee shall be charged to the hospital 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 hospitals 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 hospital 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 hospital 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 hospital 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 hospital to the appropriate decision according to the policy on accreditation suspension and revocation.

Release of Accreditation-Related Confidential Information

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

- The hospital accreditation status being posted on CBAHI website.
- The areas of the hospital 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 hospital 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 hospital director.
- The accreditation certificate.
- 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 hospital.
- Any other information related to compliance with CBAHI standards that is obtained from the hospital before, during, or following the accreditation survey.

Complaints against Accredited Hospital

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

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 hospitals that it does not accredit.

When a complaint against accredited hospital 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 hospital 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 hospital. Broadly speaking, CBAHI will take one or both of the following responses:

- CBAHI may write to the hospital about the complaint received and the hospital is required to make available, when requested, its records of complaints and subsequent action taken.
- CBAHI may decide to visit the hospital 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 hospital's accreditation decision following completion of the complaint investigation.

To file a complaint against a hospital 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 provides 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.

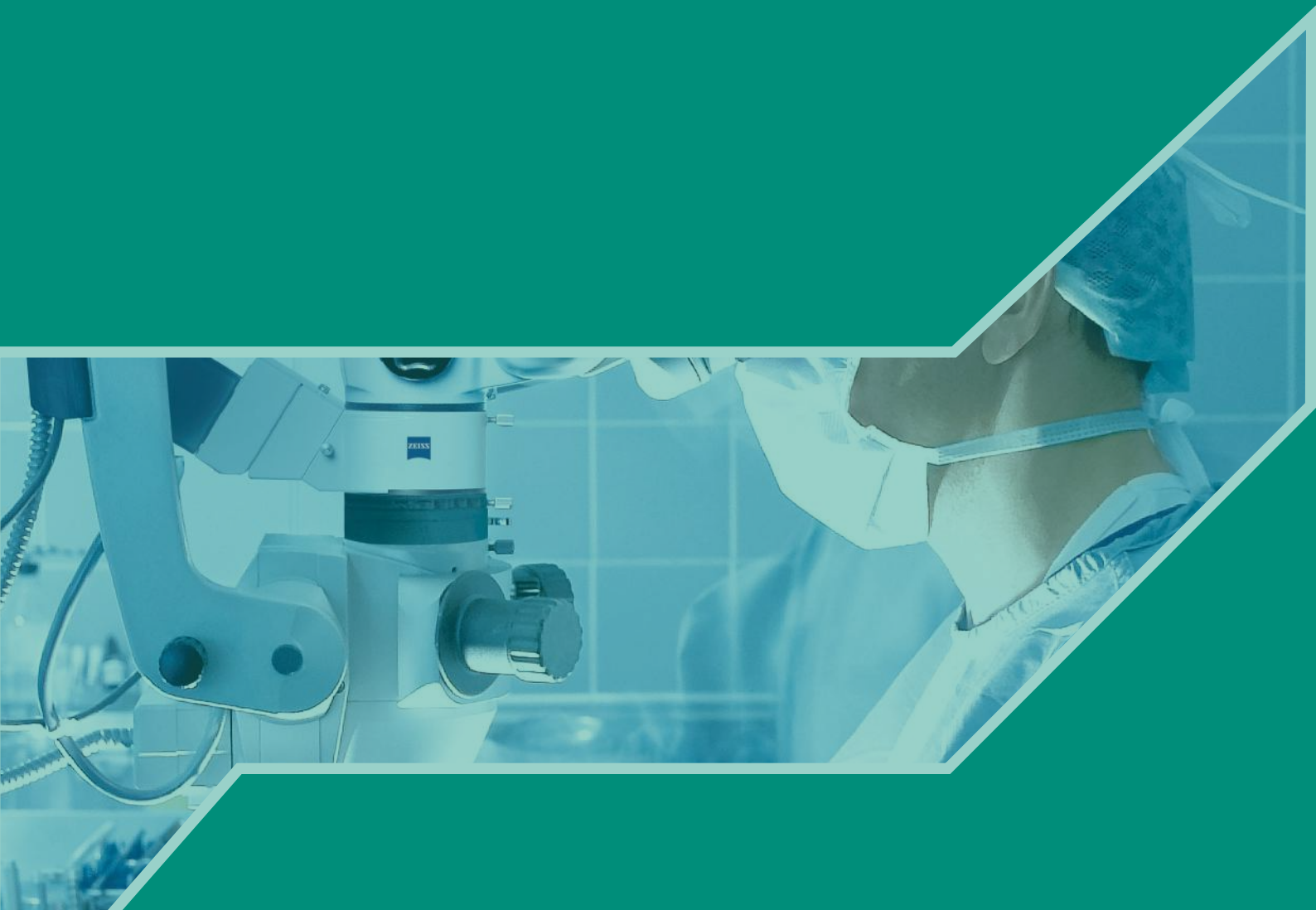
Truthfulness and Ethics Clause

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 hospitals 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 hospitals are encouraged not to offer such to the survey team. Transporting the survey team by the hospital 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 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 hospitals in order to ensure justice, confidentiality, impartiality, timeliness, and feedback to the complainant.

PART III

STANDARDS



LEADERSHIP (LD)

Introduction

For any hospital, quality and patient safety depend on effective leadership. It is important for all hospitals to have a clearly stated mission and vision, and it is the responsibility of the leadership of the hospital to develop the appropriate mission and vision and provide adequate resources to fulfill them. The leadership must come from the governing body and the executive management including the hospital director, the medical director, the nursing director, the administrators, and the heads of departments, with the governing body being the ultimate responsible for the quality and safety of health care services provided by the hospital. To ensure quality and safe care, the members of the leadership group must work collaboratively, communicate effectively through clear lines of authority, and coordinate and integrate all services provided.

Hospitals may vary in size, type of ownership, and complexity of services. Every hospital regardless of the complexity and scope of service has a governing body which might represents the Ministry of Health or its directorates, other governmental entities or a private owner. A large hospital tends to have a multi-member governing body that is ultimately accountable for the operation and performance of the hospital. In smaller hospitals, these responsibilities may be handled by just one or two individuals.

This chapter addresses the roles and responsibilities of the leadership group for several processes, the examples of which are:

- Hospital mission, vision, and values
- Organizational structure
- Development and promotion of professional ethical conduct
- Formulation and construction of the strategic plan
- Planning and designing services and structures
- Processes for collaboration, coordination, and communication
- Financial management
- Contracts oversight
- The responsibilities of the governing body
- The responsibilities of the hospital director
- The responsibilities of the departments heads

STANDARDS

LD.1 The hospital has an effective governing body.

LD.1.1 There is a governing body that fulfills its main roles for mission and strategy setting as well as performance evaluation and oversight on the hospital processes and outcomes.

LD.1.2 The governing body has its organization, membership, roles and responsibilities, meetings procedure, performance evaluation, and committees defined in a written bylaws or a similar document.

LD.1.3 The governing body's responsibilities reflect its ultimate accountability for the quality of care and patient safety, and include the following:

- LD.1.3.1 Working together with the senior management and hospital leaders to create and regularly review the hospital's mission, vision, and values.
- LD.1.3.2 Appointing a qualified hospital director.
- LD.1.3.3 Evaluating on a regular basis the performance of the hospital director.
- LD.1.3.4 Ensuring that the hospital has an effective organizational structure displayed in an organizational chart that shows the titles (or names) and the reporting relationships.
- LD.1.3.5 Approving the scope of services provided by the hospital.
- LD.1.3.6 Approving the hospital strategic and operational plans.
- LD.1.3.7 Approving the hospital-wide policies and procedures.
- LD.1.3.8 Monitoring, evaluating, and continuously improving the outcome of the quality and patient safety plans and programs.
- LD.1.3.9 Approving the medical staff bylaws.
- LD.1.3.10 Approving the annual budget of the hospital.
- LD.1.3.11 Ensuring the provision of adequate resources (e.g. manpower, financial resources, and medical supplies).
- LD.1.3.12 Defining and approving delegations of authority.

LD.1.4 The governing body meets regularly and adequate minutes of the proceedings are maintained.

LD.2 A qualified hospital director is responsible for managing the hospital.

LD.2.1 The hospital director is qualified in healthcare management by education, training or experience.

LD.2.2 The hospital director has a good command of the English language.

LD.2.3 The hospital director ensures the hospital's compliance with all relevant laws and regulations.

LD.2.4 The hospital director ensures the recruitment and selection of competent and skilled hospital staff.

LD.2.5 The hospital director is accountable to the governing body for the clinical performance and professional conduct of the hospital staff.

LD.2.6 The hospital director ensures the implementation of the policies set by the governing body.

LD.2.7 The hospital director participates actively in supporting the safety of patients, staff and visitors (e.g. through leadership safety rounds, review of reported incidents).

LD.2.8 The hospital director identifies and works closely with other hospital leaders, collectively constituting the hospital leadership group.

LD.2.9 The hospital director ensures appropriate response to reports or enquiries from relevant authorities including accreditation agencies.

LD.2.10 The hospital director ensures the availability of adequate resources (e.g. human resources, equipment, supplies, and medications).

LD.2.11 The hospital director ensures all physical properties are kept in a good state of repair and operating conditions.

LD.2.12 The hospital director ensures the efficient utilization of all resources.

LD.3 Hospital leaders ensure the hospital is in compliance with relevant laws and regulations.

LD.3.1 Hospital leaders identify all relevant laws and regulations.

LD.3.2 Hospital leaders ensure compliance with all relevant laws and regulations (e.g., laws and regulations related to recruitment, professional staff licensure and registration, waste management, food management, infection control, medications management, patient rights, radiation safety, and physical environment).

LD.4 Hospital leaders work collaboratively to develop the hospital's scope of services.

LD.4.1 Hospital leaders identify the scope of services provided by the hospital.

LD.4.2 The scope of services includes the range of services offered by the hospital (e.g., children hospital, maternity hospital, or general hospital).

LD.4.3 The scope of services includes the targeted age groups.

LD.4.4 The scope of services includes the number of patients seen annually.

LD.4.5 The scope of services includes the principal diagnostics and therapeutic modalities used in the hospital.

LD.4.6 The scope of services is approved by the governing body.

LD.5 A structure is in place for the hospital leaders to communicate and collaborate in order to fulfill the hospital's mission and plans.

LD.5.1 Hospital leaders form an executive management body (e.g., an executive management committee), led by the hospital director and includes the medical director, the nursing director, the quality director, selected heads of the departments, and other senior staff members as required.

LD.5.2 Hospital leaders are qualified in healthcare management by education, training, or experience.

LD.5.3 Hospital leaders have specific responsibilities as outlined in a current job description.

LD.5.4 Functions and meetings of the hospital leaders are outlined in specific terms of reference.

LD.5.5 Hospital leaders meet regularly (at least ten times per year) to evaluate the progress of the overall strategic plan , the quality and safety of care provided to patients, and all other clinical and non-clinical issues related to the hospital work.

LD.5.6 Discussions, decisions and actions taken by the hospital leaders are documented in a formal meeting minutes.

LD.6 The hospital administrative work and day to day operations are consistent and organized.

LD.6.1 The hospital work is guided by a manual that contains all important hospital-wide guiding administrative policies and principles.

LD.6.2 The contents of the manual are communicated with and made accessible to the hospital staff.

LD.6.3 Contents of this manual reflect the general organization of the hospital work and include, but are not limited to, the following:

LD.6.3.1 A brief general description of the hospital.
LD.6.3.2 Vision, mission and values.
LD.6.3.3 Organizational chart.
LD.6.3.4 Scope and organization of services.
LD.6.3.5 Standing meetings and committees.
LD.6.3.6 Staff code of conduct and ethics.
LD.6.3.7 Conflict of interest.
LD.6.3.8 Admission/Discharge/Referral.
LD.6.3.9 Visiting times.
LD.6.3.10 Smoking policy.
LD.6.3.11 Parking.

LD.7 The hospital work, planning, and goals setting are guided by a clear vision and mission.

LD.7.1 The hospital has a clearly stated vision and mission statements.
LD.7.2 The vision and mission are communicated to the hospital staff.
LD.7.3 The vision and mission are displayed to patients, visitors, and the wider community.
LD.7.4 The mission reflects the scope of services provided by the hospital and the health needs of the population served.
LD.7.5 The mission and vision are regularly reviewed and modified as appropriate.

LD.8 The hospital work, planning, and goals setting are guided by a set of values and professional code of conduct.

LD.8.1 Hospital leaders collaboratively develop the hospital's set of values and the code of conduct.
LD.8.2 The professional code of conduct describes the hospital's expectations of the staff regarding their behavior and communication with each other and with their patients and other external customers.
LD.8.3 The professional code of conduct includes a process to handle inappropriate behaviors of the hospital staff.
LD.8.4 The professional code of conduct includes a process to resolve conflicts among staff and between staff and external customers.

LD.9 Hospital leaders work collaboratively to establish medical and non-medical hospital-wide committees that support integration of services and communication amongst staff.

LD.9.1 There is a policy and procedure that addresses the formation of hospital-wide committees, conduct and communication amongst the committee members, committee's recommendations approval process, and annual review of accomplishments.
LD.9.2 Medical committees provide oversight on specific areas of responsibilities that include:
LD.9.2.1 Pharmacy and therapeutics.
LD.9.2.2 Morbidity and mortality.
LD.9.2.3 Infection control.

LD.9.2.4 Cardio pulmonary resuscitation.
LD.9.2.5 Credentialing and privileging.
LD.9.2.6 Operating room.
LD.9.2.7 Tissue review.
LD.9.2.8 Blood utilization review.
LD.9.2.9 Quality and patient safety.
LD.9.2.10 Medical records review.
LD.9.2.11 Patient rights.
LD.9.2.12 Utilization review.

LD.9.3 Each committee has terms of reference that define:
LD.9.3.1 Committee functions.
LD.9.3.2 Chairperson and members with their titles.
LD.9.3.3 Quorum.
LD.9.3.4 How often the committee is expected to meet (at least quarterly unless otherwise specified in this manual).
LD.9.3.5 Mechanism of disagreement resolution including when to resort for voting and members that are not allowed to vote.
LD.9.3.6 Distribution of the minutes to the executive management.

LD.9.4 There is an annual review of each committee's accomplishments and non-resolved issues submitted by the committee chair to the executive management.

LD.9.5 Feedback from the annual review is studied by the committee and recommendations are implemented.

LD.10 Hospital leaders drive effectively the quality improvement initiatives in the hospital.

LD.10.1 Hospital leaders are familiar with the basic concepts and tools used in continuous quality improvement, such as:
LD.10.1.1 Basic data analysis and interpretation of quality reports.
LD.10.1.2 Basic tools used in quality management (e.g., PDCA cycle).
LD.10.1.3 Root cause analysis.

LD.10.2 Hospital leaders participate actively in quality improvement plans and projects.

LD.10.3 Information about the quality and performance of the services offered (including the accreditation status) are communicated to the staff, governing body, public, community, and other customers in an appropriate format.

LD.11 Hospital leaders consider the community input during planning for health care needs of the population.

LD.11.1 Hospital leaders identify the relevant community leaders (e.g., members of the regional council, members of municipalities, patient's rights advocates, civil defense, health related commissions and councils, other society organizations and representatives).

LD.11.2 Local community leaders participate in planning for the current and future health care needs of the population (e.g., planning for health-relevant demographic changes, public health issues, groups with special needs).

LD.11.3 Hospital leaders plan with the community leaders to provide services related to health education and health promotion for patients and the wider community.

LD.12 Hospital leaders work collaboratively to develop an effective planning process.

LD.12.1 The planning process includes soliciting inputs from patients and staff (e.g. feedback from patient satisfaction surveys and patients/staff complaints).

LD.12.2 The planning process is consistent with the hospital's mission and strategic directions.

LD.12.3 The planning process considers cultural and religious needs of the local community.

LD.12.4 The planning considers environmental and financial factors and is consistent with the hospital's mission and strategic direction.

LD.12.5 The planning process ensures coordination and integration of services throughout the hospital.

LD.12.6 The planning process ensures efficient use of different resources through regular evaluation by hospital leaders against plans and budgets.

LD.12.7 The planning process considers the upgrade or replacement of buildings, equipment, and other resources.

LD.13 Hospital leaders work collaboratively to develop an effective budgeting process.

LD.13.1 The hospital has a finance director who is qualified by education and experience.

LD.13.2 Hospital leaders work together to address both the capital and the operating budgets.

LD.13.3 The budgeting process addresses the manpower in addition to other financial assets.

LD.13.4 The budgeting process allocates resources to all patient care units based on the scope and complexity of care, aiming to ensure a safe, efficient process.

LD.13.5 The hospital's budget is approved by the governing body.

LD.14 Hospital leaders work collaboratively to ensure the provision of a safe and quality care.

LD.14.1 Hospital leaders encourage the use of research, evidence, and best practice information to develop and improve patient care services.

LD.14.2 Hospital leaders work collaboratively to develop and execute plans, policies, and procedures related to the patient care.

LD.14.3 Hospital leaders work collaboratively to solve challenges, conflicts, and problems affecting the patient care.

LD.15 Hospital leaders work collaboratively to develop the hospital strategic plan.

LD.15.1 Hospital leaders work together to develop a strategic plan that is guided by the mission, vision, and values.

LD.15.2 The strategic plan is based on comprehensive evaluation of the internal and external environmental factors (e.g., SWOT analysis, PEST analysis).

LD.15.3 The strategic plan addresses all clinical and non-clinical services and programs.

LD.15.4 The strategic plan spans over a period of 3 - 5 years and is reviewed on a regular basis.

LD.15.5 The strategic plan includes the broad goals and objectives required to fulfill the hospital's mission.

LD.15.6 Goals and objectives are translated into operational plans with defined projects, clearly delineated responsibilities, and time frames.

LD.15.7 Resources required for executing the operational plans are properly allocated.

LD.15.8 Operational plans are implemented and closely monitored for progress toward achieving the goals and objectives.

LD.15.8.1 Key performance indicators are developed for each operational plan.

LD.15.8.2 Key performance indicators are reviewed regularly and corrective actions are taken when required.

LD.15.9 Heads of departments develop annual departmental plans in line with the hospital's strategic plan.

LD.15.10 The strategic plan is communicated to relevant staff.

LD.15.11 The strategic plan is approved by the governing body.

LD.16 Hospital leaders work collaboratively to plan for staffing needs, recruitment, and selection.

LD.16.1 Hospital leaders work together to develop a hospital-wide staffing plan.

LD.16.2 The staffing plan defines the total number and categories of staff required by all departments and their qualifications.

LD.16.3 The staffing plan ensures the services provided by staff meet the health care needs of the patients.

LD.16.4 The staffing plan is consistent with the hospital strategic plan.

LD.16.5 The staffing plan is reviewed at least annually.

LD.16.6 Hospital leaders ensure a uniform and fair process for recruitment and hiring of new staff members.

LD.16.7 Heads of departments participate in the selection of new staff.

LD.17 The hospital has a process for delegation of function and authority.

LD.17.1 There is a policy and procedure that guides the process for delegation of function and authority between two qualified peers.

LD.17.2 The process of delegation is consistent with other relevant hospital policies.

LD.18 Hospital leaders ensure an effective and efficient internal and external communication.

LD.18.1 The hospital implements a policy that outlines the process, including roles and responsibilities, for communication between the different departments, both vertical and horizontal.

LD.18.2 Departmental staff meetings are held on a regular basis and minutes are documented.

LD.18.3 Hospital-wide policies are properly communicated to all relevant staff.

LD.18.4 The hospital utilizes one or more of professional communication tools (e.g., intra-net, bulletin boards, periodic reports, newsletters, and website).

LD.18.5 The hospital implements a policy that outlines the process, roles and responsibilities for handling all incoming requests from other hospitals and external organizations.

LD.18.6 The response to the incoming requests is timely and informative.

LD.19 **Initiation of a new process or changing of an existing one is systematic and consistent throughout the hospital.**

LD.19.1 All customers of a new or modified process are identified.

LD.19.2 Customers' needs and feedback are addressed when designing a new process (e.g., new procedure, new practice guideline) or changing an existing one.

LD.19.3 Hospital leaders ensure that the initiation of a new process or the changing of an existing one is always based on evidence, research, and best practice.

LD.19.4 Hospital leaders assess new or modified processes for risk and safety issues.

LD.19.5 Whenever applicable, new or modified processes undergo pilot testing before their routine use.

LD.19.6 Hospital leaders regularly evaluate new or modified processes through process and outcome indicators to ensure an optimal performance.

LD.19.7 Hospital leaders ensure the provision of staff training on new or modified processes.

LD.20 **The hospital has a policy for controlling the development and maintenance of policies and procedures for key functions and processes.**

LD.20.1 There is a unique identification for each policy with title, number, and dates of issue and revision.

LD.20.2 Policies are developed, approved, revised, and terminated by authorized individuals.

LD.20.3 Policies are dated and are current.

LD.20.4 Policies are revised according to a defined revision due date (every 2-3 years, or when required).

LD.20.5 Policies are communicated to staff and are always accessible.

LD.20.6 A process is in place to ensure that new or updated policies are appropriately communicated to relevant staff.

LD.20.7 A process is in place to ensure that policies are always implemented.

LD.20.8 A process is in place to ensure that only the last updated versions of policies and other documents (e.g., organizational plans) are available for use in the hospital.

LD.21 **Hospital leaders ensure the overseeing of contracts for clinical and administrative services.**

LD.21.1 Policies and procedures are in place to ensure the quality and safety of all contracted services.

LD.21.2 Policies and procedures indicate how to track and monitor all contracted services for quality and safety (within the hospital premises and off-site).

LD.21.3 Hospital leaders ensure that the contracts clearly state the services to be provided by the contracted entity.

LD.21.4 Hospital leaders and other heads of departments participate in the selection, monitoring, and management of contracted services.

LD.21.5 Hospital leaders ensure that contracted services and providers both meet applicable laws and regulations.

LD.21.6 Hospital leaders ensure the services provided are consistent with the hospital's quality and safety standards.

LD.21.7 The quality of services provided is always considered by hospital leaders before contract renewal.

LD.21.8 The process for contracts oversight is documented.

LD.22 **Hospital leaders ensure coordination of care during off duty hours.**

LD.22.1 The hospital has a qualified duty manager with a clear job description to coordinate the care during off duty hours.

LD.22.2 The duty manager has the resources required to function (e.g., efficient office space, information on vacant and occupied beds, authority to allocate beds between different specialties, authority to accept referrals from other hospitals).

LD.23 **Hospital Leaders ensure there is a system for the safe management of medical supplies and devices.**

LD.23.1 Hospital leaders and relevant heads of departments identify all medical supplies and devices that are essential for the provision of a safe quality care.

LD.23.2 Suppliers of medical supplies and devices are qualified and carefully selected and evaluated.

LD.23.3 Medical supplies and devices are stored safely and in accordance with manufacturer's recommendations.

LD.23.4 Medical supplies and devices are protected against theft, damage, contamination, or deterioration.

LD.23.5 Hospital leaders conduct regular inspections to ensure the safety of medical supplies and devices (e.g., storage conditions, integrity, contamination, expiration).

LD.23.6 Hospital leaders respond to any adverse effects resulting from the use of medical supplies and devices through prompt investigation and the use of recurrence prevention measures.

LD.23.7 Hospital leaders ensure the reporting of adverse effects resulting from the use of medical supplies and devices to the relevant regulatory authorities.

LD.23.8 The hospital has a process for safe segregation and disposal of expired, damaged, or contaminated medical supplies and devices.

LD.23.9 The hospital has a process to retrieve dispensed supplies and devices when recalled or discontinued by the manufacturer or relevant regulatory authorities for safety reasons.

LD.24 **Hospital leaders work collaboratively to optimize the flow of patients.**

LD.24.1 Hospital leaders address all variations contributing to waits, delays, and cancellations that impact smooth and timely flow of patients through hospital departments.

LD.24.2 Hospital leaders implement strategies to maximize the efficiency of the flow of patients.

LD.25 **Each clinical and administrative department is directed by a qualified individual.**

LD.25.1 Each department has an assigned department head.

LD.25.2 Qualifications, experience, and training of the appointed department head match the services provided by the department.

LD.25.3 When the department head is appointed on a part-time basis (e.g., a small hospital or a hospital that is part of a corporate chain), the department head:

- LD.25.3.1 Ensures that work flow and patient safety are not compromised during his absence.
- LD.25.3.2 Ensures that the department functions are well managed through regular scheduled visits.
- LD.25.3.3 Provides guidance as well as continued assessment of the individual in charge of the department during his absence.
- LD.25.3.4 The frequency and duration of the visits must be documented in the contract.

LD.26 **The department head develops an organizational chart for the department.**

LD.26.1 Each department has an organizational chart that clearly displays all sections/divisions within the department, titles (or names), lines of authority, accountability, and reporting relationships.

LD.26.2 The organizational chart is signed by the department head and approved by the hospital management.

LD.26.3 The organizational chart is communicated to the staff working in the department.

LD.27 **The department head addresses all issues related to the customers of the department.**

LD.27.1 The department head identifies all internal and external customers of the department (patients, families, visitors, staff, suppliers, and contractors).

LD.27.2 Whenever required, there is written agreement or verbal understanding between the department and other clinical departments and/or external customers, explaining the expectations of each party.

LD.27.3 The department head has a mechanism for identifying and handling customers' needs and feedbacks (e.g., responding to complaints, satisfaction surveys).

LD.28 **The department head develops and maintains the mission of the department and its scope of services.**

LD.28.1 The department head develops a written mission for the department that is consistent with the hospital's mission.

LD.28.2 The department head provides a written scope of services provided by the department that is consistent with the hospital's scope of services.

LD.28.3 The department head ensures coordination and integration of services within the department and with other departments.

LD.29 **The department head ensures the work of the department is guided by a clear set of departmental policies and procedures.**

LD.29.1 The department head develops and maintains a manual for all relevant departmental policies and procedures.

LD.29.2 The department head collaborates with other department heads to develop multidisciplinary policies and procedures.

LD.29.3 The department head ensures and oversees the communication of policies and procedures to relevant staff and their implementation.

LD.30 **The department head ensures sufficient resources and staffing are available for the delivery of safe and quality service.**

LD.30.1 The department head defines and requests the resources required by the department for a safe and quality service (e.g., space, equipment, supplies, staffing, and other resources).

LD.30.2 The department head provides a written departmental staffing plan that defines the number, type, and qualifications required for each position to fulfill the department's responsibilities.

LD.30.3 The department head defines the qualifications- education, training, experience, license, and any other relevant certification- required by all categories of staff in the department.

LD.30.4 The department head ensures the provision of orientation, training, and continuing education for the staff working in the department.

LD.30.5 The department head monitors the performance of the staff.

LD.31 The department head ensures performance measurement and improvement of the outcomes of the department.

LD.31.1 Performance measurement and improvement are consistent with the hospital wide quality improvement, patient safety, and risk management plans.

LD.31.2 Performance measurement and improvement are based on the important processes and priorities of the department.

LD.31.3 The department head selects and monitors the appropriate performance indicators (e.g., two indicators at a time).

LD.31.4 Performance measurement and improvement involve regular data collection and analysis and appropriate improvement actions/projects.

LD.31.5 The department interacts with other departments/committees to promote the quality improvement efforts when needed.

LD.31.6 Results of performance measurement and improvement are reported periodically to the hospital leadership (e.g., the executive management committee or the quality improvement committee) and shared with staff, departments, and committees as applicable.

LD.31.7 Staff members participate in quality improvement and patient safety activities and receive training on quality assessment and improvement.

Human Resources (HR)

Introduction

In order for the hospital to provide a quality and safe care, improving the human resources practices and management is critical. In this twenty first century, it is not acceptable any more for a hospital to operate without an efficient human resources department directed by a qualified director who understands the contemporary practices for managing people in a complex setting like the healthcare industry.

Recognizing the human resources challenges and the best strategies to follow should be on the top list of the hospital management. This chapter is newly added to this manual to emphasize the importance of a successful human resources management in any hospital or healthcare organization trying to compete for a better care and more market share.

This chapter discusses the standards related to the following functions of the human resources management:

- Attraction of qualified staff
- Orientation of new staff
- Verification of credentials
- Training and education
- Continuous competency evaluation and performance appraisal
- Job description
- Personnel files
- Staff health
- Staff complaints
- Staff satisfaction

STANDARDS

HR.1 The hospital has human resources department/unit.

HR.1.1 The human resources department is well staffed and equipped to match the size and needs of the hospital.

HR.1.2 The head of the human resources department is qualified in managing human resources by education, training, or experience.

HR.1.3 Policies and procedures manual guides the work of human resources department.

HR.1.3.1 The manual includes items related to recruitment, hiring, resignation, termination, grievance and complaints, leaves, new employee orientation, on job training, and performance appraisal.

HR.1.3.2 The manual is made accessible and communicated to all staff members.

HR.1.3.3 Policies and procedures contained in the manual are implemented.

HR.2 Heads of departments, in collaboration with the human resources department, develop, implement, and monitor departmental staffing plans.

HR.2.1 Each department has a written staffing plan, developed in collaboration with the human resources department, to fulfill its part of the hospital's mission.

HR.2.2 The departmental staffing plan defines the number, type, and qualifications of staff required for each department and their job responsibilities.

HR.2.3 The staffing plans are reviewed and updated at least annually and as needed.

HR.2.4 The staffing plans are monitored to identify deficiencies and take improvement actions accordingly.

HR.3 All categories of staff have clearly written job descriptions.

HR.3.1 There is a policy that describes a standardized format for job description.

HR.3.2 The job description is used when selecting employees for hire, performance evaluation, internal promotion, and transfer.

HR.3.3 All job descriptions are revised at least every three years and as needed.

HR.3.4 The job description defines the required knowledge, skills, and attitude to perform the job responsibilities.

HR.3.5 The job description clearly defines the roles and responsibilities.

HR.3.6 The job description specifies the reporting relationships.

HR.3.7 The job description is discussed with and signed by the staff member on hiring and is kept in the personnel file.

HR.4 The hospital maintains personnel files for all employees.

HR.4.1 The hospital has a policy guiding the initiation, management, content update, and retention time and disposal of personnel files.

HR.4.2 Personnel files are complete and updated.

HR.4.3 Personnel files are kept confidential and only those who are authorized can access them.

HR.4.4 Personnel files contain the following minimum items:

HR.4.4.1 Qualifications; including current licensure, certification, or registration, if applicable.

HR.4.4.2 Current job description.

HR.4.4.3 References.

HR.4.4.4 Orientation, continuing education, and training records.
HR.4.4.5 Performance evaluations.
HR.4.4.6 Records of leave and sickness.
HR.4.4.7 Disciplinary actions, if any.
HR.4.4.8 Other documents as required by relevant laws and regulations.

HR.5 The hospital has a process for proper credentialing of staff members licensed to provide patient care.

ESR

HR.5.1 The hospital has a written policy describing the process used for the verification of credentials.
HR.5.2 The hospital gathers, verifies, and evaluates the credentials (license, education, training, certification and experience) of those medical staff, nursing staff, and other health professionals licensed to provide patient care.
HR.5.3 Credentials are verified from the original source.
HR.5.4 Job responsibilities and clinical work assignments/ privileges are based on the evaluation of the verified credentials.
HR.5.5 The hospital ensures the registration of all healthcare professionals with the Saudi Commission for Health Specialties.
HR.5.6 Staff licensed to provide patient care must always have and maintain a valid license to practice only within their profession.
HR.5.7 The hospital maintains an updated record of the current professional license, certificate, or registration, when required by laws, regulations, or by the hospital for every medical staff, nursing staff and other healthcare professionals.
HR.5.8 When verification of credentials is conducted through a third party, the hospital must request for a confirmatory documentation.
HR.5.9 Verification process applies to all clinical staff categories (full time, part time, visitor, and locum).

HR.6 New employees go through a general hospital orientation program before allowed to work independently.

HR.6.1 New employees , contract workers, students, and volunteers go through a general orientation program that provides the relevant initial training and information on the following:
HR.6.1.1 Hospital mission, vision, values, and organizational chart.
HR.6.1.2 Role of staff members in all programs related to facility management and safety (e.g., fire, safety, disasters, hazardous materials, utilities, and equipment failures).
HR.6.1.3 General information on infection control.
HR.6.1.4 General information on the paging and telephone system.
HR.6.1.5 General information on staff evaluation process.
HR.6.1.6 Definition of adverse and sentinel events along with the process of reporting.
HR.6.1.7 Hospital policy on abuse and neglect of children and adults.
HR.6.1.8 Hospital policy on credentialing and privileging.
HR.6.1.9 General information about staff health program.
HR.6.1.10 General information about important local cultural and social themes.

HR.6.1.11 General information about the hospital-wide quality, patient safety, and risk management plans.

HR.6.1.12 Ethical conduct and expected professional communication with patients and colleagues.

HR.6.1.13 Patient rights.

HR.6.2 The hospital provides all new employees with an "Employee Manual" or equivalent that contains a summary of the general orientation program as well as other relevant important information.

HR.6.3 The general orientation program is conducted before working independently.

HR.6.4 The general orientation program is documented in the employee's personnel file.

HR.7 New employees go through a departmental and job orientation program before allowed to work independently.

HR.7.1 The departmental and job orientation program is defined in a departmental policy and includes the following:

HR.7.1.1 Departmental policies and procedures.

HR.7.1.2 Specific job responsibilities within the department as outlined in the job description.

HR.7.1.3 Safe operation of equipment and medical devices including troubleshooting and malfunctions reporting.

HR.7.1.4 Clarification on all topics provided in the general orientation as needed.

HR.7.2 Additional orientation is provided upon changing the job description or introducing a new technology or equipment.

HR.7.3 The departmental orientation is conducted by the head of the department or the immediate supervisor.

HR.7.4 An evidence of attending the departmental and job orientation program is signed by the new employee and documented in the personnel file.

HR.8 The hospital has a process for initial evaluation of the competency and conduct of the new employees.

HR.8.1 The hospital has a process described in a policy or other document for initial evaluation of the competency of the new employees.

HR.8.2 All new employees go through a probationary period for competency evaluation. During this period, clinical staff can only work under direct supervision.

HR.8.3 Competency evaluation during the probationary period is a structured process that aims to assess and review the employee's knowledge, performance, capability, conduct, and suitability for the role.

HR.8.4 The competency evaluation is documented in the personnel file.

HR.9 The hospital has a process for the regular evaluation of staff performance.

HR.9.1 There is a policy describing the process used in the regular evaluation of staff performance.

HR.9.2 The performance evaluation is based on objective criteria and is linked with the job description.

HR.9.3 The performance evaluation is a two-way process conducted at least annually.

HR.9.4 The outcome of the performance evaluation is used to set objectives for performance improvement and professional development.

HR.9.5 The performance evaluation is signed by both the employee and the supervisor and is documented in the personnel file.

HR.10 The hospital identifies the staff training and educational needs.

HR.10.1 The hospital has a process in place for identification of the training and educational needs of the different categories of hospital staff.

HR.10.2 The training and educational needs are identified based on objective criteria that include, but are not limited to, the following:

HR.10.2.1 The hospital mission, vision and scope of services.

HR.10.2.2 Individual staff member's education and training history.

HR.10.2.3 Information from quality assessment and improvement activities.

HR.10.2.4 Needs generated by advancements made in the medical and healthcare management fields.

HR.10.2.5 Findings from department performance appraisals of individuals.

HR.10.2.6 Findings from peer review activities.

HR.10.2.7 Findings from the hospital's technology and safety management programs.

HR.10.2.8 Findings from infection control activities.

HR.11 The hospital supports continuing education for all staff members.

HR.11.1 There is a policy describing the structure and the process used in the continuing education of all categories of staff.

HR.11.2 The hospital grants financial support and time off for staff to attend educational activities.

HR.11.3 The hospital has an educational program with an ongoing schedule of educational activities and training based on the hospital needs.

HR.11.4 The department head recommends and evaluates the educational and training activities required to maintain staff competencies to provide care. This process is linked to performance improvement and documented in the personnel file.

HR.12 Staff members providing direct patient care are trained on cardiopulmonary resuscitation.

HR.12.1 All staff members who provide direct patient care (medical staff, nursing staff, and other healthcare professionals) maintain a valid certification in basic cardiac life support (BCLS) and certification is renewed every two years.

HR.12.2 The hospital identifies and provides training for other staff categories in areas related to advanced cardiac life support (ACLS), neonatal resuscitation program (NRP), pediatric advanced life support (PALS), and advanced trauma life support (ATLS). Examples include, but are not limited to:

HR.12.2.1 Physicians and nurses working in critical care areas must maintain additional certification in ACLS, PALS and NRP as appropriate to the patients' age groups.

HR.12.2.2 Internal medicine physicians must maintain additional certification in ACLS.

HR.12.2.3 Emergency department physicians must maintain additional certification in ACLS, PALS and ATLS.

HR.12.2.4 Pediatricians must maintain additional certification in PALS and NRP.

HR.13 The hospital has a program that addresses staff health and safety.

HR.13.1 The hospital has a staff health and safety program that is consistent with laws and regulations and covers all staff members.

HR.13.2 The program is based on assessment and where necessary, reduction of occupational health and safety risks.

HR.13.3 The program is coordinated with the hospital's quality, safety, risk management, and infection control programs.

HR.13.4 The program includes, but is not limited to, the following:

HR.13.4.1 Pre-employment medical evaluation of new employees.

HR.13.4.2 Response to the health problems of the employees through direct treatment (e.g., a staff clinic) or referral.

HR.13.4.3 Periodic medical evaluation of staff members.

HR.13.4.4 Screening for exposure and/or immunity to infectious diseases.

HR.13.4.5 Staff preventive immunizations.

HR.13.4.6 Management of exposure to blood borne pathogens and other work-related conditions.

HR.13.4.7 Measures to reduce occupational exposures and hazards, including the use of protective equipment and clothing, stress management, and ergonomics.

HR.13.4.8 Staff education on the risks within the hospital environment as well as on their specific job-related hazards (e.g., lifting techniques, safe use of medical devices, and detecting, assessing, and reporting risks).

HR.13.4.9 Documentation and management of staff incidents (e.g., injuries or illnesses, taking corrective actions, and setting measures in place to prevent recurrences).

HR.13.4.10 There is appropriate record keeping and management (e.g., employee health records that are filed separately).

HR.14 The hospital has a process for handling staff complaints and dissatisfaction.

HR.14.1 The hospital has a policy for handling staff complaints and dissatisfaction.

HR.14.2 Staff members are aware of the procedure to be followed to bring forward a complaint or a dissatisfaction issue.

HR.14.3 The hospital takes actions for addressing the complaints and dissatisfaction in a fair, objective, and timely manner.

HR.15 The hospital develops and implements strategies for retaining qualified staff.

HR.15.1 The hospital has a process for recognition and reward of distinguished staff.

HR.15.2 The hospital provides opportunities for professional development and promotion.

HR.15.3 The hospital carries out human resources policies in a fair and consistent way without discrimination.

HR.15.4 The hospital carries out exit interviews for resigning staff and uses the resulting information to make decisions about improving human resources processes.

HR.16 The hospital conducts staff satisfaction surveys on an ongoing basis.

HR.16.1 A staff satisfaction survey is conducted at least once per year.

HR.16.2 Data are aggregated and analyzed.

HR.16.3 Actions are taken to address areas for improvement.

Medical Staff (MS)

Introduction

A hospital's medical staff, the group of physicians and dentists licensed to practice medicine and prescribe medications, plays a critical role in assuring quality care and improving patients' outcomes in the hospital. The standards in this chapter define the medical staff leaders' roles and responsibilities in credentialing, privileging, bylaws development, committees and departments' management, as well as performance improvement.

A good hospital should always have a clear structure of its medical staff, including departments, divisions, and medical committees. The medical director is responsible for the organization and conduct of the medical staff, and is viewed as the critical link between the governing board, the hospital director, and the medical staff. The medical director must be a physician and must have his or her duties clearly defined in writing.

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

- Medical staff leaders' roles and responsibilities
- Medical staff evaluation, credentialing and privileging
- Medical staff committees
- Medical staff bylaws
- Medical staff collaboration with other disciplines
- Medical staff competency assessment

STANDARDS

MS.1 The organization, functions, and responsibilities of the medical staff are documented and communicated to all medical staff members.

MS.1.1 The hospital has medical staff bylaws that govern the organization, functions, and responsibilities of the medical staff.

MS.1.2 Medical staff bylaws are approved by the governing body.

MS.1.3 Medical staff bylaws are consistent with acceptable medical staff practices and laws and regulations.

MS.1.4 Medical staff bylaws describe the organizational structure of the medical staff and the reporting relationships, including all medical departments and committees.

MS.1.5 Medical staff bylaws address:

- MS.1.5.1 The medical staff ranking and the qualifications required for each rank.
- MS.1.5.2 Categories of the medical staff membership (e.g., full time, part time, and locum).
- MS.1.5.3 Roles and responsibilities of the medical staff members.
- MS.1.5.4 Appointment, promotion, and reappointment of medical staff members.
- MS.1.5.5 The process for verification of the medical staff credentials.
- MS.1.5.6 Granting and maintaining clinical privileges, including temporary privileges (e.g., for locums and emergency situations).
- MS.1.5.7 Disciplinary procedures for medical staff members, including corrective actions and appeals.

MS.1.6 Medical staff bylaws describe the acceptable standards of patient care and professional conduct, including:

- MS.1.6.1 Admission, referral, transfer, and discharge processes.
- MS.1.6.2 Documentation in medical records.
- MS.1.6.3 The conduct of care expected for all levels of medical staff (e.g., daily rounds).
- MS.1.6.4 The professional conduct (e.g., handling ethical issues) of the medical staff.

MS.1.7 The medical director and heads of medical departments ensure the medical staff bylaws are made accessible and communicated to all members of the medical staff.

MS.1.8 The medical director and heads of medical departments enforce the medical staff bylaws along with relevant rules and regulations.

MS.2 A qualified medical director is responsible for managing the medical staff and medical services.

MS.2.1 The medical director is a board certified physician or equivalent, qualified in healthcare management by education, training or experience.

MS.2.2 The medical director is responsible and accountable for the clinical performance of the medical staff, the quality of care they provide, as well as their professional conduct.

MS.2.3 The medical director recommends to the hospital director the appointment of the heads of clinical departments.

MS.2.4 The medical director has a current written job description that clearly describes his managerial roles and responsibilities.

MS.3 The hospital has an effective process that supports the professional communication and coordination of care amongst medical staff.

MS.3.1 There is a medical executive committee or equivalent, chaired by medical director and includes the heads of clinical departments, to ensure that they work together to coordinate the provision of care.

MS.3.2 The medical executive committee holds regular formal meetings (at least monthly).

MS.3.3 The medical executive committee reviews and approves policies and procedures related to clinical departments.

MS.3.4 The medical executive committee reviews all relevant reports of other hospital committees for prioritizing the services needed and guiding the credentialing and privileging process.

MS.4 Each clinical department is directed by a qualified individual.

MS.4.1 The department head is board certified or equivalent in his field and qualified in healthcare management by education, training or experience.

MS.4.2 The department head has a written job description that clearly describes his role and responsibilities.

MS.4.3 Responsibilities of the department head include:

- MS.4.3.1 Defining medical staff qualifications required for the provision of effective and safe patient care.
- MS.4.3.2 Recommending the need for further training/certification of a medical staff member.
- MS.4.3.3 Monitoring admissions to ensure that the diagnostic and therapeutic interventions are within the staff capabilities and the available hospital resources.
- MS.4.3.4 Ensuring that medical staff members work within the clinical privileges granted to them.
- MS.4.3.5 Developing a written scope of services for the department.

MS.4.4 The department head has an ongoing method of peer review (e.g., peer review committee) to evaluate care provided as well as the performance of the medical staff.

- MS.4.4.1 The department head regularly assesses important functions that include appropriateness of admissions, appropriateness and effectiveness of care, training and educational needs, length of stay, and appropriate utilization of resources.
- MS.4.4.2 The department head defines criteria or indicators for selecting cases that must be referred for peer review.
- MS.4.4.3 The activities of the peer review process are utilized as part of the physician's performance evaluation.
- MS.4.4.4 The department head shares the findings of the peer review with the medical director and works closely to improve and correct any deficiencies.

MS.5 The credentialing and privileging of the medical staff is based on an informed group decision.

MS.5.1 The hospital has a credentialing and privileging committee chaired by the medical director or a designee.

MS.5.2 The credentialing and privileging committee provides oversight on the credentialing and privileging processes.

MS.5.3 The credentialing and privileging committee ensures that only qualified physicians and dentists are appointed and granted privileges.

MS.5.4 Applicants for initial appointment submit a complete set of documents required for the credentialing and privileging process , including:

- MS.5.4.1 Curriculum vitae, detailing the professional history of the applicant.
- MS.5.4.2 Education, training, certificates, courses, experience, published research, and other relevant credentials.
- MS.5.4.3 List of references.
- MS.5.4.4 List of the privileges requested for approval.

MS.6 The hospital has clearly defined and documented processes used to credential, appoint, and grant clinical privileges to medical staff.

MS.6.1 All members of the medical staff must be registered with the Saudi Commission for Health Specialties before allowed to work independently.

MS.6.2 The hospital has a documented process for appointment, reappointment and granting of clinical privileges to all categories of medical staff.

MS.6.3 Medical staff appointment, reappointment and granting of privileges are in accordance with relevant laws and regulations.

MS.6.4 Medical staff appointment, reappointment and granting of privileges are based on:

- MS.6.4.1 Evaluation of the verified credentials (license, education, training, and experience).
- MS.6.4.2 Evaluation of the mental and physical health and capabilities.
- MS.6.4.3 Competency, actual performance and outcomes of care.
- MS.6.4.4 Category of the medical staff as stated in the professional registration with the Saudi Commission for Health Specialties (e.g., consultant, specialist).

MS.6.5 Appointment, reappointment and granting of privileges are recommended by the medical staff leaders (medical director, heads of clinical departments, credentialing and privileging committee, and senior medical staff members) and approved by the governing body, either directly or by appropriate delegation.

MS.6.6 The hospital has a process in place for appeals against credentialing or privileging decisions.

MS.7 Medical staff members have current delineated clinical privileges.

ESR

MS.7.1 Medical staff members are allowed to practice only within the privileges granted by the credentialing and privileging committee.

MS.7.2 Clinical privileges are reviewed and updated every two years and as needed.

MS.7.3 The hospital identifies the circumstances under which temporary or emergency privileges are granted.

MS.7.4 Temporary or emergency privileges are not granted for more than 90 days and are not renewable.

MS.7.5 When a new privilege is requested by a medical staff member, the relevant credentials are verified and evaluated prior to approval.

MS.8 The performance of the medical staff members is evaluated on an ongoing basis to ensure competency.

MS.8.1 The department head together with the medical director evaluate the performance and competency of medical staff members at least annually and when indicated by the findings of performance improvement activities.

MS.8.2 The hospital identifies the circumstances under which an unplanned review of the performance of a medical staff member may be initiated.

MS.8.3 The performance evaluation includes, but is not limited to, the following:

MS.8.3.1 Assessment of patients.

MS.8.3.2 Adverse events.

MS.8.3.3 Moderate and deep sedation.

MS.8.3.4 Quality of medical records.

MS.8.3.5 Medication errors.

MS.8.3.6 Sentinel events.

MS.8.3.7 Outcome of high-risk procedures and surgeries.

MS.8.3.8 Morbidities and mortalities.

MS.8.3.9 Blood and blood product usage.

MS.8.3.10 Discrepancies between pre and post-operative pathological diagnoses.

MS.8.3.11 Appropriateness of admissions from the emergency room and outpatient department.

MS.9 Medical staff leaders make use of the data and information resulting from the medical staff performance review.

MS.9.1 The data and information resulting from the medical staff performance review are used to :

MS.9.1.1 Provide feedback and counseling to the medical staff regarding their performance.

MS.9.1.2 Recommend plans for improvement.

MS.9.1.3 Amend clinical privileges as necessary, by expansion or limitation, a period of counseling and oversight, or other appropriate action.

MS.9.1.4 Make informed decisions regarding reappointment.

MS.9.1.5 Recommend training and continuous education as needed.

MS.9.2 The outcomes of the medical staff performance evaluation and actions taken are documented in the physician's credentials file.

MS.10 Medical staff leaders support the hospital-wide quality improvement, patient safety, and risk management plans.

MS.10.1 Heads of clinical departments together with the medical director work closely with other hospital leaders through formal meetings to support the implementation of the hospital-wide quality improvement, patient safety, and risk management plans.

MS.10.2 Data and information resulting from the medical staff performance review are used to continuously improve the quality and safety by :

MS.10.2.1 Studying and minimizing variances in the processes.

MS.10.2.2 Taking actions to avoid preventable medical errors and adverse events.

MS.10.2.3 Recommending equipment needed in specified areas.

MS.10.3 Heads of clinical departments together with the medical director work closely with the quality management director/risk manager in handling incidents including near misses and sentinel events.

MS.10.3.1 Root cause analysis is properly conducted.

MS.10.3.2 Emphasis is on improving systems.

MS.10.3.3 Corrective actions are documented.

MS.11 Heads of clinical departments review mortality and morbidity cases.

MS.11.1 Heads of clinical departments conduct mortality and morbidity meetings on a monthly basis to review all cases of mortality and significant morbidity.

MS.11.2 Mortality and morbidity meetings are documented and attendance is considered essential.

MS.11.3 The departmental mortality and morbidity meetings should focus on scientific discussion, improvement and prevention, with a non-punitive intent.

MS.11.4 Heads of clinical departments work with the medical director to select cases to be referred to the hospital mortality and morbidity committee.

MS.11.5 Heads of clinical departments send regularly mortality and morbidity findings to the medical director and the quality director.

MS.12 The hospital has a mortality and morbidity committee.

MS.12.1 There is a mortality and morbidity committee that is chaired by the medical director or a designee.

MS.12.2 The mortality and morbidity committee reviews mortalities in the hospital and the unusual or unexpected adverse outcomes of care.

MS.12.3 The mortality and morbidity committee receives cases for review from various sources (e.g., referral from the clinical departments, patient complaints, and the medical director).

MS.12.4 The mortality and morbidity committee evaluates cases for effectiveness, timeliness and appropriateness of care.

MS.12.5 The mortality and morbidity findings are regularly forwarded to the medical director and the quality director.

MS.12.6 The mortality and morbidity committee recommends actions for improvement and evaluates their effectiveness.

MS.13 The hospital has a medical records review committee.

MS.13.1 There is a medical records review committee with members representing the medical staff, the nursing staff and other professionals privileged to write in the medical record.

MS.13.2 The medical records review committee oversees and monitors the documentation in medical records for quality, completeness, and timeliness.

MS.13.3 The medical records review committee regularly reviews a sample (e.g., 5% on a quarterly basis) of the medical records of discharged and in-patients for:

MS.13.3.1 History and physical examination.

MS.13.3.2 Assessment upon admission.

MS.13.3.3 Progress notes.

MS.13.3.4 Plan of care.

MS.13.3.5 Operative reports.

MS.13.3.6 Histopathology reports.

MS.13.3.7 Laboratory results.

MS.13.3.8 Radiology reports.

MS.13.3.9 Discharge summary.

MS.13.4 The medical records review committee recommends actions for improvement and evaluates their effectiveness.

MS.14 The hospital has a utilization review committee.

MS.14.1 There is a utilization review committee that is chaired by the medical director or a designee with representatives from relevant services such as medical staff, nursing staff, admission office and social services.

MS.14.2 The utilization review committee assesses the medical necessity of the services furnished by the hospital and the medical staff members to patients. This includes, but is not limited to, the following:

MS.14.2.1 Appropriateness of admissions.

MS.14.2.2 Appropriateness and quality of care.

MS.14.2.3 Length of stay.

MS.14.2.4 Drug usage.

MS.14.2.5 Efficiency in using various hospital resources (e.g., overutilization or underutilization).

MS.14.3 The utilization review committee recommends actions for improvement and evaluates their effectiveness.

MS.15 The hospital has a blood utilization committee.

MS.15.1 There is a blood utilization committee that is chaired by the medical director or a designee with representatives from relevant services such as medical staff, nursing staff and blood bank.

MS.15.2 The blood utilization committee ensures the optimal use of blood and blood products by establishing Indications/triggers for the transfusion of blood, blood components and blood derivatives.

MS.15.3 The blood utilization committee approves all policies and procedures that involve the ordering and administration of blood and blood products, including:

MS.15.3.1 Handling of blood outside the laboratory.

MS.15.3.2 Use of blood warmers and infusion devices.

MS.15.3.3 Venous access.

MS.15.3.4 Addition of fluids and drugs other than 0.9%NaCL.

MS.15.3.5 Bedside Identification of the blood product and the intended recipient.

MS.15.3.6 Monitoring of patient during and after blood administration.

MS.15.4 The blood utilization committee ensures the optimal utilization of therapeutic phlebotomy and apheresis services.

MS.15.5 The blood utilization committee monitors practices related to blood ordering and blood administration.

MS.15.6 The blood utilization committee recommends actions for improvement and evaluates their effectiveness.

MS.16 The hospital has a tissue review committee.

MS.16.1 There is a tissue review committee that conducts analysis and review of tissues removed during surgeries and procedures.

MS.16.2 The tissue review committee ensures there is a hospital policy that governs how to obtain and handle specimens and tissues.

MS.16.3 The tissue review committee monitors the following:

MS.16.3.1 The collection and transportation of specimens to the laboratory.

MS.16.3.2 The accuracy and completeness of histopathology forms (e.g., site of biopsy, number of biopsies, clinical history, previous biopsies).

MS.16.3.3 The accuracy of fine needle aspirations.

MS.16.3.4 The accuracy of frozen section specimens.

MS.16.4 The tissue review committee defines and approves the list of specimens exempted from submission to surgical pathology or microscopic examination.

MS.16.5 The tissue review committee reviews the appropriateness of all surgical procedures performed in the hospital, correlating pre- and post-operative surgical diagnoses with pathological findings.

MS.16.6 The tissue review committee recommends actions for improvement and evaluates their effectiveness.

MS.17 The hospital has an operating room committee.

MS.17.1 There is an operating room committee with representatives from relevant services such as medical staff, nursing staff, operating room staff, infection control, and safety personnel.

MS.17.2 The operating room committee approves all policies required for proper conduct of the work in the operating room including, but are not limited to, the following:

MS.17.2.1 Infection control measures.

MS.17.2.2 Supply of equipment and disposables.

MS.17.3 The operating room committee develops a code of ethical conduct in the operating room to protect patient privacy and dignity.

MS.17.4 The operating room committee monitors performance in the operating room including cancellation rate and makes improvements accordingly.

MS.18 The hospital has a cardiopulmonary resuscitation committee.

MS.18.1 There is a cardiopulmonary resuscitation committee with representatives from relevant services such as medical staff, nursing staff, intensive care staff and emergency staff.

MS.18.2 The cardiopulmonary resuscitation committee ensures there is an effective system to handle all cases requiring cardiopulmonary resuscitation at all times.

MS.18.3 The cardiopulmonary resuscitation committee ensures that the cardiopulmonary resuscitation team members have cardiac life support training as appropriate to the patient population served by the hospital.

MS.18.4 The cardiopulmonary resuscitation committee discusses all codes in the hospital, recommends actions for improvement, and evaluates those actions for effectiveness.

MS.18.5 A summary of the cardiopulmonary resuscitation committee's discussions is forwarded to the medical director and the quality director.

MS.19 The hospital has a pharmacy and therapeutics committee.

MS.19.1 There is a pharmacy and therapeutics committee with representatives from relevant services involved in drug prescribing, ordering, dispensing, administering, as well as patient monitoring processes.

MS.19.2 The pharmacy and therapeutics committee provides oversight of the hospital formulary and medications use.

MS.19.3 The pharmacy and therapeutics committee meets on a regular basis (at least quarterly).

MS.19.4 The pharmacy and therapeutics committee recommends actions for improvement and evaluates their effectiveness.

Provision of Care (PC)

Introduction

Hospitals vary in the scope of services they provide and thus the types of patients they may effectively serve. The hospital should accept patients for care according to its capability to provide the services that meet the identified patient's needs.

Providing optimum care requires careful planning, coordination, and communication. The hospital must provide an appropriate and thorough assessment of each patient, and patient care must be planned and implemented to ensure the best possible outcome. To support the continuity of care, patient assessment and care process must be documented in a completed medical record that is unique for each and every patient. As the care process may need to be provided by multiple providers, a collaborative process should be in place to promote continuity and coordination of care when the patient is referred, transferred, or discharged.

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

- Screening of patients before acceptance for care
- Access to care
- Registration and admission processes
- Scope and content of patient assessment and reassessment
- Plans of care
- Continuity and coordination of care
- Consultations
- High risk and vulnerable patients
- Psychiatric patients
- Patient discharge, transfer and referral within or outside the organization

STANDARDS

PC.1 The hospital provides patients with information on care and services provided.

PC.1.1 The hospital clearly defines the services it provides.

PC.1.2 The hospital provides patients, families, and the wider community with information on the services it provides using an appropriate format and language (e.g., displayed posters, brochures, handouts, websites, and news media).

PC.1.3 The hospital provides patients with information on how to access its services.

PC.2 Patients are screened before accepted for care in the hospital.

PC.2.1 The hospital implements a policy that defines screening methods and tests required before accepting patients for care.

PC.2.2 Screening is aimed to identify and match patient needs with hospital's mission and available resources.

PC.2.3 In outpatient settings, screening is performed before registration.

PC.2.4 Screening of patients in the emergency room is performed during triage process or before deciding for admission to inpatient areas.

PC.3 The hospital has a consistent process for registration and admission of patients.

PC.3.1 A policy and procedure defines the process used for elective admissions and patients admitted for a day procedure.

PC.3.2 A policy and procedure defines the process used for admission of emergency patients.

PC.3.3 A policy and procedure defines the process used for registration of outpatients.

PC.3.4 The hospital has a process for managing patients requiring admission when no bed is available.

PC.3.5 The hospital has a process for managing patients under observation in the emergency room.

PC.3.6 Staff members are aware of and implement a consistent process for registration and admission of patients in different service settings.

PC.4 The hospital ensures a uniform standard of care.

PC.4.1 The hospital implements policies and procedures to ensure that a uniform standard of care is provided to all patients.

- PC.4.1.1 All patients receive the same standard of care across all hospital settings and departments.
- PC.4.1.2 All patients receive the same standard of care at all times (e.g., during working hours, after working hours, during weekends and holidays).
- PC.4.1.3 All patients receive the same standard of care regardless of race, gender, or religion.
- PC.4.1.4 All patients receive the same standard of care regardless of their ability to pay or source of payment.

PC.4.2 Patient care services are in accordance with professional standards and applicable laws and regulations.

PC.5 The hospital ensures easy accessibility to care and services.

PC.5.1 Hospital departments and services are physically accessible to all patients.

PC.5.2 The hospital adopts an efficient appointment system.

PC.5.3 The hospital has a process to minimize language barriers by communicating with patients in their primary language or have interpreter services provided at all times.

PC.5.4 The hospital ensures effective communication with patients having special communication needs (e.g., sign language for the hearing impaired patients, and assistance modalities for sight impaired patients).

PC.6 The hospital has a systematic process for the initial assessment of patients.

PC.6.1 The hospital implements a policy and procedure that defines the assessment process and its scope and content for all care settings (inpatients, outpatients, critical care and emergency room).

PC.6.2 The hospital implements a policy and procedure that defines the assessment process and its scope and content for all categories of patients (adults, geriatrics, pediatrics, pregnant women, trauma patients and others).

PC.6.3 The hospital implements a policy and procedure that defines the assessment process and its scope and content for all disciplines (physicians, nurses, physiotherapists, social service and others).

PC.6.4 The policy defines the staff categories qualified by license, certification, and experience to assess patients.

PC.6.5 The initial assessment aims to identify the general patient's medical and nursing needs and a provisional diagnosis so that care and treatment can be initiated.

PC.7 The initial assessment includes screening patients for pain, functional limitations, and malnutrition.

PC.7.1 The hospital implements a policy that defines the criteria and process for screening patients for pain, functional limitations including risk for fall, and malnutrition.

PC.7.2 Screening criteria are developed by qualified individuals.

PC.7.3 When pain is present from the initial screening, the patient receives a comprehensive pain assessment.

PC.7.4 Patients with functional impairment are referred for functional assessment.

PC.7.5 Patients identified as malnourished or at risk for malnutrition are referred for a nutritional assessment.

PC.8 The initial assessment includes the need for discharge planning.

PC.8.1 The hospital has criteria to identify patients requiring discharge planning before or upon admission.

PC.8.2 A proposed discharge date is set soon after admission.

PC.8.3 Staff members are aware of the discharge planning process particularly for common cases with predictable outcome.

PC.9 Initial assessment of patients is completed and documented in the medical record on a timely manner.

PC.9.1 The hospital implements a policy that defines the time frame for completing the medical, nursing, and other assessments required for different care settings and services.

PC.9.2 Medical and nursing assessments are completed and documented within the first 24 hours of admission for routine elective cases.

PC.9.3 Medical and nursing assessments are completed and documented earlier whenever indicated by the patient's condition and the hospital policy.

PC.9.4 Assessments completed within 30 days prior to admission or an outpatient visit can be used with a documented update of any significant changes.

PC.9.5 Assessments completed more than 30 days prior to admission or an outpatient visit must be repeated.

PC.9.6 Medical and nursing assessments are completed and documented for all patients prior to surgery, anesthesia or invasive procedures.

PC.10 Medical assessment is completed and documented for each patient.

PC.10.1 Each patient undergoes an initial medical assessment that includes a health history and physical examination, covering the following:

- PC.10.1.1 Main complaint.
- PC.10.1.2 Details of the present illness.
- PC.10.1.3 Systems review.
- PC.10.1.4 Past history including previous admissions and surgeries.
- PC.10.1.5 Allergies and prior adverse drug reactions.
- PC.10.1.6 Drug history.
- PC.10.1.7 Family history.
- PC.10.1.8 Psycho-social history.
- PC.10.1.9 Economic factors.
- PC.10.1.10 Pain (screening followed by assessment if required).
- PC.10.1.11 Risk for fall (screening followed by assessment if required).
- PC.10.1.12 Physical status and functionality (screening followed by assessment if required).
- PC.10.1.13 Complete physical examination.
- PC.10.1.14 Diagnostic test(s) as indicated by the patient's condition.
- PC.10.1.15 Need for additional or specialized assessment as indicated by the patient's condition.
- PC.10.1.16 Need for discharge planning as indicated by the patient's condition.
- PC.10.1.17 Provisional diagnosis.

PC.10.2 The most responsible physician ensures all patients under his care have a complete medical assessment with all diagnostic tests and referrals as required to reach a final diagnosis.

PC.10.3 Medical assessment is performed by the most responsible physician or a member of the team who is qualified by license, certification, and experience.

PC.10.4 Diagnostic tests (e.g., laboratory and radiology) are available as indicated by the hospital's scope of service and the professional standards of care.

PC.10.5 Diagnostic tests (e.g., laboratory and radiology) are appropriately and timely ordered to aid in reaching a final diagnosis.

PC.10.6 The medical assessment is documented in the patient's medical record.

PC.11 Nursing assessment is completed and documented for each patient.

PC.11.1 The nursing assessment is performed by a staff nurse.

PC.11.2 The nursing assessment identifies the patient's nursing needs.

PC.11.3 The nursing assessment must be timely and complete.

PC.11.4 The nursing assessment is documented in the patient's medical record.

PC.12 Additional and specialized assessments are performed for identified patient groups.

PC.12.1 There are criteria implemented to identify patient groups who need additional or specialized assessments.

PC.12.2 Additional assessment includes, but is not limited to, the following categories:

- PC.12.2.1 Patients in severe or chronic pain.
- PC.12.2.2 Children.
- PC.12.2.3 Frail and elderly.
- PC.12.2.4 Suspected victims of abuse, neglect, and domestic violence.
- PC.12.2.5 Drug abuse.
- PC.12.2.6 Psychiatric disorders.
- PC.12.2.7 Women in labor.
- PC.12.2.8 Terminally ill and dying patients.

PC.12.3 Specialized assessment includes patients with dental, hearing, eye or speech defects.

PC.12.4 When additional or specialized assessments are required, they are completed and documented in the patient's medical record.

PC.13 The hospital has a process to manage patients of suspected abuse, neglect, or domestic violence.

PC.13.1 The hospital has a policy and procedure that defines the initial screening criteria and subsequent assessment of cases subjected to abuse, neglect, or domestic violence.

PC.13.2 The screening criteria are developed by qualified individuals.

PC.13.3 The policy defines the staff members responsible for assessment and management of such cases in accordance with the applicable laws and regulations.

PC.13.4 Staff members are aware of the relevant laws and regulations and are educated about managing cases of abuse and neglect.

PC.14 Patients are assessed, reassessed, and managed for pain.

PC.14.1 The hospital addresses pain (acute/chronic) assessment and management as a patient's right.

PC.14.2 The hospital implements a policy that clearly defines:

- PC.14.2.1 Requirements for a comprehensive pain assessment and management.
- PC.14.2.2 Frequency of pain re-assessment.

PC.14.2.3 Role of staff in pain assessment and re-assessment.

PC.14.2.4 Items included in pain assessment (intensity, type, duration, frequency, location, and progress).

PC.14.2.5 Pain relieving measures, including medications and their dosage, frequency, and route.

PC.14.3 Patients in pain receive pain assessment and management according to the policy.

PC.14.4 The process of pain assessment and management is documented in the patient's medical record.

PC.15 In-hospital patients have their overall care managed and coordinated by one qualified physician.

PC.15.1 Each patient has one qualified physician responsible for the overall care rendered to that patient and is referred to as the most responsible physician (MRP).

PC.15.2 The most responsible physician must have the privilege to admit patients and to be a most responsible physician.

PC.15.3 The most responsible physician carries the overall responsibility and accountability for the outcome of care provided to the patient.

PC.15.4 The most responsible physician provides the principal care plan and coordinates when required for additional plans of other healthcare providers.

PC.15.5 Transfer of patient responsibility from one physician to another is guided by a hospital policy and is documented in the patient's medical record.

PC.16 A comprehensive plan of care is developed collaboratively and documented for each patient.

PC.16.1 The plan of care is developed through a collaborative approach between the healthcare team(s), patient, and family.

PC.16.2 The plan of care is based on the assessment findings and aimed to meet all patients' needs.

PC.16.3 The patient and family are involved in developing the plan of care.

PC.16.4 The plan of care contains the measurable goals/desired outcomes towards discharge.

PC.16.5 The plan of care is completed within 24 hours of admission or earlier based on the patient's condition and needs. (Nursing plan of care is completed whenever possible before the end of the shift).

PC.16.6 The plan of care is reviewed by the most responsible physician on a daily basis.

PC.16.7 The plan of care is modified as appropriate upon any significant change in the patient's condition or when new treatments are added or discontinued.

PC.16.8 The plan of care includes a provisional date of discharge set within 24 hours of admission.

PC.16.9 The plan of care is documented in the patient's medical record.

PC.17 Patients are reassessed to ensure effectiveness of care plans.

PC.17.1 All patients are reassessed at appropriate intervals to determine:

PC.17.1.1 Response to treatment.

PC.17.1.2 Compliance with treatment.

PC.17.1.3 Complications and side effects.

PC.17.1.4 Plan for continued treatment or completion of treatment.

PC.17.2 Medical reassessment must be performed at least once daily, including weekends and holidays, and in response to any significant change in the patient's condition.

PC.17.3 Nursing reassessment must be performed on every shift with a frequency dictated by the patient's condition, response to treatment, and physician's order.

PC.17.4 Reassessments are documented in the patient's medical record.

PC.17.5 The hospital defines situations where re-assessments are performed more infrequently (e.g., long stay patients mainly requiring a nursing care).

PC.18 Clinical practice guidelines, pathways, and protocols are developed or adopted to guide priority clinical care services.

PC.18.1 The hospital implements the national clinical practice guidelines, pathways, and protocols that are consistent with current evidence- based practice.

PC.18.2 Clinical practice guidelines, pathways, and protocols are updated at least every two years and as required with emphasis on the most common diagnoses.

PC.18.3 Clinical practice guidelines, pathways, and protocols are documented in the patient's medical record.

PC.19 The hospital ensures uniform patient care processes during invasive interventions.

PC.19.1 The hospital implements a policy for the assessment and management of patients undergoing invasive procedures.

PC.19.2 The policy defines all essential requirements that must be documented in the patient's medical record including, but are not limited to:

- PC.19.2.1 Date and time of the procedure.
- PC.19.2.2 Name, designation and signature of the physician performing the procedure and the names of all assistants.
- PC.19.2.3 Location of the procedure.
- PC.19.2.4 Nature and indication of the procedure.
- PC.19.2.5 Any anesthesia or analgesia used with dosage and type.
- PC.19.2.6 Patient monitoring.
- PC.19.2.7 Procedure outcome.
- PC.19.2.8 Complications
- PC.19.2.9 Laboratory specimens.
- PC.19.2.10 Specific post procedural orders.

PC.19.3 Invasive procedures are documented in the patient's medical record (or in an appropriate form) as per the policy.

PC.20 Provision of care is continued, integrated, and coordinated.

PC.20.1 Information about the patient's care and response to treatment is shared between medical, nursing, and other care providers (e.g., patient rounds, multidisciplinary teams, case management for patients requiring complex care).

PC.20.2 The patient's medical record is available to the authorized care providers to facilitate the exchange of information.

PC.20.3 Information about patient care and progress is exchanged during change- of- shift reporting (handover), between shifts, and during transfers and referrals between healthcare providers.

PC.21 Physician orders are documented in a consistent location within the medical record.

PC.21.1 There is a physician's order form where physicians document all orders relating to the patient care.

PC.21.2 Only physicians are allowed to write in the physician order form (except for telephone and verbal orders).

PC.21.3 Physician orders include medications and non-medication orders.

PC.21.4 All orders are acknowledged by the nurse in charge of the patient, dated and timed.

PC.22 Sufficient medical staff are available to meet patients' needs.

PC.22.1 Medical staff members are available in sufficient number at all times with no significant variation during holidays or weekend days.

PC.22.2 There is at least one qualified physician available at all times for each specialty according to the hospital's scope of services.

PC.22.3 Medical and other relevant staff who are "on call" are within the hospital premises during the on call hours.

PC.22.4 Medical and other relevant staff who are on call respond promptly to incoming consultations and care related requests.

PC.23 A nursing pre-operative checklist is completed to control the transfer and handover of patients to the operating room.

PC.23.1 There is a nursing pre-operative checklist that is completed by the assigned nurse.

PC.23.2 The checklist uses the "Yes", "No" and "Not Applicable" format.

PC.23.3 Patients are not transferred to the operating room if the checklist is not completed except in dire emergencies.

PC.23.4 The assigned nurse endorses all the findings of the pre-operative checklist to the receiving nurse in the operating room.

PC.23.5 The receiving nurse in the operating room reviews all the findings of the pre-operative checklist with the assigned nurse and confirms in writing.

PC.23.6 The nursing pre-operative checklist contains the following elements as a minimum:

PC.23.6.1 The nursing pre-operative checklist contains the following elements as a minimum:

PC.23.6.2 Evidence of completed relevant consents.

PC.23.6.3 Evidence of completed history and physical examination by medical and nursing staff.

PC.23.6.4 Evidence of site marking.

PC.23.6.5 Availability of results of requested investigations.

PC.23.6.6 Availability of requested blood or blood products.

PC.23.6.7 Evidence of removal of dentures and loose objects such as eye lenses, eyeglasses, and removable nails.

PC.23.6.8 Evidence of removal of jewelry and patient's valuables.

PC.24 **The hospital meets the unique needs of terminally ill patients in a culturally and age-appropriate manner.**

PC.24.1 The hospital assesses and responds to the unique needs of end of life patients, including psychological, spiritual, social, and cultural assessment.

PC.24.2 The hospital provides an effective palliative care for terminally ill patients (e.g., management of pain and management of other distressing symptoms).

PC.24.3 Family members are involved in care decisions.

PC.24.4 Family members are educated on how to care for their patient.

PC.24.5 When required, the hospital provides referral and transfer services to other facility that can provide palliative care (e.g., bed or resources availability).

PC.24.6 When applicable, the hospital provides or arrange for a nursing home care (e.g., inability to refer, or patient/family wish).

PC.25 **ESR**

Policies and procedures guide the handling, use, and administration of blood and blood products.

PC.25.1 There are policies and procedures that are developed collaboratively by the blood utilization committee, guiding the handling, use, and administration of blood and blood products.

PC.25.2 Only physicians order blood and in accordance with a policy clarifying when blood and blood products may be ordered.

PC.25.3 The physician obtain informed consent for transfusion of blood and blood products. Elements of patient consent include:

- PC.25.3.1 Description of the transfusion process.
- PC.25.3.2 Identification of the risks and benefits of the transfusion.
- PC.25.3.3 Identification of alternatives including the consequences of refusing the treatment.
- PC.25.3.4 Giving the opportunity to ask questions.
- PC.25.3.5 Giving the right to accept or refuse the transfusion.

PC.25.4 Two staff members verify the patient's identity prior to blood drawing for cross match and prior to the administration of blood.

PC.25.5 In dire emergencies, patient/family signs consent for "transfusion without NAT testing".

PC.25.6 Blood is transfused according to accepted transfusion practices from recognized professional organizations.

PC.25.7 Policies and procedures guide the administration of blood transfusions.

PC.25.8 Patients receiving blood are closely monitored.

PC.25.9 Transfusion reactions are reported and analyzed for preventive and corrective actions.

PC.25.10 Side effects or complications are immediately reported to the medical staff and blood bank and the transfused unit is sent to the blood bank for further investigations.

PC.26 **ESR**

Patients at risk for developing venous thromboembolism are identified and managed.

PC.26.1 Patients are screened for the risk of developing venous thromboembolism.

PC.26.2 Patients at risk receive prophylaxis according to current evidence-based practice.

PC.27 **The hospital provides safe psychiatric care services in accordance with professional standards and applicable laws and regulations.**

PC.27.1 Psychiatric care is provided by qualified physicians.

PC.27.2 There are admission and discharge criteria for psychiatric patients.

PC.27.3 The need for psychiatric care and choice of modality are based on sound clinical principles and a thorough clinical evaluation of medical condition and co-morbidities.

PC.27.4 The physical layout of the psychiatry service area allows for:

PC.27.4.1 Quiet and separate counseling of patients and families.

PC.27.4.2 Access only by authorized staff.

PC.27.4.3 Quick assistance from security.

PC.27.4.4 A means to separate adults from pediatrics.

PC.27.5 Seclusion areas are adequately lit, equipped with special safety features, and provide protection for patients and staff.

PC.28 **Policies and procedures guide the care of psychiatric patients.**

PC.28.1 There are policies and procedures to guide the care of psychiatric patients which include, but are not limited to, the following:

PC.28.1.1 Use of patient restraints.

PC.28.1.2 Use of sedation.

PC.28.1.3 Management and care of violent patients.

PC.28.1.4 Management of patients with depression.

PC.28.1.5 Risk assessment for identification of patients at risk for suicide.

PC.28.1.6 Environmental assessment for patients at risk for suicide.

PC.28.1.7 Management of patients at risk for suicide.

PC.28.1.8 Management of patients with psychosis.

PC.28.1.9 Use of safe seclusion.

PC.28.1.10 Guidelines for the use of electroconvulsive therapy (ECT).

PC.28.2 The policies and procedures are developed by qualified psychiatrist in collaboration with other relevant professionals.

PC.28.3 Staff members are aware of and implement all relevant policies.

PC.29 **A Policy and procedure guide the care of patients on restraints.**

PC.29.1 The hospital implements a policy and procedure that defines the Indications for restraints.

PC.29.2 Monitoring requirements for both physical and chemical restraints are clearly identified in the policy including equipment needed and the type and frequency of monitoring and its documentation.

PC.29.3 Patients are restrained only after an order by the most responsible physician or designee.

PC.29.4 The restraint order should be renewed at least every 24 hours.

PC.29.5 Patients are restrained as described in the relevant policy.

PC.30 **Restraints are applied safely and in accordance with professional standards and applicable laws and regulations.**

PC.30.1 The most responsible physician assesses and decides on the indication, the most suitable type, and the time required for applying restraints.

PC.30.2 The most responsible physician performs periodic assessment and reassessment as dictated by the patient's condition (particularly, blood circulation to the limbs restrained).
PC.30.3 The least restrictive and most effective means of restraints are always used.
PC.30.4 Use of restraints must be appropriate and safe for patient and staff, used as a last resort, and in conformance with applicable laws and regulations.
PC.30.5 Patient's dignity and rights are protected and preserved, including preventing visibility by others and covering the patient when attending to the patient's physical needs.
PC.30.6 Nursing staff provide periodic monitoring of the restrained patient.
PC.30.7 Patients are reassessed on a frequent basis (at least hourly and as appropriate).
PC.30.8 Appropriate interventions are performed when the patient's circulation is being impaired.
PC.30.9 Appropriate interventions are performed for side effects related to major tranquilizers.
PC.30.10 All assessments, reassessments, monitoring findings, orders, and interventions are properly documented in the patient's medical record.
PC.30.11 An alarm system is available in the room and at nursing station for immediate help or assistance.
PC.30.12 Staff members involved in restraint are trained and competent.

PC.31 Crash carts are readily available for cardio- pulmonary resuscitation (CPR).

PC.31.1 The hospital has standardized crash carts that are readily available in all patient care areas.
PC.31.2 The crash carts are adequately equipped and supplied with age specific requirements, including emergency medications, defibrillator, oxygen cylinder, suction machine, intubation/airway access equipment, venous access equipment, and intravenous fluids.
PC.31.3 On every shift, there is a documented process for checking the crash cart by a qualified staff.
PC.31.4 The crash carts checking includes the defibrillator battery, full oxygen tank, suction machine, pharmaceutical care lock number, ambu bags and reservoirs, drug calculation charts, endo-tracheal tube (for neonates, pediatrics, and adults) and sharp box.
PC.31.5 The crash carts are re-stocked/replenished after each use.

PC.32 The hospital has an effective system for the safe provision of care to patients requiring cardio-pulmonary resuscitation.

PC.32.1 The hospital implements a policy and procedure that guides cardio-pulmonary resuscitation across all hospital areas.
PC.32.2 The policy and procedure defines the following:
PC.32.2.1 A simple number to dial (such as 999) or other mechanism to call when summoning help for a code.
PC.32.2.2 The CPR team composition and the team leader.
PC.32.2.3 Roles and responsibilities of the staff who first discover the code, the team leader and the code team members.
PC.32.2.4 The team member responsible for documenting events with date and time.
PC.32.2.5 How the medications given during the resuscitation are prescribed.
PC.32.2.6 How the medications in the emergency cart are timely replenished.
PC.32.2.7 The CPR form that is used to standardize documentation of the CPR
PC.32.3 The CPR form includes at least the following information:
PC.32.3.1 The name of the patient.
PC.32.3.2 The date, time and location of the code.

PC.32.3.3 Names of the responders to the code.

PC.32.3.4 Medications and treatments used (e.g., electrical shocks, central lines, intubation) and times of administration.

PC.32.3.5 The outcome of the code.

PC.32.4 Clinical staff are trained on how to use the alarm system or call the code.

PC.32.5 CPR team members have the proper training on cardio-pulmonary life support.

PC.32.6 CPR team is led by:

PC.32.6.1 A physician or an anesthesiologist who is certified in ACLS for adult codes.

PC.32.6.2 A physician who is certified in PALS for pediatric codes.

PC.32.6.3 A physician who is certified in NRP for neonatal codes.

PC.32.7 All codes are reported to the cardiopulmonary resuscitation committee.

PC.33 The hospital has an effective process for responding to patients with deteriorating conditions.

PC.33.1 The hospital establishes a rapid response team(s) of qualified staff to provide rapid response for deteriorating patients outside the intensive care unit.

PC.33.1.1 Team is composed of qualified staff educated on the rapid response process.

PC.33.1.2 Team provides coverage 24 hours a day, 7 days a week.

PC.33.2 There are written criteria communicated to the staff to define how and when to call for a rapid response team before the patient "coded".

PC.33.3 Activities of the rapid response teams are documented.

PC.33.4 There is a regular evaluation of the activities and outcomes of the rapid response teams.

PC.34 Policy and procedure guides the care of vulnerable dependent patients.

PC.34.1 The hospital has policies to define and guide the care of vulnerable dependent patients (e.g., immune-compromised, comatose, elderly and frail, disabled, terminally ill, neonates, infants, and children).

PC.34.2 Policies define at least the following information:

PC.34.2.1 Relevant clinical care management plans.

PC.34.2.2 Infection control guidelines.

PC.34.2.3 Security and safety guidelines.

PC.34.2.4 Ethical guidelines.

PC.34.3 Staff members are aware of and implement all relevant policies and associated care plans.

PC.34.4 Patient's medical record reflects the use of these policies and plans.

PC.35 The hospital has a policy for patients permitted to leave the organization during the planned course of treatment.

PC.35.1 The policy defines categories of patients permitted to leave the hospital during hospitalization.

PC.35.2 The policy defines the maximum duration to go for out on pass.

PC.35.3 The policy defines the assessment requirements before leaving the hospital and upon return.

PC.35.4 The policy defines how medications will be dispensed in amounts enough to cover the out on pass period.

PC.36 The hospital has an effective process for consultations between specialty services.

PC.36.1 The consulting physician completes a consultation request that defines:
- PC.36.1.1 Date and time of consultation.
- PC.36.1.2 Name and designation of consulting physician.
- PC.36.1.3 Name and designation of consulted physician.
- PC.36.1.4 Urgency of consultation (24 hours for routine inpatient consults and one hour or less for emergency cases).
- PC.36.1.5 Case summary.
- PC.36.1.6 Rationale for consultation.

PC.36.2 The consulted physician indicates in writing:
- PC.36.2.1 Date and time of consultation visit.
- PC.36.2.2 Name and designation.
- PC.36.2.3 Opinion and recommendations, including the need to transfer the patient under his name.

PC.36.3 The consulting physician approves and follows up the implementation of the plan of care as set by the consulted physician.

PC.37 Policy and procedure guides the transfer of patients between hospital units.

PC.37.1 The most responsible physician assesses the need for transfer and matches the condition of the patient with admission criteria of the unit.

PC.37.2 Verbal or written agreement as received from the receiving unit is documented in the patient's medical record, including the name of the receiving physician.

PC.37.3 The most responsible physician assesses the transfer requirements, both staff and equipment.

PC.37.4 Summary of the patient medical and nursing assessment findings including reason for transfer, diagnoses, clinical findings, and current medications is available in the patient's medical record before transfer.

PC.37.5 The physician and the nurse at the receiving unit assess the patient at arrival to ensure safe and smooth handover.

PC.38 The hospital has an efficient discharge process.

PC.38.1 The patient and the family are involved in the discharge process with clear follow up instructions.

PC.38.2 Discharge is based on the patient's condition and relevant policies or criteria.

PC.38.3 Patients' needs after discharge are assessed as early in the care process as possible.

PC.38.4 The discharge process identifies the post-service needs and supports continuity of care after discharge.

PC.38.5 The post-service needs are communicated to relevant staff members.

PC.38.6 Staff members ensure coordination with various departments involved in the discharge process.

PC.38.7 Whenever required, staff members ensure coordination with outside organizations and post-service providers as appropriate to the patient's needs.

PC.38.8 Staff members ensure that all patients' needs are met prior to discharge.

PC.38.9 Policies and procedures guide the transfer of patients to other organizations.

PC.39 The hospital has a safe and efficient process for initiating transfer to other organizations.

PC.39.1 Policy and procedure guides the transfer of patients to other organizations.

PC.39.2 Transfer is based on the patient's health needs for continuing care and the resources available for both referring and receiving organizations.

PC.39.3 The most responsible physician determines the need for transfer, the most suitable time for transfer, resources required during transfer, and whether the receiving organization can meet the patient's health and supportive needs.

PC.39.4 There are written transfer criteria for staff to follow.

PC.39.5 There is a written acceptance for transfer of responsibility for the patient's care by the receiving provider/organization.

PC.39.6 The hospital communicates with all potential receiving organizations and necessary arrangements are made whenever applicable.

PC.40 The hospital ensures safe transportation of patients during transfer to other organizations.

PC.40.1 The most responsible physician assesses the transportation needs of the patient according to his condition.

PC.40.2 Transportation needs of the patient are communicated to the relevant staff.

PC.40.3 The transportation is provided promptly and safely in emergency cases (e.g. trauma, or cardiac emergency).

PC.40.4 The most responsible physician ensures that all patient's health needs during transportation are met.

PC.40.5 Adequate equipment and supplies are available during transportation.

PC.40.6 A qualified staff member accompanies the patient during transportation.

PC.40.7 The patient is monitored as appropriate during transfer.

PC.40.8 Handover is completed to staff at the receiving organization.

PC.41 The receiving organization of a transferred patient receives the necessary information for continuity of care.

PC.41.1 A summary of the patient's condition (e.g., a discharge summary) is sent with the patient to the receiving organization. The summary includes:

- PC.41.1.1 Reason for the patient's admission.
- PC.41.1.2 Patient diagnosis.
- PC.41.1.3 Brief summary of hospitalization and services provided (therapies, consultations, procedures to date).
- PC.41.1.4 Medication list and time of last dose(s) given.
- PC.41.1.5 Patient condition and physical status at the time of transfer.
- PC.41.1.6 Rationale for transfer.
- PC.41.1.7 Results of the patient's diagnostic investigations (e.g., laboratory and radiology).

PC.42 The hospital ensures the continuity of care after discharge or referral.

PC.42.1 Whenever required, follow up appointments are arranged for the patient prior to discharge.

PC.42.2 The patient receives information on how and when to re-access health and supportive services when required.

PC.42.3 The hospital provides a discharge summary for all inpatients upon discharge.

PC.42.4 A copy of the discharge summary is kept in the patient's medical record.

PC.42.5 A copy of the discharge summary is given to the patient.

PC.42.6 As appropriate, a copy of the discharge summary is provided to the healthcare provider responsible for the patient's continuing or follow-up care.

PC.42.7 The discharge summary is complete and typewritten.

PC.43 The hospital has a process for the donation, procurement, and transplantation of organs and tissues.

PC.43.1 The hospital complies with existing laws and regulations on organ and tissue donation, procurement, and transplantation.

PC.43.2 If the hospital performs organ transplants, it collaborates and coordinates with the Saudi Center for Organ Transplantation (SCOT).

PC.43.3 The hospital ensures appropriate retrieval, processing, preservation, and storage of organs/tissues for transplants.

PC.43.4 The hospital establishes guidelines for the donation of organs from one living person to another in accordance with laws and regulations.

Nursing Care (NR)

Introduction

The Nursing Director is considered a member of the hospital leadership. His/her role is essential in achieving high quality patient care. The Nursing Director is responsible and accountable for the standard of nursing care in the hospital along with the Medical Director and Quality Director. All should work as one team to monitor and observe the standards of clinical care provided to patients all over the hospital. The Nursing Director and other nurse Managers together with the nursing staff and nursing aides are the cornerstone for the provision of a high quality and safe care for several reasons, the most obvious of which is that the nursing staff members are the closest to the patients because of their roles and responsibilities. Medical staff members are also essential for quality and safe care but they do not spend the same amount of time besides patients like the nurses do.

Nurses have the responsibility to ensure that quality standards are adhered to in order to minimize risk and provide safe care to all patients. A major role is expected from the nursing staff in almost all aspects of the quality program and competent nursing structure is expected to participate fully in the implementation of the quality standards.

This chapter defines the important processes required by the nursing department, such as:

- Nursing department organization
- Nursing department staffing
- The role of the nursing director
- Collaboration with other departments/committees
- Nursing standards of practice
- Nursing assessment
- Nursing plan of care
- Participation in quality improvement and patient safety activities
- Nursing education

STANDARDS

NR.1 Qualified nursing director is responsible for managing nursing services in the hospital.

NR.1.1 The hospital has a full time nursing director.

NR.1.2 The nursing director is licensed and registered with the Saudi Commission for Health Specialties.

NR.1.3 The nursing director is qualified by appropriate education, training, and experience (minimum bachelor degree of science in nursing and five years of managerial experience).

NR.1.4 The nursing director is responsible for the direction, provision, and quality of nursing services provided to patients.

NR.1.5 The nursing director develops the nursing organizational chart as well as the nursing education and quality improvement.

NR.1.6 The hospital designates a deputy director of nursing to coordinate nursing activities and handle administrative and clinical issues during the absence of the nursing director.

NR.2 The nursing director assumes a leadership position in the hospital.

NR.2.1 The nursing director represents the nursing staff as one of the hospital leaders.

NR.2.2 The nursing director participates with the other hospital leaders in the decision making processes, including planning and budgeting.

NR.2.3 The nursing director participates in the hospital's multi-disciplinary structures (e.g., committees such as quality improvement, infection control and pharmacy and therapeutics).

NR.2.4 The nursing director oversees and assures that committees' recommendations are implemented at the nursing level.

NR.3 The nursing director assumes the authority, responsibility, and accountability for assuring proper and effective nursing services.

NR.3.1 The nursing director establishes, oversees, and approves nursing policies and procedures and nursing professional standards of practice and patient care.

NR.3.2 Nursing policies, procedures, and standards include all nursing units (e.g. intensive care, medical, surgical, emergency room, operating room, and dialysis units).

NR.3.3 Nursing policies, procedures, and standards are accessible to all nursing staff at all times.

NR.3.4 Nursing staff are familiar with the nursing policies and procedures.

NR.3.5 The nursing director ensures participation with other hospital leaders in the development of practices that promote patients and staff safety (e.g., infection control, safe medication management, safe use of medical equipment, and fire safety).

NR.3.6 The nursing director together with other relevant staff work to develop essential policies and procedures including, but are not limited to, the following:

- NR.3.6.1 Admission procedures.
- NR.3.6.2 Basic hygiene of patients and skin care.
- NR.3.6.3 Patient and family rights.
- NR.3.6.4 How to transcribe physician's orders.
- NR.3.6.5 Patient education.
- NR.3.6.6 General infection control policies.
- NR.3.6.7 Calling physicians.

NR.3.6.8 Patient transfer (internal and external).

NR.3.6.9 Patient discharge.

NR.3.7 The nursing director implements an effective method for organizing the delivery of patient care (e.g. functional, team, primary care).

NR.3.8 The nursing director ensures the implementation of a policy and procedure that defines patient care delivery method(s).

NR.4 Nursing reference manuals and policies are readily available and accessible to all nursing units.

NR.4.1 There are nursing reference manuals and policies that are available and accessible to all nursing units. This includes, but is not limited to, the following:

NR.4.1.1 Nursing policies and procedures manual.

NR.4.1.2 Current nursing practice manuals/books.

NR.4.1.3 Infection control manual.

NR.4.1.4 Safety manual or safety policies.

NR.4.1.5 Operating manuals for the safe use of equipment.

NR.4.1.6 Laboratory services guide.

NR.4.1.7 Dietary manual.

NR.4.1.8 Material Safety Data Sheet (MSDS).

NR.4.2 Policies and content of manuals are implemented as evidenced by the daily practice and the patient's medical record.

NR.5 The nursing director ensures the competency of the nursing staff.

NR.5.1 The nursing director participates in the recruitment and hiring of qualified nurses as outlined in the leadership chapter.

NR.5.2 The nursing director monitors the performance of the nursing staff and assures their ongoing competency.

NR.5.2.1 The nursing department develops policies and procedures to define the nursing competency assessment program aiming to ensure that nursing skills and knowledge remain current.

NR.5.2.2 Nursing staff competencies are assessed on an ongoing basis (at least annually, and whenever needed).

NR.5.2.3 Nursing staff competencies are assessed by using different methods (e.g. written test, return demonstration, peer review, feedback from health professionals and supervisors).

NR.5.3 Nursing competencies to be assessed include, but are not limited to, the following:

NR.5.3.1 Monitoring patient's vital signs and knowledge of acceptable deviations from the norm.

NR.5.3.2 Assessment/reassessment of patients according to the scope of services (e.g. critical care, labor and delivery, and surgical units).

NR.5.3.3 Medications administration.

NR.5.3.4 Intravenous therapy (insertion, maintenance, discontinuing).

NR.5.3.5 Infection control guidelines.

NR.5.3.6 Patient falls (assessment of risk and methods to prevent falls).

NR.5.3.7 Use of pulse oximetry.
NR.5.3.8 Nursing role in cardiac/respiratory arrest.
NR.5.3.9 Nasogastric, gastrostomy and feeding tubes.
NR.5.3.10 Urinary catheters.
NR.5.3.11 Sterile dressings.
NR.5.3.12 Skin care and prevention and care of pressure ulcers.
NR.5.3.13 Nursing role in disaster, fire, and other emergencies.
NR.5.3.14 Use of restraints.
NR.5.3.15 Operation of blood sugar testing equipment.
NR.5.3.16 Managing chemical spills.
NR.5.3.17 Use of blood, blood products, and blood -related procedures (e.g., phlebotomy and blood administration).

NR.6 Sufficient nurses are available to meet the needs of patients.

NR.6.1 The nursing director develops a staffing plan that maintains an adequate staffing level in all nursing units.

NR.6.2 The staffing plan identifies an evidence-based estimation of the number of staff needed per shift, considering all relevant factors (e.g., patient acuity, patient care hours, size of the hospital, scope of services provided).

NR.6.3 Nursing staff are allocated according to the skill level, qualifications, patients volume and acuity, and in accordance with laws and regulations and nursing licensing boards.

NR.7 The nursing department provides regularly updated work schedule.

NR.7.1 There is a nursing scheduling policy that defines:
NR.7.1.1 Duration of working shifts (e.g., 12 hours, or 8 hours).
NR.7.1.2 Assignment of overtime when needed.
NR.7.1.3 On-call requirements.
NR.7.1.4 Vacation schedules.
NR.7.1.5 Method for approving change of schedule.
NR.7.1.6 Participation in education/training activities.
NR.7.1.7 Participation in designated committees, departmental meetings, and quality improvement activities.

NR.7.2 The work schedule provides an adequate number of staff on every shift.

NR.8 There is a process for assignment of nurses out of their normal working areas.

NR.8.1 The nursing director ensures that nurses assigned out of their normal working area have the competency required for safe and effective patient care.

NR.8.2 The nursing director maintains a list of cross-trained nurses and makes it available for all nursing units.

NR.9 Nursing services are provided by qualified nurses.

NR.9.1 The nursing director ensures the availability of adequate number of licensed registered nurses to provide nursing care for all patients.

NR.9.2 Each unit has a head nurse/nurse manager with the required nursing and managerial experience.

NR.9.3 Nursing services are provided by registered nurses in accordance with their license and scope of practice.

NR.9.4 Qualified registered nurses are readily available to provide bedside nursing care to all patients twenty four hours a day, seven days a week.

NR.9.5 Nursing assistants or aides are supervised by a registered nurse at all times.

NR.9.6 Nursing assistants have clearly defined job description and responsibilities.

NR.9.7 There is an education program for nursing assistants performing patient-care services to orient them to their role.

NR.10 There is a comprehensive nursing assessment for each patient upon admission.

NR.10.1 The nursing assessment is timely completed by a registered nurse.

NR.10.2 The scope and content of the nursing assessment is defined in hospital policies and may include:

- NR.10.2.1 History of the patient's main complaint.
- NR.10.2.2 Drug allergies.
- NR.10.2.3 Physical condition.
- NR.10.2.4 Psychosocial status.
- NR.10.2.5 Pain assessment.
- NR.10.2.6 Nutritional Status.
- NR.10.2.7 Discharge planning.
- NR.10.2.8 Skin assessment.
- NR.10.2.9 Fall risk assessment.

NR.10.3 The nursing assessment identifies nursing care needs for each patient upon admission.

NR.10.4 All patients are reassessed at appropriate intervals (at least on every shift) to determine their response to treatment and to plan for continued treatment and discharge.

NR.10.5 The nursing assessment is documented in the patient's medical record.

NR.11 There is a nursing plan of care for each patient.

NR.11.1 A nursing plan of care is developed for all inpatients.

NR.11.2 The nursing plan of care is consistent with the medical plan of care.

NR.11.3 The nursing plan of care is reviewed on every shift, upon any significant change in the patient's condition, and when new treatments are added or current treatments are discontinued.

NR.11.4 The nursing plan of care is documented in the patient's medical record.

NR.12 The nursing department ensures adequate supplies and equipment for the safe and effective provision of care.

NR.12.1 The nursing department ensures the availability of equipment and supplies necessary for the safe and effective provision of care. This includes, but is not limited to, the following:

- NR.12.1.1 Scales appropriate to the age group and mobility needs of the patient.
- NR.12.1.2 Stretchers with safety straps.
- NR.12.1.3 Equipment for taking vital signs.
- NR.12.1.4 Wheelchairs with safety straps.
- NR.12.1.5 Sharp boxes.
- NR.12.1.6 Foot stools.

NR.12.1.7 Lifting devices.
NR.12.1.8 Soft restraints.
NR.12.1.9 Bed rails.
NR.12.1.10 Devices for treatment and prevention of skin break down.
NR.12.1.11 Patient call bell.
NR.12.1.12 Oxygen and suction.
NR.12.1.13 Glucometer.
NR.12.1.14 Nebulizers.
NR.12.1.15 Blood warmers.
NR.12.1.16 ECG machines.

NR.12.2 The Nursing department has a process to maintain adequate supplies and linen to meet patient needs.

NR.12.2.1 Critical levels are identified.

NR.12.2.2 Ordering requests are made when critical levels are reached and as needed.

NR.12.2.3 There is an emergency backup process when there are issues/delays receiving supplies.

NR.12.2.4 There is a method to track issues with supplies and linen so that patterns can be studied for quality improvement.

Quality Management and Patient Safety (QM)

Introduction

This chapter addresses the senior leaders and the hospital staff's responsibility towards implementing programs that effectively improve quality and safety and reduce risks to patients, staff and visitors. The hospital leadership plays an essential role in ensuring the provision of the resources required and clearing the direction towards achieving this goal. When the hospital leaders are themselves involved and encourage and support everyone in the organization to be involved in the quality management initiatives, a general atmosphere of confidence and inspiration to work harder and to achieve high quality of care and maximum degree of safety is established. Leadership, therefore, has to set up a planned and ongoing program where processes and systems are the focus of the improvement, not only individuals.

To be able to effectively improve quality and safety of care and reduce risks, the hospital must constantly use indicators to measure its performance and use the resulting information to identify processes which can be improved. The hospital 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 interventions.

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

- A planned and organization wide approach for quality improvement
- The required structure (quality and patient safety committee)
- The quality management department
- The quality management program
- Leadership and other 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 program
- Incidents reporting and management

STANDARDS

QM.1 Hospital leaders support a hospital-wide continuous quality improvement program.

QM.1.1 Hospital leaders provide resources required for the continuous quality improvement program, including human, financial, and time resources.

QM.1.2 Hospital leaders actively participate in quality improvement activities including improvement teams.

QM.1.3 Hospital leaders implement the recommendations resulting from the continuous quality improvement program.

QM.1.4 Hospital leaders support staff to make and participate in quality improvement initiatives and to attend quality improvement educational activities.

QM.2 Hospital leaders support staff training on their roles and responsibilities related to the continuous quality improvement program.

QM.2.1 Staff are trained on quality improvement by qualified professionals.

QM.2.2 Training on quality improvement includes the utilization of quality improvement methodologies and tools (e.g., PDCA, lean six sigma, cause-and-effect analysis, process map, Pareto chart, brain storming).

QM.2.3 Staff are trained (formally or through orientation and mentoring) on continuous quality improvement in accordance with their roles and responsibilities in the quality improvement program.

QM.3 The hospital has a quality management department that is directed by a qualified individual.

QM.3.1 The hospital has a quality management director responsible for directing all aspects of the quality management department.

QM.3.2 The quality management director is qualified by education, training, and experience in healthcare quality.

QM.3.3 The quality management department provides ongoing consultation to all departments (e.g., on the development and use of indicators to evaluate and improve performance).

QM.3.4 The quality management director reports to the hospital leadership.

QM.4 The hospital develops a quality improvement program that provides a structured framework for monitoring and improving performance as well as supporting innovation.

QM.4.1 The quality improvement program covers processes of care involving high risk, high volume, problem-prone, and high cost areas.

QM.4.2 The quality improvement program is in line with the hospital strategic plan.

QM.4.3 The quality improvement program is integrated with the risk management and patient safety activities.

QM.4.4 The quality improvement program is based on a documented quality improvement plan that is revised at least annually, with defined scope, goals, and objectives.

QM.5 There is a multidisciplinary committee responsible for the coordination of the quality improvement program.

QM.5.1 The hospital has a multidisciplinary quality improvement committee that has members from the leadership group (the hospital director, medical director, nursing director, quality management director) and other members/invitees as appropriate.

QM.5.2 The quality improvement committee provides coordination and oversight of the quality improvement program throughout the hospital.

QM.5.2.1 The quality improvement committee is responsible for development, implementation, and evaluation of the quality improvement program.

QM.5.2.2 The quality improvement committee approves all quality improvement initiatives.

QM.5.2.3 The quality improvement committee receives quality reports and provides feedback to the relevant stakeholders.

QM.5.3 The quality improvement committee meets regularly and maintains appropriate documentation of its activities.

QM.6 The hospital monitors its performance through regular data collection and analysis.

QM.6.1 The performance monitoring is based on valid data that reflect the actual performance.

QM.6.1.1 Hospital leaders define and implement a set of hospital performance indicators/ measures that focus on important managerial and clinical areas.

QM.6.1.2 Clinical indicators are referenced to current evidence based practice whenever applicable.

QM.6.2 For each indicator, there is a clear definition, sample size, data collection method, frequency, analysis, and expression (e.g., a ratio, with defined numerator and denominator).

QM.6.3 Indicators represent key care and service structures, processes and outcomes based on the mission and scope of services.

QM.6.4 Data are collected and aggregated on a regular basis from qualitative and quantitative sources.

QM.6.5 Data are coordinated with other performance monitoring activities such as patient safety and risk management.

QM.7 Hospital leaders select a set of structure indicators based on the mission and scope of services.

QM.7.1 Hospital leaders utilize the information provided by structure indicators.

QM.7.2 Structure indicators may include, but are not limited to, the following:

QM.7.2.1 Availability of essential supplies and equipment.

QM.7.2.2 Availability of medical records.

QM.7.2.3 Availability of blood and blood products.

QM.7.2.4 Availability of emergency medications.

QM.7.2.5 Vacancy rates in all departments.

QM.7.2.6 Surgical volumes.

QM.7.2.7 Staffing ratios.

QM.8 Hospital leaders select a set of process indicators based on the mission and scope of services.

QM.8.1 Hospital leaders utilize the information provided by process indicators.

QM.8.2 Process indicators may include, but are not limited to, the following:

- QM.8.2.1 The timing and use of antibiotics prior to surgery.
- QM.8.2.2 Blood and blood products administration.
- QM.8.2.3 Documentation in medical records.
- QM.8.2.4 Delay of physicians answering nurses' phone calls and pagers.
- QM.8.2.5 Waiting times for treatment.
- QM.8.2.6 Venous thrombo-embolism prophylaxis for surgical patients.
- QM.8.2.7 Neuropathy testing in diabetic patients.

QM.9 Hospital leaders select a set of outcome indicators based on the mission and scope of services.

QM.9.1 Hospital leaders utilize information provided by outcome indicators.

QM.9.2 Outcome indicators may include, but are not limited to, the following:

- QM.9.2.1 Mortality rates.
- QM.9.2.2 Healthcare associated infections.
- QM.9.2.3 Staff satisfaction.
- QM.9.2.4 Patient satisfaction.
- QM.9.2.5 Unplanned return to the operating room.
- QM.9.2.6 Return to the emergency room within 24 hours.
- QM.9.2.7 Unplanned transfer to the critical care unit.
- QM.9.2.8 Resuscitation of patients (cardiac/respiratory arrest).
- QM.9.2.9 Readmission to the hospital within 30 days of discharge.
- QM.9.2.10 Various adverse events (e.g., falls, injuries, and pressure ulcers).
- QM.9.2.11 Medication errors.
- QM.9.2.12 Sentinel events.
- QM.9.2.13 Patient complaints.
- QM.9.2.14 Length of stay.

QM.10 Data collected are aggregated and analyzed.

QM.10.1 Data collected are analyzed by staff qualified in data management.

QM.10.2 Data collected are regularly aggregated and analyzed to yield useful trends and variances.

QM.10.3 Data are utilized for internal and external benchmarking to identify deficiencies and opportunities for improvement.

QM.10.4 Information is communicated to the appropriate stakeholders in a way they can understand and use.

QM.11 The hospital uses the information resulting from data analysis to make improvements.

QM.11.1 Information resulting from data analysis is used for prioritizing quality improvement projects as well as strategic and operational planning.

QM.11.2 When appropriate, the hospital tests improvement interventions prior to full implementation.

QM.11.3 After implementing improvement interventions, the hospital measures their effectiveness to ensure that interventions have achieved a sustained improvement.

QM.12 Quality improvement teams are selected by the service leaders and these teams use quality tools to improve processes.

QM.12.1 Quality improvement teams are assigned by the service leaders.

QM.12.2 The quality improvement team includes staff members who are involved in the process under study.

QM.12.3 The quality improvement team uses the quality tools to improve processes (e.g., brainstorming and fishbone charts).

QM.13 The hospital develops and maintains a risk management program.

QM.13.1 The risk management program addresses potential managerial and clinical risks.

QM.13.2 The hospital defines the scope and objectives of the risk management program as well as the individual responsible for the program.

QM.13.3 The hospital educates the staff on their roles and responsibilities related to the activities of the risk management program.

QM.13.4 The hospital performs a systematic process to identify and analyze potential risks for severity and likelihood of occurrence.

QM.13.5 The hospital develops interventions to manage identifies potential risks (e.g., reduction and/or prevention).

QM.13.6 The hospital adopts a proactive approach to identify, analyze, and reduce potential risks (e.g. failure mode and effects analysis).

QM.13.7 Heads of clinical departments and other clinical leaders participate in the risk management program.

QM.13.8 Heads of clinical departments and other clinical leaders develop, implement, and evaluate interventions to safeguard patients from unintended consequences of care/treatment.

QM.13.9 The risk management program addresses patient safety issues and makes use of the information developed from investigation of the following:

QM.13.9.1 All litigations involving the hospital and its staff.

QM.13.9.2 Adverse incidents including near misses and sentinel events.

QM.13.9.3 Patient complaints.

QM.13.9.4 Cases of irregular discharges.

QM.13.9.5 Data and reports related to patient safety issues.

QM.13.9.6 Mortality and significant morbidity cases.

QM.13.10 The effectiveness of the risk management program is evaluated regularly and improved as required.

QM.13.11 The hospital maintains appropriate documentation of the risk management activities.

QM.13.12 The risk management activities and their results are communicated to the staff and other relevant groups and used as a basis for improvement of the hospital's processes.

QM.13.13 Relevant information developed from the risk management activities is integrated and coordinated with the quality improvement and patient safety activities.

QM.14 The hospital has an incident (occurrence/variance) management mechanism that supports improvements of care processes.

QM.14.1 There is a policy and form that are utilized for reporting incidents including adverse events and near misses.

QM.14.2 The hospital defines reportable incidents.

QM.14.3 Incidents are reported and investigated in a timely manner.

QM.14.4 Immediate remedial actions are taken as well as actions to prevent recurrence of similar incidents.

QM.14.5 Patients receive response when involved in significant incidents with documentation in the medical records.

QM.14.6 Incidents are monitored over time and the resulting information is used for improvement.

QM.14.7 Staff are educated on the incident reporting process.

QM.15 The hospital has a process to handle sentinel events.

QM.15.1 There is a policy for management of sentinel events.

QM.15.2 Sentinel events are identified in the hospital's policy and include the following:

QM.15.2.1 Unexpected death.

QM.15.2.2 Unexpected loss of limb or function.

QM.15.2.3 Wrong patient, wrong procedure, or wrong site.

QM.15.2.4 Retained instrument or sponge.

QM.15.2.5 Serious medication error leading to death or major morbidity.

QM.15.2.6 Suicide of a patient in an inpatient unit.

QM.15.2.7 Infant abduction or discharge to a wrong family.

QM.15.2.8 Maternal death.

QM.15.2.9 Hemolytic blood transfusion reaction.

QM.15.2.10 Air Embolism.

QM.15.3 Reportable sentinel events are reported to CBAHI within five working days of the internal notification of the event.

QM.15.4 The hospital forms a team to complete the root cause analysis along with an action plan for all sentinel events. The team should bring together those who have an intimate knowledge of the normal process.

QM.15.5 The root cause analysis and risk reduction plan are sent to CBAHI within thirty working days from the date of the internal notification of the event.

QM.15.6 Reportable sentinel events are reported as required to other relevant authorities.

QM.16 The hospital develops and maintains a patient safety program.

QM.16.1 Hospital leaders adopt a just culture that promotes both professional accountability and reporting of adverse events/near misses.

QM.16.2 Hospital leaders provide direction and resources to support the patient safety program.

QM.16.3 The hospital assigns a qualified individual to provide coordination and supervision of the organization-wide patient safety program.

QM.16.4 Hospital leaders establish a multidisciplinary patient safety committee (can be integrated with quality improvement committee) to provide direction and oversight of the patient safety program.

QM.16.5 Hospital leaders conduct patient safety culture assessment at least once annually. Data are analyzed and improvements are made accordingly.

QM.16.6 Hospital leaders conduct regular leadership patient safety rounds in patient care services to encourage reporting of incidents/near misses and to identify potential risks and hazards.

QM.16.7 The hospital adopts safe practices that have been proven to improve patient safety and reduce harm to patients such as those from the World Health Organization (WHO) and other national and international organizations concerned with patient safety.

QM.16.7.1 The hospital develops and implements policies, procedures, protocols, and guidelines for implementation of the patient safety practices.

QM.16.7.2 The hospital provides equipment/devices with technological features proven to reduce errors and improve safety.

QM.16.8 Relevant information developed from patient safety activities is integrated into quality improvement and risk management activities.

QM.16.9 Patient safety activities and their results are communicated to the staff and other relevant groups and used as the base for improving the hospital's processes.

QM.17 The hospital has a process to ensure correct identification of patients.

ESR

QM.17.1 At least two patient identifiers (e.g., patient full name and medical record number) are required whenever taking blood samples, administering medications or blood products, or performing procedures.

QM.17.2 The hospital has a standardized approach to patient identification (e.g., use of ID bands with standardized information).

QM.17.3 Patients are actively involved in the process of patient identification.

QM.18 The hospital has a process to prevent wrong patient, wrong site, and wrong surgery/procedure.

ESR

QM.18.1 There is a process implemented to prevent wrong patient, wrong site, and wrong surgery/procedure during all invasive interventions performed in operating rooms or other locations.

QM.18.2 The process consists of three phases: verification, site marking, and time out.

QM.18.3 A pre-procedure verification of the patient information is carried out including the patient's identity, consent, full details of the procedure, laboratory tests and images, and any implant or prosthesis.

QM.18.4 The surgical/procedural site is marked before conducting the surgery/procedure.

QM.18.4.1 The site is marked especially in bilateral organs and multiple structures (e.g. fingers, toes, and spine).

QM.18.4.2 The site is marked by the individual who will perform the procedure.

QM.18.4.3 The patient is involved in the marking process.

QM.18.4.4 The marking method is consistent throughout the hospital.

QM.18.4.5 The mark is visible after the patient is prepped and draped.

QM.18.5 A final check (time-out) is conducted before the procedure is initiated.

QM.18.5.1 The time-out is conducted in the location where the procedure will be done, just before starting.

QM.18.5.2 The time-out is initiated by a designated member of the team and involves the members of the team, including the individual performing the procedure, the anesthesia providers, and the nurse(s) involved.

QM.18.5.3 The entire procedure team uses active communication during the time out.

QM.18.5.4 During the time-out, the team members agree on the correct patient identity, the correct procedure to be performed, the correct site, and when applicable, the availability of the correct implant or equipment.

QM.18.6 The hospital documents its processes for preventing wrong patient, wrong site, and wrong surgery/procedure.

QM.19 The hospital ensures availability and safety of infusion pumps.

QM.19.1 Infusion pumps are available with adequate numbers throughout patient care areas.

QM.19.2 Infusion pumps have "free-flow" protection.

QM.19.3 Infusion pumps have documented preventative maintenance, inspection and testing on a regular basis.

QM.20 The hospital ensures the safety of the alarm systems of patient care equipment.

QM.20.1 All alarm systems for patient care equipment (such as infusion pumps and monitors) have documented preventative maintenance, inspection and testing on a regular basis.

QM.20.2 All staff are trained on the safe use of alarm systems for patient care equipment and the use of appropriate settings for sound.

QM.21 The hospital ensures appropriate communication of patient care information during patient handovers.

QM.21.1 Patient care information is appropriately documented in a clearly understandable form to all care providers within and between care settings.

QM.21.2 The hospital implements a standardized approach to handover communication between staff (e.g., Situation, Background, Assessment, Recommendation-SBAR), change of shift, and between different patient care units in the course of a patient transfer.

QM.22 The hospital has a process for effective identification, assessment, and intervention for patients who are at risk for pressure ulcers.

QM.22.1 All patients are assessed for pressure ulcers on admission using a standard risk assessment tool.

QM.22.2 All patients are re-assessed for pressure ulcers every twenty four hours.

QM.22.3 The hospital implements evidence-based interventions that prevent pressure ulcers.

QM.23 The hospital has a process for effective identification, assessment, and intervention for patients who are at risk for falling.

QM.23.1 Patients are assessed for the risk of fall on admission.

QM.23.2 Patients are reassessed for the risk of fall after a change in risk factors (e.g., post-operatively, after receiving sedating medications) and upon transfer from another unit.

QM.23.3 The hospital implements evidence-based interventions for falls reduction according to the risks identified.

QM.24 The hospital implements evidence-based interventions to prevent catheter and tubing misconnections.

QM.24.1 Patients and families are informed not to connect or disconnect devices or infusions.

QM.24.2 High-risk catheters (e.g., epidural, intra-thecal, arterial) must always be labeled.

QM.24.3 All lines (tubes or catheters) are always traced from the patient to the point of origin before connecting any new device or administering medications or infusion.

QM.24.4 All lines (tubes or catheters) are always traced from the patient to the point of origin upon the patient's arrival to a new setting or service as part of the hand-off process. The hospital standardizes this "line reconciliation" process as part of the hand-over communication.

QM.24.5 The hospital prohibits the use of standard luer-connection syringes for oral medications or enteric feedings.

QM.24.6 The hospital conducts acceptance testing (for performance, safety, and usability) and, as appropriate, risk assessment on new tubing and catheter purchases to identify the potential for misconnections and take appropriate preventive measures.

QM.25 There is a written policy on verbal or telephone orders and telephone reporting of critical test results.

QM.25.1 The policy defines situations for accepting verbal or telephone orders.

QM.25.2 The policy defines the time frame for orders authentication.

QM.25.3 The policy defines staff who may accept verbal or telephone orders.

QM.25.4 The complete verbal or telephone order or critical test result is written down by the receiver of the order or test result.

QM.25.5 The complete verbal or telephone order or critical test result is read back by the receiver of the order or test result.

QM.25.6 The order or test result is confirmed by the individual who gave the order or test result.

Patient and Family Education (PFE)

Introduction

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

This chapter outlines the following processes and activities:

- Educational resources
- Assessment of educational needs of patients
- The role of health educators
- Education plan
- Effectiveness of education

STANDARDS

PFE.1 Hospital leaders support patient and family education.

PFE.1.1 The hospital develops policies and procedures to ensure effective patient and family education process.

PFE.1.2 There is an appropriate structure and efficient resources for patient/family education throughout the hospital.

PFE.1.3 According to the size of the hospital and its scope of services, the hospital assigns adequate health educators to cover the needs of patient/family education (e.g., diabetic educator, nurse educator).

PFE.1.4 The hospital provides different teaching methods for the health education process such as pamphlets, diagrams, models to practice on, videos, or other teaching methods.

PFE.1.5 The job description of the clinical staff (e.g. nurses, physicians, dietitians) reflects their role in patient/family education.

PFE.1.6 Clinical staff and health educators are knowledgeable about their essential role in patient education.

PFE.1.7 There are discussions of patient education efforts in staff meetings as an integral part of the care process.

PFE.2 The hospital ensures proper communication between the health educator and the patient/family.

PFE.2.1 Patient/family education is provided in an easy language understandable by the patient/family.

PFE.2.2 Sufficient time is provided to allow the patient to understand the information provided and interact with the health educator.

PFE.3 Each patient's educational needs are assessed and planned.

PFE.3.1 Staff conduct educational needs assessment for every patient by:

- PFE.3.1.1 Assessing learning needs.
- PFE.3.1.2 Assessing literacy skills.
- PFE.3.1.3 Assessing caregiver/patient's readiness and ability to learn.
- PFE.3.1.4 Assessing patient's capability and motivation to provide self-care.
- PFE.3.1.5 Assessing caregiver/patient's appropriate educational materials and methods that meet their learning skills.
- PFE.3.1.6 Assessing who will provide care after discharge (caregiver and/or patient).

PFE.3.2 Staff use the assessment findings for planning and delivery of education as appropriate to the plan of care.

PFE.3.3 Staff provide the caregiver/patient with educational materials that meet their learning skills (e.g. written and verbal notes, pictures, demonstration).

PFE.3.4 When the patient is unable/unsuitable to learn (e.g., comatose, child, mentally disabled), education is provided to the family or the caregiver.

PFE.4 **Patients and their families receive education to help them give informed consent, participate in care process, and understand any financial implications of care choices.**

PFE.4.1 Patients and families are educated about informed consent.

PFE.4.2 Patients and families are educated about participation in the care process and decisions.

PFE.4.3 Patients and families are educated about any financial implications of care decisions.

PFE.5 **Patients and their families are given the necessary education and information by clinical staff and health educators as appropriate to their needs.**

PFE.5.1 The hospital provides the patient with the necessary education and information about the primary illness and all possible complications.

PFE.5.2 The hospital provides the patient with the necessary education and information about infection control practices, adding emphasis on basic hand washing.

PFE.5.3 The hospital provides the patient with the necessary education and information about the required treatments and procedures.

PFE.5.4 The hospital provides the patient with the necessary education and information about the appropriate and safe use of the medical equipment or appliances.

PFE.5.5 The hospital provides the patient with the necessary education and information about any surgical procedure needed and its benefits and potential risks.

PFE.5.6 The hospital provides the patient with the necessary education and information about the pre-operative preparations needed and their importance.

PFE.5.7 The hospital provides the patient with the necessary education and information about post-operative care (e.g., breathing exercises, diet, and wound care).

PFE.5.8 The hospital provides the patient with the necessary education and information about the necessary medications, the frequency, potential side effects, and food-drug interactions.

PFE.5.9 The hospital provides the patient with the necessary education and information about radiological procedures, their benefits, and the potential risks involved.

PFE.5.10 The hospital provides the patient with the necessary education and information about the rational and benefits of any dietary restrictions.

PFE.5.11 The hospital provides the patient with the necessary education and information about the conditions in which the patient needs to seek medical assistance and how to access it if necessary.

PFE.5.12 The hospital ensures that the patient has his follow up clinic appointments.

PFE.5.13 The hospital provides the patient with the necessary education and information about how to carry out activities of daily living.

PFE.5.14 The hospital provides the patient with the necessary education and information about community resources for additional care and how to access emergency services if necessary.

PFE.5.15 The hospital ensures that the patient can always state the name of his most responsible physician.

PFE.6 **The patient/family education is evaluated for effectiveness.**

PFE.6.1 Clinical staff and health educators obtain feedback from the patient and/or family to ensure proper understanding (e.g., demonstrates learning, verbalizes understanding).

PFE.7 **All patient education activities are documented in the patient's medical record.**

PFE.7.1 The educational needs assessment and planning is documented in the patient's medical record.

PFE.7.2 The patient's response to education is documented in the patient's medical record.

Patient and Family Rights (PFR)

Introduction

Every patient has his/her special own needs, values and spiritual beliefs. In alignment with this fact, the hospital is responsible for ensuring that patient and family rights are defined and respected while receiving care inside the hospital.

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 and participate in their care decisions and plans are well informed and involved in the care process.

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 as a patient right
- Protection of patient belongings
- Regular conduction of patient and family satisfaction surveys and making improvements accordingly
- Establishing a process for resolution of patient complaints
- Making sure that patients and their families are fully informed and protected when they are involved in research projects

STANDARDS

PFR.1 Hospital leaders support and protect the patient and family rights.

PFR.1.1 Hospital leaders establish and maintain a structure that involves hospital's leaders and others to support and oversee all patient rights activities (e.g. patient relations, patient rights/patient advocacy committee).

PFR.1.2 Patients and families have an access to communicate their concerns/inquiries regarding their rights.

PFR.1.3 Hospital leaders develop and maintain patient rights and responsibilities statement that includes all patient and family rights and responsibilities.

PFR.1.4 The hospital develops and implements policies and procedures that protect and support the implementation of patient and family rights.

PFR.1.5 The hospital makes patient rights and responsibilities available to patients and families in a format and language they can understand (e.g., providing patient rights and responsibilities document or posting in the patient's room and public places throughout the hospital).

PFR.1.6 The hospital ensures that patients are informed about their rights and responsibilities.

PFR.1.7 The hospital helps patients to exercise their rights.

PFR.1.8 The hospital educates staff on their responsibilities regarding patient and family rights (e.g., during orientation as well as refresher courses).

PFR.1.9 Staff are aware of their responsibilities in protecting patient and family rights.

PFR.2 Cultural, psychosocial, religious, and spiritual needs of patients are respected and supported.

PFR.2.1 The hospital recognizes and provides staff training on responding to patient's cultural, psychosocial, religious and spiritual beliefs, values and needs.

PFR.2.2 The hospital provides separate facilities for women where appropriate.

PFR.2.3 The hospital provides access to spiritual care or advice that meets the needs of the different populations served.

PFR.2.4 Staff members provide care to patients with respect and dignity.

PFR.3 Privacy of patients is maintained throughout the care process.

PFR.3.1 Patient privacy is respected during all interviews, examinations, and treatments.

PFR.3.2 Patient private parts are not exposed unnecessarily during care process.

PFR.3.3 The hospital mandates a written consent to photograph patients.

PFR.4 The hospital protects patient belongings.

PFR.4.1 There is a process described in a policy for the protection of patient belongings.

PFR.4.2 Patients receive information about the hospital's responsibility for safeguarding and protecting their belongings.

PFR.4.3 When the hospital assumes responsibility for safeguarding patient belongings, the hospital has a process to protect them from theft or loss.

PFR.4.3.1 The hospital defines where the patient belongings are kept.

PFR.4.3.2 The hospital defines who is responsible for obtaining the required signatures on the related form when receiving and handing over the patient's belongings.

PFR.4.4 The hospital addresses how the valuables of those patients unable to make decisions regarding their belongings (e.g., traumatized patients, patients in comatose state, confused patients, elderly and children) are handled and safeguarded.

PFR.5 The hospital provides protection for patients.

PFR.5.1 Patients are protected from neglect and abuse by physicians, nurses, or any other staff.

PFR.5.2 The hospital provides appropriate security and prevents unauthorized access to remote or sensitive areas (e.g., female wards).

PFR.5.3 The hospital provides visitors with identification badges.

PFR.5.4 The hospital has a process in place to protect infants/children from abduction.

PFR.5.5 The hospital has a process in place to protect vulnerable patients (e.g., disabled and elderly patients).

PFR.6 The hospital provides assistance to patients with special needs.

PFR.6.1 The hospital provides the necessary assistance to patients with special needs where and when needed (e.g., providing assistance in case of fire, off-street parking spaces near the entrance for disabled patients, handicapped accessible bathrooms, accessibility for wheelchair users).

PFR.7 Staff members respect and protect patient health information confidentiality throughout the care process.

PFR.7.1 The hospital implements a policy that ensures the confidentiality of information related to the patient's health and how to protect it from loss or misuse.

PFR.7.2 The policy indicates the circumstances under which such information may be released and how to obtain patient's permission if required.

PFR.8 Staff members assist patients and their families to participate in making informed decisions about the care process, treatment and services.

PFR.8.1 Patients are informed about how they can actively participate in their care decisions.

PFR.8.2 Patients' choices are respected.

PFR.8.3 Staff members provide patients and, when appropriate, their families with honest, accurate and reasonable information in a manner they can understand about their illness, the proposed treatment and other alternatives, potential benefits, potential complications and likelihood of success of treatment.

PFR.8.4 When it is medically inadvisable to provide the patient with such information, the information is provided to a legally authorized person or a person designated by the patient.

PFR.8.5 Patients are supported to discuss their plans of care with the responsible staff members and have all their questions answered.

PFR.8.5.1 The patient is provided with the name and the professional status of the physician or other professional who has the primary responsibility for managing the care process.

PFR.8.5.2 Staff members identify themselves by introduction and by displaying the name.

PFR.8.6 Patients are informed of how to contact care providers in case of emergency.

PFR.8.7 Staff members respond appropriately to patients' requests of a second opinion if necessary.

PFR.8.8 The hospital respects patients' demands and needs including their preferences in personal issues such as food, drink, clothing, and self-care.

PFR.9 The hospital informs patients, and families as appropriate, of the outcome of care.

PFR.9.1 The hospital has a defined process for informing patients, and families as appropriate, of the outcome of care including adverse events or unanticipated negative outcomes.

PFR.9.2 The disclosure process is documented in the patient's medical record.

PFR.10 Informed consent is obtained prior to high risk treatments/procedures.

PFR.10.1 The hospital has a policy and form(s) for obtaining the informed consent from the patient or a legal representative prior to starting high risk treatments and procedures.

PFR.10.2 The informed consent process includes explanation of the nature of the treatment or procedure, expected benefits and risks, alternative courses of action, and the likely consequences of not undergoing the treatment.

PFR.10.3 The informed consent is always obtained before any invasive surgery/ procedure, sedation/ anesthesia, and transfusion of blood and blood components.

PFR.10.4 The hospital identifies a list of high risk treatments and procedures that require informed consent including, but are not limited to, the following:

PFR.10.4.1 Endoscopy (e.g., colonoscopy, bronchoscopy, cystoscopy, J-tube placement, nephrostomy).

PFR.10.4.2 Biopsy (e.g., bone marrow, breast, liver, kidney, prostate).

PFR.10.4.3 CT examination with contrast.

PFR.10.4.4 MRI examination with or without contrast.

PFR.10.4.5 Invasive radiological procedures (e.g., angiography, angioplasty,drainage of an abscess under CT guidance).

PFR.10.4.6 Percutaneous aspiration of body fluids or air through the skin (e.g., arthrocentesis, bone marrow aspiration, lumbar puncture, chest tube, paracentesis).

PFR.10.4.7 Epidural injections and anesthesia.

PFR.10.4.8 Treatment with chemotherapy and radiation oncology procedures.

PFR.10.4.9 Use of radio-active material.

PFR.10.4.10 Central line placement.

PFR.10.5 When a patient is incapable of giving informed consent (e.g., minors or mentally incompetent patients), consent is sought from the patient's next of kin or guardian.

PFR.11 The hospital has a policy to deal with patients who refuse or discontinue the treatment.

PFR.11.1 There is a policy and procedure that addresses the patient's right to refuse or discontinue treatment offered.

PFR.11.2 The consequences of treatment refusal are explained to the patient.

PFR.11.3 Patients are informed about available care and treatment alternatives.

PFR.11.4 Whenever appropriate, family members are involved in the process.

PFR.11.5 Patient and family choices are respected.

PFR.11.6 The relevant discussion is documented in the patient's medical record.

PFR.12 The hospital has a policy regarding withholding resuscitation efforts.

PFR.12.1 There is a written (No Code) policy that is implemented and consistent with laws and regulations for withholding resuscitation efforts for the terminally ill or end of life patients.

PFR.12.2 Patient/family decision about the resuscitative order is documented in the patient's medical record.

PFR.13 The hospital informs patients about their responsibilities.

PFR.13.1 Patients are provided with appropriate information regarding their responsibilities.

PFR.13.2 Patient responsibilities require the patient to:

PFR.13.2.1 Provide complete and accurate information about his health, including medications, dietary supplements, and any allergies.

PFR.13.2.2 Follow the plan of care prescribed by his provider.

PFR.13.2.3 Be respectful to all staff as well as other patients.

PFR.13.2.4 Be respectful to the hospital policies and procedures (e.g., visiting hours, no smoking policy, use of electrical appliances, and safety of belongings).

PFR.13.2.5 Be responsible for the safe use of the hospital's facilities and equipment.

PFR.14 The hospital has an effective process to respond to patient complaints.

PFR.14.1 There is a policy and procedure for the fair management of patient complaints in a reasonable timeframe.

PFR.14.2 The hospital assigns a specific unit or person (e.g., patient relations) responsible for managing patients' complaints.

PFR.14.3 Hospital leaders ensure taking quality improvement and strategic actions based on trended data (e.g., quarterly and annually).

PFR.15 The hospital seeks feedback from patients regarding the services provided.

PFR.15.1 The hospital conducts patient satisfaction surveys on a regular basis.

PFR.15.2 The hospital makes improvements based on the patient satisfaction trended survey results.

PFR.16 The hospital has an effective system for clinical research activities.

PFR.16.1 The hospital implements policies, procedures, and code of ethics for the selection and participation of patients in research activities.

PFR.16.2 The policies and procedures that guide experimental research activities are in accordance with laws and regulations, professional standards, and codes of conduct.

PFR.16.3 The hospital has a research committee or another structure to oversee all research activities and ensure their appropriateness and safety.

PFR.16.4 Patient's informed consent is obtained before entering in a research protocol.

PFR.16.5 The hospital informs patients of their right to refuse participation in experimental research with no effect on access to care or the quality of care provided and respects their wishes.

PFR.16.6 The hospital implements the research outcomes to improve its services.

PFR.17 **Hospital leaders develop and adopt ethical standards in dealing with patients and their supporters and sponsors.**

PFR.17.1 Guidance is provided for clinical and non-clinical staff covering patient-care and non-patient care ethical issues.

PFR.17.2 The hospital accurately bills for services.

PFR.17.3 The hospital honestly portrays its services to patients.

PFR.17.4 The hospital maintains ethical marketing.

PFR.17.5 The hospital has a clear process to provide care for impoverished patients presenting with emergent situations.

PFR.17.6 Outcomes of ethical considerations are reviewed and system improvements are made accordingly.

PFR.18 **Hospital leaders ensure that patients, families, and staff members are informed about the choices and procedures of organ donations.**

PFR.18.1 The hospital makes patients or families aware of the options of organ donation.

PFR.18.2 The hospital assigns trained staff to inform patients and families about organ donation in a manner that is sensitive to their situation and respectful of their beliefs and wishes.

PFR.18.3 The hospital provides the family with all the necessary information about what can be donated, who can donate, how to donate, and the procedures involved in donation.

PFR.18.4 The hospital provides the family with all the necessary information about the official "Fatwa" regarding organ donation.

Anesthesia Care (AN)

Introduction

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

This chapter addresses the following processes:

- Anesthesia Staff and their qualifications
- Anesthesia equipment and supplies
- Pre-anesthesia assessment
- Monitoring of patients receiving anesthesia
- Conscious sedation
- Recovery room

STANDARDS

AN.1 Qualified anesthesiologist is responsible for managing anesthesia services in the hospital.

AN.1.1 The head of the department of anesthesia is a qualified anesthesiologist by education, training, and experience.

AN.1.2 The head of the department of anesthesia supervises the development and implementation of policies and procedures related to anesthesia practices throughout the hospital.

AN.1.3 The head of the department of anesthesia enforces the implementation of infection control guidelines inside the operating and recovery rooms.

AN.2 Anesthesia staff members have the appropriate qualifications.

ESR

AN.2.1 Qualified anesthesiologists provide anesthesia services.

AN.2.2 Qualified anesthesiologist is present inside the operating room throughout the operation.

AN.2.3 Anesthesia consultant administers and supervises anesthesia for major/specialized operations or high risk patients, including:

- AN.2.3.1 Pediatric operations.
- AN.2.3.2 Cardio-pulmonary operations.
- AN.2.3.3 Neurosurgery operations.
- AN.2.3.4 Transplant operations.

AN.2.4 Anesthesia staff are certified in advanced life support as appropriate to the patient's age.

AN.3 Policies and procedures guide the provision of anesthesia care.

AN.3.1 Policies and procedures include, but are not limited to, the following:

- AN.3.1.1 Staff responsibilities in the provision of anesthesia care.
- AN.3.1.2 Pre-anesthesia and pre-induction assessments.
- AN.3.1.3 Intra-operative monitoring of anesthetized patients.
- AN.3.1.4 Safe handling and storage of anesthetic medications/ agents.

AN.3.2 Policies are collaboratively developed with other relevant disciplines (e.g., surgery, nursing, and laboratory).

AN.4 The provision of anesthesia care is guided by the required equipment and anesthesia products.

AN.4.1 There is a multifunctional anesthesia machine and all other equipment required to meet the needs of patients, including equipment and tools required for difficult intubation.

AN.4.2 Anesthesia machines are regularly checked and maintained as evidenced by a readily accessible record of preventive maintenance.

AN.5 Sufficient information is communicated to the patient prior to administration of anesthesia to help making an informed decision.

AN.5.1 Informed consent for anesthesia is obtained from the patient/family after explaining the anesthesia plan, risks, benefits, and alternatives.

AN.5.2 The consent process is documented and witnessed.

AN.6 Pre-anesthesia assessment and anesthesia planning are conducted for each patient prior to any inpatient or outpatient surgery/procedure, by an individual qualified to administer anesthesia.

AN.6.1 The pre-anesthesia assessment should be completed and dated in less than thirty days prior to the scheduled surgery/procedure date. A review and update of the patient's current condition is documented in the medical record before conducting the procedure.

AN.6.2 The pre-anesthesia assessment includes:

- AN.6.2.1 Patient interview and physical examination, including airway assessment and limited intra-vascular access.
- AN.6.2.2 Medical history including anesthesia, drug and allergy history.
- AN.6.2.3 Other additional pre-anesthesia evaluation if applicable and as required in accordance with the standard practice prior to administering anesthesia (e.g., stress tests or additional specialist consultations).
- AN.6.2.4 Notation of anesthesia risk according to established standards of practice (ASA classification).
- AN.6.2.5 Anesthetic plan and discussion of the risks and benefits.
- AN.6.2.6 Documentation of an informed consent.
- AN.6.2.7 Appropriate pre-medication and prophylactic antibiotic orders (if indicated).

AN.6.3 The anesthesiologist reassesses the patient immediately prior to induction of anesthesia focusing on the physiologic stability and readiness of the patient for anesthesia. Findings are documented in the patient's medical record.

AN.7 There is an anesthesia record for documentation of planned anesthesia care.

AN.7.1 The planned anesthesia care is documented in anesthesia record for each patient during anesthesia. The following information must be documented:

- AN.7.1.1 Age, sex, weight, height, and pre-operative vital signs.
- AN.7.1.2 The anesthetic agent.
- AN.7.1.3 The dosage, time, and route of administration of all medications and anesthetic agents used.
- AN.7.1.4 The techniques used to administer the anesthesia.
- AN.7.1.5 If blood is used, the amount of blood, rationale for administration, and the time given.
- AN.7.1.6 Investigations carried out e.g. blood glucose, blood gases.
- AN.7.1.7 Unusual events or complications.
- AN.7.1.8 The patient's status at the end of the procedure.
- AN.7.1.9 Intravenous fluids given.
- AN.7.1.10 The anesthesiologist and anesthesia assistant(s).

AN.8 The patient's physiological status is continuously monitored and documented during anesthesia.

AN.8.1 There is a policy and procedure for monitoring of patients during anesthesia (type and frequency).

AN.8.2 The patient's physiological status is continuously monitored and documented during anesthesia.

AN.9 **Post-anesthesia patients are safely transported to the recovery room.**

AN.9.1 Patients transported to the recovery room shall be accompanied by a qualified member of the anesthesia care team.

AN.9.2 The patient shall be continually evaluated and treated during the transport with monitoring and support appropriate to the patient's condition.

AN.9.3 Upon arrival to the recovery room, the patient is properly handed over and re-evaluated.

AN.9.4 The patient's status and time of arrival to the recovery room are documented.

AN.10 **Qualified staff members provide post-anesthesia care in the recovery room.**

AN.10.1 Qualified anesthesiologist is in charge of the recovery room at all times.

AN.10.2 Qualified staff members provide post-anesthesia care in the recovery room.

AN.11 **Post-anesthesia patients are continuously monitored and managed in the recovery room.**

AN.11.1 A policy defines the monitoring requirements for patients during post-anesthesia phase.

AN.11.2 There is a recovery from anesthesia record for documentation of monitoring findings and services provided in the recovery room.

AN.12 **Patients are safely discharged from the recovery room.**

AN.12.1 There are written criteria for the discharge of patients from the recovery room.

AN.12.2 Staff in the recovery room are familiar with the discharge criteria.

AN.12.3 Patients are discharged from the recovery room when the discharge criteria are met.

AN.12.4 Patients are discharged from the recovery room by a qualified anesthesiologist or another qualified individual.

AN.12.5 Time of discharge from the recovery room and the handover process to unit staff are documented.

AN.13 **Moderate and deep sedation/analgesia are performed only in areas identified in a hospital policy.**

AN.13.1 The hospital identifies in a policy where moderate and deep sedation/analgesia are performed.

AN.13.2 The areas where moderate and deep sedation/analgesia are performed have adequate equipment and supplies that include at a minimum:

AN.13.2.1 Wall suction or suction machine.

AN.13.2.2 Oxygen source.

AN.13.2.3 Pulse oximetry.

AN.13.2.4 Automated blood pressure monitor or means of taking blood pressure.

AN.13.2.5 ECG Monitor.

AN.13.2.6 Crash cart with defibrillator, medications, IV access, and intubation equipment that is appropriate to the age of the patient.

AN.14 **There are policies and procedures for moderate and deep sedation/analgesia in the hospital.**

AN.14.1 Policies are collaboratively developed and approved by the head of anesthesia in collaboration with relevant disciplines.

AN.14.2 Policies for moderate and deep sedation/analgesia identify the permissible medications, dosage, route of administration, reversal agents and pediatric considerations.

AN.14.3 Moderate and deep sedation/analgesia is only used for patients having short diagnostic or therapeutic procedures.

AN.15 Qualified staff perform moderate and deep sedation/analgesia.

ESR

AN.15.1 Physicians who perform moderate and deep sedation/analgesia have competency-based privileges granted to perform moderate and deep sedation/analgesia.

AN.15.2 Clinical staff who participate in caring for patients receiving moderate or deep sedation are certified in advanced life support as appropriate to the age of the patients served.

AN.15.3 Clinical staff who participate in conducting sedation must successfully complete a proper education/training on moderate and deep sedation.

AN.16 Patients going for procedures under moderate or deep sedation are properly prepared.

AN.16.1 Informed consent is obtained after the physician educates the patient regarding the risk and benefits of the sedation and the consent is signed by the patient, guardian, or next of kin if the patient is unable to sign.

AN.16.2 An intravenous access is inserted and maintained until the patient is fully recovered.

AN.17 A pre-moderate and deep sedation/analgesia assessment is completed by a qualified physician.

AN.17.1 The pre-sedation assessment is performed by a qualified physician and includes:

AN.17.1.1 History and physical examination.

AN.17.1.2 History of medication allergy and adverse experience with sedation and analgesia as well as with anesthesia.

AN.17.1.3 History of systemic illness or major organ impairment.

AN.17.1.4 Verification of the patient (NPO) status.

AN.17.1.5 American Society of Anesthesiologists (ASA) physical status class.

AN.17.1.6 Vital signs.

AN.17.1.7 Age and weight.

AN.17.1.8 ECG findings.

AN.17.2 The pre-sedation assessment is documented in the patient's medical record.

AN.18 Patients are continuously monitored during and after moderate and deep sedation/analgesia.

AN.18.1 Patients are monitored during and after moderate and deep sedation/analgesia, including the following parameters:

AN.18.1.1 Vital signs.

AN.18.1.2 Oxygen saturation.

AN.18.1.3 Skin color.

AN.18.1.4 Level of consciousness/response to stimuli.

AN.18.1.5 ECG findings.

AN.18.2 Patient monitoring is continued during the recovery period until the patient is stable and adequate function is restored.

AN.18.3 Findings of monitoring are documented in the patient's medical record.

AN.18.4 The patient is always attended by a physician and nurse during and immediately after procedures involving moderate and deep sedation/analgesia.

AN.19 Patients who have received moderate or deep sedation are safely discharged.

AN.19.1 There are written criteria for the discharge of patients recovered from moderate or deep sedation.

AN.19.2 Patients are discharged when the criteria are met.

AN.19.3 When patients are transferred back to the unit:

AN.19.3.1 Patients are discharged to the unit by a qualified physician.

AN.19.3.2 The physician writes a follow up instructions for the nurses.

AN.19.4 When patients are directly discharged home:

AN.19.4.1 The physician writes a discharge order.

AN.19.4.2 Patients are discharged in the company of a responsible adult who assumes responsibility and is capable of taking care of the patient.

AN.19.4.3 Patient/family education and follow-up care instructions are provided prior to discharge.

Operating Room (OR)

Introduction

The quality and standard of surgical care in hospitals is an important issue. Despite the significant improvement of the surgical science and technology, the operating rooms continue to be a high risk and in many hospitals a high volume area where strict adherence to the standards of care is essential for better patients safety. Surgeries should be performed in a safe environment by qualified surgeons who have been granted privileges to perform specified surgeries and in accordance with the hospital's license and scope of services.

This chapter addresses the following:

- Staffing and qualifications of the operating room staff
- Requirements prior to surgery
- Documentation of the surgical procedures
- Day surgery
- Infection control in the operating room
- Post-operative care

STANDARDS

OR.1 Qualified individual directs the operating room.

OR.1.1 The operating room is directed by a qualified medical staff (e.g., surgical or anesthesia staff).

OR.2 Qualified nurse manager supervises nursing services in the operating room.

OR.2.1 The nurse manager in charge of the operating room is a qualified registered nurse with training, education, and experience in operative care.

OR.2.2 The nurse manager of the operating room develops and collaborates with other disciplines for developing all required and related policies and procedures.

OR.3 The nurse manager ensures the competency of the nursing staff.

OR.3.1 The nursing staff receive ongoing training on the following general and operating room- related needs:

- OR.3.1.1 Use of equipment.
- OR.3.1.2 Use of defibrillator.
- OR.3.1.3 Use of pulse oximetry.
- OR.3.1.4 Infection control.
- OR.3.1.5 Blood transfusion.
- OR.3.1.6 Central sterilization policy.
- OR.3.1.7 Maintenance of a sterile field.
- OR.3.1.8 Draping and gowning.
- OR.3.1.9 Surgical table operation and safe positioning of patients.
- OR.3.1.10 Assistance in operations of their specialty surgical area.
- OR.3.1.11 Pre and post-procedural handling and disposing of surgical equipment.
- OR.3.1.12 Safe operation of variable surgical equipment according to specialty.

OR.3.2 Nursing staff competencies are assessed by using different methods (e.g. written test, return demonstration).

OR.4 Patients who are admitted for surgery have medical assessment performed and plan of care documented prior to surgery.

OR.4.1 Prior to surgery, the most responsible physician performs medical assessment and ensures documentation of the following:

- OR.4.1.1 History and physical examination.
- OR.4.1.2 Pre-operative diagnosis.
- OR.4.1.3 Diagnostic tests (laboratory, radiology, etc.) as ordered.
- OR.4.1.4 Signed informed consent.
- OR.4.1.5 Planned procedure.

OR.4.2 In emergency situations where a complete medical assessment cannot be documented, a brief note is written by the most responsible physician.

OR.5 Policies and procedures guide the care of patients in the operating room.

OR.5.1 Policies and procedures guide the care of patients in the operating room. This includes, but is not limited to, the following:

OR.5.1.1 Handover process between unit nurse and operating room nurse and operating room reception.
OR.5.1.2 Prevention of wrong patient, wrong surgery/procedure, or wrong site.
OR.5.1.3 Infection control measures in operating room and recovery room including isolation precautions.
OR.5.1.4 Handling patients with infectious diseases (e.g. Tuberculosis, AIDS, and Hepatitis).
OR.5.1.5 Equipment daily checks and periodic maintenance.
OR.5.1.6 Environmental controls in operating room and recovery room.
OR.5.1.7 Safe labeling, handling, storage and transportation of laboratory specimens in operating and recovery rooms.
OR.5.1.8 Safe handling, storage and transportation of commonly used chemicals in operating and recovery rooms.
OR.5.1.9 Safe handling, transportation and storage of blood in operating and recovery rooms.

OR.5.2 Policies are collaboratively developed with operating room nurses, anesthesia staff, surgeons, and laboratory staff as per level of involvement.

OR.6 There is a policy for patient acceptance into the operating room.

OR.6.1 There is a policy for accepting patients in the operating room that mandates the following:
OR.6.1.1 Patient identification by name and medical record number as listed on the patient's ID band.
OR.6.1.2 The consent form is checked for completion.
OR.6.1.3 The operation/ procedure and the surgeon's name are checked.
OR.6.1.4 The site of surgery and its preparation and whether it is marked or not are checked.
OR.6.1.5 The laboratory and radiology results and pregnancy test as appropriate are checked.
OR.6.1.6 The pre-anesthesia sheet is checked for completion.
OR.6.1.7 The history and physical examination are checked for documentation.
OR.6.1.8 The requisition for blood is verified to ensure blood is reserved in the blood bank, if needed.

OR.6.2 The policy is collaboratively developed by the head of surgery, head of anesthesia, and the nurse manager.

OR.7 The hospital has a process to prevent inadvertent retention of instruments or sponges in surgical wounds.

OR.7.1 The hospital develops and implements a policy and procedure to prevent inadvertent retention of instruments or sponges in surgical wounds.
OR.7.2 The count process includes instruments, sharps, sponges, and others as applicable.
OR.7.3 The policy addresses procedures that are exempted from the counting process (e.g., cataract, cystoscopy).
OR.7.4 The count process is standardized.
OR.7.5 The policy addresses the procedure to follow in case of a count discrepancy.
OR.7.6 The count process is documented in the count sheet.

OR.8 The hospital develops and implements a policy for day surgery cases.

OR.8.1 The policy defines the types of surgical procedures that are performed as "day surgery".
OR.8.2 The policy addresses the categories of patients who are not candidates for day surgery.

OR.8.3 The policy defines a process for patients who have to be admitted to the hospital from the day surgery unit.

OR.8.4 The most responsible physician writes a discharge order.

OR.8.5 Patients are discharged in the company of a responsible adult who assumes responsibility and is capable of taking care of the patient.

OR.8.6 Patient/family education and follow-up care instructions are provided prior to discharge.

OR.9 An operative report is documented immediately after the surgery/procedure.

OR.9.1 There is always an operative report that includes:

- OR.9.1.1 Pre and post-operative diagnosis.
- OR.9.1.2 The name of the surgeon and assistants.
- OR.9.1.3 The operation/procedure performed.
- OR.9.1.4 Description of the surgery/procedure and findings.
- OR.9.1.5 Presence or absence of intra-operative complications.
- OR.9.1.6 Surgical specimens removed and sent to histopathology.
- OR.9.1.7 Amount of blood loss.

OR.9.2 The operative report is documented before the patient leaves the recovery room to support the continuity of patient care.

OR.9.3 The operative report is signed/authenticated by the surgeon performing the procedure.

OR.10 Tissues removed during surgery are sent for pathologic examination.

OR.10.1 Tissues or specimens removed during surgery have pathological examination unless exempted by a hospital policy.

OR.10.2 Surgical specimens are accurately identified.

OR.10.3 The report of the examination is signed by the pathologist and made part of the medical record.

OR.11 Each patient has a post-operative plan of care.

OR.11.1 A post-operative plan of care is written by the responsible surgeon.

OR.11.2 The post-operative plan of care includes:

- OR.11.2.1 Post-operative monitoring parameters and its frequency.
- OR.11.2.2 Wound care.
- OR.11.2.3 Care of drains and catheters.
- OR.11.2.4 Special patient positioning requirements.
- OR.11.2.5 Nutritional instructions.
- OR.11.2.6 When to start mobilization.
- OR.11.2.7 Special referrals (e.g. physical therapy, respiratory therapy)
- OR.11.2.8 A new order for all required medications.
- OR.11.2.9 Any other post-operative care needed including required follow up.

OR.11.3 The post-operative plan of care is available in the patient's medical record before discharge from recovery.

OR.11.4 Each patient is assessed after surgery and reassessed at intervals appropriate to the patient's condition.

OR.11.5 Medical, nursing, and other care plans are documented in the patient's medical record.

OR.12 Adequate pain relief is provided for patients after surgery.

OR.12.1 Pain is assessed by the most responsible physician or his designee after surgery.

OR.12.2 Pain medications are adjusted according to the patients' response.

OR.13 The hospital has appropriate measures against fires in the operating room.

OR.13.1 The operating room has a fire safety plan.

OR.13.2 The operating room staff are aware of the fire triangle: ignition sources, oxidizers, and fuels.

OR.13.3 The operating room staff are trained on the identification and location of medical gases, ventilation and electrical systems and controls, as well as when, where and how to shut off these systems.

OR.13.4 There are proper methods for rescue and escape.

OR.13.5 Staff participate in fire drills.

OR.13.6 There are fire-fighting equipment.

OR.13.7 Anesthesia staff determine the safe concentration of oxygen for open delivery during facial surgery.

OR.13.8 Patients are not draped until all flammable preps have dried.

OR.13.9 When performing electro-surgery, electro-cautery or laser surgery, electro-surgical instruments are placed in a holster or another location off the patient when not in active use and lasers are placed in standby when not in active use.

OR.14 Infection prevention and control standards are strictly implemented and supervised in the operating room.

OR.14.1 The operating room environment is maintained clean at all times.

OR.14.2 The use of storage cabinets in operating rooms is minimized.

OR.14.3 There is a policy for traffic control in the operating room.

OR.14.4 The operating room is maintained at positive pressure with respect to corridors.

OR.14.5 Records of pressure monitoring should be available in the operating rooms.

OR.14.6 More than (15) air changes per hour are maintained in the operating rooms.

OR.14.7 Air is introduced near the ceiling and exhausted near the floor.

OR.14.8 All re-circulated or fresh air should be filtered through High-Efficiency Particulate Air (HEPA) filters that are maintained and frequently replaced as per the manufacturer recommendation.

OR.14.9 Only operating room scrub clothing is allowed inside the restricted areas of the operating room.

OR.14.10 Scrubbing sinks are available at the entry of the operating room.

OR.14.11 Standard precautions are strictly implemented in the operating room with special emphasis on hand hygiene and the appropriate use of gloves, gowns, masks, and other barriers.

OR.14.12 There are clear procedures for cleansing and disinfecting operating rooms by housekeeping after surgical procedures.

OR.14.13 There are clear procedures for cleaning and disinfecting anesthesia machines after each case and toward the end of working hours by anesthesia technicians.

OR.14.14 The storage area of the operating room is well maintained with respect to the infection prevention and control standards.

OR.14.15 The waste management maintains safety of patients and healthcare workers.

OR.14.16 Patients with transmissible diseases are handled properly inside the operating rooms.

OR.14.16.1 Infected cases are scheduled towards the end of the operating list.

OR.14.16.2 There is an implemented policy to handle patients with air-borne transmitted disease inside the operating room.

OR.14.16.3 There is an implemented policy for contact and droplet transmission-based precaution in the recovery room.

Critical Care Services

Introduction

The standards in this chapter are designed to promote the provision of the highest quality of intensive care to critically ill patients. The intensive care unit must be capable of providing services unique to its setting such as mechanical ventilation and invasive cardiovascular monitoring. The standards in this chapter are intended to promote and improve the safe and effective practice of intensive care units including adult, pediatric, neonatal intensive care units as well as coronary care units.

This chapter addresses the following:

- Staff qualifications and plan
- Equipment and supplies
- Admission and discharge criteria
- Proper intensive care practices
- Discharge procedures

Adult Intensive Care Unit (ICU)

STANDARDS

ICU.1 Qualified physician is responsible for managing the adult intensive care unit.

ICU.1.1 The adult intensive care unit is directed by a physician qualified in critical care medicine by education, training, and experience.

ICU.1.2 The unit head takes the overall responsibility for the operation of the unit.

ICU.2 The adult intensive care unit nurse manager is a qualified registered nurse.

ICU.2.1 The nurse manager is a registered nurse qualified by education, training and, experience in managing critically-ill patients.

ICU.2.2 The nurse manager develops and collaborates with other departments as needed for developing policies and procedures for the unit (e.g., policies and practices related to infection control).

ICU.3 The adult intensive care unit is covered by qualified medical and nursing staff.

ICU.3.1 The intensive care unit is covered by physicians qualified in managing critically ill patients twenty four hours a day, seven days a week.

ICU.3.2 Medical staff working in the adult intensive care unit are certified in advanced cardiac life support (ACLS) and are trained on fundamental critical care support.

ICU.3.3 Nursing staff working in the adult intensive care unit are certified in advanced cardiac life support (ACLS).

ICU.4 The adult intensive care unit has admission and discharge criteria.

ICU.4.1 The adult intensive care unit identifies its own population based on age and diagnosis related groups.

ICU.4.2 The admission and discharge criteria are defined in writing.

ICU.4.3 The criteria for admission are based on physiological parameters.

ICU.4.4 The criteria are developed collaboratively between relevant staff.

ICU.4.5 In an open ICU setting, the Most Responsible Physician (MRP) is the admitting consultant whereas in a closed ICU setting, the MRP is a member of the medical staff in the ICU.

ICU.5 The adult intensive care unit has an effective handover process.

ICU.5.1 There is a documented evidence of handover between physicians at change of shift.

ICU.5.2 There is a documented evidence of handover between nurses at change of shift.

ICU.5.3 There is a documented evidence of handover between intensive care nurse and the unit/ward nurse at the time of transfer to a lower acuity of care.

ICU.6 **Patient care in the adult intensive care unit is provided using a multidisciplinary approach.**

ICU.6.1 The multidisciplinary team includes both ICU as well as non ICU members. This includes but is not limited to: ICU physician, ICU nurse, clinical pharmacist, respiratory therapist, dietitian, social worker, physiotherapist, and the consultant of the primary service under which the patient was first admitted.

ICU.6.2 Medically necessary services are readily available and accessible at all times.

ICU.6.3 Care is provided equally to all critical care patients whether inside the unit or those in other areas of the hospital (e.g., ventilated patients in emergency department).

ICU.6.4 Care is coordinated amongst the multidisciplinary team members and documented in the patient's medical record.

ICU.7 **The admission and discharge processes in the adult intensive care unit are coordinated.**

ICU.7.1 The ICU physician and the primary physician jointly make the decision to admit and discharge patients from the unit.

ICU.7.2 A summary of the intensive care stay is written by the ICU physician and made available at the time of discharge from intensive care to a lower acuity level.

ICU.7.3 There is a documented evidence of handover between the intensive care unit physician and the unit/ward physician at the time of transfer to a lower acuity of care.

ICU.7.4 When the patient is discharged from the unit, the intensive care unit physician ensures that the receiving team on the floor is well informed about the patient's status and ongoing patient needs.

ICU.7.4.1 The patient's plan of care and medications are written in detail by the physician including how to continue them in the floor.

ICU.7.4.2 Any special care requirements are documented (e.g., to watch for drainage tubes, tracheotomy care, and wound care) in the patient's medical record.

ICU.8 **Nursing staffing plans are available in the adult intensive care unit.**

ICU.8.1 The nursing staffing plans demonstrate an evidence based nursing to patient ratio.

ICU.8.2 The nursing staffing plans are matching the patient volume and patient acuity.

ICU.9 **Nursing staff in the adult intensive care unit receive continuous training with competency assessment.**

ICU.9.1 Nursing staff in the adult intensive care unit receive training and education on the following general and intensive care related needs:

ICU.9.1.1 Fundamental critical care support.

ICU.9.1.2 Infection control principles.

ICU.9.1.3 Blood transfusion.

ICU.9.1.4 Use of the defibrillator.

ICU.9.1.5 Care of patients with tracheostomies.

ICU.9.1.6 IV therapy.

ICU.9.1.7 Pressure ulcer prevention and care.

ICU.9.1.8 Knowledge of dosage range, side effects and complications of commonly used high alert medications in critical care including vasopressors, narcotics and controlled medications.

ICU.9.1.9 Recognizing critical ECG changes including arrhythmias.

ICU.9.1.10 Using pulse oximetry.

ICU.9.1.11 Assisting physician in placing central lines or arterial lines.

ICU.9.1.12 Assessing Glasgow Coma Scale (GCS).

ICU.9.1.13 Obtaining arterial blood gas samples.

ICU.9.1.14 Care of patients on ventilators.

ICU.9.1.15 Reading central venous pressure (CVP) and swan Ganz monitoring.

ICU.9.1.16 Care of endo-tracheal tube (ETT).

ICU.9.2 There is ongoing competency assessment for the nursing staff (e.g., written test, return demonstration).

ICU.9.3 The competency assessment of the nursing staff is documented.

ICU.10 The adult intensive care unit has adequate equipment and supplies.

ICU.10.1 There are isolation rooms with at least one negative pressure room.

ICU.10.2 The following equipment are available:

ICU.10.2.1 Ventilators.

ICU.10.2.2 Suction apparatus.

ICU.10.2.3 Airway sets.

ICU.10.2.4 Crash cart that includes defibrillator and all emergency supplies and medications.

ICU.10.2.5 ECG monitor, pulse oximetry and vital signs monitoring devices.

ICU.10.2.6 Automated blood pressure monitoring machine.

ICU.10.2.7 Intravenous infusion and blood transfusion pumps.

ICU.10.2.8 Portable monitoring equipment for patient transfer.

ICU.10.3 The availability and functionality of all tools and equipment are checked daily.

ICU.10.4 Equipment are cleaned and disinfected daily and as needed.

ICU.10.5 Laboratory and imaging services are available to meet the needs of patients receiving intensive care.

ICU.11 Policies and procedures are available to guide the work in the adult intensive care unit.

ICU.11.1 There are policies and procedures for medical and nursing initial assessment and re-assessment requirements, including time frames for completion of initial assessments and frequency of re-assessments.

ICU.11.2 There are policies and procedures for monitoring of patient circulation, respiration, and oxygenation.

ICU.11.3 There are evidence-based criteria for intubation, weaning off ventilator and extubation.

ICU.11.4 There are policies and procedures for handover procedure between staff in between shifts and at discharge to a lower acuity of care.

ICU.11.5 There are policies and procedures for infection control practices including isolation.

ICU.11.6 There are policies and procedures for dealing with ethical issues (e.g., No Code policy, end of life issues and organ donation).

ICU.11.7 Policies are collaboratively developed by the appropriate staff.

ICU.12 The adult intensive care unit has a process for detection and notification of potential deceased organ donors.

ICU.12.1 The intensive care unit establishes an effective communication and works collaboratively with the Saudi Center for Organ Transplantation (SCOT).

ICU.12.2 The intensive care unit uses criteria to identify, notify, document, and manage potential donors based on the registry of organ donation and transplantation in Saudi Arabia.

ICU.12.3 The intensive care unit reports all cases of potential deceased Donors after Brain Death (DBD) to SCOT on a timely manner.

ICU.12.4 The intensive care unit reports all cases of potential deceased Donors after Circulatory Death (DCD) to SCOT on a timely manner.

ICU.12.5 The hospital establishes and uses criteria that support the effectiveness of the donation process (e.g., patient factors, time since perfusion of the tissue stopped, maintenance of viability by appropriate care of the body between death and donation).

ICU.13 Infection control standards are strictly implemented and supervised in the adult intensive care unit.

ICU.13.1 The intensive care unit environment is maintained clean and neat at all times.

ICU.13.2 Infection control standards are strictly applied in the intensive care unit (e.g., hand hygiene and use of personal protective equipment).

ICU.13.3 Intensive care unit staff members adopt and implement care bundle for prevention of epidemiologically significant healthcare associated infections.

Pediatric Intensive Care Unit (PICU)

STANDARDS

PICU.1 **Qualified physician is responsible for managing the pediatric intensive care unit.**

PICU.1.1 The pediatric intensive care unit is directed by a physician qualified in pediatric critical care by education, training and, experience.

PICU.1.2 The unit head takes the overall responsibility for the operation of the unit.

PICU.2 **The pediatric intensive care unit nurse manager is a qualified registered nurse.**

PICU.2.1 The nurse manager is a registered nurse qualified by education, training, and experience in pediatric critical care.

PICU.2.2 The nurse manager develops and collaborates with other departments as needed for developing policies and procedures for the pediatric intensive care unit (e.g., policies and practices related to infection control).

PICU.3 **Medical and nursing staff working in the pediatric intensive care unit have appropriate cardiac life support training.**

PICU.3.1 Medical staff working in pediatric intensive care unit are certified in pediatric advanced life support (PALS).

PICU.3.2 Nursing staff working in pediatric intensive care unit are certified in pediatric advanced life support (PALS).

PICU.4 **The pediatric intensive care unit is covered by qualified physicians.**

PICU.4.1 The pediatric intensive care unit is covered twenty four hours a day, seven days a week by qualified pediatric intensive care physicians.

PICU.5 **The pediatric intensive care unit has admission and discharge criteria.**

PICU.5.1 The pediatric intensive care unit identifies its own population based on age, weight, and diagnosis related groups.

PICU.5.2 The admission and discharge criteria are defined in writing.

PICU.5.3 The criteria for admission are based on physiological parameters.

PICU.5.4 The criteria are developed collaboratively between relevant staff.

PICU.5.5 In an open pediatric intensive care unit, the Most Responsible Physician (MRP) is the admitting consultant whereas in a closed pediatric intensive care unit setting, the MRP is a member of the medical staff in the PICU.

PICU.6 **The pediatric intensive care unit has an effective handover process.**

PICU.6.1 There is a documented evidence of handover between physicians at change of shift.

PICU.6.2 There is a documented evidence of handover between nurses at change of shift.

PICU.6.3 There is a documented evidence of handover between pediatric intensive care nurse and the unit/ward nurse at the time of transfer to a lower acuity of care.

PICU.7 **Patient care in pediatric intensive care unit is provided using a multidisciplinary approach.**

PICU.7.1 The multidisciplinary team includes both Pediatric ICU as well as non-ICU members. This includes but is not limited to: Pediatric ICU physician, Pediatric ICU nurse, clinical pharmacist, respiratory therapist, dietitian, social worker, physiotherapist, and the consultant of the primary service under which the patient was first admitted.

PICU.7.2 Medically necessary services are readily available and accessible at all times.

PICU.7.3 Care is provided equally to all Pediatric ICU patients whether inside the unit or those in other areas of the hospital (e.g., ventilated patients in the emergency department).

PICU.7.4 Care is coordinated amongst the multidisciplinary team members and documented in the patient's medical record.

PICU.8 **The admission and discharge processes in the pediatric intensive care unit are coordinated.**

PICU.8.1 The PICU physician and the primary physician jointly make the decision to admit and discharge patients from the unit.

PICU.8.2 A summary of the intensive care stay is written by the pediatric ICU physician and made available at the time of discharge from pediatric intensive care to a lower acuity level.

PICU.8.3 There is a documented evidence of handover between the pediatric intensive care unit physician and the unit/ward physician at the time of transfer to a lower acuity of care.

PICU.8.4 When the patient is discharged from the PICU, the pediatric intensive care unit physician ensures that the receiving team on the floor is well informed about the patient's status and ongoing patient needs.

PICU.8.4.1 The patient's plan of care and medications are written in detail by the physician including how to continue them on the floor.

PICU.8.4.2 Any special care requirements are documented (e.g., to watch for drainage tubes, tracheostomy care, and wound care) in the patient's medical record.

PICU.9 **Nursing staffing plans are available in the pediatric intensive care unit.**

PICU.9.1 The nursing staffing plans demonstrate an evidence based nursing to patient ratio.

PICU.9.2 The nursing staffing plans are matching the patient volume and patient acuity.

PICU.10 **Nursing staff in the pediatric intensive care unit receive continuous training with competency assessment.**

PICU.10.1 Nursing staff in the pediatric intensive care unit receive training and education on the following general and intensive care related needs:

PICU.10.1.1 Pediatric fundamental critical care support.

PICU.10.1.2 Infection control principles.
PICU.10.1.3 Blood transfusion.
PICU.10.1.4 Use of the defibrillator.
PICU.10.1.5 Care of patients with tracheostomies.
PICU.10.1.6 Knowledge of dosage range, side effects and complications of commonly used high alert medications in pediatric critical care including vasopressors, narcotics, and controlled medications.
PICU.10.1.7 Recognizing critical ECG changes including arrhythmias.
PICU.10.1.8 Using pulse oximetry.
PICU.10.1.9 Assisting physician in placing central lines or arterial lines.
PICU.10.1.10 Assessing Glasgow Coma Scale (GCS).
PICU.10.1.11 Obtaining arterial blood gas samples.
PICU.10.1.12 Care of patients on ventilators.
PICU.10.1.13 Reading central venous pressure (CVP) and swan Ganz monitoring.
PICU.10.1.14 Care of endo-tracheal tube (ETT).
PICU.10.1.15 Pressure ulcer prevention and care
PICU.10.1.16 Guidelines for Monitoring & Management of IV Infiltration, Phlebitis & Extravasations
PICU.10.1.17 Pain assessment and management based on patient's age and condition (e.g., ventilated & non-ventilated patients).

PICU.10.2 There is ongoing competency assessment for the nursing staff (e.g., written test, return demonstration).
PICU.10.3 The competency assessment of the nursing staff is documented.

PICU.11 The pediatric intensive care unit has adequate equipment and supplies.

PICU.11.1 There are isolation rooms with at least one negative pressure room.
PICU.11.2 The following equipment are available:
PICU.11.2.1 Ventilators.
PICU.11.2.2 Suction apparatus.
PICU.11.2.3 Airway sets.
PICU.11.2.4 Crash cart that includes defibrillator and all emergency supplies and medications.
PICU.11.2.5 ECG monitor, pulse oximetry, and vital signs monitor.
PICU.11.2.6 Automated blood pressure monitoring machine.
PICU.11.2.7 Intravenous infusion and blood transfusion pumps.
PICU.11.2.8 Portable monitoring equipment for patient transfer.
PICU.11.3 The availability and functionality of all tools and equipment are checked daily.
PICU.11.4 Equipment are cleaned and disinfected daily and as needed.
PICU.11.5 Laboratory and imaging services are available to meet the needs of patients receiving pediatric intensive care.

PICU.12 Policies and procedures are available to guide the work in the pediatric intensive care unit.

PICU.12.1 There are policies and procedures for medical and nursing initial assessment and re-assessment requirements, including time frames for completion of initial assessments and frequency of re-assessments.

PICU.12.2 There are policies and procedures for monitoring of patient circulation, respiration, and oxygenation.

PICU.12.3 There are evidence-based criteria for intubation, weaning off ventilator and extubation.

PICU.12.4 There are policies and procedures for handover procedure between staff in between shifts and at discharge to a lower acuity of care.

PICU.12.5 There are policies and procedures for infection control practices including isolation.

PICU.12.6 There are policies and procedures for dealing with ethical issues (e.g., end of life issues and organ donation).

PICU.12.7 Policies are collaboratively developed by the appropriate staff.

PICU.13 The pediatric intensive care unit has a process for detection and notification of potential deceased organ donors.

PICU.13.1 The pediatric intensive care unit establishes an effective communication and works collaboratively with the Saudi Center for Organ Transplantation (SCOT).

PICU.13.2 The pediatric intensive care unit uses criteria to identify, notify, document, and manage potential donors based on the registry of organ donation and transplantation in Saudi Arabia.

PICU.13.3 The pediatric intensive care unit reports all cases of potential deceased Donors after Brain Death (DBD) to SCOT on a timely manner.

PICU.13.4 The pediatric intensive care unit reports all cases of potential deceased Donors after Circulatory Death (DCD) to SCOT on a timely manner.

PICU.13.5 The hospital establishes and uses criteria that support the effectiveness of the donation process (e.g., patient factors, time since perfusion of the tissue stopped, maintenance of viability by appropriate care of the body between death and donation).

PICU.14 Infection control standards are strictly implemented and supervised in the pediatric intensive care unit.

PICU.14.1 The pediatric intensive care unit environment is maintained clean and neat at all times.

PICU.14.2 Infection control standards are strictly applied in the pediatric intensive care unit (e.g., hand hygiene and use of personal protective equipment).

PICU.14.3 Pediatric intensive care unit staff members adopt and implement care bundle for prevention of epidemiologically significant healthcare associated infections.

Neonatal Intensive Care Unit (NICU)

STANDARDS

NICU.1 **Qualified physician is responsible for managing the neonatal intensive care unit.**

NICU.1.1 The department head is a qualified Pediatrician with experience in neonatology (for level 1 and 2 NICU) and certified neonatologist (for level3 NICU).

NICU.1.2 The department head takes the overall responsibility for the operation of the unit.

NICU.2 **The neonatal intensive care unit nurse manager is a qualified registered nurse.**

NICU.2.1 The nurse manager is qualified by education, training, and experience in neonatal intensive care.

NICU.2.2 The nurse manager develops and collaborates with NICU physicians and other departments as needed for developing policies and procedures for the unit (e.g., policies and practices related to infection control).

NICU.3 **Medical and nursing staff working in the neonatal intensive care unit have the appropriate cardiac life support training.**

NICU.3.1 Medical staff working in neonatal intensive care unit are certified in Neonatal Resuscitation Program (NRP).

NICU.3.2 Nursing staff working in the neonatal intensive care unit are certified in Neonatal Resuscitation Program (NRP).

NICU.4 **The neonatal intensive care unit is covered by qualified physicians.**

NICU.4.1 The neonatal intensive care unit is covered twenty four hours a day, seven days a week by qualified neonatal intensive care physicians.

NICU.4.2 For a Level 3 unit, there is certified neonatologist to cover the unit during the on call hours.

NICU.5 **The neonatal intensive care unit has admission and discharge criteria.**

NICU.5.1 The neonatal intensive care unit identifies its own population based on age and diagnosis related groups.

NICU.5.2 The admission and discharge criteria are defined in writing.

NICU.5.3 Criteria for admission are based on physiological parameters.

NICU.5.4 The criteria are developed collaboratively between relevant staff.

NICU.6 **Patient care in the neonatal intensive care unit is coordinated.**

NICU.6.1 There is a documented evidence of handover between physicians at change of shift.

NICU.6.2 There is a documented evidence of handover between nurses at change of shift.

NICU.6.3 There is a documented evidence of handover between neonatal intensive care nurse and unit nurse at the time of transfer to a lower acuity of care.

NICU.7 Patient care in the neonatal intensive care unit is provided using a multidisciplinary approach.

NICU.7.1 The multidisciplinary team includes both NICU as well as non NICU members. This includes but not is limited to: NICU physician, NICU nurse, clinical pharmacist, respiratory therapist, and dietitian.

NICU.7.2 Medically necessary services are readily available and accessible at all times.

NICU.7.3 Care is coordinated amongst the multidisciplinary team members and documented in the patient's medical record.

NICU.8 The admission and discharge processes in the neonatal intensive care unit are coordinated.

NICU.8.1 A summary of the neonatal intensive care stay is written by the NICU physician and made available at the time of discharge from critical care to a lower acuity level.

NICU.8.2 There is documented evidence of handover between the neonatal intensive care physician and the unit physician at the time of transfer to a lower acuity of care.

NICU.8.3 When the patient is discharged from the unit, the neonatal intensive care unit physician ensures that the receiving team is well informed about the patient's status and ongoing patient needs.

NICU.8.3.1 The patient's plan of care and medications are written in detail by the physician including how to continue them on the floor.

NICU.8.3.2 Any special care requirements are documented in the medical record.

NICU.9 Nursing staffing plans are available in the neonatal intensive care unit.

NICU.9.1 The nursing staffing plans demonstrate an evidence based nursing to patient ratio.

NICU.9.2 The nursing staffing plans are matching the patient volume and patient acuity.

NICU.10 Nursing staff in the neonatal intensive care unit receive continuous training with competency assessment.

NICU.10.1 Nursing staff in the NICU intensive care unit receive training and education on the following general and NICU intensive care related needs:

NICU.10.1.1 Assisting physicians in the different procedures performed in the neonatal intensive care unit including securing central lines access.

NICU.10.1.2 Using pulse oximetry.

NICU.10.1.3 Recognizing critical ECG changes including arrhythmias.

NICU.10.1.4 Assisting physician in placing central lines or arterial lines and /or umbilical arterial/venous lines.

NICU.10.1.5 Obtaining arterial blood gas samples and blood drawing from umbilical catheters.

NICU.10.1.6 Knowledge of dosage range, side effects and complications of commonly used medications such as surfactant and high alert medications used in neonatal care including vasopressors, narcotics, and controlled medications.

NICU.10.1.7 Infection control principles.

NICU.10.1.8 Blood transfusion and exchange transfusion.

NICU.10.1.9 Sarnat and Thompson Scoring.

NICU.10.1.10 Use of the defibrillator.

NICU.10.1.11 Care of patients on ventilators.
NICU.10.1.12 Care of endo-tracheal tube (ETT).
NICU.10.1.13 Care of patients with tracheostomies.
NICU.10.1.14 Care of the terminally ill and end of life patients.
NICU.10.1.15 Care of patient in incubator.
NICU.10.2 There is ongoing competency assessment for the nursing staff (e.g., written test, return demonstration).
NICU.10.3 The competency assessment of the nursing staff is documented.

NICU.11 The neonatal intensive care unit has adequate equipment, supplies, and diagnostic services.

NICU.11.1 There are isolation rooms with at least one negative pressure room.
NICU.11.2 The following equipment are available:
NICU.11.2.1 Ventilators.
NICU.11.2.2 Suction apparatus.
NICU.11.2.3 Airway sets.
NICU.11.2.4 Crash cart that includes defibrillator, all emergency supplies, and medications as appropriate to neonates.
NICU.11.2.5 Infant resuscitator.
NICU.11.2.6 Incubators.
NICU.11.2.7 Portable incubator with portable ventilator.
NICU.11.2.8 ECG monitor, pulse oximetry, and vital signs monitor.
NICU.11.2.9 Automated blood pressure monitoring machine.
NICU.11.2.10 Intravenous infusion and blood transfusion pumps.
NICU.11.3 The availability and functionality of all tools and equipment are checked daily.
NICU.11.4 Equipment are cleaned and disinfected daily and as needed.
NICU.11.5 Portable equipment for safe patient transports are available.
NICU.11.6 Laboratory and imaging services are available to meet the needs of patients receiving neonatal intensive care.

NICU.12 Policies and procedures are available to guide the work in the neonatal intensive care unit.

NICU.12.1 There are policies and procedures for medical and nursing initial assessment and re-assessment requirements, including time frames for completion of initial assessments and frequency of re-assessments.
NICU.12.2 There are policies and procedures for monitoring of patient circulation, respiration, and oxygenation.
NICU.12.3 There are evidence-based criteria for intubation, weaning off ventilator and extubation.
NICU.12.4 There are policies and procedures for handover procedure between staff in between shifts and at discharge to a lower acuity of care.
NICU.12.5 There are policies and procedures for infection control practices including isolation.

NICU.12.6 There are policies and procedures for the use of neonatal Total Parenteral Nutrition (TPN) for more sick patients.

NICU.12.7 There are policies and procedures for dealing with ethical issues (e.g., No Code policy, end of life issues, and organ donation).

NICU.12.8 Policies are collaboratively developed by the appropriate staff.

NICU.13 Infection control standards are strictly implemented and supervised in the neonatal intensive care unit.

NICU.13.1 The neonatal intensive care unit environment is maintained clean and neat at all times.

NICU.13.2 Infection control standards are strictly applied in the neonatal intensive care unit (e.g., hand hygiene and use of personal protective equipment).

NICU.13.3 Neonatal intensive care unit staff members adopt and implement care bundle for prevention of epidemiologically significant healthcare associated infections.

Coronary Care Unit (CCU)

STANDARDS

CCU.1 **Qualified physician is responsible for managing the coronary care unit.**

CCU.1.1 The department head is a physician qualified by appropriate education, training, and experience in managing intensive cardiac care patients/units.

CCU.1.2 The department head takes overall responsibility for the operation of the unit.

CCU.2 **The coronary care unit nurse manager is a qualified registered nurse.**

CCU.2.1 The nurse manager is qualified by education, training, and experience in coronary care units.

CCU.2.2 The nurse manager develops policies and procedures for the unit and collaborates with other departments as needed (e.g., policies and practices related to infection control).

CCU.3 **Medical and nursing staff working in the coronary care unit have appropriate cardiac life support training.**

CCU.3.1 Medical staff working in coronary care unit are ACLS-certified.

CCU.3.2 Nursing staff working in the coronary care unit are ACLS-certified.

CCU.4 **The coronary care unit is covered by qualified physicians.**

CCU.4.1 The coronary care unit is covered twenty four hours a day, seven days a week by physicians qualified in managing cardiac patients requiring intensive care.

CCU.5 **The coronary care unit has admission and discharge criteria.**

CCU.5.1 The coronary care unit identifies its own population based on age and diagnosis related groups.

CCU.5.2 The admission and discharge criteria are defined in writing.

CCU.5.3 Criteria for admission are based on physiological parameters.

CCU.5.4 The criteria are developed collaboratively between relevant staff.

CCU.5.5 In an open CCU setting, the Most Responsible Physician (MRP) is the admitting consultant, whereas in a closed CCU setting the MRP is the CCU physician/intensivist.

CCU.6 **The coronary care unit has an effective handover process.**

CCU.6.1 There is a documented evidence of handover between physicians at change of shift.

CCU.6.2 There is a documented evidence of handover between nurses at change of shift.

CCU.6.3 There is a documented evidence of handover between the CCU nurse and the unit nurse at the time of transfer to a lower acuity of care.

CCU.7 Patient care in coronary care unit is provided using a multidisciplinary approach.

CCU.7.1 There is a multidisciplinary team that includes both CCU as well as non CCU members (CCU physician, CCU nurse, clinical pharmacist, respiratory therapist, dietitian, social worker, physiotherapist, and the consultant of the primary service under which the patient was first admitted).

CCU.7.2 Medically necessary services are readily available and accessible at all times.

CCU.7.3 Care is provided equally to all CCU patients whether inside the unit or those in other areas of the hospital (e.g., ventilated patients in emergency department).

CCU.7.4 Care is coordinated amongst the multidisciplinary team members and documented in the patient's medical record.

CCU.8 The admission and discharge processes in the coronary care unit are coordinated.

CCU.8.1 The physician in charge of the coronary care unit together with the most responsible physician jointly make the decision to admit and discharge patients from the unit.

CCU.8.2 A summary of the coronary care stay is written by the physician and made available at the time of discharge from critical care to a lower acuity level.

CCU.8.3 There is a documented evidence of handover between the coronary care physician and the unit physician at the time of transfer to a lower acuity of care.

CCU.8.4 When the patient is discharged from the unit, the coronary care unit physician ensures that the receiving team on the floor is well informed about the patient's status and ongoing patient needs.

CCU.8.4.1 The patient's plan of care and medications are written in detail by the physician including how to continue them on the floor.

CCU.8.4.2 Any special care requirements are documented in the patient's medical record.

CCU.9 Nursing staffing plans are available in the coronary care unit.

CCU.9.1 The nursing staffing plans demonstrate an evidence based nursing to patient ratio.

CCU.9.2 The nursing staffing plans are matching the patient volume and patient acuity.

CCU.10 Nursing staff in the coronary care unit receive continuous training with competency assessment.

CCU.10.1 Nursing staff in the coronary care unit receive training and education on the following general and intensive care related needs:

CCU.10.1.1 Assisting physicians in the different procedures performed in the coronary care unit including securing central line access.

CCU.10.1.2 Using pulse oximetry.

CCU.10.1.3 Recognizing critical ECG changes including arrhythmias.

CCU.10.1.4 Obtaining arterial blood gas samples and blood drawing from umbilical catheters.

CCU.10.1.5 Reading central venous pressure (CVP) and swan Ganz monitoring.

CCU.10.1.6 Knowledge of dosage range, side effects and complications of commonly used medications such as high alert medications used in coronary care including vasopressors, narcotics, and controlled medications.

CCU.10.1.7 Infection control principles.
CCU.10.1.8 Blood transfusions.
CCU.10.1.9 Assessing Glasgow Coma Scale (GSC).
CCU.10.1.10 Use of defibrillator.
CCU.10.1.11 Care of patients on ventilators.
CCU.10.1.12 Care of Endo-tracheal tube (ETT).
CCU.10.1.13 Care of patients with tracheostomies.
CCU.10.1.14 Care of the terminally ill and end of life patients.

CCU.10.2 There is ongoing competency assessment for the nursing staff (e.g., written test, return demonstration).

CCU.10.3 The competency assessment of the nursing staff is documented.

CCU.11 The coronary care unit has adequate equipment, supplies, and diagnostic services.

CCU.11.1 There are isolation rooms with at least one negative pressure room.

CCU.11.2 The following equipment are available:

CCU.11.2.1 Ventilators.
CCU.11.2.2 Suction apparatus.
CCU.11.2.3 Airway sets.
CCU.11.2.4 Crash cart that includes defibrillator, all emergency supplies and medications as appropriate to the age of the patients.
CCU.11.2.5 ECG monitor, pulse oximetry, and vital signs monitor.
CCU.11.2.6 Automated blood pressure monitoring machine.
CCU.11.2.7 Intravenous infusion and blood transfusion pumps.
CCU.11.2.8 At least one invasive monitor.

CCU.11.3 The availability and functionality of all tools and equipment are checked daily.

CCU.11.4 Equipment are cleaned and disinfected daily and as needed.

CCU.11.5 Portable equipment for safe patient transports are available.

CCU.11.6 Laboratory and imaging services are available to meet the needs of patients in coronary care unit.

CCU.12 Policies and procedures are available to guide the work in the coronary care unit.

CCU.12.1 There are policies and procedures for medical and nursing initial assessment and re-assessment requirements, including time frames for completion of initial assessments and frequency of re-assessments.

CCU.12.2 There are policies and procedures for monitoring of patient circulation, respiration, and oxygenation.

CCU.12.3 There are evidence-based criteria for intubation, weaning off ventilator and extubation.

CCU.12.4 There are policies and procedures for handover procedure between staff in between shifts and at discharge to a lower acuity of care.

CCU.12.5 There are policies and procedures for common and high risk procedures that include, but are not limited to, the following:

CCU.12.5.1 Coronary Angiogram.

CCU.12.5.2 Temporary pace maker.

CCU.12.5.3 Permanent pace maker.

CCU.12.5.4 Moderate or deep sedation.

CCU.12.6 There are policies and procedures for infection control practices including isolation.

CCU.12.7 Policies are collaboratively developed by the appropriate staff.

CCU.13 The coronary care unit has a process for detection and notification of potential deceased organ donors.

CCU.13.1 The CCU establishes an effective communication and works collaboratively with the Saudi Center for Organ Transplantation (SCOT).

CCU.13.2 The CCU uses criteria to identify potential donors based on Saudi Center for Organ Transplantation (SCOT) guidelines.

CCU.13.3 The CCU reports all cases of potential Donation after Circulatory Death (DCD) to SCOT in appropriate time.

CCU.13.4 The CCU reports all cases of potential Donation after Brain Death (DBD) to SCOT in appropriate time.

CCU.13.5 The hospital establishes and uses criteria that support the effectiveness of the donation process (e.g., patient factors, time since perfusion of the tissue stopped, maintenance of viability by appropriate care of the body between death and donation).

CCU.14 Infection control standards are strictly implemented and supervised in the coronary care unit.

CCU.14.1 The coronary care unit environment is maintained clean and neat at all times.

CCU.14.2 Infection control standards are strictly applied in the coronary care unit (e.g., hand hygiene and using of personal protective equipment).

CCU.14.3 Coronary care unit staff members adopt and implement care bundle for prevention of epidemiologically significant healthcare associated infections.

Labor and Delivery (L&D)

Introduction

Most women have normal conception, fetal growth, labor, and birth and require minimal-to-no intervention in the process. Despite this fact, there is a considerable number of pregnant women who present to the hospital seeking help for different reasons, particularly upon the end of their pregnancies. Even in the most developed healthcare systems, labor rooms are considered high risk areas where significant morbidities and mortalities occur for various causes, most of which are preventable if the quality and safety standards were adhered to. In this modern era of medicine, deliveries should be conducted in a safe environment by qualified physicians, nurses and midwives who have been granted privileges to provide such services in accordance with the organization's license and scope of services.

This chapter addresses the following:

- Staff qualifications and plan
- Policies and procedures
- High risk patients
- Equipment and supplies
- Midwifery and nursing services
- Admission and discharge criteria
- Medical records in obstetrics department

STANDARDS

L&D.1 Qualified physician is responsible for managing the obstetrics department.

L&D.1.1 The head of the obstetrics department is an obstetrician qualified by education, training, and experience.

L&D.1.2 The head of the obstetrics department supervises the development and implementation of policies and procedures related to gynecology and obstetrics practices.

L&D.1.3 The head of the obstetrics department enforces the implementation of infection control guidelines inside the operating and recovery rooms.

L&D.2 The obstetrics department has adequate medical coverage by qualified medical staff.

L&D.2.1 A qualified obstetrician is physically present in the delivery room twenty four hours a day, seven days a week.

L&D.2.2 Obstetricians are certified in advanced life support in obstetrics (ALSO) or at least one certified obstetrician is assigned on every shift.

L&D.2.3 A qualified pediatrician/neonatologist attends all caesarean section deliveries.

L&D.2.4 Pediatricians' rosters identify the physician to be called in emergencies.

L&D.2.5 Pediatricians are certified in neonatal resuscitation program (NRP).

L&D.3 Qualified nurse manager supervises midwifery and nursing services in the obstetrics department.

L&D.3.1 The nurse manager in charge of the obstetrics department is a qualified registered nurse with education, training and experience in obstetrics.

L&D.3.2 The nurse manager ensures the competency of the midwives and nursing staff.

L&D.4 The obstetrics department has adequate coverage by qualified midwifery and nursing staff.

L&D.4.1 Nursing staffing plan is based on patient volume and patient acuity and ensures adequate coverage twenty four hours a day, seven days a week.

L&D.4.2 Nurses working in the obstetrics department have adequate experience in obstetrics.

L&D.4.3 Nurses working in the obstetrics department are certified in neonatal resuscitation program or at least one certified nurse is assigned on every shift.

L&D.4.4 Midwives are registered and are qualified by education, training, and experience in labor and delivery.

L&D.5 The obstetrics department has admission and discharge criteria.

L&D.5.1 The obstetrics department implements specific criteria for admission and discharge.

L&D.5.2 The criteria are collaboratively developed by obstetricians and other relevant departments.

L&D.5.3 The criteria are based on the gestational age of mothers, department's design, and available resources.

L&D.6 Policies and procedures guide the care of women in labor.

L&D.6.1 There are policies and procedures to guide the care of women in labor including, but are not limited to, the following:

- L&D.6.1.1 Assessment and re-assessment of women in labor, including immediate postpartum care and criteria for discharge from delivery room.
- L&D.6.1.2 Management of Ante-partum and post-partum hemorrhage.
- L&D.6.1.3 Augmentation of labor and the use of oxytocin.
- L&D.6.1.4 Use of partogram for woman in labor.
- L&D.6.1.5 Caesarian section, repeated caesarian section, and emergency hysterectomy.
- L&D.6.1.6 Management of fetal distress.
- L&D.6.1.7 The use of sedation.
- L&D.6.1.8 The use of cardio-tocography.
- L&D.6.1.9 The use of episiotomy.
- L&D.6.1.10 Induction of labor.
- L&D.6.1.11 Pain relief and regional anesthesia.
- L&D.6.1.12 Management of hypertensive disorders of pregnancy.
- L&D.6.1.13 Management of the diabetic patient in labor and postpartum.
- L&D.6.1.14 Suppression of pre-term labor.
- L&D.6.1.15 Management of multiple births.
- L&D.6.1.16 Management of abnormal positions and presentations.
- L&D.6.1.17 Instrumental vaginal delivery.
- L&D.6.1.18 Management of premature rupture of membranes.
- L&D.6.1.19 Management of un-booked deliveries.
- L&D.6.1.20 Neonatal identification and the immediate assessment and resuscitation of the new born.
- L&D.6.1.21 Infection control measures in labor and postpartum.
- L&D.6.1.22 Breast feeding.

L&D.6.2 The policies and procedures are collaboratively developed by obstetricians, pediatricians, anesthesiologists, delivery room nurses and midwives, and other staff as needed.

L&D.7 The obstetrics department has adequate resources that support the provision of safe care.

L&D.7.1 The obstetrics department has equipment, medications, and tools that meet the needs of patients, including:

- L&D.7.1.1 Cardio-tocography machines (at least one capable of simultaneous recording of twin fetal hearts).
- L&D.7.1.2 Automated blood pressure monitoring machines.
- L&D.7.1.3 Pulse oximetry.
- L&D.7.1.4 Appropriate delivery bed.
- L&D.7.1.5 Intravenous infusion pumps.
- L&D.7.1.6 Adequate light source appropriate for surgical care.
- L&D.7.1.7 Specific obstetric instruments such as amnihooks, vacuum extractor and obstetric forceps.

L&D.7.1.8 Infant resuscitation equipment and supplies.

L&D.7.1.9 Emergency obstetric medications (e.g., oxytocics).

L&D.8 Newborns receive the proper care by qualified nurses.

L&D.8.1 There is a qualified and competent nurse to receive the newborn during delivery.

L&D.8.2 The attending nurse is qualified to perform the following for each newborn:

L&D.8.2.1 Suction.

L&D.8.2.2 Placing an identity band with the medical record number and other identifier(s) according to the hospital policy.

L&D.8.2.3 Finding and documenting the APGAR score.

L&D.8.2.4 Obtaining the footprint of the newborn and the thumbprint of the mother.

L&D.9 The medical records of the obstetrics department are properly completed.

L&D.9.1 The following information must be available in patients' records before discharge from the delivery room:

L&D.9.1.1 Completed assessment and reassessment.

L&D.9.1.2 Completed partogram.

L&D.9.1.3 Secured cardio-tocography.

L&D.9.1.4 Initial neonatal assessment.

L&D.9.1.5 Delivery summary including method of delivery, date and time of delivery, name and designation of the healthcare professional who conducted the delivery and any assistants, type of anesthesia or sedation used during delivery, neonatal outcome, status of placenta and membranes, any postpartum instructions, and postpartum observations and discharge criteria.

Hemodialysis (HM)

Introduction

The standards in this chapter focus on a hospital-based dialysis unit. Physicians and allied health professionals are expected to understand and participate in the assessment and improvement of the quality of care delivered to patients in end-stage renal disease (ESRD) treatment centers and units. The dialysis unit must meet specified safety and quality standards as defined in this chapter in order to ensure safe care to patients already presenting with immune-compromised state.

This chapter addresses the following:

- Staff qualifications
- Policies and procedures to follow in the dialysis unit
- Plan of care for patients on dialysis
- Water management
- Infection control
- Nursing competencies
- Equipment and machines

STANDARDS

HM.1 Qualified nephrologist is responsible for managing the clinical services in the hemodialysis unit.

HM.1.1 Clinical services in the hemodialysis unit are led by a qualified nephrologist with experience in managing end stage renal disease (ESRD) patients.

HM.2 Qualified nurse is responsible for supervising nursing services in the hemodialysis unit.

HM.2.1 The nurse in charge of the hemodialysis unit is a qualified registered nurse with training, education or experience in hemodialysis.

HM.2.2 Nursing staff members are registered nurses qualified to care for ESRD patients by education, training or experience.

HM.3 Each patient's hemodialysis care is planned and documented in the patient's medical record.

HM.3.1 Hemodialysis procedures are ordered by a qualified nephrologist.

HM.3.2 Comprehensive assessment and reassessment is performed for each patient in the hemodialysis unit.

HM.3.3 The need for dialysis and choice of modality are based on sound clinical principles and a thorough clinical evaluation of the clinical condition and any associated co-morbidities.

HM.3.4 Informed consent is obtained for all dialysis patients after providing adequate information about the different modalities and the modality that is most appropriate for the patient's needs. The consent is updated regularly (e.g., yearly) and when the risk level is changing.

HM.3.5 Multi-disciplinary plan of care is developed for each patient in coordination with other relevant health professionals (e.g., physician, nurse, dietitian, pharmacist, and social worker).

HM.3.6 There is an appropriate multi-disciplinary patient education plan.

HM.3.7 Patients are properly monitored during and after dialysis.

HM.3.8 Plan of care is documented in the patient's medical record.

HM.3.9 Emergency medical care is available when needed.

HM.3.10 Clinical staff who participate in caring for patients on dialysis are certified in advanced life support as appropriate to the different age groups of patients, or at least one certified individual is assigned on every shift.

HM.4 The hemodialysis unit has admission and discharge criteria.

HM.4.1 The hemodialysis unit has admission and discharge criteria consistent with evidence-based practice.

HM.4.2 The criteria are collaboratively developed by nephrologists, nursing staff and other relevant departments.

HM.5 Policies and procedures guide the care of patients requiring hemodialysis.

HM.5.1 Care of patients in hemodialysis unit is guided by policies and procedures that include, but are not limited to, the following:

HM.5.1.1 Assessment and reassessment of patients.

HM.5.1.2 Assessment of volume status.
HM.5.1.3 Care and monitoring of patients with arterio-venous fistula/graft.
HM.5.1.4 Care and monitoring of tunneled/non-tunneled catheters.
HM.5.1.5 Management of clotted access.
HM.5.1.6 Preparation of hemodialysis machines.
HM.5.1.7 Dialysis procedures.
HM.5.1.8 Peritoneal dialysis.
HM.5.1.9 Anticoagulation.
HM.5.1.10 Management of electrolytes imbalance.
HM.5.1.11 Management of dialysis-induced complications.
HM.5.1.12 Management of cardiopulmonary collapse and urgent medical conditions.
HM.5.1.13 Emergency transfer of patients.

HM.5.2 Policies and procedures are implemented as evidenced in the daily practice and the patient's medical record.

HM.6 Equipment and machines in the hemodialysis unit are in good working conditions.

HM.6.1 All equipment and machines are operated within manufacturer's specifications.
HM.6.2 The preventive maintenance program -for equipment related to patient care- is developed and implemented in accordance with manufacturer's instructions.
HM.6.3 The preventive maintenance program is performed by qualified staff/entities.
HM.6.4 All records for maintenance and repair are kept on file for future reference and inspection.
HM.6.5 Staff are oriented to equipment in use.
HM.6.6 Staff are trained to identify malfunctioning equipment or machines and to report to appropriate staff for repair.
HM.6.7 Each dialysis machine is equipped with monitors and an alarm system.
HM.6.8 The preventive maintenance program includes the water treatment and distribution system.

HM.7 Infection control guidelines specific to the dialysis services are developed and implemented.

HM.7.1 Infection control guidelines are developed or adopted from authoritative sources or relevant professional organizations.

HM.7.2 Infection control guidelines include, but are not limited to, the following:

HM.7.2.1 Adequate space (1.2 -1.5 meters) between patients to prevent transmission of infection.
HM.7.2.2 Separation between patient care (contaminated) and office/supply areas (clean).
HM.7.2.3 Standard precautions are strictly implemented in the unit with special emphasis on hand hygiene and the appropriate use of gloves, gowns, masks, and other barriers.
HM.7.2.4 Adequate supply of personal protective equipment is available and readily accessible.
HM.7.2.5 Hand disinfectants for waterless hand hygiene should be available at every chair/bed. Hands are washed before and after contact with each patient.
HM.7.2.6 Sinks are available in adequate number (preferably one for every 2-4 chair/beds) and are conveniently located.

HM.7.2.7 Staff members have the required knowledge for safe practices to avoid cross contamination.

HM.7.2.8 Sharp disposal containers are available at each chair/bed and elsewhere as needed within the unit. Needles and sharps are disposed appropriately.

HM.7.2.9 Infectious wastes are disposed in accordance with hospital's waste disposal policies.

HM.7.2.10 Surfaces of machines including the control panels, blood pressure cuffs and chairs/beds are disinfected after use with an approved disinfectant.

HM.7.2.11 Blood spills are cleaned properly.

HM.7.2.12 Equipment such as blood pressure cuffs, stethoscopes, clamps, scissors and thermometers are allocated to a single patient and are disinfected at the conclusion of each patient treatment session.

HM.7.2.13 Supplies and equipment are properly handled in a way that prevents contamination.

HM.7.2.14 A process is in place to ensure multi-dose vials are adequately labeled and used for single patient only.

HM.7.2.15 A process is in place for infection control procedures for dialysis machines between patients.

HM.7.2.16 A process is in place for appropriate cleaning and disinfection of the water treatment and distribution system.

HM.8 Patients and staff are protected from blood borne pathogens during hemodialysis.

HM.8.1 All patients are screened for Hepatitis B, Hepatitis C and HIV at the beginning of dialysis.

HM.8.2 Patient whose laboratory tests for HBsAg, anti HBs, HCV, or HIV are negative should be re-screened every 3-6 months.

HM.8.3 Patients susceptible to hepatitis B are immunized with Hepatitis B vaccine.

HM.8.4 Machines used for blood-borne infectious diseases (such as hepatitis and HIV/AIDS patients) are separated. Patients infected with Hepatitis B are strictly segregated in a separate room and treated on a separate machine used exclusively for Hepatitis B.

HM.8.5 Staff and employees have checkups for Hepatitis B, Hepatitis C, and HIV upon hiring and annually.

HM.8.6 Staff and employees susceptible to Hepatitis B are immunized with Hepatitis B vaccine and tested for antibodies to evaluate response, and all non-responders are given a second series of the HBV vaccine.

HM.8.7 Records for staff screening and hepatitis immunization are available and maintained for future reference.

HM.9 Water quality is checked on a periodic basis.

HM.9.1 There is a written policy defining the periodic checking of water quality.

HM.9.2 The policy is based upon manufacturer's recommendations, regulations, and local experience.

HM.9.3 Hardness and chlorine content of feeding water are monitored on a regular basis by designated staff or authorities.

HM.9.4 Microbiologic monitoring of treated water and dialysate should be performed at least monthly and more frequently if a problem is identified.

HM.9.5 Bacteriology testing of Reverse Osmosis (RO) water as well as endotoxin assay should be performed and documented at least once per month.

HM.9.6 Chemical testing of water is performed at least once per year.

HM.9.7 Reverse Osmosis (RO) system including the feeding pipelines into the hospital is disinfected at least once per month, preferably by heat as well as by chemical disinfection.

HM.9.8 All physical and monitoring checks are verified and signed off by the nephrologist with recording of any corrective actions taken (e.g., out of range results for tests of water or dialysate).

HM.9.9 Written record and results of microbiological and chemical testing of water are in place and reviewed.

HM.10 The nurse in charge of the hemodialysis unit ensures the competency of the nursing staff.

HM.10.1 The nursing staff receive ongoing training and education on all relevant policies including, but are not limited to, the following:

HM.10.1.1 Care of patients with AV fistula/AV graft.

HM.10.1.2 Dialysis procedures.

HM.10.1.3 Care of tunneled/non-tunneled catheters.

HM.10.1.4 Peritoneal dialysis.

HM.10.1.5 Assessment of patient's volume status.

HM.10.1.6 Anticoagulation.

HM.10.1.7 Management of clotted access.

HM.10.1.8 Hyperkalemia.

HM.10.1.9 Pulse oximetry.

HM.10.1.10 Blood transfusion.

HM.10.1.11 Use of defibrillator.

HM.10.1.12 Infection control.

HM.10.2 The nursing staff competencies are assessed by using different methods (e.g., written test, return demonstration) and results are documented.

Emergency Care (ER)

Introduction

To meet the needs of the patient population being served, the hospital has to handle emergency cases that require immediate examination and treatment. The hospital must provide emergency services by setting up an emergency room that is well staffed and equipped. The emergency room services should be organized to provide optimum care for patients in a safe, appropriate, efficient, effective, responsive and caring manner. Emergency services should be directed and coordinated in a collaborative manner.

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 problems 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.

This chapter addresses the following:

- Staff qualifications, plan and availability
- Equipment and supplies
- Triage process
- Policies and procedures
- Patient assessment and care
- Medical records documentation

STANDARDS

ER.1 Qualified physician is responsible for managing the emergency department.

ER.1.1 The head of the emergency department is a physician qualified by education, training, and experience in managing emergency patients.

ER.1.2 The head of the emergency department supervises the development and implementation of policies and procedures related to managing emergency patients.

ER.2 Emergency department staff members have the appropriate qualifications.

ER.2.1 The emergency department is covered twenty four hours a day, seven days a week by qualified emergency physicians.

ER.2.2 On call rosters for all specialties are available and posted in the emergency department.

ER.2.3 There is an established policy on how to call consultants for opinions.

ER.2.4 All staff members are qualified and experienced in emergency care.

ER.2.5 Clinical staff who participate in caring for patients in the emergency department are certified in advanced life support as appropriate to the ages of the patients served (including Advanced Trauma Life Support) and are present on site or at least one certified individual is assigned on every shift.

ER.3 Qualified nurse manager supervises nursing services in the emergency department.

ER.3.1 The nurse manager in charge of the emergency department is a qualified registered nurse with bachelor degree in nursing and appropriate education, training, and experience in emergency care.

ER.4 The emergency department has adequate nursing coverage by qualified staff.

ER.4.1 Nursing staffing plan is based on patient volume and patient acuity and ensures adequate coverage twenty four hours a day, seven days a week.

ER.5 Nursing staff in the emergency department receive continuous training with competency assessment.

ER.5.1 Nursing staff in the emergency department receive training and education as relevant to the scope of services.

ER.5.2 There is ongoing competency assessment for the nursing staff.

ER.5.3 The competency assessment of the nursing staff is documented.

ER.6 The emergency department has adequate resources that support the provision of safe care.

ER.6.1 The emergency department has the necessary equipment, supplies, and medications as appropriate to the scope of services.

ER.6.2 There is a documented process to check equipment and stock refill on a regular basis or when needed.

ER.6.3 Resuscitation/trauma rooms have adequate space to perform resuscitation.

ER.6.4 The medical bag contains all essential resuscitation medications.
ER.6.5 The medical bag is checked daily and refilled after use.
ER.6.6 Waiting areas are available and are visually accessible to the medical staff.
ER.6.7 Registration clerk is available to register emergency patients.
ER.6.8 Security measures and trained personnel are planned for protection of emergency department patients and staff.

ER.7 The clinical records of the emergency department are properly completed.

ER.7.1 There is an emergency department record form that is completed for every patient presenting for care in the emergency room.
ER.7.2 The emergency record is kept in the patient's medical record.

ER.8 There is an effective triage process to prioritize emergency patients.

ER.8.1 There is a process to identify patients with urgent or emergent care needs.
ER.8.2 Patients with urgent or emergent needs are given priority for assessment and appropriate and timely care.
ER.8.3 Re-triage is performed when appropriate (e.g., change of medical condition, long waiting time).

ER.9 Policies, procedures, pathways and guidelines guide the care of patients in the emergency department.

ER.9.1 There are policies and procedures that are consistent with the hospital scope of services as well as the hospital wide policies and procedures.
ER.9.2 The policies and procedures include, but are not limited to, the following:
- ER.9.2.1 Management of medico-legal cases such as alcohol and narcotic abuse and criminal acts.
- ER.9.2.2 Management of suspected victims of abuse, neglect, and domestic violence.
- ER.9.2.3 Management of suicidal patients.
- ER.9.2.4 Care of trauma patients.
- ER.9.2.5 Care of patients not competent to care for themselves.
- ER.9.2.6 Care of minors.
- ER.9.2.7 Patient transfer from emergency department to inpatient areas or to another organization.
- ER.9.2.8 Patients who leave against medical advice.
- ER.9.2.9 Patients who leave without being seen.

ER.9.3 There are clinical practice guidelines developed as guided by the most common emergencies and the top emergency diagnoses.
ER.9.4 The policies, procedures, and guidelines are developed by the emergency department head, the nurse manager, and staff in collaboration with other relevant department heads.

ER.10 **The hospital implements a policy that defines the responsibility for patients in the emergency department.**

ER.10.1 The policy defines the physician responsible for the care of patients in the emergency department including patients under observation, patients waiting for admission, patients waiting for admission with no bed available (boarding patients) and patients waiting for transfer to another organization.

ER.10.2 Boarding patients receive the same care as inpatients.

ER.10.3 The transfer of responsibility is documented at times of shifts, handovers, referral and admission.

ER.11 **Emergency diagnostic tests are performed and results communicated on a timely manner.**

ER.11.1 Laboratory and radiological diagnostic investigations required for a safe patient care are available twenty four hours a day, seven days a week.

ER.11.2 The hospital has a process to provide all investigations that are essential but not available.

ER.11.3 Results of investigations are available to the emergency staff within a defined time frame.

ER.12 **The emergency department has a channel of communication with the designated regional drug and poison information center when needed.**

ER.12.1 The contact details of the regional drug and poison information center are available and accessible to the staff in the emergency department.

ER.12.2 The hospital communicates with regional poison center when a need arises.

ER.12.3 The emergency department is equipped to deal with the most common and/or risky poisonous injuries in the community it serves.

ER.13 **There is an efficient process for emergency consultations.**

ER.13.1 The hospital implements a clear policy and procedure that regulates consultation requests coming from the emergency department.

ER.13.2 Levels of consultations are identified including Immediate (life, limb, or function threatening) and emergent consultations.

ER.13.3 Level of consulted physicians and the ways of communications are included.

ER.13.4 Timelines of phone response and physical presence to different types of consultations are included.

ER.13.5 If a consultation from outside the hospital is needed, the process is included in the policy (e.g., admit and consult, patient transfer, city wide on call specialty).

ER.14 **Emergency department quality indicators are monitored and reported.**

ER.14.1 The Emergency department selects and monitors key quality indicators that are monitored and reported on a regular basis.

ER.14.2 The selected emergency department indicators may include, but are not limited to, the following:

ER.14.2.1 Time to ECG in chest pain patients.

ER.14.2.2 Time to antibiotics in sepsis patients.

ER.14.2.3 Triage to physician time.

ER.15 The hospital maintains effective ambulance services.

ER.15.1 Emergency department has appropriate channels of communication with Red Crescent services upon receiving or transferring patients.

ER.15.2 The ambulance services are supervised by emergency department director or emergency department nursing manager.

ER.15.3 The ambulances have adequate equipment and supplies to be ready for transfer of patients twenty four hours a day, seven days a week.

ER.15.4 Equipment and supplies are based on Trauma/resuscitation area preparation to transfer critically ill patients.

ER.15.5 A documented daily check is conducted on both medical and mechanical functions of ambulances.

ER.15.6 Maintenance of ambulance equipment is regularly conducted and documented.

Radiology Services (RD)

Introduction

The Standards in this chapter concerning radiology services in hospitals are meant to help advance the practice of radiology and improve the quality of service to patients. They promote the safe and effective use of diagnostic and therapeutic radiology by describing specific standards of staffing, qualifications, training, skills and techniques. All medical centers using x-ray equipment, from a simple dental unit to a specialized radiological center performing complex radiological image, will benefit from adopting a quality improvement program as detailed in this chapter. An established program will monitor the imaging process from start to finish and reveal potential problems that may otherwise go unrecognized.

This chapter addresses the following:

- Staff qualifications, plan and availability
- Equipment and supplies
- Results reporting including critical results
- Policies and procedures related to radiology services
- Safety plan
- Interventional radiology

STANDARDS

RD.1 Qualified radiologist is responsible for managing the radiology department.

RD.1.1 The head of the radiology department is a radiologist qualified by education, training, and experience.

RD.1.2 The head of the radiology department supervises the development and implementation of policies and procedures related to radiology services throughout the hospital.

RD.2 The radiology department has adequate qualified staff.

RD.2.1 The radiology department has adequate staff, including:

- RD.2.1.1 Technical director.
- RD.2.1.2 Medical physicists.
- RD.2.1.3 Radiation safety officer and supervisor (for radiotherapy nuclear medicine and diagnostics).
- RD.2.1.4 Quality officer.
- RD.2.1.5 PACS administrator, when applicable.

RD.2.2 Staff working in the department are trained and qualified in their field.

RD.2.3 There is twenty four hour coverage by a radiologist and a technologist.

RD.3 The radiology department has policies and procedures that guide all radiological activities.

RD.3.1 The radiology department has policies and procedures to address all important radiological investigations and procedures, including:

- RD.3.1.1 X-rays.
- RD.3.1.2 Ultrasonography.
- RD.3.1.3 Computed Tomography.
- RD.3.1.4 Magnetic Resonance Imaging.
- RD.3.1.5 Angiogram.
- RD.3.1.6 Interventional radiological procedures.
- RD.3.1.7 Fluoroscopy.
- RD.3.1.8 Contrast agent reactions.
- RD.3.1.9 Nuclear medicine imaging.
- RD.3.1.10 Molecular Imaging (Positron Emission Tomography -PET scanning).
- RD.3.1.11 Bedside and critical care radiography.
- RD.3.1.12 Radiopharmaceuticals calibration and quality control.
- RD.3.1.13 Portable radiological machines.
- RD.3.1.14 Mammography.

RD.4 Requests for radiological investigations utilize a standardized method throughout the hospital.

RD.4.1 There is a special request form utilized by the medical staff for all requests related to radiology department.

RD.4.2 Relevant information, including a brief case description and rationale for the investigation, are documented on the radiology request form for all diagnostic and/or interventional imaging procedures.

RD.5 The radiology department implements a policy and procedure that defines the process and time limits of results reporting for all radiological studies.

RD.5.1 The radiology department defines and implements the format and content of radiology reports (paper or electronic). Essential elements of the report include:

- RD.5.1.1 Patient identification.
- RD.5.1.2 Type of the procedure.
- RD.5.1.3 Identification of the ordering physician.
- RD.5.1.4 Reporting date and time.
- RD.5.1.5 Identification of the reporting radiologist.

RD.5.2 The radiological studies are reported by the radiologist within defined time limits.

- RD.5.2.1 Immediate reporting for emergency cases.
- RD.5.2.2 Urgent cases are reported within twenty four hours.
- RD.5.2.3 Routine cases are reported within forty eight hours.

RD.6 The radiology department implements a policy and procedure for reporting of critical results.

RD.6.1 There is a policy and procedure for reporting of critical results developed in consultation with clinical departments.

RD.6.2 The policy defines the notified party and mean of communication.

RD.6.3 The policy defines the "read- back" sequence of reporting of critical results.

RD.6.4 The policy defines the proper documentation of a notification event, which includes:

- RD.6.4.1 Date and time of notification.
- RD.6.4.2 Patient identification.
- RD.6.4.3 The critical result.
- RD.6.4.4 Documentation of read-back.
- RD.6.4.5 Identification of the notifying person.
- RD.6.4.6 Identification of the notified person.

RD.7 Previous radiological studies can always be accessed.

RD.7.1 There is a master X-ray jacket or an access to all archived previous radiological studies (Picture Archiving and Communication System-PACS) for every patient.

RD.8 The radiology department has a documented and implemented safety plan.

RD.8.1 There is a safety plan that indicates the periodic inspection, maintenance, and calibration of all equipment.

RD.8.2 The safety plan involves the management of radioactive materials used for therapeutic and diagnostic purposes, particularly with regard to handling, storing, and transportation.

RD.8.3 The safety plan involves posting of safety warnings on the doors.

RD.8.4 The safety plan involves checking female patients for pregnancy before exposure.

RD.8.5 The safety plan indicates monitoring of the staff for radiation exposure, at least quarterly.

RD.8.6 The safety plan involves the provision and regular testing of radiation protection aprons and thyroid and gonad shields for staff and patients.

RD.8.7 Records are available indicating the radiation dosimetry tools and staff radiation exposure for the past twelve months.

RD.8.8 The safety plan is implemented as evidenced by the daily practice.

RD.9 The radiology department has a documented and implemented protocol for interventional radiological procedures.

RD.9.1 There is a documented protocol for interventional radiological procedures, which indicates pre-procedural assessments (patient and procedure verification, rationale for the procedure, past history and history of allergic reactions, coagulation profile, informed consent with explanation of risks and benefits).

RD.9.2 The protocol indicates monitoring requirements during and after the procedure.

RD.9.3 Findings of patient assessment and monitoring are documented in the patient's medical record.

RD.10 The radiology department ensures the safety of diagnostic imaging equipment.

RD.10.1 The radiology department ensures the following tests are conducted at least annually:

RD.10.1.1 Automatic Exposure Control (AEC) test.

RD.10.1.2 Kvp reproducibility and repeatability.

RD.10.1.3 Half Value Layer test.

RD.10.1.4 Alignment of collimator and x-ray field.

RD.10.1.5 Mean glandular dose test (for mammography).

RD.10.2 The radiology department implements corrective actions accordingly.

Burn Care (BC)

Introduction

Burn care is a high risk service that requires strict adherence to certain requirements to be safe, efficient, and effective. When the hospital provides burn care, the unit should be staffed with qualified individuals. Additionally, policies and procedures should guide staff for appropriate burn care.

This chapter addresses the following:

- Staff qualifications and plans
- Admission and discharge criteria
- Policies and procedures in burn units
- Collaboration with different disciplines
- Infection control

STANDARDS

BC.1 Qualified director is responsible for managing the clinical services in the burn care unit.

BC.1.1 The clinical services in the burn care unit are led by a qualified plastic surgeon with interest/ experience in burn care.

BC.2 The burn unit is covered by qualified medical staff.

BC.2.1 The care is provided by consultant burn care five days a week during working hours.

BC.2.2 The care is supplemented by sufficient qualified surgeons twenty four hours a day, seven days a week (plastic surgeon or general surgeon who has completed initial stage training in plastic surgery).

BC.2.3 The unit has access to consultant burn care twenty four hours a day, seven days a week.

BC.3 Clinical staff members have appropriate qualifications.

BC.3.1 Clinical staff members in the burn care unit are qualified in the care of burn patients.

BC.3.2 Clinical staff who participate in providing care for burn patients are certified in advanced life support for the different age groups.

BC.3.3 On every shift, clinical staff are present on site or at least one certified professional is assigned for the burn unit.

BC.4 Qualified nurse manager is responsible for supervising nursing services in the burn unit.

BC.4.1 The nurse manager in charge of the burn unit is a qualified registered nurse with training, education, or experience in burn care.

BC.5 The burn unit has adequate nursing coverage.

BC.5.1 Nursing staffing plan is based on patient volume and patient acuity and ensures adequate coverage twenty four hours a day, seven days a week.

BC.6 The burn unit has admission and discharge criteria.

BC.6.1 The burn unit has admission and discharge criteria consistent with evidence-based practice.

BC.6.2 The criteria are collaboratively developed by the unit medical and nursing staff.

BC.6.3 The admission and discharge criteria are implemented.

BC.7 Services provided in the burn unit are coordinated with other services to meet the needs of patients.

BC.7.1 Medical services are readily available and accessible including, but are not limited to:

BC.7.1.1 Critical care services.

BC.7.1.2 Anesthesia services.

BC.7.1.3 Social services.

BC.7.1.4 Pharmaceutical care.

BC.7.1.5 Physiotherapy services.

BC.7.2 Care is coordinated with the different disciplines participating in the plan of care.

BC.8 Policies, procedures, guidelines, and protocols guide the care in the burn unit.

BC.8.1 There are policies, procedures, protocols and guidelines covering, but are not limited to:

BC.8.1.1 Inhalation injury.

BC.8.1.2 Varying degrees/types of burns.

BC.8.1.3 Infections.

BC.8.1.4 Use of skin or synthetic grafts.

BC.9 Policies and procedures guide all practices relating to infection control in the burn unit.

BC.9.1 There are policies and procedures to guide all practices relating to infection control and this includes, but is not limited to:

BC.9.1.1 Separation of cases.

BC.9.1.2 Use of masks, gowns and gloves.

BC.9.1.3 Cleaning and disinfecting all equipment and tools.

BC.9.1.4 Visitor restrictions.

BC.9.1.5 Aseptic dressing change.

BC.9.1.6 Care of skin graft.

BC.9.1.7 Transport of patients into and out of the unit.

BC.9.1.8 Burn bath management.

BC.9.2 The burn care unit is under positive pressure with High Efficiency Particulate Air (HEPA) filters.

BC.9.3 Policies and procedures relating to infection control are implemented as evidenced in the daily practice and the patient's medical record.

BC.10 The burn care unit has all necessary equipment and supplies for the provision of safe care.

BC.10.1 The burn care unit has the necessary equipment, supplies, and medications including, but are not limited to:

BC.10.1.1 Crash Cart.

BC.10.1.2 Automated blood pressure monitoring machines.

BC.10.1.3 Cardiac monitors.

BC.10.1.4 Suction machines.

BC.10.1.5 Pulse oximeters.

BC.10.1.6 Intravenous infusion pumps and syringes.

BC.10.1.7 Ventilators.

BC.10.1.8 Blood warmers.

BC.10.1.9 Glucometers.

BC.11 **Nursing staff in the burn care unit receive continuous training with competency assessment.**

BC.11.1 Nursing staff in the burn care unit receive training and education that include , but is not limited to the following:

BC.11.1.1 Use of pulse oximetry.

BC.11.1.2 Principles of infection control.

BC.11.1.3 Use of the defibrillator.

BC.11.1.4 Knowledge of the dosage, side effects, and complications of commonly used high alert medications.

BC.11.2 There is ongoing competency assessment for the nursing staff (e.g., written test, return demonstration).

BC.11.3 The competency assessment of the nursing staff is documented.

Oncology and Radiotherapy (ORT)

Introduction

Medical and radiation oncology is a high risk service that requires adherence to certain requirements to be safe, efficient, and effective. When the hospital provides medical and radiation oncology, the unit should be staffed with qualified individuals. Additionally, policies and procedures should guide staff for appropriate medical and radiation oncology care.

This chapter addresses the following:

- Staff qualifications
- Safety plan
- Admission and discharge criteria
- Policies and procedures

STANDARDS

ORT.1 Qualified physician is responsible for managing the oncology and radiotherapy services.

ORT.1.1 The individual(s) responsible for the oncology and radiotherapy services is qualified by education, training, and experience in the fields of oncology/radiation oncology.

ORT.2 The hospital ensures full compliance with the relevant regulations on radiation.

ORT.2.1 The hospital has a valid license for the provision of radiotherapy services from relevant authorities (King Abdulaziz City for Science and Technology).

ORT.3 Oncology and radiotherapy services are provided by qualified staff.

ORT.3.1 Oncology and radiotherapy services are adequately staffed as follows:

ORT.3.1.1 Oncologists/Radiation oncologists.

ORT.3.1.2 Medical physicists.

ORT.3.1.3 Radiation therapists.

ORT.3.1.4 Mould room technicians.

ORT.3.1.5 Radiation safety officer and supervisor.

ORT.3.1.6 Quality officer.

ORT.3.2 Staff are trained and qualified in their fields.

ORT.3.3 Clinical staff maintain registration with the Saudi Commission for Health Specialties.

ORT.4 Qualified nurse manager(s) supervises nursing practices in the oncology and radiotherapy services.

ORT.4.1 The nurse manager is a registered nurse qualified by education, training, and experience in the field of oncology/radiotherapy.

ORT.4.2 The nurse manager develops and collaborates with other disciplines for developing all relevant policies and procedures including, but are not limited to:

ORT.4.2.1 Chemotherapy administration, side effects, and safety precautions.

ORT.4.2.2 Radiation therapy administration, side effects, and safety precautions.

ORT.4.2.3 Targeted therapy, immunotherapy and contrast media administration and education.

ORT.4.2.4 Spill management.

ORT.4.2.5 Special radiation techniques (brachytherapy, stereotactic radiotherapy, unsealed sources, other techniques), including preparation and delivery guidelines.

ORT.4.2.6 Extravasations and anaphylaxis management guidelines.

ORT.4.2.7 Radioactive iodine management.

ORT.4.2.8 Dying and end of life care management.

ORT.4.2.9 Bone marrow and stem cell transplant management.

ORT.4.2.10 Management of neutropenia and other related complications of chemo/radiation therapy.

ORT.5 **Oncology and radiotherapy services are guided and overseen by a multidisciplinary committee.**

ORT.5.1 There is a multidisciplinary committee to guide and oversee oncology and radiotherapy services.

ORT.5.2 The committee meets at least four times a year. The record of the minutes of meetings is maintained.

ORT.5.3 The committee assists in developing and reviewing policies, procedures, safety plan, guidelines and protocols for the provision of a safe patient care.

ORT.5.4 The committee ensures implementation of policies and procedures.

ORT.6 **Oncology and radiotherapy services include a palliative care unit/service.**

ORT.6.1 The unit has policies and procedures, guidelines and protocols for the palliative care including pain management and management of illness/treatment-related symptoms.

ORT.6.2 Staff are well trained on palliative care practices.

ORT.7 **There is a safety plan to ensure the safety of oncology and radiotherapy services.**

ORT.7.1 There is a written safety plan that includes:

ORT.7.1.1 Periodic inspection, maintenance and calibration of the linear accelerator and other radiation equipment.

ORT.7.1.2 Guidelines on how to inspect and monitor the medical equipment.

ORT.7.1.3 Management of nuclear material used for therapeutic and diagnostic purposes, especially in regard to its handling, storing, and transportation.

ORT.7.2 The safety plan is implemented and audited for effectiveness.

ORT.8 **Oncology and radiotherapy services implement admission and discharge criteria.**

ORT.8.1 There are admission and discharge criteria for patients receiving oncology and radiotherapy services.

ORT.8.2 The criteria are collaboratively developed by physicians and nursing staff.

ORT.9 **The nurse manager ensures the competency of the nursing staff.**

ORT.9.1 The nursing staff receive training and education that are necessary for the provision of effective and safe care including, but are not limited to:

ORT.9.1.1 Central and peripheral venous access device.

ORT.9.1.2 Care of tracheostomies.

ORT.9.1.3 Chest tube management.

ORT.9.1.4 Advanced medication administration, including targeted therapy, chemotherapy, immunotherapy, and hormonal therapy.

ORT.9.1.5 Line management including extravasations.

ORT.9.1.6 Radiation side effects management.

ORT.9.1.7 Assisting and preparing for lumber puncture.

ORT.9.1.8 Assisting in intrathecal administration of chemotherapy.

ORT.9.1.9 Infection control, including hazardous material and blood spill.

ORT.9.1.10 Blood transfusion.

ORT.9.1.11 Use of defibrillator.

ORT.9.2 Nursing staff competencies are assessed and are documented.

ORT.10 Appropriate documentation is maintained for quality control activities of the oncology and radiotherapy services.

ORT.10.1 Quality records are maintained, which include:

ORT.10.1.1 Periodic inspection, maintenance and calibration of the linear accelerator and other radiation equipment.

ORT.10.1.2 Records of the isotopes used in treatment that include its energy, calibration, and disposal.

ORT.10.1.3 Records of the radiation dosimetry and staff radiation exposure for the past twelve months.

Specialized Care Services

Introduction

Hospitals vary in the services provided according to their size and the population served. However, there are services required to be provided in the majority of hospital settings in coordination and integration with other clinical services. They are collectively labeled as specialized services for the purpose of this manual. They all play a significant role in the outcome of care and also in the degree of patient satisfaction about care and services.

Specialized Services include:

- Respiratory Care Services
- Dietary Services
- Social Care Services
- Physiotherapy Services

Respiratory Care Services (RS)

STANDARDS

RS.1 The hospital provides respiratory care services.

RS.1.1 Respiratory care services are provided twenty four hours a day, seven days a week.

RS.1.2 A qualified respiratory therapist with a minimum of bachelor's of science in respiratory care directs the work of the respiratory care therapists and provides the general administration of the respiratory care services department/unit.

RS.1.3 A qualified physician (e.g., pulmonologist, anesthesiologist, or intensivist) provides the medical supervision on the clinical activities of the respiratory care services department/unit.

RS.1.4 Personnel providing respiratory services are trained professionals in respiratory care.

RS.1.5 Clinical staff providing respiratory care services are certified in advanced life support as appropriate to the age of the patients served and are present on site or at least one certified individual is assigned on every shift.

RS.2 Policies and procedures guide respiratory care services.

RS.2.1 There are policies and procedures to guide respiratory care services including, but are not limited to:

- RS.2.1.1 Use of equipment.
- RS.2.1.2 Pulmonary function testing.
- RS.2.1.3 Coughing and breathing exercise.
- RS.2.1.4 Obtaining arterial blood gasses.
- RS.2.1.5 Mechanical ventilator support.
- RS.2.1.6 Dealing with open cases of Tuberculosis.

RS.2.2 Policies and procedures are implemented.

RS.3 All equipment and machines in the respiratory care services are operated within manufacturers' specifications and maintained free of defects.

RS.3.1 All equipment and machines are operated within manufacturers' specifications.

RS.3.2 The periodical preventive maintenance is developed and implemented in accordance with manufacturers' instructions.

RS.3.3 All maintenance and repair records are maintained for future reference and inspection.

RS.4 Each patient's respiratory care is planned and documented in the medical record.

RS.4.1 The plan of care is developed through an evidence-based and collaborative approach among the team members involved.

RS.4.2 Comprehensive assessment and reassessment are performed for each patient.

RS.4.3 The plan of care and the response to treatment are documented in the patient's medical record.

RS.5 There is an ongoing competency assessment of the respiratory care staff.

RS.5.1 Staff members receive ongoing training and education, as applicable, on the unit's protocols, policies and procedures.

RS.5.2 Competencies are assessed and results are documented.

Dietary Services (DT)

STANDARDS

DT.1 **Dietary services are provided by qualified dietitians.**

DT.1.1 A qualified dietitian supervises all aspects of dietary services in the hospital.

DT.1.2 Services provided by the dietitian include, but are not limited to, the following:

- DT.1.2.1 Nutritional screening, assessment and reassessment of patients.
- DT.1.2.2 Development of nutritional plan of care.
- DT.1.2.3 Highlighting "food-drug interaction" to clinical staff.
- DT.1.2.4 Making recommendations related to patient dietary needs.
- DT.1.2.5 Nil Per Os (NPO) monitoring.
- DT.1.2.6 Education of other health staff, patients, and families.
- DT.1.2.7 Reviewing and updating the dietary manual.

DT.1.3 Activities conducted by the dietician as part of the process of care is documented in the patient's medical record.

DT.2 **Patients identified to be at nutritional risk undergo comprehensive nutritional assessment.**

DT.2.1 Nutritional screening is conducted by qualified hospital staff (e.g., registered nurse) to determine the patient's need for comprehensive nutritional assessment by a licensed dietitian.

DT.2.2 The criteria used for nutritional screening during the initial assessment of patients are developed and approved by a qualified dietitian.

DT.2.3 Comprehensive nutritional assessment is performed by a qualified dietitian for:

- DT.2.3.1 All patients identified at nutritional risk during the initial screening or assessment.
- DT.2.3.2 All patients identified at nutritional risk during the course of treatment.
- DT.2.3.3 All patients prescribed for a therapeutic diet.

DT.2.4 Patients identified at nutritional risk are referred to a licensed dietitian for comprehensive nutritional assessment.

DT.2.5 Nutritional assessment is preferably completed within twenty four hours of referral.

DT.2.6 The comprehensive nutritional assessment is described in a policy and procedure that includes, but is not limited to, the following:

- DT.2.6.1 Height and weight chart for children.
- DT.2.6.2 Body mass index (BMI) for adults.
- DT.2.6.3 Eating habits.
- DT.2.6.4 Food allergies.
- DT.2.6.5 Need for therapeutic diet.
- DT.2.6.6 Physical difficulties with eating and drinking and the need for any assisting devices.

DT.2.7 The nutritional screening and assessment findings are documented in the patient's medical record.

DT.3 **Patients with nutritional disorders have the appropriate nutritional plans that meet their medical needs.**

DT.3.1 The dietitian, in collaboration with other clinical staff, develops an appropriate nutritional plan of care for patients with nutritional disorders.

DT.3.2 Patients cultural and food preferences are respected to the extent possible.

DT.3.3 The nutritional plan allows for consideration of:

DT.3.3.1 Enteral tube feeding for malnourished or patients at risk of malnutrition and have inadequate oral intake and a functioning gastrointestinal tract.

DT.3.3.2 Parenteral nutrition for patients with a non-functioning gastrointestinal tract.

DT.3.3.3 Therapeutic diet prescribed for specific health conditions.

DT.3.4 Patients are reassessed for response by the dietitian at regular intervals and adjustments are made accordingly.

DT.3.5 The nutritional plan is documented in the patient's medical record.

DT.4 The hospital has a current dietary manual.

DT.4.1 There is a current dietary manual that is developed by the dietitian and other relevant staff.

DT.4.2 The dietary manual is approved by the medical staff.

DT.4.3 The dietary manual is used as the basis for diet orders and for planning therapeutic diets.

DT.4.4 The dietary manual includes the following items:

DT.4.4.1 Different types of diets used in the hospital.

DT.4.4.2 Nutritional supplements used and how to use them.

DT.4.4.3 Appropriate storage method for snacks and beverages.

DT.4.4.4 Mealtimes and working hours of the kitchen.

DT.4.5 The dietary manual is reviewed, revised, and updated at least every two years.

DT.4.6 Copies of the dietary manual are readily available to all medical, nursing, and food services personnel.

DT.5 Therapeutic diets are provided when ordered.

DT.5.1 Therapeutic diets are prescribed by the most responsible physician based on the patient's needs.

DT.5.2 Therapeutic diets are planned, prepared, and served with supervision or consultation from the dietitian.

DT.5.3 The plan for a therapeutic diet must emphasize:

DT.5.3.1 Total calories required.

DT.5.3.2 Any restrictions.

DT.5.3.3 The route and frequency of feeds.

DT.5.3.4 When required, education about nutritional needs is provided to the patient and family upon discharge.

DT.5.4 Discharge diets are prescribed by the most responsible physician in collaboration with the supervising dietitian.

DT.5.5 Patients are educated on their nutritional needs upon discharge.

DT.5.6 Education is documented in the patient's medical record.

DT.6 The hospital provides safe food services.

DT.6.1 Food preparation, handling, storage, and distribution is safe and guided by professional organizations standards and management systems (e.g., Hazard Analysis and Critical Control Points, HACCP).

DT.6.2 Food preparation, handling, storage, and distribution comply with laws and regulations.

Social Care Services (SC)

STANDARDS

SC.1 **The hospital provides social care services.**

SC.1.1 A qualified social worker directs social care services provided by the hospital.

SC.1.2 Social care services are adequately staffed and have all other required resources according to the hospital's size and scope of services.

SC.2 **Patients identified at psychosocial risk undergo comprehensive psychosocial assessment.**

SC.2.1 Psychosocial screening is conducted by qualified hospital staff (e.g., registered nurse) to determine the patient's need for comprehensive psychosocial assessment by a licensed social worker.

SC.2.2 The criteria used for psychosocial screening during the initial assessment of patients are developed and approved by a qualified social worker.

SC.2.3 Psychosocial assessment is preferably completed by a qualified social worker within twenty four hours of referral.

SC.2.4 The psychosocial assessment is described in a policy and procedure that defines factors facilitating/impeding healthcare progress, including:

- SC.2.4.1 Emotional, social, and psychological factors.
- SC.2.4.2 Home situation.
- SC.2.4.3 Financial factors.
- SC.2.4.4 Noncompliance to treatment
- SC.2.4.5 Physical/mental disabilities.

SC.2.5 The psychosocial screening and assessment findings are documented in the patient's medical record.

SC.3 **Patients with psychosocial risk have an appropriate plan that meets their needs.**

SC.3.1 The social worker works collaboratively with clinical staff (physicians, nurses, and other clinical staff) to develop a suitable plan of care that meets the psychosocial needs of the patient and ensures the continuity of care.

SC.3.2 Patients are reassessed by social worker at regular intervals, their response to the plan of care is monitored, and adjustments are made accordingly.

SC.3.3 The plan of care is documented in the patient's medical record as part of multidisciplinary team planning.

SC.4 **The hospital ensures the provision of effective social care services for inpatients and outpatients.**

SC.4.1 Social worker helps patients cope with illness, treatment, and recovery.

SC.4.2 Social worker helps patients subjected to abuse, neglect, or violence.

SC.4.3 Social worker assists patients and families communicating meaningfully with healthcare teams.

SC.4.4 Social worker assists patients and families during grief and bereavement.

SC.4.5 Social worker assists patients in job-related and school concerns.

SC.4.6 Social worker assists patients to gain access to hospital and other community-based services including home health care and financial assistance.

SC.4.7 Social worker participates with the treating team in discharge planning.

SC.5 The social worker documents all relevant patient information in the medical record.

SC.5.1 The social worker documents relevant information in the patient's medical record , which include:

SC.5.1.1 Reason for referral.

SC.5.1.2 Patient/family assessment and reassessment findings.

SC.5.1.3 Plan of care including goals and interventions such as counseling, education, and facilitation of resources.

SC.5.1.4 Evaluation of the plan of care.

SC.5.1.5 Regular progress notes that include the patient/family understanding, care progress, and needs for different or additional services.

Physiotherapy services (PT)

STANDARDS

PT.1 **Physiotherapy services are provided by qualified therapists.**

PT.1.1 A physiotherapist qualified by education, training, and experience manages the physiotherapy department.

PT.1.1.1 The department head supervises all aspects of physiotherapy services in the hospital.

PT.1.1.2 The department head develops a written scope of services of the physiotherapy department.

PT.1.1.3 The department head recommends space and equipment to meet the scope of services.

PT.1.2 Staff members are qualified by appropriate education, training, and experience in physical rehabilitation.

PT.2 **Policies, procedures and protocols guide the care of patients undergoing physiotherapy in the hospital.**

PT.2.1 Policies, procedures, and protocols include, but are not limited to, the following:

PT.2.1.1 Management of strokes.

PT.2.1.2 Management of hip replacements.

PT.2.1.3 Management of knee replacements.

PT.2.1.4 Management of back pain.

PT.2.1.5 Safety measures.

PT.2.1.6 Communication with the physicians.

PT.2.2 Policies are collaboratively developed with the medical staff, nursing staff, and other relevant departments.

PT.3 **Patients identified to be at functional risk have comprehensive functional assessment performed.**

PT.3.1 Functional screening is conducted by qualified hospital staff (e.g., registered nurse) to determine the patient's need for a comprehensive functional assessment by a licensed therapist.

PT.3.2 The criteria used for functional screening during the initial assessment of patients are developed and approved by qualified therapists

PT.3.3 Comprehensive functional assessment is performed by a qualified therapist for each patient identified at functional risk during the initial screening or assessment.

PT.3.4 Functional assessment is completed within twenty four hours of referral.

PT.3.5 The comprehensive functional assessment is described in a policy and procedure.

PT.3.6 Functional screening and assessment findings are documented in the patient's medical record.

PT.4 Patients with functional disorder(s) have an appropriate plan of care that meets their needs.

PT.4.1 The physiotherapist, in collaboration with other clinical staff, develops a suitable plan of care for patients with functional disorders.

PT.4.2 The plan of care meets the medical needs of the patient.

PT.4.3 The plan of care has measurable goals.

PT.4.4 Patients are educated about the plan of care and the procedures and rehabilitative exercises.

PT.4.5 Patients are reassessed by a physiotherapist at regular intervals, their response to the plan of care is monitored, and adjustments are made accordingly.

PT.4.6 The plan of care is documented in the patient's medical record as part of multidisciplinary team planning, whenever applicable.

Dental Services (DN)

Introduction

The standards included in this chapter represent the minimal standards for dental service delivery in a hospital-based dental unit. Dental care services need to be provided with strict hygiene and infection prevention measures. They represent a type of ambulatory care services that could exist as a part of a healthcare organization or as a stand-alone facility. In general, patients attending ambulatory care should receive care that is similar to the care provided in other departments.

The standards in this chapter address the following:

- Staff qualifications
- Patient and family education
- Patient assessment and care
- Documentation in medical records
- Patient education
- Infection prevention and control
- Safety in dental laboratory

STANDARDS

DN.1 Qualified dentist directs the dental services.

DN.1.1 The head of the dental department is a dentist qualified by education, training, and experience.

DN.2 Dental department staff members have appropriate qualifications.

DN.2.1 Dentists perform dental treatments and procedures within their approved privileges.

DN.2.2 Qualified dental technicians are available as needed.

DN.2.3 There is one dental assistant per chair.

DN.3 Education is provided to the patient and family.

DN.3.1 Patients are educated and informed about the nature of the problem.

DN.3.2 Patients are educated and informed about treatments and procedures required.

DN.3.3 Patients are educated and informed about time needed to complete the course of treatment.

DN.3.4 Where applicable, patients are educated and informed about cost of services.

DN.4 Each patient's dental care is planned and documented in the medical record.

DN.4.1 Comprehensive assessment is performed for each patient to include:

- DN.4.1.1 History of allergic reactions.
- DN.4.1.2 Chronic illnesses (e.g., congenital heart disease, rheumatic heart and diabetes).
- DN.4.1.3 Infectious diseases.
- DN.4.1.4 Hematological diseases (e.g., hemophilia).
- DN.4.1.5 Chief complaints.
- DN.4.1.6 The need for antibiotic prophylaxis.
- DN.4.1.7 Radiological procedures needed.
- DN.4.1.8 Treatment plan including procedure(s) to be performed.
- DN.4.1.9 Dose of local anesthesia, the tooth treated and the material used.

DN.4.2 The assessment findings and the treatment plan are documented in the patient's medical record.

DN.5 The dental department adopts the hospital wide policies and procedures as applicable.

DN.5.1 Informed consent is obtained for all high-risk procedures.

DN.5.2 General anesthesia and moderate or deep sedation are performed safely and according to the hospital's related policies and procedures.

DN.6 Infection control guidelines are strictly implemented in the dental department.

DN.6.1 There are infection control guidelines that include, but are not limited to:

- DN.6.1.1 Using gloves and masks for each case.
- DN.6.1.2 Wearing protective eyewear.
- DN.6.1.3 Providing eye protection for patients.
- DN.6.1.4 Cleaning surfaces of working area between patients.
- DN.6.1.5 Maintaining updated evidence-based disinfection and sterilization practices.

DN.6.1.6 Implementing the hospital infection control plan, policies and procedures as outlined in the "Infection Control" chapter of this manual.

DN.6.2 The infection control guidelines are strictly implemented.

DN.7 Safety rules are applied in the dental laboratory.

DN.7.1 Fire detection and abatement equipment are available.

DN.7.2 Fire blankets are available.

DN.7.3 Cautionary signs are posted.

DN.7.4 A hooded exhaust is available in the casting area.

DN.7.5 Oxygen cylinders are safely stored.

DN.7.6 Fumes are safely evacuated.

DN.7.7 Eye wash station is available.

Management of Information (MOI)

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 hospital should have a process to meet the information needs of its clinical and managerial leaders and to compare its performance with other databases when relevant.

Among the main requirements of this function found in this chapter are:

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

STANDARDS

MOI.1 Hospital leaders ensure the conduction of needs assessment related to information management in the hospital.

MOI.1.1 The hospital conducts a needs assessment related to information management based on the hospital's scope of services, complexity of care and affordable resources including technology.

MOI.1.2 The needs assessment involves both clinical and managerial staff.

MOI.1.3 The needs assessment identifies the needs/ requirements of external organizations (e.g., Ministry of Health, accrediting bodies, national research and databases).

MOI.1.4 Information technology needs are identified and integrated with existing information management processes.

MOI.1.5 Relevant clinical and managerial staff participate in selecting, integrating, and using information management technology.

MOI.2 The hospital maintains an effective information management system to serve its internal and external users and stakeholders.

MOI.2.1 The hospital provides adequate resources for an effective information management system.

MOI.2.2 The hospital describes the categorization of the needed information into manual and computerized.

MOI.2.3 Data elements are defined and forms are developed for designated staff to enter the necessary data.

MOI.2.4 Data are collected within predetermined time frames and frequency.

MOI.2.5 There is a process for secure storage of data and information with easy retrieval.

MOI.2.6 Data and information are accurately and timely disseminated to the targeted internal and external users.

MOI.2.7 Data and information are disseminated in a format useful for decision making.

MOI.3 The hospital develops a process for the information management system modifications, updates, and validation.

MOI.3.1 There is process for documentation, approval, and validation of any modification or update related to the information management system.

MOI.4 Data collected are transformed into information that is used to support patient care and management decisions.

MOI.4.1 Aggregate data and information include information requirements for key functions as specified in this manual (e.g., facility management and safety, infection control, clinical data and information, identified hospital-wide indicators, department-specific indicators, physician-specific information).

MOI.4.2 Aggregate data and information are used for self-comparison over time and benchmarking against similar hospitals as well as best practices.

MOI.4.3 The hospital uses the information to make decisions, strategically plan, identify and prioritize quality improvement projects.

MOI.5 **Hospital leaders as well as users and other staff receive education and training on data management relevant to their roles and responsibilities.**

MOI.5.1 There is an education/training process for decision makers and other relevant staff on the principles of data management.

MOI.5.2 The data management education/training is appropriate to the staff roles and responsibilities within the hospital.

MOI.5.3 The data management education/training includes, but is not limited to, the following:

MOI.5.3.1 Selection and use of indicators (measures) in assessment and improvement of work processes.

MOI.5.3.2 Data collection and analysis.

MOI.5.3.3 Use of data and information for decision-making.

MOI.5.3.4 Data/information confidentiality and security.

MOI.6 **The hospital has a policy and procedures on how confidentiality, security, and integrity of data and information including the medical records are maintained.**

MOI.6.1 The policy defines data and information confidentiality, security, and integrity.

MOI.6.2 The policy is in compliance with laws and regulations.

MOI.6.3 The hospital defines appropriate levels of security and confidentiality for data and information and provides appropriate confidentiality measures accordingly.

MOI.6.4 Staff access to different categories of information is restricted on a need to know basis.

MOI.6.5 There is an appropriate mechanism for response to requests for access to information.

MOI.6.6 Data and information are safeguarded against loss, destruction, tampering, damage, and unauthorized access or use.

MOI.6.7 There are measures for protecting data and information in the event of a disaster such as flood, fire, loss of power, and abnormal temperature conditions.

MOI.6.8 Staff responsibilities to maintain confidentiality of data and information are defined (e.g., signing a confidentiality agreement).

MOI.6.9 Information confidentiality and security incidents are reported and acted upon.

MOI.7 **The hospital uses a standardized definitions, abbreviations, and symbols.**

MOI.7.1 The hospital uses standardized and approved definitions.

MOI.7.2 The hospital implements a list of approved and prohibited abbreviations and symbols.

MOI.7.3 The lists are consistent with national standards and professional organizations concerned with patient safety.

MOI.7.4 The lists are developed and approved by the medical staff and other relevant structures (e.g., medical records review committee, pharmacy and therapeutics committee).

MOI.7.5 The lists are revised periodically (e.g., annually).

MOI.8 **The hospital has a policy on the retention of data and information.**

MOI.8.1 There is a policy on the retention of data and information that is consistent with relevant laws and regulations.

MOI.8.2 The policy defines the length of time required to retain the data and information.

MOI.8.3 The policy addresses how confidentiality, integrity, and security of the data and information will be maintained during retention.

MOI.9 **The hospital maintains sufficient provisions that ensure the operation of the information system during scheduled or unscheduled (unexpected) downtime.**

MOI.9.1 There are procedures and forms to be used during scheduled or unscheduled (unexpected) downtime.

MOI.9.2 End-users are trained on procedures to follow during interruptions of the information system.

MOI.9.3 Patient information are documented and reported during the downtime (e.g., reporting laboratory results).

MOI.9.4 The integrity of the system and data entry is verified after the downtime.

MOI.9.5 There is review of the downtime assessment report.

MOI.9.6 The downtime system is regularly tested for effectiveness.

MOI.10 **The hospital implements a process for data backup.**

MOI.10.1 The hospital has a process in place for regular information system data backup and retrieval.

MOI.11 **The hospital uses and contributes to comparative reference databases in accordance with national guidelines.**

MOI.11.1 The hospital contributes to external databases in accordance with national laws and regulations.

MOI.11.2 The hospital uses external reference databases for comparative purposes to identify areas in which performance deviates from expected patterns.

MOI.12 **There is a process for the clinical and administrative staff to obtain information that support safe patient care.**

MOI.12.1 Information resources are available to address clinical and administrative staff needs and support them to maintain and improve their competencies.

MOI.12.2 Information resources support patient care, patient safety, patient education, performance improvement, educational functions for hospital and medical staff, research, and other appropriate functions.

MOI.12.3 Information resources are accessible when needed (e.g., books and journals).

Medical Records (MR)

Introduction

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

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

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

STANDARDS

MR.1 The Health Information Management (Medical Records) department has adequate qualified staff.

MR.1.1 The health information management (Medical Records) department is directed by individual qualified by education (bachelor in health information management) and experience.

MR.1.2 The department director is credentialed in health information management through formal training as per the national/international guidelines.

MR.1.3 The department has adequate staff to carry out its functions.

MR.1.4 Staff working in the department are credentialed in health information management through formal training as per the national/international guidelines .

MR.1.5 Clinical coding staff working in the department are credentialed/certified in clinical coding through formal training as per the the national/international guidelines.

MR.1.6 The department has one or more staff members who are credentialed in Clinical Documentation Improvement (CDI) through formal training as per the national/international guidelines.

MR.2 A medical record is initiated for every patient.

MR.2.1 The hospital initiates a medical record for each patient on his first contact with the hospital, whether it is for an admission, emergency department or outpatient clinic visit.

MR.2.2 Each medical record is assigned a unique identification number.

MR.2.3 The hospital keeps only one medical record for each patient.

MR.2.4 There is patient identification on each page of the medical record.

MR.3 The hospital maintains a master patient index (either manual or computerized) of all patients who have ever been admitted to or treated by the hospital.

MR.3.1 The master patient index is used to identify a patient's medical record number.

MR.3.2 The master patient index provides basic patient demographic information (identification information collected during the registration process) as well as patient activity (visit) information:

MR.3.2.1 The patient demographic information (identification information) includes: medical record number, patient's full name, date of birth, sex, marital status, address, national identification number, next of kin (and his contacts) and/or a person that the patient wishes to be contacted in an emergency, or authorized representative/designee.

MR.3.2.2 The patient activity (visit) information includes: admission and discharge/transfer dates for inpatient hospitalizations, date of death when a death occurs, encounter date or date of service for outpatient visits, most responsible physician, and mother's name for newborns.

MR.3.3 The patient demographic information (identification information) of the master patient index is recorded on the front sheet of the medical record.

MR.3.4 The master patient index is updated for each new episode of care for any change in information.

MR.3.5 The master patient index is retained permanently to provide historical access to basic patient information and dates of stay in the hospital.

MR.4 **Medical records contain sufficient information to promote continuity and coordination of care and communication among care providers.**

MR.4.1 The medical record contains sufficient information to identify the patient and his care provider, support the diagnosis, justify the treatment, and document the results of care provided.

MR.5 **The hospital has a complete and accurate medical record for every patient.**

MR.5.1 The hospital identifies in a policy all staff members authorized to make entries in medical records.

MR.5.2 All entries in the medical records must be legible, indelibly verified, dated, and authenticated.

MR.5.3 Clinical staff authorized to make entries in the medical record receive formal training in clinical documentation improvement as per the national/international guidelines.

MR.5.4 The author of each entry must be identified and authenticated by official stamp, signature, written initials, or computer entry.

MR.5.5 Medical record completion is a requirement within thirty days of patient discharge and before any elective vacation or period of absence of the staff member entering the notes in the medical record.

MR.5.6 The hospital has a policy to deal with delinquent medical records.

MR.5.7 The most responsible physician is responsible for the completion of his own records.

MR.6 **The hospital maintains the medical records in one central place.**

MR.6.1 The hospital has a medical records department that accommodates all medical records.

MR.6.2 The hospital has processes to manage the different parts of the medical records.

MR.6.2.1 The different parts of multiple records are cross referenced to the patient's unique identifier to enable records linkage.

MR.6.2.2 The different parts can be easily located when not stored together.

MR.6.2.3 The hospital ensures that all information are available and accessible when needed.

MR.6.3 The processes include, but are not limited to, the following:

MR.6.3.1 Records that are partly paper-based and partly electronic.

MR.6.3.2 Records that include items requiring incompatible storage systems such as videos and audio recordings.

MR.7 **A discharge summary is completed for all discharged patients.**

MR.7.1 There is a discharge summary for all discharged patients.

MR.7.2 The discharge summary is complete and includes:

MR.7.2.1 The reason for the patient's admission.

MR.7.2.2 The patient's diagnosis.

MR.7.2.3 Brief summary of hospitalization (therapies, consultations, interventions and results of any important diagnostic testing).

MR.7.2.4 A list of medications used.

MR.7.2.5 Any surgery or procedures performed and their outcome.

MR.7.2.6 The patient's condition at discharge.

MR.7.2.7 All medications to be taken by the patient after discharge.

MR.7.2.8 Any special care the patient requires after discharge.

MR.8 **The hospital uses nationally recognized standardized diagnosis and procedure codes.**

MR.8.1 The hospital uses the International Statistical Classification of Diseases and Related Health Problems, 10th Revision, Australian Modification (ICD-10-AM) for diagnosis coding.

MR.8.2 The hospital uses Australian Classification of Health Interventions (ACHI) for procedure coding.

MR.9 **There is a process to ensure availability of the medical records in a timely manner.**

MR.9.1 The hospital determines in a policy all disciplines who may have access to the medical records.

MR.9.2 Care providers have access to current and past medical records.

MR.9.3 Medical records are readily retrievable for each patient encounter.

MR.9.4 Medical records are available within thirty minutes of being requested.

MR.9.5 Medical records can be retrieved any time of the day.

MR.10 **Medical records are consistently organized.**

MR.10.1 Individual medical records are securely compiled.

MR.10.2 Medical records are organized into sections. (e.g., a section for test results, operative reports, consultations, discharge summary).

MR.10.3 The different sections of the medical record are organized chronologically (e.g., the physician orders start with the initial set written when the patient was admitted to the hospital and end with the discharge order).

MR.10.4 During each hospitalization episode, both in-patient and outpatient medical records are separated into different sections in the patients' medical record (e.g., for doctors' orders, nursing notes, progress notes).

MR.11 **The hospital has a system to manage voluminous medical records.**

MR.11.1 There is a system that enables medical record linkage.

MR.11.2 When the medical record is divided into volumes, the number of each volume should be clearly visible on the folder and on the sign-out slip (e.g., "Volume 1 of 2", "Volume 2 of 2,").

MR.11.3 When the hospital practices thinning of voluminous medical records:

MR.11.3.1 The hospital develops thinning guidelines that remain consistent for the type of documentation contained.

MR.11.3.2 The hospital retains documentation in the medical record that reflects the current plan of care and services provided.

MR.11.3.3 The hospital removes parts of the medical record older than a certain date and moves them into a secondary record (the overflow record).

MR.12 **The hospital has a system for the retention of medical records in accordance with laws and regulations.**

MR.12.1 The hospital has a policy on the retention of medical records.

MR.12.2 The policy is consistent with laws and regulations.

MR.12.2.1 The medical records are retained for a minimum of five years after the patient was last seen unless otherwise specified by laws and regulations. For minors, records shall be kept until he/she is eighteen years of age, and then for a minimum additional five years.

MR.12.2.2 The policy addresses the retention period of the different types of the medical records as well as the permanent types (e.g., records of medico-legal cases).

MR.12.2.3 The policy addresses the retention period of the different parts of the medical records as well as the permanent parts (master patient index, admission and discharge dates, name of the most responsible physician, diseases treated and operations performed; and a discharge summary for each admission).

MR.12.3 The method used for medical records destruction, when the retention period is complete, renders the information unreadable.

MR.13 There is a policy that outlines how the medical records are stored.

MR.13.1 The policy addresses how the medical records are protected from loss, theft and deliberate alterations or destruction.

MR.13.2 The procedures for protection of medical records are implemented.

MR.13.3 The policy addresses how confidentiality, integrity, and security of the records will be maintained during storage.

MR.14 The hospital develops and implements a policy for the release of medical records from the medical records department.

MR.14.1 There is a policy that describes the process for the release of medical records for patient care encounters (inpatient, outpatient, and emergency department).

MR.14.2 The hospital determines when to release medical records for reasons not related to direct patient care (e.g., research, utilization management, quality improvement, morbidity and mortality, and governmental requests).

MR.14.3 The hospital has an approval mechanism for the release of medical records for reasons not related to patient care .The approval mechanism is implemented.

MR.15 The hospital has a system for tracking of medical records.

MR.15.1 There is a medical records tracking system to identify the location of any record not in the medical records department and its date and time of movement as well as subsequent movements, when applicable.

MR.15.2 The medical records tracking system includes all components of the medical records.

MR.16 The hospital uses standardized forms in medical records.

MR.16.1 The hospital uses standardized forms in medical records, generated based on hospital needs and the needs of healthcare professionals.

MR.16.2 The hospital assigns a structure to control the development of medical records forms (e.g., a forms committee or the medical records review committee).

MR.17 **The hospital has a system in place for monitoring completion of medical records.**

MR.17.1 The medical records are reviewed on an ongoing basis (e.g., monthly or quarterly).

MR.17.2 The review includes a representative sample.

MR.17.3 The review is conducted by care providers authorized to make entries in medical records.

MR.17.4 The review process focuses on the appropriate and comprehensive documentation, timeliness, and legibility.

MR.17.5 Data collected are analyzed and corrective actions are taken.

Infection Prevention and Control (IPC)

Introduction

The hospital requires processes in place to support the prevention and control of infections that might be acquired or transmitted by patients, staff, and visitors while in the hospital. These processes reduce risk and spread of infection and ensure that care is provided in a clean environment. To ensure staff and patient safety, the hospital needs an effective organization-wide infection prevention and control program that identifies, reduces and eliminates risks for infection.

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

- Infection control program
- Staff education
- Personal protective equipment
- Hand hygiene
- Sharps safety
- Cleaning, decontamination, disinfection, and sterilization
- Healthcare-associated infections
- Employees health
- Blood exposure
- Communicable diseases
- Waste management
- Laundry
- Infection control precautions during renovations and constructions

STANDARDS

IPC.1 Hospital leaders support an infection prevention and control program.

IPC.1.1 Hospital leaders allocate adequate resources such as equipment and supplies for the support of the infection prevention and control program.

IPC.1.2 Information management system supports the infection prevention and control program.

IPC.1.3 When some infection prevention and control functions are outsourced (e.g., sterilization or laundry), the hospital provides oversight and management of the contract through the process described in the "Leadership" chapter in this manual.

IPC.2 There is a qualified professional responsible for directing the infection prevention and control program.

IPC.2.1 The infection prevention and control Program is supervised by a healthcare professional qualified by education, training and experience.

IPC.2.2 The supervisor of the infection prevention and control program reports to the hospital leadership.

IPC.2.3 The supervisor of the infection prevention and control program is responsible for managing and strategizing the infection prevention and control program, including:

- IPC.2.3.1 Developing the annual infection prevention and control plan and assuring its implementation.
- IPC.2.3.2 Reviewing the daily activities of the structure responsible for infection prevention and control (e.g., infection prevention and control department or team).
- IPC.2.3.3 Ensuring coordination of all aspects of the infection prevention and control activities.
- IPC.2.3.4 Ensuring effective implementation of infection prevention and control policies.
- IPC.2.3.5 Ensuring that healthcare associated infection surveillance is conducted in a systematic manner.
- IPC.2.3.6 Providing ongoing consultation to all hospital departments.

IPC.3 The hospital has an infection prevention and control structure (e.g., department, team) with adequate qualified staff, based on its size, level of risks, and program scope and complexity.

IPC.3.1 At least one full time infection prevention and control practitioner is assigned per hundred beds (including emergency beds, dental chairs, day case, dialysis and others).

- IPC.3.1.1 An additional ratio of one infection prevention and control practitioner per thirty intensive care beds is considered where ventilation and hemodynamic monitoring are routinely performed.
- IPC.3.1.2 An additional ratio of one infection prevention and control practitioner per one hundred twenty patients dialyzed per day.

IPC.3.2 The infection prevention and control practitioners are qualified in infection prevention and control practices by education (physician, registered nurse, or certified professional in infection prevention and control), training or experience.

IPC.3.3 The infection prevention and control practitioners acquire and maintain current knowledge and skills in the field of infection prevention and control and epidemiology.

IPC.4 **ESR**

There is a designated multidisciplinary committee that provides oversight of the infection prevention and control program.

IPC.4.1 The infection prevention and control committee is chaired by the hospital director or the medical director.

IPC.4.2 The membership of the infection prevention and control committee includes representatives from the medical staff, nursing staff, microbiology, operating room, central sterilization service, pharmaceutical care, dietary services, housekeeping, infection prevention and control staff, and other departments as needed.

IPC.4.3 The infection prevention and control committee meets on a regular basis (at least quarterly).

IPC.4.4 Functions of the infection prevention and control committee include, but are not limited to, the following:

- IPC.4.4.1 Review of the hospital infection prevention and control policies and procedures.
- IPC.4.4.2 Review of the reports of healthcare-associated infections surveillance submitted regularly by the infection prevention and control team and suggestion of appropriate actions.
- IPC.4.4.3 Revision of the yearly plan submitted by infection prevention and control team and suggestion of additions/changes if necessary.
- IPC.4.4.4 Evaluates and revises on a continuous basis the procedures & the mechanisms developed by the infection prevention & control team to serve established standards and goals.
- IPC.4.4.5 Brings to the attention of the infection prevention & control team new infection control issues arising in different departments of the hospital & suggests solutions.
- IPC.4.4.6 Each member of the committee acts as an advocate of infection prevention & control in his department, trying to promote its principles, and ensures application of its rules.

IPC.5

The hospital designs and implements a coordinated program to reduce the risk of healthcare-associated infections (HAIs) in patients, visitors, and healthcare workers.

IPC.5.1 There is a program to reduce the risk of healthcare-associated infections which involves patients, families, staff, volunteers, trainees and visitors.

IPC.5.2 The program applies to all areas of the hospital.

IPC.5.3 The program is guided by an annual infection prevention and control plan.

IPC.5.4 The program addresses the unique situations of the hospital and its community such as patient populations, complexity of care provided, climate, and location.

IPC.5.5 The infection prevention and control program is based on:

- IPC.5.5.1 Risk assessment.
- IPC.5.5.2 Current scientific knowledge.
- IPC.5.5.3 Referenced practice guidelines.
- IPC.5.5.4 Applicable laws and regulations.

IPC.6 The hospital has an infection prevention and control annual plan.

IPC.6.1 The hospital has infection prevention and control annual plan that addresses the epidemiologically important infections, processes, and devices that are associated with risk of healthcare-associated infections as identified by the hospital.

IPC.6.2 The plan includes measures for patient safety (standard precautions, transmission based isolation, different care bundles).

IPC.6.3 The plan includes measures for staff safety (e.g., staff immunization and post exposure management).

IPC.6.4 The plan includes measures for staff, and patient/family education.

IPC.6.5 The plan is evaluated and approved annually by the infection prevention and control committee.

IPC.6.6 The plan includes metrics of required changes in targets and goals to reduce hospital acquired infections.

IPC.7 Policies and procedures guide the infection prevention and control program.

IPC.7.1 Infection prevention and control policies and procedures are developed by the infection prevention and control staff and approved by the infection prevention and control committee.

IPC.7.2 Infection prevention and control policies and procedures are collaboratively developed with medical staff, nursing staff, and other internal and external relevant stakeholders.

IPC.7.3 Infection prevention and control policies and procedures are organized in one manual.

IPC.7.4 The infection prevention and control manual is readily available to all relevant staff and in all patient care areas.

IPC.8 The hospital provides continuing education on infection prevention and control practices to staff, patients, families, and other caregivers as indicated by their involvement in the care process.

IPC.8.1 The hospital provides continuing education for relevant staff on:

IPC.8.1.1 Hospital wide policies, procedures, and practices of the infection prevention and control program.

IPC.8.1.2 Departmental policies, procedures, and practices of the infection prevention and control program based on the service provided.

IPC.8.2 The hospital provides education on infection prevention and control to patients, families, and other caregivers as appropriate.

IPC.8.3 New staff receive an orientation to the hospital's infection prevention and control policies and procedures upon hiring. Training records are maintained in their files.

IPC.9 There is a continuous surveillance of healthcare-associated infections.

IPC.9.1 There are policies and procedures which define the types of surveillance to be carried out with regard to healthcare-associated infections.

IPC.9.2 There are written standardized definitions for identification of healthcare-associated infections.

IPC.9.3 The policies and procedures define how data will be collected, analyzed, and used.

IPC.9.4 The monitoring process includes using indicators related to infection issues that are epidemiologically important to the hospital.

IPC.10 Results of healthcare-associated infections surveillance are integrated into the hospital's quality improvement program.

IPC.10.1 The hospital selects indicators based on the projected use of data (internal and external benchmarking).

IPC.10.2 The hospital defines the data collection methods and sources (e.g., hospital information system, verbal and written communication, medical record review, direct observation and review of clinical indicators).

IPC.10.3 The results of infection monitoring in the hospital are regularly communicated to staff, physicians, and management.

IPC.10.4 The hospital uses risk, rate, and trend information to design or modify processes to reduce healthcare-associated infections to the lowest possible level.

IPC.10.5 The hospital makes the necessary improvements for the identified epidemiologically important infections, processes, and devices that are associated with risk of healthcare-associated infections.

IPC.11 The hospital designs and implements a comprehensive system for investigation and management of outbreaks of infectious diseases.

IPC.11.1 There is a policy and procedure that guides staff for investigation and control of outbreaks of infectious diseases.

IPC.11.2 The policy defines how an outbreak is determined.

IPC.11.3 The infection prevention and control team leads the investigation and control of outbreaks of infectious diseases.

IPC.11.4 The results of investigation of an outbreak are used to prevent recurrence.

IPC.12 The hospital implements a comprehensive program for preventing and managing sharp injuries.

IPC.12.1 There is a policy and procedure that addresses handling of sharps.

IPC.12.2 Needles are not bent, broken, or recapped except in special and approved circumstances (if recapping is necessary, the "scoop method" is used).

IPC.13 Sharps are discarded in appropriate containers.

IPC.13.1 Sharp boxes used are puncture-proof, leak-proof, and present no risk to staff or patients.

IPC.13.2 Sufficient number of sharp boxes is available in patient care areas (ideally one per patient's room or at least one per procedure trolley).

IPC.13.3 Sharp boxes are available in appropriate size according to the size of sharps used.

IPC.13.4 Sharp boxes are properly used: not overfilled, not opened to transfer sharps into other containers, and mounted at or below eye level.

IPC.13.5 Sharp boxes are disposed in accordance to laws and regulations when their contents are 3/4 of their sizes and/or when an odor arises.

IPC.14 There is a system that separates patients with communicable diseases and those who are colonized or infected with epidemiologically important organisms.

IPC.14.1 There are policies and procedures that address standard and transmission-based precautions.

IPC.14.1.1 The policies and procedures address separating patients with communicable diseases and those who are colonized or infected with epidemiologically important organisms from other patients, staff, and visitors.

IPC.14.2 The transfer of patient outbound or inbound should secure the prevention of spread of Methicillin-resistant staphylococcus aureus (MRSA) or other epidemiologically significant organisms.

IPC.14.2.1 All patients for transfer outbound known to have MRSA or other epidemiologically significant organisms must be reported upon requesting the transfer with the supporting document.

IPC.14.2.2 All patients transferred to the hospital must be kept under contact transmission-based precaution unless proving otherwise.

IPC.15 Facility design and available supplies support isolation practices.

ESR

IPC.15.1 There is at least one negative pressure airborne isolation room in the emergency room and one in patient care areas (one negative pressure room for every 25-30 beds in general hospitals).

IPC.15.2 The infection prevention and control team decides the need for more airborne isolation rooms depending on the volume of patients in need for airborne isolation admitted to the hospital.

IPC.15.3 The ventilation system serving airborne isolation facilities provides pressure patterns that prevent airborne pathogens from being distributed to other areas of the hospital.

IPC.15.3.1 Rooms designed for airborne isolation patients are under negative pressure.

IPC.15.3.2 Air is exhausted to the outside and is not re-circulated unless it is filtered through High-Efficiency Particulate Air (HEPA) Filter.

IPC.15.3.3 There is evidence of daily air exchange monitoring (12 air changes per hour) when a patient is isolated. Weekly monitoring of the air exchange is needed when no patient is isolated.

IPC.15.4 The entry of the isolation room is through a work area or ante-room that serves as a site for hand washing, gowning and storage of protective clothing (gloves, aprons, masks).

IPC.15.5 Toilet, shower, or tub and hand washing facilities are provided for each isolation room.

IPC.15.6 Transmission-based precaution cards (isolation signs) are consistent with the patient diagnosis and are posted in Arabic and English and indicate the type of precautions required.

IPC.15.6.1 Transmission-based precaution cards (isolation signs) are color coded for isolation of different categories (e.g., contact: green, airborne: blue, droplet: pink or red).

IPC.15.6.2 Transmission-based precaution cards (isolation signs) should contain short statements and supported with the required figures.

IPC.15.6.3 Isolation instructions must highlight the transmission-based precaution cards (isolation signs) needed while transporting the patients under transmission-based precautions to other department (e.g., radiology).

IPC.15.7 Respirator (high filtration) masks (N-95, N-99) are used by staff during direct care of patients on airborne precautions and are available on all units likely to admit patients on airborne precautions.

IPC.15.8 Respirator (high filtration) masks (N95, N-99) can be reused by the same patient care giver as per the period specified by the manufacturer.

IPC.16 Disinfectants use is supervised by the infection prevention and control team.

IPC.16.1 The purchase of equipment and supplies used for sterilization and disinfection is reviewed by the infection prevention and control team.

IPC.16.2 Antiseptics and disinfectants are used in accordance with current scientific guidelines and recommended practice (e.g., approved by recognized professional organizations such as the Food and Drug Administration and Environmental Protection Agency).

IPC.17 The hospital ensures environmental safety when disinfectants are used outside the central sterilization service.

IPC.17.1 In endoscopy units, a proper approved disinfectant is used in a way to protect the patient, the staff and the environment from possible infectious hazard.

IPC.17.1.1 The procedure room and the decontamination room are physically separated and the decontamination room has infection control requirements to prevent spread of infection to healthcare workers and to patients.

IPC.17.1.2 Appropriate personal protective equipment (respirator, gloves: nitrile or butyl rubber, goggles and gowns) are used.

IPC.17.1.3 Unauthorized persons are not allowed in the processing area.

IPC.17.1.4 Well closed containers are used to keep the disinfectant solution.

IPC.17.1.5 A policy and procedure is implemented on how the endoscope is processed (cleaning, decontamination, and disinfection) between patients.

IPC.17.1.6 Endoscopes are cleaned with disposable brushes or with reusable brushes that are sterilized after every use. Heat-stable parts and accessories of the endoscopes such as biopsy forceps are cleaned by mechanical cleaners and stabilized after use.

IPC.17.1.7 Quality tests (strips or other method) used to confirm the stability of the disinfectant are performed every day and records are maintained.

IPC.17.2 For bronchoscopy, the following is applied:

IPC.17.2.1 Bronchoscopy is performed in a room with negative air pressure and at least twelve air changes per hour. Personal protective equipment are available including N-95/N-99 masks.

IPC.17.2.2 Cleaning of the bronchoscopes begins immediately after the procedure to prevent drying or hardening of organic debris.

IPC.17.2.3 Bronchoscopes are disinfected as per manufacturer's recommendation.

IPC.18 The hospital ensures efficient and quality sterilization service.

IPC.18.1 The hospital provides central sterilization service.

IPC.18.2 There are policies and procedures for the central sterilization service.

IPC.18.2.1 The policies and procedures are consistent with scientific guidelines.

IPC.18.2.2 The policies and procedures are reviewed and approved by the infection prevention and control committee.

IPC.18.2.3 There are policies and procedures on transportation, cleansing, decontamination, disinfection, sterilization, storage, and recall of sterile items.

IPC.18.3 Contaminated items are transported in safe closed containers with biohazards sign from the outside to prevent spills or aerosolization of infectious fluids.

IPC.19 Central sterilization service staff are qualified by education, certification, or training in the field of sterilization and disinfection.

IPC.19.1 The supervisor of the central sterilization service has experience, knowledge, and certification in sterilization practice and is registered with the Saudi Commission for Health Specialties as a central sterilization service technician.

IPC.19.2 Central sterilization service staff are qualified by education, certification, or training in the field of sterilization and disinfection.

IPC.19.3 Staff are able to explain the sterilizers' operation and to name the main parameters to be followed: sterilization time, temperature, and pressure.

IPC.19.4 Proper sterilization parameters are recorded.

IPC.19.4.1 Records include load list, daily function test, spore test results, lot number, and name of operator.

IPC.19.4.2 Sterilization records are kept for one year to allow inspection.

IPC.19.5 Sterilization time and temperature cycles used are in accordance with the manufacturer's guidelines.

IPC.20 The central sterilization service design supports its functions.

IPC.20.1 There is a uni-directional flow of traffic from dirty to clean areas (i.e. decontamination area ? packing ? sterilization ? storage areas).

IPC.20.2 Traffic control signs are in place.

IPC.20.3 The decontamination area is under negative pressure with exhaust to the outside; the clean area is under positive pressure with at least ten air cycles/hour.

IPC.20.4 There is complete physical separation between the decontamination area, the area where clean items are packaged and sterilized, and the area were sterilized items are stored.

IPC.21 The central sterilization service has measures to ensure staff safety and proper function.

IPC.21.1 Personal protective equipment are available and used during decontamination (heavy-duty gloves, waterproof aprons, facemask, plastic durable boots and goggles or face shield).

IPC.21.2 If manual cleaning is performed, at least two sinks are used, one for soaking and cleaning and one for rinsing before the final wash.

IPC.21.3 The cleansing brushes are disposable. When the cleansing brushes are auto-clavable, the manufacturer's instructions are followed and the brushes are replaced when needed.

IPC.21.4 Staff inspect instrument after cleansing to ensure that they are in good practical condition and fit to be used.

IPC.21.5 Sterilizers are in good working order. Instructions on sterilizers' use are available.

IPC.21.6 Preventive maintenance records for sterilizers are available and clearly show the maintenance history of the sterilizers.

IPC.21.7 Chemical indicators are used in every package. Biological indicators are used at least weekly. Records of results are kept for one year.

IPC.21.8 Use of flash steam sterilizer is limited to urgent situations which preclude use of other sterilizer methods. This use is closely monitored and recorded. Policies in this regard are reviewed by central sterilization service staff.

IPC.21.9 Where ethylene oxide is used, safety and health hazards are addressed.

IPC.22 The hospital ensures safe reprocessing of single use items.

IPC.22.1 The hospital implements a policy and procedure regarding reprocessing of single use items. The policy defines the following:

IPC.22.1.1 The items that can be reused.

IPC.22.1.2 Patients and conditions for reuse of single-use items.

IPC.22.1.3 Measures taken to ensure safety and integrity including testing and maintenance by biomedical engineering.

IPC.22.1.4 Manufacturer approval as a prerequisite, whenever applicable.

IPC.22.2 The policy is approved by the infection prevention and control committee and hospital director.

IPC.22.3 Justification of reprocessing is provided by the head(s) of the concerned department(s).

IPC.23 The hospital has policies and procedures for housekeeping.

IPC.23.1 The housekeeping has policies and procedures that describe the areas to be cleaned, the schedule for cleaning, and the procedures to be used for cleaning different environmental surfaces.

IPC.23.2 Policies and procedures, schedules, and agents utilized are reviewed by infection prevention and control staff.

IPC.23.3 All units have a cleaning/ disinfection schedule which lists all environmental surfaces to be cleaned.

IPC.24 The hospital environment is kept clean.

IPC.24.1 Hospital environment, lockers, and cabinets are clean.

IPC.24.2 Food is stored under sanitary conditions and is consumed in designated places.

IPC.24.3 Food refrigerators are clean and are used only for food storage.

IPC.24.4 There are separate clean and dirty utility areas in each patient care area.

IPC.24.5 There are policies and procedures on pest control that address the regular schedule for pest control, chemical list, and time and place of exposure.

IPC.24.6 Routine environmental microbiological cultures are not performed unless recommended by the infection prevention and control team.

IPC.25 There is a system to handle blood/body fluids spills.

IPC.25.1 The hospital implements a policy on blood/body fluids spill kit use.

IPC.25.2 Blood spill kits are available in all patient care units, including all necessary components. Hospital staff working in patient care areas are capable of cleaning of blood/body fluids spills.

IPC.26 The hospital implements a program that is consistent with laws and regulations for safe disposal of medical waste.

IPC.26.1 There is a policy and procedure for safe disposal of medical waste.

IPC.26.2 Medical waste is disposed by specialized company and includes all types of medical waste.

IPC.26.3 Medical waste segregation, collection, and storing is conducted as per applicable laws and regulations.

IPC.26.4 Yellow bags are used for all non-sharp disposable materials contaminated with patient's blood and/or body fluids.

IPC.26.5 Yellow bags are distributed in the hospital in sufficient number and location.

IPC.26.6 Red bags are used for tissues, body parts, and amputated parts to be saved and then collected by the municipality to be buried.

IPC.26.7 Medical waste containers are cleaned and maintained regularly.

IPC.26.8 Hazard signs are fixed on all medical waste containers.

IPC.26.9 Medical waste collection points are cleaned and maintained regularly.

IPC.26.10 Labor working in medical disposal are well trained and vaccinated against blood borne pathogens.

IPC.27 The mortuary and postmortem area are supervised by infection prevention and control.

IPC.27.1 There are written policies on how to handle bodies post mortem especially bodies that have multiple open wounds.

IPC.27.2 The temperature of the morgue is kept at 2-4°C and logged daily.

IPC.27.3 For long term preservation of dead bodies, the facility must provide a deep freezing compartment (temp < -15°C).

IPC.27.4 The morgue is regularly cleaned and disinfected.

IPC.28 Kitchen environment and functions are supervised by infection prevention and control.

IPC.28.1 Kitchen design supports its function.

IPC.28.2 Kitchen areas are separated based on assigned function. (Separate area for vegetables, meat, desert preparation, etc.).

IPC.28.3 Adequate number of hand washing facilities are present in each area.

IPC.28.4 Food containers are properly labeled and expiry dates noted.

IPC.28.5 Temperature requirements are met during storage, preparation, and transportation.

IPC.28.6 Food is protected from environment during storage, preparation, display, and transportation.

IPC.28.7 Garbage containers or receptacles are adequate in number, insect and rodent proof, and are covered.

IPC.28.8 Refrigerator temperatures are checked daily and documented on log sheets.

IPC.28.9 Kitchen environment is clean.

IPC.28.10 The kitchen environment and functions are addressed in policies and procedures that are reviewed by the infection prevention and control team.

IPC.28.11 Food delivery to the receiving area must be checked for quality and temperature.

IPC.28.12 Fruits and vegetables are washed and disinfected thoroughly.

IPC.28.13 Food containers are washed immediately after being emptied from food.

IPC.28.14 Boards used to cut meat, poultry, chicken, or vegetables are identifiably separated and immediately washed after use.

IPC.29 Kitchen staff hygiene and health are supervised by infection prevention and control.

IPC.29.1 There are policies and procedures that address staff hygiene and health in the kitchen and are reviewed by infection prevention and control team.

IPC.29.2 While handling food, hands are washed, hair is covered, and gloves are worn.

IPC.29.3 Personnel with respiratory infections or gastroenteritis are restricted from handling food.

IPC.29.4 Stool tests and cultures are performed routinely upon hiring, every six months, and after returning back from vacation.

IPC.29.5 Results of stool analysis and cultures are reviewed by the infection prevention and control practitioner.

IPC.30 Laundry functions are supervised by infection prevention and control team.

IPC.30.1 There are policies and procedures on linen management that cover all steps starting from collecting linen from patients' rooms until completion of the cleaning process.

IPC.30.2 Clean linen is transported, handled, and stored in a way that keeps it protected from contamination and dust.

IPC.30.3 Clean and used linen are separated during storage and transport.

IPC.30.4 Linen carts used for clean and used linen are clearly identified.

IPC.30.5 Loose (un-bagged) linen is not to be put down a laundry chute.

IPC.30.6 Hand washing facilities are located in all areas where un-bagged linen is handled.

IPC.30.7 Soiled linen (contaminated with patient's blood, excreta, or other body fluids) and linen from patients under isolation precautions are contained and transported in accordance with current professional standards:

- IPC.30.7.1 Soiled linen must be handled as little as possible and with minimal agitation.
- IPC.30.7.2 Appropriate barriers (gloves, gowns, and masks) should be used when handling soiled linen.
- IPC.30.7.3 Linen is bagged at the location where it is used and is not stored or pre-rinsed in patient's care areas.
- IPC.30.7.4 Linen is put into special color-coded and water-proof laundry bags.

IPC.30.8 Laundry functions are supervised by the infection prevention and control team.

IPC.31 The infection prevention and control team reviews and supervises construction projects in the hospital.

IPC.31.1 There are policies that address infection prevention and control considerations during demolition, renovation, and construction projects.

IPC.31.2 There is a mechanism to ensure involvement of infection prevention and control team prior to any demolition, renovation, and construction projects.

IPC.31.3 Accepted infection prevention & control measures are followed during any demolition, renovation & construction projects e.g. infection control risk assessment (ICRA).

IPC.32 Personal protective equipment use is supervised by infection prevention and control team.

IPC.32.1 Personal protective equipment (gown, gloves, masks, and protective eyewear) are readily available in all patient care areas.

IPC.32.2 Policies and procedures are available on the appropriate use of gloves, gowns, facemasks, protective eyewear, and high filtration respirator masks (N-95, N-99).

IPC.32.3 Proper training for the use of personal protective equipment is conducted.

IPC.33 The hospital supports appropriate hand hygiene practices.

IPC.33.1 The hospital develops policies and procedures on the proper hand hygiene practices.

IPC.33.2 Hand hygiene is practiced according to the relevant policies.

IPC.33.3 Compliance with hand hygiene is regularly monitored.

IPC.34 The hospital provides sufficient hand hygiene facilities.

IPC.34.1 Toilets, hand washing, and bathing facilities meet the needs of the hospital and are clean and in good repair.

IPC.34.2 Hand washing sinks are available in all patients' rooms (including clinics and emergency rooms) and nursing stations.

IPC.34.3 Hand washing sinks and bathing facilities are supplied with hot and cold water under pressure.

IPC.34.4 Hand washing sinks are conveniently accessible to staff.

IPC.34.5 Antiseptic soap and towels are available for hand washing.

IPC.34.6 Hand disinfectants are available in adequate number (one dispenser per patients room in general wards and clinics, one per bed in critical care areas and emergency rooms, and one in every nursing station).

IPC.35 The hospital reports communicable diseases to the relevant authorities.

IPC.35.1 Communicable diseases are timely reported internally to the infection prevention and control team by the treating team.

IPC.35.2 The hospital reports communicable diseases to the Ministry of Health in accordance with laws and regulations and to other authorities whenever required.

IPC.36 There are policies and procedures that address employees' immunization and post exposure management.

IPC.36.1 There is a structure (e.g., staff health clinic) that provides pre-employment counseling and medical services related to screening, immunization, and post exposure management.

IPC.36.2 Employees' immunization and post exposure management are addressed in written policies and procedures.

IPC.36.3 Employees' immunization and post exposure management are consistent with laws and regulations and recommendations of professional organizations.

IPC.36.4 All employees have baseline screening for hepatitis B, C, HIV, and tuberculosis.

IPC.36.5 The immune status of newly hired staff against hepatitis B, measles, mumps, rubella, and varicella is determined by serological testing. Appropriate vaccine(s) is administered to those who are susceptible.

IPC.36.6 Response to hepatitis B vaccination is monitored in vaccinated employees four weeks after completing vaccine series. Non-responders to hepatitis B vaccine are offered at least a second series of the vaccine.

IPC.36.7 Newly hired staff are screened for tuberculosis upon contracting with PPD test, and the test is repeated annually for those who are non-reactive.

IPC.36.8 PPD conversion rates are calculated and monitored.

IPC.36.9 There is a system for reporting, follow up and management of exposure to open pulmonary TB and vaccine-preventable viruses: chickenpox, measles, mumps, and rubella.

IPC.36.10 There is a system for reporting, follow up, and management of needle prick and sharp injuries.

IPC.36.11 The infection prevention and control team regularly monitors exposure of staff to pathogens and take corrective actions to prevent recurrence.

IPC.36.12 The screening, immunization, and post exposure management data are kept in staff medical records.

IPC.37 The hospital develops an anti-biogram that is regularly reviewed.

IPC.37.1 The anti-biogram is prepared at least once yearly.

IPC.37.2 The anti-biogram is regularly discussed by infection prevention and control committee.

IPC.38 The hospital adopts safe injection practices that minimize or prevent transmission of infection.

IPC.38.1 Staff use aseptic technique for injections preparation.

IPC.38.2 Staff use sterile syringes and needles.

IPC.38.3 Staff use single-dose vials as appropriate.

IPC.38.4 Staff use mask during injecting a medicine or placing a catheter into a spinal place.

IPC.39 The hospital implements evidence-based interventions to prevent ventilator–associated pneumonia.

IPC.39.1 The hospital adopts and implements care bundle for prevention of ventilator-associated pneumonia (VAP) consistent with recognized professional practices

IPC.39.2 Data on the care bundle for prevention of ventilator-associated pneumonia are regularly collected, analyzed, and evaluated. Improvement interventions are taken accordingly.

IPC.40 The hospital implements evidence-based interventions to prevent surgical site infection.

IPC.40.1 The hospital adopts and implements care bundle for prevention of surgical site infection consistent with recognized professional practices.

IPC.40.2 Data on the care bundle for prevention of surgical site infection are regularly collected, analyzed, and evaluated. Improvement interventions are taken accordingly

IPC.41 The hospital implements evidence-based interventions to prevent catheter-associated urinary tract infection.

IPC.41.1 The hospital adopts and implements care bundle for prevention of catheter-associated urinary tract infection consistent with recognized professional practices.

IPC.41.2 Data on the care bundle for prevention of catheter-associated urinary tract infection are regularly collected, analyzed, and evaluated. Improvement interventions are taken accordingly.

IPC.42 The hospital implements evidence-based interventions to prevent central intravascular catheter-associated blood stream infection. scular catheter-associated blood stream infection are regularly collected, analyzed, and evaluated. Improvement interventions are taken accordingly.

IPC.42.1 The hospital adopts and implements care bundle for prevention of central intravascular catheter-associated blood stream infection consistent with recognized professional practices.

IPC.42.2 Data on the care bundle for prevention of central intravascular catheter-associated blood stream infection are regularly collected, analyzed, and evaluated. Improvement interventions are taken accordingly.

IPC.43 The hospital implements evidence-based interventions to reduce the burden of epidemiologically significant organisms.

IPC.43.1 The hospital adopts and implements care bundle for prevention of Multidrug Resistant Organisms (MDROs) consistent with recognized professional practices.

IPC.43.2 Data on the care bundle for prevention of Multidrug Resistant Organisms (MDROs) are regularly collected, analyzed, and evaluated. Improvement interventions are taken accordingly.

IPC.44 Staff accommodation is healthy.

IPC.44.1 Staff accommodation is clean, well ventilated, not overcrowded, well maintained, and free from pets.

IPC.44.2 Staff accommodation provides facilities for staff isolated or restricted from work due to infection issues.

Medication Management (MM)

Introduction

Medication management is an important part of the preventive, curative and palliative treatment of many diseases and conditions that are dealt with by healthcare professionals in hospitals. Medication safety is becoming a priority in all safety programs because the magnitude of harm that can be caused by wrong medication or wrong dose is great and many sentinel events occurring in hospitals today are actually medications-related. To eliminate any potential harm that could be caused by medications, hospitals need to develop their own medication management systems that fulfill two important components: effectiveness and safety.

This chapter outlines the requirements for the following processes and activities related to medication management:

- Staff planning and qualifications
- Staff education
- Selection and procuring of medications
- Storage
- Ordering
- Preparing and dispensing
- Administration
- Monitoring and evaluation
- Using evidence-based practices to develop safe medication management processes
- Reducing variations, errors and misuse
- Reporting of medication errors

STANDARDS

MM.1 Patient specific information is readily accessible to all healthcare professionals involved in the medication management system.

MM.1.1 The hospital has a multidisciplinary policy and procedure on patient specific information to be readily accessible to all healthcare professionals. The information includes, but is not limited to, the following:

- MM.1.1.1 Patient's age and sex.
- MM.1.1.2 Current medications.
- MM.1.1.3 Diagnoses, co-morbidities.
- MM.1.1.4 Laboratory values.
- MM.1.1.5 Allergies.
- MM.1.1.6 Body weight and height.
- MM.1.1.7 Pregnancy and lactation status.

MM.1.2 Except in emergency situations, patient specific information is accessible when needed to all healthcare professionals involved in the medication management system.

MM.2 The pharmaceutical care department has a clear organizational structure and is directed by a qualified pharmacist.

MM.2.1 The pharmaceutical care department has a clear organizational structure.

MM.2.2 The head of pharmaceutical care is a licensed pharmacist, qualified by education, training, and experience.

MM.2.3 The head of pharmaceutical care has a valid professional registration with the Saudi Commission of Health Specialties and Ministry of Health practice license in Saudi Arabia, as applicable.

MM.2.4 The authorities and accountabilities of the head of the pharmaceutical care is clearly delineated in a job description and updated every three years.

MM.3 The pharmaceutical care department has adequate number of qualified staff.

MM.3.1 The pharmaceutical care department has adequate number of staff qualified by education, training, and experience.

MM.3.2 There is a current staffing plan based on work load statistics that ensures availability of sufficient staff resources to deliver the service.

MM.3.3 The staff responsible for intravenous admixtures, parenteral nutrition, chemotherapy, and drug information services have appropriate training and competency assessment.

MM.3.4 The quality coordinator has appropriate certification/training.

MM.3.5 There is a structured orientation program where new staff are briefed on pharmaceutical care and relevant aspects of the facility to prepare them for their roles and responsibilities.

MM.3.6 There is a process to ensure that the new employee's competency is evaluated before allowed to work independently.

MM.3.7 There are continuing professional development activities for all pharmaceutical care staff.

MM.4 The pharmaceutical care and medication use in the hospital are well planned and comply with laws and regulations of relevant authorities and the Saudi Food and Drug Authority (SFDA).

MM.4.1 Organization and management of medications throughout the hospital (procurement, storage, prescribing, preparing and dispensing, administration, and monitoring) are guided by clear multidisciplinary plan or policy.

MM.4.2 Policies and procedures are developed in collaboration with relevant staff, such as medical, nursing, and management staff.

MM.4.3 Updated policies and procedures manual is readily accessible to all healthcare professionals involved in medication use.

MM.4.4 Appropriate sources of drug information are readily available to all healthcare professionals involved in medication use. (e.g., books, manuals, CDs/DVDs, online subscription to drug information resources).

MM.4.5 The pharmaceutical care services are provided twenty four hours a day, seven days a week for inpatients and emergency patients.

MM.4.6 There is a pharmacist on-call whenever the inpatient pharmacy is closed.

MM.5 The hospital has a system for the safety of high-alert medications.

ESR

MM.5.1 There is a written multidisciplinary plan for managing high-alert medications and hazardous pharmaceutical chemicals. It includes identification, location, labeling, storage, dispensing, and administration of high-alert medications.

MM.5.2 The hospital identifies an annually updated list of high-alert medications and hazardous pharmaceutical chemicals based on its own data and national and international recognized organizations (e.g., Institute of Safe Medication Practice, World Health Organization). The list contains, but is not limited to, the following:

- MM.5.2.1 Controlled and narcotics medications.
- MM.5.2.2 Neuromuscular blockers.
- MM.5.2.3 Chemotherapeutic agents.
- MM.5.2.4 Concentrated electrolytes (e.g., hypertonic sodium chloride, concentrated potassium salts).
- MM.5.2.5 Antithrombotic medications (e.g., heparin, warfarin).
- MM.5.2.6 Insulins.
- MM.5.2.7 Anesthetic medications (e.g., propofol, ketamine).
- MM.5.2.8 Investigational (research) drugs, as applicable.
- MM.5.2.9 Other medications as identified by the hospital.

MM.5.3 The hospital plan for managing high-alert medications and hazardous pharmaceutical chemicals is implemented. This includes, but is not limited to, the following:

- MM.5.3.1 Improving access to information about high-alert medications.
- MM.5.3.2 Limiting access to high-alert medications.
- MM.5.3.3 Using auxiliary labels or computerized alerts if available.
- MM.5.3.4 Standardizing the ordering, transcribing, preparation, dispensing, administration, and monitoring of high-alert medications.

MM.5.3.5 Employing independent double checks.

MM.5.4 The hospital develops and implements standard concentrations for all medications administered by intravenous infusion.

MM.6 The hospital has a system for the safety of look-alike and sound-alike (LASA) medications.

ESR

MM.6.1 There is a multidisciplinary policy and procedure on handling look- alike/sound-alike (LASA) medications.

MM.6.2 The hospital reviews and revises annually its list of confusing drug names, which include LASA medication name pairs that the hospital stores, dispenses, and administers.

MM.6.3 The hospital takes actions to prevent errors involving LASA medications including the following, as applicable:

MM.6.3.1 Providing education on LASA medications to healthcare professionals at orientation and as part of continuing education.

MM.6.3.2 Using both the brand and generic names for prescribing LASA medications.

MM.6.3.3 Writing the diagnosis/ indication of the LASA medication on the prescription.

MM.6.3.4 Changing the appearance of look-alike product package.

MM.6.3.5 Reading carefully the label each time a medication is accessed, and/or prior to administration.

MM.6.3.6 Minimizing the use of verbal and telephone orders.

MM.6.3.7 Checking the purpose/indication of the medication on the prescription prior to dispensing and administering.

MM.6.3.8 Placing LASA medications in locations separate from each other or in non-alphabetical order.

MM.7 The hospital establishes a multidisciplinary pharmacy and therapeutics committee or equivalent to provide oversight of the hospital formulary and medication use.

MM.7.1 There is a pharmacy and therapeutics committee chaired by a senior medical or pharmaceutical care staff member.

MM.7.2 There are terms of reference for the pharmacy and therapeutics committee that include committee's functions, membership, quorum, frequency of meetings, approval, and distribution of minutes.

MM.7.3 The pharmacy and therapeutics committee meets on a regular basis (at least quarterly).

MM.7.4 The meeting minutes of the committee reflects the members in attendance, items discussed, decisions reached, lead accountability assigned for action undertaken and subsequent reporting, as well as follow-up data for these activities.

MM.7.5 Functions of the pharmacy and therapeutics committee include, but are not limited to, the following:

MM.7.5.1 Serve in an evaluative, educational, and advisory capacity to the medical staff and hospital management in all matters pertaining to the use of medications.

MM.7.5.2 Develop and approve criteria for selecting medications that include at least indications, effectiveness, risks (potential for medication errors, abuse potential, and sentinel events), or cost.

MM.7.5.3 Develop a formulary of drugs accepted for use in the hospital and provide for its constant revision.

MM.7.5.4 Establish programs and procedures that help ensure safe and effective drug therapy.

MM.7.5.5 Establish programs and procedures that help ensure cost-effective drug therapy.

MM.7.5.6 Establish or plan suitable educational programs for the hospital's professional staff on matters related to drug use.

MM.7.5.7 Participate in quality improvement activities related to distribution, administration, and use of medications.

MM.7.5.8 Monitor and evaluate adverse drug events and make appropriate recommendations to prevent their recurrence.

MM.7.5.9 Establish evidence-based therapeutic guidelines according to the scope of services of the hospital (e.g., intravenous iron, intravenous immunoglobulin, albumin, heparin, chemo protocols, high alert medications, and electrolyte management guidelines).

MM.7.5.10 Initiate and/or direct drug use evaluation programs and studies, review the results of such activities, and make appropriate recommendations to optimize drug use.

MM.7.5.11 Advise the pharmaceutical care department in the implementation of effective drug distribution and control procedures.

MM.7.5.12 Disseminate information on its actions and approved recommendations to all staff.

MM.7.5.13 The committee conducts an annual review of its hospital formulary based on safety and efficacy information (e.g., Saudi FDA warnings, international medication safety alerts, hospital-based adverse drug reaction reports, and drug utilization evaluation studies).

MM.8 The hospital has an updated, structured, and well organized drug formulary.

MM.8.1 The hospital has a structured and well organized formulary that is updated annually.

MM.8.2 Healthcare professionals involved in prescribing, ordering, dispensing, administering, and patient monitoring processes are involved in developing, evaluating, updating and maintaining the hospital formulary.

MM.8.3 The hospital formulary is accessible to all those involved in medication management.

MM.8.4 The hospital formulary is properly indexed (alphabetical index for generics and trade names of drugs), and properly classified using therapeutic classification.

MM.8.5 The hospital formulary includes short drug monographs that illustrate the generic drug name, strength, and dosage form(s), indication(s), adverse drug reactions, and prescribing information.

MM.8.6 The hospital formulary provides guidance on antibiotics use (both prophylactic and therapeutic uses).

MM.8.7 The hospital formulary provides a list of approved prescribing abbreviations.

MM.8.8 The hospital formulary provides a list of prohibited prescribing abbreviations.

MM.8.9 The hospital formulary provides appendixes on important policies, therapeutic guidelines, drug safety in pregnancy and lactation, and dose adjustment in organ failure.

MM.9 The hospital has a system for procurement of medications that are not on the hospital's formulary (non-formulary medications).

MM.9.1 There is a policy and procedure for selection, approval, and procurement of non-formulary medications within an acceptable time frame.

MM.9.2 A patient-specific non-formulary drug request form is readily available.

MM.9.3 There is proper handling of non-formulary drug requisition within an acceptable time frame.

MM.9.4 There is a regular review of non-formulary drug requests by the pharmacy and therapeutics committee or an equivalent multidisciplinary body.

MM.10 The hospital has a system for handling out of stock, shortage and disaster needs of medications.

MM.10.1 The hospital implements a policy and procedure on proper communication of medication shortage and outage to prescribers and other healthcare professionals involved in medication management and obtaining medications in the event of a disaster.

MM.10.2 The pharmacy and therapeutics committee develops and approves medication substitution protocols in the event of medication shortage or outage.

MM.10.3 There is implementation of the hospital approved medication substitution protocols and staff awareness.

MM.10.4 There is a plan for emergency preparedness to respond to the special and large demand of medications during internal and external disasters. The plan is tested for effectiveness and integrated with the general hospital plan.

MM.11 The hospital has a safe and secure system for the storage of regular medications and nutrition products in stores, pharmacies, and patient care areas.

MM.11.1 There is a policy and procedure on proper storage and control of medications, nutrition products, and free medical samples (from the point of receipt until the point of administration).

MM.11.2 There is a policy and procedure to control the access of pharmaceutical care and non-pharmaceutical care staff to stores, pharmacies, and patient care areas including after hours and in case of emergency (e.g., fire, flood).

MM.11.3 There are measures in place to secure medications storage areas including limited access, proper locking procedures, and door keys handling.

MM.11.4 Only authorized individuals have access to stored medications.

MM.11.5 Medications are stored in a way to avoid mixing with labels showing the drug name and expiry date.

MM.11.6 No medications are stored directly on floor (a minimum of ten centimeters is left to manage spills). Medications are not stacked so high to block sprinklers or come in contact with overhead lights or pipes.

MM.11.7 Medications are stored according to manufacturer's recommendations (temperature, light, humidity, sanitation).

MM.11.8 There is an appropriate storage area for regular medications with controlled temperature (between 18 and 25 degrees centigrade), twenty four hours a day, seven days a week.

MM.11.9 The room air temperature is checked and documented at least once daily on the temperature log sheet.

MM.11.10 Temperature records are kept for at least three years.

MM.11.11 All antiseptics, disinfectants, and medications for external use are stored separately from enteral and injectable medications.

MM.11.12 The "first expiry/ first out" (FEFO) principle is followed.

MM.11.13 All medication storage areas are inspected at least monthly by the pharmaceutical care according to the hospital policy to ensure proper storage of medications. Inspection includes, but is not limited to: availability, stock level, expiry date, and storage conditions.

MM.11.14 Expired and damaged medications are clearly labeled and separated from other drugs until its removal and proper destruction.

MM.11.15 Medication quality issues are reported to the Saudi FDA, as required.

MM.12 The hospital has a safe and secure system for storage of refrigerated and frozen medications, biologicals, and vaccines in stores, pharmacies, and patient care areas.

MM.12.1 There is a policy and procedure on proper storage and control of refrigerated and frozen medications from the point of receipt until the point of administration.

MM.12.2 There are medication refrigerators and freezers for storing refrigerated and frozen medications, biologicals and vaccines.

MM.12.3 All medication refrigerators and freezers are equipped with appropriate thermometers or equivalent device for temperature recording.

MM.12.4 The refrigerators' temperature is checked and documented at least once daily on the temperature log sheet.

MM.12.5 The refrigerator's temperature is kept between (2-8°C).

MM.12.6 The freezer's temperature is kept between (-10 and -25°C).

MM.12.7 All vaccine refrigerators are connected to emergency power source and electric outlets are marked accordingly.

MM.12.8 Vaccine refrigerator's temperature is continuously recorded around the clock or an equivalent process is in place to monitor temperature around the clock.

MM.12.9 Temperature records are kept for at least three years.

MM.12.10 There is a clear and defined mechanism to deal with electric power outage or out-of-range temperature of the medication refrigerators and freezers to ensure the integrity of the affected medications before its reuse.

MM.12.11 Food, drinks, biological samples, and culture media are not allowed inside any medication refrigerator or freezer.

MM.13 The hospital has a safe and secure system for the storage and safe management of hazardous medications and pharmaceutical chemicals.

MM.13.1 There is a written policy on proper storage and handling of hazardous medications and pharmaceutical chemicals.

MM.13.2 The hospital has a list of hazardous medications and pharmaceutical chemicals in areas where they are stored or used.

MM.13.3 Hazardous medications and pharmaceutical chemicals are stored separately on low shelves and in the original labeled containers.

MM.13.4 Flammables and volatile substances are stored in appropriate safety cabinets in well ventilated areas.

MM.13.5 Spill kits and personal protective equipment are readily available.

MM.13.6 For staff involved in the handling of chemicals and hazardous medications (such as chemotherapeutic agents) who are attempting to conceive, pregnant, or breast feeding, a structured process is in place to review potential exposure risks and offer alternative work assignment.

MM.13.7 Material safety data sheets (MSDS) for all available hazardous medications and pharmaceutical chemicals are available and accessible to staff.

MM.13.8 Eye wash station and emergency water shower are available where hazardous medications and pharmaceutical chemicals are located.

MM.13.9 The hospital staff are well educated on the proper storage and handling of hazardous medications and pharmaceutical chemicals and spill management.

MM.14 The hospital has a system for ensuring stability of medications available in multi-dose containers.

MM.14.1 The hospital develops and maintains a set of guidelines for ensuring stability of multi-dose vials, vaccines, multi-dose oral liquids, and other multi-dose medications (e.g., eye, ear, and nasal drops, creams, ointments, nebulization solutions).

MM.14.2 The hospital ensures that all open multi-dose containers are labeled with open date, expiry date, initials, and time (if necessary).

MM.14.3 The hospital ensures that no expired open or unlabeled open multi-dose containers are available in patient care areas.

MM.15 The hospital has a system for ensuring accessibility, availability, monitoring, and security of emergency medications.

MM.15.1 The hospital develops and maintains a standardized set of guidelines for emergency drugs for crash carts and emergency medical bags in accordance with the current Saudi Heart Association recommendations.

MM.15.2 Emergency medications are available in the patient care units and readily accessible to meet emergency needs.

MM.15.3 The emergency medications in the crash carts and emergency medical bags are protected from loss or theft using safety plastic seal.

MM.15.4 Plastic seals of crash carts and emergency bags are stocked in a safe place under supervision of pharmaceutical care or nursing.

MM.15.5 There is a process in place for monitoring emergency medications and replenishing them in a timely manner after use or when expired or damaged.

MM.15.6 The hospital maintains documents of emergency medications inspection on every shift by nursing staff.

MM.15.7 The hospital maintains documents of emergency medications inspection every month by pharmaceutical care staff.

MM.16 **The hospital has a safe and secure system for managing medications in the patient care areas.**

MM.16.1 The hospital implements a multidisciplinary policy and procedure on medications assignment as floor stocks in limited quantities according to the needs of each service unit.

MM.16.2 Anesthesia reversal agents are available in operating rooms and areas where moderate or deep sedation is performed.

MM.16.3 Oxytocics are available in the labor and delivery unit.

MM.16.4 Benzodiazepine and narcotics antagonists are available in all patient care areas where benzodiazepines and narcotics are stocked.

MM.16.5 All medications in the patient care areas are well separated and properly labeled.

MM.16.6 Concentrated electrolytes are not allowed in patient care areas (unless patient safety necessitates their immediate use). All necessary precautions and separate locked cabinet with proper signage are in place to prevent inadvertent administration of concentrated electrolytes.

MM.17 **There is a system to identify all medications brought into the hospital by patients or their families.**

MM.17.1 The hospital implements a multidisciplinary policy and procedure on handling medications brought into the hospital by patients or their families (patient's own medications).

MM.17.2 Patient's own medications are checked for integrity and properly labeled if permitted for use, by a qualified pharmacist.

MM.17.3 There is proper documentation of patient's own medications in the medical record (ordering, dispensing, and administration records).

MM.17.4 When patient's own medication is not permitted, both patient and prescriber are informed.

MM.18 **There is a system for storing narcotics, psychotropic and other controlled medications in accordance with relevant laws and regulations.**

MM.18.1 The hospital implements a multidisciplinary policy and procedure on proper storage of narcotics, psychotropic and other controlled medications.

MM.18.2 Controlled and narcotics medications are kept behind steel doors with double locks.

MM.18.3 The hospital allows a limited floor stock supply of controlled and narcotics medications to meet patients' needs.

MM.18.4 The hospital maintains proper documentation of drug count, endorsement, and accountability.

MM.18.5 The hospital maintains proper documentation of empty containers of narcotics and proper disposal of unused portions.

MM.19 **The hospital identifies qualified healthcare professionals permitted to prescribe or order controlled and narcotic medications.**

MM.19.1 The hospital has a multidisciplinary policy and procedure on identification of those individuals permitted to prescribe or order controlled and narcotic medications and their prescribing privileges.

MM.19.2 Only individuals permitted by the hospital and relevant laws and regulations prescribe or order controlled and narcotic medications.

MM.19.3 Individuals permitted to prescribe or order controlled and narcotic medications are known to pharmaceutical care staff and nursing staff who dispense medications.

MM.19.4 The hospital implements its policy on prescribing privileges such as those for controlled and narcotic substances, chemotherapy agents, high-alert, radioactive or investigational, and other specialty medications.

MM.20 Safe prescribing, ordering, and transcribing of medication orders are guided by a clear policy and procedure.

MM.20.1 There is a multidisciplinary policy and procedure that clearly defines a complete prescription.

MM.20.2 All currently prescribed or ordered medications are written in a uniform location in the patient's medical record.

MM.20.3 Medication reconciliation is conducted at the time of admission and discharge.

MM.20.4 Patient identification, diagnosis, indication, or clinical condition are made available with each medication order.

MM.20.5 Medications are prescribed by generic name except when brand names are acceptable or required.

MM.20.6 Staff comply with the proper use of approved and prohibited prescribing abbreviations.

MM.20.7 The pharmaceutical care team conducts corrective actions when medication order is incomplete, illegible, or unclear.

MM.20.8 All medications are accurately transcribed into the medication administration record (MAR) after being verified against the original physician order or prescription.

MM.21 The hospital ensures safe prescribing, ordering and transcribing of specific types of medication orders.

MM.21.1 The hospital implements a policy and procedure on specific types of medication orders including as needed (PRN), standing, automatic stop (ASO), titrating, tapering, range, weight-based, body surface area-based medication orders, and discharge or transfer orders.

MM.21.2 The hospital prohibits blanket orders (e.g., resume pre-op medications).

MM.21.3 Prescribing controlled drugs is according to laws and regulations of the Saudi Food and Drug Authority and other relevant authorities.

MM.21.4 The transcription of medication order into the medication administration record (MAR) clearly reflects the type of order.

MM.22 The hospital has a system for prescribing antibiotics.

MM.22.1 The hospital implements updated and approved multidisciplinary guidelines on the proper prescribing of antibiotics.

MM.22.2 The antibiotics guidelines are updated as recommended by the pharmacy and therapeutics committee utilizing the hospital anti-biogram.

MM.22.3 There is proper implementation of the approved guidelines for antibiotics prophylaxis before surgery and/or dental procedures.

MM.22.4 There is proper implementation of the approved guidelines for empiric and therapeutic use of antibiotics.

MM.22.5 There is proper implementation of the approved prescribing privileges for antibiotics.

MM.23 The hospital has a system for managing the use of verbal and telephone orders of medications.

MM.23.1 The hospital has a multidisciplinary policy and procedure that control ordering, verifying, authenticating and limiting the use of verbal and telephone orders of medications. The policy includes a list of medications not allowed to be prescribed by verbal and telephone order.

MM.23.2 The hospital staff understand the proper use of verbal and telephone orders (accepting, documenting, verifying, authenticating, and executing orders).

MM.23.3 Verbal and telephone orders are limited to emergent and urgent situation where immediate written or electronic medication order is not feasible. Clear definition of emergent and urgent situations should be included.

MM.23.4 Time frame for authentication of verbal (as soon as the emergency is over) and telephone orders (within twenty four hours) is clearly stated and implemented.

MM.24 The hospital has a system for prescribing non-formulary medications and prescribing formulary medications for off-label (unapproved) indication or investigation.

MM.24.1 The hospital has a multidisciplinary policy and procedure on prescribing non-formulary medications.

MM.24.2 The hospital has a multidisciplinary policy and procedure on prescribing formulary medications for off-label (unapproved) indications.

MM.24.3 There is clear documentation, on a special request form, of every individual case where non-formulary medication is used.

MM.24.4 There is clear documentation, on a special request form, of every individual case where a formulary medication is used for unapproved indication or investigation.

MM.24.5 The department head approves every single case where non-formulary medication is used or where a formulary medication is used for unapproved indication or investigation.

MM.24.6 The pharmacy and therapeutics committee reviews and monitors all cases of using non-formulary medication and all cases of using formulary medication for unapproved indication or investigation.

MM.25 The hospital has a system for reviewing the appropriateness of medication orders before medication is dispensed.

MM.25.1 The hospital maintains an updated and complete medication profile (electronic or paper record) for each patient in the pharmaceutical care department.

MM.25.2 A trained pharmacist reviews all medication orders or prescriptions before dispensing (except in emergencies, life saving situations, or diagnostic imaging where the prescriber is physically present).

MM.25.3 All medication orders are reviewed for:

MM.25.3.1 Patient's allergies or sensitivities.

MM.25.3.2 Approved indications for use.

MM.25.3.3 Therapeutic duplications.

MM.25.3.4 Existing or potential interactions (drug-drug and drug-food interactions).

MM.25.3.5 Appropriateness of the medication dose, frequency, and route of administration.

MM.25.3.6 Contraindications.

MM.25.4 All issues, concerns, or questions regarding medication order or prescription are clarified with the prescriber and documented before medication dispensing.

MM.26 The hospital has a system for safe preparation of sterile compounded preparations.

MM.26.1 The hospital has a manual for proper aseptic technique and intravenous admixture (e.g., the guidelines of the Saudi Food and Drug Authority, the American Society of Health-System Pharmacists, United States Pharmacopoeia USP <797>).

MM.26.2 Sterile compounded preparations are performed by the pharmaceutical care except during emergency or urgency situations in which a delay could harm the patient or when product stability is short.

MM.26.3 Sterile compounded preparations are performed in the clean room by pharmaceutical care staff, qualified in intravenous admixture and aseptic technique.

MM.26.4 The hospital provides and documents training and competency assessment of non-pharmaceutical care staff involved in compounding sterile preparations outside the pharmaceutical care department during emergency or urgency situations.

MM.26.5 There is full compliance with aseptic technique in all medication preparation areas all over the hospital.

MM.26.6 Visual inspection is performed for all compounded sterile products by a trained individual for particulate, discoloration, or evidence of loss of integrity.

MM.26.7 The pharmaceutical care has a clean room that is a functionally separate facility to maintain product sterility.

MM.26.8 The design of the clean room is guided by the professional organizations' standards (e.g., the American Society of Health-System Pharmacists, United States Pharmacopoeia USP <797>).

MM.26.9 The pharmaceutical care uses ISO Class 5 laminar airflow hood for preparing sterile injectable preparations and all other sterile preparations.

MM.26.10 The laminar airflow hood is tested at least every six months and in accordance with the manufacturer's requirements, the Saudi Food and Drug Authority guidelines and the professional organizations' standards (e.g, American Society of Health-System Pharmacists, United States Pharmacopoeia USP <797>).

MM.26.11 The hospital implements the written and approved guidelines on intravenous drug stability and compatibility.

MM.26.12 Any sterile preparation compounded outside the clean room (e.g., in the patient care area during emergency or urgency situation) is done in an appropriate environment (location, space, cleanliness, traffic, etc.) to prevent contamination.

MM.26.13 The pharmaceutical care regularly (at least once a month) inspects all areas where sterile preparations are compounded outside the pharmaceutical care clean room.

MM.26.14 The pharmaceutical care monitors the performance and qualifications of non-pharmacists permitted to prepare sterile compounded medications outside the pharmaceutical care department.

MM.26.15 There are written guidelines for safe recycling of returned (un-used) sterile preparations.

MM.27 The hospital has a system for safe preparation of parenteral nutrition products.

MM.27.1 There is a multidisciplinary policy and procedure on preparation and dispensing of parenteral nutrition products.

MM.27.2 All parenteral nutrition products are compounded in the pharmaceutical care clean room under the laminar air flow hood.

MM.27.3 The hospital permits only pharmaceutical care staff qualified in aseptic technique and parenteral nutrition to prepare parenteral nutrition products.

MM.27.4 Aseptic technique is strictly followed by all staff in the parenteral nutrition compounding area.

MM.27.5 Double check policy is implemented at each stage of compounding and visual inspection of the final parenteral nutrition product.

MM.27.6 All essential macro-and micro-nutrients of parenteral nutrition are available.

MM.27.7 Appropriate membrane filters are available for the different types of parenteral nutrition and different patient-age groups.

MM.27.8 The hospital implements the written and approved guidelines on stability and compatibility of parenteral nutrition products.

MM.27.9 When parenteral nutrition products are compounded by an outside vendor, the pharmaceutical care team maintains a copy of the contract and ensures the compliance of the vendor with quality and safety standards. Contract monitoring is conducted at least annually with corrective actions accordingly.

MM.28 The hospital has a system for safe preparation of sterile chemotherapy compounded preparations.

MM.28.1 There is a multidisciplinary policy and procedure on preparation and handling of sterile compounded chemotherapy preparations.

MM.28.2 The chemotherapy compounding services is operated and managed by the pharmaceutical care.

MM.28.3 The hospital permits only pharmaceutical care staff qualified in chemotherapy compounding to work in the chemotherapy compounding area.

MM.28.4 Aseptic technique is strictly followed by all staff in the chemotherapy compounding area.

MM.28.5 Visual inspection is performed for all compounded sterile chemotherapy preparations by a trained pharmacist for particulate, discoloration or evidence of loss of integrity.

MM.28.6 The chemotherapy compounding area is physically and functionally separate area to maintain product sterility and prevent cross contamination.

MM.28.7 The design of the chemotherapy compounding area is guided by the professional organizations' standards (e.g., the American Society of Health-System Pharmacists, United States Pharmacopoeia USP <797>).

MM.28.8 The pharmaceutical care uses ISO Class 5 biological safety cabinet with 100% exhaust air outside the building (class II B vertical laminar airflow hood) for preparing chemotherapy.

MM.28.9 The biological safety cabinet is tested at least every six months and in accordance with the manufacturer requirements. the Saudi Food and Drug Authority guidelines, and the professional organizations' standards such as the American Society of Health-System Pharmacists (ASHP) and United States Pharmacopoeia (USP <797>).

MM.28.10 The hospital implements written and approved guidelines on chemotherapy drug stability and compatibility.

MM.28.11 The hospital uses chemotherapy ziploc plastic bags to prevent accidental spills during transportation and storage of compounded chemotherapy preparations.

MM.28.12 Special chemotherapy protective materials such as gloves, gowns, and masks are adequately available and consistently used.

MM.28.13 Chemotherapy spill kits are available in all areas where chemotherapy agents are stored, prepared, dispensed, and/or administered.

MM.28.14 Relevant staff are trained on the proper handling of chemotherapy spills.

MM.28.15 Trash plastic bags for collection and disposal of contaminated materials and articles used for preparation, dispensing and/or administration of chemotherapy are as guided by the Saudi Food and Drug Authority (SFDA) and the international organizations standards such as Occupational Safety & Health Administration (OSHA).

MM.28.16 When chemotherapy products are compounded by an outside vendor, the pharmaceutical care team maintains a copy of the contract and ensures compliance of the vendor with quality and safety standards. Contract monitoring is conducted at least annually with corrective actions accordingly.

MM.29 The hospital has a system for safe preparation of non-sterile compounded preparations (extemporaneous compounds).

MM.29.1 There is a multidisciplinary policy and procedure on non-sterile compounding of oral and topical preparations not readily available from manufacturers.

MM.29.2 The pharmaceutical care has proper facilities for non-sterile compounding that include clean work bench with smooth surface, stainless steel sink with water supply, and storage cabinets.

MM.29.3 The pharmaceutical care has essential equipment and glass wares that include sensitive balance, electric heater, mortar and pestle, beakers, flasks, and measuring cylinders.

MM.29.4 The pharmaceutical care has a preparation manual (formulation book) that is properly referenced.

MM.29.5 A log book is maintained for preparation name, strength, prepared quantity, batch number, preparation date and expiration date, prepared by and checked by.

MM.29.6 When non-sterile compounded preparations are compounded by an outside vendor, the pharmaceutical care team maintains a copy of the contract and ensures compliance of the vendor with quality and safety standards. Contract monitoring is conducted at least annually with corrective actions accordingly.

MM.30 The pharmaceutical care enforces the hospital guidelines for infection prevention and control.

MM.30.1 All areas where medications are stored, compounded, prepared, dispensed, and /or administered are clean, neat and well organized.

MM.30.2 The pharmaceutical care has a separate housekeeping materials dedicated for the clean room.

MM.30.3 A sink, antiseptic soap, and/or antiseptic hand rub are available in the pharmaceutical care department and all other areas where medications are stored, compounded, prepared, dispensed, and /or administered.

MM.30.4 Hand washing technique, and antiseptic soap are in accordance with the hospital's policy and procedures.

MM.30.5 Pharmaceutical care staff observe the hospital approved standard precautions and understand the hospital's isolation policy and procedure to reduce the risk of transmission of infection.

MM.30.6 Food, drinks, or smoking are not allowed in the pharmaceutical care department and all other areas where medications are stored, compounded, prepared, dispensed, and /or administered.

MM.30.7 Laminar air flow hood certification for operational efficiency and maintenance such as checking, cleaning and/or replacing filter are performed regularly and according to the manufacturer's specifications.

MM.30.8 The pharmaceutical care has a schedule for proper cleaning of laminar air flow hood work surface.

MM.31 The hospital has a system for safe dispensing of medications.

MM.31.1 The hospital has a uniform system for dispensing and distribution of medications.

MM.31.2 The hospital dispenses medications in the most ready-to-administer form possible (such as repackaged unit-doses) to minimize chance of error during distribution or administration.

MM.31.3 The hospital dispenses quantities of medications consistent with patient needs.

MM.31.4 The hospital dispenses no more than twenty four hours supply of medications for inpatient at a time except for bulk oral liquids and topical preparations.

MM.31.5 The hospital dispenses medications with time frames defined by the hospital (such as STAT, now, routine).

MM.31.6 The hospital maintains records for all dispensed medications.

MM.31.7 There is implementation of the independent double check during preparation and before dispensing of all high-alert medications.

MM.32 The hospital has a system for labeling medications.

MM.32.1 Medications prepared but not intended for immediate administration are labeled. This includes all injectable medications drawn into syringes or mixed with intravenous fluids for use inside the operating rooms or procedure areas.

MM.32.2 Multiple medications for a single patient, such as those in the operating room or emergency room, must be labeled for drug name and dose/concentration.

MM.32.3 All individualized medications prepared for multiple patients are labeled with all necessary information in a standardized format.

MM.32.4 All individualized medications prepared for multiple patients are labeled with:

- MM.32.4.1 Patient name and medical record number.
- MM.32.4.2 Patient location (ward, unit, room, bed number).
- MM.32.4.3 Medication name, dosage form, strength, and amount.
- MM.32.4.4 Directions for use.
- MM.32.4.5 Relevant cautionary instructions (e.g., refrigerate, shake before use, may cause drowsiness).
- MM.32.4.6 Date of preparation, beyond use date, and time (when beyond use date occurs in less than twenty four hours).

MM.32.5 All compounded intravenous admixture preparations are labeled with diluent name concentration, and its volume.

MM.32.6 All compounded parenteral nutrition solutions are labeled with individual components quantities, and total volume.

MM.32.7 All outpatient medications are labeled with patient name, medical record number, medication name, dosage form, strength, direction and duration for use, and cautions in a language and form the patient can understand.

MM.33 The hospital has a system for obtaining medications when the pharmacy is closed.

MM.33.1 There is a multidisciplinary policy and procedure on obtaining medications when the pharmacy is closed.

MM.33.2 The hospital permits only trained registered nurses and those authorized to prescribe medications to access pharmacy after working hours.

MM.33.3 The hospital has a limited list of approved medications to be accessible to non-pharmaceutical care staff when the pharmacy is closed.

MM.33.4 A qualified on-call pharmacist is available to answer questions and provide medications other than those accessible to non-pharmacists

MM.34 The hospital has a system for handling recalled, discontinued, and damaged medications.

MM.34.1 There is a multidisciplinary policy and procedure on retrieval and handling of recalled, discontinued, and damaged medications within specified time frame for patient safety.

MM.34.2 The hospital recognizes and maintains on file all drug recall memorandums from the Saudi Food and Drug Administration, manufacturer, and/ or other relevant legal bodies.

MM.34.3 The hospital notifies prescribers and individuals involved in prescribing, dispensing and administration of recalled, damaged, and discontinued medications.

MM.34.4 The hospital informs patients that their medication has been recalled or discontinued for safety reasons.

MM.34.5 The hospital complies with handling recalled, discontinued, and damaged medications guidelines.

MM.35 The pharmaceutical care department has a system for provision of outpatient education and counseling.

MM.35.1 The pharmaceutical care department has a system for provision of outpatient education and counseling that includes verbal explanation and instructions by a pharmacist to patients and their families on the safe and effective use, administration, and storage condition of medications.

MM.35.2 Written educational information is given in a language and form the patient can understand.

MM.35.3 Patient privacy is maintained during education and counseling.

MM.36 The hospital has a safe system for drug administration.

MM.36.1 The hospital defines nurses and other clinical staff authorized to administer medications with or without supervision.

MM.36.2 Qualifications, experiences, and competency assessments of individuals involved in drug administration are available in their personnel files.

MM.36.3 The hospital guidelines for safe administration of intravenous push medications are available, disseminated and implemented in all patient care units. The guidelines include medication name, infusion time, nurse qualification and patient care unit.

MM.36.4 The hospital has approved, disseminated, and implemented guidelines on standard drug administration time.

MM.36.5 The hospital maintains accurate records of the disposal of the unused portion of narcotic drugs and controlled substances.

MM.36.6 The hospital maintains updated and accurate records of drug administration.

MM.36.7 Independent double check of all high alert medications is performed.

MM.36.8 The hospital adopts safe administration and disposal of chemotherapy.

MM.37 The hospital has a system to review and verify medications before administration.

MM.37.1 The hospital implements a multidisciplinary policy and procedure on proper verification of dispensed medications before administration (right patient, right medicine, right dose, right frequency, right route, and right time).

MM.37.2 Medications are verified against the medication administration record (MAR) before administration.

MM.37.3 Medications are administered in the prescribed dose and by the correct route.

MM.37.4 Medications are administered at the correct time (the approved hospital standard administration time).

MM.37.5 Medications are administered after verifying the expiry date.

MM.37.6 Medications are administered after visual inspection for discoloration, particulate, or other clues of loss of integrity or instability.

MM.37.7 Medications are administered after verifying that there are no contraindications.

MM.38 The hospital has a safe system for self-administration of medications.

MM.38.1 The hospital educates patients and families involved in self-administration of medications about:

MM.38.1.1 Medication name, type, and indication.

MM.38.1.2 Time, frequency, route, and dose of medication.

MM.38.1.3 Expected medication effect and potential side effects.

MM.38.1.4 Monitoring and reporting of medication effects.

MM.38.2 The hospital does not allow administration of any medication brought from outside the hospital unless prescribed by the treating physician.

MM.38.3 The hospital does not allow administration of free medical samples.

MM.39 The hospital has a system to monitor the patient response to medications.

MM.39.1 There is a multidisciplinary policy and procedure on monitoring the patient response to medications.

MM.39.2 There is an annually updated list of all formulary medications that cause changes in the patient's equilibrium and may raise the risk of falls.

MM.39.3 The hospital has a collaborative process, involving physicians, nurses, and pharmacists, to monitor the patient's response to medications.

MM.39.4 Monitoring includes the following:

MM.39.4.1 The medication's effect on patient's clinical condition, as well as blood count, liver and renal functions and other relevant therapeutic monitoring parameters.

MM.39.4.2 The patient's perception of side effects to the first dose of a new medication.

MM.39.4.3 Unanticipated drug-drug interactions.

MM.39.4.4 Changes in the patient's equilibrium that may raise the risk of falls

MM.39.4.5 Allergic reactions including documentation and flagging of medical records.

MM.40 **The hospital has a process for detecting, managing and reporting adverse drug reactions (ADRs).**

MM.40.1 The hospital has a multidisciplinary policy and procedure on handling Adverse Drug Reaction (ADR) reports.
MM.40.2 The policy has a clear definition of ADR and its severity.
MM.40.3 The treating physician is notified at the appropriate time.
MM.40.4 The patient affected by ADR receives appropriate care at the appropriate time.
MM.40.5 The ADR report forms are readily available and in use.
MM.40.6 All ADRs are documented in the patient's medical record.
MM.40.7 The hospital conducts analysis of all significant and serious ADRs.
MM.40.8 The hospital has a system for improving ADR reporting.
MM.40.9 The hospital reports all serious or unexpected ADRs to the Saudi Food and Drug Authority.

MM.41 **The hospital has a process for monitoring, identifying, and reporting significant medication errors, including near misses, hazardous conditions, and at-risk behaviors that have the potential to cause patient harm.**

ESR

MM.41.1 There is a multidisciplinary policy and procedure on handling medication errors, near misses, and hazardous situations (e.g., confusion over look-alike/sound-alike drugs or similar packaging).
MM.41.2 The policy has a clear and acceptable definition of significant medication error, near misses, and hazardous situations.
MM.41.3 The treating physician is notified of the medication error at the appropriate time.
MM.41.4 Medication error reporting is completed within the specified time frame after discovery of the error.
MM.41.5 The hospital has a standard format for reporting medication errors.
MM.41.6 Staff are educated on the process and importance of medication error reporting.
MM.41.7 There is active reporting of medication errors, near misses, and hazardous situations.
MM.41.8 The hospital conducts intensive root-cause analysis for all significant or potentially significant medication errors.
MM.41.9 Medication errors, near misses, and hazardous situations are documented in the patient's medical record.
MM.41.10 The hospital utilizes reported data to improve the medication use process, prevent medication errors, and improve patient safety.
MM.41.11 Healthcare professionals are provided with feedback on reported medication errors, near misses, and hazardous situations.
MM.41.12 The hospital reports sentinel events related to serious medication errors to the relevant authorities.

Laboratory (LB)

Introduction

The assessment/reassessment of patients to determine the proper diagnosis, the course of treatment, and evaluation of treatment plan for future decisions almost always require the utilization of laboratory services. To meet the patient needs, the hospital should provide appropriate laboratory services required by its patient population, clinical services offered, and healthcare provider needs. The critical importance of quality control and safety measures in medical laboratories is unquestionable, and hence this chapter includes extended number of quality and safety standards that look in depth into almost every single aspect of the daily work in hospital-based medical laboratories.

This chapter addresses the following:

- Physical structure of the medical laboratory
- Staffing plan and qualifications
- Safety program
- Specimen collection, handling and management
- Equipment management program
- Labeling
- Results reporting
- Quality management program
- Point of care testing
- Blood bank and blood transfusion services
- Anatomical pathology

STANDARDS

LB.1 Laboratory services are available to meet patient needs and are in accordance with applicable national standards.

LB.1.1 The laboratory has a clearly defined scope of services.

LB.1.2 The laboratory services are in compliance with applicable national standards.

LB.1.3 Basic laboratory services (e.g., hematology, blood bank and biochemistry) are available twenty four hours a day, seven days a week.

LB.1.4 When laboratory services are provided through a contract, the hospital provides oversight and management of the contract through the process described in the "Leadership" chapter in this manual.

LB.1.5 The laboratory has a defined organizational chart that displays key positions including the laboratory director, sections' heads and supervisors, quality management officer, facility and safety officer, and, as applicable, infection control officer, point of care testing coordinator, and training and education coordinator.

LB.2 The laboratory has adequate and functional space and facilities that maintain safe and proper working conditions.

LB.2.1 There is a space allocated for the laboratory which provides:

- LB.2.1.1 Proper location and design.
- LB.2.1.2 Adequate patient and donor waiting areas and lavatories.
- LB.2.1.3 Adequate area for each laboratory activity/section.
- LB.2.1.4 Proper, safe, and adequate storage space for reagents, supplies, consumables, samples, records, paraffin blocks, and glass slides.
- LB.2.1.5 Adequate area for administrative and clerical staff.

LB.2.2 The laboratory management ensures the availability of the following facilities:

- LB.2.2.1 Adequate water taps and sinks.
- LB.2.2.2 Adequate electrical outlets and emergency power.
- LB.2.2.3 Adequate temperature and humidity control.
- LB.2.2.4 Adequate ventilation.
- LB.2.2.5 Adequate lighting.
- LB.2.2.6 Adequate emergency exits, access control, and all ways are not obstructed.
- LB.2.2.7 Adequate safety signs.
- LB.2.2.8 Clean and well maintained floors, walls, ceilings, bench tops, and sinks.
- LB.2.2.9 Conveniently located telephones.

LB.2.3 Personnel safety, quality of work, patient care, and donor care are not compromised by the allocated laboratory space.

LB.3 The laboratory services are carried out by qualified staff.

LB.3.1 The laboratory services are provided by staff qualified by education, training, and experience.

LB.3.2 The laboratory director, sections' heads and supervisors are appropriately qualified according to the complexity of laboratory scope of services.

- LB.3.2.1 The laboratory director of a high complexity laboratory (laboratories of tertiary care hospitals/referral facilities or laboratories providing anatomical pathology and/or transfusion medicine services) is a licensed/registered anatomical or clinical pathology consultant (board certified or equivalent).

LB.3.2.2 The laboratory director of a moderate or low complexity laboratory (laboratories with no anatomical pathology and transfusion medicine services) is a licensed/registered clinical scientist or laboratory specialist.

LB.3.2.3 The sections' heads/supervisors are qualified (by education, training and experience) in the discipline of their assigned sections.

LB.3.2.4 The laboratory staff participate in relevant hospital committees.

LB.4 The laboratory has a system for personnel audit trail.

LB.4.1 The system allows for the identification of who performed a critical task/step.

LB.4.2 The system allows for the identification of when, where, and why the task/step is performed.

LB.5 The laboratory has a comprehensive training and competency assessment program.

LB.5.1 The laboratory implements an orientation, training and competency assessment program that ensures:

LB.5.1.1 Satisfactory completion of training program for all lab personnel in their assigned area.

LB.5.1.2 Training on new equipment or method.

LB.5.1.3 Competency assessment of all laboratory personnel before working independently and annually thereafter.

LB.5.1.4 Corrective action plan and reassessment in the event of unsatisfactory performance.

LB.5.1.5 Utilization of the appropriate competency assessment tools, including technique observation for technical competency, assessment of personnel's knowledge about the contents of the procedures and instruments operation manuals (written/verbal exam), and assessment of personnel's problem solving skills (unknown samples).

LB.5.1.6 Laboratory personnel performing tests or tasks requiring color discrimination undergo a color discrimination test.

LB.6 The laboratory has a system for the receipt of incoming supplies and services, inventory management, and tracking of critical materials.

LB.6.1 The laboratory implements policies and procedures on documenting the receipt, inspection, and testing (as applicable) of incoming critical material or service.

LB.6.2 The laboratory implements policies and procedures on inventory management and tracking the use of critical materials, supplies, and reagents to ensure the following:

LB.6.2.1 Materials are used within their expiration dates.

LB.6.2.2 New reagents lot numbers are tested against old lots or suitable reference materials before use.

LB.6.2.3 Kit components are used within the kit lot number.

LB.6.2.4 Lot number use is traceable to patient/blood donors or inclusive dates of use.

LB.7 The laboratory has reagents and solutions management system.

LB.7.1 The laboratory implements policies and procedures to ensure that prepared/reconstituted reagents and solutions are labeled, as applicable, with:

LB.7.1.1 Content

LB.7.1.2 Concentration/titer.

LB.7.1.3 Preparation/reconstitution date.

LB.7.1.4 Expiration Date.

LB.7.1.5 Storage requirements.

LB.7.2 Laboratory supplies and reagents are stored under appropriate conditions.

LB.7.2.1 Critical laboratory supplies and reagents are stored according to the manufacturer's recommendations under controlled conditions or in an appropriate storage device.

LB.7.2.2 Critical supplies and reagents storage conditions are continuously monitored using appropriate temperature monitoring/recording system.

LB.7.2.3 In the event of monitoring systems failure, the storage temperature is monitored and recorded every eight hours using a standardized thermometric device.

LB.7.3 The laboratory defines and specifies water types.

LB.7.3.1 There is definition of the specific type of water required for each of its testing procedures.

LB.7.3.2 Water quality is tested at least annually.

LB.8 The laboratory has a process describing its role in equipment management.

LB.8.1 The laboratory has a role in the selection of critical laboratory equipment (equipment that must be operated at defined specifications to ensure the quality of the product or service).

LB.8.2 The laboratory has a role in the receipt, installation and identification of critical laboratory equipment.

LB.9 The laboratory has a system for equipment validation.

LB.9.1 The laboratory implements policies and procedures describing the validation of critical laboratory equipment for its intended use, including:

LB.9.1.1 Installation Qualification.

LB.9.1.2 Operational Qualification.

LB.9.1.3 Detailed functional validation study with predefined acceptance criteria.

LB.9.1.4 Critical laboratory equipment are not used before completing the validation studies.

LB.10 The laboratory develops a process for test method validation.

LB.10.1 The laboratory implements policies and procedures on test method validation including:

LB.10.1.1 Verification of accuracy/precision.

LB.10.1.2 Verification of sensitivity (lower detection limit).

LB.10.1.3 Verification of carryover acceptability.

LB.10.1.4 Verification of the Analytic Measurement Range (AMR).

LB.10.1.5 Approval of the method for clinical use.

LB.11 The laboratory develops a process for establishing or verifying and evaluating reference ranges/intervals and cut off values for each analyte and specimen source.

LB.11.1 The laboratory implements policies and procedures that define:

LB.11.1.1 Circumstances and method for establishing reference ranges.

LB.11.1.2 Circumstances and method for verifying published reference ranges.

LB.11.1.3 Circumstances and method for the re-evaluation of reference ranges.

LB.12 The laboratory has a system for standardizing critical laboratory instruments.

LB.12.1 The laboratory implements policies and procedures defining the calibration, adjustment and/or standardization of critical laboratory instruments. This includes:

LB.12.1.1 Calibrations and adjustment are performed before use, after activities that may alter the calibration and at predefined intervals.

LB.12.1.2 All thermometers used in the laboratory are checked against certified standardized thermometric device before being placed in use and annually thereafter.

LB.12.1.3 All stopwatches and instrument timers are checked against standardized stopwatch before the initial use and every six months thereafter.

LB.12.1.4 All pipettes (fixed volume and/or adjustable) are checked for accuracy and reproducibility before being placed in use and semi-annually thereafter.

LB.12.1.5 Balances are placed on vibration resistance surface and checked against standardized weights before being placed in use and every six months thereafter.

LB.12.1.6 Actions are taken in the event of unsatisfactory results.

LB.12.2 Calibration, adjustment and/or standardization procedures conform to the manufacturer's instructions and best practices.

LB.13 The laboratory has a system for instruments/methods correlation.

LB.13.1 When the laboratory uses more than one method and/or instruments to test for a given analyte, the laboratory develops and implements policies and procedures on correlation to ensure the following:

LB.13.1.1 The correlation studies are conducted every six months.

LB.13.1.2 There is clear description of the correlation study.

LB.13.1.3 There are clearly defined acceptance criteria.

LB.13.1.4 There is a process for review and approval of the correlation results.

LB.14 The laboratory has a system for controlling the quality of test methods.

LB.14.1 The laboratory implements policies and procedures on quality control of test methods to satisfy the following:

LB.14.1.1 Assignment of performance and review responsibility (control specimens are handled and tested in the same manner and by the same laboratory personnel testing patient samples).

LB.14.1.2 Number and frequency of running controls.

LB.14.1.3 Tolerance limits of controls results.

LB.14.1.4 Corrective action to be taken in the event of unacceptable results.

LB.14.2 The laboratory quality control system conforms to the manufacturer's instructions.

LB.15 The laboratory has comprehensive work instructions and procedures manuals.

LB.15.1 The laboratory develops work instructions and procedures manuals that fulfill the following:

LB.15.1.1 Conform to the hospital document control/management system.

LB.15.1.2 Readily available at the work areas.

LB.15.1.3 Prepared in accordance with the instrument operating manual, reagent inserts and/or manufacturer's instructions.

LB.16 The Laboratory develops a process for the control of deviations and exceptions.

LB.16.1 There is a written policy, process, and forms for the control and documentation of deviations and exceptions to policies and procedures.

LB.16.2 Deviations and exceptions warranted by clinical situations or special circumstances are justified, pre-approved, and documented on a case-by-case basis.

LB.16.3 Deviations and exceptions must be approved for only one implementation event by the authorized person who signs the policy or procedure for implementation.

LB.17 The laboratory has a comprehensive safety and infection control programs.

LB.17.1 The laboratory implements safety and infection control policies and procedures that are in compliance with the national and international laboratory safety standards as well as the hospital safety and infection control plan. Policies define the following:

LB.17.1.1 Chemical hygiene plan.

LB.17.1.2 Mercury reduction/elimination plan.

LB.17.1.3 Mechanism of fumes and vapors monitoring.

LB.17.1.4 Mechanism of compressed and flammable gases control.

LB.17.1.5 Radiation safety plan.

LB.17.1.6 Biological safety procedures and use of standard precautions.

LB.17.1.7 Tuberculosis and other biological hazards exposure plan.

LB.17.1.8 Electrical safety plan.

LB.17.1.9 Fire prevention and control plan.

LB.17.1.10 Provision and use of Personal Protective Equipment (PPE).

LB.17.1.11 Provision and control of negative pressure in sections dealing with highly infectious materials.

LB.17.1.12 Provision, use, and control of fume hoods.

LB.17.1.13 Provision, use, and control of biological safety cabinets.

LB.17.1.14 Provision of safety equipment (eye wash, emergency shower, fire extinguisher, fire blanket, biological and chemical spill kits).

LB.17.1.15 Waste disposal/control plan (chemical, biological and sharps) using prick proof containers and leak proof bags.

LB.17.1.16 Provision and use of first aid kits.

LB.17.1.17 Reporting of infection and safety incidents.

LB.17.2 The laboratory has safety and infection control training program that includes:

LB.17.2.1 Initial training and competency assessment.

LB.17.2.2 Annual training, recertification and competency assessment.

LB.17.3 The laboratory has a system for monitoring the laboratory safety and infection control program.

LB.17.3.1 Documented safety and infection control audits are conducted at regular predefined-intervals (at least twice yearly).

LB.17.3.2 Findings of the audits are reported to the laboratory director, the facility safety officer, the infection control department, and other concerned parties.

LB.17.3.3 Corrective actions, whenever needed, are taken and documented.

LB.18 The laboratory has a services/specimen collection manual.

LB.18.1 The laboratory develops a services/specimen collection manual that includes the following:

LB.18.1.1 Available tests and services on and off-site (reference laboratory) and their Turn Around Times (TAT).

LB.18.1.2 Methods of patient preparation.

LB.18.1.3 Procedures for positive patient identification.

LB.18.1.4 Quality and quantity of sample.

LB.18.1.5 Phlebotomy and sample collection procedures.

LB.18.1.6 Recognizing and handling adverse reactions to phlebotomy.

LB.18.1.7 Specimen labeling.

LB.18.1.8 Requisition and required clinical data.

LB.18.1.9 Specimen handling and transportation.

LB.18.1.10 Specimen rejection criteria.

LB.18.2 Laboratory services/specimen collection manual is available to all relevant departments.

LB.19 The laboratory establishes Turn Around Times (TAT) for routine and STAT tests.

LB.19.1 Turnaround Times are clearly defined for routine and STAT tests.

LB.19.2 Turnaround Times are established in agreement with relevant clinical departments.

LB.19.3 Turnaround Times are communicated, Implemented, and monitored.

LB.20 Requests for laboratory tests or services are complete and legible.

LB.20.1 Requests for laboratory tests or services bear sufficient information, including:

LB.20.1.1 Two patient's identifiers (patient's full name and medical record number).

LB.20.1.2 Patient Age and Sex.

LB.20.1.3 Patient location.

LB.20.1.4 Identification of the authorized ordering physician.

LB.20.1.5 Type of specimen and required test.

LB.20.1.6 Date and time of specimen collection.

LB.20.1.7 Identification of the phlebotomist or the person who collected the specimen.

LB.20.1.8 Additional clinical information, as required.

LB.21 The laboratory ensures correct specimen labeling.

LB.21.1 The laboratory implements policies and procedures to ensure correct specimen labeling, including:

LB.21.1.1 Labeling of the specimen containers is conducted immediately after sample collection at the patient side.

LB.21.1.2 Two Patient's identifiers (patient's full name and medical record number).

LB.21.1.3 Date and time of sample collection.

LB.21.1.4 Identification of the person collecting the specimen.

LB.22 The laboratory develops a process for sample handling after collection.

LB.22.1 The laboratory has policies and procedures on proper sample handling, transporting, and tracking. This covers:

LB.22.1.1 Packing instructions (use of biohazard leak-proof containers).

LB.22.1.2 Personnel training (including safety and proper packaging).

LB.22.1.3 Specimen tracking system.

LB.22.2 The laboratory has a system to maintain the identity of laboratory specimen during receipt, processing, examination, and archiving.

LB.23 The laboratory develops a process for specimen receipt.

LB.23.1 The laboratory implements policies and procedures for the receipt and inspection of laboratory specimen to ensure the performance and documentation of:

LB.23.1.1 Date and time of specimen reception.

LB.23.1.2 Check for proper packaging.

LB.23.1.3 Check for quality and quantity of specimen.

LB.23.1.4 Check for adequacy of specimen labeling.

LB.23.1.5 Check for request completion.

LB.23.1.6 Check for label/request discrepancies.

LB.23.1.7 The use of suboptimal specimen is clearly highlighted in the reported results.

LB.23.1.8 Final decision (accept/reject).

LB.24 The laboratory has a written description for the format and contents of its reports.

LB.24.1 The laboratory has a written description for the format and contents of its reports which include:

LB.24.1.1 Identification of the testing laboratory.

LB.24.1.2 Patient identification (full name and medical record number, age and sex).

LB.24.1.3 Identification of the ordering physician.

LB.24.1.4 Date and time of specimen collection and the source of specimen.

LB.24.1.5 Reporting date and time.

LB.24.1.6 Test results and reference intervals.

LB.24.1.7 Identification of the authorized person releasing the report.

LB.25 The laboratory develops a process for critical results reporting.

LB.25.1 The laboratory implements policies, procedures and records in consultation with clinical departments to address the following:

LB.25.1.1 Identification of results that should be reported as critical.

LB.25.1.2 Identification of the notified party.

LB.25.1.3 Identification of the means of communicating critical results.

LB.25.1.4 Description of the sequence of conveying the result and read-back.

LB.25.2 Documentation of critical results notification event includes:

LB.25.2.1 Date and time of notification.

LB.25.2.2 Patient identification.

LB.25.2.3 Test results.

LB.25.2.4 Documentation of read-back.
LB.25.2.5 Identification of the notifying person.
LB.25.2.6 Identification of the notified person.

LB.26 The laboratory develops a process for amending reported laboratory results.

LB.26.1 The laboratory implements policies and procedures for amending/correcting reported results. This includes:
LB.26.1.1 Definitions of report corrections and amendments.
LB.26.1.2 Format of the corrected report.
LB.26.1.3 Requirement to include the previous result in the corrected report.
LB.26.1.4 Notification of clinical departments.
LB.26.1.5 Application of general reporting requirements.

LB.27 The laboratory has a process for reference laboratory services.

LB.27.1 There is a clearly defined and implemented process describing the laboratory role in selecting and evaluating providers of reference laboratory service, including:
LB.27.1.1 Selection criteria (including accreditation status) for the provider of reference laboratory services.
LB.27.1.2 Inclusive list of send-out tests.
LB.27.1.3 Detailed procedure for specimen transportation and results reporting.

LB.28 The laboratory develops a comprehensive system for Point-of Care-Testing (POCT).

LB.28.1 The laboratory implements policies and procedures to address the following:
LB.28.1.1 Clear definition of POCT.
LB.28.1.2 Assignment of the responsibility of managing the POCT to the laboratory.
LB.28.1.3 Guidelines describing the process of acquiring POCT devices/methods.
LB.28.1.4 Training and competency testing requirements.
LB.28.1.5 Maintenance, quality control, and quality management of the POCT devices/methods.
LB.28.2 The laboratory assigned a qualified individual as POCT coordinator.

LB.29 Laboratory records are retained for defined periods.

LB.29.1 The laboratory implements a general laboratory records retention system that ensures the following:
LB.29.1.1 Laboratory test request forms, specimen accessioning logs, instrument printouts, reported results, records of quality control, proficiency testing records, and quality management reports (quality indicators, audits, process improvement projects) are retained for three years.
LB.29.1.2 Method/instrument validation records are retained for the entire period of using the method/instrument and three years after discontinued.
LB.29.1.3 Maintenance records are retained for the life time of the instrument and three years after retirement.

LB.29.1.4 Employee identification records (signature, initials, identification code, and inclusive dates of hiring) are retained for the entire period of hiring and three years after departure.

LB.29.2 The implemented blood bank and transfusion services records retention system ensures the following:

LB.29.2.1 Inspection records (blood, blood components and critical supplies), proficiency testing records, and quality management reports (quality indicators, audits, process improvement projects) are retained for five years.

LB.29.2.2 Whole blood collection, apheresis collection, therapeutic phlebotomy, therapeutic apheresis, component preparation, component modification, quality control, and normal pre-transfusion testing records are retained for ten years.

LB.29.2.3 Donation history, donor testing, donor notification, deferred donors, final disposition of blood/blood components, and look back records are retained permanently.

LB.29.2.4 Abnormal patients testing records (records of patients with antibodies, transfusion reactions or special requirements), patient's transfusion history, transfusion reaction, and transfusion transmitted diseases investigation records are retained permanently.

LB.29.3 The implemented anatomical pathology records retention system ensures the following:

LB.29.3.1 Surgical pathology reports, outside consultations reports and images of studies are retained for ten years.

LB.29.4 Discontinued (retired) blood bank and transfusion controlled documents are retained for five years after the retirement date.

LB.29.5 Discontinued (retired) general laboratory controlled documents are retained for three years after the retirement date.

LB.30 The laboratory has a system for sample retention.

LB.30.1 There is a sample retention policy to ensure that general laboratory specimens are retained under appropriate conditions for no less than the periods specified below:

LB.30.1.1 Whole blood specimens and urine specimens are retained for twenty four hours.

LB.30.1.2 Serum, plasma, cerebrospinal fluid and other body fluids specimens are retained for forty eight hours.

LB.30.1.3 Permanently fixed and stained blood films are retained for seven days.

LB.30.1.4 Permanently fixed and stained microbiology slides are retained for seven days.

LB.30.2 The sample retention policy ensures that donors and patients samples are retained under appropriate conditions for no less than the periods specified below:

LB.30.2.1 Outpatient specimens (not for compatibility testing) are retained for twenty four hours.

LB.30.2.2 Inpatient specimens are retained for seventy two hours.

LB.30.2.3 Specimens of patients who receive blood transfusion are retained for seven days after transfusion.

LB.30.2.4 Segment/specimens from transfused RBC are retained for seven days after transfusion.

LB.30.2.5 Specimens for transfusion reaction investigation are retained for seven days.

LB.30.3 The sample retention policy ensures that anatomical pathology specimen are retained under appropriate conditions for no less than the periods specified below:

LB.30.3.1 Gross specimens of wet or fixed tissues are retained for fourteen days after the release of final report.

LB.30.3.2 Paraffin blocks are retained for ten years.

LB.30.3.3 Glass slides are retained for ten years.

LB.31 The laboratory develops a process for internal (self) and external assessment of operations and quality management system.

LB.31.1 The laboratory develops and implements policies and procedures on quality indicators and systems checks.

LB.31.2 The implemented system covers the selection, data collection, reporting, and monitoring of quality indicators.

LB.31.3 The laboratory selects and monitors key quality indicators covering the pre-analytical, analytical, and post-analytical phases of the laboratory operations.

LB.31.4 Selected general laboratory indicators may include, but are not limited to, the following:

LB.31.4.1 Patient identification errors.

LB.31.4.2 Rejected specimens.

LB.31.4.3 Turnaround Time (TAT) of routine, STAT and urgent requests.

LB.31.4.4 Critical value reporting failures.

LB.31.4.5 Customer satisfaction.

LB.31.4.6 Corrected laboratory reports.

LB.31.4.7 Blood culture contamination.

LB.31.5 The selected transfusion services indicators may include, but are not limited to, the following:

LB.31.5.1 Rejected donors.

LB.31.5.2 Rejected units.

LB.31.5.3 Donor satisfaction.

LB.31.5.4 Adverse donor reactions.

LB.31.5.5 Usage and discards.

LB.31.5.6 Ability to meet the patient's needs.

LB.31.5.7 Blood ordering practices (cross matched/transfused ratio).

LB.31.5.8 Blood administration practices.

LB.31.6 The laboratory has a system for process improvement that covers the following activities:

LB.31.6.1 Identification of opportunities for improvement.

LB.31.6.2 Corrective and preventive actions.

LB.31.6.3 Description of the selected quality improvement tool used in the laboratory.

LB.31.7 The laboratory is involved in hospital-wide/multidisciplinary improvement projects. During the current accreditation cycle, the laboratory was engaged in at least four quality improvement projects, including:

LB.31.7.1 Two general laboratory projects.

LB.31.7.2 One blood bank project.

LB.31.7.3 One transfusion services project.

LB.32 The laboratory has a comprehensive system for Proficiency Testing (PT) sufficient for the extent and complexity of the laboratory scope of services.

LB.32.1 The laboratory implements policies, processes and procedures on Proficiency Testing to ensure the following:

LB.32.1.1 All laboratory analytes are covered with Proficiency Testing.

LB.32.1.2 Alternative Proficiency Testing is performed when appropriate.

LB.32.1.3 Clear instruction for the receipt, processing and reporting of Proficiency Testing results.

LB.32.1.4 Proficiency Testing samples are tested by the same personnel handling patient/donor samples.

LB.32.1.5 Proficiency Testing sample are tested by the same method used for testing patient/donor samples.

LB.32.1.6 Proficiency Testing samples are not referred to other laboratory for testing.

LB.32.1.7 Proficiency Testing results are not shared with other laboratories.

LB.32.1.8 Proficiency Testing results are evaluated and compared to the acceptable performance.

LB.32.1.9 Whenever appropriate, unacceptable performance is investigated and appropriate corrective actions are taken.

LB.32.1.10 Proficiency Testing records are reviewed and approved by laboratory management.

LB.32.1.11 Corrective actions are implemented and monitored (if applicable).

LB.33 The blood bank has a process for identifying and delivering pre-donation education to prospective blood donors.

LB.33.1 There are policies and procedures to ensure proper donor identification through:

LB.33.1.1 Definition of acceptable form(s) of identification (Saudi national I.D/Iqama).

LB.33.1.2 Linking the donor identification information to existing donor history (records) on each donor encounter.

LB.33.2 The policies and procedures ensure that donors receive appropriate information/education materials, including:

LB.33.2.1 Educational materials regarding the donation process.

LB.33.2.2 Educational materials regarding infectious diseases transmitted by blood transfusion.

LB.33.2.3 Importance of providing accurate information.

LB.33.2.4 Importance of withdrawing themselves from the donation process if they believe that their blood is not suitable for transfusion.

LB.33.2.5 Donors acknowledge that the educational materials have been read and understood.

LB.34 The blood bank develops acceptance criteria for blood donors.

LB.34.1 The laboratory implements criteria for accepting blood donors to minimize the risk of harm to them. The criteria include:

LB.34.1.1 Whole blood is not collected from a donor weighing less than fifty Kilograms or under seventeen years of age.

LB.34.1.2 Whole blood is not collected from a donor more frequently than once every eight weeks and not from donors who donated apheresis product less than forty eight hours ago.

LB.34.1.3 The blood pressure and pulse rate of prospective donor are within normal ranges; Diastolic blood pressure less than 100 mm Hg, Systolic blood pressure less than 180 mm Hg and pulse rate between 50-100 beats/minute.

LB.34.1.4 The hemoglobin level of the prospective donor should be greater than 12.5g/dL or a hematocrit of more than 38%.

LB.34.1.5 The prospective donor has no history of heart or lung disease.

LB.34.1.6 Female donors are not pregnant or have been pregnant within the last six weeks.

LB.34.1.7 Prospective donor's history is evaluated and the donor examined by a qualified person before whole blood collection.

LB.34.2 The policies and procedures minimize the risk of harm to blood recipients by preventing donations by individuals who has:

LB.34.2.1 Evidence of disease transmissible by blood transfusion.

LB.34.2.2 Conditions thought to compromise the suitability of the blood or blood component.

LB.34.2.3 Body temperature exceeding 37.5C.

LB.34.2.4 History of liver diseases, cancer or bleeding tendency.

LB.34.2.5 History of laboratory or clinical evidence for viral hepatitis, HIV, HTLV.

LB.34.2.6 History of laboratory or clinical evidence for malaria within the last three years.

LB.34.2.7 History of syphilis treatment or unconfirmed test result for syphilis within the past twelve months.

LB.34.2.8 Been excluded as per the current recommendations for the prevention of HIV infection.

LB.34.3 The prospective donor's travel history checked against the current travel deferral list for the risk of HIV, vCJD and Malaria.

LB.34.4 The prospective donor's medications checked against current deferral list. Other medications are assessed by the blood bank physician.

LB.34.5 The prospective donor's vaccinations checked against the current vaccination deferral list. Other vaccinations must be assessed by the blood bank physician.

LB.34.6 Prospective donor's arms are free of lesions suggestive of skin disease or parenteral drug abuse.

LB.35 The blood bank develops acceptance criteria for platelets pheresis donors.

LB.35.1 The laboratory implements additional acceptance criteria for platelet pheresis donors. The criteria include:

LB.35.1.1 Donation Intervals meet the following conditions: eight weeks after whole blood donations, not more than once every forty eight hours, not more than twice a week, not more than four times a month, not more than twenty four times a year, and eight weeks after failure to return the donor red cells during apheresis procedure or the total RBC loss during apheresis procedure exceeds 200 ml.

LB.35.2 Use of medications that inhibit platelet function (such as Aspirin and Piroxicam) defers the platelet apheresis donation for seventy two hours after the last dose.

LB.35.3 The prospective apheresis donor should have a qualifying platelet count of more than 150,000/µl.

LB.35.4 The acceptance criteria of blood donors outlined in this chapter apply.

LB.36 The blood bank has a process for consenting blood donors.

LB.36.1 The laboratory implements a process for consenting blood donors to ensure:

LB.36.1.1 Receiving explanation of the donation procedure.
LB.36.1.2 Being informed about the risks of the procedure.
LB.36.1.3 Being informed about the tests performed and the risks of transmission of infectious diseases.
LB.36.1.4 Being informed about the donor confidentiality and the requirement to report test results to health authorities.
LB.36.1.5 Being informed that there are circumstances in which blood/blood components are released for transfusion before the completion of infectious disease testing.
LB.36.1.6 Having read and understood the information presented to him/her
LB.36.1.7 Having the opportunity to ask questions and having them answered.

LB.37 The blood bank develops a system for donor notification of significant findings detected during donor screening or after performing laboratory testing.

LB.37.1 A policy and procedure defines events requiring official donor notification.
LB.37.2 The policy and procedure mandates the provision of proper education, counseling, and referral for donors with significant findings.
LB.37.3 The policy and procedure mandates that acknowledgment of the notification is documented within eight weeks of donation.

LB.38 The Blood Bank develops a system for the calibration of collected blood volume regulators.

LB.38.1 The laboratory implements a system for calibration/adjustment of blood volume regulators (blood shakers) to ensure that calibration and adjustment are performed at regular intervals, on every day of use, and after activities that may alter the calibration.
LB.38.2 Calibration and adjustment procedures conform to the manufacturer's instructions.

LB.39 The blood bank adopts the appropriate system for providing the necessary care for blood donors before, during, and after the procedure.

LB.39.1 There is a policy and procedure for venipuncture site preparation to reduce the risk of bacterial contamination of the collected blood/blood component that includes:
LB.39.1.1 Detailed and appropriate procedure for the collection site preparation.
LB.39.1.2 Regular assessment of personnel competency on proper venipuncture site preparation.
LB.39.2 The blood bank uses appropriate whole blood and apheresis products collection sets. The collection sets used in the blood bank are:
LB.39.2.1 Sterile and pyrogen-free.
LB.39.2.2 Closed system.
LB.39.2.3 Equipped with diversion pouch.
LB.39.3 The blood bank has sufficient provisions for providing appropriate care for blood donors during and after the procedure.
LB.39.3.1 Donors are given proper written post donation instructions.

LB.39.3.2 Supplies and equipment needed for donors' care are available.

LB.39.3.3 Personnel are trained and competent in recognition and handling of adverse donor reactions.

LB.39.3.4 Personnel have valid basic life support certification.

LB.39.4 The blood bank has a process for confidential self unit exclusion and handling post donation information.

LB.39.4.1 The policies and procedures describe the receiving and documenting self or third party information about the donor.

LB.39.4.2 The blood/blood product is kept in quarantine for further actions.

LB.39.4.3 The laboratory management review and decision are documented.

LB.40 The blood bank develops a system for managing adverse donation events.

LB.40.1 The laboratory has a system for managing adverse donation events that covers:

LB.40.1.1 Recognition and handling of adverse donation events.

LB.40.1.2 Reporting and monitoring of adverse donation events.

LB.41 The blood bank develops a process for the collection of donor blood specimen.

LB.41.1 The Laboratory implements a process to ensure that donor blood specimens are:

LB.41.1.1 Collected during the donation.

LB.41.1.2 Properly labeled and crosschecked with the collected product label.

LB.41.1.3 Stored under appropriate and controlled conditions.

LB.42 The blood bank develops a system for the preparation, storage, transportation, and quality control of Red Blood Cells (RBC) components.

LB.42.1 RBC components are prepared by separating the RBC from the plasma proteins.

LB.42.2 RBC components are stored under properly controlled conditions between 1 and 6°C.

LB.42.3 RBC components are transported in properly insulated container between 1 and 10°C.

LB.42.4 RBC components are assigned an expiration date according to the manufacturer's recommendations or:

LB.42.4.1 21 Days for RBC in CPD.

LB.42.4.2 35 Days for RBC in CPDA-1.

LB.42.4.3 42 Days for RBC in additive solution.

LB.42.4.4 24 hours post opening the RBC unit.

LB.42.5 Policies and procedures ensure that 1% of the monthly production- but not less than 4 units every month- are subjected to quality control testing. All tested RBC units have a hematocrit of less than 80% (RBC in additive solution are exempted from quality control requirement).

LB.43 The blood bank develops a system for the preparation, storage, transportation, and quality control of Platelet Concentrates (PC) components.

LB.43.1 PC components are prepared by separating the platelets from whole blood within eight hours of collection.

LB.43.2 PC components are stored under properly controlled conditions between 20 and 24°C with continuous agitation.

LB.43.3 PC components are transported in properly insulated container as close as possible to 20 and 24°C.

LB.43.4 PC components are assigned an expiration date of twenty four hours to five days from the day of whole blood collection according to the manufacturer's recommendations or four hours of opening PC unit.

LB.43.5 Policies and procedures ensure that 1% of the monthly production but not less than four units every month are subjected to quality control testing. On the expiration date or at issue, 90% of the subjected units have a platelet count of 5.5X1010 platelets/unit or more and a minimum pH of 6.2.

LB.44 The blood bank develops a system for the preparation, storage, transportation, and quality control of Fresh Frozen Plasma (FFP).

LB.44.1 FFP components are prepared by separating and freezing the plasma from the whole blood within eight hours of collection and within six hours for plasma collected by apheresis.

LB.44.2 FFP components are stored under properly controlled conditions below -18°C.

LB.44.3 During transportation, FFP units are maintained at frozen state in properly insulated container.

LB.44.4 FFP components are assigned an expiration date of one year from the day of whole blood collection.

LB.44.5 If cryoprecipitate is not prepared, 1% of the quarterly production- but not less than twelve units every three months- are subjected to quality control testing. 75% of the tested units must have minimum factor VIII level of 700 IU/L.

LB.45 The blood bank develops a system for the preparation, storage, transportation, and quality control of Cryoprecipitate (CRYO).

LB.45.1 CRYO components are prepared by separating cold insoluble proteins from Fresh Frozen Plasma and re-freezing of the product within one hour of preparation.

LB.45.2 CRYO components are stored under properly controlled conditions below -18°C.

LB.45.3 During transportation, the CRYO units are maintained at frozen state in properly insulated container.

LB.45.4 CRYO components are assigned an expiration date of one year from the day of whole blood collection.

LB.45.5 Policies and procedures ensure that 1% of the quarterly production- but not less than twelve units every three months- are subjected to quality control testing. 75% of the tested units must have minimum factor VIII level of 80 IU/unit and 150mg of fibrinogen/bag.

LB.46 The blood bank develops a system for the preparation, storage, transportation, and quality control of platelet apheresis units.

LB.46.1 Platelet apheresis units are prepared by separating the platelets from whole blood using apheresis machine.

LB.46.2 Policies and procedures ensure that 1% of the monthly production-but not less than 4 units every month- subjected to quality control testing. On the expiration date or at issue, all of the subjected units must have a platelet count of 3.0X1011 platelets/unit or more, a minimum pH of 6.2, and a residual WBC count of 5X106 WBC/ unit.

LB.46.3 Requirements for PC storage, transport, and expiration apply.

LB.47 The blood bank and transfusion services develop policies and procedures to ensure that the prepared and/or transfused Leukocyte-Reduced Red Blood Cells (LR-RBC) units are handled in an appropriate manner.

LB.47.1 Policies and procedures ensure that LR-RBC units are prepared by a method known to retain 85% of the RBC in the original product and a residual WBC count of less than 5X106 WBC/ unit.

LB.47.2 Policies and procedures ensure that 1% of the quarterly production -but not less than 12 units every three months- are subjected to quality control testing. All tested LR-RBC units have a RBC recovery rate of more than 85% and a residual WBC count of less than 5X106 WBC/unit in all subjected units.

LB.47.3 Requirements for RBC preparation, storage, transport and expiration apply.

LB.48 The blood bank and transfusion services develop policies and procedures to ensure that the prepared and/or transfused Leukocyte-Reduced Platelet concentrates (LR-PC) units are handled in an appropriate manner.

LB.48.1 Policies and procedures ensure that LR-PC units are prepared by a method known to retain 85% of the platelets in the original product and a residual WBC count of less than 8.3X105 WBC/ unit or 5X106 WBC/pool of six units.

LB.48.2 Policies and procedures ensure that 1% of the quarterly production -but not less than twelve units every three months- are subjected to quality control testing. All tested LR-PC units have a platelets recovery rate of more than 85% and a residual WBC count of less than 8.3X105 WBC/ unit or 5X106 WBC/pool of six units.

LB.48.3 Requirements for PC preparation, storage, transport and expiration apply.

LB.49 The blood bank and transfusion services develop policies and procedures to ensure that the prepared and/or transfused irradiated cellular blood products are handled in an appropriate manner.

LB.49.1 Policies and procedures ensure that irradiated cellular blood products are prepared by a method known to ensure that irradiation has occurred at each time of use.

LB.49.2 Policies and procedures ensure that the preparation method used is known to deliver a minimum of 25 GY to the central part of the canister and a minimum of 15 GY at any point. Verification of dose delivered must be performed and evaluated annually.

LB.49.3 Policies and procedures ensure that irradiated RBC components assigned an expiration date not exceeding twenty eight days from the date of irradiation or the original assigned expiration date (whichever occurs first).

LB.49.4 Policies and procedures ensure that irradiated platelet components retain their original expiration date.

LB.50 The blood bank develops a process for initial immune-hematological testing of blood donor samples.

LB.50.1 There are policies and procedures mandating that a sample of blood obtained from the donor during blood/ blood component collection is subjected to the following testing:

LB.50.1.1 Determination of the donor's forward ABO group (RBC grouping).

LB.50.1.2 Determination of the donor's reverse ABO group (serum grouping).

LB.50.1.3 Determination of the donor's Rh-D type (including a test for weak-D).

LB.50.1.4 Detection of unexpected antibodies to red cell antigens (antibody screening).

LB.50.1.5 There is a confirmation of agreement between donor's current and historical group/type.

LB.50.2 Discrepancies are solved before releasing any blood/blood components.

LB.51 The blood bank develops a process to prevent disease transmission by blood/platelet transfusion.

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LB.51.1 There are policies and procedures mandating that a sample of blood obtained from the donor during blood/ blood component collection is subjected to the following infectious diseases testing:

LB.51.1.1 HBsAg.

LB.51.1.2 Anti-HBc.

LB.51.1.3 Anti-HCV.

LB.51.1.4 Anti-HIV-1/2.

LB.51.1.5 Anti-HTLV-I/II.

LB.51.1.6 HIV-1 RNA.

LB.51.1.7 HCV RNA.

LB.51.1.8 HBV DNA.

LB.51.1.9 Serological test for syphilis.

LB.51.1.10 Other additional or supplemental tests as mandated by relevant health authorities.

LB.51.2 The blood bank has a process to limit and detect bacterial contamination in platelet components. The process:

LB.51.2.1 Describes the blood bank approach to limit bacterial contamination and the investigations of positive cases.

LB.51.2.2 Ensures the employed detection method is sensitive enough to detect significant bacterial contamination.

LB.52 The blood bank establishes a process for the identification and discard of unacceptable blood/blood product.

LB.52.1 The process mandates two qualified staff members to perform and document this activity.

LB.52.2 The process mandates discarding unacceptable components before the initial labeling of blood and blood components.

LB.53 The blood bank develops a process for initial labeling of blood and blood components.

LB.53.1 There are policies and procedures to ensure that:

LB.53.1.1 Blood and blood components are not labeled before completion of the donor testing.

LB.53.1.2 Blood and blood components are not labeled before the discard of unacceptable units.

LB.53.2 Initial labeling requirements include:

LB.53.2.1 Identification of the collecting facility.

LB.53.2.2 Product name.

LB.53.2.3 Unit number.

LB.53.2.4 ABO/Rh.

LB.53.2.5 Expiration date and time.

LB.54 The blood bank has a process to confirm the ABO/Rh-D of donated blood.

LB.54.1 There is a process to confirm the ABO/Rh-D of donated blood which mandates that segment from RBC components is subjected to the following testing:

LB.54.1.1 Determination of the donor's forward ABO group (RBC grouping).

LB.54.1.2 Determination of the donor's Rh-D type.

LB.54.1.3 ABO/Rh-D conformation is performed after initial labeling.

LB.54.2 Discrepancies are solved before releasing any blood/blood components.

LB.55 The blood bank establishes a process to prevent the release of units that are not suitable for transfusion to the available inventory.

LB.55.1 Policies, processes, and procedures ensure the accuracy and legibility of identification information.

LB.55.2 Policies, processes, and procedures ensure the agreement of the identification information (records and donor units).

LB.55.3 Policies, processes, and procedures ensure the performance of visual inspection for discoloration, clots, hemolysis, and adequacy of seal.

LB.55.4 Policies, processes, and procedures ensure two qualified staff members perform and document this activity.

LB.56 The transfusion services establish a process for the release of incompletely tested blood/blood components.

LB.56.1 There are implemented policies, processes and procedures to ensure that incompletely tested blood/blood components can be released under the following circumstances:

LB.56.1.1 For urgent need only.

LB.56.1.2 Upon the discretion of the medical director of the transfusion medicine, the agreement of the attending physician and the consent of the patient or next of kin, when applicable.

LB.56.1.3 Approved only for a particular patient and one transfusion event.

LB.56.1.4 The released blood products are conspicuously labeled to this effect.

LB.56.2 Testing of the blood/blood components must be completed and reported promptly to the attending physician.

LB.56.3 Deviations and exceptions standard in this chapter applies.

LB.57 **The blood bank has a process for request, approval, and execution of therapeutic procedures.**

LB.57.1 The process ensures all therapeutic procedures are ordered and justified by an authorized physician.

LB.57.2 The process ensures the blood bank medical director or designee is responsible for reviewing therapeutic procedures orders for appropriateness and evaluating patient clinical and laboratory data before approving the procedure.

LB.57.3 The process ensures therapeutic procedures are explained to the patient and consented.

LB.57.4 The process ensures that blood/ blood components discarded immediately after collection.

LB.58 **The blood bank and transfusion services use appropriate blood and blood components storage devices.**

LB.58.1 The blood and blood components storage devices are:

LB.58.1.1 Designed for the intended use.

LB.58.1.2 Equipped with continuous temperature monitoring system (temperature recording).

LB.58.1.3 Equipped with audio/visual alarm systems.

LB.58.2 The device's alarm and monitoring system conforms with the following:

LB.58.2.1 Activates at a temperature that allows for intervention before the contents reaches unacceptable temperature.

LB.58.2.2 Activates at an area staffed 24 hours a day, seven days a week.

LB.58.2.3 Connected to a separate or DC power supply.

LB.58.3 The alarm system is checked weekly.

LB.58.4 Alarm activation temperatures are checked quarterly.

LB.58.5 The inner temperature of blood storage devices is monitored and recorded at least once a day using a standardized thermometric device.

LB.58.6 In the event of failure of continuous temperature monitoring, temperature recording, or alarm systems, the inner temperature is monitored and recorded every four hours.

LB.59 **The blood bank and transfusion services develop policies and procedures to ensure that the thawed Fresh Frozen Plasma (FFP) units are handled in an appropriate manner.**

LB.59.1 Thawed FFP units are prepared by thawing the FFP between 30 and 37°C without direct contact with the water.

LB.59.2 Thawed FFP units are stored under properly controlled conditions between 1 and 6°C.

LB.59.3 Thawed FFP units are transported in properly insulated container between 1 and 10°C.

LB.59.4 Thawed FFP units are assigned an expiration time of twenty four hours from the thawing time.

LB.59.5 Requirements for FFP preparation, storage, transport and expiration apply.

LB.60 **The blood bank and transfusion services develop policies and procedures to ensure that the thawed CRYO units are handled in an appropriate manner.**

LB.60.1 Thawed CRYO units are prepared by thawing CRYO units between 30 and 37°C without direct contact with the water.

LB.60.2 Thawed CRYO units are stored and transported at room temperature (between 20 and 24°C).

LB.60.3 Thawed CRYO units are assigned an expiration time of six hours from the thawing time for individual units and four hours from the thawing time of pooled units.

LB.60.4 Requirements for CRYO preparation, storage, transport and expiration apply.

LB.61 The Blood bank and transfusion services develop a system for reagents quality control.

LB.61.1 Policies and procedures ensure performance of reagents quality control on each day of use.

LB.61.2 Policies and procedures ensure anti-sera are checked against known positive and negative cells.

LB.61.3 Policies and procedures ensure reagent Red Blood Cells are checked against known positive and negative anti-sera.

LB.61.4 Policies and procedures ensure results are checked against predefined acceptable results.

LB.61.5 Policies and procedures ensure results are reviewed and reagents are approved before use for patient testing.

LB.61.6 Corrective actions are taken for unacceptable results.

LB.62 The blood bank and transfusion services implement a system for receiving or sending blood and blood products to outside facilities.

LB.62.1 There are written blood supply/exchange agreements with outside facilities covering the following:

- LB.62.1.1 Agreement conditions (including accreditation status).
- LB.62.1.2 Agreement on adequate blood/blood components inventory.
- LB.62.1.3 Role of the involved parties in look back and transfusion transmitted diseases investigation.
- LB.62.1.4 Release of blood, blood components or information to a third party.
- LB.62.1.5 Validity of agreement and agreement review schedule.
- LB.62.1.6 Resolving disputes.

LB.62.2 There is a written procedure describing the process for requesting or releasing blood from or to outside facilities.

LB.62.3 Policies and procedures on receipt and inspection of incoming blood/blood components include:

- LB.62.3.1 Evaluation and verification of the shipping condition of each blood component.
- LB.62.3.2 Checking for meeting predefined acceptance criteria for each blood component received.
- LB.62.3.3 Evaluation and verification of the agreement of units' identification information (unit numbers, ABO/Rh-D and Expiration dates).
- LB.62.3.4 Conformation of ABO/Rh-D for RBC components.
- LB.62.3.5 Actions taken for unsatisfactory consignment.

LB.63 The blood bank and transfusion services implement a system for pre-transfusion testing of the recipient.

LB.63.1 Pre-transfusion testing is performed on a specimen collected from the recipient with every admission and within three days of the scheduled transfusion time.

LB.63.2 There is a consistency between patient's current and historical records (including group/type, antibody screening). Discrepancies are resolved before performing compatibility testing.

LB.63.3 When there is no history for the patient in the transfusion services records or computer system, two determinations of the patients ABO/RhD must be made on two specimens collected during the current admission.

LB.63.4 Pre-transfusion testing includes:

LB.63.4.1 Determination of the patient's forward ABO group (RBC grouping).

LB.63.4.2 Determination of the patient's reverse ABO group (Serum Grouping).

LB.63.4.3 Determination of the patient's Rh-D type.

LB.63.4.4 Detection and Identification (if applicable) of unexpected antibodies to red cell antigens.

LB.64 The transfusion services develop a system for the selection of blood/ blood product for transfusion.

LB.64.1 There are policies and procedures for the selection of blood/blood product for transfusion to ensure the following:

LB.64.1.1 The selected red blood cells component is ABO group-specific or ABO group-compatible with the recipient's plasma.

LB.64.1.2 Only Rh-D negative red blood cell components are transfused to Rh-D negative patients.

LB.64.1.3 Identification of the conditions for the release of Rh-D positive red blood cells components to Rh-D negative patients.

LB.64.1.4 If the patient has current or previous history of clinically significant antibodies in the patient serum, the selected red cells must lack the corresponding antigen(s).

LB.64.2 There are policies and procedures for the selection of plasma components for transfusion to ensure the following:

LB.64.2.1 The selected plasma component is ABO group-specific or ABO group-compatible with the recipient's RBC.

LB.64.2.2 Conditions for the release of ABO-incompatible plasma are identified.

LB.64.2.3 In the presence of clinically significant antibody in the donor's plasma, the recipient red cells must lack the corresponding antigen.

LB.64.2.4 If the plasma components are visually contaminated with red blood cells (more than 2 ml of RBC), RBC selection criteria apply.

LB.64.3 There are policies and procedures for the selection of blood/blood components for patients with special requirements that address the following:

LB.64.3.1 The use of leukocyte-reduced cellular blood components.

LB.64.3.2 The use of irradiated-cellular blood components.

LB.64.3.3 Transfusion of known hemoglobin-S patients.

LB.64.3.4 Massive transfusions.

LB.65 The transfusion services establish a process for compatibility testing.

LB.65.1 There is a process to ensure the detection of ABO incompatibility between the recipient's serum/ plasma and the donor's RBC.

LB.65.2 The process ensures the compatibility testing is performed on integrally attached segment from the donor's RBC unit.

LB.65.3 The process ensures the checking for presence, now or in the past, of clinically significant antibody in the patient's serum.

LB.65.4 The process ensures the proper labeling of cross-matched units with patient's name, patient's identification number and patient's ABO /Rh-D.

LB.66 The transfusion services develop a process for intra-uterine and neonatal testing and transfusion.

LB.66.1 There is a process for intra-uterine and neonatal testing and transfusion that entails determination of the neonate ABO/Rh and conditions for repeat of ABO/Rh testing.

LB.66.2 The process entails performance and interpretation of Direct Anti-globulin Test (DAT).

LB.66.3 The process describes conditions for omitting re-typing and serological cross-match.

LB.66.4 The process considers the clinically significant antibodies of maternal origin.

LB.66.5 The process describes selection of RBC and plasma components for top-up, exchange and intrauterine transfusions.

LB.67 The transfusion services develop a process for the issue of blood/blood component for transfusion.

LB.67.1 There is a process for the issue of blood/blood component to ensure accurate identification of the intended recipient and the required blood components.

LB.67.2 The process ensures the integrity of the donor unit identification label and the recipient identification label.

LB.67.3 The process ensures confirmation that the donor's ABO/Rh is identical with the recipient's, or marked compatible.

LB.67.4 The process ensures proper documentation of the release event.

LB.68 The transfusion services develop a process for emergency release of uncross-matched or incompletely cross-matched blood.

LB.68.1 There is a process for emergency release of uncross-matched or incompletely cross-matched blood that ensures a proper ordering procedure and required ordering information.

LB.68.2 The process considers age and sex factors.

LB.68.3 The process ensures ABO/Rh-D and labeling of the selected blood.

LB.68.4 The process ensures subsequent compatibility testing and notification of the results.

LB.68.5 The process ensures documentation of the release event (including the ordering physician signature).

LB.69 The medical director of the transfusion services participates (through the blood transfusion committee) in the development of a process for the management of adverse or suspected transfusion events.

LB.69.1 There is a process for the management of adverse transfusion events which covers:

LB.69.1.1 Recognition and handling of adverse transfusion events.

LB.69.1.2 Reporting and monitoring of adverse transfusion events.

LB.69.2 There is a process for management of suspected transfusion reactions which covers:

LB.69.2.1 Clerical check of the identification information and records.

LB.69.2.2 Visual inspection of the blood product, pre and post transfusion samples.

LB.69.2.3 Initial immune-hematological testing and conditions for performing additional testing (minor/major cross-match, urine analysis, biochemistry, microbial culture).

LB.69.2.4 Conclusion and instructions for future transfusion.

LB.69.3 Transfusion reaction reports are reviewed by the transfusion services medical director and the transfusion committee.

LB.70 The medical director of the transfusion services participates (through the blood transfusion committee) in the development and implementation of a process for the investigation of suspected cases of post-transfusion infection.

LB.70.1 There is a process for the investigation of suspected cases of post-transfusion infection which ensures the following:

LB.70.1.1 Prompt identification of the implicated donors.

LB.70.1.2 Prompt notification of the collecting facility (if applicable).

LB.70.1.3 Prompt quarantine of available components from the implicated donors.

LB.70.1.4 Investigating the implicated donors.

LB.70.1.5 Assigning appropriate deferrals to the implicated donors.

LB.70.1.6 Reporting the investigation results (internally and externally), as applicable.

LB.70.2 The process for investigation of donors subsequently found to have transfusion transmissible disease (Look Back)ensures the following:

LB.70.2.1 Prompt quarantine of available components from the same donor.

LB.70.2.2 Prompt identification of the recipients.

LB.70.2.3 Prompt notification of the facility where the transfusion was conducted (if applicable).

LB.70.2.4 Prompt notification of the patient's physician and/or infection control.

LB.70.2.5 Investigation and follow-up of recipients.

LB.70.2.6 Reporting the investigation results (internally and externally), as applicable.

LB.71 Gross examination of surgical pathology specimens is performed by a qualified pathologist.

LB.71.1 Surgical specimens are subjected to gross examination by a qualified pathologist or another qualified individual under the supervision of a qualified pathologist.

LB.71.2 When gross examination is performed by individuals other than pathologists, the laboratory maintains the following:

LB.71.2.1 Training records.

LB.71.2.2 Extent of their activity.

LB.71.2.3 Scheme of supervision.

LB.72 There is a process for daily review by a pathologist of all technical activities in the anatomical pathology laboratory.

LB.72.1 There is a process that mandates a documented daily review of all activities in the anatomical pathology lab, including :

LB.72.1.1 Specimen processing.
LB.72.1.2 Quality of histology and cytology preparation.
LB.72.1.3 Quality of routine and special stains.

LB.73 The anatomical pathology develops a process for the provision of intra-operative surgical pathology services.

LB.73.1 There is a process for the provision of intra-operative surgical pathology services which addresses:
LB.73.1.1 Scheduling of cases.
LB.73.1.2 Specimen acceptance, accessioning, processing and testing.
LB.73.1.3 Documentation of direct verbal communication with the surgeon.
LB.73.1.4 Inclusion of the frozen section results with the final surgical pathology report.

LB.74 The anatomical pathology develops a process for intra-departmental and extra-departmental consultations.

LB.74.1 There is a process for intra-departmental and extra-departmental consultations that addresses circumstances for the inclusion of the consultation in the final pathology report.
LB.74.2 The process addresses circumstances for separate filing of the consultation report.

LB.75 The anatomical pathology develops guidelines for compiling surgical pathology reports.

LB.75.1 There are implemented guidelines for compiling surgical pathology reports, addressing the following elements:
LB.75.1.1 Gross description (type, number, dimensions).
LB.75.1.2 Essential processing information and performed studies.
LB.75.1.3 Other relevant report elements necessary for the management of the patient.

LB.76 The anatomical pathology has a process for reviewing the previous cytology and histology material and solving disparities.

LB.76.1 There is a policy mandating the inclusion of review results with the current patient report.
LB.76.2 The policy covers solving and documenting disparities between frozen section/ cytology/ gross examination and the final pathology report.

Facility Management and Safety (FMS)

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 hospital leadership has to provide all necessary support and resources to improve safety in the work place in alignment with the regulatory requirements.

The hospital must have plans for managing the safety of the environment and must implement these plans. The hospital must collect and analyze data to determine the effectiveness of the plans and facilitate continuous quality improvement.

Staff must also 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 addressed in this chapter include the following:

- Facility safety
- Security
- Fire safety
- Emergency preparation and plans
- Hazardous materials
- Medical equipment
- Utilities

STANDARDS

FMS.1 Hospital Leaders establish and support a facility management and safety program.

FMS.1.1 The facility management and safety program includes the following written and approved plans:

FMS.1.1.1 Safety of the Building.

FMS.1.1.2 Security.

FMS.1.1.3 Hazardous materials and waste disposal.

FMS.1.1.4 External emergency.

FMS.1.1.5 Internal emergency.

FMS.1.1.6 Fire Safety.

FMS.1.1.7 Medical equipment.

FMS.1.1.8 Utility System.

FMS.1.2 Hospital leaders support the facility management and safety program to acquire the necessary equipment.

FMS.1.3 The program includes regular inspection, testing, and maintenance of all the operating components of the program.

FMS.1.4 The program has a budget for the necessary upgrading or replacement as identified by monitoring data or to meet applicable laws and regulations.

FMS.1.5 There is an orientation program conducted for new hires on the facility management and safety plans.

FMS.2 There is a qualified individual(s) responsible for directing and coordinating the facility management and safety program.

FMS.2.1 The hospital has a facility management and safety program director who directs and coordinates all aspects of the facility management and safety program.

FMS.2.2 The program director is qualified by education (e.g., bachelor's degree in engineering science), training, and experience in healthcare facility management and safety.

FMS.2.3 The program director is assisted by qualified staff (e.g., safety officer) as required, according to the size and complexity of the hospital services.

FMS.2.4 The program director provides ongoing consultation to all departments.

FMS.2.5 Each department has an assigned "liaison safety officer" to liaise all safety issues within the department.

FMS.3 There is a multidisciplinary safety committee that provides oversight of the facility management and safety program.

FMS.3.1 The committee's membership consists of representatives from relevant departments such as safety, security, housekeeping, infection control, risk management, biomedical engineering, laboratory, medical staff (E.R), nursing, radiation safety, maintenance, and quality management.

FMS.3.2 The safety committee provides oversight of the facility management and safety program.

FMS.3.3 Safety committee meets at least ten times per year on a monthly schedule. Minutes are documented to be approved by the hospital leadership.

FMS.3.4 The safety committee, through a multidisciplinary team, conducts quarterly and as needed facility safety tours to identify risks and hazards related to the facility and physical plants as well as evaluation of staff knowledge.

FMS.3.5 The committee uses the resulting information for corrective and preventive actions, planning, and budgeting of long-term upgrading and replacement.

FMS.4 The hospital is in compliance with applicable laws and regulations.

FMS.4.1 The hospital has a valid Saudi Civil Defense license.

FMS.4.2 The hospital has a valid Saudi Civil Defense report and action plan as applicable.

FMS.4.3 Hospital leaders ensure compliance with applicable building and environmental protection standards, laws, and regulations (e.g., MOMRA's hospital building requirements, Saudi building code, discharges to drainage systems, safe disposal of waste).

FMS.5 The hospital ensures safety and security of staff and patients during construction, renovation, or demolition projects.

FMS.5.1 The hospital implements a policy for safety and security of patients, staff and visitors during construction, renovation, or demolition that includes:

- FMS.5.1.1 Safety and security instructions.
- FMS.5.1.2 Education of contractors.
- FMS.5.1.3 Proper isolation of construction and renovation sites.
- FMS.5.1.4 How to eliminate the risks of fire and spread of dust.
- FMS.5.1.5 Penalties incurred on contractors for violating the policy.
- FMS.5.1.6 Safety rounds on construction/renovation sites by facility management and safety and infection control staff.

FMS.5.2 A work permit is signed by the construction team and posted in the construction, renovation, or demolition sites.

FMS.6 Warning and directive signs are posted inside the hospital as appropriate.

FMS.6.1 There are warning signs posted as appropriate in the hospital and include:

- FMS.6.1.1 Signs for the radioactive materials including warning signs for pregnant women.
- FMS.6.1.2 Signs for wet floors during cleaning.
- FMS.6.1.3 No smoking signs.
- FMS.6.1.4 Signs and warning lights for x-ray room(s).
- FMS.6.1.5 Signs to restrict cellular phones in sensitive areas as appropriate, e.g. MRI or critical care units.

FMS.6.2 There are directive signs posted as appropriate in the hospital and include:

- FMS.6.2.1 Signs indicating the hospital name and main entrances/exits.
- FMS.6.2.2 Directional signs.
- FMS.6.2.3 Signs to direct staff and patients to the different services in the hospital.
- FMS.6.2.4 Fire exit signs.
- FMS.6.2.5 Signs to identify floor level at staircases and in front of elevators.
- FMS.6.2.6 Signs to instruct staff, patients, and visitors in restricted areas.
- FMS.6.2.7 MRI patient safety measures and steel restriction signs.
- FMS.6.2.8 Signs for populations with special needs.

FMS.7 The hospital is equipped for vulnerable individuals and others with special needs.

FMS.7.1 The hospital is equipped with special parking spots.

FMS.7.2 The hospital is equipped with wheel chairs and relevant ramps are in all elevated areas.

FMS.7.3 The hospital is equipped with handrails in the corridors and stairs.

FMS.7.4 The hospital is child safe in the public areas (tamper free outlets, no sharp ends).

FMS.8 Safety measures and equipment are applied where needed in the hospital to ensure safety of patients and staff.

FMS.8.1 The patients bathrooms and showers are provided with the following safety measures:

- FMS.8.1.1 Non-slipping floors' surfaces.
- FMS.8.1.2 Bars to support patients.
- FMS.8.1.3 Bell or a system to call for help.
- FMS.8.1.4 Lock system that allows opening from outside.

FMS.8.2 The kitchen has safety equipment that include:

- FMS.8.2.1 Eye wash stations.
- FMS.8.2.2 Fire blankets.
- FMS.8.2.3 First aid kit.
- FMS.8.2.4 Fire Extinguishers.
- FMS.8.2.5 Emergency shut off valve for liquid propane gas.
- FMS.8.2.6 Emergency shower.

FMS.8.3 The laundry has safety equipment that include:

- FMS.8.3.1 Eye wash stations.
- FMS.8.3.2 Fire blankets.
- FMS.8.3.3 First aid kit.
- FMS.8.3.4 Fire Extinguishers.
- FMS.8.3.5 Emergency shower.

FMS.8.4 The Laboratory has safety equipment that include:

- FMS.8.4.1 Eye wash stations.
- FMS.8.4.2 Fire blankets.
- FMS.8.4.3 First aid kit.
- FMS.8.4.4 Fire extinguishers.
- FMS.8.4.5 Emergency shower.
- FMS.8.4.6 Fire resistant safety cabinets for laboratory chemicals.

FMS.9 The hospital ensures that all its occupants are safe from radiation hazards.

ESR

FMS.9.1 The hospital has a radiation safety policy and procedure and it is implemented.

FMS.9.2 All radio-active materials are clearly labeled and safely and securely stored.

FMS.9.3 The hospital has the relevant valid license(s) from King Abdulaziz City for Science and Technology.

FMS.9.4 Staff handling nuclear materials are qualified and certified by King Abdul-Aziz City for Science and Technology.

FMS.9.5 There is a valid shielding certificate of the x-ray room(s) including regular test to ensure permissible radiation levels.

FMS.9.6 Lead aprons and gonad/thyroid shields are available to cover patients and staff needs and are annually tested according to a hospital-wide inventory.

FMS.9.7 Personal radiation dosimeters (TLD cards) are available, tested every 3 months, and actions taken when test results exceed permissible levels.

FMS.10 Patients and staff are protected from unnecessary exposure to laser beams in areas where it is used.

FMS.10.1 There are laser warning signs at all areas where the laser is used.

FMS.10.2 Laser is performed in rooms that do not have refractive surfaces such as glass and mirrors.

FMS.10.3 Staff working or assisting in laser procedures are provided with protective eye goggles appropriate to the wavelength used.

FMS.10.4 Laser safety manuals are available for the concerned staff.

FMS.11 The hospital environment is secure for patients, visitors, and staff.

FMS.11.1 There are identification badges for the following staff categories:

FMS.11.1.1 Hospital staff.

FMS.11.1.2 Temporary employees.

FMS.11.1.3 Contractor staff.

FMS.11.2 Security personnel or alternative security systems are utilized to restrict access to sensitive areas that include, but are not limited to, the following:

FMS.11.2.1 Delivery room.

FMS.11.2.2 Neonatal intensive care unit.

FMS.11.2.3 Nursery.

FMS.11.2.4 Female wards.

FMS.11.2.5 Operating room.

FMS.11.2.6 Central sterilization service department.

FMS.11.2.7 Morgue.

FMS.11.2.8 Medical records.

FMS.11.2.9 Hospital roof.

FMS.11.2.10 Medical equipment and goods stores including pharmacy narcotic vault.

FMS.11.3 There are policies and procedures for the following:

FMS.11.3.1 Preventing children and neonates abduction.

FMS.11.3.2 Lost and found items.

FMS.11.3.3 Safe keeping of patient belongings.

FMS.11.3.4 Involvement of police in cases of trauma, motor vehicle accidents, and medico-legal incidents.

FMS.11.3.5 Incidents of violence (violence code).

FMS.11.3.6 Women and child abuse.

FMS.11.4 Staff are trained on response to all security alerts.

FMS.12 The hospital has a mechanism to deal with a bomb threat.

FMS.12.1 There is a written policy on how to deal with a bomb threat in the hospital which includes:

FMS.12.1.1 Defining the code or alert.

FMS.12.1.2 Defining the role of the person receiving threat alerts.

FMS.12.1.3 Defining the response team including the individual responsible for announcing the emergency status and contacting the local authorities.

FMS.12.1.4 Defining the duties and the responsibilities of all staff involved and their action cards.

FMS.12.1.5 The command center location.

FMS.12.1.6 Defining the steps to be taken during the bomb threat.

FMS.12.2 Staff are trained on response to bomb threat alerts.

FMS.13 The hospital has qualified individuals assigned to maintain security.

FMS.13.1 The number of security personnel is proportional to the size of the hospital, number of entrances, and the availability of supporting security systems.

FMS.13.2 The security personnel have written job descriptions.

FMS.13.3 The security personnel receive orientation about:

FMS.13.3.1 Scope of work and job description.

FMS.13.3.2 Emergency codes.

FMS.13.3.3 Fire safety.

FMS.13.4 The security personnel roles are clearly defined for the following:

FMS.13.4.1 External disaster plan.

FMS.13.4.2 Internal disaster plan.

FMS.13.4.3 No smoking policy.

FMS.13.5 The security personnel have a dress code.

FMS.13.6 The security personnel conduct hospital wide security rounds and significant findings are documented.

FMS.14 The hospital ensures safe management of hazardous materials.

FMS.14.1 There is a written hazardous materials plan that includes the following:

FMS.14.1.1 Appropriate handling, storing, transporting, and disposing of hazardous materials.

FMS.14.1.2 Education and training on signs and symptoms of exposure to hazardous materials and the appropriate treatment according to Material Safety Data Sheets (MSDS).

FMS.14.2 Each department has a current list of hazardous materials used in the department. The list covers:

FMS.14.2.1 Purpose of use.

FMS.14.2.2 The responsible person.

FMS.14.2.3 Permitted quantity.

FMS.14.3 Each department dealing with hazardous materials has Material Safety Data Sheets (MSDS) relevant to its current list of hazardous materials.

FMS.14.4 Each department using hazardous materials has proper personal protective equipment (PPE) and spill kits to handle any spill or exposure.

FMS.14.5 All hazardous materials are labeled clearly and this includes:

FMS.14.5.1 Anti-neoplastic drugs.

FMS.14.5.2 Radioactive materials.

FMS.14.5.3 Corrosives, acids, and toxic materials.

FMS.14.5.4 Hazardous gases and vapors.

FMS.14.5.5 Anesthetic gases.

FMS.14.5.6 Flammable liquids.

FMS.14.6 Any leak, spill, or exposure to any hazardous material is reported.

FMS.15 The hospital implements a waste management plan.

FMS.15.1 The hospital has a waste management plan that includes handling, storing, transporting, and disposing all kinds of waste (e.g., clinical waste, radioactive waste, and hazardous gases).

FMS.15.2 The plan is implemented.

FMS.15.3 Staff (including contractors' staff) are trained on dealing with hazardous waste.

FMS.16 The hospital ensures preparedness for external disasters.

FMS.16.1 The hospital has a plan to deal with potential external disasters. The plan includes:

FMS.16.1.1 Identification of all potential external emergencies and disasters.

FMS.16.1.2 Names and titles of all staff to be called including their contact numbers and action cards.

FMS.16.1.3 Duties and responsibilities of hospital leaders.

FMS.16.1.4 The triage areas, their locations, and triage action cards.

FMS.16.1.5 The individual responsible for announcing the emergency state and contacting the local authority.

FMS.16.1.6 The control room location and the person in charge.

FMS.16.1.7 The total number of beds that can be evacuated.

FMS.16.1.8 The role of the security personnel.

FMS.16.1.9 The role of each department in the hospital.

FMS.16.2 The hospital conducts an external disaster drill at least annually.

FMS.16.3 The hospital ensures the availability of ambulances and medical supplies and equipment required in case of external disasters (e.g., medical bags, drugs and mobile monitors).

FMS.16.4 There is an orientation on the external disaster plan for new hires with an annual update for all staff.

FMS.17 The hospital ensures preparedness for internal disasters.

FMS.17.1 The hospital has a plan to deal with potential internal disasters. The plan includes:

FMS.17.1.1 Names and titles of all staff to be called in case of internal disaster, their contact numbers, and action cards.

FMS.17.1.2 The control room location and the position of the individual in charge.

FMS.17.1.3 The duties and responsibilities of hospital leaders.

FMS.17.1.4 The procedure for relocation of patients.

FMS.17.1.5 The individual responsible for announcing the emergency state and contacting local authority.

FMS.17.1.6 Individual(s) authorized to deal with the electricity supply and medical gas system and to shut them off as needed in case of fire or explosions in the hospital.

FMS.17.1.7 The meeting point for the staff in case of horizontal evacuations (assembly points) inside the building.

FMS.17.1.8 The meeting point for the full evacuation (holding area) outside the building.

FMS.17.1.9 The evacuation procedure for patients, visitors, and employees.

FMS.17.2 Every department has a specific internal disaster plan that addresses departmental actions in case internal disasters.

FMS.17.3 There are evacuation maps posted hospital wide indicating locations of:

FMS.17.3.1 You are here.

FMS.17.3.2 Fire extinguishers.

FMS.17.3.3 Fire hose reel/cabinets.

FMS.17.3.4 Fire blankets.

FMS.17.3.5 Escape routes.

FMS.17.3.6 Assembly points.

FMS.17.3.7 Fire exits.

FMS.17.3.8 Call points break glass/pull station.

FMS.17.3.9 Medical gas isolation valves.

FMS.18 The hospital has a system for scheduling and conducting fire drills regularly.

FMS.18.1 Fire drills are scheduled and conducted regularly in all departments.

FMS.18.2 Fire drills are conducted during different shifts to test:

FMS.18.2.1 Using Rescue, Alarm, Confine, Extinguish/Evacuate (RACE) procedure.

FMS.18.2.2 Using Pull, Aim, Squeeze, Sweep (PASS) procedure.

FMS.18.2.3 The ability to contain the fire when it starts.

FMS.18.2.4 Staff performance in the event of fire.

FMS.18.2.5 Evacuation procedures.

FMS.18.2.6 Whether the oxygen and electricity supplies were shut off at the right time.

FMS.18.3 All staff participate in the fire drills.

FMS.18.4 All fire drills' results and corrective actions are documented and integrated into the quality improvement program.

FMS.18.5 A full fire drill is conducted for the internal disaster plan once a year and this drill is evaluated.

FMS.19 The hospital supports fire prevention.

FMS.19.1 The hospital ensures procuring materials like curtains and drapes that are fire retardant.

FMS.19.2 The hospital ensures separating all dangerous materials or flammables from heat generating areas.

FMS.19.3 The hospital ensures installing fire rated walls as appropriate, especially in high risk areas like the laboratory, electrical rooms, and kitchen.

FMS.19.4 The hospital ensures installing fire stop materials to seal penetrations as appropriate (especially in technical rooms, electrical rooms, and escape routes).

FMS.19.5 The hospital ensures developing and scheduling staff training programs on the use of fire extinguishers.

FMS.20 Fire extinguishers are available in the hospital and are properly distributed.

FMS.20.1 The fire extinguishers are adequate in number as per civil defense guidelines.

FMS.20.2 The fire extinguishers are appropriately distributed throughout the hospital.

FMS.20.3 The fire extinguishers are appropriately positioned as per civil defense guidelines.
FMS.20.4 The fire extinguishers are inspected monthly to assess functionality.

FMS.21 The hospital has an effective fire alarm system.

FMS.21.1 There is a fire alarm system that is functioning and regularly inspected as per civil defense guidelines.
FMS.21.2 The fire alarm system testing results are documented.
FMS.21.3 The fire alarm system has preventive maintenance.
FMS.21.4 The elevators are connected to the fire alarm system.

FMS.22 The hospital has a fire suppression system available in the required area(s).

FMS.22.1 The hospital has a functional sprinkler system.
FMS.22.2 The hospital has clean agent suppression system.
FMS.22.3 The hospital has wet chemical system.
FMS.22.4 The hospital has stand pipes and hose system.

FMS.23 There are fire exits that are properly located in the hospital.

FMS.23.1 Fire exits are available and are properly located in the hospital.
FMS.23.2 Fire exits are not locked.
FMS.23.3 Fire exits are not obstructed.
FMS.23.4 Fire exits have panic hard ware.
FMS.23.5 Fire exits are fire resistant.
FMS.23.6 Fire exits are clearly marked with illuminated exit sign.

FMS.24 The hospital and its occupants are safe from fire and smoke.

FMS.24.1 The hospital implements a strict "No Smoking" policy.
FMS.24.2 There are no obstructions to exits, fire extinguishers, fire alarm boxes, emergency blankets, safety showers, and eye wash stations.
FMS.24.3 Emergency lighting is adequate for safe evacuation of the hospital.
FMS.24.4 Storage areas are properly and safely organized:
FMS.24.4.1 Shelves and racks are sturdy and in good condition.
FMS.24.4.2 No items stored directly on the floor (a minimum of ten centimeters is left to manage spills).
FMS.24.4.3 Items should be stacked on a flat base.
FMS.24.4.4 Heavier objects are close to the floor and lighter/smaller objects are higher.
FMS.24.4.5 Items are not stacked so high to block sprinklers or come in contact with overhead lights or pipes (a minimum distance of fifty centimeters from ceiling level).
FMS.24.5 Fire rated doors are available according to the hospital zones with no separation between walls and ceiling to prevent smoke spread between rooms and areas.

FMS.25 The hospital has a biomedical equipment plan to ensure that the medical equipment are regularly monitored, maintained, and ready for use.

FMS.25.1 The hospital has adequate number of qualified biomedical staff.

FMS.25.2 There is a written biomedical equipment plan that covers the following:

FMS.25.2.1 A comprehensive inventory of medical equipment with their corresponding locations.

FMS.25.2.2 Preventive maintenance program that conforms with the manufacturer's instructions.

FMS.25.2.3 The program specifies, for each equipment, the frequency of checks, methods of checks, acceptance criteria, and actions to be taken in the event of unsatisfactory results.

FMS.25.2.4 The program includes the process for investigation and follow-up of equipment failure that addresses reporting of failure, immediate remedial actions, assessment of the failure effect on reported results and services (needs alignment), and requalification of the equipment.

FMS.25.2.5 Electrical safety testing for patient related equipment.

FMS.25.2.6 History record for the maintenance schedule, failure incidence, and repairs done.

FMS.25.3 Technical service manuals for all equipment are available at the biomedical workshops.

FMS.25.4 Operator manuals are available at all departments using the equipment.

FMS.25.5 The hospital ensures that all maintenance works are conducted by qualified and trained staff.

FMS.25.6 Equipment maintenance and repairs are documented to help in the decision making for replacement.

FMS.25.7 Investigation procedures conform to manufacturer's instructions.

FMS.25.8 There is an equipment recall system that is implemented.

FMS.25.9 Each department has a back-up or alternative for each critical equipment to cover for prolonged downtime.

FMS.25.10 Preventative Maintenance data are used for upgrading/replacing of equipment.

FMS.26 The hospital has policies and procedures that support the medical equipment management program.

FMS.26.1 There is a policy to perform inspection on all new equipment for conformity before commissioning including those brought for "demos".

FMS.26.2 There is a written policy for tagging medical equipment as follows:

FMS.26.2.1 Preventive maintenance with testing date and due date.

FMS.26.2.2 Inventory number.

FMS.26.2.3 Removal from service.

FMS.26.2.4 Electrical safety check.

FMS.26.3 There is a policy for removal of equipment from service.

FMS.26.4 There is a policy to address agent or contractor repairs.

FMS.26.5 There is a policy to eliminate the use of extension cords.

FMS.26.6 There is a policy to restrict the use of cellular phones in the intensive care units, operating room, and cardiology units, as needed.

FMS.27 Hospital staff are trained on safe operation of medical equipment.

FMS.27.1 Hospital staff are trained to operate safely all medical equipment.

FMS.27.2 The training includes physicians, nurses, and paramedics.

FMS.27.3 The training considers the following:

FMS.27.3.1 New equipment.

FMS.27.3.2 Staff transferred from a department to another.

FMS.27.3.3 New staff hired.

FMS.27.3.4 Recurrent misuse of equipment.

FMS.28 The hospital has a utility system management plan.

FMS.28.1 The hospital has adequate number of qualified staff to manage the utility system.

FMS.28.2 There is a utility system management plan that includes management of failure or interruption of the following utilities:

FMS.28.2.1 Normal power.

FMS.28.2.2 Emergency power, cases of no power at sockets at critical areas, and lamp failure at critical areas.

FMS.28.2.3 Elevators.

FMS.28.2.4 Water supply.

FMS.28.2.5 Reverse osmosis plant.

FMS.28.2.6 Air-conditioning fan coil unit (FCU) at patient rooms.

FMS.28.2.7 Air-conditioning air handling unit (AHU) at operating rooms.

FMS.28.2.8 Medical gas system.

FMS.28.2.9 Sewer lines.

FMS.28.2.10 Boiler.

FMS.28.2.11 Telephone service (Public Address Exchange - PABX).

FMS.28.2.12 Intercom, nurse call, and overhead paging.

FMS.28.2.13 Fire alarm.

FMS.28.3 The utility system management plan includes description of necessary hospital programs to:

FMS.28.3.1 Acquire necessary equipment.

FMS.28.3.2 Upgrade equipment.

FMS.28.3.3 Upgrade physical condition of the building.

FMS.28.4 Emergency plans are tested in simulation at least once a year and the test results are evaluated.

FMS.28.5 The utility system plan ensures the availability of the following:

FMS.28.5.1 Technical utility drawings that show the distribution lines for all utilities and how to control them centrally and peripherally so that lines can be controlled as required in case of emergency.

FMS.28.5.2 Statistical data produced by the maintenance management system as an indicator to evaluate performance of the systems, suggest improvements and upgrade as required.

FMS.29 The hospital implements a preventive maintenance plan.

FMS.29.1 There is a preventive maintenance plan that covers at least the following:

FMS.29.1.1 Electrical system.

FMS.29.1.2 Elevators.

FMS.29.1.3 Refrigerators/Freezers.

FMS.29.1.4 Air conditioning system.

FMS.29.1.5 Medical gas system.

FMS.29.1.6 Medical suction.

FMS.29.1.7 Domestic water system, including water pumps and fire hydrants.

FMS.29.1.8 Fire water system, including fire pumps.

FMS.29.1.9 Boilers.
FMS.29.1.10 Plumbing.
FMS.29.1.11 Low current and communication system.
FMS.29.1.12 Pavement and ground.
FMS.29.1.13 Hospital building and ancillaries.

FMS.29.2 The hospital ensures all maintenance works are conducted by qualified and trained staff.

FMS.30 The hospital ensures electrical safety.

FMS.30.1 The electrical outlets are identified for:
FMS.30.1.1 Voltage (110/220).
FMS.30.1.2 Source (essential/prime).

FMS.30.2 Thermal inspection of circuit breakers is annually conducted for:
FMS.30.2.1 Operating Room.
FMS.30.2.2 Laboratory.
FMS.30.2.3 Critical care units.
FMS.30.2.4 Alarm system.
FMS.30.2.5 Blood storage.
FMS.30.2.6 Medical gas system.

FMS.30.3 There is an earthing system in the roof top and sockets used for medical equipment.

FMS.31 The hospital ensures that emergency power covers the critical areas in case of failure.

FMS.31.1 The hospital has an emergency power that covers at least the following critical areas:
FMS.31.1.1 Operating room.
FMS.31.1.2 Labor and delivery.
FMS.31.1.3 Critical care units.
FMS.31.1.4 Alarm system.
FMS.31.1.5 Fire pumps
FMS.31.1.6 Blood storage.
FMS.31.1.7 Medical gas system.
FMS.31.1.8 Refrigerators in the pharmacy, laboratory, medical store, and kitchen.
FMS.31.1.9 Elevators.
FMS.31.1.10 Escape routes/corridors.
FMS.31.1.11 Morgue.
FMS.31.1.12 Medications stores.
FMS.31.1.13 Emergency room.

FMS.31.2 The hospital ensures the readiness of its emergency power generator(s).
FMS.31.2.1 The hospital maintains its generator(s) on a periodic basis. The maintenance results are documented.
FMS.31.2.2 The hospital performs weekly test without load for ten minutes.
FMS.31.2.3 The hospital performs monthly on load test for thirty minutes.
FMS.31.2.4 The hospital performs full load test every three years on external load.
FMS.31.2.5 The hospital generator starts normally without load for ten minutes.

FMS.32 The hospital ensures proper maintenance of the medical gas system.

ESR

FMS.32.1 The medical gas system is regularly tested for:
- FMS.32.1.1 Pressure.
- FMS.32.1.2 Leaks.
- FMS.32.1.3 Functionality of valves, alarms, pressure gauge, and switches.

FMS.32.2 There is a policy and procedure that ensures effective use of medical gas system. Areas covered include, but are not limited to, the following:
- FMS.32.2.1 The procedures to follow for taking any part of the system offline.
- FMS.32.2.2 Commissioning and testing new branching or modifications.
- FMS.32.2.3 The procedure for ordering and filling liquid oxygen.
- FMS.32.2.4 Documenting all repairs/alterations/tests/filling logs/consumption.

FMS.32.3 Compressed medical air is regularly tested for humidity and purity.

FMS.32.4 The central medical gas station is in a safe and secure place.

FMS.32.5 The outlets of medical gases in patient care areas are clearly marked with the type of gas and have different connections according to the gas type.

FMS.32.6 All medical gas pipes are clearly marked and labeled for the contents and direction of gas flow.

FMS.32.7 In case of gas pipe repairs or new extensions, outlets are tested for the type of gas to ensure the correct type is delivered through the new pipe. Results of testing are recorded and maintained with engineering and the unit manager.

FMS.32.8 The hospital keeps standby oxygen and medical air cylinders enough for forty eight hours of average consumption.

FMS.32.9 The gas cylinders are regularly tested for gas type, amount, and any leaks.

FMS.32.10 Emergency shut off valves are available in all units and are clearly marked with areas/rooms affected.

FMS.32.11 The hospital dedicates the responsibility of the closure of shut off valves to well-trained individual(s) available in the unit concerned.

FMS.32.12 The hospital has adequate medical gases outlets in the patient care areas as appropriate and these outlets are to be error proof medical gas outlets- preferred to be in accordance with DIN standards related to gases piping, outlets and valves.

FMS.33 The hospital has a documented system for handling the various types of compressed gasses.

FMS.33.1 There is a policy on how to handle various types of compressed gasses, which includes:
- FMS.33.1.1 Storing them in a well-ventilated area.
- FMS.33.1.2 Positioning them upright the wall and secured by a chain.
- FMS.33.1.3 Separating any flammables from oxidizing gases.

FMS.33.2 Exhausts of the following gases are extended to the roof and identified:
- FMS.33.2.1 Laboratory safety cabinet gases of a certain classes.
- FMS.33.2.2 Central vacuum gases.
- FMS.33.2.3 Scavenger gases of certain types.
- FMS.33.2.4 Bone marrow transplantation (BMT) laboratory gases.

FMS.34 There is a periodic preventive maintenance plan for heating, ventilating, and air- conditioning.

FMS.34.1 There is a periodic preventive maintenance (PPM) plan for heating, ventilating, and air-conditioning (HVAC) that is supported by trained and specialized staff/contractor.

FMS.34.2 The HVAC maintenance records are maintained.

FMS.34.3 The HVAC is maintained to control the air quality by:

FMS.34.3.1 Cleaning /replacement of filters.

FMS.34.3.2 Cleaning of diffuser.

FMS.34.3.3 Cleaning of ducts.

FMS.34.4 HEPA filters are monitored on a monthly basis and the results are documented.

FMS.34.5 Air change per hour is maintained as per national and international guidelines (e.g., American Society of Heating, Refrigerating & Air-Conditioning Engineers, ASHRAE).

FMS.35 The hospital ensures proper air flows (positive, negative, balanced) in the required locations.

FMS.35.1 Appropriate air flows (positive, negative, balanced) are established and monitored in operating room(s).

FMS.35.2 Appropriate air flows (positive, negative, balanced) are established and monitored in labor and delivery.

FMS.35.3 Appropriate air flows (positive, negative, balanced) are established and monitored in isolation room(s).

FMS.35.4 Appropriate air flows (positive, negative, balanced) are established and monitored in critical care unit(s).

FMS.35.5 Appropriate air flows (positive, negative, balanced) are established and monitored in clean and dirty utility.

FMS.35.6 Appropriate air flows (positive, negative, balanced) are established and monitored in janitorial closet.

FMS.35.7 Appropriate air flows (positive, negative, balanced) are established and monitored in the laboratory.

FMS.35.8 Appropriate air flows (positive, negative, balanced) are established and monitored in triage and trauma management areas.

FMS.35.9 Appropriate air flows (positive, negative, balanced) are established and monitored in the central sterilization and supply department.

FMS.36 The hospital provides appropriate control of temperature and humidity in the required locations.

FMS.36.1 Temperature and humidity are controlled and regularly monitored in operating and recovery room(s).

FMS.36.2 Temperature and humidity are controlled and regularly monitored in nursery.

FMS.36.3 Temperature and humidity are controlled and regularly monitored in critical care unit(s).

FMS.36.4 Temperature and humidity are controlled and regularly monitored in sterile storage supply.

FMS.36.5 Temperature and humidity are controlled and regularly monitored inpatient rooms.

FMS.37 **The hospital has a periodic preventive maintenance plan for the water system.**

FMS.37.1 There is a periodic preventive maintenance plan (PPM) for the water system that is supported by trained and specialized staff/contractor.

FMS.37.2 The PPM records are maintained for the following:

FMS.37.2.1 Water is available twenty four hours a day, seven days a week.

FMS.37.2.2 The incoming water supply is checked regularly for at least: chemicals (once every six months) and bacteria (monthly), and results are monitored.

FMS.38 **The hospital ensures safe sewage handling and disposal.**

FMS.38.1 Sewage handling and disposal is safely conducted in an efficient and sanitary manner according to professional codes of practice.

FMS.39 **The hospital maintains the kitchen and laundry equipment in good working condition.**

FMS.39.1 Laundry equipment are regularly inspected and tested.

FMS.39.2 Results of inspection and testing of kitchen equipment are documented as follows:

FMS.39.2.1 Hoods' fans are in good operating condition and free from grease.

FMS.39.2.2 Hood filters are cleaned weekly and no cooking is done with missing filters.

FMS.39.2.3 Cold room temperature is monitored.

FMS.39.2.4 Kitchen and pantry microwaves, stoves, and ovens are at least annually tested and maintained.

Glossary

Glossary

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

Accountability
The ability of a system to track an individual's actions, or the acknowledgment and assumption of responsibility for actions, products, decisions, and policies.

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

Adverse Drug Reaction
A response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function.

American society of health-system pharmacists (ASHP)
A professional organization of pharmacists and pharmacy technicians in the United States of America. It has been on the forefront of efforts to improve medication use and enhance patient safety.

Antibiogram
The result of a laboratory testing for the sensitivity of an isolated bacterial strain to different antibiotics. It is also known as in-vitro sensitivity.

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

Automatic Stop Order
A type of medication orders that originates not with the physician but with the hospital pharmacy. Medication orders for certain types of drugs (e.g., controlled substances) are only valid for a certain number of days as determined by the hospital's Pharmacy Committee while the patient is in the hospital. After that time, the pharmacy automatically stops sending the drug to the patient's nursing unit, and the attending physician must write an entirely new order if the patient is to continue to receive that drug. It is known as "Hard Stop "in electronic pharmacy profiles.

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 the best practices.

Blanket Order

A summary order to resume previous medications. Blanket orders can be confusing or imprecise and are not indicating a safe practice (e.g., resume previous medications, for a patient post-operation).

Clinical Practice Guidelines

Systematically developed statements that help practitioners and patients choose appropriate healthcare for specific clinical conditions.

Code of Conduct

A set of principles and expected behaviors that are expectations of employee performance within a healthcare setting or as defined by the leadership group.

Collaborative Work

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

Competency

Knowledge, skills, and attitudes required to perform the job. Knowledge is the understanding of facts and procedures. Skill is the ability to perform specific actions.

Committee

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

Confidentiality

The restricted access to data and information to individuals who have a need, a reason, and permission for such access. An individual's right to personal and informational privacy, including his or her healthcare 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. Patients and their families, staff, contractors, and visitors are all examples of internal and external customers of a hospital.

Continuous Quality Improvement Tools

Tools focusing on the process rather than the individual, and promote the need to analyze and improve that process.

Credentialing

The process of obtaining, verifying and assessing the qualifications of a healthcare professional to determine if that individual can provide patient care services in or for a healthcare 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

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.

Drug Utilization Evaluation (DUE)

A system of ongoing, systematic, criteria-based evaluation of drug use that will help ensure that medicines are used appropriately (at the individual patient level). DUE is drug or disease-specific and can be structured so that it will assess the actual process of prescribing, dispensing or administering a drug (indications, dose, drug interactions, etc.).

Effectiveness

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

Efficacy

The power to produce an effect, for example: clinical trials in medicine provide evidence or efficacy.

Evidence Based Medicine

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

Extemporaneous Preparations

The timely non-sterile preparation of a drug product according to a physician's prescription, a drug formula, or a recipe in which calculated amounts of ingredients are made into a homogenous (uniform) mixture under the direct supervision of a pharmacist. Extemporaneous compounding is performed when certain medical needs of individual patients cannot be met by the use of an approved commercial drug product.

Family or Responsible Person

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

Functional Status

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

Formulary

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

Goal

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

Governance

The function of determining the organization's direction, setting objectives, and developing policy to guide the organization in achieving its mission.

Governing Body

In healthcare, it represents 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 provided by the hospital.

Guidelines

Principles guiding or directing actions.

Hazardous Materials

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

Hazardous Waste

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

Healthcare-Associated Infections (HAIs)

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

Healthcare Organization

A generic term used to describe many types of organizations that provide healthcare services.

Healthcare Professional

Any person who has completed a course of study and is skilled in a field of health. This includes physicians, dentists, nurses, or other healthcare professionals. Healthcare professionals are often licensed by a government agency or certified by a professional organization.

High-Alert Medications

Medications that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these medications, the consequences of an error with these medications are clearly more devastating to patients.

Medical Record

A record that contains patient health information generated by one or more 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.

Incidents

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

Indicator of Performance

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

Information

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

Information Management

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

Informed Consent

Person's voluntary agreement of one who has sufficient mental capacity with full knowledge of the risks involved, probable consequences, and the alternatives to make an informed decision. It allows a patient to balance the probable risks against the probable benefits of any potential care.

Job Description

A written statements that describes the duties, responsibilities, required qualifications of candidates, and reporting relationship and coworkers of a particular job.

Leaders

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

Look-Alike Sound-Alike (LASA) Medications

Medications with generic or proprietary names that look or sound like other medication names.

Management

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

Medication Administration Record (MAR)

Documentation of all medications administered to a patient and the date and time of delivery.

Medication Error

Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

Medication Management

The overall effort by hospitals and manufacturers to reduce medication errors, which can occur during the various stages of the medication use cycle: Selection, procurement, prescription, transcription, dispensing, distribution, administration, and monitoring.

Medication Order

The handwritten, preprinted or electronic record of a physician's order to the pharmacist to dispense a drug to a patient who is in a hospital or other healthcare facility.

Medication Recall

The act of requesting the return of a batch or entire production run of a medication, usually because of a defect, safety concern, or efficiency problem. Recalls may be conducted by the national healthcare authorities such as the Saudi FDA or voluntarily by the manufacturer.

Medication Reconciliation

The process of creating the most accurate list possible of all medications the patient is taking – including drug name, dosage, frequency, and route – and comparing that list against the physician's admission, transfer, and/or discharge orders, with the goal of providing correct medications to the patient at all transition points within the hospital.

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

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

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

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

Near-Miss
An event that could have resulted in unwanted consequences, but did not because either by chance or through timely intervention the event did not reach the patient.

Non-Formulary Medication
Any medication not on the list of approved medications by the pharmacy and therapeutics committee.

Objectives
Concrete measurable steps taken to achieve goals.

Occupational Safety and Health Administration (OSHA)
A government agency under the United States Department of Labor that helps employers reduce injuries, illnesses, and deaths in the workplace.

Off-Label
Where prescribing or supply of a licensed medication is outside the indications named in its license or summary of product characteristics. There are a number of circumstances where medicines may be prescribed or supplied for the purposes for which they are not licensed e.g. children.

Organizational Chart
A diagram representing the structure of the hospital and reporting relationships. It shows employee positions, reporting relationships, and lines of authority.

Orientation
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 hospital accepts responsibility for treatment, care and/or service.

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

Patient Safety
Freedom from accidental injuries during the course of medical care; activities to avoid, prevent, or correct adverse outcomes which may result from the delivery of health care.

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

PDCA
A scientific method utilized to improve processes. Acronym components: PLAN the improvement, DO the improvement, collect 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.

Pharmaceutical Care
A patient-centered pharmaceutical practice in which the pharmacist assumes responsibility for a patient's medication management issues and is held accountable for this commitment.

Pharmacovigilance
The science and activities relating to the detection, assessment, understanding and prevention of the adverse effects of pharmaceutical products.

Plan
To formulate or describe the approach to achieving the goals related to improving the performance of the organization.

Plan of care (Care Plan)
A treatment plan especially designed for each patient, based on individual strengths and needs. The caregiver(s) develop(s) the plan with input from the family and communication with each other. 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 written document which outlines the rules and expected performance of staff within the organization. Policies are dynamic and reflect current knowledge and practice and need to be reviewed on a regular basis.

Privileging

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

PRN Order

Orders acted upon based on the occurrence of specific indication or symptom (e.g., acetaminophen 500 mg PO Q4H, PRN for fever ≥38.5ºC).

Procedure

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

Process

A set of interrelated steps directed at one particular outcome.

Process Improvement

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

Probationary period

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

Protocols

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

Psychosocial

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

Quality

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

Quality Control

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

Quality Improvement Team

Individuals (cross-department functions/services) knowledgeable about a particular aspect of care or service and commissioned to improve a process that has been identified as requiring attention.

Range Order

Order in which the dose or dosing intervals varies over a prescribed range, depending on the situation or patient's status (e.g., pethidine 50-100 mg IM Q3-4H, PRN for pain).

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, either for consultation or care that the referring source is not prepared or qualified to provide.

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 healthcare practitioners.

Scope of Services

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

Screening

A system for examining and separating into different groups.

Screening Criteria

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

Sentinel Event

An event that, when noted, requires intensive assessment and prompt response.

Serious Adverse Drug Reaction

An adverse drug reaction which results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity.

Standard

Statement of structure, process or outcome expectations necessary to enhance quality care.

Standardization

To confirm with a predetermined set of expectations.

Standing Orders

Group of specific orders that are preprinted on a facility's physician's order sheet. They often pertain to a protocol of treatment related to a specific disease or surgical procedure. They contain standard common orders that are the same for any patient who has that specific disease or is scheduled for that surgical procedure. For example, a patient admitted for bowel surgery would have preoperative standing orders for a clear liquid diet and enemas, for an antibiotic drug to kill bacteria in the bowel, and for no food (NPO) after midnight before the surgery. Another example: for anaphylactic reaction, give 0.3ml of Epinephrine 1:1,000 intramuscularly and Diphenhydramine 1mg/kg intramuscularly. Monitor BP, Pulse and Respiratory rate.

Strategic Planning

A management tool to help an organization do a better job. 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 direction.

Structure

Environmental features which shape process and outcome: resources, money, equipment, supplies, staff, and policies.

System

A group of related processes.

Tapering Order

Order in which the dose is deceased by a particular amount with each dosing interval. Taper orders shall include the starting dose, the entire taper, the medication amount for each step of the taper, and frequency of the taper (e.g., Prednisone 20 mg PO for 2 days, then taper dose on successive days to give 15 mg for 1 day, then 10 mg for 1 day, then stop).

Transcribing

Any act by which medicinal products are written from one form of direction to administer to another is "transcribing" (whether hand written or computer generated).

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.

Titrating Order

Order in which the dose is either progressively increased or decreased in response to the patient's status. Titrated orders shall include the starting medication dose, assessment parameters, and final endpoint (e.g., Dopamine 5mcg/kg/min. Titrate infusion rate every 15 minutes to maintain MAP of 60-80 mmHg).

Transfer

The formal shifting of responsibility for the care of a patient from one care unit to another, one clinical service to another, one qualified practitioner to another, or one organization to another organization.

Trending

The evaluation of data collected over a period of time for the purpose of identifying patterns or changes.

Triage

A system of establishing the order in which acts are to be carried out in an emergency, prioritize patients by their problems, symptoms determining the order of being managed.

Turn Around Time

Initial time from the starting point to the end point. For example: For a stat order, the time the doctor's order was written or stated to the time it is carried out.

USP <797>

A general chapter in the United States Pharmacopoeia that describes requirements for the preparation of sterile drugs. USP is a nongovernmental, scientific body responsible for setting standards for drug quality and related practices.

Utilization

The use, patterns of use, or rates of use of a specified healthcare 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 or to reach in the future.

About This Manual

This third edition of the National Standards for Hospitals was developed through a consensus process which entailed the participation of all the relevant stakeholders.

From the beginning , the aim was to have a set of standards that are detailed and descriptive , assembled around the key departments and services common to all hospitals, and based on the current status of the healthcare practices within our hospitals.

The goal of this manual is to be used as a reference for achieving the optimal care for patients and their families , given the local challenges that we are facing today. All standards and policies included in this manual are effective 1 January 2016

About CBAHI

The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) is a non-profit organization emerging from the Saudi Health Council and is responsible for setting and implementing the quality and patient safety standards in Saudi Arabia.

CBAHI national hospital standards are accredited by the International Society for Quality in Health Care (ISQUA).

CBAHI began few years ago with only few hospitals enrolled in the accreditation process and limited number of surveyors and staff.

Today, CBAHI is proud to have a comprehensive set of evidence-based standards that are utilized for the assessment of thousands of healthcare facilities across the country.

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