CBAHI

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

رؤية VISION 2030
المملكة العربية السعودية
KINGDOM OF SAUDI ARABIA

المعايير الوطنية للمراكز والمجمعات الطبية الخارجية

NATIONAL STANDARDS FOR AMBULATORY CARE CENTERS

FIRST EDITION 2019
EFFECTIVE FROM 1st January 2020

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Saudi Central Board for Accreditation of Healthcare Institutions

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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 healthcare facilities to continuously comply with the accreditation standards. CBAHI does this through the provision of preparation, on-site assessment, monitoring, education, publications and consultation services.

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

The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI), a not-for-profit governmental organization, has been required by its formation order to support all healthcare organizations in Saudi Arabia through different mechanisms, including the production of scientific peer reviewed standards, materials and publications.

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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 بشكلٍ 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 dates 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 of 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 operating licenses, and a step towards encouraging more participation in this ambitious national initiative.

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Foreword

Healthcare system in Saudi Arabia is currently witnessing a major shift at all levels. Under the new vision 2030, the government is determined to bridge the long-standing gap between the healthcare we have and the healthcare we should have. It is evident we need to change the way in which we deliver the care and to re-design the health care system to become more efficient and more productive. The main goal however, remains the same under all conditions. That is to focus on improving the community health, while increasing the capacity and capability of healthcare services for meeting one of the fastest growing population rates.

The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) has a pivotal role to play now and in the future. It represents an independent entity, that is responsible for setting the standards of healthcare provision and assessment of healthcare organizations against those standards. The aim is to ensure better quality and a more reliable environment of care. This manual is directed towards thousands of ambulatory healthcare centers, mainly polyclinics scattered all over the country. They represent an important partner with the public sector in providing healthcare to more than thirty-two million people. Ensuring that the healthcare provided in these centers is compatible with the desired standards is of a prime importance. Benefits are numerous, but most notably is the reduction of variations in the quality of care among different providers, minimization of waste and increasing patients and staff satisfaction.

Healthcare accreditation in Saudi Arabia is an example to follow for different countries in the region. Being accredited by the International Society for Quality in Healthcare (ISQua), CBAHI is adding more to its credibility as a trusted accreditation body that is in compliance with the international standards.

We are all thankful to the country's sincere and committed leadership for its endless support towards a better and safer healthcare.

H.E. Dr. Tawfig AlRabiah
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 the National Ambulatory Healthcare Standards. Several professional bodies have assisted as well with the development and refinement of the standards. CBAHI would like to extend thanks and appreciation to all health authorities, organizations and individuals who participated in or provided external commentaries to this important national initiative. The following is a list of participants in alphabetical order.

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Preface

The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) is proud to introduce this first edition of the National Standards for Ambulatory Healthcare Centers. Over the past decade or so, 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 ambulatory healthcare centers and clinics, and the complexity of healthcare services they provide to more than thirty-two million population scattered over more than two million square kilometers area. This comes along with a great advancement in the medical field globally, with more focus on the need for environments of care that support performance measurement and continuous quality improvement. Here comes the rationale for a national, evidence-based standard that would support ambulatory healthcare centers in Saudi Arabia in improving the quality and safety of patient care and treatment.

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

During the development of this manual, one of the most important challenges we faced was to develop standards that would apply to all ambulatory care centers, considering the variation in the quality levels across the continuum of care, as we move from smaller centers in towns and peripheries, to the larger medical centers in major cities. Being comprehensive, detailed and sometimes prescriptive in design and nature, this edition of the National Standards for Ambulatory Healthcare Centers was built to be as relevant and applicable as possible, once implemented in the relevant centers licensed to practice in the Kingdom of Saudi Arabia.

Upon pursual of this 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 relevant chapters.

Our sincere appreciation and gratitude are extended to the Committees Teams and Task Forces who contributed to the development, compilation, design, review, revision and production of this manual. We would like to convey our appreciation to the healthcare professionals who have been obliging and generous with their professional feedback, time, constructive comments and suggestions. We wish to also mention, our heartfelt gratitude to H.E Dr. Mohammed H. Khosheim, an inspiring leader in the sphere of Healthcare Quality and the founder of CBAHI.

For further information on other accreditation programs of CBAHI, including all comments and suggestions for improvement, please contact us on **cbahi@cbahi.gov.sa**

Dr. Salem Al Wahabi
Director General - CBAHI

PART I

INTRODUCTION & EXPLANATORY NOTES

CBAHI at a Glance

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

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

The mission of the Saudi Central Board is to support all healthcare facilities, through accreditation to continuously comply with quality and patient safety standards.

The vision of the Saudi Central Board is to be the leading healthcare accreditation agency in the region.

In addition to the Ambulatory Healthcare Accreditation program, CBAHI currently has three other accreditation programs (Primary Healthcare, Hospital Healthcare and Clinical Laboratories and Blood Banks). Other accreditation programs are under process.

CBAHI's goal is to achieve two conjoined initiatives, in congruence with (the 2030) vision. The first initiative is to expand the range of efficient and effective accreditation programs to cover healthcare services. The second initiative is to work with several partners to support the health system in Saudi Arabia and the region by increasing the depth of quality improvement and patient safety, as well as by disseminating knowledge through training and education. Driven by its core values, a dedicated team of surveyors and staff, 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 one of the few healthcare accreditation agencies globally, accredited by the International Society for Quality in Healthcare (ISQua), for hospital standards, surveyor training programs and for 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 Healthcare Facility (HCF) undergoes an appraisal of its systems, processes and performance by peer reviewers or surveyors, to ensure that all tasks are conducted in a manner that meets applicable predetermined and published national standards. Before the external evaluation, i.e., the survey visit, the HCF is expected to conduct a comprehensive self-assessment to determine its level of preparedness, and how close it is to achieving full compliance with the standards. Therefore, accreditation represents the healthcare accreditation body's public recognition of the achievement of accreditation standards by an HCF. Standards set out a common framework to support HCFs in providing effective, timely and quality services. They are designed to deliver improved levels of care and treatment to the citizens and residents of Saudi Arabia. Evidence from scientific research shows that engagement in a robust healthcare accreditation program improves the structure, process and outcome of care that healthcare facilities provide. Accreditation is not merely a certificate to obtain and hang on the wall. If utilized properly, accreditation can provide the following benefits:

- Accreditation provides a framework for organizational structure and management. Accreditation standards focus on the governance and leadership structures and functions within a HCF and the appropriate management of its business and day-to-day activities.

- Accreditation helps improve patient safety and minimizes the risk of near misses, adverse outcomes and medical errors. Ensuring patient safety through risk management and risk reduction is at the center of all accreditation standards and is the ultimate goal of the self-assessment and survey activities.

- Accreditation enhances community confidence in the quality and safety of care provided. When a HCF achieves accreditation, the message is clear – its leaders are committed to providing a nationally accepted standard of care in health services delivery.

- Surveyed HCFs have found that seeing their operation through the eyes of experienced surveyors gave them a useful, more objective assessment of their internal administrative and clinical processes, as well as effective proposals for improving their processes and services delivered to the community.

- Accreditation in the long term, increases efficiency and enhances lean practices, which in turn leads to decreasing waste and achieving optimal results with less consumption of resources.

- Accreditation helps improve a healthcare facility's competitiveness.

- Boosting public confidence in an accredited facility will encourage more patients to seek care and treatments in that facility. This will positively impact its competitiveness in the healthcare sector and increase its market share.

- Achieving accreditation will fulfill the regulations required by the Ministry of Health, which is now considering linking the national accreditation by CBAHI to the licensing of healthcare facilities.

- Registration with CBAHI and enrollment in its national accreditation program are accepted by the Ministry of Health (at this stage) as satisfactory evidence for the purpose of license renewal. Eventually all HCFs operating in Saudi Arabia must achieve CBAHI accreditation.

- Accreditation has a link to reimbursement from insurers and other third parties. There is a growing tendency, nationally and internationally, to link accreditation with eligibility for insurance reimbursement.

- Accreditation provides a robust tool for continuous quality improvement efforts in the HCFs and helps facility leadership to ensure the sustainability of quality improvement projects and initiatives.

- Accreditation offers great learning and educational opportunity. This is achieved through staff education on best practices and by emphasizing the importance of patient education and patient rights.

Scope of Accreditation Surveys

The scope of the CBAHI survey includes all standard related functions of the surveyed HCF. Each assessment survey is tailored to the type, size and range of services the facility offers. Applicable standards from this manual are determined by CBAHI, based on the scope of the services provided by the HCF undergoing a survey. Additionally, the onsite survey team will consider the specific applicability of individual standards.

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 HCFs to ensure the provision of safe, quality care and services.

Standards are developed by peer experts in their specific field and it is against these standards to which conformity of the healthcare facility is evaluated. Simply stated, a standard describes a HCF'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. When met, they will establish a high-quality level in a system.

Broadly speaking, CBAHI standards, as well as those of all other relevant accrediting agencies, focus on three major aspects depending on which area they are addressing.
Structure; standards address the system's inputs, such as manpower, design of the HCF 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 HCF in the care of patients or the management of the facility or its staff. Examples include patient assessment, patient education and medication administration.
Outcome; standards involve the assessment of an intervention's benefits and whether the activity's expected purpose was achieved. They provide information regarding predicted outcomes which are being realized. Examples include patient satisfaction, health-care-associated infections, medication errors, sentinel events and adverse events such as falls and injuries.

CBAHI standards set expectations for HCF performance which are reasonable, attainable, measurable and therefore, conducive to a survey. Standards were built to serve as the basis of an objective evaluation process that can help HCFs 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 HCFs meet rigorous standards of quality and operational integrity that emphasize consumer protection and patient engagement. Therefore, the process of standards development at CBAHI follows a long and robust methodology to ensure our standards are correct, evidence-based, relevant and clear. As with previous accreditation books, this book contains standards of quality and patient safety that are descriptive in nature and department-oriented. Specialized task forces develop the first draft of CBAHI standards, including focus groups and standards development committees that utilize input from a variety of sources, including:

- The standards set by professional scientific societies, both 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 healthcare professionals, providers, and patients.
- Panels of experts and consensus on best practices, given the current state of knowledge and technology.

The process of standard development can last up to18 months 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 during 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 Steering Standards Development Committee and provided to the CBAHI Board for comments and remarks before submission to the Saudi Health Council for approval. Thereafter, standards are provided in both paper and electronic formats and distributed to HCFs.

An e-version is also made available on the CBAHI website. To comply with the guidelines of the International Society for Quality in Healthcare (ISQua), a period of six months is allowed for publishing of the standards before they are effective. Once the standards are in effect, ongoing feedback is sought for continuous improvement. The survey process is then tailored to address the new standards, and surveyors are taught how to assess compliance with the standards.

Accreditation Survey

CBAHI surveyors typically employ a variety of evaluation techniques and strategies to objectively decide whether the facility meets standards related to key systems and functions, such as governance and leadership, patient care processes, medication management, infection control, management and safety of the facility environment and quality assurance. For example, the survey team may review written documents (e.g., strategic and operational plans and budgets, and clinical policies and procedures). In addition to reviewing documents, surveyors will interview facility leaders, physicians, nurses, employees and patients to determine the facility's performance and compliance with standards. For example, the surveyor might interview a staff member to check on the process he or she would complete to report a medical error, that caused harm to one of the patients receiving care in that facility. Similarly, a surveyor might interview a patient about his or her level of satisfaction with the care the HCF provides.

HCF leaders, including members of the governing body, may be interviewed regarding facility processes and how they are designed to meet standards related to planning, budgeting, quality assurance activities and human resources management. Surveyors tour the facility's buildings and patient care areas 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 the laboratory, radiology, pharmacy, central sterile services and day procedure unit are also assessed for safety, effectiveness, quality control and equipment management.

In summary, during an on-site survey, surveyors use a variety of evaluation approaches to determine the facility's compliance or performance regarding applicable structure, process and outcome standards. These methods might include any combination of the following:

In summary, during an on-site survey, surveyors use a variety of evaluation approaches to determine the facility's compliance or performance regarding applicable structure, process and outcome standards. These methods might include any combination of the following:

- Interviews with facility leadership, clinical and support staff, patients and family.
- Observation of patient care and services.
- Facility 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, budgets and quality improvement plans.

- Review of personnel files.
- Review of patients' medical records.
- Evaluation of the facility's achievement of specific outcome measures (e.g., acquired infection rates, patient satisfaction) through review and discussion of monitoring and improvement activities.

The CBAHI team surveys a HCF depending on the volume and complexity of the services that the facility provides, the number of locations or care settings included in the survey and the type of survey such as focused or full. The scope of the survey visit includes all standards-related functions in the HCF. This implies that any service/function/area not covered by CBAHI standards will not be assessed during the survey visit. CBAHI determines applicable standards from this book based on the scope of services and the onsite survey team's decision regarding the applicability of individual standards.

Structure of the National Standards for Ambulatory Care Centers

The National Standards for Ambulatory Care Centers are assembled into eleven chapters consisting of key services and functions that ambulatory healthcare centers provide in Saudi Arabia. The standards within these chapters are arranged according to the workflow within the services.

The chapters are:

- Leadership of the Organization (LD)
- Provision of Care (PC)
- Laboratory Services (LB)
- Radiology Services (RD)
- Dental Services (DN)
- Medication Management (MM)
- Management of Information (MOI)
- Infection Prevention and Control (IPC)
- Facility Management and Safety (FMS)
- Day Procedure Unit (DPU)
- Dermatology & Aesthetics Medicine (DA)

Each chapter includes a brief introduction that explains the chapter's relevance and contribution to safety and quality patient care. Each standard consists of a stem represented by a concise statement. This is followed by one or more sub standards to further illustrate the standard's requirements. Each substandard is constructed in a way to serve by itself as the evidence of compliance that is going to be measured and scored during the on-site survey. Each standard is accompanied by an explanation to help the ambulatory HCFs understand the intent behind it.

No matter how robust the methodologies used in building the standards, room for improvement will always exist. Therefore, all comments and remarks on standards can be made and viewed on the CBAHI website, which includes an electronic form that allows HCFs, experts and other interested parties to comment on current standards. The form allows for continual stakeholder feedback on the standards. This is one of several CBAHI initiatives for improving the efficiency and effectiveness of internal processes, including standards development to better meet the needs and expectations of our partners.

Survey Process

The goal of the survey process is to ensure that the CBAHI standards are integrated into the HCF's daily practices. In addition to conferences, interviews and a review of documents, the major part of the survey visit will involve an evaluation of standards implementation and the performance of different processes within the HCF.

Preventable adverse events commonly occur in HCFs all over the world. Thus, CBAHI realizes that compliance with the standards does not guarantee a safe patient environment. The ambulatory healthcare facilities undergoing CBAHI accreditation must fully comply with these standards.

The central principle behind CBAHI standards selection is to ensure that the center has well-qualified and competent staff working in a well-organized setting to deliver effective and reliable services.

If you cannot imagine the importance of the presence, of the following standards, try to imagine the adverse effect and impact of their absence. However, accreditation itself is not the end. Rather, it should be viewed as the first step in an endless journey towards quality improvement and excellence.

There are (133) Standards distributed throughout the chapters.
* **(C)** denotes core standard, i.e. full compliance is mandatory for all.

List of Standards	
Number	**Standard**
LD.1	The governing body defines its structure and operational responsibilities in a written document.
LD.2	The governing body approves and evaluates the center's quality and patient safety program and risk management program.
LD.3	The center has a current organizational chart.
LD.4	The center is managed effectively by a qualified director.
LD.5	The leaders together with governance develop the center's scope of services based on community needs.
LD.6	The leaders work collaboratively to develop the center's strategic plan.
LD.7	The leaders transform the approved strategic plan into an operational plan.
LD.8	The leaders work collaboratively to develop the operational budget.
LD.9	The leaders work collaboratively to fulfill the mission and provide quality care.
LD.10	The leaders develop a staffing plan for the center.
LD.11	The leaders develop a policy and procedure for staff recruitment.
LD.12	All categories of staff have clearly written job descriptions.
LD.13 **(C)**	The leaders develop an effective process for credentialing and re-credentialing all healthcare providers.
LD.14 **(C)**	All medical staff members have current delineated clinical privileges.
LD.15	All new employees attend a mandatory orientation program.

List of Standards	
Number	**Standard**
LD.16	The leaders develop and implement a policy that ensures nurses and other allied healthcare staff are competent in specific procedures.
LD.17	The leaders ensure staff are trained and test competent in the safe operation of equipment including medical devices.
LD.18	The leaders support continuing education and training for all categories of staff.
LD.19	Staff are trained and kept up to date with cardiopulmonary resuscitation.
LD.20	The leaders develop an effective process to evaluate staff performance at least annually.
LD.21	The leaders implement a comprehensive program to protect the health and safety of staff.
LD.22	The leaders support and protect the patient and family rights.
LD.23	The leaders ensure that patients/families have the right to be involved in their own care and treatment.
LD.24	The leaders develop and implement a policy and procedure to describe the patients' right to voice their complaints and concerns.
LD.25	The leaders ensure that patients/families have the right to accurate billing for provided services.
LD.26	The leaders develop ethical standards to guide patients' care and employees' code of conduct.
LD.27	The center provides assistance to patients with special needs.
LD.28	The center has an implemented policy for controlling the development and maintenance of key documents.
LD.29	The center develops a comprehensive quality improvement and patient safety program.
LD.30	The leaders prioritize and select a set of indicators that focus on the structure, process, and outcome of the services provided within the center.
LD.31	The leaders develop and implement a comprehensive risk management program.
LD.32	The leaders develop and implement an incident reporting policy.
LD.33	The leaders oversee any contracts for clinical or operational services.
LD.34	The leaders ensure the integrity and security of telemedicine, teleradiology and interpretation of other diagnostic remote contracted services.
LD.35	The leaders implement policies and procedures to guide the efficient procurement of equipment either purchased or donated, medications and essential medical consumables in accordance with national laws and regulations.
LD.36	The leaders ensure an aesthetic appeal for the center.
PC.1	Patients have access to services based on their health needs and available services and are registered with the center for providing such services.
PC.2 **(C)**	The center has a process to ensure the correct identification of patients.

List of Standards	
Number	**Standard**
PC.3	Patients are clinically assessed through an established assessment policy and procedure.
PC.4	Physicians are provided with the results of requested investigations according to a time frame.
PC.5	The center develops and implements a process for reporting critical test results whether on-site or outsourced.
PC.6	A care plan is developed by the attending physician to meet the patient's needs considering patient and family's cultural and spiritual matters.
PC.7	Consultations are available to meet the healthcare provider's request and patient's needs in a timely manner.
PC.8	Staff members assist patients and, when appropriate, their families in fully participating in making informed decisions about their care, treatment and procedures.
PC.9	Patients and, when applicable, their families are educated about their healthcare needs.
PC.10	Informed consent is obtained from the patient or guardian.
PC.11	Patients planned for a surgery/procedure give their informed consent to the surgery/procedure and the anesthesia/sedation.
PC.12	The center has an effective process to safely provide care to patients who require Cardio Pulmonary Resuscitation (CPR).
PC.13	Policies and procedures guide the transfer of patients in need of urgent admission to hospitals.
PC.14	Ambulance services are available and meet the patient's needs.
PC.15	The center has an emergency services to deal with minor emergencies.
LB.1	Laboratory services are available or outsourced to meet the needs of the patient population served.
LB.2	The laboratory has the right space and facilities relevant to the services provided.
LB.3	The laboratory develops and implements a comprehensive safety program.
LB.4	The laboratory develops and implements a comprehensive infection control program.
LB.5	The laboratory has a clearly defined and implemented process describing its role in selecting and evaluating providers of reference laboratory services.
LB.6	The laboratory has a clearly defined and implemented process for laboratory instrument and equipment management.
LB.7	The laboratory develops and implements a policy for the documentation of specimen receipt and inspection.
LB.8	The laboratory develops a policy and procedure for the quality control of test methods.

List of Standards	
Number	**Standard**
LB.9	The laboratory develops a policy and procedure for Proficiency Testing (PT) sufficient for the extent, complexity and scope of services.
LB.10	The laboratory defines the format and contents of laboratory reports.
LB.11	The laboratory has a process for correcting or amending reported results.
LB.12	The laboratory develops and implements a comprehensive process for Point-of-Care-Testing (POCT).
RD.1	Radiology services are available or planned with other institutions to meet patient needs and in accordance with applicable national standards, laws and regulations.
RD.2 **(C)**	The center has a radiation safety program.
RD.3	There is implemented process to keep the radiology equipment in safe, functional condition.
DN.1	Dental staff have appropriate qualifications.
DN.2	A comprehensive assessment is performed and documented for each patient.
DN.3	The dentist documents the treatment plan in the patient's medical record.
DN.4	Infection control guidelines are available and implemented by dental staff.
DN.5	Safety rules are applied in the dental laboratory.
MM.1	Medication use processes are available to meet patient needs and in accordance with applicable laws and regulations.
MM.2	The center has an updated and well-structured formulary.
MM.3	The center has a process for the appropriate storage of medications.
MM.4	The center has a process for ensuring the stability of medication available in multi-dose containers.
MM.5	The center has a process for identifying and handling expired medications.
MM.6	The center develops a policy and procedure for the safe prescribing of medications.
MM.7	The center develops and implements guidelines for the correct prescribing of antibiotics.
MM.8	The center develops a process to manage narcotics, psychotropic medications, and other controlled medications according to laws and regulations.
MM.9	The center safely manages high-alert and look-alike, sound-alike, LASA medications.
MM.10	The center evaluates the appropriateness of prescriptions before dispensing.
MM.11	Medication preparation areas comply with infection control measures and safe practices.
MM.12	The center develops and implements a policy and procedure on medication error reporting.
MM.13	The center monitors allergies to medications.

List of Standards	
Number	**Standard**
MM.14	The center develops and implements a policy and procedure for the reporting of adverse drug reactions ADR's.
MOI.1	The leaders define in a plan the information that is shared among the staff and with other governmental and non-governmental entities and its format.
MOI.2	The leaders develop standardized diagnosis codes, procedure codes and symbols, and minimize abbreviations.
MOI.3	All patients seen in the center have unique medical records.
MOI.4	The leaders develop a policy on the rules and regulations for writing in patients' medical records.
MOI.5	The leaders develop a process for completing and storing the patient medical record.
MOI.6	The center has an implemented policy and procedure for the use of information technology.
MOI.7 **(C)**	The center has an effective clinical documentation improvement (CDI) program.
IPC.1	The center implements a coordinated program to reduce the risk of healthcare-associated infections.
IPC.2	Infection prevention and control activities are integrated and coordinated by an interdisciplinary team.
IPC.3	The leaders develop and ensure the implementation of infection control policies and procedures targeting the most important infection risk processes.
IPC.4	Communicable diseases are tabulated and reported as required by laws and regulations.
IPC.5	The leaders develop and implement a policy and procedure for healthcare associated infection prevention.
IPC.6	The leaders design and ensure the implementation of an effective hand hygiene program.
IPC.7 **(C)**	Centers providing sterilization services strictly follow rigorous sterilization rules.
IPC.8	Patients with communicable diseases and those who are colonized or infected with epidemiologically important organisms are separated from other patients, staff and visitors.
IPC.9	Personal protective equipment is readily accessible and available and is used correctly by staff in all patient care areas.
IPC.10	The leaders define in a policy the cleaning, decontamination and disinfection processes in all patient care areas.
IPC.11 **(C)**	The leaders define in a policy the safe procedures for waste collection, storage and disposal.
IPC.12	The leaders develop and ensure the implementation of a program for the prevention and management of sharp injuries.
IPC.13	Sharps are discarded in appropriate containers.

List of Standards	
Number	**Standard**
IPC.14	Housekeeping has policies and procedures describing its functions.
FMS.1	The leaders establish and support a facility management and safety program.
FMS.2	Interdisciplinary rounds are scheduled and conducted to ensure safety.
FMS.3	The center's environment is safe for patients, visitors and staff.
FMS.4	The leaders develop and monitor the implementation of a fire prevention program.
FMS.5	The center is secured and protects its users.
FMS.6	The leaders develop a plan for the inspection, testing and maintenance of medical equipment.
FMS.7	The leaders develop an emergency plan, and staff are trained on it.
FMS.8	The leaders develop a hazardous materials (HAZMAT) and waste disposal plan.
FMS.9	The leaders develop a policy and procedure for the safe use of various types of compressed gasses.
DPU.1	All day surgeries and procedures are performed in the day procedure unit.
DPU.2	Leaders develop and implement a policy and procedure to guide the care of patients in the day procedure unit.
DPU.3	The patient is accepted into the unit by the nursing staff after a rigorous verification procedure.
DPU.4	The procedure/surgery room is a functional operating room.
DPU.5	The day procedure unit is fully equipped for managing difficult intubations.
DPU.6	Patients booked for a surgery/procedure shall have a pre-sedation/anesthesia assessment performed by the anesthesiologist prior to the surgery.
DPU.7	The center ensures the correct implementation of the policy on preventing wrong patient, wrong site and wrong procedure.
DPU.8	The patient's condition is continuously monitored during sedation or anesthesia, including local anesthesia and the information is documented in the patient medical record before the patient leaves the operating room.
DPU.9	The unit has a recovery room.
DPU.10	Each patient's post-sedation/anesthesia physiological status is continuously monitored and documented in the patient's medical record.
DPU.11	An operative report is documented immediately after the surgery/procedure, before the patient leaves the recovery room and is signed by the surgeon.
DPU.12	The patient is discharged home by an attending physician after the procedure.
DA.1	Dermatology and aesthetics services are managed by an experienced physician.
DA.2	Physicians' privileges outline the exact procedures to be done by each physician.
DA.3	The unit performs periodic education and competency testing for clinical staff assisting in procedures.

List of Standards	
Number	**Standard**
DA.4	The managing physician ensures the compliance of procedural rooms with all required safety rules.
DA.5	The unit maintains a dated and timed list of the procedures performed.
DA.6	Implemented evidence based clinical practice guidelines are developed by the unit physicians and approved by the service manager for all procedures performed in the unit.

Effective Date of the National Standards for Ambulatory Care Centers

The effective date is 1st January 2020. This applies to ambulatory healthcare centers seeking accreditation by CBAHI.

PART II

ACCREDITATION POLICIES

Eligibility for Accreditation

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

- The HCF 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 HCF meets any additional licensing requirements as indicated by other relevant authorities (e.g., Civil Defense, Saudi Commission for Health Specialties, Saudi Food and Drug Authority).

- The HCF meets the legal definition as per the regulations of the Ministry of Health and the international guidelines in this regard:

  - Licensed as a an ambulatory healthcare center under the law governing healthcare institutions in Saudi Arabia.
  - Has an organized medical staff and nursing services.
  - Maintains permanent and full-/partial-time facilities.
  - Provides diagnostic and therapeutic services for patients.

- The HCF provides healthcare services addressed by CBAHI's National Standards.

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

- The HCF completes and returns an application form.

Registration with CBAHI

Registration with CBAHI for accreditation is required for all eligible HCFs. This is the first step towards accreditation.

HCFs are required to register by completing the Healthcare Facility Registration Form located on CBAHI's portal. Registration is a quick yet essential step, that provides the Healthcare Accreditation Department at CBAHI with necessary information about the registering facility. Upon successful registration, a system-generated auto-reply with a code number will be provided to the registering facility. The code number will be used for all future communications with CBAHI.

Accreditation Pathway

To obtain CBAHI accreditation, a healthcare facility must complete several activities. Upon successful registration, the following resources will be provided to HCFs seeking CBAHI accreditation:

- National Standards
- Healthcare Accreditation Guide

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

Each year, CBAHI decides based on "first-come, first-served" scheduling and in accordance with its yearly operational plan, which HCFs will be enrolled in its accreditation program for that particular year. CBAHI will notify by a letter of enrollment those HCFs included in its yearly accreditation program.

CBAHI provides ongoing HCF Orientation Programs in different locations throughout the year. HCFs must to attend at least one of the HCF Orientation Programs that CBAHI offers. Although any HCF can attend, preference is giving to facilities selected for the current year accreditation program. During these orientation sessions, the standards, accreditation policies and survey process are explained in detail. This is a good opportunity for HCF representatives to ask about the intent of a standard and how it will be implemented. Dates and venues of the orientation programs will be communicated to the HCFs in a timely manner.

All HCFs enrolled in accreditation are encouraged to conduct a comprehensive self-assessment using the Self-Assessment Tool (SAT) that CBAHI provides. This tool is intended to help the facility assess how close it is to satisfactory compliance with the standards and requirements. It also provides an idea of how much preparation and time the HCF needs before it can be ready for a survey visit. Usually, SAT is for the HCF's internal use, but CBAHI might require it before conducting a survey to help determine the facility's preparedness.

Several other accreditation organizations use self-assessment. If objectively and adequately conducted, self-assessment obtains better insight into the baseline situation of each facility and provides a common communication tool between the facility 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 for a tentative date suitable for both.

Some HCFs (especially those with no experience in accreditation) may choose a Mock Survey Visit. This visit is offered by CBAHI (subject to the availability of resources) mainly as an educational tool to clarify accreditation policies, standards and their explanation. In addition to the survey process, the applicability of the different chapters of the standards manual, as well as to further assess the position of the facility by verifying the self-assessment's findings.

The Mock Survey is recommended, but not mandatory. Some HCFs may choose for an upfront Real Survey.

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

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

- The HCF must submit a completed Survey Application Form, located on CBAHI's portal.
- The Service Agreement must be acknowledged and duly signed by the facility, and a copy returned to CBAHI a minimum of 45 days before the actual survey date.
- The HCF must provide evidence of payment of the required accreditation fees.

It should be noted that the maximum number of mock surveys in which a HCF can participate is subject to several variables (e.g., the available resources at CBAHI, the level of commitment demonstrated by the HCF towards achieving compliance with the standards, the findings of the self-assessment and so forth). A mock survey is a valuable opportunity for education and learning from experienced peer surveyors who, through their work in healthcare organizations, are exposed to a wide variety of best practices. There is no limit to the number of real surveys

a facility can have before achieving accreditation, but six months is the minimum time interval between two consecutive real surveys. However, this should not be misinterpreted as an "open-ended" exercise. The time interval between registration and the achievement of accreditation is 6 to 18 months, on average. Therefore, the facilities that will eventually prove incapable of achieving accreditation as reasonably persuaded by CBAHI will be excluded, either temporarily or permanently from the national accreditation program and referred to the relevant authorities for further action.

Survey Visit/Survey Team

To earn and maintain accreditation, a HCF must undergo an on-site survey conducted by the CBAHI survey team. CBAHI handles all scheduling arrangements for surveys in coordination with the healthcare facility. The date of the survey visit will be determined 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.

HCFs enrolled in the accreditation program will be notified by CBAHI to complete and submit the Survey Application Form (SAF) available on CBAHI's portal, and to indicate the type of survey requested (e.g., mock or real survey). A survey notification letter will be sent to the facility indicating the date of the survey and other relevant information.

The size and specialties of facility survey team members are usually fixed, but this might change according to the size of the HCF and its scope of services. As mentioned before, compliance assessment is accomplished through various survey activities and methods, such as a review of documents, a review of medical records and personnel files, staff or patient interviews and the findings observed during the facility tour and unit visits. Whatever the methodology used, the CBAHI survey is structured to be an intelligent search for areas of noncompliance with the standards rather than as a checklist exercise. Generally, the survey team is composed of two healthcare professionals.

The survey is conducted under the leadership that has been designated by CBAHI. The team leader is responsible for assuring that all survey activities are completed within the specified timeframes and according to CBAHI's policies and survey protocols. The HCF under survey is required to facilitate the work of the survey team members and to allow the survey team leader to practice his/her role and responsibilities, which include:

- Preparing and communicating the survey plan to the HCF;
- Chairing the opening and closing meetings;
- Communicating with facility leadership regarding survey progress and initial findings;
- Evaluating team progress and adjusting survey plans as needed;
- Coordinating and preparing the survey report and submitting it to CBAHI.

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

Rescheduling of Surveys

HCFs scheduled for surveys are strongly encouraged to adhere to the survey date proposed by CBAHI. However, rescheduling may be considered for review at CBAHI's discretion on a case-by-case basis, only upon:

- A rationale for rescheduling that is acceptable to CBAHI (e.g., events that will hinder the flow of the survey process such as changes in the ownership of the facility, natural or other disasters, or relocation of the facility to another building).
- At least thirty (30) days' notice with an official letter from the HCF chief executive officer indicating the reason(s) for the rescheduling request.

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

Accreditation Decision Rules

In general to become accredited, the HCF must meet all applicable standards at an acceptable level. CBAHI utilizes a multilevel process for making accreditation and reaccreditation decisions. This is to ensure fairness, consistency, objectivity, and accuracy. Therefore, CBAHI benefits from any relevant report and/or significant findings or issues of concern related to the surveyed facility that were brought to attention by relevant health authorities or past accreditation surveys.

Accreditation decisions are released and communicated to the HCF within thirty (30) days after the conclusion of the survey visit. The accreditation decision-making process is 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 HCF for feedback or correction of any issues of fact before the accreditation decision is made.
- Review/discussion during the meeting of the Accreditation Decision Committee (ADC). This committee may request additional evidence before making a final recommendation for an accreditation decision. All accreditation decisions are then ratified by the CBAHI Director General.

It is important to note that the decision to grant accreditation is based primarily on the findings of the on-site survey as recorded by the surveyors in the survey report. However, the overall numerical score the HCF obtains is one important factor, among others, upon which the ADC members rely when making their recommendation. Other factors are:

- Criticality of the non-compliant standard(s), for example the degree of severity and immediacy of risk to patients, visitors or staff safety.
- Any concerns regarding the non-compliant standard(s), for example the degree of severity and immediacy of risk to patients, visitors or staff and the facility.

Criticality has several levels. The most serious is when the surveyor notices an immediate threat to safety or quality of care. Examples include:

- Expired material is being used.
- A bare electrical wire is hanging down without any protection.
- A patient is not properly identified.

When a CBAHI surveyor notices an immediate threat, whether or not it is directly linked to the standards, the survey team leader will notify the HCF director and include the findings in the survey report.

Each standard is composed of a stem statement and sub-standard(s). The substandard is the evidence of compliance to be scored by the surveyor during the on-site survey. Each substandard 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 85% compliance with the standard).
2 = Satisfactory Compliance (85% and more compliance with the standard).
N/A = Not Applicable

The score of each standard is calculated using the sum of the scores of the sub standards divided by the maximum score of all the sub-standards. Partial compliance is not acceptable for core standards.

The overall score of the HCF is calculated using the sum of the scores of all the applicable sub-standards divided by the maximum score.

When one or more chapters of this manual are not applicable to a particular HCF, 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.

The ADC shall recommend one of the following accreditation decisions:

Accredited

Accreditation will be awarded when the surveyed HCF demonstrates an overall acceptable compliance with all applicable standards at the time of the initial (or re-accreditation) on-site survey, and when there are no issues of concern related to the safety of patients, staff, visitors or the facility itself. Accreditation will also be recommended when the HCF has successfully addressed all post-survey requirements and does not meet any rules for denial.

Scoring Guidelines:

- Overall score 75% or above.
- All Core standards are fully met.
- All applicable standards score 50% and above.

Denial of Accreditation

Denial of accreditation results when an HCF shows 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 the denial of accreditation have not been resolved. When the HCF 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.

- Overall score less than 75%, or one of the core standards is not in full compliance, or an applicable standard scores less than 50%.
- 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 to submit the post-survey requirements in a timely manner.
- The HCF was subjected to a 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 HCF through redrafting, additions or deletions of a document's

content without proper attribution. CBAHI perceives plagiarism as the deliberate use of other HCF original (not common knowledge) material without acknowledging its source.
- Refusal by the HCF to conduct a survey.

Appeal against an Accreditation Decision

A surveyed HCF can appeal the following accreditation outcomes:

- Denial of Accreditation (provided this is not due to a failure to submit the post-survey requirements in a timely manner after granting accreditation or a failure to meet requirements after a follow-up focused survey).
- Suspension/Revocation of Accreditation.

All appeals shall be made within a maximum of fifteen (15) calendar days from receipt of the official survey report, through a cover letter sent from the center director to the CBAHI Director General via registered mail/fast courier. This should include documentation to support the 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 Appeal

The HCF is entitled to an appeal if the appeal 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.
- The existence of perceived bias among the surveyor(s).
- Information provided by the survey team was not duly considered in the survey report.
- The outcome of the appeal, if in favor of the appealer, will result in a change in the accreditation status. CBAHI will not consider appeals that will not result in a change of accreditation status.

Upon the initial acceptance of the appeal request (only when clear and convincing evidence indicates that the facility sustained one of the grounds for appeal), the prior status of the HCF, 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 HCF wishes to include. A HCF 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 a study of all relevant reports and evidence, one of the following decisions shall be made and communicated to the appealer in a timely manner:

- The adverse decision is upheld.
- The healthcare facility's appeal is upheld, and the denial of accreditation is modified or reversed. In this circumstance, a full or focused re-survey may be decided upon.

Accreditation Maintenance (Post-Survey Requirements)

CBAHI has redesigned its accreditation to represent a continuous process versus a once-every-three-years evaluation. Accredited HCFs must 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 HCF, a Corrective Action Plan (CAP) addressing all standards that were not in satisfactory compliance during the on-site survey may be requested by CBAHI for review and acceptance within one hundred and twenty (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 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 thirty (30) days beyond the due date without justification might result in temporary suspension of the accreditation certificate.

2- Midterm Self-Assessment

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

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

For those areas, self-identified as non-compliant with CBAHI standards, the HCF may be required to submit a CAP to CBAHI that includes evidence to substantiate the fact that the standard has been brought into compliance. The relevant department at CBAHI will review each facility's plan of action via a telephone interview and will indicate whether the action plan and timetables are acceptable for bringing the standard into compliance.

During the next on-site visit following submission of the midterm assessment, the surveyor will look for evidence of compliance/correction that the HCF provided as part of the plan of action. When, at the time of the midterm assessment, a legitimate concern exists about the safety and quality of services provided by an accredited HCF, CBAHI may require the HCF to undergo a mid-cycle survey (a fee will be charged to cover the costs) and to submit a plan of action for areas of non-compliance.

when required to do so, a delay in submitting the midterm assessment by more than sixty (60) days from the due date without an acceptable justification to CBAHI may result in temporary suspension of accreditation, followed by revocation of accreditation if the total delay exceeds ninety (90) days.

Ad Hoc Requirements for Accreditation Maintenance

1- Reporting of a sentinel event (effective date for reporting will be announced later)

When a sentinel event occurs, it must be reported to CBAHI within five (5) working days of the internal notification of the event. A Root Cause Analysis (RCA) with a risk reduction action plan must then be submitted to CBAHI within thirty (30) working days.

2- Notification of significant changes

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

- A national regulatory body has mandated closure for all or part of the HCF.
- HCF accreditation by other international accrediting organizations has been suspended or revoked.
- A new service is initiated for which CBAHI has standards, and that was not included in the last survey.
- Any of the services are being offered in a new location or branch.
- Major construction/destruction/renovation work (building, floor or unit) has been undertaken.
- A significant (30% or above) increase (or decrease) in the volume of services has been experienced.
- The HCF has merged with or acquired an unaccredited facility.
- A significant change has occurred in the governance or ownership.

CBAHI will evaluate the impact of these changes, and a decision for conducting a focused survey may be warranted accordingly.

A delay in notifying CBAHI of such significant changes in an accredited facility by more than sixty (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 ninety (90) days.

Sentinel Events

A sentinel event is defined as any event leading to serious patient harm or death and that 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.

CBAHI has adopted the following as must-report events:

- Unexpected death
- Wrong patient, wrong procedure or wrong site
- Retained instrument or sponge
- Medication error leading to death or major morbidity
- Infant or child abduction
- Unexpected loss of a limb or function

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.

- When a reportable sentinel event occurs in an HCF accredited by CBAHI, it must be reported to CBAHI as indicated in the relevant policy. Healthcare facilities that are not accredited by CBAHI are encouraged, but not required to report. Outside reporting,

CBAHI may become aware of the occurrence of a sentinel event through a communication from one of CBAHI's surveyors, from the media, from a patient or relative, from the healthcare facility's employees or through other means of communication.

- CBAHI is interested in knowing about reportable sentinel events when they occur in accredited facilities for learning and disseminating lessons learned to the medical community, thereby avoiding the recurrence of such events in the future. Medical errors and adverse events are opportunities for education and quality improvements.

- Reporting must be safe. Patients, families, and staff are encouraged and should be empowered by the HCF leadership to report any sentinel event without fear of retribution. CBAHI has zero tolerance for accredited HCFs taking disciplinary actions against a staff member who reports a sentinel event. If the disciplinary action proves to be related to reporting, this might negatively impact the HCF's accreditation status.

- The HCF must report to CBAHI all sentinel events by filling out and submitting the Sentinel Event Reporting Form (SERF), which is available at the CBAHI portal, within five (5) working days of the internal notification of the sentinel event (the date when the relevant authority in the HCF was notified of the incident). This should be followed by a Root Cause Analysis (RCA) and Risk Reduction Action Plan within thirty (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. It might also include a validating focused survey scheduled or unannounced at CBAHI's discretion.

- The outcome of a reported sentinel event is dependent on the level of commitment the HCF demonstrates towards studying the root cause(s) of the incident and re-designing its processes and systems to prevent recurrence. When CBAHI is persuaded of this constructive approach of the concerned HCF in dealing with sentinel events, accreditation is usually maintained. When this is not the case, CBAHI will pursue this further to decide on the HCF's eligibility to maintain its accreditation until the required corrections are made. In other situations, in which the accreditation certificate is less than six (6) months, and CBAHI is not persuaded that the corrections have been made, an early full re-accreditation survey may be warranted.

Accreditation Suspension and Revocation

CBAHI expects nothing but truth, honesty and sincere intentions in all dealings and propositions from HCFs engaged in its accreditation program. This "good faith" engagement applies continuously throughout the accreditation cycle, and the HCF must ensure that it is not violated. In addition, accredited HCFs must maintain the same momentum both before and after accreditation. Some might argue that it is a natural tendency to ease back after a survey visit, but compliance with the standards must not drop simply because the survey is completed, and accreditation has been awarded. If CBAHI becomes aware, by any means of an accredited HCF that is not in compliance with the standards, CBAHI will verify the situation and take appropriate action.

CBAHI may receive information regarding possible violations from accredited HCFs through several channels, most importantly reports of related government agencies, written or verbal complaints and the media. Types of violations 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 HCF.

- The HCF is not committed to the specified timeframes for accreditation, for example maintenance of timely submission of a corrective action plan after accreditation or timely submission of a midterm self-assessment.

- The HCF failed to report a sentinel event as per the relevant policy without an acceptable justification.

- The HCF 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 the ethics clause).

- The HCF is discouraging communication or taking disciplinary action/reprisal against patients or staff members trying to communicate directly with CBAHI about concerns regarding safety or quality of care.

- The HCF intentionally lacks commitment to continuous compliance with CBAHI standards. This might represent an overweening behavior and is a strong violation of the CBAHI accreditation process.

- The HCF is deliberately violating any of the other accreditation policies mentioned in this manual or other supporting documents and manuals provided by CBAHI for accreditation.

Once CBAHI is convinced that one or more of the aforementioned violations exists in an accredited HCF, it 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 determines the level of response to a certain violation based on several factors, including the severity of the violation, its frequency, previous accreditation history, the source of information regarding the violation, and the findings and conclusion of CBAHI's inquiry. When necessary, a focused or full survey might be conducted for validation purposes before a response can be given or an action taken. This kind of survey is always for one or more of the above causes (e.g., when concerns have been raised about an accredited facility's continued compliance with CBAHI standards). An accredited HCF may undergo a survey at any time, at the discretion of CBAHI, and the survey is usually unscheduled (the HCF receives 48 hours' notice before the survey) or unannounced (without advance notice) depending on the seriousness and type of violation. Surveys can include either all of HCF's services or only those areas in which a serious concern may exist. HCFs are usually charged for these surveys, regardless of the outcome, and results can affect the HCF's accreditation status. If the HCF does not allow CBAHI surveyors to conduct the survey, CBAHI may change the facility's status to Revocation of Accreditation.

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

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

Random Surveys

To support CBAHI's ongoing quality assurance initiatives, an accredited facility may be selected for a random survey from nine (9) to thirty (30) months after an accreditation survey. Random surveys are unannounced. A five percent sample of all accredited HCFs is randomly selected each year for this activity. These random, unannounced surveys are a means by which CBAHI evaluates the consistency and quality of its program, while also demonstrating to the public and regulators that accredited HCFs remain committed to CBAHI standards throughout the accreditation cycle. Random surveys also provide CBAHI and its surveyors with opportunities to further consult with accredited HCFs in the interval between regular surveys. No fee shall be charged to the HCF when a random survey is conducted.

The HCF may be selected for a validation survey visit as part of an inter-rater reliability program for CBAHI surveyors within one (1) month after receipt of the accreditation decision report. This visit outcome has no impact on the accreditation status granted in the real accreditation survey visit. The HCF will not bear any cost.

Accreditation Certificate and Seal

Once accreditation is granted, HCFs are encouraged to display the CBAHI logo, accreditation certificate and seal on the facility's bulletin boards, banners, website, newsletters, brochures and headed stationery.

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 is used in a way that may mislead the public or others or provide false information related to a healthcare facility's accreditation status.

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

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

Release of Accreditation-Related Confidential Information

CBAHI acknowledges that HCFs undergoing its accreditation survey are expected to provide access to information related to the evaluation of their compliance with CBAHI standards.

As a guiding policy, to HCFs engaged in its different accreditation programs, CBAHI commits to keeping confidential all information obtained or received during the accreditation process,

including all survey data and information that surveyors come across during the survey process.

For an HCF that is a participating member of the CBAHI accreditation program, some information is subject to public release. This includes:

- The healthcare facility accreditation status being posted on the CBAHI website.
- The areas of the HCF that 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 HCF in question. The exception to this rule is when the CBAHI receives an official request for clarification from relevant health authorities or public health agencies. This information includes:

- The mock and final accreditation survey reports.
- Accreditation Committee minutes and agenda materials.
- The notification letter of the survey report to the healthcare facility's director.
- The accreditation certificate.
- The post-survey requirements, including any CAPs.
- The results of investigations related to a sentinel event, including the root cause analysis prepared in response to that event.
- The results of investigations involving any falsified information the healthcare facility provided to CBAHI.
- Any other information related to compliance with CBAHI standards obtained from the HCF before, during or after the accreditation survey.

Complaints against an Accredited Healthcare Facility

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

CBAHI addresses all complaints that would help identify possible noncompliance with its accreditation standards, thereby posing a possible threat to the safety of patients, staff or the public. More precisely, CBAHI can evaluate complaint information only in terms of its relevance to compliance with CBAHI's standards. Issues of a personal nature or individual disputes should be dealt with by the concerned facility or the regional health authority. CBAHI cannot follow up on complaints about HCFs which are not accredited.

When CBAHI receives a complaint against an accredited HCF, CBAHI will conduct an initial screening to determine its relationship to standards and its impact on patient safety. If the complaint does not relate to compliance with CBAHI standards, a response of "non-relevance" will be forwarded to the complainant, who will be advised to forward the complaint to the HCF leadership or the regional health authority. If the complaint relates to compliance with one or more CBAHI standards, a response shall be made accordingly. The response will depend on a risk assessment matrix that determines the probability and severity of the complaint. CBAHI will check for other complaints about the same HCF. Broadly speaking, CBAHI will give one or both of the following responses:

- CBAHI may write to the HCF about the complaint. When requested, the HCF must make available its records of complaints and subsequent actions taken.

- CBAHI may decide to visit the healthcare facility to verify whether a problem exists in terms of meeting the standards involved in the complaint. Such visits are usually unannounced, and the outcome may change the accreditation decision.

It is CBAHI policy not to disclose any information related to patients or complainants unless it is authorized to do so. In addition to information about the complaint's relevance to CBAHI standards, the complainant will receive the following information:

- The course of action CBAHI took regarding the complaint.
- Whether CBAHI has decided to take action regarding an HCF accreditation decision following completion of the complaint's investigation.

To file a complaint against a CBAHI-accredited healthcare facility, an individual can send his/her concern via the contact form on the CBAHI website. The individual can also file the complaint directly by calling the Universal Access Number 920012512. CBAHI requires that the complainer reveal his or her identity. Therefore, CBAHI will not consider anonymous complaints.

Conflict of Interest

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

In addition, all healthcare facilities engaged in the 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, contracting or having any financial relationship with CBAHI employees or surveyors for the purpose of providing consulting or related services in any capacity, either directly or through another party. This includes services provided in preparation for the survey, assisting in preparation of the self-assessment, conducting mock surveys, helping with the interpretation of the standards and the like. All requests for consulting services utilizing CBAHI employees or surveyors shall be directed to CBAHI.

- Not declaring to CBAHI any business (including consulting) or recruiting relationship with one or more 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 honesty, transparency, and truthfulness in all its dealings, with avoidance of all situations that might appear unethical or illegal. The same is expected from the HCFs seeking CBAHI accreditation. CBAHI employees are committed to politely declining any gifts or gratuities offered to them or to members of their families, including spouses, children, and parents, when the donor expects something in return. Such gifts or gratuities may be attempts to gain an unfair advantage or influence the manner in which the employee or surveyor performs his/her job duties. Gifts of nominal value may be accepted as tokens of appreciation or goodwill provided they are given as gestures of a professional relationship and do not involve or create the appearance of any commitment in terms of survey results or accreditation decisions.

Business lunches, tea, coffee and snacks during the survey are permitted. Other social gatherings are prohibited, and HCFs are encouraged to not offer such to the survey team. Using the HCF vehicle to transport the survey team to and from the survey site is acceptable.

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

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

CBAHI is also committed to resolving complaints and ethical issues raised by CBAHI employees or client HCFs to ensure justice, confidentiality, impartiality, timeliness and feedback to the complainants.

PART III

ACCREDITATION STANDARDS

Chapter I
Leadership of the Organization (LD)

Introduction

For any ambulatory care center, quality and patient safety depend on effective leadership. Ambulatory care centers may vary in size, type of ownership and complexity of services. The owner of the center may be a single private owner, a group of private owners, or a governmental entity. In all cases, the owner (private or governmental) constitutes the center's governing body or governance. The governance or governing body is responsible for providing safe and quality patient care. The center's director, whom the governing body selects, is accountable for ensuring the provision of safe and quality patient care. The center may be directed by a single owner who maintains the dual role of governance and leadership
Large centers may have several divisions, such as nursing, medical, administrative, and facilities, among others. A director manages each division.

In such large centers, the center's director and division directors constitute the leadership group. In small centers, leadership may be presented only by the center's director. It is crucial for all ambulatory care centers to have a clearly stated mission. The leadership of the center is responsible for developing the mission and providing adequate resources, through the governing body, to fulfill this mission. Ambulatory care centers are of a much smaller size and are much less complex than hospitals. Therefore, it is expected that the leader(s) will carry out most of the administrative work, as explained in the following standards.

The leadership chapter addresses the following:

- Organizational structure
- Structure and function of the governing body
- Roles and responsibilities of the center's leaders
    - o Mission and vision and values, scope of services and strategic planning
    - o Effective human resource management
        - Staffing plan
        - Job descriptions for all types of employees
        - Staff recruitment
        - Credentialing and privileging
        - Staff orientation and education
        - Staff performance evaluation
        - Staff health and safety program
    - o Patient and family rights
    - o Quality improvement and patient safety
        - Developing and maintaining center's policies
        - Developing and supporting a quality improvement and patient safety program
        - Developing and supporting a risk management program
        - Contract oversight
        - Supplies oversight

Standards

LD.1. The governing body defines its structure and operational responsibilities in a written document.

LD.1.1. The governing body approves and periodically reviews, the center's mission, vision and values and makes it public.
LD.1.2. The governing body approves the center's scope of services, the center's plans, programs and all policies and procedures.
LD.1.3. The governing body approves the center's operating and capital budgets, as well as other resources required to manage the center efficiently.
LD.1.4. When the center is part of network, the governing body plans for services and functional relationships among the network components.
LD.1.5. The governing body defines any approval authority delegation.
LD.1.6. The governing body appoints a qualified director responsible for managing the center.

Explanation

The governing body (owner(s), board of directors) should highlight its structure, role, and responsibilities in a written document. Roles and responsibilities include approval of strategic and operational plans and budget, mission and vision, scope of services, the risk management program, and policies and procedures. Roles and responsibilities of the governing body also include appointing the center's director and defining any leadership delegation authority that highlights the person responsible for managing the center in the absence of the center's director.

LD.2. The governing body approves and evaluates the center's quality and patient safety program and risk management program.

LD.2.1. The governing body annually approves the quality and patient safety program, including risk management.
LD.2.2. The governing body receives and evaluates the quality and patient safety reports, including the corrective actions and outcomes from the center, including risk management, at least quarterly.
LD.2.3. Recommended corrective actions by the governance are documented and received by the center director for implementation.

Explanation

The governing body should ensure patient, staff and visitor safety by approving the quality and patient safety and risk management programs and periodically evaluating their effectiveness. At least every three months the governance should receive reports on selected indicators, all safety concerns that staff reported, all medical complications, and all financial and other administrative risk issues. Governance, together with leadership, should work to formulate an action plan to prevent errors and mitigate risk. Governance should observe and document the implementation and outcomes of corrective actions.

LD.3. The center has a current organizational chart.

LD.3.1. An approved and updated organizational chart identifies the relationship between the center's governance, leadership, and other directors with names and titles.
LD.3.2 The organizational chart is communicated to all staff.
LD.3.3. The staff are aware of the organizational chart and its intent and can demonstrate their relationship to it.

Explanation

Efficient and effective healthcare organization management requires effective staff communication and clear reporting lines. The organizational chart should be developed to present the relationship between the governance (the owner or board of directors) and the center's managing director(s), and between the managing director(s) and the front-line staff. Managerial positions in the chart should be reported by title and name. All center staff should be aware of their position in relation to the organizational chart and their line of command and required reporting. The chart should be updated regularly, signed by the center's director and communicated to staff and displayed clearly in the center.

LD.4. The center is managed effectively by a qualified director.

LD.4.1. The center director has a written job description and his/her qualifications match the requirements in the job description.
LD.4.2. The center director, with other leaders, develops the mission, vision and values statements.
LD.4.3. The center director ensures the center's compliance with all relevant laws and regulations.
LD.4.4. The center director recommends to the governing body required new policies for approval and ensures compliance with approved policies.
LD.4.5. The center director ensures the availability of adequate and proper resources for the planned services in accordance with the approved operating budget.
LD.4.6. The center director ensures a safe and functional facility environment for patients, visitors, and staff.

Explanation

The center must be managed daily by a director. The job description of the center's director clearly highlights his/her roles and responsibilities as well as the required job qualifications and experience. The director is responsible for the center's compliance with all applicable governmental laws and regulations, including, but not limited to, patient care regulations, medication management, MOH regulations for the opening licensure, staffing licensure and certification, civil defense requirements, municipality requirements, and MOH reportable diseases. The director is responsible for responding to all governmental inspections, including clear action plans for compliance. Accreditation of the center by the CBAHI is the ultimate responsibility of the center's director. The director ensures the availability of the adequate number and the right mix of staff required for the day-to-day activities. He/she also ensures the continuous availability of the required supplies, medications, and resources to safely run the center. The director recommends all required policies, procedures, protocols, and clinical practice guidelines that are required for the clinical, managerial and financial integrity of the center. The director ensures the facility is designed to deliver the intended services in a safe and secure environment for patients, staff and visitors.

LD.5. The leaders together with governance develop the center's scope of services based on community needs.

LD.5.1. The scope of services includes the range of coverage in relation to preventive medicine, health promotion, curative and rehabilitative medicine.
LD.5.2. The scope of services includes the specialty services that the center provides, the number of clinics for each specialty, the level of professional coverage.
LD.5.3. The scope of services includes the age group that can be served and the working hours.
LD.5.4. Services are displayed in the center, and patients and, when needed, families can obtain additional related information from the reception staff.

Explanation

The center shall function according to a predefined scope of services document developed collaboratively between governance and the center's leaders (the center's director, medical director, nursing director, human resources director, finance director, and administration director, as applicable). The scope of services includes the range of clinical services in each provided specialty based on the center's location and the community needs (i.e., preventive, health promotion, curative, and rehabilitative). The scope of services includes the number of clinics for each specialty, age group, and working hours. The average number of patients anticipated to be seen, as well the maximum number who can be seen, should also be highlighted. The scope of services also includes the level of professional coverage for example consultants versus specialist.

LD.6. The leaders work collaboratively to develop the center's strategic plan.

LD.6.1.	The strategic plan is guided by the mission, vision and inputs from patients/service users, their families, staff and where possible the wider community.
LD.6.2.	The strategic plan is based on a comprehensive evaluation of the internal and external environmental factors.
LD.6.3.	The strategic plan addresses all clinical and non-clinical services and programs.
LD.6.4.	The strategic plan spans a period of three to five years and is reviewed on a regular basis.
LD.6.5.	The strategic plan includes the broad goals and objectives required to fulfill the center's mission.

Explanation

Ambulatory care centers require forward planning to continue their mission and achieve their vision. The planning may include mastering current services (centers of excellence) or introducing new services. This strategic planning should be based on a comprehensive evaluation and analysis of the internal and external operational and environmental factors that may affect the center's mission and vision, such as SWOT analysis and PEST analysis. The plan should have clear goals and objectives to achieve in a time frame.

LD.7. The leaders transform the approved strategic plan into an operational plan.

LD.7.1.	Goals and objectives are translated into operational plans with defined projects, clearly delineated responsibilities, required resources and time frames.
LD.7.2.	Governance approves the resources required for executing the operational plans.
LD.7.3.	Operational plans are implemented and closely monitored for progress by structure and process indicators.
LD.7.4.	The plans are communicated to department directors and other staff.
LD.7.5.	Department directors develop annual departmental plans in alignment with the center's strategic plan.

Explanation

Strategic plan should be converted into an operational plan that contains steps to follow and staff to lead and execute. Plans and resources are all approved by governance and tabulated for further timely implementation. Staff involved in and/or affected by the plan should be informed accordingly.

LD.8. The leaders work collaboratively to develop the operational budget.

LD.8.1. The leaders plan and budget for the upgrade or replacement of buildings, equipment, and other resources.

LD.8.2. The budget process allocates resources to all patient care units based on the scope of care and complexity of patient must ensure a safe and effective facility.

Explanation

The leaders should develop an annual budget. This budget should take into consideration any additional cost for replacing or upgrading equipment, upgrading services, and periodic maintenance and repair. The budget should be distributed between the different patient care areas (e.g., space, equipment, supplies, staffing, and other resources) to ensure seamless and safe patient care.

LD.9. The leaders work collaboratively to fulfill the mission and provide quality care.

LD.9.1. The leaders communicate the mission, vision and values to all staff and customers.

LD.9.2. The leaders ensure the use of evidence-based and best practice information to develop and improve the center's services.

LD.9.3. The leaders work collaboratively to develop and carry out plans, policies, and procedures.

LD.9.4. The leaders meet regularly to review the key performance indicators of services, survey, audits and feedback and use the collected data to improve the center's operations.

Explanation

All staff should know the center's mission and vision, and any amendments or changes should be communicated to staff. The services should be evidence-based, and all policy and practice guidelines that he leaders develop should be based on referenced and updated practices. Regular leadership meetings shall take place to ensure that all plans are carried out effectively, and that policies and practice guidelines are followed. Plans, policies, and practice guidelines should have process indicators to ensure staff compliance, and outcome indicators to ensure their effectiveness.

LD.10. The leaders develop a staffing plan for the center.

LD.10.1. The staffing plan ensures that services meet the needs of safe patient care.

LD.10.2. The staffing plan defines the number, type, and credentials of required staff, and their roles.

LD.10.3. The center recruits and assigns appropriately qualified staff in accordance with the staffing plan.

Explanation

The center's leaders (the HR director together with the center director, medical director, nursing director, and administrative director) should formulate a staffing plan for the center based on the scope of services the center provides and the center's capacity and working hours. The plan should include the number, type, and qualifications of staff required in all the center's areas (medical and non-medical) to ensure safe patient care, according to MOH rules and regulations, and the smooth operation of other administrative areas.

LD.11. The leaders develop a policy and procedure for staff recruitment.

LD.11.1. The policy and procedure highlight the receiving authority(s) of staff resumes, the shortlisting process, and the accepted method for interview.

LD.11.2. Applicants are informed of their acceptance or refusal within a set time frame.

Explanation

For the center to recruit the right staff, it must have a policy and procedure for staff recruitment. The policy highlights the shortlisting process whereby all applicants' CVs are reviewed to ensure that they match the description of the job for which the candidate applied. An objective process must exist for assessing the interviewee or the applicants; this process must include an approved interview form. The applicants should be informed of their acceptance or denial of appointment within the time frame specified in the policy.

LD.12. All categories of staff have clearly written job descriptions.

LD.12.1. The job description outlines the knowledge, skills, and attitude necessary to perform the job responsibilities.

LD.12.2. The job description clearly defines roles and responsibilities for the position.

LD.12.3. Job responsibilities and clinical work assignments are based on evaluation of staff credentials.

LD.12.4. The job description is discussed with and signed by the employee upon his/her hiring and is located in his/her personnel file.

Explanation

For smooth operational performance and accountability, each staff member must have his/her own job description that outlines daily responsibilities, necessary qualifications, skills, and experience. This job description shall help in recruiting the right staff for vacant positions and shall constitute the basis for the staff evaluation, whether it is probationary or carried out at the end of the year. This job description must be discussed with each staff personally, and it must be signed at the time of hiring to acknowledge that the staff are fully aware of the job, its requirements, and responsibilities.

LD.13. (C) The leaders develop an effective process for credentialing and recredentialing all healthcare providers.

LD.13.1. The credentialing process applies to all clinical staff members: medical staff, nursing staff, and other clinical staff licensed to provide patient care.

LD.13.2. The credentialing process includes gathering, verifying, and evaluating credentials including license, education, training, experience and competence.

LD.13.3. To the extent possible, the credentials are verified from the original

source directly or through a third party with documented evidence.

LD.13.4. The center ensures the registration of healthcare professionals with the Saudi Commission for Health Specialties and licensing by the Ministry of Health in accordance with laws and regulations.

LD.13.5. The credentialing process guides the appointment of healthcare staff to their appropriate job assignment and is repeated every two (2) years to ensure that staff are still capable of performing their job functions.

LD.13.6. Information about staff credentials, privileges, competencies, orientation, training, education, and evaluation are kept securely in an updated personnel file.

Explanation

The center must make all efforts to ensure the placement of new staff in the right position initially, and every two years thereafter. This process of credentialing applies to all clinical staff licensed to provide patient care (physicians, nurses, physiotherapists, technicians).
The credentialing process involves collecting all the information related to the staff (education, training, experience, competencies, and licensure), verifying it from the primary source, and evaluating it to ensure the staff fits in his/her assigned position. The center ensures that all healthcare professionals are registered with the Saudi Commission and licensed by the MOH according to rules and regulations. All staff who are credentialed and approved to work in the center should have a record of their credentials kept safely with the administration. The process is repeated every two years to ensure that staff remain authorized and capable of providing the same job functions.

LD.14. (C) All medical staff members have current delineated clinical privileges.

LD.14.1. The center has a policy and procedure for granting privileges to medical staff.

LD.14.2. Clinical privileges are determined based on the center's documented competency and available services.

LD.14.3. The medical staff's clinical privileges are recommended by the medical director and approved by the governing body, either directly or by appropriate delegation.

LD.14.4. The clinical privileges are reviewed and updated every two (2) years, and earlier if needed.

Explanation

The privileging of physicians is the most rewarding proactive risk management approach with respect to patients' safety. It allows physicians to perform procedures and surgeries for which they have been made qualified by education, training, and certification. This prevents patients' exposure to risk of morbidities. Each physician should have a list of the invasive procedures that he/she is allowed or privileged to perform.
The center must have a policy and procedure for granting individual privileges. Clinical privileges should be distributed in the areas where the physician is practicing. The privileging process should be reviewed and updated every two (2) years, and earlier if a physician receives new training on a certain procedure or is found to be potentially dangerous in performing other procedures.

LD.15. All new employees attend a mandatory orientation program.

LD.15.1. The new employees' general orientation program includes information about the center's mission, vision, values, and organizational structure; patient and family rights; safety and security; the basics of infection control; and an introduction to the center's quality and patient safety and risk management programs.

LD.15.2. Each new employee attends a department-specific orientation program, including specific infection prevention and safety issues, that helps in executing the specific job responsibilities as outlined in the job description.

LD.15.3. The new employee orientation is documented in the employee's personnel file.

Explanation

All new employees (full-time, part-time, visiting, and volunteers) should be oriented to the center. A general orientation should include information about the center:

- Mission, vision, and values
- Current organizational structure
- Code of conduct and ethical framework
- Patient and family rights
- Safety and security
- Infection control
- Quality and patient safety and risk management programs

The orientation also includes a specific job orientation, which teaches the staff the requirements for patients' assessment and documentation, and how to deal with patient transfers, among other essential processes in the staff's area of practice. Policies related to vacations, penalties, grievances, and separation may be compiled into a manual that is provided or accessible to staff.

LD.16. The leaders develop and implement a policy that ensures nurses and other allied healthcare staff are competent in specific procedures.

LD.16.1. The policy contains a list of procedures requiring competency assessment in each and every staff category.

LD.16.2. All newly hired staff are initially tested for the required competencies.

LD.16.3. All staff are tested annually for the required competencies.

LD.16.4. All test results are available in staff personal files.

Explanation

To ensure patients' safety, staff must be tested both and annually on their competency in certain procedures, according to their scope of work, such as:

- Taking blood samples
- Inserting intravenous lines
- Inserting an indwelling urinary catheter or simple urinary catheterization
- Inserting nasogastric tubes
- Performing electrocardiograms and cardiotocography
- Infection control practices and precautions (isolation procedures, hand hygiene, the use of personal protective equipment, preventing needle stick injuries)
- Positioning patients for common radiological procedures

Competency assessment results are documented in staff personal files for evidence and monitoring of compliance with the policy.

LD.17. The leaders ensure staff are trained and test competent in the safe operation of equipment including medical devices.

LD.17.1. A policy is in place to ensure staff are trained on the safe operation of the current and newly introduced equipment and medical devices.
LD.17.2. The policy addresses the required training and competency testing of staff operating specialized equipment.
LD.17.3. Only trained and competent staff handle specialized equipment and medical devices.

Explanation

To safely operate medical equipment, reducing risk to patients and staff and increasing operational efficiency, staff must receive appropriate training on this medical equipment. Periodic competency testing is required, and newly introduced equipment should not be used until staff are trained and tested competent on its use.

LD.18. The leaders support continuing education and training for all categories of staff.

LD.18.1. The center has a scheduled educational and training program based on the center's needs and person-centred care including quality, patient safety, risk management and infection control practices.
LD.18.2. The leaders grant financial support and/or time off for staff to attend educational and training activities relevant to the center's scope of services and in line with labor law.
LD.18.3. Employees' records show documented evidence of training and education.

Explanation

Staff professional development is important for improving the center's services. The center should drive continuous medical and nursing education and other categories of staff. The simplest way is to provide a scheduled educational program fulfilling person-center care and the center's scope of services and needs, including quality, patient safety, risk management and infection control practices, patient/service user rights, complaint management, shared decision-making, communication skills, informed consent, and the cultural beliefs, needs and activities of different patient/service user groups. Also, the center can grant either financial support or time off so that staff can attend conferences, symposia, training courses and other educational activities. Employees' personnel files should show documentation of training and education.

LD.19. Staff are trained and kept up to date with cardiopulmonary resuscitation.

LD.19.1. All staff members who provide direct patient care receive training on basic life support (BCLS).
LD.19.2. The center identifies other staff members to be trained in advanced life support as appropriate to the age groups they serve (ACLS, PALS, NRP).
LD.19.3. All staff maintain the validity of their life support certification.

Explanation

Although the scope of services of most of the centers does not include high-risk patients, sudden cardiopulmonary arrest may occur and potentially be lethal. Therefore, all staff members providing direct patient care must have at least basic life support skills and certification. The center should also identify other staff members who will be required to receive training in advanced life support, such as those serving in emergency rooms. Age group life support skills and certification may also be warranted for advanced pediatric life support and neonatal life support.

LD.20. The leaders develop an effective process to evaluate staff performance at least annually.

LD.20.1. The performance evaluation is based on objective criteria and is consistent with the expected competencies such as knowledge, skills and attitude required to perform the employee's job responsibilities as outlined in his/her job description.

LD.20.2. The evaluation is done at the end of the initial probationary period and annually thereafter.

LD.20.3. Staff are involved in the evaluation of their performance by commenting on the required corrective action.

LD.20.4. Evaluations include personal goals to achieve for the next year that the employee will carry out.

LD.20.5. Both the employee and his/her supervisor sign the performance evaluation, which is kept in the employee's personnel file.

Explanation

To ensure satisfactory staff performance according to job descriptions and privileges, a standardized objective process for gathering and assessing the staff's performance, scope of practice, professional development, and attitude must be developed for each staff category. The evaluation is carried out at the end of the initial probationary period and at least yearly thereafter. Staff should acknowledge their performance and comment on any required actions for improving their performance as set forth by their supervisors.
The performance evaluation should always include goals to achieve for the next year (part of the evaluation for the next year). Both the employee and his/her supervisor sign the performance evaluation, which is kept in the employee's personnel file.

LD.21. The leaders implement a comprehensive program to protect the health and safety of staff.

LD.21.1. The program covers all employees and is consistent with laws and regulations.

LD.21.2. The program is based on the protection of staff from occupational health and safety hazards and violence in the workplace.

LD.21.3. The program is coordinated with the center's quality, safety, risk management, and infection control programs, including health screening, immunization, and post exposure management.

LD.21.4. Staff have confidential and secure medical records that reflect their health status.

Explanation

The health and safety of staff are vital for the provision of best care. A staff health and safety program should be available in all healthcare organizations. The program should cover working areas to reduce occupational risks. There should be a vaccination program to protect staff liable to infection from common viral illness (e.g., varicella zoster and hepatitis B).
Staff working in offices should receive random checks of their posture behavior and their furniture to ensure its safety for their extended office hours. Manual workers should receive information about the safe handling of goods and about avoiding strains and sprains and should be monitored for the implementation of this information.
The program should have a policy for the prevention of needlestick injuries and other occupational hazards, such as radiation and chemical exposures. The program should also focus on the use of personal protective clothing and equipment when dealing with infectious diseases patients. The program should focus on security issues to manage violence and aggression against staff. The program should be well coordinated with the quality and patient safety and risk management programs. Reports about staff health and safety should reach the governance as per requirements for the quality and patient safety program. Staff files containing information about staff members' vaccinations and illnesses should be available and kept safe and secure.

LD.22. The leaders support and protect the patient and family rights.

LD.22.1. The leaders develop and maintain a patient rights and responsibilities statement and develop processes that support their implementation.
LD.22.2. The leaders ensure that patient rights and responsibilities are available to patients and families and ensure patients are informed about their rights and responsibilities in a manner they can understand.
LD.22.3. The leaders ensure that patients' dignity, privacy and confidentiality are respected.
LD.22.4. The leaders ensure that staff are provided training and education on patient and family rights and responsibilities.

Explanation

Patient and family rights and responsibilities are paramount for ethical and safe patient care. The leaders should develop all policies and procedures pertaining to patients and family rights, including the bill of rights. Such policies and procedures should be available to patients and their families in written documents that are close at hand or clearly displayed in the center. The leaders ensure that staff are fully aware of – and trained on executing – the rights and responsibilities. The leaders should exert all efforts to ensure that patients are treated with dignity and that their privacy is always respected. Leaders should also ensure the safety and security of patients' personal belongings. Patient and family rights respect their preferences and choices to the extent possible within rules and regulations.

LD.23. The leaders ensure that patients/families have the right to be involved in their own care and treatment.

LD.23.1. Patients/families have the right to be informed of their illness, the proposed treatment and its prognosis.
LD.23.2. Patients/families have the right to be involved in the decision making of their care plans.
LD.23.3. Patients/families have the right to professional assessment and management of pain.
LD.23.4. Patients/families have the right to refuse or discontinue treatment or ask for a second opinion.
LD.23.5. Patients/families have the right to request a detailed medical report and sick leave notification.

Explanation

Patients and their families should be granted the right to be informed of their illness, the proposed treatment, the cost incurred, and the prognosis of their treatment in a manner and language they understand. Patients should agree to their care plans and should have the right to manage their pain effectively. Patients are granted the right to ask for a second opinion if necessary, without fearing that their care may be compromised. Patients have the right to request a detailed medical report to be presented to other centers and sick leave notification for regulatory purposes.

LD.24. The leaders develop and implement a policy and procedure to describe the patients' right to voice their complaints and concerns.

LD.24.1. Patients' complaints are resolved in a time frame described in the policy.
LD.24.2. The center assigns a staff member responsible for managing complaints.
LD.24.3. Patient satisfaction surveys are conducted at least quarterly.
LD.24.4. Data collected from surveys and complaints are analysed and trended, and the information collected is used for improvement and integrated into the quality and safety program.

Explanation

Patients' satisfaction is a measure of their appreciation of the services that the center provides. Patients' complaints identify areas that require the immediate attention of leaders. The leaders support the patients in their right to complain in a manner they prefer. The complaint system is the responsibility of the patients' relations officer or similar staff, who should have a policy and procedure to follow. Every effort must be made to finalize patients' complaints in a time frame defined in the policy. All complaints are analyzed and trended, and information presented to leaders for corrective actions is to be developed and implemented. Patients' satisfaction surveys should be conducted at least quarterly. Information and action plans from complaints and surveys should be included in the quality and safety program and reported to governance.

LD.25. The leaders ensure that patients/families have the right to accurate billing for provided services.

LD.25.1. The leaders ensure the availability of the price list for services provided to patients and their sponsors.
LD.25.2 The patients and families have the right to receive an initial estimated cost of required services.
LD.25.3. The patients and families have the right to obtain an invoice for services rendered.

Explanation

The center's price list should be accessible to patients and families and a receipt should be given for services rendered, including insurance patients. It is the right of the patient and family to receive an initial estimated cost for their treatment if requested. The request for an itemized bill should be honored if requested by patients and families unless the service given is under the price list of a "package deal".

LD.26. The leaders develop ethical standards to guide patients' care and employees' code of conduct.

LD.26.1. Marketing for staff and services, if performed, is carried out ethically as per laws and regulations.
LD.26.2. The leaders develop a set of values and a professional code of conduct for all employees.
LD.26.3. The leaders ensure that patients and their families are fully informed and protected when they are involved in clinical research projects.
LD.26.4. The leaders develop a process to receive and resolve ethical dilemmas, patient and non-patient related in a reasonable timeframe as determined by the center.

Explanation

The leaders are responsible for developing the framework that governs how patient care is conducted in an ethical manner across the center's activities. The values and professional code of conduct describe the center's expectations of staff regarding their behavior and communication with each other and with their patients. This includes the ethical portraying of services; reasonable and accurate billing; the assuring that staff are engaging in ethical behavior with patients, visitors, and staff; and the assuring that staff are wearing appropriate attire. Patient-related dilemmas related to ethics may include decisions to not treat, to withdraw treatment, or to discontinue treatment.

LD.27. The center provides assistance to patients with special needs.

LD.27.1. Dedicated street parking and drop-off points are available.
LD.27.2. Handrails for staircases are constructed.
LD.27.3. Ramps for elevated areas are available.
LD.27.4. The center's entrance allows wheelchair access and elevators have wheelchair access doors.
LD.27.5. Wheelchair-accessible toilets are available.

Explanation

Requirements critical for dealing with special needs patients should be considered in the planning of all HCFs and services. Special needs patients should be looked after by providing them with dedicated parking slots, wide entrances, accessible elevators, ramps for elevated areas, handrails in corridors and stairs, and accessible toilets.

LD.28. The center has an implemented policy for controlling the development and maintenance of key documents.

LD.28.1. The center has a unique identification for each key document, with title, number, date of issue, and date of revision.
LD.28.2. Key documents are developed, approved, revised, and terminated by an authorized individual.
LD.28.3. Key documents are dated and current.
LD.28.4. Key documents are revised according to a defined revision due date.
LD.28.5. Key documents are communicated to relevant staff and are always accessible.
LD.28.6. A process is in place to ensure that key documents are always implemented.
LD.28.7. A process is in place to ensure that only the last updated versions of key documents are available for use in the center.

Explanation

For the proper execution of key function documents, policies, procedures, and processes, they must be identical in their format for writing, and have tags that identify the originating department, date of issue, date of revision, date of implementation, and date of expiry. Only authorized individuals can change policies. Key function documents, policies, procedures, and processes carry the name(s) of the author(s) and approving authority. A system must be in place to ensure that only approved and non-expired policies are circulating and available to staff. All staff should be familiar with the available key function documents, policies, procedures, and processes relevant to their practice.

LD.29. The center develops a comprehensive quality improvement and patient safety program.

LD.29.1. The leaders develop the program collaboratively.
LD.29.2. The program utilizes key performance indicators, and patient and staff surveys to measure performance and improve clinical and managerial areas.
LD.29.3. The information generated is readily accessible on a timely basis to those responsible for and/or involved in the delivery of the services, and is utilized for making improvements and supporting the leaders' decision making.
LD.29.4. The program utilizes an evidence-based quality improvement method such as "FOCUS – PDCA."
LD.29.5. The center implements at least one improvement project per year.

Explanation

The center should ensure the quality of its services and its continuous improvement by developing a quality management and patient safety program. Key performance indicators are utilized to measure the performance of the services provided. Staff are notified of the performance findings, and the information provided is utilized to further improve the clinical and managerial areas (structure, process, and outcome). Improvements in quality utilize an evidence-based approach such as FOCUS-PDCA.

LD.30. The leaders prioritize and select a set of indicators that focus on the structure, process, and outcome of the services provided within the center.

LD.30.1. The selection process is based on the center's important processes and priorities.
LD.30.2. Each indicator has an operational definition, data collection method, frequency for collection, analysis by qualified staff, mathematical expression such as a ratio, with a defined numerator and denominator or a percentage and a desirable target.
LD.30.3. Structure indicators may include, but not be limited to the following: availability of essential supplies and equipment, availability of medical records, availability of emergency medications, surgical volume, and staff ratios.
LD.30.4. Process indicators may include, but not be limited to the following: waiting time, documentation in medical records, site marking, and time out processes.
LD.30.5. Outcome indicators may include, but not be limited to the following: Patient and staff satisfaction, patient's complaints, health-care-associated infections, medication errors, sentinel events and various adverse events.

LD.30.6. The performance monitoring results are discussed with staff, utilized in their evaluation, and reported quarterly to the governance together with action plans taken for improvement.

LD.30.7. The indicators are compared internally by historical trends and externally by benchmarking to other similar centers when available.

Explanation

The collection of key performance indicators should follow an evidence-based approach as outlined in LD.30.1 through LD.30.7. The indicators should cover a variety of issues based on structure, process, and outcome. The indicators should regularly be presented to staff to enhance their performance and also be utilized in their evaluation. Benchmarking of one's own performance should be carried out internally (comparing historical data) and externally, either locally or internationally, to define the center's position in terms of performance. A quarterly report should be presented to the governance with improvement action plans if required.

LD.31. The leaders develop and implement a comprehensive risk management program.

LD.31.1. The program addresses clinical, managerial and financial risk.

LD.31.2. The reporting of incidents and variances, patients' morbidities, and clinical and financial claims constitute the program's essential reactive arm.

LD.31.3. The center develops and implements at least one proactive risk management approach per year.

LD.31.4. The center develops and periodically updates a risk register for all potential clinical, managerial, and financial processes in the center.

LD.31.5. The center utilizes an evidence-based process for grading risks based on severity, frequency, and/or likelihood of occurrence.

LD.31.6. Information from the risk management program, including incidents, analysis, and improvement projects, is communicated to staff and the governing body at least quarterly.

Explanation

Healthcare organizations are risky places to visit and work in. The center should develop and implement a risk management program that covers all aspects of its activities: clinical, managerial, and financial. The program should be based on both reporting incidents and analyzing them to prevent recurrences as well as a proactive approach such as failure mode and effects analysis (FMEA) or any similar proactive risk management approach. The proactive approach should target improving practices that are high risk, problem prone, or high volume, that have a substantial financial impact, such as insurance rejections or that can markedly improve patients or staff satisfaction. Risks should be graded according to an evidence-based unified score system, and the center should maintain a list registering all its risky practices and procedures. Information collected from the risk management program should be used to improve the system, and staff should be informed of the findings and improvement projects at least quarterly.

LD.32. The leaders develop and implement an incident reporting policy.

LD.32.1. The policy outlines the types of incidents to be reported internally and to relevant regulatory authorities and the time frame and mechanism for reporting.

LD.32.2. The center utilizes a risk scoring matrix to categorize the severity of incidences.

LD.32.3. Incidences, including near misses, involving patients are documented in the medical record and patient and family are informed by the physician of any investigation results.

LD.32.4. The center compiles a report on incidences according to type and severity, and an action plan to prevent its recurrence is distributed to staff and governance at least quarterly.

LD.32.5. Sentinel events and severe near miss incidents are reported and investigated and findings utilized to prevent recurrence.

Explanation

The center should develop an incident reporting policy with a unified reporting mechanism for all occurrences, variances, or accidents. Reporting should include near misses as well (accidents that were prevented or discovered before reaching the patient). To encourage staff to report, it is preferable that the reporting be anonymous. Reporting any adverse event to the MOH or other relevant authorities when required by rules and regulations is a must. All incidents are categorized by type and severity. The center uses a risk scoring matrix to identify the severity of the incidence. The center prepares a report on all incidences (including near misses) by its type and severity and leaders develop an action plan to prevent its recurrence. The report is distributed to staff and to the governing body at least quarterly.
Sentinel events are situations that lead to the death or serious incapacitation of a patient, and may include the following:

a. Unexpected death
b. Unexpected loss of a limb or function
c. Retained instruments or sponge
d. Serious medication error leading to death or major morbidity
e. Infant or child abduction
f. Wrong site, wrong patient, or wrong procedure or surgery

Sentinel events are reported to CBAHI within 5 working days and a credible root cause analysis is also reported to CBAHI within 30 working days. Sever near misses, that could lead to sentinel events if reaches the patient, are a great opportunity to investigate and find a root cause that is mitigated to prevent its recurrence.

LD.33. The leaders oversee any contracts for clinical or operational services.

LD.33.1. Contracted entities are selected based on evidence-based criteria that the relevant department develops.

LD.33.2. The center director ensures relevant leaders' recommendations and approval on contracts.

LD.33.3. The leaders ensure that the contracted entity and services provided meet applicable laws and regulations.

LD.33.4. The leaders ensure that the services provided are integrated into the overall quality and patient safety program.

LD.33.5. The leaders regularly monitor and document the compliance of contracted services with the appropriate standards and take documented corrective actions for improvement when standards are not met.

Explanation

To ensure the best cost-effective outcomes from contracted services, the process owners should closely monitor the implementation of contracts related to outsourced services, such as housekeeping or laboratory services. To ensure that the monitoring process is translated into agreed-upon process and outcome indicators, the process owners should approve contracts before leaders give their final approval. Contract renewal should be based on the findings of the indicators' monitoring.

LD.34. The leaders ensure the integrity and security of telemedicine, teleradiology and interpretation of other diagnostic remote contracted services.

LD.34.1. Telemedicine, teleradiology and interpretation of other diagnostic remote contracted services are registered with Ministry of Health.
LD.34.2. The leaders ensure the credentialing and privileging of the physicians involved before starting the service.
LD.34.3. The leaders ensure the security and confidentiality of patient information that may be exposed as a result of the telecommunication process.

Explanation

The provision of telemedicine and teleradiology among other remote diagnostic services such as ECG interpretation has been recently introduced in the kingdom and has its own regulation. The services provider should be approved and registered with the ministry of health. The center should ensure the competency of the physicians providing the services by subjecting them to the center's credentialing and privileging process like other practicing physicians in the center. The confidentiality and security of patient information should be secured by allowing access to the relevant required information from the patient's file only.

LD.35. The leaders implement policies and procedures to guide the efficient procurement of equipment either purchased or donated, medications and essential medical consumables in accordance with national laws and regulations.

LD.35.1. Leaders ensure that all medical devices and supplies contractors and suppliers have a Medical Device Establishment License (MDEL).
LD.35.2. Leaders ensure that all newly purchased medical devices have a Medical Device Marketing Authorization (MDMA) certificate.
LD.35.3. Leaders approve newly introduced consumables based on a formal testing and feedback process from end users.

Explanation

Non-approved medical equipment and supplies may not provide accurate investigation results, accurate monitoring parameters, or safe patient care. Therefore, leaders should develop a procurement policy to ensure the purchase of nationally approved medical equipment, medications, and essential supplies. SFDA provides such information and performs visits to institutions to ensure that only approved equipment, medications, and supplies are in use. Newly introduced consumables require formal testing and approval by the end user before purchase.

LD.36. The leaders ensure an aesthetic appeal for the center.

LD.36.1. The center is clean and tidy at all times.
LD.36.2. The center is free of broken furniture, scratched and distorted walls.
LD.36.3. The ambient temperature is maintained between 20 - 24.4 Celsius.
LD.36.4. Nonirritant air freshener is used to control unwanted odor in the center.

Explanation

Confidence of patients' in the center starts from the first impression. Patients' experience is also enhanced by feeling comfortable being treated in a clean and relaxing environment. The center should always maintain cleanliness at all times with room temperatures ranging between 20 and 24.4 Celsius as per Occupational Safety and Health Administration "OSHA" standards. Nonirritant air freshener is used to control odor of the different areas. Maintenance team should always ensure the integrity of wall paint, floor tiles and furniture.

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ISQua (www.isqua.org)

Chapter II
Provision of Care (PC)

Introduction

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

- Access to care
- Scope and content of patient assessment
- Plan of care
- Consultations
- Patient's and family's education and participation in the treatment plan
- Cardiopulmonary resuscitation process
- Transfer and referral
- Emergency care

Standards

PC.1. Patients have access to services based on their health needs and available services and are registered with the center for providing such services.

PC.1.1. A standardized process is in place for registering patients for services based on their full name and ID number or passport number for visitors.
PC.1.2. Registration creates a medical record number that is unique to every patient.
PC.1.3. Appointment staff are aware of the services that the center offers and to direct patients to the appropriate services.
PC.1.4. An appointment system is in place to book patients in advance.
PC.1.5. Patients who present with emergencies beyond the capacity of the center are stabilized before transfer to a higher center.

Explanation

A uniform process for registering patients ensures a strong link between the patient and the unique medical record number generated. The use of a patient's full name and medical record number in identifying patients avoids miscorrelation with investigation results or the performing of a procedure on the wrong patient. Appointments reduce congestion and ensure the availability of services. Appointment staff should be made fully aware of the services provided and trained to direct patients to the appropriate services. If the appointment staff are not fully aware of the services, at a minimum, a nurse should be available at the appointment desk to book patients into the appropriate clinics. Patients should be registered. Patients presenting with emergencies beyond the center's capacity should be stabilized before transfer to a higher center. The center provides patients, families, and the wider community with information about accessing its services, using an appropriate format and language (e.g., displayed posters, brochures, handouts, and websites).

PC.2. (C) The center has a process to ensure the correct identification of patients.

PC.2.1. Patients are identified by at least two identifiers, full name as in identification document and unique medical record number.

PC.2.2. Patients are identified prior to any blood withdrawal, investigation, administration of medications and surgery or procedure.

PC.2.3. Patients are actively involved in the process of patient identification.

Explanation

Ensuring that the right patient receives the right care is an essential aspect of safe care. Patient identification errors can occur in all types of clinical activities, whether diagnostic or therapeutic. The intent is to precisely identify the individual as the person for whom the service or treatment is intended and, additionally, to match the service or treatment to that individual. Acceptable identifiers may be the patient's name (at least three names) and medical record number, the date of birth, etc. At least two identifiers are used, and the patient's name should be one of them. Patients are identified at the point when they enter the healthcare facility.
Patient identification is reconfirmed during the:

- Collecting of blood samples and other specimens for clinical testing.
- Administration of medications.
- Performing of a surgery or procedure.
- Performing of an X-ray or imaging procedure.

PC.3. Patients are clinically assessed through an established assessment policy and procedure.

PC.3.1. The policy and procedure are developed collaboratively, highlighting the scope and content of assessment by different specialties and in different locations.

PC.3.2. The policy and procedure ensure the availability of a comprehensive patient assessment in the first center's visit.

PC.3.3. The policy and procedure highlight required screening for nutritional needs, functional needs, the presence or absence of pain, the risk of fall, and social needs.

PC.3.4. The policy and procedure explain the specific assessments when the initial screening labels the patient "at risk" for the screening elements in PC.3.3.

Explanation

Patient's assessments are of paramount importance to reach the right diagnosis and establish the appropriate plan of care. The center should have an assessment policy and procedure that the various entities have developed collaboratively. This policy should clearly identify the scope and content of the history and physical examination of the different specialties. During their first clinic visit, all patients should undergo a comprehensive history and physical examination, regardless of the nature of the disease. Patients should be screened for nutritional needs, functional needs, the presence or absence of pain, the risk of fall, and any social needs. Those patients who screen positive should be fully assessed and managed according to the findings.

PC.4. **Physicians are provided with the results of requested investigations according to a time frame.**

PC.4.1. The time frame for routine and stat or urgent investigations is developed collaboratively with the laboratory, radiology and other services.
PC.4.2. The Turnaround Time document is available for routine and stat or urgent radiology, laboratory and other services tests.

Explanation

For an effective treatment planning, physicians should receive the results of ordered investigations in a time frame acceptable for the type of investigation carried out. The document should be available for the turnaround time of routine and urgent investigations, whether carried out inside or outside the center.

PC.5. **The center develops and implements a process for reporting critical test results whether on-site or outsourced.**

PC.5.1. The process defines staff who receive the result.
PC.5.2. The process involves writing down the result by the receiver and reading back the findings to the result provider.
PC.5.3. The read-back process and the physician's intervention are documented in the patient's medical record.
PC.5.4. The center develops a process for contacting patients who left the center when critical test results were reported.

Explanation

Critical test results are reported following a process developed cooperatively. The process clearly defines the notified parties, means of communication, read-back sequence, and elements required for documenting the event (date, time, patient identification, critical test result, read-back documentation, and identification of both the notifying and notified persons).

PC.6. **A care plan is developed by the attending physician to meet the patient's needs considering patient and family's cultural and spiritual matters.**

PC.6.1. The attending physician develops and documents the care plan by utilizing the assessment information obtained by the nurse and other disciplines participating in the care and the investigation results, as applicable.
PC.6.2. The care plan is designed to achieve desired outcomes specified as measurable goals.
PC.6.3. The care plan, is reviewed during every visit based on the outcome measures and other significant changes in the patient's condition.

Explanation

A documented care plan is vital to managing a patient's condition. The care plan is developed according to the assessment information that the healthcare team obtains. The plan should be tailored to the patient and family's spiritual and cultural needs as well.
The care plan should be in measurable goals, for example, maintain blood pressure between 120 over 80, maintain a pain score below 4, and maintain fasting blood sugar between 90 to 110 mg%. The attending physician should review this care plan during every visit and change it according to the patient's response, if necessary.

PC.7. **Consultations are available to meet the healthcare provider's request and patient's needs in a timely manner.**

PC.7.1. The consultation clearly states the reason for and urgency of the request.
PC.7.2. Consultation requests provide appropriate answers to the issues that the referring physician raised.
PC.7.3. Arrangements are made to ensure that consultations are immediately available for emergency cases. Urgent consultations are referred to the emergency room.

Explanation

Patients may need consultations to other specialties, and such consultations should be available if the service sought is available. The consultation should clearly state the reason and its nature (urgent or routine).
The consultation should be formulated in a manner that will help the consulted physician provide the appropriate answers to the issues that the referring physician raised. All urgent consultations are immediately referred to the emergency room if one is available in the center.

PC.8. **Staff members assist patients and, when appropriate, their families in fully participating in making informed decisions about their care, treatment and procedures.**

PC.8.1. Staff members provide patients/families with honest and accurate information in a manner they can understand, about their illness, options for treatment, proposed treatment, potential benefits, potential complications, and the likelihood of success of treatment, respecting their choices.
PC.8.2. Patients are supported in discussing their plan of care with the physician and having all their questions answered.
PC.8.3. Patients are provided with all the information regarding the identity and the professional status of his/her treating physician and how to contact him/her.
PC.8.4. When a surgery or procedure is performed, the patient/family receive from the surgeon information related to the surgery and from the anesthesiologist information related to anesthesia or sedation.

Explanation

To help patients and families make the right decision in accepting a treatment or procedure, the treating staff should strictly follow the elements in PC.8.1 through PC.8.4.

PC.9. **Patients and, when applicable, their families are educated about their healthcare needs.**

PC.9.1. Patients' and families' education is based on their healthcare needs, which include, but are not necessarily limited to: the nature of their disease; necessary treatments; infection control practices; safe use of medications, diet, and nutrition; medical equipment use; and preoperative and postoperative care.
PC.9.2. Each patient and his/her family receive education to help them give informed consent, participate in the care process, and understand any financial implications of care choices.
PC.9.3. The clinical staff educate patients and families in easily understandable language, and the provided education is evaluated for effectiveness.

Explanation

Patient and family education is a cornerstone of the success of any treatment plan. A patient and his/her family must be educated on the elements mentioned in PC.9.1 and PC.9.2. Staff should make every effort to ensure the patient/family clearly understand the education provided. e.g., the patient/family member demonstrates learning or verbalizes understanding. This education is documented in the patient's medical record.

PC.10. Informed consent is obtained from the patient or guardian.

PC.10.1. Informed consent is obtained before surgery, invasive procedures, anesthesia and sedation, the administration of blood and blood products, and other high-risk treatments.

PC.10.2. Informed consent is obtained prior to taking photographs of body parts, even if this is deemed critical for care.

PC.10.3. Informed consent is obtained before involving the patient in a research project.

PC.10.4. The center develops and regularly updates a list of procedures and conditions requiring informed consent.

Explanation

Patients have the right to be fully aware of the benefits, risks, complications, and consequences of refusing treatments or investigations of an invasive nature, such as surgery, sedation, anesthesia, contrast injections for radiology, chemotherapy, or blood administration. This consenting process should also take place before the taking of any photographs for the patient or body parts and before the patient's involvement in any research project that may expose the patient's identity or jeopardize the patients' safety.

PC.11. Patients planned for a surgery/procedure give their informed consent to the surgery/procedure and the anesthesia/sedation.

PC.11.1. The leaders develop and monitor the implementation of a policy for obtaining informed consent for a surgery or procedure, or for anesthesia or sedation.

PC.11.2. The physician/dentist performing the procedure conducts the informed consent process, which includes an explanation of the nature of the procedure, the benefits of the procedure, the risks of the procedure, alternative modalities, and the risks of not undergoing the procedure.

PC.11.3. A qualified physician/dentist conducts the informed consent process for surgery/procedure.

PC.11.4. A qualified anesthesiologist conducts the informed consent process for anesthesia/moderate and deep sedation.

Explanation

Patients and families have the right to fully understand the nature of the intended surgery or procedure, including the expected benefits and risks, alternative methods for treatment or investigation, the likelihood of success, and the risks of refusing the surgery or procedure. The information must be given by the physician performing the surgery or procedure, and be relayed in a manner understandable to the patient. It may include drawings or animations. The anesthesiologist is responsible for providing information related to sedation or anesthesia. The giving physician must sign the information. The patient (or substitute decision maker) must acknowledge receipt of the information by signing against the information given. The consenting process must be witnessed by another healthcare provider (for example, the nurse), who shall also sign against the information as a witness. The center must have a policy outlining the consenting process as in PC.11.1 through PC.11.4.

PC.12. The center has an effective process to safely provide care to patients who require Cardio Pulmonary Resuscitation (CPR).

PC.12.1. The center develops and implements a policy and procedure outlining the process.
PC.12.2. Standardized crash cart(s) are available in the patient care areas and are age specific.
PC.12.3. The crash cart is checked every shift by a qualified staff.
PC.12.4. The role of staff involved in the CPR process is clearly defined in the policy and monitored for implementation.

Explanation

To effectively resuscitate patients in cardiopulmonary arrest, policy and procedure must be developed. The policy should emphasize the unification of all crash carts so that staff familiarize themselves with crash carts in different locations. The crash cart should have a conversion table for pediatric emergency medications and pediatric paddles for the defibrillator. The policy highlights the frequency of checking the crash cart by the responsible nursing staff to ensure its readiness at all times. The policy also highlights the team members responsible for the resuscitation, and the role of each member.

PC.13. Policies and procedures guide the transfer of patients in need of urgent admission to hospitals.

PC.13.1. Transfers are based on the patient's need for continuing care and the center's capabilities.
PC.13.2. The receiving hospital clearly accepts responsibility for the patient's care.
PC.13.3. The receiving hospital receives the necessary information to provide care to the patient.
PC.13.4. The patient is monitored during the transfer process and the monitoring data is kept in the patient's medical record. The time of transfer is documented.
PC.13.5. The receiving hospital acknowledges receiving the patient, the time of arrival, and the patient's condition, and the document is kept in the patient's medical record.

Explanation

The safety of patients requiring transfer to a higher healthcare setting is important and is based on patients' acuity and the center's clinical capability. The patient should be monitored closely during the transfer process, and the monitoring findings recorded on a transfer monitoring sheet. The receiving hospital receives a report on the patient's condition. On the monitoring sheet, the receiving hospital acknowledges having received the patient. The sheet should be kept in the patient's medical record back in the referring center.

PC.14. Ambulance services are available and meet the patient's needs.

PC.14.1. The center owns or contracts with a fully equipped ambulance capable of transferring sick patients of all age groups to higher centers when needed.

PC.14.2. The required equipment is checked for proper functionality daily and after each dispatch by the emergency services nurse or technician. Findings are documented.

PC.14.3. Ambulance medications are checked for availability and expiry daily and after each dispatch by the emergency services nurse or technician. Findings are documented.

PC.14.4. During the transportation, the accompanying staff have the appropriate life support certification.

PC.14.5. The ambulance is tested daily for proper operation and periodically maintained. Findings are documented.

PC.14.6. The ambulance is included in the center's infection prevention and control program.

Explanation

A fully equipped ambulance should be available at all times to transport patients requiring a higher level of care in a hospital setting. The ambulance should be equipped with life support measures for all age groups for whom the center cares. The ambulance should be periodically maintained with documented logs. The ambulance's patient care compartment should be disinfected after the transfer of patients, and should be included in the center's infection control program.

PC.15. The center has an emergency services to deal with minor emergencies.

PC.15.1. Qualified staff manage the emergency services with a minimum of two (2) years of experience.

PC.15.2. At a minimum, a physician and a nurse are ACLS certified per shift.

PC.15.3. The emergency service have the necessary equipment for the stabilization and resuscitation of major emergencies.

PC.15.4. The center has a formal agreement with hospitals to transfer major emergencies after stabilization.

Explanation

The center should be able to manage minor emergencies in a dedicated emergency area that is easily accessible by the public. The staff managing the emergency area should be qualified and trained in emergency care and in immediately identifying critical cases that require immediate stabilization prior to transfer to a hospital. At a minimum, on each shift, a physician and a nurse are ACLS certified to manage complicated cases and help with cardio-pulmonary resuscitation. To expedite the transfer of emergency cases requiring a hospital, the center should have formal agreements with several hospitals, and the staff should have the required contact information for the referral centers.

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ISQua (www.isqua.org)

Chapter III
Laboratory Services (LB)

Introduction

The assessment/reassessment of patients to determine the proper diagnosis, the course of treatment, and the evaluation of the treatment plan for future decisions may require laboratory services. To meet the patient's needs, the center should either provide basic laboratory services or outsource them to a recognized laboratory through a formal contracting process.
This chapter addresses the following:

- Physical structure
- Staffing
- Safety program
- Specimen collection
- Equipment management program
- Labeling
- Quality management program
- Point of care testing

Standards

LB.1. Laboratory services are available or outsourced to meet the needs of the patient population served.

LB.1.1. The laboratory develops a services and specimens' manual that is distributed to all patient care areas.
LB.1.2. The manual includes the available tests either in-house or send-out and their Turn Around Times (TATs).
LB.1.3. The manual includes the prescribed process for requesting the introduction of a new test.
LB.1.4. The manual includes patient preparation for specimen collection.
LB.1.5. The manual includes positive patient identification.
LB.1.6. The manual includes quality and quantity of sample.
LB.1.7. The manual includes phlebotomy, sample collection and labeling procedures.
LB.1.8. The manual includes requisition and required clinical data.
LB.1.9. The manual includes specimen packing, handling and transportation.
LB.1.10. The manual includes specimen rejection reasons.

Explanation

Developing and maintaining a current scope of services that meets the needs of the patient population, clients, and customers is a sign of commitment to quality and professional practice. The laboratory scope of services should be clearly defined, and easily accessible to all lab staff, as well as internal and external customers. Equally important is the availability of a comprehensive specimen collection manual to guide the clinical staff in the process of lab test requisition, specimen collection, labeling, and handling.

LB.2. The laboratory has the right space and facilities relevant to the services provided.

LB.2.1. The laboratory's design and location meet applicable local and international regulations.
LB.2.2. The laboratory has adequate patient waiting areas and lavatories.
LB.2.3. Adequate spaces are available for each laboratory activity/section.

LB.2.4. The laboratory has adequate storage space for reagents, supplies, consumables, samples, waste holding, and records.
LB.2.5. The laboratory has adequate space for administrative and clerical staff.
LB.2.6. The laboratory has adequate water taps and sinks for handwashing and for washing contaminated equipment.
LB.2.7. The laboratory is equipped with adequate electrical outlets and emergency power.
LB.2.8. The laboratory has adequate lighting, ventilation and adequate temperature and humidity controls.
LB.2.9. The laboratory corridors are not obstructed and maintain access control and adequate emergency exits.
LB.2.10. Safety signs are adequately displayed and distributed in the laboratory.
LB.2.11. The laboratory workplace is free of hazards, clutter and distractions, with clean and well-maintained floors, walls, ceilings, bench tops, and sinks.
LB.2.12. Means of communication and telephones are conveniently located in the laboratory.

Explanation

Deficiencies in space and/or facilities are regarded as minor unless they are so severe that they interfere with the quality of work or quality control activities and safety. In this case, they become a major issue.

LB.3. The laboratory develops and implements a comprehensive safety program.

LB.3.1. The laboratory safety program complies with the national and international laboratory safety standard and is readily available to all laboratory personnel.
LB.3.2. The safety program includes a chemical hygiene plan, control of compressed and flammable gases, and the monitoring of fumes and vapors, as well as their respective Safety Data Sheets.
LB.3.3. The safety program includes biological safety procedures, the use of standard precautions, and the use of eyewash stations and emergency showers.
LB.3.4. The safety program includes electrical safety as well as fire prevention and control plans.
LB.3.5. The safety program mandates an annual safety training and competency assessment.
LB.3.6. The laboratory has a process for the monitoring of the safety program through regular safety inspections and analysis of the findings. The process is used to improve the laboratory's safety, and its findings are integrated with the center's quality improvement and patient safety program.

Explanation

The laboratory director is the person who is ultimately responsible for laboratory safety. He/she will be responsible for providing laboratory personnel with a comprehensive safety manual and assigning a safety officer to provide guidance and monitoring. The safety manual outlined above addresses common laboratory risks and hazards. To meet specific risk factors, specialized laboratories might need to develop additional safety requirements.
Regardless of how much experience they may have, laboratory personnel must be properly trained on all applicable safety procedures and assessed for competence, both upon their hire and periodically thereafter.
The director of the laboratory or a designee is responsible for conducting regular safety inspections/audits to ensure the proper state of readiness and function of safety apparatuses, alarms, and evacuation procedures. Appropriately trained personnel should conduct inspections/audits.

LB.4. The laboratory develops and implements a comprehensive infection control program.

LB.4.1. The laboratory infection control program complies with the national and international laboratory infection control standards and is readily available to all laboratory personnel.
LB.4.2. The infection control program includes the provision and use of Personal Protective Equipment.
LB.4.3. The infection control program includes biological safety procedures, the use of standards precautions, and the use of fume hoods and biological safety cabinets.
LB.4.4. The infection control program includes an infectious diseases and viral exposure plan.
LB.4.5. The infection control program mandates an annual training and competency assessment.
LB.4.6. The laboratory maintains a process for monitoring the infection control program through regular infection control inspections and analysis of the findings, which are utilized to improve the laboratory infection control and integrated with the center's infection control program.

Explanation

Labs, because of their equipment and function, constitute a key area. All efforts should be made to prevent infection. Therefore, the elements in LB.4.1 to LB.4.6 should be strictly followed.
Regardless of how much experience they have, laboratory personnel must be properly trained on all applicable infection control procedures and assessed for competence, both upon their hire and periodically thereafter.
The director of the laboratory or a designee is responsible for conducting regular infection control inspections/audits to ensure the proper state of infection prevention and control practices. Appropriately trained personnel should conduct inspections/audits.

LB.5. The laboratory has a clearly defined and implemented process describing its role in selecting and evaluating providers of reference laboratory services.

LB.5.1. The process requires selection criteria, including accreditation status.
LB.5.2. The process outlines an inclusive list of send-out tests.
LB.5.3. The process describes specimen collection, labeling, handling, transportation, and results reporting.
LB.5.4. A service contract specifies agreements' conditions with the reference laboratory.

Explanation

Laboratories may outsource advanced testing for better quality and/or cost-effectiveness. Reference laboratory services are some of the critical services that should be adequately controlled. Proper control of reference laboratory services includes:

- Selection: Selection of reference laboratories must be based primarily on the quality of such laboratories' performance. Referral specimens should be sent to an accredited laboratory. The laboratory director should ensure that the reference laboratories provide turnaround times that meet clinical needs.
- Scope of service: An inclusive list of outsourced services/tests must be kept current.
- Specimen requirements: The referring laboratory should follow all requisition, collection, and handling instructions that the reference laboratory specifies.
- Result reporting: Testing records and patient reports must state the name of the reference lab performing the test and the identification of the person authorizing the release of the results.

- Agreement/service contract: a signed document specifying the expectations of the two parties involved should be readily available for quick reference. Essential elements of such a document may include:

    - Scope of service
    - Agreement conditions (including accreditation status)
    - Sample requirements
    - Turn Around Time
    - Result reporting
    - Release of information to the third party
    - Solving disputes
    - Validity of the agreement and review schedule

LB.6. The laboratory has a clearly defined and implemented process for laboratory instrument and equipment management.

LB.6.1. The process defines the selection, receipt, installation, and identification of equipment.

LB.6.2. The process outlines the validation of laboratory equipment for its intended use.

LB.6.3. Manufacturer instructions related to monitoring, maintenance, calibration, and standardization are referenced.

LB.6.4. The process includes the required investigation and follow-up of equipment malfunction or failure.

Explanation

The process of critical equipment selection should consider the criteria that the laboratory established. In the selection of new equipment, it is important to consider not only the performance of equipment as it will be used in the facility but also any supplier issues regarding ongoing service and support. Also, a mechanism should be in place to uniquely identify and track all critical equipment.

The unique identifier may be the manufacturer's serial number or a unique identification applied by the laboratory or organization-wide identification system.

Upon receipt of critical equipment, the laboratory should develop a written plan for installation and operational and performance qualifications;

- Install according to the manufacturer's specifications.
- Verify the equipment's functionality by ensuring that the criteria the manufacturer established for the equipment's intended use are met.
- Assure that the equipment performs as expected in the facility's processes.

After installation, activities designed to ensure that equipment functions as intended should be scheduled and performed according to the manufacturer's recommendations and regulatory requirements. Such activities include calibration, maintenance, monitoring, functional and safety checks, and preventive maintenance. Recalibration and requalification may be necessary if repairs are made that affect the equipment's critical operating functions. Recalibration and requalification should also be considered when existing equipment is relocated. Evaluation and trending of equipment calibration, maintenance, and repair data will help the facility identify equipment that may need replacement. When equipment is found to be operating outside acceptable parameters, the potential effects on the quality of products or test results must be evaluated and documented. Good laboratory practices call for a defined process for dealing with reported results and delivered services when the system is later found to be compromised.

LB.7. **The laboratory develops and implements a policy for the documentation of specimen receipt and inspection.**

LB.7.1. The policy includes the required checks for proper packaging.
LB.7.2. The policy includes the required checks for quality and quantity of the specimen.
LB.7.3. The policy includes the required checks for the adequacy of specimen labeling.
LB.7.4. The policy includes the required checks for request completion.
LB.7.5. The policy includes the required checks for label/request discrepancies.

Explanation

Because patient/specimen misidentification may cause morbidities or mortalities, the best hope for prevention lies in preventing or detecting errors in every phase of the laboratory processes. When a sample is received in the laboratory, documented checks must be made to confirm that the information on the sample label and the information on the request are identical. If any doubt exists about the identity of the patient or about the labeling of the sample, a new sample must be obtained.
Requests for tests or services may be submitted in electronic or written format. Requests must contain sufficient information for accurate patient identification. Other information necessary to process a lab request includes gender, age, diagnosis, and the name of the authorized prescriber ordering the test. Verbal requests are acceptable in urgent situations but should be documented in accordance with facility policies.

LB.8. **The laboratory develops a policy and procedure for the quality control of test methods.**

LB.8.1. Quality control follows the manufacturer's instructions.
LB.8.2. The policy and procedure clearly identify the performance and review responsibility. Control specimens are handled and tested in the same manner and by the same laboratory personnel who are testing patient samples.
LB.8.3. The policy and procedure highlight the number and frequency of running controls.
LB.8.4. The policy and procedure mandate the acquisition of the correct reference range when the reagents/methodology change.
LB.8.5. The policy and procedure mandate the establishment of tolerance limits for results.
LB.8.6. The policy and procedure highlight the corrective action(s) to be taken in the event of unacceptable results.

Explanation

Quality control (QC) testing is performed to ensure the proper functioning of materials, equipment, and methods during operations. QC performance expectations and acceptable ranges should be defined and readily available to staff so that they will recognize unacceptable results and trends to respond appropriately. The facility determines the frequency of QC testing in accordance with the applicable regulatory requirements, accreditation standards, and manufacturer instructions. QC results should be documented concurrently with performance. Unacceptable QC results must be investigated, and corrective action must be taken, if indicated, before continuing the operational process. If products or services were provided since the last acceptable QC results were obtained, it may be necessary to evaluate the conformance of these products or services. The review of quality control data must be documented and include follow-up for outliers, trends, or omissions not previously addressed.

LB.9. The laboratory develops a policy and procedure for Proficiency Testing (PT) sufficient for the extent, complexity and scope of services.

LB.9.1. The policy and procedure ensure all analytes are covered with PT.
LB.9.2. The policy and procedure highlight alternative PT performed when appropriate.
LB.9.3. The policy and procedure have clear instructions for the receipt, processing, and reporting of PT results.
LB.9.4. PT samples are tested by the same personnel handling the patient samples.
LB.9.5. PT samples are tested using the same method used for testing the patient samples.
LB.9.6. PT samples are not referred to another external laboratory for testing.
LB.9.7. PT results are not shared with another external laboratory.
LB.9.8. PT results are evaluated and compared to the acceptable performance.
LB.9.9. Unacceptable performance is investigated, and appropriate corrective actions are taken.
LB.9.10. Laboratory management review and approve PT records.
LB.9.11. Corrective actions are implemented and monitored.

Explanation

Assessments are systematic examinations to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Assessments can be internal or external and can include quality assessments, peer reviews, self-assessments, and proficiency testing.
The laboratory must establish and maintain a process for proficiency testing (External Quality Assessment). The laboratory director must review the results of assessments to determine the appropriateness and effectiveness of corrective/ preventive actions (if taken).

LB.10. The laboratory defines the format and contents of laboratory reports.

LB.10.1. The report identifies the testing laboratory.
LB.10.2. The report includes full patient identification.
LB.10.3. The ordering physician is identified.
LB.10.4. The date and time of specimen collection and the source of the specimen are clearly written.
LB.10.5. The reporting date and time are identified.
LB.10.6. The test result(s) and reference intervals/range are highlighted.
LB.10.7. The condition of the specimen that may limit the test's adequacy is written down.
LB.10.8. Identification of the authorized person releasing the report is highlighted.

Explanation

As applicable, all the above elements of a laboratory report must be available in the laboratory information system or in paper records.

LB.11. The laboratory has a process for correcting or amending reported results.

LB.11.1. The process highlights the definitions of report corrections and amendments.
LB.11.2. The process describes the format of the corrected report.
LB.11.3. The process requires the inclusion of the previous result in the corrected report.
LB.11.4. The process requires the notification of the ordering physician.

Explanation

If a formal reference interval study is not possible or practical, the laboratory should carefully evaluate the use of published data for its own reference ranges, and retain documentation of this evaluation. The reference interval can be verified by testing samples from 20 healthy representative individuals; if no more than two results fall outside the proposed reference interval, that interval can be considered verified for the population studied.
For many analytes (e.g., therapeutic medications and CSF total protein), literature references or a manufacturer's package insert information may be appropriate.
Criteria for evaluating reference intervals include the introduction of a new analyte, a change in analytic methodology, or a change in patient population.
If it is determined that the range is no longer appropriate for the patient population, corrective action must be taken.

LB.12. The laboratory develops and implements a comprehensive process for Point-of-Care-Testing (POCT).

LB.12.1.	POCT is defined in writing.
LB.12.2.	The responsibility of managing the POCT is assigned to the laboratory.
LB.12.3.	Guidelines are available describing the process of acquiring POCT devices/ methods.
LB.12.4.	The process defines the training and competency testing requirements.
LB.12.5.	A list and location of all POCT devices is available around the center.
LB.12.6.	The process defines the maintenance and quality control of POCT devices/methods.

Explanation

Point-of-Care Testing (POCT) is defined as tests that are designed to be used at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside the physical facilities of the clinical laboratories. Other standards for quality management, results reporting, and safety are applied. The POCT program should be centrally coordinated in the laboratory, with designated qualified personnel who review testing and quality control procedures, and conduct/oversee the training and competency assessment of testing personnel. The surveyor will review all centrally maintained records and visit at least three testing sites to evaluate compliance.

References

The Clinical & Laboratory Standards Institute (CLSI) guidelines
https://clsi.org/standards/

Chapter IV
Radiology Services (RD)

Introduction

The assessment/reassessment of patients to determine the proper diagnosis, course of treatment, and evaluation of the treatment plan for future decisions may require radiology services. To meet patient needs, the center should offer radiology services or outsource them through a formal agreement with a recognized radiology center. If the center provides radiology services, the services are expected to meet the necessary national guidelines on radiation safety.

This chapter addresses the following:

- Staffing
- Radiation safety program
- Equipment maintenance program

Standards

RD.1. **Radiology services are available or planned with other institutions to meet patient needs and in accordance with applicable national standards, laws and regulations.**

RD.1.1. When radiology services are provided through a contract, the center is responsible for providing oversight of the contracts.
RD.1.2. A licensed radiology technician carries out radiology services.
RD.1.3. Radiology services are supervised by, at a minimum, a radiology specialist who reads, reviews, and authorizes all radiology reports.

Explanation

Basic radiological investigations should be available in the center, or the center should contract with a licensed radiology unit to ensure timely performance of the investigations and receipt of the written radiology report. The center's radiology unit should be supervised by, at a minimum, a radiology specialist who reads, reviews, and authorizes reports, and a licensed technician(s) is responsible for performing the procedure. In the case of contracted radiological services, the center should ensure the safety of its patients and the quality of its procedures by periodically reviewing the radiation safety report and the maintenance reports of the radiology machine(s).

RD.2. (C) **The center has a radiation safety program.**

RD.2.1. The program covers all areas that use ionizing radiation.
RD.2.2. All rooms where ionizing radiation is administered are tested and certified radiation leak proof by the appropriate certifying local authority.
RD.2.3. Safety warnings are posted on the doors in clear and appropriate locations.
RD.2.4. Prior to X-ray tests, women in the childbearing period with missed menstruation are checked for the possibility of pregnancy.
RD.2.5. Personnel are monitored for radiation exposure by thermoluminescence dosimeters (TLD) that are regularly checked.
RD.2.6. All types of radiation protection aprons are periodically inspected and tested for integrity and effectiveness with documentation.

Explanation

Patients, staff, and the environment should be protected from radiation by a well-constructed radiation safety program. The program includes all areas utilizing ionizing radiation, such as the dental panorama and mobile x-rays. Radiology rooms should be tested initially to ensure the absence of a radiation leak. Equipment should be tested periodically to ensure the absence of a leak. The same testing should be done for the dental panorama (if present). Warning signs should be clearly posted. Women in childbearing periods should undergo a pregnancy test if they have missed a period. Staff exposure to radiation should be monitored using thermoluminescence dosimeters that are examined periodically, and staff should receive replacement cards during the test time. Radiation protection aprons should also be tested periodically for their integrity.

RD.3. There is implemented process to keep the radiology equipment in safe, functional condition.

RD.3.1. An operation and service manual is available for all equipment.
RD.3.2. Qualified personnel maintain the equipment.
RD.3.3. Maintenance and repair records are properly maintained, including corrective actions.
RD.3.4. Equipment is periodically inspected and calibrated for proper functioning.

Explanation

To ensure the quality of films, avoid radiation leaks, and prevent overexposure, the radiology equipment should follow a radiology maintenance program or system that must include, at a minimum, the elements in RD.3.1 to RD.3.4.

References

MOH Publications - Guideline on the Assessment of Radiology
https://www.moh.gov.sa/en/Ministry/MediaCenter/Publications/Pages/default.aspx

Radiation Safety – FDA.
https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/default.htm

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http://smps.org.sa/en/wp-content/uploads/2016/11/Al-Shareef-SFDA-Requirements.pdf

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ISQua (www.isqua.org)

Chapter V
Dental Services (DN)

Introduction

Dental clinics pose a risk to patients that is different from the risks posed in other clinics in the center. This chapter addresses the peculiar dental standards that mitigate such risk, including:

- Staffing requirements
- Patients' assessment and treatment planning
- Patients' and families' education
- Medical records documentation requirements
- Infection control requirements

Standards

DN.1. Dental staff have appropriate qualifications.

DN.1.1. The head of the dental services is a dentist qualified by education, training and experience.
DN.1.2. Dentists perform dental treatments and procedures within their approved privileges.
DN.1.3. During dental procedure the dentist is assisted by dental assistant.

Explanation

To avoid unwanted complications, dentists should work within their assigned privileges, assisted by qualified dental assistants. To provide the best assistance to dentists, a minimum of one dental assistant is required per chair.

DN.2. A comprehensive assessment is performed and documented for each patient.

DN.2.1. Chief complaint, chronic illnesses, medication history and allergies are assessed and documented for each patient before dental procedures.

Explanation

Not knowing that a patient has a valvular lesion or is on anticoagulation medicines or suffer from chronic illnesses (e.g., congenital heart disease), infectious diseases, hematological diseases (e.g., hemophilia), can lead to serious morbidities if such patients undergo dental procedures before following the appropriate precautions. Therefore, a comprehensive assessment must be documented beforehand.

DN.3. The dentist documents the treatment plan in the patient's medical record.

DN.3.1. The dentist documents the required radiological procedures.
DN.3.2. The dentist documents the type of antibiotic prophylaxis when needed.
DN.3.3. The dentist documents the procedure(s) to be performed and highlights the teeth involved.
DN.3.4. The dentist documents the type and dose of local anesthesia or moderate sedation if needed.
DN.3.5. The dentist documents the material used for filling.
DN.3.6. The need for informed consent is highlighted.

Explanation

Based on assessment and dental examination findings, and to be both efficient and effective, a treatment plan should be agreed upon by the patient and documented before the initiation of any dental procedure. The plan includes elements in DN.3.1 to DN.3.6.

DN.4. Infection control guidelines are available and implemented by dental staff.

DN.4.1.	A new pair of gloves and a new mask are used by the dentist and assistant for every case.
DN.4.2.	Protective eyewear is used by the dentists and assistant for every case.
DN.4.3.	Patients receive eye protection by the assistant.
DN.4.4.	Working area surfaces are cleaned by the assistant between patients.
DN.4.5.	Evidence-based disinfection and sterilization practices are maintained and updated by the assistant.

Explanation

Dental practice is a recognized source of infection for patients and staff. All efforts should be made to prevent cross infection. The elements in DN.4.1 to DN.4.5 should be implemented and monitored.

DN.5. Safety rules are applied in the dental laboratory.

DN.5.1.	Fire detection and abatement equipment is available.
DN.5.2.	Butane and other flammable gases are stored safely outside the laboratory.
DN.5.3.	A hooded exhaust is available in the casting area.
DN.5.4.	Oxygen cylinders are safely stored.
DN.5.5.	Fumes and dust are safely evacuated.
DN.5.6.	An eyewash station is available and in good functioning condition.

Explanation

Dental labs, by nature of their equipment, pose serious safety risks. Therefore, staff safety is crucial in dental labs. The safety rules in DN.5.1 to DN.5.6 must be strictly followed.

References

Infection prevention and control manual for dental settings, MOH, 2013
https://www.moh.gov.sa/Ministry/MediaCenter/Publications/Documents/2018-11-22-005.pdf

ISQua (www.isqua.org)

Chapter VI
Medication Management (MM)

Introduction

The standards in this chapter focus on medication management as it applies to outpatient prescriptions, and medication use in the day procedure unit, the emergency room, and owned outpatient pharmacies. Therefore, some standards may not apply to a specific center. The standards focus on the following:

- Scope of medication services
- Safe storage of medications
- Safe medication preparation
- Review of prescriptions for appropriateness
- Handling of expired medications
- Management of narcotics and psychotropic medications
- Management of medication errors and adverse drug reactions

Standards

MM.1. Medication use processes are available to meet patient needs and in accordance with applicable laws and regulations.

MM.1.1. The medication use processes are managed by qualified staff who have a valid registration with the Saudi Commission for Health Specialties.

MM.1.2. The center establishes an interdisciplinary mechanism for overseeing and monitoring medication management processes.

MM.1.3. An updated list exists of the signatures of medical staff who are authorized to prescribe medications, along with their prescribing privileges.

Explanation

Medications are an important resource and a cornerstone of patient care. As such, they must be managed by qualified licensed staff as per the Saudi commission and MOH regulations. All healthcare providers involved in purchasing, storing, prescribing, dispensing, and administering medications are involved in overseeing medication management in the center. The appropriate medication room space, in ED and DPU, and its hours of operation should allow for the optimal and satisfactory delivery of medications to patients. To facilitate communication and safe prescribing practices, the center maintains an updated list of current prescribers in the center, including their signatures and prescribing privileges.

MM.2. The center has an updated and well-structured formulary.

MM.2.1. The formulary contains all the essential medications and is updated annually.

MM.2.2. The formulary is adopted from a relevant source that is available for Saudi Arabia and approved by the Saudi Food and Drug Authority.

MM.2.3. The medication formulary is available to the healthcare team.

Explanation

The formulary process is the cornerstone of proper medication management and rational use. It consists of preparing, using, and updating a formulary list of essential medications. The formulary manual provides adequate information about all essential medications that should be available in the center at all times. Formulary medications are selected based on the standard treatment guidelines or protocols that the center has developed or adapted for use. Periodic review is necessary because of changing costs and indications, new information about safety, and the emergence of new medicines. The formulary supports clinical staff in choosing the most appropriate therapies and selecting the most cost-effective, good-quality medication according to the standard treatment guidelines. This ensures the provision of better-quality care and more efficient, equitable use of resources.

MM.3. The center has a process for the appropriate storage of medications.

MM.3.1. The center has an appropriate storage area for non-refrigerated medications and refrigerators for storing vaccines and commonly refrigerated medications.
MM.3.2. Medications are stored as per manufacture guidelines.
MM.3.3. All medication and vaccine refrigerators are connected to alternate power source and a temperature log is maintained at all times.
MM.3.4. The center develops and implements a process for the handling of medications and vaccines when temperature monitoring indicates out of range.

Explanation

Medications can lose its potency if not stored in the appropriate environment as recommended by the manufacturer. Loss of potency during storage may influence pharmaceutical efficacy and safety. Proper environmental control (i.e., proper temperature, light, and humidity; sanitation, ventilation, and segregation conditions) must be maintained wherever drugs and supplies are stored anywhere in the center. Vaccines are more susceptible to temperature fluctuations, therefore it is best to be stored separately from other refrigerated medications that are in a more demand for opening and closing the refrigerator. All medication refrigerators must be connected to an electrical outlet that has an alternate power supply that starts immediately if there is an interruption to the main power supply. The center must develop a process on what to do with medications that are stored in an area that had out of range temperature.

MM.4. The center has a process for ensuring the stability of medication available in multi-dose containers.

MM.4.1. The center develops and maintains a set of guidelines for ensuring the stability of sterile multi-dose vials, vaccines, and other multi-dose medications.
MM.4.2. The center ensures all open multi-dose containers are labeled with the opening date and time, the expiry date and staff initials.

Explanation

Multiple-dose vials (MDVs) are widely used in all healthcare settings. By definition, an MDV contains antibacterial preservatives and, according to manufacturer's recommendations, may be used more than once. It is important to recognize that although common preservatives used in MDVs are effective against most bacteria, they are not antiviral agents. They do not protect against contamination when healthcare personnel fail to follow safe injection practices. In addition, contaminating pathogens are able to survive in MDVs for approximately two hours before the preservative takes full effect. Endotoxins can survive even after the preservative inactivates the organism. The contamination rate of MDVs in published studies has been as low as 0% and as high as 27%.

Whenever possible, multi-dose vials should be dedicated to a single patient. If multi-dose vials must be used for more than one patient, they should not be kept or accessed in the immediate patient treatment area. If a multi-dose has been opened or accessed (e.g., needle-punctured), the vial should be dated and discarded within 30 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. If a multi-dose vial has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer's expiration date. The manufacturer's expiration date refers to the date after which an unopened multi-dose vial should not be used. The beyond-use date refers to the date after which an opened multi-dose vial should not be used. The beyond-use date should never exceed the manufacturer's original expiration date.

MM.5. The center has a process for identifying and handling expired medications.

MM.5.1. The center has a written and implemented process for detecting and returning the nearly expired medications before the expiration date.
MM.5.2. Expired medications are not found in any patient care areas.
MM.5.3. The center maintains documents of return of expired medications to the supplier or manufacturer, or evidence of its proper destruction.
MM.5.4. All expired and/or nearly expired medications are properly labeled and stored separately from other medications.

Explanation

Multiple-dose vials (MDVs) are widely used in all healthcare settings. By definition, an MDV Expired medications may lose all their potency over time and become ineffective for treatment. The center should maintain a written policy for managing near-expiry and expired medications following the requirements in MM.5.1 through MM.5.4

MM.6. The center develops a policy and procedure for the safe prescribing of medications.

MM.6.1. All prescriptions are identified by accurate patient demographics including name, age and medical record number.
MM.6.2. Allergy status is clearly identified on the prescription.
MM.6.3. For all pediatric prescriptions, weight is identified.
MM.6.4. Abbreviations are not used in prescriptions.
MM.6.5. Prescribed medication is documented in the medical record.
MM.6.6. The prescribing of narcotics and controlled medications follows Ministry of Health laws and regulations.

Explanation

Inappropriate prescriptions account for 30% of medication errors; some of these errors can be serious. Medication prescription in the center should follow the elements mentioned in MM.6.1 through MM.6.6.

MM.7. The center develops and implements guidelines for the correct prescribing of antibiotics.

MM.7.1. A multidisciplinary team from the center adopts and updates the antibiotics guidelines.
MM.7.2. The guidelines for antibiotics prophylaxis are properly implemented before surgery and/or dental procedures and monitored.
MM.7.3. The guidelines for empiric and therapeutic use of antibiotics are properly implemented and monitored.

Explanation

Antibiotics misuse is a global concern. Misuse of antibiotics has a negative impact on the safety of patients and the community, increasing antibiotic-resistant micro-organisms and the overall cost of healthcare. The development and implementation of antibiotic guidelines are scientifically proven to prevent, control, and treat infections. Each center should develop and update its own evidence-based guidelines, taking into consideration its own anti-bigram and pathogens identified by the surveillance system. Guidelines should include surgical prophylaxis and the empiric and therapeutic use of antibiotics. Appropriate antibiotic use can be challenging nowadays. To prevent the development of resistance, centers are expected to define the prescribing privileges of antibiotics.

MM.8. The center develops a process to manage narcotics, psychotropic medications, and other controlled medications according to laws and regulations.

MM.8.1. The center has a process for receiving, storing and dispensing narcotics, psychotropic medications, and other controlled medications.
MM.8.2. The center maintains an inventory of narcotics, psychotropic medications, and other controlled medications.
MM.8.3. The center has a process for prescribing narcotics, psychotropic medications, and other controlled medications.

Explanation

Narcotics and controlled medicines are those agents, either naturally or compounded, that have been included in schedule #1 and schedule #2 in the SFDA regulations manual. The center must implement the related rules and regulations of the SFDA and MOH as stated. Medications are stored and secured behind locked steel doors or inside steel cabinets with double locks and/or double doors all over the center. Limited quantities of essential controlled and narcotics medications may be allowed in patient care units according to clinical needs. The documentation process should be maintained for all related steps, such as requisition, procurement, ordering, dispensing, distribution, endorsement, registration, and discarding of the unused portion and empty containers.

MM.9. The center safely manages high-alert and look-alike, sound-alike (LASA) medications.

MM.9.1. The center identifies, in writing, its high-alert and LASA medications.
MM.9.2. The center has a process for managing high-alert and LASA medications.

Explanation

Throughout the medication use process, medication errors related to look-alike and/or sound-alike medications and/or packages are common in the healthcare setting. Look-alike, sound-alike medications account for an estimated 25% to 30% of medication errors. With tens of thousands of medications currently on the market, the potential for serious error due to confusing medication names is significant. Contributing to this confusion are incomplete knowledge of medication names; newly available products; similar packaging or labeling; similar clinical use; illegible prescriptions; and misunderstandings during the issuing of verbal orders. Examples of high-alert medications include concentrated electrolytes, controlled medications and narcotics, antithrombotic medications (e.g., heparin, warfarin), and insulin. The full list is published by the Institute of Safe Medication Practice and the World Health Organization. The process for managing such medications may include separating the look-alike/sound-alike medications and limiting access to high-alert medications.

MM.10. The center evaluates the appropriateness of prescriptions before dispensing.

MM.10.1. The appropriateness review includes allergies, indications, dosage, frequency, route of administrations therapeutic duplication and possible interactions.
MM.10.2. The center maintains an updated medication profile for each patient treated in the emergency room or day procedure unit.
MM.10.3. The review process is done by a pharmacist or a physician.
MM.10.4. The reviewer discusses any concerns in the process with the prescriber before medication dispensing.

Explanation

The following could harm patients or render treatment ineffective: dispensing unclear prescriptions; dispensing prescriptions without ensuring the relevant diagnosis; dispensing prescriptions without determining allergies or the presence of interactions, and dispensing the wrong dose. The center should adopt a safety culture allowing the pharmacist to contact physicians for clarification of prescriptions or receipt of additional information pertinent to the prescription, and to notify the physician if the medication is not available so an alternative may be prescribed. Drug-drug and drug-food interactions should be clearly documented in the medical records. Pharmacist should dispense medications only for their approved indications.

MM.11. Medication preparation areas comply with infection control measures and safe practices.

MM.11.1. Medication preparation areas are clean and tidy, with clean preparation surfaces.
MM.11.2. The preparation area is equipped with a wash sink, antiseptic soap, and a sharps container of appropriate size.
MM.11.3. Parenteral medications are prepared aseptically.
MM.11.4. Medications that are prepared and not immediately utilized are labeled with the medication name, dose, route of administration, and patient's identifiers.

Explanation

Prepared medications can be a cause of patient morbidity if they were prepared aseptically or given to the wrong patient. Therefore, medication preparation should follow the elements mentioned in MM.11.1 through MM.11.4

MM.12. The center develops and implements a policy and procedure on medication error reporting.

MM.12.1. The pharmacy maintains a written policy and procedure for medication error reporting.
MM.12.2. The policy defines significant medication error, the time frame for reporting, and the reporting format.
MM.12.3. Medication error reporting is active and ongoing.
MM.12.4. The center performs an intensive root-cause analysis for all significant medication errors.
MM.12.5. The center utilizes the reported information to improve the medication use process and reduce the error rate.

Explanation

Reporting medication errors prevents recurrence and enables the immediate management of the incident to reduce patient harm. The center should maintain a policy for the reporting of medication errors, including classification, definition, reporting format, time frame for reporting, and immediate intervention for patients to reduce harm. All significant medication errors should undergo a root cause analysis. Data gathered from the reporting and the root cause analysis is used to modify the medication management process to prevent recurrence of errors.

MM.13. The center monitors allergies to medications.

MM.13.1. The center has a process in place to ensure the reporting of medication allergies.
MM.13.2. The newly discovered allergies are documented in patient medication profile.

Explanation

Allergies can be a source of morbidity among patients if they are not highlighted to caregivers, including pharmacy staff. All prescriptions should clearly highlight the patient's allergy status. As part of the prescription review process, relevant staff should discuss allergy status with the prescriber to stop or change prescribed medication.

MM.14. The center develops and implements a policy and procedure for the reporting of adverse drug reactions (ADR's).

MM.14.1. The policy and procedure defines significant ADRs and the time frame for reporting.
MM.14.2. An intensive analysis is performed for all significant ADRs.
MM.14.3. Treating physicians are notified of the analysis results.
MM.14.4. The medical record is flagged for significant ADRs and the patient receives the appropriate medical care for the reaction.
MM.14.5. Significant ADRs are reported to the relevant authorities as per laws and regulations.

Explanation

Adverse drug reaction (ADR) is a response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function. An unexpected adverse reaction refers to a reaction whose nature or severity is not consistent with domestic labeling or market authorization or expected based on the drug's characteristics. A serious adverse reaction is any medical occurrence

that, at any dose normally used in humans, results in death, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability, or is life-threatening.

The monitoring of medication effects includes observing and documenting any adverse effects. The healthcare institution establishes a mechanism for reporting adverse events and the time frame for reporting. Healthcare organizations are responsible for ensuring that patients are treated as safely as possible. Prevention of ADRs is possible and, indeed, necessary. Studies have shown that over 50% of adverse drug reactions may be preventable. Most ADRs are related to the prescribing of an incorrect dose or the administration of a drug to a patient with a known allergy. Many ADRs could be avoided if the relevant healthcare worker had asked specific questions before prescribing and/or dispensing a drug. ADRs are to be reported to the SFDA.

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ISQua (www.isqua.org)

Chapter VII
Management of Information (MOI)

Introduction

Information management is a cornerstone of patient care and the decision support process by center leaders. Center leaders are required to design and implement an information management plan that defines the following:

- Managing the information required by governmental and external agents
- Managing internal information requirements
- Maintaining the security and confidentiality of information
- Retaining records
- Documenting and completing patients' unique medical record

Standards

MOI.1. The leaders define in a plan the information that is shared among the staff and with other governmental and non-governmental entities and its format.

MOI.1.1. The plan highlights how patient demographic and medical information is shared among medical and administrative staff.

MOI.1.2. The plan identifies how the types of information are communicated by leaders to staff and vice versa.

MOI.1.3. The plan includes the Ministry of Health required information and the frequency of reporting.

MOI.1.4. The plan highlights the patient's personal and medical information required to refer the patient to a higher center.

MOI.1.5. The plan identifies the staff security levels for accessing the information.

MOI.1.6. The plan identifies how the various information is secured and safely stored.

MOI.1.7. The plan highlights the different documents retention time consistent with Ministry of Health rules and regulations.

Explanation

Communication failures are responsible for a third of the causes of morbidities and mortalities in healthcare. Identifying and organizing the flow of information inside the organization and with external customers helps streamline communication and eliminate communication errors. All stakeholders should collaboratively develop a management of information plan that includes the following:

- Managing the patients' information (medical records and whether it is in paper format, electronic or combined)
- Managing the internal communication between staff and the leaders such as memoranda, management notifications and staff complaints.
- Managing externally required information by MOH and other regulatory bodies.
- The plan identifies how information is secured.
- The plan identifies the level of security for each type of document and how staff can access only the information authorized to see.
- The plan identifies how the information is backed up and restored if needed.
- The plan identifies the retention time of the different documents and information relevant to the rules and regulations of MOH and other regulatory bodies.

MOI.2. The leaders develop standardized diagnosis codes, procedure codes and symbols, and minimize abbreviations.

MOI.2.1. The staff use diagnosis and procedure codes consistent with Ministry of Health and other regulatory bodies' requirements.
MOI.2.2. A list of approved abbreviations and symbols is distributed in all patient care areas for reference.

Explanation

Abbreviations can be problematic and at times even dangerous, particularly in the context of the prescribing of medications. In addition, when one abbreviation is used for multiple medical terms, confusion regarding the author's intent may result in medical errors.
Standardized diagnoses and procedure codes help centers track pathology and common procedures, and complies with insurance companies' requirements. Abbreviations and symbols could be interpreted differently, thus inadvertently changing the intended care plans. Therefore, a limited list should be circulated to all staff in all areas, and its correct use monitored.

MOI.3. All patients seen in the center have unique medical records.

MOI.3.1. Each patient has a unique medical record number.
MOI.3.2. Each patient has only one medical record or historical volumes of the same.
MOI.3.3. The medical record's contents are arranged according to a standardized process.
MOI.3.4. Medical record contains the required patient demographics, including national identification, contact information, emergency contacts and insurance category.
MOI.3.5. Medical record contains updated medical information sufficient to safely manage the patient and promote continuity of medical care.
MOI.3.6. Patient allergies, prior adverse reactions, and chronic infections are confidentially documented and consistently displayed in a specified area of the patient's record.

Explanation

To ensure continuity of care, each patient cared for in the center should have his/her own medical record that has a unique medical record number. The medical record shall contain, at a minimum history and physical examination, plan of care, investigations, consultations, observations, allergies, consents, procedure reports, and medications, all the elements in MOI.3.3 through MOI.3.6.

MOI.4. The leaders develop a policy on the rules and regulations for writing in patients' medical records.

MOI.4.1. The policy identifies the category of staff allowed to write in the medical record.
MOI.4.2. All entries are legible, dated, timed, and signed by the author.
MOI.4.3. Entries written in error are not deleted or erased. Instead, a line is passed through the error text and dated, timed, and signed by the author.
MOI.4.4. Only standardized and approved abbreviations and symbols are used in medical records.

Explanation

Uniformity of writing in medical records ensures proper documentation and avoids misinterpretation of written information. Therefore, a policy should be developed and implemented based on the elements in MOI.4.1 through MOI.4.4

MOI.5. The leaders develop a process for completing and storing the patient medical record.

MOI.5.1. The center has a dedicated and secure storage area for medical records.
MOI.5.2. Regular checks are made on returned medical records to ensure their completion.
MOI.5.3. Non-completed medical records are clearly separated from completed ones in the storage area and are completed within a timeframe that the organization defines.
MOI.5.4. The center maintains a record of the percentage of incomplete records over time and uses this information to improve staff compliance with record completion.

Explanation

At the end of a patient's visit, the medical record should be returned to the medical records store. This keeps the medical records safe, secure, and in good order. Upon its receipt in the store, the medical record should be checked for completeness according to a written process that includes complete demographics, medical information, and authentication. Every effort should be made to complete the incomplete records within a time frame that the organization has identified. On a monthly basis, the center should check a percentage of its records for completion, and the collected information should be conveyed to staff and used to improve staff compliance with completion.

MOI.6. The center has an implemented policy and procedure for the use of information technology.

MOI.6.1. The policy and procedure highlight how the generated information is stored and regularly backed up.
MOI.6.2. The policy and procedure describe the manual procedures required to execute the various activities in the event of system failure, maintenance or repair.
MOI.6.3. Staff can demonstrate the manual procedure for the downtime regulation.

Explanation

Despite advances in infrastructure robustness, many HCFs still face database, hardware, and software downtime, lasting short periods or shutting down work for days. To maintain the completeness and comprehensiveness of data, an adequate data capturing process during downtimes is critical. Gaps in patient data may result in gaps in patient care. A complete manual system must be prepared for use during the downtime period and include both managerial and clinical activities to prevent the interruption of care processes. End users involved in providing center services should be trained on the planned manual system and know how to shift once the electronic system is down. The downtime system must be assessed for effectiveness regularly and after actual downtime incidents.
Documented reports of this assessment should be available, and actions taken in response to any deficiencies.
Even though organizations may treat their storage media with care, these media can be damaged accidentally or on purpose, and medical records can be unconsciously changed or erased. The creation of backup copies limits the amount of information lost. Backup media should be safely stored.

As part of information and data integrity, organizations are expected to have a clear mechanism for backing up data to ensure ease of retrieval. The backup process is regularly implemented to avoid any data loss or gaps in information which may affect gaps in the care and service provided, as well as to avoid misinformed decision-making by leaders.

MOI.7. (C) The center has an effective clinical documentation improvement (CDI) program.

MOI.7.1. There is a policy and procedure for clinical documentation improvement in the center.

MOI.7.2. The center has at a minimum a physician and a nurse who are properly trained on clinical documentation improvement.

Explanation

Clinical Documentation Improvement (CDI) is fundamental in any healthcare organization. CDI ensures the accurate reporting of the diagnoses and procedures to the health authorities as per local regulations. Moreover, health Insurance payments and reimbursement are directly linked to the proper documentation of the clinical episode, so that over and under-payments are avoided. Documentation also helps in the proper utilization of resources, including time, medications, supplies, investigations, and usage of the operating theatre.

CDI ensures timely completion of the medical records which would support safer care for patients as well as all research activities related to the prevalence of medical errors, utilization of resources, areas for improvement and so forth. A proper documentation translates into proper coding which makes it possible for healthcare leaders plan for better delivery of healthcare services.

The center leadership is responsible for ensuring that clinical staff are well trained on all aspects of clinical documentation as per CBAHI guidelines in this regard. Auditing of the quality of clinical documentation in the medical records will be part of the survey activities.

References

HIM Body of Knowledge – AHIMA
http://bok.ahima.org/

ISQua (www.isqua.org)

Chapter VIII
Infection Prevention and Control (IPC)

Introduction

The ambulatory care center requires processes to support the prevention and control of infection that might be acquired or transmitted by patients, staff, and visitors while in the center. These processes reduce the risk or spread of infection and ensure that care is provided in a clean, sterile environment. To ensure staff and patient safety, infection prevention and control requires an effective center-wide infection prevention and control program that identifies, reduces, and eliminates infection risks.

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

- Infection control program
- Staff education
- Hand hygiene
- Communicable diseases
- Cleaning, decontamination, disinfection, and sterilization
- Healthcare-associated infection
- Personal protective equipment
- Sharps safety
- Waste management
- Housekeeping

Standards

IPC.1. The center implements a coordinated program to reduce the risk of healthcare-associated infections.

IPC.1.1. A qualified individual, acting on a full-time or part-time basis, is responsible for the infection control program.
IPC.1.2. The program involves patients, visitors, staff, and volunteers.
IPC.1.3. The program involves all patient care areas and support services.
IPC.1.4. The infection control program is based on current scientific knowledge, accepted practice guidelines, and applicable laws and regulations.
IPC.1.5. The infection control program's components are contained in a manual that is available to all staff members.

Explanation

The center should establish an evidence-based infection control program according to its scope of services. The program must cover all related IC prevention and control activities that could ensure maximum safety for patients, visitors, staff, volunteers, contractors, etc. Infection prevention and control activities should be overseen by a person qualified in infection prevention and control practices through education, training, experience, or certification. This qualified staff member should directly report to higher administrative authority to ensure the presence of an independent administrative unit that oversees IC issues in the whole center. The person fulfills program oversight responsibilities as per standard requirements that should be described in the job description.

IPC.2. Infection prevention and control activities are integrated and coordinated by an interdisciplinary team.

IIPC.2.1. The interdisciplinary team reviews and approves the infection control policies and procedures and the improvements plans.
IPC.2.2. The interdisciplinary team evaluates and revises, on a continuous basis, the procedures and mechanisms that the center develops to serve established standards and goals.
IPC.2.3. The interdisciplinary team brings to the center's attention new infection control issues arising in different departments and suggestions for solutions.
IPC.2.4. The interdisciplinary team evaluates the infection control program annually and suggests any necessary additions or changes.

Explanation

Infection control personnel, in collaboration with quality personnel and the medical director (or representative), must regularly review, approve, monitor, and evaluate all infection control program components and activities to maintain optimum IC activities, outcomes, and safety.

IPC.3. The leaders develop and ensure the implementation of infection control policies and procedures targeting the most important infection risk processes.

IPC.3.1. Disinfection and sterilization.
IPC.3.2. Handling of sharps.
IPC.3.3. Infectious materials and waste disposal.
IPC.3.4. Prevention and management of patients' and workers' exposure to healthcare-associated infections.
IPC.3.5. Laundry and linen management processes.
IPC.3.6. Renovation projects guidelines.
IPC.3.7. Practices for support services departments.

Explanation

To ensure a safe workplace for all the center's attendees, all activities at the center should be regulated and controlled by scientifically based infection control policies and procedures.

IPC.4. Communicable diseases are tabulated and reported as required by laws and regulations.

IPC.4.1. The center tabulates and reports communicable diseases to the Ministry of Health.

Explanation

To ensure that the center complies with MOH health requirements with regards to the reporting of notifiable communicable diseases, the center should maintain evidence of reporting communicable diseases to MOH as per the center policy. The center should also maintain evidence of staff awareness of the center reporting system.

IPC.5. The leaders develop and implement a policy and procedure for healthcare associated infection prevention.

IPC.5.1. Evidence based bundles are used for the insertions of devices.
IPC.5.2. Staff regularly collect and analyze data on device related and surgical site infections.

Explanation

To optimize urinary catheter and peripheral line insertion and other procedures in patient care areas, the center should maintain a policy for device-related infection prevention and the care bundle (when applicable). The staff must be fully educated about the elements of the adopted care bundle (when applicable). The center should regularly collect and analyze the data and assess the bundle compliance rate for performance improvement.

IPC.6. The leaders design and ensure the implementation of an effective hand hygiene program.

IPC.6.1. Written policies and procedures for implementing and monitoring appropriate hand hygiene are available.
IPC.6.2. The center provides hand washing facilities sufficient to meet its needs.

Explanation

Hand hygiene (HH) is the most effective method of preventing infectious disease transmission. The center should develop HH policies and procedures. The center supports HH by providing sinks and appropriate hand washing soap and sanitizers in appropriate locations in the facility. The center should maintain a monitoring process to continuously evaluate HH compliance among staff. In addition, data about HH compliance and monitoring should be analyzed and integrated into improvement projects.

IPC.7. (C) Centers providing sterilization services strictly follow rigorous sterilization rules.

IPC.7.1. Qualified staff conduct the sterilization processes.
IPC.7.2. Adequate space is available for sterilization services that support sterilization processes, and no instrument or equipment sterilization

takes place outside this area.

IPC.7.3. A policy and procedure on the safe reprocessing of single-use items have been implemented.

IPC.7.4. Personal protective equipment is available and used during decontamination: heavy-duty gloves, waterproof aprons, facemasks, goggles, and face shields.

IPC.7.5. Sterilizers are in good working order, and instructions for their use are available.

IPC.7.6. Proper sterilization parameters are recorded.

IPC.7.7. Sterilization records are retained for one year.

IPC.7.8. Chemical indicators are used in every package. Biological indicators are used at least weekly. Records of results are kept for one year.

Explanation

Infection risk is minimized through proper cleaning, disinfection, and sterilization of surgical supplies and other invasive or noninvasive patient care equipment. To ensure the proper method of collection, decontamination, cleaning, and sterilization, these services must be centralized and maintained. CSSD staff must set clearly written policies and procedures that guide collection and transportation, decontamination and disinfection, cleaning and sterilization, the storage of sterile items, and a mechanism for the recall of sterile items in the event that the sterilization process fails. The policy must be scientifically sound, and reviewed and approved by the infection prevention and control, quality, and administration. When this service is outsourced, the center should ensure that the contractor complies with all required safety standards. Re-sterilization of single-use items should be carried out according to an evidence-based policy that ensures safe sterilization without affecting the integrity of the item's use and that specifies the number of re-sterilization cycles and the point at which the item cannot be further re-sterilized.

IPC.8. Patients with communicable diseases and those who are colonized or infected with epidemiologically important organisms are separated from other patients, staff and visitors.

IPC.8.1. Written and implemented policies and procedures address standard and isolation precautions for cases of suspected or proven communicable diseases.

IPC.8.2. Patients with suspected communicable diseases are dealt with in an isolation room equipped with a sink and personal protective equipment.

IPC.8.3. The isolation room is a negative pressure ventilation that is exhausted to the outside unless it is filtered through a High-Efficiency Particulate Air (HEPA) filter, or, at a minimum, is equipped with a portable HEPA filter that is regularly maintained according to the manufacturer's recommendation.

IPC.8.4. Staff are trained to triage suspected communicable disease cases and isolate them before transfer to the appropriate healthcare setting.

IPC.8.5. During direct care of patients on airborne precautions, staff use high-filtration respirator masks (N-95, N-99).

Explanation

This is to ensure proper implementation of the appropriate type of isolation precautions (contact, droplet, and airborne isolation precautions). Center preparedness for isolation precautions includes: the availability of a negative pressure airborne isolation room (or an isolation room with a portable HEPA filter) and of required supplies, particularly a respirator (high-filtration mask, e.g., N95) in patient care areas.

IPC.9. **Personal protective equipment is readily accessible and available and is used correctly by staff in all patient care areas.**

IPC.9.1. Written policies and procedures are available for the appropriate use of gloves, gowns, facemasks, and protective eyewear.
IPC.9.2. Gloves are worn when the potential exists for contact with blood/body fluids.
IPC.9.3. Gowns, masks, eyewear, or face shields and other protective equipment are worn during all procedures which are likely to generate splashes, soiling, or droplets of blood or other body fluids.

Explanation

Personal protective equipment (PPE) is a fundamental tool for proper infection prevention and control practices. The center identifies those situations in which masks, eye protection, gowns, or gloves are required in written policy, and provides a sufficient supply of PPEs as well as training in their proper use.

IPC.10. **The leaders define in a policy the cleaning, decontamination and disinfection processes in all patient care areas.**

IPC.10.1. The policy has a list of appropriate detergents and disinfectants as defined and approved by the infection control personnel.
IPC.10.2. Detergents and disinfectants are available in all patient care areas.
IPC.10.3. Patient care areas are clean, and equipment is properly disinfected.

Explanation

Disinfectants are frequently used to eliminate infectious organisms. The choice of disinfectant to be used depends on many factors. Some disinfectants have a wide spectrum (kill many different types of microorganisms), while others kill a narrower range of disease-causing organisms but are preferred for other properties (they may be non-corrosive, non-toxic, or inexpensive). To ensure the proper use of disinfection, the selections and indications for use must be based on scientific references and national laws and regulations, reviewed and supervised by infection control personnel.

IPC.11. (C) **The leaders define in a policy the safe procedures for waste collection, storage and disposal.**

IPC.11.1. The policy differentiates between regular waste and infectious waste.
IPC.11.2. The infectious waste is treated and disposed of in accordance to laws and regulations.

Explanation

To protect the public and the environment from infectious organisms and to provide a safe, healthy environment for the patient, healthcare worker, and visitors, the center should implement a Medical Waste Management Program that regulates the segregation, handling, storage, and disposal of medical waste and provide oversight for its implementation as per center policy. The program should be implemented under national laws and regulations. The center should ensure the availability of required supplies (yellow bags, red bags, medical waste containers, etc). Medical waste workers should be vaccinated and trained on the safe handling of medical waste as reflected in their employee health records.

IPC.12. The leaders develop and ensure the implementation of a program for the prevention and management of sharp injuries.

IPC.12.1. Needles are not bent, broken, or recapped except in special and approved circumstances. If recapping is necessary, the "scoop method" is used.

IPC.12.2. Needle sticks or sharps injuries are reported in a timely manner and investigated. Data are trended over time and used to develop improvement interventions.

Explanation

To prevent sharps injuries with exposure to blood-borne infections, the center should have a defined system to prevent sharps injuries and ensure the proper handling of sharps. The handling, use, and disposal of sharps within the center should be practiced according to a written policy and procedure. Center staff should have the knowledge and skills necessary to handle sharps (i.e., needles are not bent or broken, the scoop method is used for necessary recapping, etc.).

IPC.13. Sharps are discarded in appropriate containers.

IPC.13.1. At least one puncture-proof and leak-proof sharps container is available in a convenient place in every patient care area

IPC.13.2. Sharp containers are not overfilled and are disposed of as medical waste when their contents are three-quarters of their sizes. They are not opened to facilitate the transfer of sharps into other containers.

Explanation

The center should provide the necessary resources to implement a comprehensive program for preventing sharps injuries. The center should ensure that the type of sharps box used is puncture-resistant and leak-proof and that it presents no risks to staff or patients. A sufficient number of appropriate sharp containers should be made available. Sharps boxes are properly located and used, and sharps box disposal is handled in accordance with national laws and regulations.

IPC.14. Housekeeping has policies and procedures describing its functions.

IPC.14.1. All units have a cleaning/disinfection schedule that lists all environmental surfaces and items to be cleaned.

IPC.14.2. The infection control staff periodically review the cleaning procedures, schedules, and agents.

IPC.14.3. A process is in place to safely handle blood/ body fluids spills and waste.

Explanation

Environmental cleaning is a fundamental principle of infection prevention and control in the center. The policy ensures appropriate decontamination of surfaces that could play an important role in the transmission of dangerous pathogens including Clostridium difficile, and antibiotic-resistant organisms such as methicillin-resistant staphylococcus aureus (MRSA), vancomycin-resistant enterococci (VRE), etc. The center must implement clearly written housekeeping policies and procedures that are reviewed by infection control staff. The center must also maintain detailed cleaning schedules listing the center environmental surfaces, prepared and implemented by housekeeping staff and monitored by Infection Control staff.

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Chapter IX
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 center leadership must provide all necessary support and resources to improve safety in the workplace in alignment with regulatory requirements.

The center must maintain plans for managing the safety of the environment and must implement these plans. The center must collect and analyze data to determine the effectiveness of the plans and facilitate continuous quality improvement.

Staff members must also receive education about their responsibilities. Education must commence at orientation and continue on a regular basis thereafter.

Important aspects of facility management and safety that this chapter addresses include the following:

- Safety
- Security
- Fire safety
- Emergency
- Hazardous materials
- Medical equipment
- Utilities

Standards

FMS.1. The leaders establish and support a facility management and safety program.

FMS.1.1. A qualified individual is responsible for the facility management and safety program as a full-time or part-time employee.

FMS.1.2. The leaders establish an interdisciplinary team for overseeing and monitoring the facility management and safety program.

FMS.1.3. The safety management program includes plans for emergency management, utility systems, hazardous materials, fire safety, medical equipment, building safety and security.

FMS.1.4. The safety management program includes the regular inspection, testing, and maintenance of all the program's operating components.

FMS.1.5. Data related to safety concerns are reviewed and analyzed with proper action to prevent reoccurrences.

FMS.1.6. The leaders maintain adequate and complete documentation for the facility management and safety program.

FMS.1.7. All staff including new hires, locum and trainees receive education on the program. This education is repeated annually as relevant to their practice.

Explanation

The center develops individual programs or one master program that includes the following:

a) Safety and Security
Safety—The degree to which the center's buildings, grounds, and equipment do not pose a hazard or risk to patients, staff, and visitors.
Security— Protection from loss, destruction, tampering, or unauthorized access or use .
b) Hazardous materials—Handling, storage, and use are controlled, and hazardous waste is safely disposed of.
c) Emergencies—Response to disasters and emergencies is planned and effective.
d) Fire safety—Property and occupants are protected from fire and smoke.
e) Medical technology—Technology is selected, maintained, and used in a manner that reduces risks.
f) Utility systems—Electrical, water, and other utility systems are maintained to minimize the risks of operating failures. A backup system is available in case of failure.

Such programs are written and up to date in that they reflect actual conditions within the center's environment. A process exists for their review and updating. When the center has other entities within the facilities to be surveyed (e.g., coffee shop or gift shop), the center has an obligation to ensure that these independent entities comply with the facility management and safety program.
To ensure these plans are properly disseminated to the center's newly hired staff, an orientation program should be established, covering all aspects of the program to ensure patient, staff and visitor safety.

FMS.2. Interdisciplinary rounds are scheduled and conducted to ensure safety.

FMS.2.1. The interdisciplinary team conducts a facility inspection round at least four times per year.
FMS.2.2. The resulting information is documented and used for corrective actions, planning, and budgeting for long-term facility upgrading and replacement.

Explanation

Safety rounds by the safety team and other disciplines should take place regularly in the center. The rounds are designed to discover any inconsistencies and to identify existing safety or security hazards related to settings and environment.
The results of rounds are formally documented. Corrective actions are taken to ensure that safety requirements are met. The center should be able to establish a systematic approach for the necessary safety expenditures (allocated budget).

FMS.3. The center's environment is safe for patients, visitors and staff.

FMS.3.1. The leaders ensure that the building and its services comply with national standards, environmental protection standards, laws and regulations and the recommendations of professional centers.
FMS.3.2. The building and its surroundings are hazard free.
FMS.3.3. Periodic preventive maintenance (PPM) and corrective maintenance are performed and recorded for all electrical and mechanical systems.
FMS.3.4. Maintenance records are kept for all electrical and mechanical systems, including periodic preventive maintenance.
FMS.3.5. The center has adequate parking space, waiting areas and toilets.

Explanation

To ensure occupants' safety and manage the risks within the healthcare environment, all centers, regardless of size and resources, must comply with national standards, environmental protection standards, laws and regulations, and the recommendations of professional agencies. The leadership is responsible for:
The building and its surroundings should be free of hazards such as; potentially loose objects, exposed outlets or wiring, slippery floors, sharp ends and holes in the ground.

- Knowing which national and local laws, regulations, and other requirements apply to the center's facilities;
- Planning and budgeting for the necessary upgrading or replacement as identified by monitoring data or to meet applicable requirements and providing evidence of progress toward implementing the improvements.

The center must develop and implement a plan for periodic preventive and corrective maintenance for the center's setting, including electrical and mechanical systems. Maintenance records are kept for all mechanical and electrical equipment, such as air conditioning, power and equipment to help in decisions regarding replacement or upgrades.
When the center has been cited for not meeting requirements, center leadership takes responsibility for planning for and meeting the requirements in the prescribed time frame.

FMS.4. The leaders develop and monitor the implementation of a fire prevention program.

FMS.4.1.	At least annually, staff are trained on fire drills and evacuation plans.
FMS.4.2.	Records of fire and evacuation training are kept in personal staff files.
FMS.4.3.	Egress routes, corridors, and fire escapes are marked and free from obstacles.
FMS.4.4.	Fire systems, including the fire alarm and fire equipment, are in place and functioning.
FMS.4.5.	Fire extinguishers are tested and distributed in the center according to the type of extinguisher required.
FMS.4.6.	The fire alarm system is maintained and tested and all maintenance records are maintained.
FMS.4.7.	A no smoking policy is approved and enforced.
FMS.4.8.	"No smoking signs" are posted at all entrances and waiting areas.

Explanation

The fire safety of the center and its occupants must be ensured through a number of facility control measures, in addition to staff training on fire drills including the use of acronyms such as RACE/PASS and evacuation techniques. These measures must include the procurement of fire-rated materials such as furniture and curtains (proven through the materials' specifications) and the establishment of fire and smoke compartments, especially for high-risk areas like the laboratory. Fire rating should also include windows, glass, and doors along the compartment.
Also, a staff training schedule on fire extinguisher use should be provided and consider different types of fire extinguishing systems. The fire alarm system is to be maintained and tested, and all maintenance records are to be kept and updated.
The NFPA rates cigarette smoking as one of the three main causes of fire in healthcare facilities. Cigarette smoking also poses a health risk for others in the form of passive smoking. "No smoking" signs are posted and a no smoking policy is enforced.

FMS.5. The center is secured and protects its users.

FMS.5.1.	Trained security personnel are available in the center according to its size and design complexity.
FMS.5.2.	The center's equipment and data are secured.
FMS.5.3.	The patient's privacy is respected.
FMS.5.4.	Security personnel or security systems restrict access to sensitive and high risk areas.
FMS.5.5.	Patient and staff files are accessible only to authorized persons.
FMS.5.6.	All staff wear properly displayed identification badges.

Explanation

The center's security program must ensure that everyone in the center is protected from harm, loss, or damage to property. Staff, vendors and others that the center identifies, such as contractors, wear badges (temporary or permanent) or other forms of identification.
Restricted areas such as operating rooms, labs, and intensive care units , medical records and IT server rooms must be secure and monitored by security personnel and/or security access control systems.
Children, elderly people and other vulnerable patients unable to protect themselves or signal for help must be protected from harm. In addition, remote or isolated areas of the facility and grounds may require the use of security cameras or the presence of security staff.
Security program policies and procedures must be disseminated to center staff to clarify their roles and responsibilities in different situations.
To ensure security coverage of facilities, a security risk-assessment must be conducted to determine the number of security personnel necessary to cover the center's main gates, entrances, and security-sensitive areas, and to conduct security actives such as security rounds. Patients, employees, and others must be able to sense the security presence in the center. This presence must be available throughout the center's operational time.
Security personnel must be oriented to and familiar with their job descriptions, roles, and responsibilities during various security scenarios and emergency cases.
Female security personnel must be available as required, and security personnel must be able to communicate properly with the center's employees and patients, without language barriers.

FMS.6. The leaders develop a plan for the inspection, testing and maintenance of medical equipment.

FMS.6.1.	An updated inventory list is available of all medical equipment.
FMS.6.2.	Medical equipment with special installation requirements, HVAC, or room modifications is installed following the manufacturer's recommendations and safety requirements.
FMS.6.3.	The periodic preventive maintenance (PPM) program is implemented for all medical equipment, according to the supplied and available manufacturer's service manual, and records are maintained.
FMS.6.4.	The medical equipment is tagged with a PPM label.
FMS.6.5.	All defective medical equipment is labeled accordingly.
FMS.6.6.	Medical equipment is discontinued according to a clear policy including lifespan, beyond economic repair, and vendor or governmental recalls. Equipment is disposed of as per governmental rules and regulations.

Explanation

The medical equipment management program must be supported by policies and procedures that mitigate the risks associated with the introduction of new medical equipment, the tagging of medical equipment, the removal of equipment from service, agent/sub-contractors' repairs, and the use of extension cords and cellular phones.
To ensure that medical equipment is safe to use through proper installation, regular inspection, maintenance, and testing, a medical equipment management program must be implemented. Such a program must include:

1. An inventory of medical equipment that covers, at a minimum, the equipment name, its manufacturer, its model, its serial number, its location, its organization number, and its maintenance history.
2. Installation requirements including modification of HVAC requirements and safety precautions (for some types of laser equipment in ophthalmology and dermatology clinics).
3. The availability of a system for medical equipment alerts and recall monitoring through SFDA and manufacturer notifications and reporting medical equipment failures in a serious injury or illness to SFDA.
4. The availability of a necessary service and operation manual, whether a hardcopy or softcopy, for reference when needed.
5. The availability of calibrated necessary test and calibration equipment.

Because medical equipment failures are expected, the center must develop a risk-assessment-based backup plan for failed medical equipment through the provision of standby medical equipment or by shifting to an equal medical intervention alternative.

FMS.7. The leaders develop an emergency plan, and staff are trained on it.

FMS.7.1. The center's emergency plan details how to respond to different emergencies and how to minimize risks in the center.
FMS.7.2. The emergency plan defines the staff roles.
FMS.7.3. Staff are trained on the emergency drills annually. Staff are certified in completing the emergency drills.
FMS.7.4. The emergency plan includes contact persons and authorities.
FMS.7.5. The emergency plan identifies the nearest healthcare facilities and staff know where to refer patients during emergencies if needed.
FMS.7.6. The center has alternative power and water sources as part of its emergency preparedness.
FMS.7.7. The emergency plan is documented, evaluated annually, and updated as needed.

Explanation

To ensure the life safety of all occupants within the center and provide the utmost protection for the facility and its equipment, staff must participate positively in protecting the environment and responding to emergencies.
The center has a documented, evaluated, and updated (as needed) emergency plan.
The center must assess the types of emergencies it is more likely to encounter and determine the types of action needed to ensure that patients and staff remain safe.
A clear plan must outline leader and staff duties and responsibilities in such emergencies. Staff are well trained in emergency drills and know where to refer patients during emergencies if needed. Ongoing training is required to help ensure that staff are aware of those duties and responsibilities. To test staff readiness, all department staff must participate in a mix of announced and unannounced drills, which must be documented.
Contingency plans are available for water and power sources during an emergency to ensure the availability of alternate sources if needed.

\FMS.8. The leaders develop a hazardous materials (HAZMAT) and waste disposal plan.

FMS.8.1. The leaders keep an updated register of all hazardous materials in the center, along with their "Safety Data Sheets".
FMS.8.2. Staff are trained in dealing with available hazardous materials and waste disposal.
FMS.8.3. Hazardous materials and waste are controlled. The center exerts a continuous effort to reduce hazardous materials.
FMS.8.4. Hazardous materials are stored, handled, transported, used, and disposed of as per the "Safety Data Sheets".
FMS.8.5. Waste disposal is done in an effective manner within the facility or through an authorized contractor.
FMS.8.6. Fire-rated cabinets are used for flammable hazardous materials.

Explanation

The center must protect its occupants from the effects of hazardous materials and waste. Centers produce a considerable amount of potentially infectious waste every day. Thus, the proper handling, segregation of and disposal of waste contribute to the reduction of infection risk in the center.

A hazardous materials plan is in place that includes identifying and safely controlling hazardous materials and waste throughout the facility. A hazardous material is any solid, liquid, or gas that can harm people, other living organisms, property or the environment.

Hazardous materials may be radioactive, flammable, explosive, toxic, corrosive, oxidizers, asphyxiants, pathogens, or allergens, or may have other characteristics that render them hazardous in specific circumstances.

The hazardous materials program includes processes for:

- Inventory of hazardous materials.
- Handling, storage, and use of hazardous materials.
- Proper protective equipment and procedures to use and follow during use, spill, or exposure.
- Proper labeling of hazardous materials and waste.
- Reporting and investigation of spills, exposures and other incidents.
- Documentation, including any permits, licenses or other regulatory requirements.
- Education and training on the signs and symptoms of exposure to hazardous materials and the appropriate treatment according to Safety Data Sheets (SDSs).

Information regarding procedures for handling or working with hazardous materials in a safe manner must be immediately available at all times, and include the physical data of the material (such as its boiling point, flash point, etc.), its toxicity, its health effects, identification of proper storage and disposal after its use, the type of protective equipment required during its use, and spill-handling procedures, including the required first aid for any type of exposure.
Waste (medical and non-medical) must be disposed of according to local rules and regulations.

FMS.9. The leaders develop a policy and procedure for the safe use of various types of compressed gasses.

FMS.9.1. The document highlights the use of cylinder transporters.
FMS.9.2. The document emphasizes the cylinder storage in well-ventilated areas.
FMS.9.3. The document describes how to secure the cylinders by positioning upright against the wall and securing it by a chain or inside special containers.
FMS.9.4. The document ensures the timely replacement of empty cylinders and the availability of a backup system.
FMS.9.5. Centers equipped with piped gas systems follow the regulatory body's testing and safety requirements.

Explanation

Compressed gas systems are a standard feature of most healthcare facilities, and they require special monitoring and maintenance to ensure their proper operation. Unlike other medical equipment and systems, the use of gas under pressure can lead to a unique set of potential failures that may not be readily apparent. This makes medical gas preventative maintenance critical to a problem-free working environment.
Medical gas source equipment will vary depending on the type of gas and the size of the institution. For smaller needs, cylinder-only solutions are often adequate. Compressors are also used to provide medical air, and vacuum pumps are needed for suction. Failing to properly monitor these complex pressurized systems can be costly, in terms of both increased use of consumables and damage to permanent equipment.
Due to the nature of gas cylinders, special storage and handling precautions are necessary. The hazards associated with compressed gases include oxygen displacement, explosion, toxicity, and the physical hazards of a ruptured cylinder. HCFs must develop and implement a policy for handling, storing, transporting, and disposing of various types of compressed gasses. Centers equipped with piped gas systems should follow the regulatory body's testing and safety requirements.

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Chapter X
Day Procedure Unit (DPU)

Introduction

Ambulatory care centers may have a day procedure unit where all day procedures are performed under local anesthesia, sedation analgesia, or general anesthesia. This chapter focuses on the standards required to safely manage patients in the day procedure unit, utilizing evidence-based criteria.

This chapter addresses the following:

- Staffing
- Required policies and procedures
- Patients' acceptance criteria
- Space and equipment requirements
- Patients' assessment requirements
- The prevention of wrong patient, wrong procedure, and wrong site
- Monitoring of the patient during and after the procedure
- Discharge from recovery

Standards

DPU.1. All day surgeries and procedures are performed in the day procedure unit.

DPU.1.1. A qualified physician or anesthesiologist directs the unit.

DPU.1.2. A Saudi board-certified or equivalent anesthesiologist performs anesthesia and/or sedation as required and is in charge of monitoring the patient until the patient is discharged home.

DPU.1.3. The unit has a patient receiving area, procedure room(s), and a recovery area with an ICU setup.

DPU.1.4. The unit has its own staff changing area.

DPU.1.5. The unit design follows infection control standards for the segregation of clean and potentially infectious areas and air-conditioning requirements.

DPU.1.6. Dental procedures requiring sedation are performed under the same conditions developed for the day procedure unit, and patients recover in either a dedicated recovery room or the same dental room where the procedure was performed.

DPU.1.7. The center maintains a registry of all the day cases performed.

Explanation

For patients' safety, all procedures done in the center as day cases should be performed in a special day procedure unit. The unit design should enable a patient and instrument flow that prevents the spread of infection to patients and should have special positive pressure ventilation to prevent the influx of potentially contaminated air. Bed space for pre-procedure and post-recovery areas should follow minimum requirements. The procedure room measurement and design should follow MOH requirements. A qualified physician should oversee the unit. The administration of sedation or anesthesia should be done by a board-certified anesthesiologist, who shall also be responsible for monitoring patients during the procedure and in the recovery area. One or two ICU beds should be available in the unit in case a patient requires a longer recovery time or must be observed overnight. All cases performed in the unit should be registered in a log book for statistical purposes and for possible tracking of cases. Dental cases requiring sedation should follow the same rules.

DPU.2. Leaders develop and implement a policy and procedure to guide the care of patients in the day procedure unit.

DPU.2.1.	The policy highlights the types of operations and procedures that may be performed in the unit.
DPU.2.2.	The policy describes how patients are received in the operating room.
DPU.2.3.	The policy clearly explains the timeout procedure.
DPU.2.4.	The policy includes the daily checking of anesthesia equipment.
DPU.2.5.	The policy describes the required pre-sedation/anesthesia assessment and pre-induction assessment.
DPU.2.6.	The policy describes the intra-procedural/operative monitoring of patients with or without anesthesia or sedation.
DPU 2.7.	The policy describes how patients are received and discharged from the recovery room.
DPU.2.8.	The policy highlights the special considerations for surgeries involving implantable devices or lenses.
DPU.2.9.	The policy includes the identification and storage of gametes in assisted reproduction units.

Explanation

To streamline activities in the day procedure unit and prevent morbidities, the unit must have implemented policies and procedures for the activities mentioned in DPU.2.1 through DPU.2.9..

DPU.3. The patient is accepted into the unit by the nursing staff after a rigorous verification procedure.

DPU.3.1.	The patient is properly identified.
DPU.3.2.	Informed consent is available.
DPU.3.3.	The attending physician documents patient assessment and the operational plan.
DPU.3.4	Surgical/procedural site marking is done, if required.
DPU.3.5.	Relevant laboratory and radiology results are available.
DPU.3.6.	The pre-sedation/anesthesia assessment is documented.

Explanation

To ensure the patient readiness for the procedure, staff should ensure the availability of the elements in DPU.3.1 to DPU.3.6 before accepting the patient in the procedure room.

DPU.4. The procedure/surgery room is a functional operating room.

DPU.4.1.	The room has an anesthetic machine.
DPU.4.2.	A scavenging system is connected to the room.
DPU.4.3.	An ECG machine is available within the vicinity.
DPU.4.4.	A cardiac defibrillator is available and regularly checked.
DPU.4.5.	A ventilator is available and regularly checked.
DPU.4.6.	Medical gases and suction are available with a backup system.

Explanation

The equipment mentioned in DPU.4.1 to DPU.4.6 constitute the minimum requirement in the procedure room to safely operate on patients.

DPU.5. The day procedure unit is fully equipped for managing difficult intubations.

DPU.5.1. Laryngeal mask.
DPU.5.2. Gum elastic bogie.
DPU.5.3. Lighted stylet.
DPU.5.4. Cricothyroidotomy kit.
DPU.5.5. Fiber optic intubations scope.

Explanation

The equipment mentioned in DPU.5.1 to DPU.5.5 has proven to be lifesaving in cases of difficult intubation and should be present in the day procedure unit.

DPU.6. Patients booked for a surgery/procedure shall have a pre-sedation/anesthesia assessment performed by the anesthesiologist prior to the surgery.

DPU.6.1. The pre-sedation/anesthesia assessment is performed no more than thirty (30) days before the surgery date. If the pre-anesthesia assessment is performed within thirty (30) days, the pre-anesthesia assessment is updated with documentation in the medical record.
DPU.6.2. The pre-sedation/anesthesia assessment highlights anesthetic risk score and the patient's suitability for the type selected.
DPU.6.3. The assessment results in a sedation/anesthetic plan that is agreeable to both the physician performing the procedure and the patient/family.
DPU.6.4. The anesthesiologist reassesses the patient immediately before sedation/anesthesia induction to assess the patient's immediate suitability for the procedure.

Explanation

To decide on the most suitable type of sedation or anesthesia, patients must have a full pre-anesthesia/sedation assessment performed before any procedure in the day procedure unit. A sedation or anesthesia written plan is crucial for the patient's safety. The pre-sedation/anesthesia assessment is valid for up to thirty days before the procedure. The assessment should highlight the anesthesia risk score, such as the "ASA." The immediate pre-induction anesthesia assessment focuses on the patient's immediate readiness for the procedure and excludes findings that may require changing the anesthetic technique or postponing the procedure.

DPU.7. The center ensures the correct implementation of the policy on preventing wrong patient, wrong site and wrong procedure.

DPU.7.1. The procedure site is marked before surgery if required, as in multiple organs, laterality, or different levels.
DPU.7.2. A preoperative verification process is used and documented in the day procedure unit before the patient is placed in the procedure room to ensure the availability of the appropriate assessments, plans, consents, diagnostics, equipment, instruments and implants.
DPU.7.3. The team which comprises of the surgeon, anesthesiologist and circulating nurse performs and documents a time-out process immediately before the procedure.

Explanation

Unfortunately, wrong patient, wrong site, and wrong procedure are still reported worldwide. The evidence-based approach to prevent it is mentioned in DPU.7.1 to DPU. 7.3 and must be followed and documented.

DPU.8. The patient's condition is continuously monitored during sedation or anesthesia, including local anesthesia and the information is documented in the patient medical record before the patient leaves the operating room.

DPU.8.1. The patient's vital signs, oxygen saturation, and ECG findings are recorded by the anesthesiologist.
DPU.8.2. The anesthetic technique is recorded by the anesthesiologist.
DPU.8.3. The anesthetic or sedation agent, IV medications and other medications, including dosage and the timing of administration are recorded by the team.
DPU.8.4. Any unusual events are recorded.
DPU.8.5. Any investigations carried out are recorded.
DPU.8.6. The status of the patient at the end of the procedure is recorded.

Explanation

Patients may bleed unnoticed during surgery, develop lowered or raised blood pressure, or experience cardio-respiratory compromise. Therefore, the patient's general status should be continuously monitored, even if the procedure is performed under local anesthesia. Monitored findings should be recorded regularly on a specific monitoring sheet. The sheet should also include the time that anesthesia began, the anesthetic agent used and its amount, the starting time of the surgery or procedure, the fluid used, any investigations done during the procedure, any unusual events, and the patient's general status at the end of the procedure.

DPU.9. The unit has a recovery room.

DPU.9.1. A qualified anesthesiologist covers the recovery room.
DPU.9.2. The recovery room is equipped with continuous vital signs monitoring, ECG, and pulse oximetry.
DPU.9.3. The recovery room is equipped with oxygen and suction.
DPU.9.4. The recovery room is equipped with a crash cart and defibrillator.
DPU.9.5. The recovery room is equipped with facilities for mobile ventilation in the event that transportation to a hospital is required.

Explanation

Following surgery or procedure, patients must be monitored for some time until their general condition returns to the pre-anesthesia/sedation status and to ensure the absence of immediate complications. Therefore, patients should be observed in a special unit equipped with the elements mentioned in DPU 9.1 through DPU. 9.5. In the absence of a specified recovery room, patients shall recover in the procedure room until they are fit enough and able to be escorted home.

DPU.10. Each patient's post-sedation/anesthesia physiological status is continuously monitored and documented in the patient's medical record.

DPU.10.1. The date and time of admission to the day procedure and discharge to recovery are recorded.
DPU.10.2. The patient's vital signs, oxygen saturation, and level of consciousness are recorded.
DPU 10.3. The pain score is recorded.
DPU.10.4. Fluid output including urine and drains is recorded.
DPU.10.5. Tolerance to oral fluid is recorded.

Explanation

To follow the patient's recovery status and anticipate possible delays in recovery or potential procedure complications, the parameters in DPU.10.2 through DPU 10.5 should be recorded at regular intervals and documented in the patient's records. The date and time of the patient's receipt and discharge from recovery should be documented to assist in the overall evaluation of the patient's recovery period.

DPU.11. An operative report is documented immediately after the surgery/procedure, before the patient leaves the recovery room and is signed by the surgeon.

DPU.11.1. The report highlights the pre- and post-operative diagnosis.
DPU.11.2. The operative report documents the name of the surgeon, anesthesiologist, and assistants.
DPU.11.3. The operative report clearly documents the operation or procedure performed.
DPU.11.4. The operative report includes a description of the surgery or procedure, findings, and complications, if any.
DPU.11.5. The amount of blood loss is documented.
DPU.11.6. The operative report flags any drains or packs left, the type of wound closure, and the type of dressing used, with instructions on how and when to remove.
DPU.11.7. The operative report includes specimens removed and the need for histopathological examination.

Explanation

A complete operative or procedure report is essential for the immediate post-procedure care and for continuing the care of the patient as an outpatient. The elements mentioned in DPU.11.1 to DPU.11.7 are the minimum required to be written down before the patient leaves the recovery room.

DPU.12. The patient is discharged home by an attending physician after the procedure.

DPU.12.1. The physician examines the patient to ensure the patient's suitability and stability for home discharge.
DPU.12.2. Post-procedure instructions are written in the patient medical record and the patient/family are given a copy and educated on it.
DPU.12.3. The patient is informed about how to obtain help. An emergency contact number is available outside normal working hours.

Explanation

It is of utmost importance to ensure the safety of the patient who is going home straight from recovery. Day procedure unit patients shall be looked after at home by their relatives and must be fully recovered from sedation and anesthesia, with no potential for complications. Such patients are not allowed to drive home and should be escorted. The discharging physician should give clear instructions on diet, the activity of daily living, medications and wound care (if required). The patient should also receive clear and written instructions on how to seek medical help in case of emergency.

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ISQua (www.isqua.org)

Chapter XI
Dermatology & Aesthetics Medicine (DA)

Introduction

Although dermatology and aesthetics medicine are recognized scopes of medical services that can be covered by the other chapters in this standards' manual, yet their wide spread practices in the ambulatory arena and their specific risky procedures warrants a separate chapter. The chapter, therefore, focuses on specific human resources and structural requirements as well as clinical risk management requirements.

Standards

DA.1. Dermatology and aesthetics services are managed by an experienced physician.

DA.1.1. The managing physician is appointed by the center's director.
DA.1.2. The managing physician is a board-certified dermatologist or plastic surgeon.
DA.1.3. The managing physician has a job description that matches his / her supervisory role and accountability for the provision of safe and effective services.

Explanation

A reliable and safe dermatology and aesthetics services requires well experienced and knowledgeable leaders with a background of the specialty. The center leaders must design a job description that explicitly defines the roles, responsibilities and accountabilities of the service manager in the provision of safe, effective and customer focused services. The job description highlights the supervisory role of the manager. The job description highlights the involvement of the manager in ensuring the safety of patients and staff.

DA.2. Physicians' privileges outline the exact procedures to be done by each physician.

DA.2.1. Privileges approved by the managing physician based on the physicians' competency and experience.
DA.2.2. New procedures are performed by a physician only after updating his / her privilege.
DA.2.3. The managing physician ensures that copies of privileges are available at the procedural areas.
DA.2.4. The managing physician empowers the nurses to stop and report physicians performing outside the scope of their privileges.
DA.2.5. The managing physician ensures that only registered trained nurses perform aesthetics procedures "under physician's supervision".

Explanation

As outlined in the leadership chapter, the privileging of physicians is the most proactive risk reduction event in clinical practice. The center exerts all efforts to delineate the privileges of the dermatology and aesthetics physicians based on their credentials and competency. The center ensures that the physicians are performing enough number of procedures to maintain their skills. Neither the physician nor the center can introduce a new procedure without ensuring the competency of the physician performing the procedure and without updating his / her privileges.

All privileges must be available at the site, or where procedures are performed in order for nurses to ensure that the physician is privileged to do the procedure before preparing the patient for it. Nursing empowerment avoids unnecessary interactions between physicians and nurses and ensures patients' safety. All dermatology and aesthetic procedures are to be done by the physicians due to the delicate nature of the procedures and the its narrow safety margin, however some procedures could be done by trained nurses under the direct supervision of the physician.

DA.3. The unit performs periodic education and competency testing for clinical staff assisting in procedures.

DA.3.1. Education and competency assessment takes place at the initial appointment and for every newly introduced equipment.
DA.3.2. The education includes how to manage related procedure complications.
DA.3.3. The education and competency assessment is repeated yearly, and whenever a change takes place in a procedure.

Explanation

The center ensures that staff assisting in the procedures are competent in doing so. The competency assessment takes place at the initial appointment of the staff and whenever a new equipment or procedure is introduced. The assessment includes observing the patient for possible complications and how to deal with it. The competency assessment is repeated at least yearly and whenever the procedure is done differently. Evidence of education and competency is kept in staff's personnel file.

DA.4. The managing physician ensures the compliance of procedural rooms with all required safety rules.

DA.4.1. Safety signs are posted outside the room.
DA.4.2. Laser procedural rooms do not have reflecting surfaces and do not store flammable material.
DA.4.3. Personal eye protective goggles are worn by patient and team performing laser procedure.
DA.4.4. Laser generated airborne contaminants are controlled by local exhaust ventilation.
DA.4.5. The center's director and the managing physician perform weekly documented safety visits to all procedural rooms.

Explanation

The unit manager takes the ultimate responsibility of ensuring the safety of patients, visitors and staff during the use of laser therapy and other invasive equipment inside the dermatology and aesthetic unit. Procedures described in DA.4.1. to DA.4.4. must be strictly followed. The unit manager performs weekly safety rounds on areas where laser and other invasive procedures are performed and documents findings for both immediate correction and follow up of other requirements.

DA.5. **The unit maintains a dated and timed list of the procedures performed.**

DA.5.1. The list highlights the medical equipment used and the name of the physician who performed the procedure.
DA.5.2. The list highlights the outcomes and any complications of the procedures.
DA.5.3. The list highlights the specimens sent for pathological examination.

Explanation

Collecting data on procedures helps to recognize common system mistakes for the sake of its correction. Biopsy and other pathology specimens must be also recorded in this register to strengthen the process of histopathology processing and facilitate the follow up of the results.

DA.6. **Implemented evidence based clinical practice guidelines are developed by the unit physicians and approved by the service manager for all procedures performed in the unit.**

DA.6.1. The guidelines highlight the indications and contraindications of the procedures.
DA.6.2. The guidelines outline the pre-procedural assessment and investigations required and consent requirements.
DA.6.3. The guidelines highlight the safety precautions to be followed.
DA.6.4. The guidelines outline the post-procedural recovery and follow up and any pathology specimen processing required.

Explanation

All procedures performed in the unit must be evidence based. Practice guidelines facilitate the performance of procedures by highlighting the indications, contra-indications, pre-procedural requirements, how to manage pain, safety precautions during the procedure, recovery from procedure and further follow up requirements.

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GLOSSARY AND ACRONYMS

Glossary

Access

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

Accountability

The ability of a system to track an individual's actions, or the acknowledgment and assumption of responsibility for actions, 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.

Accident

An event or circumstance that could have resulted, or that did result, in unnecessary harm as a result of an unplanned deviation in system operation.

Action Plan

A list of actions that must be undertaken to implement a strategy. An action plan states what is to be done, who is to do it and when it is to be completed.

Activity

The description of how the task is carried out in practice.

Admission

A patient who has been physically placed in a bed. There are three types. **Emergent**: When there is an immediate threat to life or the function of a limb is endangered. **Urgent**: A prolonged delay might be injurious to the patient's health. **Elective**: When a patient's health will not be endangered by a delay in admission.

Adverse Drug Reaction

A response to a medicinal product that is noxious and unintended and that occurs at doses normally used in a human for the prophylaxis, diagnosis, or therapy of disease or for the restoration, correction, or modification of a physiological function.

Ambulatory Care

Medical care provided on an outpatient basis, including diagnosis, observation, treatment, and rehabilitation services. Describes medical care or treatment that does not require an overnight stay

Ambulatory Patients

Patients who are being treated in ambulatory care settings rather than as hospital inpatients. They come and go in the care setting and do not spend the night.

Appraisal

Determines the suitability of continuing medical staff membership or privileges.

Appropriateness

The 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. The degree to which the provided care services are relevant to an individual's clinical needs, given the current state of knowledge. Doing the right things in accordance with the purpose.

Attitude

A settled way of thinking or feeling about something reflected in a person's behavior.

Auditing

An ongoing process of reviewing an organization, its processes, its projects, its products, its services, or the subsystem's performance and compliance with standards or expectations.

Authority

The power and right of a person to use and allocate resources efficiently, to make decisions, and to give orders to achieve the organizational objectives.

Availability

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

Backup

The saving of files on magnetic tape or other offline mass storage media for the purpose of preventing the loss of data in the event of equipment failure or destruction.

Benchmarking

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

Best Practice

A procedure that research and experience has been shown to produce optimal results and that is established or proposed as a standard suitable for widespread adoption.

Budget

A plan that represents an estimate of future cost against the expected revenue or allocated funds to spend.

Capability

Power that gives a person, an organization or equipment the ability to do something difficult – fulfill the customer requirement.

Capacity

Availability of resources to complete work.

Cause

An event or action that makes something else happen.

Clinical Pathway

A multidisciplinary tool that describes routine interventions for a group of patients with similar needs. It focuses on the patient and includes the expected outcomes at each step.

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 constitute the expectations of employee performance within a healthcare setting or as defined by the leadership group. How an organization ensures that all its decisions and actions conform to morals.

Competency

Possession of the required skills, attitudes, and knowledge to perform the job.

Committee

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

Complaint

A verbal/written statement by a patient/family/visitor explaining a problem and/or requesting a solution.

Compliance

Conformity in fulfilling requirements.

Confidentiality

Access to data and information only among individuals who have a need, a reason, and permission for such access. An individual's right to personal and informational privacy, including his/her healthcare records.

Consistency/Uniformity

Having control over a process, to repeat itself over time regardless of other factors that may introduce variability into the system.

Continuity of Care

The degree to which patient care 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 an HCF's internal and external customers.

Continuous Quality Improvement Tools

TTools focusing on the process rather than the individual and promoting the need to analyze and improve that process.

Corrective Maintenance

The repair of equipment/machinery to return it to original operating condition.

Credentialing

The process of obtaining, verifying, and assessing a healthcare professional's qualifications to determine whether 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..

Critical Test

A stat test with critical values/results or other results that the laboratorian, radiologist, or other diagnostician has determined to be critical to the patient's subsequent treatment decisions.

Culture

The invisible, intrinsic, and informal consciousness of the organization that guides the behavior of individuals and shapes itself from their behavior.

Customer Focus

Points at the importance of finding out what customers want and need, and then trying to fulfill these needs.

Data

Raw facts and figures from which information can be generated.

Database

An organized, comprehensive collection of stored data.

Day Case Surgery

Surgical procedures that can be performed in a single day, without the need to admit the patient for an overnight stay. Patients are admitted according to selection criteria, operated on and discharged from the center on the same day as the surgery.

Day Procedure Surgery

The patient is admitted for investigation or operation on a planned non-resident basis.

Defect

A product that deviates from specifications or fails to meet the customers' expectations, or a nonconformance or departure from expected quality.

Delegate

The act of empowering to act for another.

Delegation of Authority

The division of authority and powers downwards to the subordinate.

Discharge Instructions

Instructions given to the patient to ensure continuity of patient care at home. They usually cover use of medication, use of equipment, wound care, limitations to diet or mobility, how and when to seek urgent care, and follow-up equipment.

Discipline

Making a habit of properly maintaining correct procedures.

Dosimeter

A 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.

Education

Instruction in how to think. Focuses on integrating abstract concepts into one's knowledge of the world.

Effect

A result. It is what happens because, or as the result, of another event or action.

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 of efficacy.

Equity

Fairness in the distribution of care and its effect on health.

Evaluation

The process of examining a subject and rating it based on its important features.

Elective Surgery

Surgery that is scheduled in advance because it does not involve a medical emergency.

Employee

A person working for another person or a business firm for pay.

Evidence-Based Medicine

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

Error

Any deviation from the intended process; errors can be made by machines or people.

Experience

A particular knowledge, skill, or practice initiated from direct observation of or participation in a particular activity.

Expertise

Skill in or knowledge of a particular event.

External disaster

Any event in which there is a much larger demand for services than the usual load required.

Facility

The physical plant.

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 he or she is authorized to make care decisions for a patient when the patient loses decision-making ability.

Failure Mood Effect Analysis (FMEA)

A systematic method of identifying and preventing process problems before they occur through mitigation risk by determining what is likely to go wrong, the probability of it going wrong and the severity if it does go wrong and then acting against it.

Flow

The uninterrupted movement of patients, information, and materials.

Formulary

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

Function

Refers to the set of activities required to produce a certain outcome.

Functional Status

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

General Anesthesia

A medication-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilator function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or medication-induced depression of neuromuscular function. Cardiovascular function may be impaired.

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 with ultimate authority, responsibility, and accountability for the overall strategic direction, methods of operation (management and planning), establishment of policies, and maintenance of the safety and quality of care that the facility provides.

Guidelines

Principles guiding or directing actions.

Harm

An unexpected or normally avoidable outcome that negatively affects a patient's health and/or quality of life and that occurs or has occurred during the course of receiving healthcare or services.

Hazardous Materials

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

Hazardous Waste

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

Hazards

Situations with the potential to cause harm.

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 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.

HEPA Filter

A type of air filter. "HEPA" is an acronym for "high-efficiency particulate air" filter.

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.

High Risk

High probability that a severe injury will occur.

Hospital

A healthcare institution that has organized medical and other proficient staff and inpatient facilities and delivers services 24 hours per day, seven days per week. It offers a varying range of acute, convalescence and terminal care using diagnostic and curative services.

Immunization

The process by which an individual's immune system becomes fortified against an agent (known as the immunogen).

Incidents

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

Indicator

An observation expected to measure a certain aspect of performance. It is a quantitative measure that can be used to assess and improve the performance of important administration, clinical and supportive functions that affect patient outcomes.

Indicator of Performance

A measurement tool 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

A term used to designate the manual or computer-based conveying of information throughout the department/organization, or 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

A person's voluntary agreement of one who has sufficient mental capacity with full knowledge of the risks involved, probable consequences, and alternatives to make an informed decision. It allows a patient to balance the probable risks against the probable benefits of any potential care.

Input

Work/information fed to the beginning of a process.

Internal Disaster

Any event that may endanger normal operation or when the HCF becomes non-functioning within a given area. It may jeopardize the safety or well-being of patients, staff, and visitors.

Job Description

A written statement that describes the list of rules, duties, responsibilities, and required qualifications of candidates, and the reporting relationship and coworkers of a particular job.

Key Performance Indicators (KPIs)

Measures of performance that are central to success.

Kit

A collection of components used to support the task.

Knowledge

A capacity that enables a person to fulfill certain tasks by selecting, interpreting, assessing, and making decisions. The understanding of facts and procedures.

Leaders

The identified and designated individuals who have the responsibility of overseeing the effective functioning of processes within a defined scope of services and determining a correct path.

Licensure

A legal right granted or evidenced by documentation issued by SCFHS (such as a physician, nurses, psychiatrist, or clinical social worker, or the operation of a health facility) in the form of a license, registration or certification.

Look-Alike Sound-Alike (LASA) Medications

Medications with generic or proprietary names that look or sound like other medications.

Manager

Someone who works with people and systems to produce predictable results and who does the correct things to stay on the path.

Medical Device

Any instrument, apparatus, machine, appliance, implant, reagent for in vitro use, software, material, or other similar or related articles that the manufacturer intends to be used, alone or in combination for human beings for one or more of the specific medical purpose(s): diagnosis, prevention, monitoring, treatment or alleviation of disease, alleviation of or compensation for an injury, investigation, replacement, modification, support of the anatomy or a physiological process and the support or sustaining of life.

Note: Products that may be considered medical devices in some jurisdictions but not in others include: disinfection substances, aids for persons with disabilities, devices incorporating animal and/or human tissues, devices for in-vitro fertilization, or assisted reproduction technologies.

Medical Equipment

Equipment used for the specific purposes of diagnosing and treating disease or for rehabilitation following disease or injury. It can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment (e.g., EKG machines, diagnostic ultrasounds, surgical lights, patient beds, surgical tables, anesthesia machines and defibrillators).

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.

Medication Error

Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is under the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems including prescribing, order communication, product labeling, packaging, nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use.

Medication Management

The overall effort by facilities and manufacturers to reduce medication errors that can occur throughout the various stages of the medication use cycle: selection, procurement, prescription, transcription, dispensing, distribution, administration and monitoring.

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.

Near-Miss

An event or situation that could have resulted in an adverse event that caused patient harm but that did not, either by chance or through timely intervention.

Objectives

Concrete measurable steps taken to achieve goals.

Organization Structure

The style in which resources are assigned to tasks.

Organizational Chart

A diagram representing the structure of the facility 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 used to describe the end result of a service, practice, procedure or intervention.

Patient

A person for whom a healthcare organization accepts responsibility for treatment, care and/or service. An individual who is a direct recipient of care.

Patient Assessment

The gathering of information to evaluate a person's health and healthcare needs.

Patient Complaint Process

The defined process describing the roles/responsibilities and time frames for handling any patient complaint regarding the provision of his/her care.

Patient Safety

Freedom from accidental during the course of medical care; activities to avoid, prevent, or correct adverse outcomes that may result from the delivery of healthcare.

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. Check the results. Act to improve the process and hold gains. Also known as the Shewhart cycle or learning cycle of change.

Personnel File

Collection of information about a staff member, covering personnel issues such as licensure, certifications, leaves, appraisal reviews and job description.

Plan

To formulate or describe the approach to achieving goals related to improving the organization's performance.

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 patient's special needs. The planning is an interdisciplinary process.

Policy

A written document that outlines the law, rule, regulation, or set of guidelines that drives the processes or procedures. Policies are dynamic and reflect current knowledge and practices and must be reviewed on a regular basis.

Predictive Maintenance Management

Performing tasks based on a historical pattern of breakdown, or techniques that help determine the condition of in-service equipment to predict when maintenance should be performed. Completing routine tasks at set intervals to prolong the life of the equipment. The scheduling of planned maintenance actions aimed at preventing breakdowns and failures.

Privileging

The process of reviewing an individual's credentials through a 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.

Probationary Period

The time period that the organization identifies for determining whether the employee is competent to perform his/her duties and continue employment with the organization. Generally, the time period for probation is three months.

Procedure

A written set of instructions that describes the approved and recommended steps for a particular act or sequence of acts, or a specific, detailed series of actions that staff members must take to implement a process and comply with a policy.

Process

A high-level set of interrelated steps (procedure) that must be executed, outlining what must happen to ensure compliance with a policy.

Process Improvement

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

Project

A temporary activity aimed at achieving specific/narrow organization objectives.

Program

Organizational activities aimed at achieving broader organization objectives by coordinating a group of projects.

Protocols

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

Quality

The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) has adopted the following definition of quality: "Quality refers to the extent to which processes, products, and services are free from constraints, waste, variation and defects with stability around optimum target, on a consistent basis even under stressful condition, to achieve customer's trust and loyalty." (S.AlWahabi, CBAHI,2015)

Quality Control
A management process in 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.

Reappraisal/Reevaluation

An appraisal is to be conducted at least every 24 months. The medical staff appraisal procedures must evaluate each individual practitioner's qualifications and demonstrated competencies to perform task/privileges.

Recovery Room

A place to provide immediate close observation to a post-anesthesia patient.

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.

Relevance

The overall pattern and balance of services; the best that could be achieved, taking into account the needs and wants of the population as a whole.

Reliability

An organization's potential to perform the promised service dependably and accurately.

Re-Privileging

The process of granting privileges to a practitioner who currently holds privileges within the facility.

Resource

Something that is needed or consumed while a function is carried out.

Risk

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

Root Cause

The ultimate reason for an event/condition.

Root Cause Analysis

A collective term used to describe a wide range of approaches, tools and techniques used to uncover causes of problems.

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.

Safety Data Sheet (SDS)

A form containing data regarding a particular substance's properties. An important component of workplace safety, it is intended to provide workers and emergency personnel with procedures for handling or working with that substance in a safe manner and includes information such as physical data (melting point, boiling point, flash point, etc.), toxicity, health effects, first aid, reactivity, storage, disposal, protective equipment and spill handling procedures. The exact format of an SDS can vary from source to source.

Scope of Practice

The range of activities that practitioners perform. The scope is determined by training, law or regulations.

Scope of Services

The range of activities provided to 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), the diagnostics provided, the therapeutic interventions provided, and the number of patients who receive each service annually. All the resource and competency requirements flow from the organization's scope of services.

Screening

A system for examining and separating into different groups.

Sedation

Minimal sedation: A medication-induced state during which patients respond normally to verbal commands. **Moderate Sedation:** A medication-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or after light tactile stimulation. **Deep Sedation:** A medication-induced depression of consciousness during which patients respond purposefully following repeated or painful stimulation.

Sentinel Event

An event that, when noted, requires intensive assessment and prompt response. An unexpected occurrence involving death, serious physical or psychological injury, or the risk thereof, and any event that might cause embarrassment or risk to the healthcare organization, with potential legal ramifications and/or media inquiries or coverage. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "Sentinel "because they signal the need for immediate investigation and response.

Serious Adverse Drug Reaction

An adverse drug reaction that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, or results in persistent or significant disability or incapacity.

Skill

The ability to perform specific actions.

Stability

The extent to which a process has a predictable range of output or results over time.

Staff

A group of persons, as employees, charged with carrying out the work of an establishment, or executing some undertaking, e.g., independent practitioners (temporary, visiting, part-time) and volunteer.

Staffing Plan

The database document listing all HCF employees and positions. This also includes all other details pertaining to the HCF's manpower resources.

Stakeholders

Individuals and groups of people who have the ability to influence direction and success, either positively or negatively.

Standard

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 services.

Standard work

Standardized tasks performed in a standardized sequence in a standardized amount of time and with a standardized amount of medicines, supplies and equipment to support them.

Standardization

The system of documenting and updating procedures for ensuring that everyone knows exactly what is expected of them with a predetermined set of expectations.

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.

Strategy

The process that involves goal setting, the specific actions to achieve those goals, and the allocation of the resources to execute the actions.

Structure

Environmental features that shape process and outcomes: resources, money, equipment, supplies, staff, and policies.

Surveys

Methods by which an organization can measure customer satisfaction and obtain feedback on written materials and oral presentations.

System

The infrastructure that enables the processes to achieve targets. A dynamic, purposeful collection of interrelated, interacting, and interdependent groups of components working together to achieve the same goals.

Task

The formal description of any piecework as it is expected to be carried out.

Team

A group of five to eight people consisting of a leader, facilitator, and members who are addressing an issue that affects the operations of a process.

Terms of Reference

A formal, leadership-approved document that outlines the roles/responsibilities of a committee. This document describes the committee's expected performance and how often the committee is expected to meet and 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.

Training

Instructions and practices designed to teach staff how to perform a job's tasks.

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.
Temporary Transfer: This shifting will be for a short period of time, usually for the duration of the care to be provided by the entity receiving the temporary transfer.
Permanent Transfer: The permanent shifting of responsibility to another institution or unit constitutes a discharge situation from either the unit or organization.

Transport

The movement of an individual from one place to another using a transport aid or vehicle, either motorized or manual (wheelchair, trolley, bed).

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. Prioritizing patients according to their problems and symptoms. Determining the order of being managed.

Turn Around Time

The initial time from the starting point to the end point (e.g., for a stat order, the time the doctor's order was written or stated to the time it was carried out).

Utilization

The use, patterns of use, or rates of use of a specified healthcare service.

Values

The beliefs and philosophy of an organization that establish the basis for the operation and provide guidelines for daily behavior.

Variance

Any event or circumstance not consistent with the standard routine operations.

Variation

The difference between an observed event and a standard or norm.

Vision

A description of what the organization would like to be or reach in the future.

Visitor

A transient individual who temporarily appears at the HCF for the purpose of visiting.

Waste

Anything other than the minimum amount of equipment, materials, parts, space, and worker's time which are absolutely essential for adding value to the product/service, or any activity that does not contribute to operation.

Acronyms Frequently Encountered in the CBAHI Accreditations

ARF: Appeal Request Form.
CAP: Corrective Action Plan.
CBAHI: Saudi Central Board for Accreditation of Healthcare Institutions.
HCF: Health Care Facility.
(ISQua): International Society for Quality in Healthcare.
MOH: Ministry of Health**.**
PDA: Preliminary Denial of Accreditation.
RCA: Root Cause Analysis.
SAT: Self-Assessment Tool.
SERF: Sentinel Event Reporting Form.


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المملكة العربية السعودية
KINGDOM OF SAUDI ARABIA

المعايير الوطنية للمراكز والمجمعات الطبية الخارجية

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