CBAHI

Saudi Central Board for Accreditation of Healthcare Institutions

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

VISION 2030 رؤيـــة
المملكة العربية السعودية
KINGDOM OF SAUDI ARABIA

المعايير الوطنية لخدمات

متلازمة الشرايين التاجية الحادة

NATIONAL STANDARDS FOR ACUTE CORONARY SYNDROME SERVICES

FIRST EDITION 2022

NATIONAL STANDARDS FOR ACUTE CORONARY SYNDROME SERVICES

Saudi Central Board for Accreditation of Healthcare Institutions

First Edition
2022

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 (144187) وتاريخ 1-9-1426هـ، واستمر في تأدية المهام المناطة به حتى صدور قرار مجلس الوزراء الموقر رقم (371) وتاريخ 24-11-1434هـ، 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 (58/8) وتاريخ 9-1-1433هـ، 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.

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 Central Board for Accreditation of Healthcare Institutions (CBAHI) was founded in October 2005 by the Ministerial Order Number (144187). Since its formation, CBAHI continued to pursue its mission until 30 September 2013 at which time 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 national accreditation by CBAHI on all healthcare facilities. To encourage more participation in this ambitious national initiative, the Ministry of Health plans to mandate CBAHI accreditation as a future prerequisite for the renewal of operating licenses for all private Organizations.

Table of Contents

Foreword

The healthcare sector in Saudi Arabia is witnessing an ambitious transformation at all levels, particularly in terms of service quality. This transformation is intended to bridge the gap between the current and desired healthcare system. The Kingdom's leadership has been eager to undertake such transformational actions to assure the availability, sufficiency, efficiency, and safety of the healthcare services offered to more than 35 million citizens and residents. The main goal focuses on improving the health of communities whilst increasing the capacity of healthcare services to meet the demands of one of the fastest growing population rates.

The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) plays a vital role in the Saudi health system. It is the independent entity responsible for setting the healthcare provision standards and assessing the compliance of healthcare organizations against these standards. CBAHI has strived to establish evidence-based standards that encompass a wide range of healthcare organizations with various scopes, in order to enhance the quality and safety of healthcare services.

The burden of ischemic heart disease is the primary cause of morbidity and mortality, nationally and internationally. Its burden is increasing due to the high prevalence of cardiovascular risk factors. This manual is designed to serve healthcare facilities providing acute coronary syndrome services across the country, hence ensuring that the acute coronary syndrome services they provide are effective and meet the desired standards which is of prime importance in terms of quality of care and patient satisfaction. We hope that this manual serves as a road map for administrators and health practitioners providing acute coronary syndrome services in building a patient-centric care system.

CBAHI is a reputable entity that is recognized in the region and internationally for promoting the quality of the Saudi healthcare system through its accreditation process. The International Society for Quality in Healthcare (ISQua) accreditation further adds to CBAHI's standing and its credibility in the healthcare community.

On behalf of all staff members working in the Saudi health sector, I extend our appreciation and gratitude for the limitless support coming from our top leadership to ensure the health and lasting prosperity of the people of Saudi Arabia.

Fahad AlJalajel
Minister of Health & Chairman of Saudi Health Council

Standards Development Committee/ Advisory Committees and Experts Panel

Experts, representing all health sectors in Saudi Arabia, including physicians, nurses, pharmacists, laboratory specialists, infection control practitioners, biomedical engineers, administrators, and public policymakers, have actively guided the development of the National Acute Coronary Syndrome Services. In addition, several professional bodies have assisted as well with the development and refinement of the standards. CBAHI would like to thank all health authorities, organizations, and individuals who participated in or provided external commentaries on this important national initiative. The following is a list of participants in alphabetical order.

Dr. Adel A. Tash
Consultant Cardiac Surgeon
Director General of the National Heart Center,
Saudi Health Council – Riyadh

Dr. Ayman S. Alkhadra
Consultant Cardiac Electrophysiologist,
Dr. Suliman Al Habib Medical Group
Senior Advisor to the CEO, Health Sector
Transformation Program – Riyadh

Dr. Hossam M. Ghoneim
Senior Healthcare Quality Consultant
Chief Operating Officer, International
Medical Center – Jeddah

Dr. Hussam F. Alfaleh
Professor of Cardiac Sciences, Consultant
Interventional Cardiologist
King Saud University – Riyadh

Dr. Khalid A. Al Faraidy
Consultant Interventional Cardiologist
Hospital Director
King Fahad Military Medical Complex –
Dhahran

Dr. Waleed A. Alhabeeb
Consultant Cardiologist
President of the Saudi Heart Association
King Saud University – Riyadh

Dr. Waleed M. Alharbi
Consultant Interventional Cardiologist
Director of King Fahad Cardiac Center
King Saud University – Riyadh

Advisory Team

Dr. Abdullah M. Alshehri
Interventional Cardiologist
Imam Abdulrahman Bin Faisal
University- Dammam

Dr. Anas A. Khan
Associate Professor, Consultant Emergency
Medicine
Director General of Global Center for Mass
Gathering Medicine, MOH- Riyadh

Dr. Faisal M. Alsamadi
Electrophysiologist,
Director of King Salman Cardiac Center,
King Fahad Medical City- Riyadh

Dr. Faisal T. Alqoofi
Interventional and Structural Cardiologist,
Johns Hopkins Aramco Healthcare- Dhahran

Dr. Heba M. Almattar
Senior Cardiovascular Nurse
Executive Healthcare Leadership
Dr. Soliman Fakeeh Hospital- Riyadh

Dr. Mohammed A. Hussein
Group Quality Manager
Saudi German Health – Jeddah

Dr. Mohammad I. Kurdi
Interventional Cardiologist
Chief Executive
Procare Hospital-Alkhobar

Dr. Samih R. Lawand
Interventional Cardiologist
Director of Cardiac Center
Dallah Hospital- Riyadh

CBAHI Team

Dr. Abdulmunim F. Alsuhaimi
Assistant Director General for
Research and Development
CBAHI – Riyadh

Ms. Dlal A. Almazrou
Senior Accreditation Specialist
CBAHI – Riyadh

Dr. Hamad M. Alsalhi
Assistant Director General for
Accreditation
CBAHI – Riyadh

Dr. Jamal Abo Shamalah
Accreditation Specialist
CBAHI – Riyadh

Ms. Maha A. Albaalharith
Principal Accreditation Specialist
CBAHI – Riyadh

Mr. Mohammed A. Alkhairi
Supervisor of Standards Development
Committees
CBAHI – Riyadh

Dr. Salem A. Alwahabi
Director General
CBAHI – Riyadh

Dr. Sultan Y. Alhowti
Principal Accreditation Specialist
CBAHI – Riyadh

Preface

 In the healthcare industry, evaluation is an essential part of every executive activity. Globally, appealing approaches have been employed to regulate and evaluate healthcare quality internally and externally. Accreditation has been cited as the most used strategic external quality evaluation tool in healthcare. It is a systematic evaluation based on predefined standards that focus on sustainable quality improvement, patient-centeredness, and patient safety. In Saudi Arabia, since its inception in 2005, the Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) has strived to support healthcare facilities by ensuring continuous compliance with quality and patient safety standards.

Over the last decade or so, the Saudi health system has witnessed significant progress at all levels. One remarkable area was the great expansion in the number and complexity of acute coronary syndrome services. This is in alignment with worldwide advancement in the medical field, with a greater emphasis on continuous performance improvement and measurement. In that, CBAHI is pleased to introduce the first edition of the national standards for acute coronary syndrome services. These evidence-based standards are intended to support healthcare facilities providing acute coronary syndrome services in Saudi Arabia in improving the quality and safety of patient care. Being comprehensive, detailed, and occasionally prescriptive in design and nature, this edition of the standards was built to be relevant and applicable to the licensed healthcare facilities providing acute coronary syndrome services across the country.

During the development of this manual, the development team considered the variety in the quality levels across the continuum of care provided to acute coronary syndrome patients and strived to create a set of standards that would apply to all healthcare facilities providing such services. This manual contains important information on certification eligibility, scheduling of surveys, survey preparation, survey visit, and accreditation/certification decision rules. In the remaining part, certification standards are distributed among relevant chapters.

We sincerely thank the committees, teams, and task forces that contributed to the development, compilation, designing, reviewing, and producing of this manual. We would like also to convey our appreciation to the healthcare professionals who have been obliging and generous with their professional feedback, time, constructive comments, and suggestions.

CBAHI welcomes all stakeholders' perspectives, suggestions, and comments. Only through this constructive collaboration, we can improve the quality and safety of our patients.

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 nonprofit organization, CBAHI is primarily responsible for setting quality and safety standards to ensure a better and safer healthcare system. Its first official inauguration occurred after 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 2013, the Council of Ministers mandated accreditation by CBAHI and gave the board its current name.

The mission of CBAHI is to set standards and assess performance for better healthcare, and the vision is to lead healthcare accreditation in the Middle East. CBAHI is aiming 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 a variety of 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 and 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.

In addition to the acute coronary syndrome services certification program, CBAHI currently provides other accreditation programs to healthcare facilities such as primary healthcare centers, hospitals, ambulatory centers, clinical laboratories and blood banks, dental centers, and home healthcare services.

CBAHI is proud to be one of the few healthcare accreditation agencies in the world to be accredited by the International Society for Quality in Healthcare (ISQua).

Healthcare Accreditation/Certification: Definition and Importance

Healthcare accreditation/certification is an assessment process that involves a rigorous, transparent and comprehensive evaluation by an external, independent accreditation body. The healthcare facility (HCF/Service) 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/service 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/certification represents the healthcare accreditation body's public recognition of the achievement of accreditation standards by an HCF/service. The standards set out a common framework to support HCFs/services to provide effective, timely, and quality services. They are designed to promote the delivery of 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 structures, processes, and outcomes of care that healthcare facilities provide. Accreditation/certification is more than just a certificate to be obtained and hung on the wall. Accreditation/certification, when used correctly, can provide the following advantages:

- Accreditation/certification provides a framework for organizational structure and management. Accreditation/certification standards focus on the governance and leadership structures and many diverse functions within a healthcare facility/service; and the appropriate management of its business and day-to-day activities.
- Accreditation/certification helps improve patient safety and minimizes the risk of medical errors. Ensuring patient safety through risk management and risk reduction is at the center of all accreditation/certification standards and is the ultimate goal of the self-assessment and survey activities.

- Accreditation/certification enhances community confidence in the quality and safety of care provided. When a healthcare facility/service achieves accreditation/certification, the message is clear – its leaders are committed to providing a nationally accepted standard of care in health services delivery.
- Surveyed healthcare facilities/services 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 the services delivered to the community.
- In the long term, accreditation/certification increases efficiency and enhances lean practices, which in turn leads to decreasing waste and achieving optimal results with less consumption of resources.
- Accreditation/certification helps improve a healthcare facility's/service's competitiveness. Increased public trust in an accredited facility will encourage more patients to seek care and treatment there. This will increase its market share and improve its competitiveness in the healthcare sector.
- Achieving accreditation/certification will fulfil the regulations required by the national authorities as CBAHI national accreditation currently is linked to the licensing of healthcare facilities.
- Accreditation/certification has a link to reimbursement from insurers and other third parties. There is a growing tendency, nationally and internationally, to link accreditation/certification with eligibility for insurance reimbursement.
- Accreditation/certification provides a robust tool for continuous quality improvement efforts in healthcare facilities/services and assists facility leadership to ensure the sustainability of quality improvement projects and initiatives.
- Accreditation/certification provides excellent learning and educational opportunities. This is accomplished by educating staff on best practices and emphasizing the importance of patient education and patient rights.

Scope of Certification Survey

The scope of the CBAHI survey includes all standard-related functions of the surveyed ACS service. Each assessment survey is tailored to the type, size, and range of services offered. Any special medical procedures/services performed in the acute coronary syndrome services covered in any other CBAHI set of standards should also be followed. This might include services like pharmacy services and medication use/prescription, and so on.

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

Peer experts in their specific fields develop standards. It is against these standards that the conformity of the ACS service is evaluated. Stated succinctly, a standard describes an ACS service's acceptable performance level. Within this context, there should be no confusion between certification standards and licensure standards. When applied to the licensure of an individual practitioner or facility, the licensure standard is usually set at a minimal level designed to protect public health and safety. Certification standards, on the other hand, are designed as optimal and achievable. When met, standards establish a high-quality level in a system.

CBAHI standards and those of all other relevant accrediting agencies focus on three significant aspects depending on which area they are addressing structure, process, and outcome:

Structure: standards related to structure address the system's inputs, such as workforce, building design, and the availability of equipment and supplies such as personal protective equipment.

Process: standards address the clinical and administrative processes or interventions carried out within the facility/service in terms of patient care, facility management, or staff management. Examples include patient assessment, patient education, and medication administration.

Outcome: standards related to outcome involve assessing an intervention's benefits and whether the activity's expected purpose was achieved. They provide information regarding predicted outcomes that are being realized. Examples include data regarding patient satisfaction, healthcare-associated infections, medication errors, and adverse events.

CBAHI standards set expectations for ACS service's performance that 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 ACS services measure, assess, and improve performance. CBAHI strives to be a nationally recognized symbol of excellence, respected throughout the industry and by other relevant authorities as an assurance that certified ACS services meet rigorous standards of quality and operational integrity that emphasize consumer protection and patient engagement. Therefore, the standards development process at CBAHI follows a long and robust methodology to ensure our standards are correct, evidence-based relevant, and straightforward.

There are a variety of methodologies or approaches that have been used globally for healthcare accreditation/certification standards development such as department-oriented standards, scope of services-oriented standards, or quality system essentials. The National Standards for Acute Coronary Syndrome services contain standards of quality and patient safety that are descriptive in nature. Standards are included in three chapters: Leadership of the service (LD), Provision of Care (PC), and Cardiac Catheterization Laboratory (CCL). These standards and the surveyor programs aim to provide answers to the following four questions:

- Is the ACS service well-led?
- Is the care delivered safe, effective, and patient-centered?
- Is the environment, in which the ACS care is provided, safe and suitable?
- Are the internal and external customers satisfied?

CBAHI used a 'hybrid methodology' to help answer these four questions positively. Some of the standards are departmental-based, whereas others are based on quality metrics to ensure standards implementation, environmental safety, and internal and external customer satisfaction. Specialized task forces, including focus groups and standards development committees, develop the first draft of CBAHI standards. A variety of sources are utilized 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.
- Environmental inspection.
- Evaluation results from previous surveys, if available.

The process of standard development can last several months before an initial draft is produced. The draft standards are then distributed nationally for review and made available for comment on the standards through a field review process. 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 reviewed and approved by the Standards Development Steering Committee and provided to the CBAHI Board for comments and remarks before submission to the Saudi Health Council for approval. Thereafter, the standards are made available to the target facilities/ services and an e-version is made available too 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 the publishing of the standards before they are effective. Through this, ACS services are given adequate time to familiarize themselves with and implement the standards. Also, CBAHI surveyors are taught how to assess compliance with these standards.

No matter how robust the methodologies used in developing the standards, room for improvement will always exist. Therefore, once the standards are in effect, ongoing feedback is sought for continuous improvement purposes. 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.

Certification Survey Visit

CBAHI determines applicable standards from this book based on the scope of services and the on-site survey team's decision regarding the applicability of individual standards. CBAHI surveyors typically employ a variety of techniques and strategies to objectively decide whether the ACS service meets the standards related to key systems and functions such as leadership, patient care processes, medication management, infection prevention and control, and safety of the facility environment. For example, the survey team may review written documents such as strategic and operational plans and budgets as well as clinical policies and procedures. In addition to reviewing documents, surveyors will interview ACS service leaders, physicians, nurses, employees, and patients to determine the ACS service'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 any 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 ACS service provides.

The ACS service leaders may be interviewed regarding ACS service processes and how they are designed to meet standards related to planning, budgeting, quality improvement 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. Diagnostic and support services such as the laboratory, radiology, pharmacy, and central sterile services are also assessed for safety, effectiveness, and quality control.

In summary, during an on-site survey, surveyors use a variety of evaluation approaches to determine the ACS service's compliance or performance regarding applicable structure, process, and outcome standards. These methods might include any combination of the following:
- Interviews with the ACS service leadership, clinical and support staff, patients, and families.
- 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 staff personnel files.
- Review of patient medical records.
- Evaluation of the ACS service achievement of specific outcome measures (e.g., acquired infection rates, patient satisfaction) through review and discussion of monitoring and improvement activities.

Structure of the National Standards for Acute Coronary Syndrome Service

The National Standards for Acute Coronary Syndrome Service (ACS) is assembled into three chapters consisting of critical services and functions of ACS services provided in Saudi Arabia. The standards within these chapters are arranged according to the workflow within the services. The chapters are:
- Leadership of the Service (LD)
- Provision of Care (PC)
- Cardiac Catheterization Laboratory (CCL)

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 standard that consists of a concise statement, followed by a number of sub-standards to further illustrate the standard's requirements. Each sub-standard is constructed to independently serve 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 ACS services understand the intent behind it.

This manual contains 44 standards distributed throughout three chapters. The standards are:

Number	Standard
	List of Standards
LD.1.	The ACS service is effectively managed by a qualified director.
LD.2.	There is an adequate number of qualified and competent staff to run the ACS service.
LD.3.	There is a process in place for credentialing and re-credentialing all healthcare providers in ACS service.
LD.4.	Medical staff providing ACS services have current delineated clinical privileges.
LD.5.	The ACS service supports continuing education and training for all categories of staff.
LD.6.	The ACS service steering committee ensures the provision of reliable, timely, and safe service.
LD.7.	The ACS service enhances community participation and education to improve public awareness.
LD.8.	The ACS service seeks feedback from patients and service users regarding the services provided.
LD.9.	The ACS service develops and monitors the implementation of the quality improvement and patient safety plan.
LD.10.	The ACS service develops and implements a risk management plan that is aligned with the hospital-wide risk management program.
LD.11.	The ACS service maintains an effective information management system to serve its users and stakeholders.
LD.12.	The ACS service provides secure telehealth ACS services to ensure integrated ACS care, whenever the need arises.
LD.13.	The ACS service participates in research activities.
LD.14.	There is a process to manage the supply chain, related to the ACS service, cost-effectively.
LD.15.	The ACS leaders implement policies and procedures to guide efficient procurement of equipment, either purchased or donated, medications, and medical consumables following national laws and regulations.
LD.16.	The ACS service maintains a safe environment for patients, visitors, and staff, through an effective facility management and safety program.
PC.1.	The ACS services are accessible in an equitable manner to all patients whose medical needs can be met within the ACS service.
PC.2.	The hospital's layout, structure, and function facilitate the delivery of reliable, timely, streamlined, and safe care to patients.
PC.3.	The hospital's emergency room is efficiently designed, and appropriately equipped, and has qualified and competent staff to manage ACS patients.
PC.4.	The ACS service uses clinical pathways and protocols to guide the process of providing effective emergency care.
PC.5.	A multidisciplinary team is involved in the management of ACS patients and develops a policy and procedure for the assessment/reassessment of patients.
PC.6.	The ACS team develops a comprehensive multidisciplinary plan of care, based on assessment findings, and directed by clinical practice guidelines.

List of Standards	
Number	**Standard**
PC.7.	The general cardiology ward's design, structure, and function facilitate the delivery of reliable, timely, and safe care to ACS patients.
PC.8.	The intensive care unit's design, structure, and function facilitate the delivery of reliable, timely, and safe care to ACS patients.
PC.9.	The radiology and laboratory services are fully equipped and have adequate resources to meet the ACS patients' needs.
PC.10.	The ACS service is active in preventing disease recurrences and supports patients to pursue an independent healthy lifestyle.
PC.11.	A skilled multidisciplinary team guides the provision of comprehensive cardiac rehabilitation services.
PC.12.	The ACS service conducts mortality and morbidity meetings, regularly.
PC.13.	The ACS service ensures the timely management of ACS patients when their medical needs exceed the available services.
PC.14.	There is a referral pathway to guide the patient referral process based on the patient's health needs.
PC.15.	The ACS service discharges patients through an efficient, safe, and timely process.
CCL.1.	Qualified staff effectively manage the activities of a CCL procedure suite.
CCL.2.	The CCL's design, structure, and function facilitate the delivery of reliable, timely, and safe care, to meet patients' needs.
CCL.3.	The interventional procedures team develops a policy to guide appropriate pre-procedure preparation.
CCL.4.	The interventional procedures team develops and implements a cardiovascular assessment policy prior to the CCL procedure.
CCL.5.	Pre-sedation/ pre-anesthesia assessment and anesthesia planning are conducted by an anesthesiologist, prior to the procedure.
CCL.6.	The interventional procedures team develops a policy to guide the care of patients in procedural areas.
CCL.7.	The ACS service performs effective percutaneous coronary interventional (PCI) therapeutic procedures based on the prioritization of needs and identified patient risks.
CCL.8.	The CCL team develops evidence-based policies and procedures for the monitoring of patients during a procedure.
CCL.9.	The CCL team ensures that patients and staff are safe from radiation hazards during interventional radiological procedures, in alignment with the hospital radiation safety program.
CCL.10.	The CCL team establishes post-cardiac catheterization procedure assessment and documentation.
CCL.11.	Post-sedation/ post-anesthesia patients are recovered and discharged to an appropriate setting according to an evidence-based policy and procedure.
CCL.12.	The patient's post-procedure care is planned and documented.
CCL.13.	The CCL standardizes the reporting of preprocedural, procedural, and post-procedural data.

PART I I

CERTIFICATION POLICIES

Eligibility Requirements for ACS Certification

- The ACS service is provided in a facility accredited by CBAHI and the accreditation certificate remains valid for at least 6 months at the time of the certification survey.
- The ACS service has a written agreement with other hospitals/centers for the timely transfer of ACS patients when the medical needs exceed the available services. The agreement ensures that the receiving hospital/center has a "No refusal policy" to accept transferred ACS patients.
- The cardiac catheterization laboratory operates 24/7 for both diagnostic and therapeutic coronary procedures.
- The service has access to comprehensive radiology and clinical laboratory services.
- The service has a dedicated general cardiology ward and cardiac care unit/ intensive care unit.
- The service has a cardiac rehabilitation service, on-site or outsourced.
- The service has an outpatient preventive cardiology service.
- The service has been in full operation for at least 12 months before the certification on-site survey.
- The service completes and returns an ACS certification application form.

Registration with CBAHI

Registration with CBAHI for certification is required for all eligible ACS services. This is the first step towards certification. The ACS service is required to register by completing the registration form located on CBAHI's website. Registration is a quick yet essential step that provides the Healthcare Accreditation Department at CBAHI with the necessary information about the registering ACS service. A system-generated autoreply with a code number will be provided to the registering ACS service upon successful registration. This code number will subsequently be used for all future communications with CBAHI.

Certification Pathway

To obtain CBAHI ACS certification, the ACS service must complete several activities. Upon successful registration, the manual of the national standards for ACS will be provided to the ACS service seeking CBAHI certification.

Each year CBAHI decides on which ACS service to be visited in its specific certification program, based on the operational plan and the certification cycle, for that particular year. CBAHI will notify those ACS services included in its yearly certification plan by the manner of a letter of enrolment.

CBAHI provides ongoing ACS service orientation programs in different locations throughout the year. The ACS services are encouraged to attend at least one of these orientation programs. Although any facility that provides ACS service can attend, preference is given to facilities selected for the current year's certification plan. During these orientation sessions, certification policies and survey processes are explained in detail. In that, ACS service representatives are given the opportunity to enquire about the intent of standards and how they should be implemented. The dates and venues of the orientation programs will be communicated to the facilities that provide ACS service promptly.

All ACS services enrolled in the ACS certification program are encouraged to conduct a comprehensive self-assessment using the Self-Assessment Tool (SAT) that CBAHI provides upon registering for certification. This tool is intended to help the ACS service 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 ACS service needs before the real survey visit. If objectively and effectively conducted, self-assessment provides better insight into the baseline situation of each ACS service and provides a common communication tool between the facility seeking ACS certification and the accrediting body. As a rule, the SAT is for the ACS service's internal use, but CBAHI might require it before conducting the survey to help determine the level of preparedness.

Some ACS services may choose to have a mock survey visit. This visit is offered by CBAHI mainly as an educational tool by experienced peer surveyors to clarify certification policies, standards, and intents. In addition to determining the applicability of the certification standards and verifying the self-assessment's findings. It should be noted, however, that mock surveys are subject to the available resources at CBAHI and the level of commitment demonstrated by the ACS service toward achieving compliance with the standards.

The ACS service may choose to participate directly in an on-site real survey visit. The time interval between registration and the achievement of certification is 6 to 18 months, on average. The ACS service is allowed to have a maximum of (2) on-site survey attempts within (2) years time frame. Therefore, the ACS service that will eventually prove incapable of achieving certification, as reasonably persuaded by CBAHI, will be suspended temporarily from participation in the national certification program.

Once an ACS service has applied for an on-site real certification survey visit and completed the pre-survey requirements as mentioned above, the tentative year of the visit will be determined based on CBAHI operational plan and communicated to the ACS service by the registration department. As CBAHI real certification visits are unannounced, the ACS service will be notified about the date of the survey and the survey team, seven days before the date of the real survey. However, the time frame may be extended in some circumstances.

In all cases, the service agreement must be acknowledged and duly signed by the facility/service and a copy returned to CBAH, and the ACS service must provide evidence of payment of the required certification fee.

Survey Team

To earn and maintain ACS certification, the ACS service must undergo an on-site survey conducted by the CBAHI survey team. CBAHI handles all scheduling arrangements for surveys in coordination with the ACS service leaders. The date of the survey visit will be determined following CBAHI's yearly operational plan.

Generally, the survey team is composed of one or two healthcare professionals, who specialized in the surveyed service. However, the size of the survey team members and the duration of the visit might change according to the size and scope of the ACS service.

The survey is conducted under the leadership of a visit team leader (VTL) that has been designated by CBAHI. The visit team leader is responsible for assuring that all survey activities are completed within the specified timeframe and according to CBAHI's policies and survey guide. The ACS service under survey is required to facilitate the work of the survey team members and to allow the visit team leader to practice his/her role and responsibilities, which include:
- Preparing and communicating the survey plan to the ACS service.
- Chairing the opening and closing meetings.
- Communicating with the ACS service leadership regarding survey progress and initial findings.
- Evaluating team progress and adjusting survey plans as needed; when required.
- Coordinating and preparing the survey report and submitting it to CBAHI.

Rescheduling of Surveys

ACS service scheduled for a survey is strongly encouraged to adhere to the survey date set by CBAHI. However, rescheduling may be considered for review at CBAHI's discretion on a case-by-case basis and following the postponement of the certification survey policy.

CBAHI makes every possible effort to carry out survey visits as per schedule. Under limited circumstances, postponement may be considered if the two conditions of accepting postponement exist. The two conditions are a justifiable cause, and an official letter reaching CBAHI at least 60 calendar days prior to the survey date. Justifiable causes may include:
- Significant natural or internal disasters (e.g., food, thunder, earthquake, major fire).
- Major renovation work that hinders the daily operation of the service.
- A mandate to stop the ACS service operation by a governmental authority.
- Change of ownership or affiliation (e.g., merge) within 6 months prior to the date of the survey.
- Relocation of the service to another building/campus within 6 months prior to the date of the survey.
- State of war when the healthcare facility/service might be affected or involved.

In all cases, postponement must not exceed 6 months. For an extended period, in case the postponement cause still exists, approval from the CBAHI is required.

Certification Decision Rules

In general, the ACS service must meet all applicable standards at an acceptable level to be certified. CBAHI utilizes a multilevel process for making certification and recertification decisions. This is to ensure fairness, consistency, objectivity, and accuracy. As such, CBAHI benefits from any relevant report and/or significant finding or issue related to the surveyed ACS service that was brought to CBAHI's attention by relevant health authorities or previous certification surveys.

Certification decisions are released and communicated to the ACS service within 30 days after the conclusion of the survey visit. The certification decision-making process is based on:
- The findings of the survey team members as recorded in the survey report.
- The factual accuracy review of the draft report by the participating ACS service of any issue of fact found in the report before the certification decision is made.
- Review/discussion during the meeting of the accreditation decision committee (ADC) for a significant finding that makes the survey outcome undetermined. This committee may request additional evidence before making a final recommendation for an accreditation/certification decision. All accreditation/certification decisions are then ratified by the CBAHI Director General.

It is important to note that the decision to grant certification 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 of the ACS service performance is one important factor, among others, upon which the ADC members rely when making their recommendations. Other factors include the non-compliant standard(s); for example, the degree of severity and immediacy of risk to patients, families, or staff safety.

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 being used, a bare electrical wire hanging down without any protection, and a patient 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 ACS service director and include the findings in the survey report.

Each standard is composed of a stem statement and sub-standard/s. The sub-standard is the measurable element to be scored by the surveyor during the on-site survey. Each sub-standard has equal weight and is scored on a numerical scale as set by CBAHI policies.

The overall score is calculated using the sum of the scores of all the applicable sub-standards divided by the maximum score. When one or more standards of this manual do not apply to a particular ACS service, they are indicated as "Not Applicable (NA)." Non-applicable standards are not scored and are not included in either the numerator or denominator of the overall score.

The decision committee shall recommend one of the following certification decisions:

Certified

Certification will be awarded when the surveyed ACS service demonstrates overall acceptable compliance with all applicable standards at the time of the initial (or re-certification) on-site survey, and when there are no criticality or concern related to non-compliant standard(s) that may impact the safety of patients, families, staff, or the service itself. Certification will also be recommended when the ACS service has successfully addressed all post-survey requirements and does not meet any rules for denial.

Denial of Certification

Denial of certification results when the ACS service shows significant noncompliance with the certification 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 certification have not been resolved. When the ACS service is denied certification, it is prohibited from participating in the certification program for six months unless CBAHI, for good reason, waives all or a portion of the prohibition period. Factors cited as reasons leading to the denial of certification include:
- The overall score is less than the minimum required score as set by CBAHI policies.
- The presence of an immediate threat, to the safety of patients, families, or staff, is observed by CBAHI surveyors during the on-site survey.
- Failure to submit the post-survey requirements promptly.
- The ACS service was subjected to a focused survey but still could not meet the requirements for certification.
- Reasonable evidence exists of fraud, plagiarism, or falsified information related to the certification 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 certified service through redrafting, additions, or deletions of a document's content without proper attribution. CBAHI perceives plagiarism as the deliberate use of another facility/service's original (not common knowledge) material without acknowledging its source.
- Refusal by the facility to conduct the survey.

Appeal Against a Certification Decision

A surveyed ACS service can appeal against the following certification outcomes:
- Denial of certification provided this is not due to a failure to submit the post-survey requirements promptly after granting certification or a failure to meet requirements after a follow-up focused survey.
- Suspension/revocation of certification.

All appeals shall be made within a maximum of 15 calendar days from receipt of the official survey report by submitting a cover letter to be sent from the facility director or ACS service 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 ACS service 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 certification decision.
- The report of the surveyors was inconsistent with the information presented to the survey team.
- The existence of perceived bias among the surveyor(s).
- The outcome of the appeal, if in favor of the appealing ACS service, will result in a change in the certification status. CBAHI will not consider appeals that will not result in a change of certification status.

Initial acceptance of the appeal request can occur only when clear and convincing evidence indicates that the ACS service meets at least one of the grounds for 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 facility/service desires to include. ACS services 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. Accepted appeals, including all relevant reports and evidence, are thoroughly studied by the appeal committee. One of the following decisions shall be made and communicated to the appealing ACS service promptly:
- The adverse decision is upheld.
- The ACS service's appeal is upheld, and the denial of certification is modified or reversed. In this circumstance, a full or focused re-survey may be conducted.

Certification Maintenance (Post-Survey Requirements)

CBAHI has redesigned its certification to represent a continuous process versus a once-every-three-year evaluation. Certified ACS services must maintain their certification status by showing their continued compliance with the standards and requirements of CBAHI throughout the certification cycle and following the specified time frames. This translates into standing and ad hoc requirements:

Standing Requirements for Accreditation/ Certification Maintenance

- Corrective Action Plan (CAP)

When certification is awarded to an ACS service, a corrective action plan (CAP) addressing some or all standards that were not in satisfactory compliance during the on-site survey will be requested by CBAHI for review and acceptance within a specified time frame from the date of the certification decision. The CAP ideally focuses on demonstrating what has been done rather than what will be done. The CAP addresses 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 the sustainability of the actions taken. A delay in the submission of the CAP that exceeds 30 days beyond the due date without justification can result in the suspension of the certification.

- Midterm Self-Assessment

Certified ACS services must participate in a mid-cycle self-evaluation of standards compliance known as the Midterm Self-Assessment. Fifteen months from the date of certification, the ACS service should start utilizing the self-assessment tool to assist in the periodic review of its performance against the standards. The ACS service then has three months to complete the assessment.

Completion of the midterm assessment will allow the ACS service to identify areas of standard non-compliance and create a plan for correction of deficient areas to ensure the ACS service comes into compliance before the next on-site survey. For those areas self-identified as non-compliant with CBAHI standards, the ACS service is 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 plan of action to indicate whether the plan and timetables are acceptable for bringing the standard into compliance.

A delay in submitting the midterm assessment by more than 60 days from the due date without an acceptable justification to CBAHI will result in the suspension of certification, followed by revocation of certification if the total delay exceeds 90 days.

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

Ad Hoc Requirements for Accreditation Maintenance

- Reporting of a sentinel event

When a sentinel event occurs, as defined by CBAHI, in an accredited facility, it must be reported immediately. A subsequent root cause analysis (RCA), and the risk reduction action must be submitted within the time frame defined by CBAHI.

A sentinel event is defined as any event leading to serious patient harm or death that is caused by healthcare rather than the patient's underlying illness. By investigating sentinel events, one can identify deficiencies in healthcare systems and processes and put actions in place to prevent a recurrence. CBAHI calls for the following concerning sentinel events:

- 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 ACS service certified by CBAHI, the ACS service must provide evidence of reporting to CBAHI. ACS services that are not certified by CBAHI are not required to report. In addition to reporting, CBAHI may become aware of the occurrence of a sentinel event through communication from one of CBAHI's surveyors, the media, a patient or relative, the facility's employees, or through other means of communication.
- CBAHI is interested in knowing about reportable sentinel events when they occur in certified ACS services 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 facility leadership and ACS service leadership to report any sentinel event without fear of retribution. CBAHI has zero tolerance for certified ACS services taking disciplinary actions against a staff member who reports a sentinel event. If the disciplinary action proves to be related to reporting, this can negatively impact the ACS service certification status.
- The outcome of a reported sentinel event is dependent on the level of commitment the facility/ACS service demonstrates towards studying the root cause(s) of the incident and re-designing its processes and systems to prevent a recurrence. When CBAHI is persuaded of this constructive approach by the concerned ACS service in dealing with sentinel events, certification is usually maintained. When this is not the case, CBAHI will pursue this further to decide on the ACS service eligibility to maintain its certification until the required corrections are made. In situations where the certification is valid for less than six months and CBAHI is not persuaded that the corrections have been made, an early full re-certification survey may be warranted.

- <u>Notification of significant changes</u>

Certified ACS services must notify CBAHI in writing about any significant structural, functional, or regulatory changes that took place after the certification survey was conducted. Written notification should be submitted no more than 30 days after the initiation/occurrence of such changes through the CBAHI portal. Subsequently, CBAHI will evaluate the impact of these changes and a decision for conducting a focused survey may be warranted accordingly. These changes include, but are not limited to the following:
- A national regulatory body has mandated closure for all or part of the ACS service.
- ACS service is not in compliance anymore with other relevant rules and regulations.
- ACS service certification by other international accrediting organizations has been suspended or revoked.
- Any of the services are being offered in a new location or branch.
- Major construction, destruction, or renovation work has been undertaken in any of the facility's buildings, floors, or units, where ACS services are provided.
- A significant increase (30% or above) or decrease in the volume of services/bed capacity has been experienced.

Certification Suspension and Revocation

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

CBAHI may receive information regarding possible violations by certified ACS services 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 an immediate threat to the safety of patients or staff in a certified ACS service.
- The ACS service is not committed to the specified time frames for certification, for example, maintenance of timely submission of a corrective action plan after certification or timely submission of a midterm self-assessment.
- The ACS service failed to report a sentinel event as per the relevant policy without an acceptable justification.
- The ACS service is committing an act of misuse (see the policy on certificate and seal), deception, or any deliberate misrepresentation of the truth (see the policy on truthfulness and the ethics clause).
- The ACS service is discouraging communication or taking disciplinary action/reprisal against patients or staff members trying to communicate directly with CBAHI about safety or quality of care concerns.
- The ACS service intentionally lacks commitment to continuous compliance with CBAHI standards. This complacent behavior is incompatible with the CBAHI certification process.
- The ACS service is deliberately violating any of the other certification policies mentioned in this manual or other supporting documents and manuals provided by CBAHI for certification.

Once CBAHI is convinced that one or more of the above-mentioned violations exists in a certified ACS service, it responds by taking one of the following actions, <u>in any order</u>:
- Issuing a letter of "At Risk of Suspension of Certification"
- Suspension of certification
- Revocation of certification

CBAHI determines the level of response to a specific violation based on several factors, including the severity of the violation, its frequency, previous certification history, the source of information regarding the violation, and the findings and conclusion of CBAHI's inquiry. When necessary, a focused or complete survey might be conducted for validation 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 a certified service's continued compliance with CBAHI standards). A certified service may undergo a survey at any time, at the discretion of CBAHI, and the survey is usually unscheduled (the ACS service 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 ACS services or only those areas in which a severe concern may exist. ACS services are usually charged for these surveys, regardless of the outcome. Results can affect the ACS service's certification status. If the ACS service does not allow CBAHI surveyors to conduct the survey, CBAHI may change the ACS service's status to Revocation of Certification.

It should be noted that when the ACS service certification is suspended, the ACS service can regain certification once the causative violation has been rectified. However, the suspension will not be lifted before a probation period of more than 12 months from the date of suspension. Revocation of certification is a more severe consequence that prohibits participation in the CBAHI certification as per CBAHI policy. In both, suspension and revocation of certification, CBAHI will communicate the new certification decision to the relevant authorities and display it on its website. 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, a certified ACS service may be selected for a random unannounced survey at any time after the certification survey. A sample of 5% of all certified ACS services 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 certified ACS services remain committed to CBAHI standards throughout the certification cycle. Random surveys also provide CBAHI and its surveyors with opportunities to further assess the certified ACS services in the interval between regular surveys. No fee shall be charged to the ACS service when a random survey is conducted.

The ACS services may be selected for a validation survey visit as part of an inter-rater reliability program for CBAHI surveyors within one month after receipt of the certification decision report. The visit outcome has no impact on the certification status granted in the actual certification survey visit. The ACS service will not bear any financial cost.

Certification Certificate and Seal

Once certification is granted, ACS services are encouraged to display the CBAHI logo, certificate, and seal on the facility's/service's bulletin boards, banners, website, newsletters, brochures, and headed stationery denoting their certification status.

CBAHI requires all certified ACS services to follow the guidelines and conditions for the appropriate use of the CBAHI logo, certificate, and seal. Specifically, CBAHI works to ensure that no certification material is used in a way that may mislead the public or others or provide false information related to certification status.

The Guidelines for proper use of the CBAHI logo and certificate include the following:
- The printing of the certification seal is accurate and legible, with no degradation or distortion.
- The size of the CBAHI logo and its certification 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 added graphics or words.

26

- The ACS service abides by 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 ACS service is prohibited from using the CBAHI logo or certification seal on business cards.

Upon expiry of the certificate validity period or suspension/revocation of the certification, the ACS service shall immediately take action to refrain from using the CBAHI logo, certificate, and seal.

Release of Certification-Related Confidential Information

CBAHI asserts that ACS services undergoing its certification survey are expected to provide access to information related to the evaluation of their compliance with CBAHI standards. As a guiding policy to ACS services engaged in any certification programs, CBAHI commits to keeping all information obtained or received during the certification process confidential, including all survey data and information that surveyors come across during the survey process.

For an ACS service that is a participating member of the CBAHI certification program, some information is subject to public release. This includes the ACS service certification status and the standards under which the certification survey was conducted. Other certification-related information is not subject to public release except to the ACS service on a 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:
- Decision committee minutes and agenda materials.
- The certificates.
- 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 involved falsified information the ACS service provided to CBAHI.
- Other information related to compliance with CBAHI standards obtained from the ACS service before, during, or after the certification survey.

Complaints Against Certified ACS Service

CBAHI is interested in collecting information from a variety of sources to improve the quality and safety of all certified ACS services. These sources include complaints from patients, their families, staff, government agencies, the media, and the public. Staff members at ACS service certified by CBAHI must be informed that they may make complaints directly to CBAHI without fear of retaliatory actions from their complaints.

CBAHI addresses all complaints that would help identify possible noncompliance with its certification 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 personal nature or individual disputes should be dealt with by the concerned facility/service or the regional health authority. CBAHI cannot follow up on complaints about ACS services that are not certified.

When CBAHI receives a complaint against a certified ACS service, CBAHI will conduct an initial screening to determine its relevance to compliance with CBAHI 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 ACS service leadership or the regional health authority. If the complaint relates to compliance with one of the 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 any other complaints regarding the same facility/ACS service. Broadly speaking, CBAHI will give one or both of the following responses:

- CBAHI may write to the ACS service about the complaint. When requested, the ACS service must make available its records of complaints and subsequent actions taken.
- CBAHI may decide to visit the ACS service to verify whether a problem exists in terms of standards compliance involved in the complaint. Such visits are usually unannounced, and the outcome may change the certification 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 act regarding the ACS service certification decision following the completion of the complaint's investigation.

To file a complaint against a certified ACS service, 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 complainant reveals his/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/services engaged in the CBAHI accreditation/certification 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 the performance of their duties or survey-related activities.
- Employing, contracting, or having any financial relationship with CBAHI employees or surveyors to provide consulting or related services in any capacity, either directly or through another party. This includes services provided in preparation for the survey, assisting in the preparation of the self-assessment, conducting mock surveys, and helping with the interpretation of the standards. 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 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, and avoidance of all situations that might appear unethical or illegal. The same is expected from the HCFs/ACS services seeking CBAHI certification. 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 certification decisions.

Business lunches, tea, coffee, and snacks during the survey are permitted. Other social gatherings are prohibited, and ACS services are encouraged to not offer such activities to the survey team.

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. In line with CBAHI's core values, CBAHI maintains the confidentiality of all data and information about both CBAHI and HCFs/services. CBAHI is also committed to resolving complaints and ethical issues raised by CBAHI employees or client HCFs/services to ensure justice, confidentiality, impartiality, timeliness, and feedback to the complainants.

PART I I I

CERTIFICATION STANDARDS

Leadership of the Service (LD)

Introduction:

Acute coronary syndrome (ACS) is a term used to describe a range of conditions associated with sudden, reduced blood flow to the heart. This includes non-ST segment elevation acute coronary syndrome (NSTE-ACS) and ST-segment elevation myocardial infarction (STEMI). The burden of ACS is on the rise globally and is a primary cause of morbidity and mortality. In the Kingdom of Saudi Arabia, ACS is a significant cause of mortality, and its burden is increasing due to the high prevalence of cardiovascular risk factors.

ACS is a medical emergency that affects millions of people each year and requires immediate attention. It is a broad term that covers a range of potentially life-threatening cardiac conditions. It is almost always associated with the rupture of an atherosclerotic plaque and partial or complete thrombosis of the infarct-related artery. The effectiveness of ACS service depends heavily on prompt diagnosis and treatment, as well as on effective leadership. The ACS program director is accountable for ensuring this provision of care. Administratively, leaders of ACS service need to clearly define the mission, scope of service, plans, programs, and policies to govern the service. In addition, leaders must work collaboratively, communicate effectively, allocate adequate resources to fulfil the mission, and integrate provided services, to ensure the quality and safety of ACS services.

This chapter focuses on the roles and responsibilities of the ACS service's leaders in the provision of reliable, timely, and safe services. The standards are organized as follows:
- Roles and responsibilities of the ACS service director.
- Availability of qualified and competent staff.
- Credentialing and privileging processes.
- Continuous professional development.
- Roles and responsibilities of the ACS steering committee.
- Community participation.
- Patients and service user feedback.
- Quality improvement and patient safety programs.
- Risk management program and incident reporting.
- Management of information system.
- Telehealth in ACS services.
- ACS Research activities.
- Supply chain management.
- Efficient procurement process.
- ACS environmental safety.

LD.1. **The ACS service is effectively managed by a qualified director.**
- LD.1.1. The director of ACS service is an interventional cardiologist with a minimum of 3 years of experience in the care of ACS patients.
- LD.1.2. An approved and updated organizational chart identifies the lines of authority between hospital leaders and ACS service leaders.
- LD.1.3. The director, together with the other leaders, defines a mission statement for ACS service that is aligned with the hospital's strategic plan.
- LD.1.4. The director, together with the other leaders, develops the ACS scope of services based on community needs.
- LD.1.5. The director ensures the ACS service's compliance with all relevant laws, regulations, and policies.
- LD.1.6. There is a written job description describing the ACS director's roles and responsibilities.
- LD.1.7. The director supports and protects patients' and families' rights and responsibilities.

Explanation

The ACS service must be managed by a director qualified in education, skills, training, and experience. The director must be a certified interventional cardiologist by the Saudi commission of health specialties, with a minimum of 3 years of experience in the care of ACS patients. The director manages the interrelationships among access, quality, safety, cost, resource allocation, accountability, ACS care setting, community need, and professional roles. The director defines, requests, organizes, and monitors all required resources to meet the patient's needs. The director uses data to assess performance, set targets, monitor indicators and trends, and determine if deliverables are met. The director is responsible for the ACS service's compliance with all applicable governmental laws and regulations, including, but not limited to, patient care regulations, medication management, opening licensure regulations, staffing licensure and certification, civil defense requirements, municipality requirements, and other regulatory requirements. Efficient and effective healthcare organization management requires effective staff communication and clear reporting lines. Hence, the organizational chart should be developed to present the relationship between hospital leaders, ACS service leaders, and the front-line staff. The director ensures patient and family rights and responsibilities are established and implemented.

LD.2. **There is an adequate number of qualified and competent staff to run the ACS service.**
- LD.2.1. ACS service appoints and assigns qualified staff to meet the needs of safe patient care based on staffing plan, recruitment policy, and the scope of service.
- LD.2.2. The director defines the number, type, and credentials of the required staff.
- LD.2.3. There are at least two full-time interventional cardiologists available to ensure the ACS services coverage 24 hours a day, 7 days a week.
- LD.2.4. The ACS staffing plan is updated annually, monitored to identify deficiencies, and actions for improvement are implemented as required.
- LD.2.5. The director designs specific job descriptions that outline the knowledge, skills, and attitude necessary to perform the job responsibilities for each position.
- LD.2.6. The director develops an effective process to evaluate staff performance at least annually.

Explanation

The ACS service director recommends the appointment of qualified leaders to manage the service and identifies the required number, type, and credentials of staff to meet the needs of safe patient care. The ACS service director designs job descriptions for each position to outline the roles, responsibilities, knowledge, skills, and attitude of each staff member. The ACS service exerts all efforts to delineate the privileges of the clinicians based on their credentials and competency. The service ensures that the clinicians are performing an adequate number of procedures to maintain their skills. Neither the clinicians nor the program can introduce a new procedure without first ensuring the competency of the clinicians performing the procedure and updating the clinicians' privileges to reflect this competency. To ensure satisfactory staff performance according to the job descriptions and privileges, a standardized objective process for gathering and assessing the staff's performance, scope of practice, professional development, and attitude is developed for each staff category. The performance evaluation's objective criteria are shared with the staff.

LD.3. There is a process in place for credentialing and re-credentialing all healthcare providers in ACS service.

    LD.3.1. The credentialing process applies to all ACS service staff licensed to provide patient care on a full-time, part-time, or visiting basis.

    LD.3.2. The credentialing process includes gathering, verifying, and evaluating staff credentials including licenses, educational certificates, training certifications, and evidence of experience.

    LD.3.3. Credentials are verified from the original source directly or through a third party with documented evidence kept in personal files.

    LD.3.4. The ACS service ensures the registration of healthcare professionals with the Saudi Commission for Health Specialties and licensing by the Ministry of Health (MOH) following national laws and regulations.

Explanation

This process of credentialing applies to all clinical staff licensed to provide patient care such as cardiologists and catheterization laboratory technicians. The credentialing process involves collecting all the information related to staff education, training, experience, and licensure, verifying it from the primary source, and evaluating it to ensure the staff fits his/her assigned position. Credentialing must be performed upon employment and re-credentialing must be performed every two years thereafter. In addition, all healthcare practitioners must be registered with the Saudi Commission for Health Specialties and licensed by the Ministry of Health (MOH).

LD.4. Medical staff providing ACS services have current delineated clinical privileges.

    LD.4.1. The ACS service has a policy and procedure that defines the process of granting clinical privileges to its medical staff based on the staff's current competence and available services.

    LD.4.2. The clinical privileges are recommended by the ACS service director and approved by the delegated relevant committee.

    LD.4.3. The ACS service director ensures that all clinicians practice within the approved clinical privileges that are assigned to them.

    LD.4.4. The clinical privileges are reviewed and updated every two years or earlier if needed.

Explanation

The privileging of medical staff is one of the most beneficial proactive risk management approaches concerning patients' safety. It allows medical staff to perform procedures for which they are qualified through education, training, and certification. This prevents patients' exposure to the risk of morbidities. Each medical staff should have a list of the invasive procedures that he/she is allowed or privileged to perform. The ACS service must have a policy and procedure for granting individual privileges. These clinical privileges should be accessible, in the areas where the ACS medical staff are practicing, and should be reviewed and updated every two years, or earlier if needed. The clinical privileges are recommended by the ACS service director and approved by the hospital-wide privileging committee.

LD.5. The ACS service supports continuing education and training for all categories of staff.

    LD.5.1. The ACS service has a schedule for education and training programs based on staff needs, including quality, patient safety, risk management, and infection control practices.

    LD.5.2. The ACS service leaders encourage staff to attend educational and training activities relevant to the ACS scope of service.

    LD.5.3. All ACS staff members who provide direct patient care maintain a valid certificate on basic life support (BLS).

    LD.5.4. The ACS service identifies other staff members to be trained in advanced life support as appropriate to the scope of service.

    LD.5.5. Staff personnel records show documented evidence of training and education.

Explanation

Staff professional development is essential for improving ACS services. The service should drive continuous education in different disciplines including quality, patient safety, risk management, medication safety, infection control practices, patient/service user rights, complaint management, shared decision-making, communication skills, informed consent, cultural beliefs, the needs and activities of different patient/service user groups and how to deal with end-of-life patients. All ACS staff members providing direct patient care must have valid basic life support certification and some members must be trained in advanced life support as appropriate to the scope of service. The ACS service uses both direct physical and virtual means to disseminate knowledge. Training and education may include on-site or remote training, workshops, lectures, case studies, morbidity & mortality rounds, and journal clubs. The service assesses the effectiveness of the training through direct and indirect feedback and takes action accordingly.

LD.6. **The ACS service steering committee ensures the provision of reliable, timely, and safe service.**
- LD.6.1. The ACS service director establishes and leads a steering committee for the ACS service.
- LD.6.2. The steering committee meets regularly to integrate all organizational services involved in the management of ACS patients.
- LD.6.3. The steering committee ensures that protocols, clinical practice guidelines, and standards are followed.
- LD.6.4. The steering committee receives and resolves, patient-related and administrative ethical dilemmas regarding ACS service, within an identified timeframe.
- LD.6.5. The steering committee summarizes and reports ethical issues regarding ACS service to the hospital leadership.

Explanation

The steering committee is led by the service director and includes the appropriate leaders of the ACS units and other senior staff members as required. The leaders must integrate program services with all organizational relevant services such as social services, patient relations, laboratory…etc. The leaders of the ACS service need to ensure that operations in each service follow ACS protocols, guidelines, and standards. The service leaders are responsible for developing the framework that governs how patient care is conducted ethically across the program's activities. The committee ensures receiving and resolving ethical issues concerning patients, visitors, and staff in ACS service.

LD.7. **The ACS service enhances community participation and education to improve public awareness.**
- LD.7.1. The ACS service provides the community with appropriate information on its scope of services and how to access care.
- LD.7.2. The service coordinates with the community's key stakeholders to improve public awareness of the ACS risk factors and early symptoms of ACS.
- LD.7.3. Appropriate and understandable educational resources on ACS are made available and accessible to the community through various communication channels.
- LD.7.4. Continuous community education is regularly conducted and evaluated for its effectiveness and impact on community health and wellbeing.

Explanation

Health education focuses on prevention, early detection, and risk reduction. The ACS service conducts training for a wide range of organizations that encounter ACS patients. The ACS service conducts onsite/offsite educational activities/workshops targeting its public awareness objectives. Health education is available through a variety of sources including the hospital website and social media and displayed in the facility. The ACS service considers the perspective of the community as partners in healthcare decision-making processes. The service identifies the relevant community stakeholders, including transport authorities and local governments to undertake accessibility planning and how they meet current and future healthcare needs. The educational activities provided to the community must be regularly evaluated for their effectiveness and improvements are planned accordingly.

LD.8. **The ACS service seeks feedback from patients and service users regarding the services provided.**
    LD.8.1. Patients' complaints are resolved within the time frame described in the policy.
    LD.8.2. The ACS service assigns a staff member to be responsible for managing complaints.
    LD.8.3. Patient satisfaction surveys are conducted regularly.
    LD.8.4. Data collected from surveys, complaints, and suggestions are analyzed and trended, and the results are used for improvement and integrated into the quality and safety program.

Explanation

The ACS service develops and implements a policy and procedure to ensure and facilitate the patients' right to voice their complaints, concerns, and suggestions and assigns a staff member to be responsible for managing complaints. In addition, patient satisfaction surveys must be conducted biannually to assess the level of patient satisfaction with the services provided. The service can conduct direct patient/service user interviews at the provision point and/or through focus groups, telephone calls, and social media. The findings from patient complaints data and patient satisfaction surveys must be used for performance improvement.

LD.9. **The ACS service develops and monitors the implementation of the quality improvement and patient safety plan.**
    LD.9.1. The ACS service develops a quality and patient safety plan that is aligned with the hospital-wide quality and patient safety program.
    LD.9.2. The quality and patient safety plan of ACS service utilizes various evidence-based quality tools and methodologies to measure performance and improve clinical and managerial areas.
    LD.9.3. The ACS service implements at least one improvement project per year utilizing an evidence-based quality improvement methodology.
    LD.9.4. The ACS service develops and prioritizes a set of indicators that cover the essential structures, processes, and outcomes of the services provided, based on standardized criteria.
    LD.9.5. The indicators' results are benchmarked and accessible on a timely basis to those involved in the delivery of the services and hospital leadership.
    LD.9.6. The service continuously evaluates the gap in its reported outcomes and utilizes the results of benchmark evaluations to improve ACS services.
    LD.9.7. The quality team supports the quality and patient safety plan of ACS service through integrating data collection, aggregation, validation, analysis, and interpretation.

Explanation

The ACS service should ensure the quality of its services and its continuous improvement by developing a quality management and patient safety program, according to national initiatives on quality and patient safety. The quality and patient safety program of ACS service utilizes key performance indicators, surveys, audits, peer reviews, feedback, risk assessment, safety incidence, complaints, and suggestions for prioritizing quality improvement projects and improving the program's operational planning as well as clinical and managerial operations. Staff are notified of the performance findings, and the information provided is utilized to further improve clinical and managerial areas (structure, process, and outcome). The quality staff support and facilitate the implementation of different quality management, patient safety, and risk management plans and coordinate activities with the hospital's quality improvement and patient safety program. The quality staff support integrated data collection, aggregation, validation, analysis, and interpretation of relevant data from multiple sources including quality indicators. The ACS service implements at least one improvement project per year, based on prioritization, using an evidence-based approach such as FOCUS-PDCA or DMAIC models.

Performance indicators are measurable values expected to measure a specific aspect of performance. These indicators reflect the quality of care provided and are used as a guide to monitor, evaluate, and improve the quality of services. The collection of key performance indicator (KPI) measurements should follow an evidence-based approach and the selection criteria are based on essential priorities. The indicators should cover a variety of issues based on structure, process, and outcome.

These indicators may include adherence to the ACS pathway, Door-to-ECG, Door-to-device, the proportion of patients with high-risk NSTE-ACS that have a coronary angiography within 72 hours, ACS discharges with dual antiplatelet therapy, LVEF evaluation prior to discharge, secondary prevention plan, the proportion of patients diagnosed with ACS readmitted within 30 days after discharge, and crude/risk-adjusted mortality. The results of the indicators must be discussed with staff and reported regularly to hospital leadership along with action plans taken for improvement. Internal and external benchmarking with peer services must be conducted to check performance compared to other similar services.

LD.10. **The ACS service develops and implements a risk management plan that is aligned with the hospital-wide risk management program.**
    LD.10.1. The ACS service risk management plan addresses clinical, managerial, and financial risks related to ACS service.
    LD.10.2. The plan utilizes an evidence-based process for grading risks based on severity, frequency, and potential impact on the program and organization.
    LD.10.3. The plan details how risks are assessed identified, analyzed, recorded, reported, managed, and monitored within a timeframe.
    LD.10.4. The plan highlights utilizing the incident reporting process to report and identify performance concerns and identify areas of improvement.
    LD.10.5. The ACS service reports and discusses the identified risks, reported incidences, and action plans with frontline staff and hospital leaders regularly.
    LD.10.6. ACS service participates in a multidisciplinary committee that is responsible for developing and evaluating the quality and risk management program and any corrective actions are taken as needed to address any deficiencies.

Explanation
The ACS service risk management plan describes its roles and responsibilities, time frames, risk grading criteria, and details on how risks are assessed identified, analyzed, recorded, reported, managed, and monitored. The ACS service participates actively in a multidisciplinary committee that is responsible for developing and evaluating the quality and risk management program and any corrective actions are taken as needed to address any deficiencies. The ACS risk management plan highlights the use of an incident reporting policy with a unified reporting mechanism for all occurrences, variances, or accidents. Reporting includes near misses (accidents that were prevented or discovered before reaching the patient). ACS staff are encouraged to report incidents without fear of retribution.

LD.11. **The ACS service maintains an effective information management system to serve its users and stakeholders.**
    LD.11.1. The ACS service maintains an internal register containing at least demographic data, disease-specific code, and procedure code for each registered patient.
    LD.11.2. The ACS service uses diagnosis codes and procedure codes including international classification of diseases (ICD), or an equivalent coding system, consistent with the applicable laws and regulations.
    LD.11.3. Patient medical record contains sufficient updated medical information to safely manage the patient and promote continuity of care including history, physical examination, plan of care, investigations, consultations, consents, procedure reports, medications, and allergies.
    LD.11.4. All entries in the patient's medical record are legible, dated, timed, signed, and made by staff who are allowed to write in the medical record as per medical records policy.
    LD.11.5. Only standardized/approved abbreviations and symbols are used in medical records.
    LD.11.6. The ACS service conducts regular checks on returned medical records to ensure the completion of medical information and authentication. The results of the regular check are used to improve compliance with record completion.
    LD.11.7. The ACS service implements a policy and procedure for the clinical documentation improvement (CDI) program.

Explanation

To ensure continuity of care, each patient cared for in the ACS service has an individual medical record that has a unique medical record number. The ACS service needs to develop a policy to ensure uniformity and legibility of writing in medical records and avoid misinterpretation of written information. Also, the policy should specify the category of staff allowed to write in the medical record. In the patient medical record, only standardized and approved abbreviations and symbols must be used because abbreviations can be problematic, confusing, interpreted differently, and may result in inadvertent medical errors. Standardized diagnoses, procedures, and services codes help programs track pathology and standard procedures and comply with the requirements of regulatory entities and insurance companies. Hence, a clinical documentation improvement (CDI) program is fundamental in any healthcare facility or service to ensure timely completion of the medical records, proper utilization of data, and accurate data reporting to the health authorities as per local regulations. If an electronic healthcare information system is used, an adequate data-capturing process during downtimes is critical to maintaining the completeness and comprehensiveness of data. At the end of a patient's visit, the medical record is returned to a safe medical records store or electronically stored.

LD.12. **The ACS service provides secure telehealth ACS services to ensure integrated ACS care, whenever the need arises.**
- LD.12.1. The ACS service develops criteria for treating patients in the telehealth ACS service.
- LD.12.2. The ACS service leaders ensure the credentialing and privileging of all healthcare providers involved in the process of providing telehealth ACS services before starting the service.
- LD.12.3. Telecardiology and teleradiology services are registered and comply with national health laws and regulations.
- LD.12.4. The ACS service leaders ensure the security and confidentiality of patient information exposed because of the telecommunication process.

Explanation

The ACS service should have defined criteria to accept the patient in telemedicine settings and when the patient needs to visit the clinic physically. The ACS service ensures the competency of the physicians providing the services by subjecting them to the ACS's service credentialing and privileging process similar to other practicing physicians in the ACS service. The confidentiality and security of patient information are secured by allowing access only to the relevant ACS staff members and only to required information from the patient's file.

LD.13. **The ACS service participates in research activities.**
- LD.13.1. The ACS service conducts or participates in at least one research project each year.
- LD.13.2. The hospital research committee or similar structure oversees all research activities.
- LD.13.3. The service implements the research outcomes to improve its services.

Explanation

Medical research has great value in modern medicine in terms of the improvement of healthcare services. Research activities should be implemented with regulatory guidelines, professional requirements, selection criteria, code of conduct, appropriateness, and safety. Findings from research should be used in daily operations to improve services.

LD.14. There is a process to manage the supply chain, related to the ACS service, cost-effectively.

 LD.14.1. The ACS service director works collaboratively with hospital leadership to manage ACS service-related supply chain.

 LD.14.2. The director ensures optimal use of the supply within the program by addressing overuse, underuse, and misuse of supplies.

 LD.14.3. The ACS service has an appropriate and organized storage area for medical supplies with labels showing the name of the item and the expiry date.

 LD.14.4. Contracted entities, when applicable, meet applicable national regulations and are selected based on relevant evidence-based criteria.

Explanation

The ACS service director works collaboratively with hospital leadership to adhere supply to procurement regulations in terms of contract management and tendering guidelines and to manage the interface between the links and logistics of supply chain services within the organization and the program as well as to work to achieve timelines and efficiency in supply delivery, warehousing, and distribution. The ACS service regularly monitors and documents the compliance of contracted services with laws, regulations, and the appropriate standards, and implements documented corrective actions for improvement when standards are not met.

LD.15. The ACS leaders implement policies and procedures to guide efficient procurement of equipment, either purchased or donated, medications, and medical consumables following national laws and regulations.

 LD.15.1. The ACS leaders ensure that contractors and suppliers of devices and consumables have a Medical Device Establishment License (MDEL).

 LD.15.2. The ACS leaders ensure that all newly purchased devices have a Medical Device Marketing Authorization (MDMA) certificate.

 LD.15.3. The ACS 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. The Saudi Drug and Food Authority (SFDA) provides such information and performs visits to institutions to ensure that only approved equipment, medications, and supplies are in use. Prior to purchasing newly introduced consumables, there should be formal testing and feedback obtained from end-users.

LD.16. The ACS service maintains a safe environment for patients, visitors, and staff, through an effective facility management and safety program.

 LD.16.1. The ACS leaders ensure that the building used to provide ACS service complies with national standards, environmental protection standards, laws and regulations, and the recommendations of professional entities.

 LD.16.2. Fire systems covering ACS service, including the fire alarm, fire extinguishers, and fire equipment, are in place and functioning.

 LD.16.3. Hazardous materials used in ACS service are stored, handled, transported, used, and disposed of effectively as per the "Safety Data Sheets".

 LD.16.4. ACS staff, including new hires, volunteers, and trainees, receive education on fire drills, evacuation plans, dealing with hazardous materials, and dealing with waste disposal, with a training record kept in personal staff files.

Explanation

The ACS service leaders must ensure that the service is provided in a safe building (includes the building and its surroundings) that comply with national standards, environmental protection standards, laws and regulations, and the recommendations of professional entities. Also, the ACS service must protect its occupants from the effects of hazardous materials and waste through proper handling, segregation, and disposal of waste. In addition, the fire safety of the facility, where ACS service is provided, must be ensured through several facility control measures. In addition, staff training must be conducted through fire drills including the use of RACE/PASS and evacuation techniques.

References

- Arabiat D, et al. Parents' experiences of family centered care practices. J Pediatr Nurs. 2018;42:39–44. Retrieved June 2022 from https://doi.org/10.1016/j.pedn.2018.06.012.

- Agency for Healthcare Research and Quality (AHRQ). TeamSTEPPS®: Strategies and Tools to Enhance Performance and Patient Safety. Rockville, MD: AHRQ, 2016. Retrieved June 2022 from https://www.ahrq.gov/teamstepps/index.html

- American College of Obstetricians and Gynecologists. Patient Safety and Health Information Technology (2015). Retrieved June 2022 from https://www.acog.org/-/media/Committee-Opinions/Committee-on-Patient-Safety-and-Quality-Improvement/co621.pdf?dmc=1&ts= 20190901T1157446882

- American Health Information Management Association (AHIMA). HIM Body of Knowledge. 2021. Retrieved June 2022 from http://bok.ahima.org/

- Barends E, Rousseau DM, Briner RB. Evidence-Based Management: The Basic Principles. Amsterdam: CEBMa, 2014. Retrieved June 2022 from https://www.cebma.org/wp-content/uploads/Evidence-Based-Practice-The-Basic-Principles-vs-Dec-2015.pdf

- Carroll RL. Enterprise Risk Management: A framework for success. Chicago, IL: American Society for Healthcare Risk Management, 2014. Retrieved June 2022 from http://www.ashrm.org/resources/patient-safety-portal/pdfs/ERM-White-Paper-8-29-14-FINAL.pdf

- Center for Health Design. Designing for Patient Safety: Developing Methods to Integrate Patient Safety Concerns in the Design Process. Joseph A, et al. 2012. Retrieved June 2022 from https://www.healthdesign.org/sites/default/files/chd416_ahrqreport_final.pdf

- Chassin MR, Loeb JM. High-reliability healthcare: getting there from here. Milbank Q. 2013;91(3):459-90. Retrieved June 2022 from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3790522/

- Fernandez-Aleman JL, Garcia ABS, Garcia-Mateos G, et al. Technical solutions for mitigating security threats caused by health professionals in clinical settings. Conf Proc IEEE Eng Med Biol Soc. 2015:1389–92. Retrieved June 2022 from https://pubmed.ncbi.nlm.nih.gov/26736528/

- Lee H, Lee H, Baik J, et al. Failure mode and effects analysis drastically reduced potential risks in clinical trial conduct. Drug Des Devel Ther. 2017;11:3035-43. Retrieved June 2022 from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5655157/

- National Fire Protection Association. Structure Fires in Healthcare Facilities. Campbell R. 2017. Retrieved June 2022 from https://www.nfpa.org/-/media/Files/News-and-Research/Fire-statistics-and-reports/Building-and-life-safety/oshealthcarefacilities.pdf

- Saunders LW, McCoy AP, Kleiner BM, et al. International benchmarking for performance improvement in construction safety and health. Benchmarking: An International Journal. 2016;23(4):916–936. Retrieved June 2022 from https://www.emerald.com/insight/content/doi/10.1108/BIJ-11-2013-0105/full/html

- The International Society for Quality in Healthcare (ISQua). Guidelines and Standards for External Evaluation Organizations. http://www.isqua.org

- World Health Organization. WISN: Workload Indicators of Staffing Need User's Manual. 2010. Retrieved June 2022 from
https://www.who.int/hrh/resources/WISN_Eng_UsersManual.pdf?ua=1.

- World Health Organization. Management and Safe Use of Medical Devices. Accessed June 2022 from
https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/management-use

- Zakaria H, Abas H, Roslinda R, et al. A systematic literature review of security perimeter in hospital facility. Open International Journal of Informatics. 2018;6(4):104–129. Retrieved June 2022 from
http://apps.razak.utm.my/ojs/index.php/oiji/article/view/68/49.

Provision of Care (PC)

Introduction

Acute coronary syndrome (ACS) includes a range of conditions affecting the blood supply to the heart muscles; these include non-ST segment elevation acute coronary syndrome (NSTE-ACS) and ST-segment elevation myocardial infarction (STEMI). Providing optimum care for ACS patients requires careful planning, coordination, and communication. The ACS services must provide an appropriate and thorough assessment for each patient, and patient care must be planned and implemented to ensure the best possible outcome. Patient assessment and care must be documented in the medical record to support continuity of care. As the care process may need to be distributed between multiple providers, a collaborative process should be in place to promote continuity and coordination when the patient is referred, transferred, or discharged.

This chapter focuses on the provision of safe and effective care. It covers the patient's journey in the following domains:
- Access to care.
- The layout of the service.
- Emergency layout and care.
- ACS assessment/reassessment.
- ACS plan of care.
- Design and functions of the cardiology ward and intensive care unit.
- Diagnostic services.
- Prevention services.
- Rehabilitation services.
- Monitoring of morbidities and mortalities.
- The referral processes.
- The discharge process and continuity of care.

PC.1. **The ACS services are accessible in an equitable manner to all patients whose medical needs can be met within the ACS service.**

    PC.1.1. The ACS service informs patients on how to access care, treatment, and services, including after-hours.

    PC.1.2. The ACS service ensures that all relevant services for its ACS population are available.

    PC.1.3. The ACS service provides care, treatment, and services to patients in a planned and timely manner.

Explanation

The ACS service must inform patients on how to access care, treatment, and services including after-duty hours. The service must ensure that all relevant services and resources are available based on patient and community needs in a planned and timely manner.

PC.2. **The hospital's layout, structure, and function facilitate the delivery of reliable, timely, streamlined, and safe care to patients.**

    PC.2.1. The ACS service director works collaboratively with the hospital leadership to develop a flow that defines all parts of the ACS patient's journey.

    PC.2.2. The hospital's layout optimizes the flow of patients between the cardiac critical unit /intensive care unit, emergency room, radiology department, and operating room.

    PC.2.3. The program's specialized units including the cardiac catheterization laboratory and the diagnostic coronary angiography unit have an appropriate design, function, and safe facilities following applicable national and international guidelines.

    PC.2.4. The diagnostic services are accessible within an identifiable timeframe as needed.

Explanation

Optimizing patient flow means moving patients smoothly through acute care settings. This is part of the proper utilization of resources which includes optimizing the flow of patients between different hospital departments (such as operation rooms, emergency department, and cardiac catheterization laboratory) and between the hospital and other acute care settings. This also includes minimizing patient and staff waiting time and canceling scheduled services. The cardiac catheterization laboratory and diagnostic coronary angiography are designed and equipped with the necessary tools to meet patients' demands within an identifiable timeframe as needed. The director of the ACS service works collaboratively with hospital leadership to reduce patient waiting time, backlogs, avoidable admissions, and length of stay. Also, to improve the net response time as well as the patient planning process for transfer or discharge. The director must select representatives from relevant clinical services to facilitate the patient's journey and overcome obstacles.

PC.3. **The hospital's emergency room is efficiently designed, and appropriately equipped, and has qualified and competent staff to manage ACS patients.**

    PC.3.1. The emergency room is appropriately equipped to meet the ACS patients' needs.

    PC.3.2. The emergency room is covered by a certified emergency medicine consultant physician and nurse with knowledge and experience in managing ACS patients.

    PC.3.3. The emergency room maintains an on-call schedule for a cardiology consultant, interventional cardiology consultant, cardiology specialist, and catheterization laboratory staff.

Explanation

The emergency room is appropriately equipped with the medical devices, medications, and consumable materials required to meet the patient demands. In addition, competent staff are available to meet patient demands including an emergency physician certified by the Saudi Commission for Health Specialties (SCFHS) as an emergency medicine consultant and an experienced nurse. The emergency room maintains an on-call schedule for a cardiology consultant, interventional cardiology consultant, cardiology specialist, and catheterization laboratory staff.

42

PC.4. **The ACS service uses clinical pathways and protocols to guide the process of providing effective emergency care.**

PC.4.1. The ACS service implements a standardized protocol following the national ACS guidelines for the immediate triaging and management of a suspected ACS patient.

PC.4.2. The ACS service utilizes an evidence-based chest pain management pathway.

PC.4.3. The ACS service uses a protocol to rapidly diagnose an ACS patient by performing a 12-lead ECG with the goal of completion within 10 minutes of first medical contact.

PC.4.4. The ACS service uses a protocol for a STEMI alert system for prompt activation of the STEMI team within 10 minutes.

PC.4.5. The catheterization laboratory on-call team arrives on-site within 30 minutes of STEMI activation.

PC.4.6. The catheterization laboratory is accessible within a maximum of 15 minutes, whenever the need for catheterization arises in the emergency room.

PC.4.7. The ACS service administers thrombolytic therapy for STEMI patients undergoing mechanical reperfusion therapy within 30 minutes of the first medical contact.

PC.4.8. The catheterization laboratory-capable hospitals/centers maintain the total time from first medical contact to the first device activation within 90 minutes, and within 120 minutes for transferred patients in non-PCI capable hospitals/centers.

Explanation

The ACS service develops written guidelines, protocols, and clinical pathways for the diagnosis and management of ACS. Compliance with these protocols must be monitored regularly to ensure effective emergency care for patients with ACS.

PC.5. **A multidisciplinary team is involved in the management of ACS patients and develops a policy and procedure for the assessment/reassessment of patients.**

PC.5.1. The policy defines the scope, content of the patient assessment, frequency of the reassessment process, and the assessment time frame for all disciplines in all ACS care settings.

PC.5.2. The team utilizes validated risk-based assessment and reassessment tools.

PC.5.3. The assessment identifies the patient discharge or referral planning based on the patient's identified needs.

Explanation

Patient assessments are of paramount importance to determine the correct diagnosis and establish an appropriate plan of care. The ACS service should have an assessment and reassessment policy and procedure. This policy should identify the scope, content, and frequency of assessing the history and physical examination. On the first visit, all patients should undergo a comprehensive history and physical examination, regardless of the nature of the disease. In ACS service, the multidisciplinary team (i.e. Heart Team) is a specialized care team that may include interventional cardiologists, cardiothoracic surgeons, imaging specialists, anesthesiologists, cardiac cath lab staff, and a cardiologist. Together, the specialized Heart Team will conduct a comprehensive assessment, evaluation, and care plan. In this, patients would be screened for nutritional needs, functional needs, the presence or absence of pain, the risk of falls, and psychological and social needs. In addition to the comprehensive cardiovascular assessment and evaluation.

PC.6. **The ACS team develops a comprehensive multidisciplinary plan of care, based on assessment findings, and directed by clinical practice guidelines.**

PC.6.1. The most responsible physician (MRP) ensures that the plan of care is patient-centered and developed collaboratively by the members of the healthcare team.

PC.6.2. The plan of care is based on the assessment findings.

PC.6.3. The plan of care sets measurable desired outcomes and is documented for each patient.

PC.6.4. The plan of care is based on the ACS management pathway/protocol that guides the management of ACS patients in all ACS care settings.

PC.6.5. Patients' needs are reassessed when indicated and the care plan is revised and modified accordingly.

PC.6.6. Patient educational needs are identified and documented in parallel to providing ACS services.

Explanation

A documented plan of care is vital to managing a patient's condition. The plan of care is developed according to the assessment information that the healthcare team obtains and tailored to accommodate the patient and family's spiritual and cultural needs as well as the patient's medical condition. A collaborative plan of care is developed involving nurses, dieticians, physiotherapists, social workers, occupational therapists, speech therapists, and clinical pharmacists as needed. The plan of care includes measurable goals, for example, maintaining a pain score below 4. The most responsible physician (MRP) reviews the plan of care during each visit and if necessary changes it according to the patient's response. Patients' education needs must be identified and documented in the plan of care.

PC.7. **The general cardiology ward's design, structure, and function facilitate the delivery of reliable, timely, and safe care to ACS patients.**

PC.7.1. The general cardiology ward has an appropriate design, functional areas, and safe facilities following applicable national guidelines.

PC.7.2. The general cardiology ward has both a nominal and surge capacity management plan to meet any changes in demand.

PC.7.3. The general cardiology ward has the necessary equipment to continuously and concurrently monitor and record the patient's cardiac rhythm.

PC.7.4. Patients are admitted and discharged from the general cardiology ward according to standardized criteria, supported by national guidelines.

Explanation

The general cardiology ward is appropriately and safely designed and equipped with beds, medical devices, medications, and consumable materials required to meet the patient's needs. The admission and discharge processes should be coordinated between the physicians, nurses, and other healthcare practitioners involved in the patient's care.

PC.8. **The intensive care unit's design, structure, and function facilitate the delivery of reliable, timely, and safe care to ACS patients.**

PC.8.1. The intensive care unit, where ACS service is provided, has an appropriate design, functional areas, and safe facilities following applicable national guidelines.

PC.8.2. The intensive care unit has both a nominal and a surge capacity management plan to meet any changes in demand.

PC.8.3. Patients are admitted and discharged from the intensive care unit according to standardized criteria, supported by national guidelines.

Explanation

The ICU is appropriately equipped with medical devices, medications, and consumable materials required to meet the patients' demands. The admission and discharge processes should be coordinated between the physicians, nurses, and other healthcare practitioners involved in the patient's care. The most responsible physician (MRP) should be assigned to each patient based on the hospital policy and procedures.

PC.9. **The radiology and laboratory services are fully equipped and have adequate resources to meet the ACS patients' needs.**
   PC.9.1. The radiology service is fully equipped for a wide spectrum of diagnostic procedures to match ACS patients' needs.
   PC.9.2. Qualified and competent staff perform, evaluate, and report all radiological procedures conducted for ACS patients.
   PC.9.3. The clinical laboratory service is fully equipped to conduct a wide spectrum of investigative procedures to meet ACS patients' needs.
   PC.9.4. Qualified and competent staff perform and report the tests in the clinical laboratory.

Explanation
Radiology services are provided to ACS patients around the clock by a variety of qualified and experienced staff, competent in their field. The staff should be sufficient in number to match the patient volume and have valid SCFHS registration. Also, the radiology service is fully equipped for a wide spectrum of diagnostic procedures to match ACS patients' needs. The radiology department has an appropriate digital archiving system, departmental and portable echocardiography, and exercise stress treadmill testing. Additionally, laboratory services are provided to ACS patients around the clock by a variety of qualified, and experienced staff, competent in their field. The staff should be sufficient in number to match the patient volume and have valid SCFHS registration.

PC.10. **The ACS service is active in preventing disease recurrences and supports patients to pursue an independent healthy lifestyle.**
   PC.10.1. The service has a well-established multidisciplinary secondary outpatient preventive cardiology clinic protocol.
   PC.10.2. All ACS patients have a documented ACS secondary prevention plan based on the identified and documented risks.
   PC.10.3. All ACS patients are counseled and educated about activities, medications, risk factors modifications, and followed up for lifestyle modification.
   PC.10.4. Patients and their families actively participate in the secondary prevention plan.

Explanation
The ACS services have a preventive cardiac protocol to meet the patient's needs. A prevention care plan is developed based on the individual patient's needs and risks, shared with the patient, and documented in the patient medical record. The patient/family are educated and actively participate in the prevention plan of care.

PC.11. **A skilled multidisciplinary team guides the provision of comprehensive cardiac rehabilitation services.**
   PC.11.1. The ACS service defines, in a written policy, the admission and discharge criteria for the inpatient and outpatient rehabilitation service.
   PC.11.2. The policy defines the components of individualized patient assessment.
   PC.11.3. The rehabilitation services are provided promptly based on individualized patient assessment findings.
   PC.11.4. The rehabilitation services encompass dietetics, endocrinology, pharmacy, smoking cessation, psychiatry, and other services as required.
   PC.11.5. The rehabilitation services provide individualized education and counseling to each patient.

Explanation
Cardiac rehabilitation programs help patients to understand how to manage their disease, how to control and modify their cardiovascular risk factors, and how to begin an exercise program to gradually improve their cardiac function, capacity, and physical fitness safely after their acute cardiac event. This will lead to improvement in the patient's overall cardiac function, stabilize or reverse the progression of atherosclerotic disease, reduce the risk of mortality secondary to cardiovascular disease, and increase the patient's self-confidence through gradual conditioning so that patients can achieve the highest

quality of life possible. The ACS service must have a written policy that defines the admission and discharge criteria for the inpatient and outpatient rehabilitation service. The cardiac rehabilitation services ensure that comprehensive, timely, and individualized patient assessment covers nutritional counseling, weight management, blood pressure management, lipids management, diabetes management, tobacco cessation, psychosocial management, physical activity counseling, and exercise training. The ACS rehabilitation team recommends timing for the safe return to normal daily activities and lifestyle modifications. The rehabilitation service must provide the necessary education and counseling to each patient based on their needs.

PC.12. **The ACS service conducts mortality and morbidity meetings, regularly.**
    PC.12.1. The ACS service reviews mortality and significant morbidity cases at least monthly to highlight avoidable and potentially avoidable cases.
    PC.12.2. The ACS service focuses on scientific discussion, improvement, and prevention, with a non-punitive intent during mortality and morbidity meetings.
    PC.12.3. The ACS service, in the mortality and morbidity meetings, recommends actions for improvement and evaluates their effectiveness.
    PC.12.4. The ACS service refers mortality and morbidity cases, that involved other departments, to the medical director for a decision and discussion in the hospital morbidity and mortality committee.

Explanation
Mortality and morbidity meetings are conducted regularly. Highlighted cases are distributed among peers before the meeting to identify areas for improvement. The meetings should focus on scientific discussion, improvement, and prevention, with a non-punitive intent. Shared cases between departments are referred to the medical director for a decision on presenting to the hospital morbidity and mortality committee.

PC.13. **The ACS service ensures the timely management of ACS patients when their medical needs exceed the available services.**
    PC.13.1. The ACS service has a written agreement and clear communication channels with other hospitals/centers for the timely transfer of ACS patients when the medical needs exceed the available services.
    PC.13.2. The ACS service has access to cardiac surgery either onsite or through a written agreement with a cardiac surgery-capable hospital/center within an acceptable timeframe.
    PC.13.3. The emergency department in a hospital without percutaneous coronary intervention (PCI) facilities maintains a door-in-door-out (DIDO) time of ≤30 minutes for STEMI patients who require a transfer to a PCI-capable center.
    PC.13.4. The ACS service maintains a transport time of ≤60 minutes for inter-hospital transfer or STEMI patients diagnosed in the field.

Explanation
Hospital readiness is comprehensive and integrated with initial management being uniform. However, when the indicated care is above that which the current healthcare facility can provide, a transfer to a higher level of care should be initiated to ensure the timely management of ACS patients. A written agreement is secured between the transferring and the receiving facility, with evidence of effective utilization of the agreement through a set of measures to ensure the timely and safe transferring of ACS patients.

PC.14. **There is a referral pathway to guide the patient referral process based on the patient's health needs.**
    PC.14.1. The patient referral pathway defines referral acceptance criteria and the communication channels to facilitate the immediate transfer.
    PC.14.2. The patient referral pathway defines the required essential information to be communicated and the care needed during transfer.

46

PC.14.3. The patient referral pathway addresses the infection prevention and control measures to be considered and followed before and during referral.

PC.14.4. Patients and their families are involved in the transfer decision and plan of referral.

PC.14.5. There are capable ambulance services and staff to promptly and safely transfer critical cases.

PC.14.6. The patient is monitored during the transfer process and the monitoring record is kept in the patient's medical record.

PC.14.7. A summary of the patient's condition is sent with the patient to the receiving organization and the receiving organization acknowledges the patient's condition upon arrival as part of the handover process.

Explanation

Patient referral is based on the patient's health needs for continuing care that is available in the receiving organization. The pathway highlights the patient's eligibility and physiologic acceptance criteria. The summary of the patient's condition is sent with the patient to the receiving organization. The receiving organization obtains an essential information summary for continuity of care. The summary highlights the reason for the patient's initial admission, admission diagnosis, and the reason for transfer. The summary contains the in-hospital course, investigations, services provided, the patient's medication list and the time of the last dose(s) given, and infection prevention and control measures. The referral pathway determines staff accountability on both ends of the transfer process. The condition and status of the patient determine the qualifications of the staff member monitoring the patient and the type of medical technology needed during transfer. A consistent process for how patients are transferred from one facility to another is required to ensure that patients are transferred safely. The hospital evaluates the quality and safety of the transfer process to ensure that patients were transferred with qualified staff and the correct medical technology for the patient's condition. The patient must be monitored during the transfer process and the monitoring record must be kept in the patient's medical record. The receiving organization must check the patient's condition upon arrival.

PC.15. **The ACS service discharges patients through an efficient, safe, and timely process.**

PC.15.1. The most responsible physician (MRP) specifies the estimated date of discharge for each patient upon admission and updates that throughout the duration of the stay.

PC.15.2. The most responsible physician (MRP) decides the identifiable clinical criteria for discharge and ensures the patient's suitability for discharge.

PC.15.3. All ACS patients receive a pre-discharge evaluation of the left ventricular ejection fraction (LVEF).

PC.15.4. All medications and support services necessary for a safe discharge should be organized and documented in the discharge summary.

PC.15.5. The discharge summary and follow-up plan are discussed with and provided to the patient prior to discharge.

PC.15.6. Post-discharge care is coordinated based on the assessment of the patient and identified needs.

PC.15.7. The patient, and family are educated about how to access care when needed.

Explanation

Patients and families should have the opportunity to identify and discuss their post-discharge needs (e.g., physical, emotional, social, and community support needs) with members of the multidisciplinary team making decisions for discharge. A documented post-discharge care plan is developed upon admission in partnership with the patient and family and a copy is provided to them. This may include relevant community services, self-management strategies (e.g., medication information and compliance advice, goals, and therapy to continue at home), ACS support services, any further rehabilitation or outpatient appointments, and an appropriate contact number for any queries. The patient and family are informed about how to obtain help. An emergency contact number that is available outside normal working hours is provided to the patient. The patient and family receive information on how and when to re-access health and supportive services when required.

References

- Agency for Healthcare Research and Quality (AHRQ). Care Coordination. 2016. Retrieved June 2022 from
https://www.ahrq.gov/professionals/prevention-chronic-care/improve/coordination/index.html

- Baughman AW, Cain G, Ruopp MD, et al. Improving access to care by admission process redesign in a Veterans Affairs skilled nursing facility. Jt Comm J Qual Patient Saf. 2018;44(8):454–62. Retrieved June 2022 from
https://pubmed.ncbi.nlm.nih.gov/30071965/

- Collet JP, Thiele H, Barbato E, et al. 2020 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation. Eur Heart J. 2021 Apr 7;42(14):1289-1367. Retrieved June 2022 from
https://pubmed.ncbi.nlm.nih.gov/32860058/

- ECRI Institute. Patient identification: Executive summary. 2016. Retrieved June 2022 from
https://www.ecri.org/Pages/Patient-Identification-Deep-Dive.aspx

- Guedeney P, Collet JP. Diagnosis and Management of Acute Coronary Syndrome: What is New and Why? Insight From the 2020 European Society of Cardiology Guidelines. J Clin Med. 2020 Oct 28;9(11):3474. Retrieved June 2022 from
https://pubmed.ncbi.nlm.nih.gov/33126578/

- Hughes P, Latino RJ, Kelly T. Preventing patient identification errors. Patient Safety & Quality Healthcare. 2017. Retrieved June 2022 from
https://www.psqh.com/analysis/preventing-patient-identification-errors/.

- January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society in Collaboration With the Society of Thoracic Surgeons. Circulation. 2019 Jul 9;140(2):e125-e151. Retrieved June 2022 from
https://www.ahajournals.org/doi/10.1161/CIR.0000000000000665

- Nasarwanji MF, Badir A, Gurses AP. Standardizing handoff communication: Content analysis of 27 handoff mnemonics. J Nurs Care Qual. 2016;31(3):238–44. Retrieved June 2022 from
https://doi. org/10.1097/NCQ.0000000000000174.

- Saudi Arabian Ministry of Health. MOH Guideline on the Assessment of Radiology (2016). Retrieved June 2022 from
https://www.moh.gov.sa/en/Ministry/MediaCenter/Publications/Pages/Publications-2016-08-07-001.aspx

- The International Society for Quality in Healthcare (ISQua). Guidelines and Standards for External Evaluation Organizations.
https://www.isqua.org

- World Health Organization (2015). WHO Global Strategy on People-Centred and Integrated Health Services: Interim Report. Retrieved June 2022 from
https://apps.who.int/iris/bitstream/handle/10665/155002/WHO_HIS_SDS_2015.6_eng.pdf

- World Health Organization (2018). Continuity and coordination of care: a practice brief to support implementation of the WHO Framework on integrated people-centred health services. Retrieved June 2022 from
https://apps.who.int/iris/bitstream/handle/10665/274628/9789241514033-eng.pdf?ua=1

Cardiac Catheterization Laboratory (CCL)

Introduction:

A cardiac catheterization laboratory (CCL) is a specialized area in the hospital where doctors perform minimally invasive tests and advanced cardiac procedures to diagnose and treat cardiovascular disease. The CCL should be equipped with imaging technologies to view the arteries and determine how effectively blood flows to and from the heart. This gives the care team information to help diagnose and treat blockages and other issues in the arteries often without requiring patients to undergo surgery. The CCL should be covered by an expert team who has special training in a variety of invasive diagnostic and interventional cardiac procedures.

This chapter focuses on the availability of qualified and competent staff, equipment, and other essential resources, as well as illustrates how the procedures are performed.

- Management of the activities of the CCL procedure suite.
- The CCL layout.
- The cardiovascular assessment/reassessment of patients.
- Pre-sedation/pre-anesthesia assessment.
- The pre-procedure preparation.
- The diagnostic procedures.
- The multidisciplinary procedure committee.
- The percutaneous coronary interventional therapeutic procedures.
- Monitoring of patients during a procedure.
- Post-procedure assessment and documentation.
- The CCL reporting process.

CCL.1. **Qualified staff effectively manage the activities of a CCL procedure suite.**

CCL.1.1. An interventional cardiologist/ electrophysiologist with a minimum of 3 years of experience in invasive cardiology directs the CCL procedure suite.

CCL.1.2. Qualified nurse manager directs the nursing services of the CCL procedure suite.

CCL.1.3. The procedures are performed and reported by licensed and privileged CCL consultants as primary operators.

CCL.1.4. The procedures are assisted by licensed qualified and competent staff.

CCL.1.5. The procedure suite has essential anesthesia equipment operated by an anesthesia consultant.

Explanation

Cardiac Catheterization Laboratory (CCL) is directed by an interventional cardiologist/ electrophysiologist to effectively manage the CCL service requirements. Qualified staff direct and operate the CCL service including a qualified nurse manager, and licensed and privileged CCL and anesthesia consultants. Infection prevention and control measures must be strictly implemented.

CCL.2. **The CCL's design, structure, and function facilitate the delivery of reliable, timely, and safe care, to meet patients' needs.**

CCL.2.1. The CCL has an appropriate location, design, access control, fittings, fixtures, functional areas, and safe facilities following applicable national and international guidelines.

CCL.2.2. The CCL ensures the availability of adequate equipment and supplies necessary for the safety and effectiveness of the procedures.

CCL.2.3. The angiography is fully equipped for a defined range of diagnostic procedures to meet ACS patients' needs.

CCL.2.4. The CCL has an initial receiving area for patients.

CCL.2.5. The procedure suite has nominal and surge capacity management planning to meet any changes in demand, including equipment, medical devices, medications, and consumable materials required to meet patient needs.

CCL.2.6. The CCL design follows infection control standards for the segregation of clean and potentially infectious areas, including the segregation of clean and dirty utility areas.

CCL.2.7. The CCL has an adequate patient waiting area, change cubicles, storage area, handwashing facilities, and a workstation for the staff.

Explanation

The CCL is appropriately and safely designed and equipped with medical devices, medications, and consumable materials required to meet the patients' demands. The design and structure of CCL should facilitate the delivery of safe, reliable, and timely care. The CCL suite requires receiving, treatment, and supportive areas. The entry/reception area may be shared with an adjacent unit along with a patient/visitor waiting area, change cubicles, and an interview room for patient/family discussions. The CCL treatment area will include catheter laboratory(s), computer modules for imaging equipment, a control room, and an electrophysiology laboratory room as required. In addition, a scrub area for catheter laboratory(s) should be available and located outside laboratories. The support areas will include a clean utility room, a dirty utility room, handwashing facilities, a staff workstation, and a storage area for linens, blankets, equipment, and supplies.

In addition, the CCL maintains adequate equipment and supplies to ensure safe procedures. These equipment and supplies include but are not limited to sheaths, diagnostic catheters, guide catheters, guidewires 0.035, guidewires 0.014, drug-eluting stents, covered stents, intravascular ultrasound (and/or optical coherence tomography), functional flow reserve, temporary pacemaker, pericardiocentesis kit, aspiration thrombectomy, compliant balloons, non-compliant balloons, cutting balloons, snares, coils, blood gas analyzer, ACT machine, vascular device closure, guide extension, and microcatheters.

50

CCL.3. **The interventional procedures team develops a policy to guide appropriate pre-procedure preparation.**

    CCL.3.1. The policy highlights the investigations, consultations, and patient preparations required prior to a procedure.

    CCL.3.2. Procedure preparations include appropriate skin preparation for a vascular access site and a minimum of one large bore intravenous access.

    CCL.3.3. The procedure preparations include assessing the readiness of monitoring equipment and emergency cardiovascular surgical backup.

    CCL.3.4. The policy designates which procedures require type and crossmatch for the availability of blood products.

    CCL.3.5. Procedure preparation ensures the availability of paddle or self-adhesive external defibrillation pads prior to and during the procedure.

    CCL.3.6. The operator is aware of prior cardiac procedures/operations data, device and lead hardware present, and associated imaging report(s).

Explanation

Procedure preparations ensure the functionality of appropriate required equipment/devices including diagnostic or pre, intra, and post-intervention angiographic imaging and pre, intra, and post-intervention ultrasound imaging, when applicable. Monitoring equipment must be available to perform intravascular pressure; non-invasive blood pressure; pulse oximetry; activated coagulation time (ACT) analyzer; and electrocardiogram. In high-risk procedures, the staff must use self-adhesive external defibrillation pads, and they must be placed on the patient's chest before the onset of the procedure. The locked emergency response cart or kit must be checked at least monthly, with documentation to assure that all expected items are present, and the supplies are not expired.

CCL.4. **The interventional procedures team develops and implements a cardiovascular assessment policy prior to the CCL procedure.**

    CCL.4.1. The cardiovascular assessment policy defines the scope and content of the cardiovascular assessment process to document preprocedural status.

    CCL.4.2. Pre-procedure assessment includes medical and surgical history, relevant laboratory testing, medications, allergies, bleeding disorders, and physical examination that is obtained within 30 days prior to the procedure.

    CCL.4.3. In emergencies where a comprehensive cardiac assessment is not feasible, a brief note is written by the most responsible physician (MRP) before performing the procedure.

Explanation

The interventional procedures team must develop a cardiovascular assessment policy that defines the scope and content of the assessment process. Laboratory testing includes but is not limited to, electrolytes, blood urea nitrogen (BUN), creatinine, complete blood count (CBC), blood type, and screening (if indicated, within 30 days of the procedure) prothrombin time (INR), if taking warfarin and pregnancy test (in females of childbearing age), should be performed within 24 hours of the procedure. If pre-procedure laboratory testing is performed outside the facility, the results of that testing must be included inside the facility's medical record (e.g., intake history and physical). Positive blood cultures must also be documented in the facility's medical record and interpreted by the responsible physician. The pre-procedure assessment includes heart rate and rhythm, blood pressure, and a cardiovascular exam with documentation of all peripheral pulses, symptoms, comorbidity(s), medications, and allergies.

CCL.5. **Pre-sedation/ pre-anesthesia assessment and anesthesia planning are conducted by an anesthesiologist, prior to the procedure.**

CCL.5.1. The pre-anesthesia assessment includes assigning an anesthesia risk score for the patient and the patient's suitability for the type of sedation/anesthesia selected.

CCL.5.2. The pre-sedation/ pre-anesthesia assessment is performed, within thirty (30) days, prior to the procedure date.

CCL.5.3. The anesthesia plan is based on the pre-anesthesia assessment findings and includes the management of postoperative pain.

CCL.5.4. The anesthesia plan is communicated and agreed upon by both the physician performing the procedure and the patient/family.

CCL.5.5. The anesthesiologist reassesses the patient immediately prior to induction of anesthesia focusing on the physiologic stability and readiness of the patient for anesthesia.

CCL.5.6. The policy describes anesthetic equipment and staffing skills and competencies required to manage high-risk patients, difficult and failed intubations, malignant hyperthermia, anaphylaxis, local anesthetic toxicity, and massive hemorrhage.

Explanation

To decide on the most suitable type of sedation or anesthesia, patients must have a full pre-anesthesia/pre-sedation assessment performed before any procedure. A sedation or anesthesia written plan is crucial for the patient's safety. The pre-anesthesia/pre-sedation assessment is valid for up to thirty days before the procedure. The assessment should highlight the anesthesia risk score, such as the "ACS." 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. If the pre-anesthesia assessment is performed within thirty (30) days, the pre-anesthesia assessment is updated with documentation in the medical record.

CCL.6. **The interventional procedures team develops a policy to guide the care of patients in procedural areas.**

CCL.6.1. The policy describes the types of performed procedures, patient transportation, receiving, preparation, and monitoring inside the procedure area, and the movement of the patient to an appropriate bed.

CCL.6.2. The policy describes the periprocedural routine and special types of preparation, including special considerations for procedures involving implantable devices.

CCL.6.3. The policy describes the intraprocedural monitoring of patients with or without anesthesia or sedation.

CCL.6.4. The CCL team ensures the functionality, maintenance, calibration, and quality control of equipment and medical devices in the procedure room, including anesthesia equipment.

CCL.6.5. The CCL team monitors safety and infection prevention and control standards in the procedure areas, as per the national guidelines.

Explanation

The CCL policy details the types of procedures and the patient's journey throughout the procedures room, including the pathway to verify the correct procedure is performed, for the correct patient, with patient involvement when possible. In addition, the policy must describe the periprocedural routine and intraprocedural monitoring for the patients. A special type of preparation for the procedures and special considerations for procedures involving implantable devices must be included in the policy. Regularly, the CCL team ensures the functionality, maintenance, calibration, and quality control of equipment and medical devices used in the procedure room for ACS patients. As well, they monitor quality standards, safety requirements, and infection prevention and control standards.

CCL.7. The ACS service performs effective percutaneous coronary interventional (PCI) therapeutic procedures based on the prioritization of needs and identified patient risks.

CCL.7.1. Performance of PCI is based on the patient's needs and clinical risk of ACS adverse outcomes and is directed by national ACS clinical practice guidelines.

CCL.7.2. The ACS service maintains a report showing the total number, types, staff response time, appropriateness, outcomes of PCI procedures, and the cancellation rate with the reasons behind it.

CCL.7.3. The ACS service ensures meeting the procedure volume requirements following the national and international standards of ACS care.

Explanation

Based on patient needs and clinical risks, a licensed and privileged consultant interventional cardiologist performs the percutaneous coronary interventional (PCI). The ACS service maintains a report(s) showing the total number and the outcomes of PCI procedures by the following types, Primary PCI, Pharmaco-invasive approach PCI/Rescue PCI, PCI for NSTE-ACS, and PCI for elective procedures. The outcomes of the PCI procedures report include acute complications and the failure rate. The ACS service ensures meeting the procedure volume requirements following the standards of ACS care.

CCL.8. The CCL team develops evidence-based policies and procedures for the monitoring of patients during a procedure.

CCL.8.1. The level and frequency of monitoring depend on the patient's pre-anesthesia status, the type of procedure performed, and the anesthesia/sedation used.

CCL.8.2. A protocol guides the management of the anticoagulant patient.

CCL.8.3. Adequate anticoagulation should be monitored with activated clotting time (ACT) throughout the procedure whenever unfractionated heparin is used.

CCL.8.4. The monitoring findings and status of the patient at the end of the procedure are documented in the medical record before the patient leaves the procedure room.

Explanation

The CCL team follows evidence-based policies and procedures to monitor the patients during the procedure. The policies and procedures cover the level and frequency of monitoring and anticoagulation. Monitoring findings must be documented in the patient medical record. Protocols must guide the management of anticoagulant patients, patients at high risk of contrast-induced nephropathy, radiographic contrast allergy, and anaphylaxis.

CCL.9. The CCL team ensures that patients and staff are safe from radiation hazards during interventional radiological procedures, in alignment with the hospital radiation safety program.

CCL.9.1. The interventional radiological procedures protocol indicates pre-procedural assessments, including patient identification, procedure verification, the rationale for the procedure, and history of allergic reactions.

CCL.9.2. A protocol guides the management of patients at high risk of contrast-induced nephropathy, radiographic contrast allergy, and anaphylaxis.

CCL.9.3. There is a valid shielding certificate for the rooms where ionizing radiation is administered for ACS patients to ensure permissible radiation levels.

CCL.9.4. Personnel shielding devices, including radiation protection aprons, are available for patients and staff, and periodically inspected and tested for integrity and safety compliance as per the documentation.

CCL.9.5. Personnel are monitored for radiation exposure by thermoluminescence dosimeters (TLD) that are regularly tested, and actions are taken when test results exceed permissible levels.

CCL.9.6. The CCL posts safety warnings in clear and appropriate locations where radiological procedures are performed.

CCL.9.7. Radiation usage is monitored during the procedure by the angiographic system and documented in the final procedure report.

Explanation

Patients, staff, and the environment should be protected from radiation by a well-constructed radiation safety program that includes all areas utilizing ionizing radiation, such as CCL. Radiology rooms and equipment should be tested initially to ensure the absence of a radiation leak. Equipment should be tested periodically to ensure proper functioning. Warning signs should be posted where radiological procedures are performed. In addition, 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. The protocol must guide the management of patients at high risk of contrast-induced nephropathy, radiographic contrast allergy, and anaphylaxis.

CCL.10. **The CCL team establishes post-cardiac catheterization procedure assessment and documentation.**

CCL.10.1. The CCL team performs a basic cardiovascular evaluation to assess immediate post-procedure symptoms or complication(s); prior to moving the patient off the table.

CCL.10.2. The post-procedure evaluation includes assessing the patient blood pressure, heart rate and rhythm, possible complications, and the status of the puncture site

CCL.10.3. A protocol is in place to address and evaluate any post-procedural complications.

CCL.10.4. A protocol is in place to address sheath removal and appropriate personnel is available to manage sheath removal.

CCL.10.5. A post-procedure documentation summarizes the procedure and addresses any immediate complications and/or deviation of the patient's status at the end of the procedure.

CCL.10.6. A post-procedure cardiovascular assessment report is available within approximately 24 hours or earlier if the patient is for discharge.

Explanation

Before moving the patient off the cardiac catheterization table, a cardiovascular assessment must be performed to check vital signs and rhythm and to address potential complications (e.g., acute neurologic events, cardiac arrest, cardiac tamponade). Sheath removal protocol must be implemented by competent staff. The assessment report must be available within 24 hours and/or before discharge.

CCL.11. **Post-sedation/ post-anesthesia patients are recovered and discharged to an appropriate setting according to an evidence-based policy and procedure.**

CCL.11.1. The CCL has a fully equipped recovery room to continuously monitor patients' post-sedation/ post-anesthesia.

CCL.11.2. Patients are continuously monitored by qualified staff during the recovery period according to specified parameters, as defined in the policy.

CCL.11.3. Time spent in the recovery, monitoring findings, discharge time, and handover process are recorded in the patient medical record.

CCL.11.4. Patients are discharged from the recovery area by a qualified anesthesiologist, with the required equipment, based on established discharge criteria.

Explanation

The patients must be continuously monitored during the recovery period by qualified nursing staff. The patient must be moved to an appropriate setting such as a separate periprocedural area, the general cardiology floor, or a cardiac critical care/intensive care/step-down unit with the equipment and trained personnel necessary to perform cardiovascular and hemodynamic monitoring and assessment. When appropriate, continuous telemetry should be available for the evaluation of heart rhythm.

CCL.12. **The patient's post-procedure care is planned and documented.**
  CCL.12.1. The post-procedure plan of care is comprehensive and multidisciplinary.
  CCL.12.2. The post-procedure plan of care is goal-oriented, dynamic, and may change according to the reassessment findings.
  CCL.12.3. Immediate post-procedure instructions are written by the primary operator or designee before the patient leaves the recovery room.

Explanation

A comprehensive post-operative plan must be developed to include procedures, anesthesia nursing, rehabilitation, and other disciplines as required. The plan is dynamic and can change based on patient needs. The immediate post-procedure instructions must be written before the patient leaves the recovery room.

CCL.13. **The CCL standardizes the reporting of pre-procedural, procedural, and post-procedural data.**
  CCL.13.1. Qualified physician is responsible to generate a consistent report that accurately reflects the content and results of the study/procedure.
  CCL.13.2. The physician who performs the procedure documents information regarding all components of the procedure and any significant changes between the preliminary and final reports, in the patient medical record.
  CCL.13.3. The anesthesiologist documents all aspects of the procedure relating to anesthesia or sedation, and the patient's response, in the patient medical record.
  CCL.13.4. The technical record includes all technical aspects of the procedure.
  CCL.13.5. A summary of the results of the procedure, including any positive and negative findings or adverse outcomes and the results of the baseline adult diagnostic catheterization testing is documented in the patient medical record.
  CCL.13.6. The study report clarifies any need for additional studies or procedures based on the results of the procedure being reported.

Explanation

The complete final report is typewritten within 24 hours after the procedure. The final report is reviewed, signed, and dated manually or electronically by the interpreting physician. Complete information about the procedure must be written by the physician, anesthesiologist, and nursing staff. A complete study report must reflect the content and results of the study, any pertinent positive and negative findings, a demographic summary of the technical aspects of the procedure, and a summary of the results.

References

- Albugami S, Al-Husayni F, Bakhsh L, Alhameed F, Alsulami A, Abumelha K, Balubaid M, Al-Harbi M, Mufti HN. The Perception of Coronary Artery Disease and Cardiac Catheterization in Saudi Arabia: "What the Public Know". Cureus. 2020 Jan 5;12(1):e6570. Retrieved July 2022 from https://pubmed.ncbi.nlm.nih.gov/31956466/

- Bahaidarah S, Al-Ata J, Abdelmohsen G, et al. Cardiac catheterization addressing early post-operative complications in congenital heart surgery-a single-center experience. Egypt Heart J. 2020;72(1):83. Retrieved July 2022 from https://pubmed.ncbi.nlm.nih.gov/33226532/

- January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society in Collaboration With the Society of Thoracic Surgeons. Circulation. 2019 Jul 9;140(2):e125-e151. Retrieved July 2022 from https://www.ahajournals.org/doi/10.1161/CIR.0000000000000665

- Naidu, SS, Abbott, JD, Bagai, J, et al. SCAI expert consensus update on best practices in the cardiac catheterization laboratory. Catheter Cardiovasc Interv. 2021;98:255-276. Retrieved July 2022 from https://scai.org/publications/clinical-documents/scai-expert-consensus-update-best-practices-cardiac-catheterization

- The International Society for Quality in Healthcare (ISQua). Guidelines and Standards for External Evaluation Organizations. https://www.isqua.org

Glossary

Glossary

Acute Coronary Syndrome (ACS)
A medical emergency that affects millions of people each year and requires immediate attention. It is a broad term that covers a range of potentially life-threatening cardiac conditions. It is almost always associated with the rupture of an atherosclerotic plaque and partial or complete thrombosis of the infarct-related artery.

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 the restoration, correction, or modification of a physiological function.

Bystander
An individual who may be affected by the production use of the product/service.

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.

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.

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

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

Governance
The function of determining the organization's direction, setting objectives, and developing policy to guide the organization in achieving its mission.

Healthcare Organization
A generic term used to describe many types of organizations that provide healthcare services.

Incidents
Unusual events that may have an element of risk or may have a negative effect on patients, staff, or the hospital.

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 organizational 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.

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.

Licensure
A legal right granted or evidenced by documentation issued by SCFHS (such as physicians, nurses, psychiatrists, or clinical social workers, or the operation of a health facility) in the form of a license, registration, or certification.

Medical Device
Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or other similar or related article 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.

Medical Equipment
Equipment used for the specific purposes of diagnosing and treating diseases or for rehabilitation following disease or injury. It can be used either alone or in combination with any accessory, consumable, or other pieces of medical equipment (e.g., EKG machines, diagnostic ultrasounds, surgical lights, patient beds, surgical tables, anesthesia machines, and defibrillators).

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.

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.

Medication Recall
The act of requesting the return of a batch or entire production run of a medication, usually because of a defect, safety concern, or efficiency problem. Recalls may be conducted by the national healthcare authorities, such as the Saudi Food and Drug Authority, or voluntarily by the manufacturer.

Medication Reconciliation
The process of creating the most accurate list possible of all medications the patient is taking – including drug name, dosage, frequency, and route – and comparing that list against the physician's admission, transfer, and/or discharge orders to provide correct medications to the patient at all transition points within the hospital.

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

Personnel File
Collection of information about a staff member, covering personnel issues such as licensure, certifications, leaves, appraisal reviews, and job descriptions.

Care Plan (Plan of Care)
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. Care planning is an interdisciplinary process.

60

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 labor law specifies 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.

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.

Referral
The process by which a patient is sent (1) from one clinician to another clinician or specialist; or (2) from one setting or service to another, either for consultation or care that the referring source is not prepared or qualified to provide.

Risk
The combination of the assessment of 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.

Scope of Services
The range of activities provided to patients and/or other customers by the leadership, clinical, and support personnel.

Screening
A system for examining and separating into different groups.

Sentinel Event
An event that 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.

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.

Transport
The movement of an individual from one place to another using a transport aid or vehicle, either motorized or manual (wheelchair, trolley, bed).

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.

About This Manual

This first edition of the National Standards for Acute Coronary Syndrome Services was developed through a consensus process which entailed the participation of all the relevant stakeholders. From the beginning, the aim was to have a set of standards that are detailed and descriptive, assembled around the key elements of Acute Coronary Syndrome Services, based on the current best healthcare practices. The goal of this manual is to be used as a reference for achieving the optimal care for patients and their families.

About CBAHI

The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) is a non-profit organization emerging from the Saudi Health Council and is responsible for setting and assessing the quality and patient safety standards in Saudi Arabia. CBAHI began with only a few hospitals enrolled in the accreditation process and a limited number of surveyors and staff. Today, CBAHI is proud to have a comprehensive set of evidence-based standards that are utilized for the assessment of thousands of healthcare facilities across the country.