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STANDARDS FOR INTERVENTIONAL CARDIOLOGY SERVICES

Version 1

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Health Policies and Standards Department
Health Regulation Sector (2021)

INTRODUCTION

Health Regulation Sector (HRS) plays an essential role in regulating the health sector and is mandated by the Dubai Health Authority Law No. (6) of 2018 to undertake several functions:

- Developing regulation and standards to improve patient safety, quality and also support the growth and development of the Dubai health sector;
- Licensure and inspection of health facilities and healthcare professionals;
- Managing patient complaints and upholding patient rights;
- Regulating the use of narcotics, controlled and semi-controlled medications;
- Strengthening health tourism and assuring ongoing growth; and
- Assuring the management of e-health and innovation.

The Standards for Interventional Cardiology aims to fulfil several overarching Strategic Objectives and Programs within the Dubai Health Strategy (2016–2021):

- **Objective 1:** Position Dubai as a central medical tourism destination through a comprehensive, integrated, value-based and high-quality service delivery system;
- **Objective 2:** Direct resources to assure a happy, healthy and safe environment for Dubai population; and
- **Objective 4:** Foster innovation throughout the continuum of patient care.

Strategic Program 1: Care Model Innovation, Care Model Innovation Program. The ambition is to promote innovation, efficiency and ensure residents and visitors in Dubai have access to high-quality services; and

- **Strategic Program 10: Excellence and Quality.** The ambition is to promote excellence in healthcare service delivery and enhance patient experience and satisfaction.

ACKNOWLEDGMENT

The Health Policy and Standards Department (HPSD) would like to acknowledge experts in the field for their continued dedication and support to develop the standard and improve patient safety and quality of care in the Emirate of Dubai.

Health Regulation Sector

Dubai Health Authority

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EXECUTIVE SUMMARY

DHA is pleased to present the Standards for Interventional Cardiology Services, which is essential to promote patient safety and improve healthcare quality within DHA licensed facilities. Interventional Cardiology is the specialised branch of cardiology that comprises different approaches for diagnosing and treating coronary artery diseases. Interventional Cardiologists are trained to perform procedures on cardiac valves and other cardiac structures. The Standard was developed as per current best practice and to meet the health sector's evolving needs. The Standard includes the registration and licensure requirements for health facilities, minimum requirements for healthcare professionals, staff management plan, case assessment, patient referral, pre-operative and post-operative care, equipment requirements and documentation management requirements. Additionally, the standards establish the minimum number of IC procedures for the health facility.

When reviewing the Standard, it is recommended to review the DHA Health Facility Guidelines 2019- Part B- Health Facility Briefing and Design, 40 – Cardiac Investigations Unit. DHA licensed health facilities or professionals should not construe the Standard for delivering healthcare services in a manner not authorised by federal and local laws and regulations.

DEFINITIONS

Angiography: Coronary angiography is an x-ray examination of the coronary arteries (right, left and circumflex) which are narrow tubes that lie on the outside surface of the heart. Their function is to take blood to the heart muscle.

Angioplasty: is a procedure in which a narrow tube (catheter) is threaded into the heart with a deflated balloon at the tip. The procedure is also known as percutaneous intervention. The balloon is inflated to open areas where blood flow has been reduced or blocked. During an angioplasty, the physician may also implant a stent (mesh tube) to help open the artery, reducing the chance of another blockage. In laser angioplasty, the catheter carries a laser tip that sends pulsating beams of light to clear blockages instead of a balloon.

Atherectomy: is a procedure in which a rotational shaver ("burr") is placed at the tip of a catheter, and guided to the affected area, and used to remove plaque from the artery walls. It may also be used from time to time to vaporise the plaque.

Balloon valvuloplasty: also known as balloon valvotomy, is typically used to repair heart valves that do not open properly (e.g., aortic stenosis, narrow or constricted valves). During the procedure, a balloon is used at the tip of the catheter and inflated to stretch the valve open.

Cardiac catheterisation: is used to determine the severity and extent of cardiovascular problems, in which an incision is made in either the arm or groin to thread a catheter into a blood vessel.

The catheter is carefully guided through to the blood vessel to reach the heart. Cardiac catheterisation, physicians can:

- Collect blood samples;

- Take blood pressure readings;
- Analyse the size and location of plaque deposits;
- Assess the strength of the valves and heart muscle; and
- Inject dyes that are visible on x-rays into arteries to see how well blood is flowing. Information from the cardiac Cath can help determine if a cardiac surgery or another IC procedure, such as angioplasty, is necessary.

Cardiologist: is a physician who diagnoses and treats heart problems.

Cardiology: is the study of the heart and its functions in health and disease.

Coronary Angioplasty: Coronary Angioplasty or Percutaneous Coronary Intervention (PCI) is a procedure used to open arteries that have become narrow due to atherosclerosis. An incision is made on the leg or wrist, and a catheter is inserted through a blood vessel and threaded to the heart. Once the catheter (with a balloon at the tip) reaches the blockage, it may be inflated more than once to push plaque to the artery walls and widen the artery to improve blood flow.

Health Facility: A DHA licensed entity authorised to provide medical services whether its owner or manager is an individual or an organisation.

Healthcare Professional: shall mean healthcare personal working in health facilities and required to be licensed as per the United Prequalification Requirements for licensure.

License: Authorisation granted by DHA to the health facility to provide healthcare services within the Emirate of Dubai under the jurisdiction of DHA.

Medical Director: is a DHA licensed physician or dentist who manages and runs, and has clinical oversight of a DHA licensed health facility and its clinical staff.

Patient: An individual who receives medical attention, care or treatment by any healthcare professional or is admitted to a health facility.

Percutaneous Coronary Intervention (PCI): This is a method of opening narrow coronary arteries using fine tubes called catheters. Catheters can be inserted from the wrist or groin. Severe narrowing of the arteries is typically treated with stents (fine mesh tubes).

Physician: refers to a DHA licensed physician or dentist who, by education, training and certification, is qualified to provide healthcare services within their scope of license with privileges granted by the Medical Director.

Percutaneous Valve Repair: is a procedure in which an interventional cardiologist uses a catheter to guide small devices through the blood vessels to repair a damaged valve. The devices are used to repair the valve to allow blood to flow properly again.

Privileges: This is the process of issuing a DHA licensed physician/dentist permission to carry out specific duties as per the DHA Clinical Privileging Policy.

Stent: A wire mesh tube inserted into a narrowed coronary artery to allow the heart muscle to function normally/reinforce the artery wall. A stent may be placed in narrowed carotid arteries to treat patients at high risk for stroke. A balloon and catheter are often used when stenting and removed. The stent remains permanently, and in a few weeks, tissue from the artery lining grows over the stent.

ABBREVIATIONS

ACLS	:	Advanced Cardiac Life Support
BLS	:	Basic Life Support
CPD	:	Continuing Professional Development
DHA	:	Dubai Health Authority
DM	:	Dubai Municipality
HFG	:	Health Facility Guidelines
HRS	:	Health Regulation Sector
IC	:	Interventional Cardiology
IEC	:	International Electro-technical Commission
MD	:	Medical Director
PALS	:	Pediatric Advanced Life Support
RN	:	Registered Nurse

1. BACKGROUND

Interventional cardiology sits under the umbrella of cardiology and is a subspecialty that uses specialised diagnostic and imaging techniques to evaluate blood flow and pressure in the heart and coronary arteries. Interventional Cardiology entails catheter-based treatment of heart diseases, which impair the cardiovascular system's function, for example, coronary artery diseases, vascular diseases, and acquired structural heart diseases. The majority of the interventions involve treating narrowing valve(s) or stenoses in the coronary system. Percutaneous Coronary Intervention (PCI), also known as coronary angioplasty, is the most common coronary revascularisation procedure. Other techniques and interventions include Angioplasty and Valvuloplasty (usually mitral, aortic, or pulmonary). The main advantages of interventional cardiology include avoiding scars, pain, reduced length of stay and faster recovery.

Operational efficiency forms an integral part of day-to-day hospital business operations and has become increasingly relevant to cardiac catheterisation laboratories due to changes in reimbursement models globally. Optimal performance for coronary interventional procedures also forms an important part of the practice and requires extensive knowledge, substantial technical skills and adequate patient volumes. Hospitals that provide interventional procedures must put plans for operational efficiency and optimal performance to assure patient safety and high quality of care.

2. SCOPE

2.1. Management of Interventional Cardiology services authorised by DHA.

3. PURPOSE

3.1. To strengthen the quality and patient safety for Interventional Cardiology services.

4. APPLICABILITY

4.1. DHA Licensed General Hospital.

4.2. DHA Licensed Specialty Hospital.

5. STANDARD ONE: HEALTH FACILITY LICENSURE

5.1. A health facility seeking to provide Interventional Cardiology services is required to be licensed by DHA.

5.2. DHA licensed health facilities opting to add Interventional Cardiology services to an existing hospital license are required to:

5.2.1. Apply to HRS to obtain permission to add the service to the existing health facility license.

5.2.2. Meet the facility design requirements as per DHA Health Facility Guidelines (HFG), 2019, Part B - Health Facility Briefing and Design, 40 - Cardiac Investigations Unit.

5.2.3. Be accredited by an internationally recognised accreditor for Interventional Cardiology Services.

5.2.4. Install and operate equipment required for Interventional Cardiology Services
(**Appendix 1**) in accordance with the manufacturer's specifications and requirements.

- a. Make use of new technology recommended to keep up to date with complex cases.
- b. Drug-eluting stents, covered stents, intracoronary ultrasound and distal protection and intracoronary pressure measurements should be readily available for certain patients.

5.2.5. Develop policies and procedures related to the Interventional Cardiology Services to include but not limited to:

- a. Service Description and Scope.
- b. The clinical care pathways to be followed.
- c. Cath Lab Workflow (Schedule to Discharge).
- d. Staffing Plan.
- e. Emergency and Disaster Management Plan.
- f. Equipment maintenance.
- g. Incident reporting.
- h. Infection control measures and hazardous waste management.
- i. Medication management.
- j. Patient acceptance criteria.

- k. Patient assessment and admission.
 - l. Patient discharge/transfer.
 - m. Patient education and Informed consent.
 - n. Patient health record.
 - o. Patient privacy.
 - p. Use of thrombolytics as per international best practice.
 - q. Transfer of emergency/critical/complicated cases.
- 5.2.6. Provide documented evidence for the following services:
- a. Ambulance service.
 - b. Clinical laboratory service.
 - c. Equipment maintenance service.
 - d. Laundry service.
 - e. Medical waste management as per Dubai Municipality (DM) requirements.
 - f. Housekeeping services.
- 5.2.7. Have in place a contract for elective and emergency patient transfer to a higher facility to manage complex cases.
- 5.2.8. Maintain a Charter of patients' rights and responsibilities at the entrance and reception in two languages (Arabic and English).
- 5.2.9. Maintain and document a plan for monitoring electrical and mechanical safety equipment, with monthly visual inspections for apparent defects.

- 5.2.10. *Have at least one (1) fully equipped cardiac catheterisation lab with sophisticated digital high-quality radiographic cardiac imaging, multi-angle rotation, and multiple image manipulation.*
- a. *Where volume exceeds 500 procedures per year per cath lab, the facility should agree with at least one nearby facility with a cath lab for elective referral to ensure continuity of the service in the case of breakdown or for effective management of emergency cases.*
- 5.2.11. Fulfil the complete setup for cardiopulmonary support and procedures under general anaesthesia.
- 5.2.12. Ensure surgical backup with a cardiac surgeon to accommodate emergency bypass surgery due to life-threatening anatomy or suboptimal PCI results.
- 5.2.13. Intra aortic balloon pump should be readily available.
- 5.2.14. Intravascular ultrasound should be readily available.
- 5.2.15. Flow measurements by wire technology, instruments for intracoronary pressure and physiological measurement system should be readily available.
- 5.2.16. Radiation protection programme to comply with optimal radiation safety measures.
- 5.2.17. Maintain adequate adjunctive medication, such as IIb/IIIa inhibitors, must be readily available.
- 5.2.18. Maintain comprehensive stock and choice of guiding catheters, balloons, stents, wires and special devices.

5.2.19. Ensure adequate lighting and utilities, including temperature controls, water taps, medical gases, sinks and drains, lighting, electrical outlets and communications.

6. STANDARD TWO: HEALTHCARE PROFESSIONAL REQUIREMENTS

6.1. All healthcare professionals providing Interventional Cardiology services must hold a valid DHA professional license for Interventional Cardiology and work within their scope of practice.

6.2. Interventional Cardiology services shall be Specialist or Consultant-led with a minimum of five years of experience.

6.3. Minimum staffing requirements dedicated to an Interventional Cardiology Unit shall include the following:

6.3.1. Two full-time Specialists or Consultant Interventional cardiologists for 24/7 coverage.

a. For Pediatric cases, a Consultant pediatric interventional cardiologist shall be appointed.

6.3.2. Two full-time registered Nurses trained in IC procedures.

6.3.3. Two Technicians (Cardiovascular Technologist or Cardiovascular Technician).

6.3.4. One Administration staff.

6.3.5. One Biomedical Engineer or a contract with a certified maintenance company to ensure safety and efficiency of equipment used.

- 6.3.6. Access to an on-site full-time Anesthetist to manage emergency cases.
- 6.3.7. Access to an on-site full-time Cardiac Surgeon to manage emergency cases.
- 6.4. Arrangements for additional staff should be made to manage complex procedures.
- 6.5. The Medical Director (MD) and the privileging committee of the health facility shall privilege the physicians aligned with their education, training, experience and clinical competencies and reviewed as per DHA Clinical Privileging Policy.
- 6.5.1. *The health facility licensed to perform Interventional Cardiology shall achieve a minimum of two hundred (200) Interventional Cardiology procedures over two years to assure quality and patient safety.*
- a. Failure to meet the minimum requirements may lead to the following:
- i. Clinical Audit and performance review.
 - ii. Suspension of the facility license for Interventional Cardiology services.
 - iii. Exclusion from the Insurance network.
- 6.5.2. The physician licensed to perform IC should aim to undertake a minimum of one hundred (100) Interventional Cardiology procedures over a two-year period to maintain competencies in the related field and quality and patient safety.
- a. At least thirty-six (36) procedures per year should be done as the primary operator per year.

- b. Evidence of procedures shall be maintained and documented in the physician logbook.
- 6.6. The Registered Nurse (RN) designated to assist the physician during the IC procedures must be trained for six (6) months and be competent in critical care and/or emergency room and/IC procedures.
- 6.7. Healthcare professionals providing Interventional Cardiology Services must fulfil the following minimum annual Continuing Professional Development (CME) requirements relevant to the subject as per the Unified Healthcare Professional Qualification Requirements (PQR).
- 6.8. A written policy on staff training and the frequency of core competency assessment should be documented and monitored regularly.

7. STANDARD THREE: PATIENT CARE

7.1. Patient Assessment

- 7.1.1. The Interventionalist Cardiologist should undertake a comprehensive assessment before referring to the technician or technologist or confirming the IC procedure.
- 7.1.2. Decisions on complex cases should be made with more than one Interventionalist Cardiologist and, where necessary, with a multidisciplinary team.
- 7.1.3. The patient assessment shall include, but not be limited to the following:

- a. Verification of patient identification.
- b. Complaint/Procedure requested/prescribed.
- c. Medical history.
- d. Physical assessment.
- e. Psychological assessment.
- f. Medication and contraindications.

7.1.4. The Cardiovascular Technologist or Cardiovascular Technician should undertake patient assessment prior to providing appropriate diagnostic and therapeutic services.

7.1.5. Before starting the Interventional Cardiology procedure, nursing staff, anesthesiologist and performing physician must verify and assess the following:

- a. The correct patient and procedure being performed.
- b. Patient consent.
- c. Medical history.
- d. Factors that may negatively affect the procedure, e.g. medications, identification of any condition in the patient history, insufficient patient preparation or artefact producing objects.
- e. Patient laboratory values before the procedure.
- f. Patient risk for allergic reaction to medication.
- g. Medication and contraindications.

7.2. Information Analysis

7.2.1. The information obtained during the assessment shall be analysed to identify the most appropriate plan of action for the procedure in conjunction with the cardiovascular team to enhance patient safety and comfort, optimise diagnostic and therapeutic quality and improve efficiency.

- a. Consultation with the most appropriate medical personnel should take place.
- b. To determine the best action plan.
- c. The need for select supplies, accessory equipment, shielding, positioning and immobilisation devices should be determined.
- d. The best course of action for an emergent situation should be determined.
- e. All procedural requirements should be in place to achieve a quality diagnostic or therapeutic procedure.

7.3. Patient Education

7.3.1. The patient and/or their carer should always be issued information on the recommended procedure and alternatives. The physician should:

- a. Address questions and concerns regarding the procedure.
- b. Address the effects and potential side effects of medications.
- c. Provide information regarding the risks and benefits of radiation.
- d. Seek consent and document the discussion points in the patient medical record.

7.4. Procedure

- 7.4.1. On the day of the procedure, confirm the patients' details and the procedure being undertaken.
 - 7.4.2. Adhere to the World Health Organisation Surgical Safety Checklist.
 - 7.4.3. All members of the team shall be present before the procedure and confirm the plan of action.
 - 7.4.4. The team should be ready for any changes in the action plan due to changes in the patients' clinical situation.
 - 7.4.5. The adoption of sterile techniques should be maintained during the procedure.
 - 7.4.6. The patient should be monitored for blood pressure, respiration, cardiac activity, oxygen saturation, level of consciousness pain and reactions to medications.
 - 7.4.7. Blood and tissue samples should be labelled and documented when required.
- #### 7.5. Documentation and performance evaluation
- 7.5.1. Assure documentation is maintained for quality improvement and Audit.
 - a. A database should be used to register all procedures. The database should document the following:
 - i. Indication for the procedure, technique performed and materials used, radiation exposure time, and procedure time (from the first puncture to removing the guiding catheter).

- ii. The procedure results in different vessels, complications in the catheterisation laboratory, coronary bypass surgery and mortality.

There should be information at hospital discharge.

7.5.2. Performance evaluation should be conducted to determine if the goals of the action plan have been achieved.

- a. The evaluation should be undertaken in a timely, accurate and comprehensive manner.
- b. The procedure should be measured against established policies, protocols and benchmarks.
- c. Exceptions to the expected outcome should be identified.
- d. The revised action plan to achieve the intended outcome should be developed if required.
- e. The action plan and subsequent outcome must be communicated to all team members.

7.6. Post-procedural

7.6.1. Post-procedural care is an essential part of the PCI procedure. Patient selection for early discharge versus close electrocardiographic and haemodynamic monitoring is essential.

- a. Protocols for sheath removal, mobilisation, post-procedural medication, and managing bleeding complications should be in place.

- b. General instructions on risk factor modification should be given, and the medication for secondary prevention should be checked.

7.7. Discharge plan

7.7.1. The discharge plan should start at admission and include various personnel, information and resources. Considerations for discharge preparation should consist of but not be limited to:

- a. The pickup person.
- b. Travel distance to home.
- c. No driving policy.
- d. Environmental conditions, such as stairs, access to toilet or bedroom.
- e. The carer's contact details and their awareness of possible issues and requirements following discharge.
- f. Contact numbers after discharge, such as the physician or emergency contact.
- g. Discharge arrangements regarding home care, where this is identified as required and available.
- h. Healthcare professionals should use a formal risk assessment process.
- i. Food and drink consistent with the patient's condition and clinical care shall be provided.
- j. Provision of procedure report and appropriate medication.
- k. Follow up appointments.

8. STANDARD FOUR: EMERGENCY MANAGEMENT

- 8.1. Health facilities with limited capacity or expertise should refer elective or complex patients to a higher health facility with expertise for the procedure or patient group.
- 8.1.1. There should be a written agreement between transferring and receiving health facilities.
- a. Transfer of patient information shall be as per Patient Referral and Inter-Facility Transfer Policy.
- 8.2. A fully stocked and up to date crash cart shall be in place as per DHA Regulations for hospitals.
- 8.3. Appropriate pharmaceutical agents, oxygen, oral suction, laryngoscope, ambu-bag and defibrillator shall be readily available in the health facility.
- 8.4. The health facility shall ensure periodic training and education of staff in the use of equipment and the management of medical emergencies. Training and assessment of staff competencies shall be documented as per the requirements of the training provider.
- 8.5. Physicians shall have a valid Advanced Cardiac Life Support (ACLS) and Pediatric Advanced Life Support (PALS) certification where pediatric patients are treated, and Neonatal Resuscitation Program (NRP) whenever Neonatal patients are managed.
- 8.6. RNs and Cardiovascular Technologists or Cardiovascular Technician shall have a valid Basic Life Support (BLS).

9. STANDARD FIVE: EQUIPMENT USE AND MAINTENANCE

- 9.1. Instruments and equipment used in the performance of cardiovascular catheterisation procedures must be in good working condition. The instruments and equipment should comply with the International Electrotechnical Commission (IEC) 60601-2-43 Interventional Standard.
- 9.2. All equipment and instrumentation should be routinely inspected for safety, and proper functionality and records of the inspections should be maintained in a file.
- 9.3. Equipment used in the Cardiac Catheter Laboratories and Cardiac Diagnostic Unit should be safe to minimising potential hazards.
- 9.4. Ensure that equipment performance, maintenance and operation comply with the manufacturer's specifications.
- 9.5. The physician is responsible to check the final status, readiness, functionality and safety of the equipment.
- 9.6. All equipment shall be calibrated and adjusted.
- 9.7. All repairs and maintenance should be documented for quality control and Audit.

10. STANDARD SIX: KEY PERFORMANCE INDICATORS (KPIs)

- 10.1. Key Performance Indicators shall be captured by IC providers and maintained for audit and performance review. Submission of performance report will follow DHA Guidelines for IC and will predominately include metrics for access and quality.

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APPENDICES

APPENDIX 1: COMMON PROCEDURES CONDUCTED BY INTERVENTIONAL CARDIOLOGISTS

1. Invasive Diagnostic and IC procedures:

- Coronary Angiography/Cardiac Catheterisation/Percutaneous Coronary Interventions;
- Angioplasty, Stent Implantation and Rotablator Treatment;
- The Percutaneous Device Closure of Atrial Septal Defect (ASD);
- Patent Foramen Ovale (PFO);
- Percutaneous Balloon Valvuloplasty Of Mitral, Aortic And Pulmonary Valves;
- Percutaneous Aortic Valve Replacement;
- Intra-aortic Balloon Counterpulsation;
- Intravascular Ultrasound Imaging;
- Pressure Wire Measurement;
- Percutaneous Cardiopulmonary Bypass; and
- Rotational Coronary Atherectomy.

2. Percutaneous coronary interventions using currently available technologies, including:

- Drug-eluting stents;
- Rotational Atherectomy;
- Thrombectomy devices;
- Distal protection devices;
- Intravascular ultrasound; and
- Fractional-flow reserve.

3. Diagnostic and therapeutic coronary and endovascular procedures, including:

- Hemodynamic evaluation of patients;
- Diagnostic angiography;
- Pericardiocentesis; and
- Variety of closure devices to include left ventricular assist devices (and Impella).