Cardiac Catheterization Laboratory (CCL)

Standards and Best Practice Guidelines for Pakistan 2017

CARDIAC CATHETERIZATION LABORATORY (CCL) STANDARDS AND BEST PRACTICE GUIDELINES FOR PAKISTAN 2017

1. STANDARDS FOR HOSPITALS:

A). FULL SERVICE LABORATORIES (LEVEL-I) are defined as those offering a wide variety of diagnostic and interventional procedures (all sorts of coronary and peripheral endovascular interventions, Primary PCI, structural heart disease interventions), with on-site cardiac surgical services to accept patients requiring immediate surgery because of clinical instability or complications of procedures.

REQUIREMENTS

Full-service CCLs must document the on-site presence of:

i. Cardiovascular surgery
ii. Cardiovascular anesthetists
iii. Intensive care unit
iv. Nephrology consultative services and dialysis (on-site or on-call)
v. Neurology consultative services (on-site or on-call)
vi. Hematologic consultative and blood bank services
vii. Echocardiography (TTE &TOE) and Doppler
viii. MRI, CT – Optional
ix. If a pediatric catheterization laboratory, similar services for pediatric-aged patients
x. Mechanical support devices are also required and, at a minimum include an adequate number of intra-aortic balloon or Impella catheters to support the function of the lab 24/7 on call service to handle emergencies resulting from procedures during the day
xi. Full-service CCLs must define the procedures performed and excluded in their laboratory and define the process for the introduction of new procedures into their laboratory setting.

B. LABORATORIES WITHOUT ON-SITE CARDIAC SURGERY (LEVEL-11) offer a limited range and interventional services i.e., coronary and peripheral endovascular interventions/ Primary PCI (subject to meeting of patient eligibility criteria mentioned below) and require patients needing urgent surgery to be transferred to another facility.

REQUIREMENTS

Level-Il CCLs must document the on-site presence of:

i. Coronary care unit
ii. Intensive care unit
iii. Hematologic consultative and blood bank services
iv. Echocardiography (TTE&TOE) and doppler
v. Mechanical support devices are also required and, at a minimum include an adequate number of intra-aortic balloon or impella catheters to support the function of the lab
vi. A working relationship between the interventional cardiologists and cardiac surgery service at the receiving hospital documented by a letter of support from e surgical group to accept cases
vii. A mechanism whereby a cardiac surgeon has the ability to review coronary angiograms before elective procedures and provide comments to the cardiologist and, if necessary, patients.
viii. Surgical backup available at all hours for urgent cases and for elective cases at mutually agreeable times.
ix. Confirmed availability of cardiac sur and a next available Operating Room before elective procedures begin per written agreement.
x. Mechanism for direct discussion between the Cardiologist and cardiac surgeon should urgent transfer be necessary.
xi. A written transfer agreement endorsed by both facilities and documentation of a rehearsed plan for the transport of patients to a facility with cardiac surgery and the ability to have patients on cardiopulmonary bypass within 90 minutes of the onset of the emergency.
xii. A transport provider able to begin transfer within 20 minutes.
xiii. A PCI consent form that explains that the procedure is being performed without on-site surgery and what will occur if surgery is necessary.

Patient Eligibility Criteria:

i. CCLs without on-site surgery must define the diagnostic and interventional procedures performed and excluded from their laboratories.

ii. Diagnostic procedures excluded from facilities without on-site surgery include patients with pulmonary edema due to ischemia, complex congenital heart disease, and all pediatric procedures.

iii. Therapeutic procedures excluded from facilities without on-site surgery are therapeutic procedures for pediatric and adult congenital heart disease. Elective and primary PCI procedures are permitted in sites without on-site cardiovascular surgery if there is strict adherence to national guidelines and a documented working relationship with a full service facility. There must also be a tested emergency transport system in place.

iv. Elective High-risk patients and high-risk lesions may be unsuitable for intervention at facilities without onsite surgery.

v. **High-risk patients are defined by:**

   a. decompensated CHF (Killip Class 3 to 4)
   b. recent (<8 weeks) CVA
   c. known clotting disorder,
   d. left ventricular ejection fraction ≤30%,
   e. chronic kidney disease (creatinine> 2.0 mg/dL or creatinine clearance < 60 mL/min)
   f. serious ongoing ventricular arrhythmias.

vi. High-risk lesions are defined by:

   a. left main stenosis > 50% or 3-vessel disease (>70% proximal or mid lesions) unprotected by prior bypass surgery diffuse disease,
   b. target lesion that jeopardizes an extensive amount of myocardium,
   c. diffuse disease (>20 mm length),
   d. extremely angulated segment or excessive proximal or in-lesion tortuosity (defined as > two 45-degree bends before the target stenosis,
   e. greater than moderate calcification visible proximal and at the target stenosis,
   f. inability to protect major side branches,
   g. older degenerated vein grafts with friable lesions,
   h. thrombus in the target vessel or at lesion site,
   i. chronic total occlusions (defined as >3 months in duration and or bridging collaterals),

j. vessel characteristics that, in the operator's judgment, would impede stent deployment and k) anticipated probable need for rotational or other atherectomy device, cutting balloon etc.

C. HOSPITAL-BASED DIAGNOSTIC ONLY LABORATORIES (LEVEL III) and freestanding laboratories that do not perform coronary interventions and are usually only for elective diagnostic procedures.

REQUIREMENTS

Level-III CCLs must document the on-site presence of

i. Coronary Care unit
ii. Hematologic consultative and blood bank services
iii. Echocardiography (TTE&TOE) and Doppler
iv. Mechanical support devices are also required and at a minimum include and adequate number of intra-aortic balloon or impella catheters to support the function of the lab.
v. Such laboratories must have a written and rehearsed plan for the transport of patients to a facility with surgery. A formal transfer agreement is a requirement.

Patient Eligibility Criteria: Patient exclusions for such laboratories should include:

i. NYHA Class 4,
ii. pulmonary edema due to ischemia,
iii. those with known peripheral vascular disease if no vascular surgery available,
iv. complex congenital heart disease,
v. acute coronary syndromes and
vi. all pediatric procedures

2. STANDARDS FOR EQUIPMENTS:

a. Digital fluoroscopy and angiography with multiple image intensifier/ flat panel sizes and on-line image storage and retrieval capabilities
b. Physiologic monitoring with pressure, pulse oximetry and ECG channels.
c. Appropriate inventory of disposable supplies for vascular access management, diagnostic coronary angiography and ventriculography
d. Facilities performing PCIs must have a varied inventory of coronary guiding catheters, coronary guide wires, angioplasty balloons coronary stents and other

treatment devices commensurate with the scope of services provided by the laboratory

e. Emergency management equipment and systems that are readily available in the CCL. This includes resuscitation equipment, a biphasic defibrillator, vasoactive and antiarrhythmic drugs, endotracheal intubation, temporary trans-venous pacemakers, intra-aortic balloon pump, pericardiocentesis equipment, and personnel trained on their indications and use.

f. A process documenting routine preventive maintenance and testing of laboratory equipment based on vendor recommendations, including a comprehensive radiation safety program.

g. For radiographic systems this includes but is not limited to:

i. image quality,
ii. dynamic range,
iii. modulation transfer function,
iv. fluoroscopic spatial resolution,
v. fluoroscopic field of view size accuracy,
vi. low contrast resolution,
vii. record fluoroscopic mode
viii. automatic exposure control under standard conditions and at maximum output
ix. Calibration of integrated radiation dose meters.

h. The operational efficiency of infrequently used equipment by regular assessment of their function with logs kept to include personnel training updates.

i. Functional UPS/Generator with service log book is compulsory

3. STANDARD FOR CATH LAB OPERATORS AND STAFF

a) Eligibility to Perform "Independent" Interventional Cardiology Procedures:

The operator can perform interventional cardiology procedures in only a PSIC registered cath lab. For registration, log on to psic.com.pk

All hospitals should have a Credentialing committee that reviews the individual physician's credentials and allows them privileges of carrying out defined procedures in that hospital. All certified labs should have a cath. Lab director, who should be a credentialed interventional cardiologist with preferably 5 years of experience as interventional cardiologist. The operators should be granted eligibility to perform the procedures

independently based on the following proposed qualification and clinical experience criteria:

1. Training Pathway

i. FCPS in interventional cardiology/ American Board of Interventional Cardiology/ MRCP with specialized cardiology training in interventional cardiology post fellowship (Completed Certificate of Specialized Training in Cardiology (CCT) UK, or equivalent.

ii. FCPS cardiology, or equivalent, with at least 3 years post fellowship adequate supervised training/experience in interventional cardiology at CPSP recognized and PSIC registered Catheterization laboratory under the supervision of a certified interventional cardiologist. He /She should have done at least 75 procedures/year as primary operator. Training Experience certificate to this effect should be provided by the Catheterization laboratory director HOD or Head of institute.

2. Practice Pathway:

i. FCPS medicine/MRCP Diplomate American Board of Interventional Cardiology/ MRCP with at least 15 years of practical experience in interventional cardiology with at least 75 procedures per year in last 2 years. This exemption is given till 2023 only after which formal 2 years training FeIlowship in Interventional cardiology will be mandatory.

ii. One-time exemption would be given to all senior cardiologists with MBBS, with at least 25 years of active interventional cardiology practice within the country or outside. (This relaxation will be considered a one-time only exemption and will NOT be applicable to anyone in future).

These Criteria would be monitored on yearly basis till 2023 when FCPS in interventional cardiology or equivalent training abroad, would become mandatory to practice interventional cardiology in country. If demand of interventional cardiology fellows is not met by 2023 than time line for implementation of this condition may be extended.

b. Physician Extenders and Cardiology Fellows:

i. The primary operator should always be a physician. Non-physician health care providers should always be viewed as extensions of the primary operator's hands, with the responsibility for safety ultimately residing with the invasive cardiologist. Interventional fellows may be considered primary operators for training purposes only at PSIC approved lab or equivalent foreign facility. An attending must be administratively identified as the primary operator.

ii. Appropriately trained and credentialed non-physician providers may perform pre-procedural evaluation and post procedural follow-up care.

iii. Physician extenders should be proficient in both the technical and cognitive aspects of cardiac catheterization and Percutaneous intervention including:

a. pre-procedure evaluation,
b. indications,
c. the anatomy and pathophysiology of the conditions in which they will assist the physician,
a. emergency cardiac care,
b. radiation safety, and
c. the application of diagnostic data to the management of patients.

iv. Facilities should have policies regarding the supervising role of the primary operating physician during the procedure when secondary operators are performing the procedure and direct the non-physician provider or cardiology fellow in addition to providing all clinical decision making.

C. Nursing Personnel:

I. There must be a Registered Nurse that functions as Nursing Supervisor for the CCL. This individual must be familiar with the overall function of the laboratory. This individual may or may not also function as the Technical Supervisor of the CCL.
II. The nursing supervisor should be in charge of the pre and post procedure areas as well as the procedure laboratories.
III. The nursing supervisor must ensure that all local patient care policies and procedures are followed and that all laboratory nurses are properly trained for the level of patient care they deliver.
IV. The number and type of nursing personnel required depend on the laboratory caseload and types of procedures performed. Personnel may include nurse practitioners, registered nurses, licensed vocational practical nurses, or nursing assistants.
V. The experience of catheterization laboratory registered nurses should preferably include one-year critical care practice, knowledge of cardiovascular medications, ability to start IVs and administer drugs, sterile technique, skills in monitoring vital signs, neurologic status and pain level. Nurses administering conscious or deep sedation require additional training established by the facility and demonstration of competence.
VI. Properly trained nursing assistants may also be used for some functions in laboratories.
VII. Skilled allied health professionals in the laboratory (nurses and technicians) must be trained and experienced in evaluating patients before and after catheter based interventional procedure.

d. Technologists and other Personnel:

i. Each CCL should have at least one technologist. If not a certified radiological technologist there should be at least one certified technologist skilled in radiographic and angiographic imaging principles and techniques such as the performance of X-ray generators, cine-pulse systems, image intensification, video and digital image storage, radiation safety principles and pressure injection systems.

ii. The responsibilities of technicians in the laboratory should be defined and can include responsibility for the routine maintenance' of radiological equipment, monitoring radiation safety, management of blood samples and calculations, monitoring and recording of ECG and hemodynamic data, data storage, operation of other equipment (i.e. IABP, IVUS, rotational atherectomy, etc.) and other responsibilities as established by the facility including administering medications.

4. STANDARDS OF PRE-PROCEDURE PRACTICE:

4.1. Informed Consent:

i. Informed consent is necessary before every procedure and is consistent with the ethical principles of patient autonomy. Informed consent for non- emergent procedures must be obtained and documented before the procedure and in a non-pressured environment before any sedation is given. To be valid, the patient must be competent and voluntarily provide consent; otherwise, a person with power of attorney may act as a surrogate. Ideally, the IC process should be witnessed by a third party, preferably by the patient's family or a staff member independent of the CCL, and subsequently entered into the medical record. The consent must' be obtained within 30 days (sooner, if indicated by hospital policy), and must be reaffirmed on the day of the procedure.

ii. The hospital must have a written policy on IC that describes the process used to obtain consent, including documentation and surrogate decision-maker issues. Each facility must have an approved consent form present in the medical record that includes risks, benefits, and alternatives to the procedure in terns the patient or a layperson can understand. This should include the potential for ad hoc PCI and its risks/benefits, and alternatives when appropriate. The IC should be in the patient's native language.

iii. The written informed consent may be obtained by trained secondary operators or non-physician providers. Confirmation of consent should be obtained during preparation or time out.

iv. Procedures that the patient has not consented to must not be performed unless it is a life-threatening emergency and the reasons for this must be documented.

v. If possible informed consent should be obtained for emergent procedures. However, it is recognized that there are circumstances where written informed consent may not be feasible, in which case local standards for documentation of necessity should apply and the need clearly documented in the patient's records.

4.2 Ethical concerns:

i. A physician's primary obligation is to act in the best interest of his or her patient; Associated with this is the obligation to "do not harm," and respect patient autonomy.
ii. The respect for autonomy mandates that patients be given appropriate and un-coerced choices about their health and potential medical care and requires that physicians provide accurate and unbiased information about the patient's medical condition, and disclose all potential avenues of care.
iii. The physician is responsible for obtaining satisfactory informed consent, and delineating the potential risks, benefits, and alternatives of the agreed-upon diagnostic and/or therapeutic strategy.
iv. The physician is responsible for documentation of the indication for the procedure and to document review of appropriate data (e.g., noninvasive tests).
v. In addition, the physician must be transparent concerning any and all potential ethical or financial conflicts concerning therapies or devices employed in the patient's care.
vi. Although many challenges face cardiologists today, high ethical standards, including maintenance of proficiency, avoidance of real or perceived financial conflict of interest, disclosure of potential conflicts, and, most important, maintaining the patient's best interest as primary, remain of paramount importance.

4.3 Allergies:

i. Allergies to latex, contrast, heparin (and heparin-induced thrombocytopenia), aspirin, narcotics, and other medications should be documented.

ii. Each CCL should have a protocol for preventing contrast reactions, written protocol or standardized order sets for the treatment of patients with known radiographic contrast allergy and a protocol for the treatment of anaphylaxis should it occur.

4.4 Laboratory values and outside reports:

i. should be available and reviewed by the physician before the procedure. Hemoglobin, platelet count, electrolyte panel, renal function testing and, in the anti-coagulated patient or.one with known important liver disease a prothrombin time/INR should be obtained on all patients within 30 days of the procedure. A pre-procedure type and screen is optional.

4.5 Medications:

i. Initiate antiplatelet therapy prior to the procedure when PCI is possible/likely.

ii. Review potential issues with long-term DAPT for these patients.

íii. Discontinue warfarin with goal INR <1.8 on day of procedure. (Consider radial access especially for emergency cases).

iv. Discontinue novel oral anticoagulants 1-2 days prior to procedure.

v. Adjust insulin dosing for NPO status.

vi. Hold Metformin on day of procedure and restart a minimum of 48 hours after the procedure.

5. STANDARDS FOR INTRA PROCEDURE PRACTICE:

a. Upon arrival to the procedure room, a nurse, technologist, APP, physician extender, or physician should review the pre-procedure checklist.

b. Noninvasive hemodynamic and oximetric monitoring of patient vital signs should be routine. Defibrillation pads should be attached to all STEMI patients.

c. Access related risks should be considered with the goal ok choosing the optimal access site to reduce complications.

d. CCL staff should ensure that at least one working IV is in place prior to the start of the procedure.

6. STANDARDS FOR POST PROCEDURE PRACTICE:

6.1 Physician to Patient Communication:

I. The physician should discuss the findings, interventions performed, and complications directly with the patient and family.
II. The post procedure management plan should also be addressed
III. Discussions with patients should be delayed until cognitive impairment due to sedation has resolved.

6.2 Access Site Management and Closure Devices:

i. **Femoral**: Manual compression, compression devices, and VCDs are all options in cases of femoral access.
ii. **Radial**: Hemostasis by manual compression for the radial access site is usually obtained with wristband compression devices.

7. PATIENT OUTCOMES:

a) Adverse in-hospital patient outcomes (complications) must be reviewed for diagnostic procedures. Participation in the NCDR or CROP-Cath PCI Registry fulfills the data collection requirements for diagnostic procedure complications. All cath labs must become part of NCDR or CROP — Cath PCI Registry. In the absence of participation in the NCDR or CROP —Cath PCI Registry, the complications assessed must include:

i. In-hospital mortality for patients with STEMI and without STEMI,
ii. rate of unplanned CABG
a. Same Day b. Same Hospitalization c. Emergent d. Urgent e. Elective
iii. proportion of STEMI patients receiving immediate PCI within 90 minutes,
iv. rate of procedure-related q-wave MI or ischemia,
v. rate of post procedure stroke, TIA or other neurological event,
vi. rate of vascular complication
vii. rate of arrhythmia requiring treatment a. rate of cardiac arrest in the Cath Lab.
viii. rate of new hemodynamic instability in the Cath Lab.
ix. rate of non-obstructive disease (all stenoses in major arteries < 50% diameter reduction in severity for elective procedures)

b) Although risk adjustment for mortality and bleeding are reported for NCDR Cath PCT Registry participants, it is recognized that these algorithms may not be available for those facilities not participating in the registry.

c) Facilities must have written definitions of the complications that are consistent with and allow comparisons to NCDR/CROP benchmarks. Complications should be assessed through hospital discharge.

d) Facilities should have an established system for the follow-up of renal function in patients at high-risk (i.e. GFR <60) for contrast nephropathy.

e) Participation in a national database or international database fulfills all the data collection requirements for interventional procedure outcomes and complications.

f) If the facility does not participate in any registry, the complications assessed must include death, MI, stroke, cardiogenic shock, emergency CABG, peripheral vascular/access site complications (significant hematoma, pseudoaneurysm, AV fistula, loss of radial pulse, need for vascular surgery or blood transfusion), pericardial tamponade, and the occurrence of contrast-associated nephropathy. Facilities must have written definitions of the complications with risk-adjustment of these complications using a documented methodology, Complications should be assessed through hospital discharge. Many laboratories also have mechanisms to assess 30-day outcomes. This is suggested.

1. Reporting of results:

I. Preliminary procedure reports must be written or dictated immediately after the procedure.

II. There must be enough information in the record immediately after the procedure to manage the patient throughout the post-procedure period. This information could be entered as the procedure report or as a hand-written operative progress note.

III. If the procedure report is not placed in the medical record immediately after the procedure due to transcription or filing delay, then a progress note should be entered in the medical record immediately after the procedure to provide pertinent information for anyone required to attend to the patient. Immediately after the procedure is defined as "upon completion of procedure, before the patient is transferred to the next level of care."

IV. The procedure progress note should contain at a minimum information including: a) name of the operator, b) procedures performed and description of each procedure, c) findings, d) estimated blood loss, e) specimens removed if appropriate f) complications, g) post-operative diagnosis and h) recommendations.

V. All procedure reports at a facility should be individualized to the institution, standardized among operators and contain relevant content on each of the following topics:
VI. Patient demographics, primary operator and supporting staff present and procedures performed.
VII. Indications for each component the procedure (e.g. right heart catheterization, renal angiography, etc.)
VIII. Appropriate supporting history, physical findings, and laboratory findings.
IX. The time course and procedural events with technical comments if helpful.
X. Access site information.
XI. All catheters, sheaths, guide wires, and interventional equipment used should be reported in a procedural section.
XII. Drugs and doses given during the procedure, type and amount of radiographic contrast used, estimation of radiation exposure should be included in the procedure report.
XIII. Clear description of any complications or a positive statement that there were no apparent complications.
XIV. For diagnostic procedures a complete summary of hemodynamic findings (pressures, outputs, resistances, valve areas, etc.)

8. STANDARDS FOR RADIATION SAFETY:

a. Each CCL should have a program to document the radiation exposure to patients and staff.
b. Each CCL facility must establish a radiation safety education program either in conjunction with the hospital Health Physics Department/ Medical Physicist and/or an outside consultant and/or assistance from a web-based tutorial. Documentation of personnel training in radiation safety must be provided.
c. Each facility must monitor staff radiation dose through the use of personal dose monitors. Follow-up should occur if an individual's dosimeter readings are substantially above or below the expected range for their in-laboratory responsibilities.
d. This program should have the following mandated components:
    i. Initial training or verification of prior training for all physicians and staff using fluoroscopy in the CCL;
    ii. Annual updates on radiation safety;

iii. Hands on training for new operators in a facility and existing operators on newly purchased equipment.

e. All CCL procedures should be performed with the goal of keeping radiation doses as low as reasonably achievable (ALARA).
f. All personnel in the room should wear personal protective equipment, including lead aprons and thyroid shields as well as radiation badges. For team members closest to the radiation source, leaded glasses should be used.
g. A wide array of strategies to reduce radiation exposure to patients and operators should be practiced.
h. Patient radiation dose needs to be monitored and recorded.
i. This should include the fluoroscopic time (FT, min), and total air kerma at the interventional reference point (Ka,r, Gy) and/or air kerma area product (PKA , Gycm2). Peak skin dose (PSD), Gy) should be included if technology permits its measurement.
j. A surveillance program should be in place for patients whose recorded total air kerma at the interventional reference point (Ka,r,) is 5 Gy or greater, Pka of 500 Gycm2, and/or fluoroscopy doses that exceed 60 minutes. This program should include the dose and a reason for this dose, patient notification, medical physicist/health physics involvement for Ka,r>IOGy, and a mechanism for patient follow up of potential adverse effects from rad radiation.