2015

ACE Standards

for Catheterization Laboratory Accreditation

Accreditation for Cardiovascular Excellence
Quality in Invasive Cardiovascular Care

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Specific criteria required for accreditation by ACE are highlighted in red.

1. STANDARDS: Facility

A variety of different procedures are now available in the cardiac catheterization laboratory (CCL). These include, but are not limited to hemodynamic evaluation, coronary and bypass graft angiography, abdominal and thoracic aortography, percutaneous coronary intervention (PCI), peripheral angiography and intervention, cervico-cerebral angiography and interventions and interventions for structural heart disease. Depending on local needs, some laboratories may be used for electrophysiology diagnostic and therapeutic procedures with device implantation plus other non-vascular interventional procedures. The standards herein relate to the core functions of all CCLs, specifically diagnostic cardiac studies and percutaneous coronary intervention (PCI). Separate standards exist specifically for carotid artery stenting and are being developed for other procedures such as peripheral angiography and interventions, valvular interventions and structural heart disease interventions performed in the modern CCL.

Each facility must document that they have the resources to safely perform the procedure offered in their laboratory. These vary with the type of CCL as defined below:

Full service laboratories are defined as those offering a wide variety of diagnostic and interventional procedures with on-site cardiac surgical services to accept patients requiring immediate surgery because of clinical instability or complications of procedures. Full-service laboratories operate 24/7, 365 days/year.

For ACE accreditation:

1.1. Full-service CCLs must document the on-site presence of cardiothoracic surgery and cardiovascular anesthesia services, intensive care services, vascular surgery services, nephrology consultation and dialysis, neurology consultation, hematology consultation and blood bank services, advanced imaging (echo/Doppler, MRI, CT, etc…). Mechanical support devices are also required and, at a minimum include an adequate number of intra-aortic balloon pumps to support the function of the lab.

1.2. 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.

1.2.1. The existence of a relationship between procedure volumes and outcomes is controversial. Although doing more does not guarantee excellence, to maintain adequate skills and proficiency within the laboratory a minimum number of procedures is required.

1.2.1.1. Full-service laboratories should perform no less than 400 diagnostic coronary angiograms and 200 PCIs of which 36 PCIs are primary PCIs for acute myocardial infarction annually with outcomes equivalent to national performance benchmarks as established by the NCDR CathPCI Registry. The performance metrics examined will be:

a) in-hospital risk-adjusted mortality for patients with STEMI and without STEMI,
b) rate of unplanned CABG
    a. Same Day
    b. Same Hospitalization
    c. Emergent
    d. Urgent
    e. Elective
c) proportion of STEMI patients receiving immediate PCI within 90 minutes,
d) rate of procedure-related q-wave MI or ischemia,
e) rate of post procedure stroke, TIA or other neurological event,

f) rate of vascular complications
   a. risk adjusted bleeding
g) rate of arrhythmia requiring treatment
   a. rate of cardiac arrest in the cath lab
h) rate of new hemodynamic instability in the cath lab
i) rate of non-obstructive disease (all stenoses in major arteries < 50% diameter reduction in severity for elective procedures as defined in the NCDR Cath/PCI registry).

1.2.1.1.1 Alternative volume minimums will be considered for CCLs operating in remote geographic areas.

1.3 Any facility with risk-adjusted procedure mortality or the need for same-day emergency CABG in the lowest quartile of performance for 2 consecutive individual quarters (compared to the most recent NCDR CathPCI Registry benchmarks) must conduct an external audit.

Laboratories without on-site cardiac surgery offer a limited range of diagnostic and interventional services and require patients needing urgent surgery to be transferred to another facility be transferred to another facility. These laboratories must operate 24/7, 365 days/year if they offer PCI.

For ACE accreditation:

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

1.4.1. 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

1.4.2. 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.

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

1.4.2.2. High-risk patients are defined by: a) decompensated CHF (Killip Class 3 to 4), b) recent (<8 weeks) cerebrovascular accident, 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) and f) serious ongoing ventricular arrhythmias.

1.4.2.3. 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, or laser. (1-3)

1.4.3. CCLs without on-site cardiac surgery must have an internal audit process to validate that > 90% of PCI procedures meet their defined inclusion/exclusion criteria for procedures that can be performed in a facility without on-site cardiac surgery

1.4.4. Laboratories without on-site cardiac surgery must perform no less than 400 diagnostic coronary angiograms and 200 PCIs of which 36 PCIs are primary PCIs for acute myocardial infarction annually with documented satisfactory outcomes as established by the NCDR. (2) The performance metrics examined will be:

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

1.4.4.1. Alternative volume minimums will be considered for CCLs operating in remote geographic areas (defined as greater than 1 hour transfer time for STEMI or greater than 2 hours driving time for elective patients) based on an assessment of their quality metrics and case review.

1.4.5. Facilities performing PCI procedures without on-site surgery must demonstrate the presence of (1):

1.4.5.1. A working relationship between the interventional cardiologists and cardiac surgery service at the receiving hospital documented by a letter of support from the surgical group to accept cases

1.4.5.2. 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

1.4.5.3. Surgical backup available at all hours for urgent cases and for elective cases at mutually agreeable times

1.4.5.4. Confirmed availability of cardiac surgery and a next available Operating Room before elective procedures begin per written agreement

1.4.5.5. Mechanism for direct discussion between the cardiologist and cardiac surgeon should urgent transfer be necessary

1.4.5.6. 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 (1)

1.4.5.7. A transport provider able to begin transfer within 20 minutes

1.4.5.8. A PCI consent form that explains that the procedure is being performed without on-site surgery and what will occur if surgery is necessary

1.4.5.9. Documentation of a review (occurring quarterly at a minimum but recommended to occur in near real time) of all patients transferred for emergency surgery

1.4.5.10. Submission of data to a national registry such as the NCDR ACTION-GWTG for STEMI and NSTEMI and/or the NCDR-CathPCI registry is required for facilities without on-site surgery

1.4.6. Any facility with risk-adjusted procedure mortality or the need for same-day emergency CABG in the lowest quartile of performance for 2 consecutive individual quarters (compared to the most recent NCDR benchmarks) must conduct an external audit.

Hospital-based diagnostic only laboratories and freestanding laboratories that do not perform coronary interventions and may perform selected peripheral interventions. These laboratories often do not operate 24/7 or 365 days/year and are usually only for elective diagnostic and some peripheral interventional procedures.

These standards only apply to the coronary diagnostic procedures.

For ACE accreditation:

1.5. Such laboratories must define the procedures performed and excluded from their laboratories.

1.5.1. Patient exclusions for such laboratories should include: a) NYHA Class 4, b) pulmonary edema due to ischemia, c) those with known peripheral vascular disease if no vascular surgery available, d) complex congenital heart disease, e) acute coronary syndromes and f) all pediatric procedures

1.6. Such laboratories must perform no less than 400 diagnostic coronary angiograms annually with outcomes equivalent to national performance benchmarks as established by the NCDR. The performance metrics examined will be: a) in-hospital mortality for patients undergoing diagnostic cath, b) procedure-related q-wave MI, c) post procedure stroke, d) vascular complication requiring transfusion or surgery, e) rate of emergency CABG or transfer to a PCI center and f) incidence of non-obstructive disease (all stenoses in major arteries < 50% diameter reduction in severity for elective procedures)

1.6.1. Alternative volume minimums will be considered for laboratories operating in remote geographic areas based on an assessment of their quality metrics and case review.

1.7. 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.

1.8. Any facility with risk-adjusted procedure mortality or the need for same-day emergency CABG in the lowest quartile (compared to the most recent NCDR benchmarks) of performance for 2 consecutive individual quarters) must conduct an external audit.

2. STANDARDS: Equipment

For ACE accreditation, all CCLs must demonstrate (4):

2.1. Digital fluoroscopy and angiography with multiple image intensifier sizes and on-line image storage and retrieval capabilities

2.2. Multichannel physiologic monitoring (minimum of 2 pressure and 3 ECG channels) with real-time and archived physiologic, hemodynamic and rhythm monitoring equipment with support staff capable of interpreting results and responding appropriately. Capability to perform cardiac output measurements by the Fick or thermodilution method.

2.3. Appropriate inventory of disposable supplies for vascular access management, diagnostic coronary angiography and ventriculography

2.4. 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

2.5. 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 transvenous pacemakers, intraaortic balloon pump, pericardiocentesis equipment, and personnel trained on their indications and use.

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

2.6.1. For radiographic systems this includes but is not limited to: a) image quality, b) dynamic range, c) modulation transfer function, d) fluoroscopic spatial resolution, e) fluoroscopic field of view size accuracy, f) low contrast resolution, g) record fluoroscopic mode automatic exposure control under standard conditions and at maximum output h) calibration of integrated radiation dose meters.

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

3. STANDARDS: Leadership Structure

For ACE accreditation CCLs must have:

3.1. A licensed, ABIM board-certified cardiologist as a Medical Director. If PCI procedures are performed, it is expected that the Medical Director be board-certified in interventional cardiology. Exceptions to this requirement will only be made in unusual circumstances.

3.1.1. The medical director should have a minimum of 5 years' experience in invasive (interventions for PCI facilities) cardiology and with strong leadership qualities and no undisclosed conflicts of interest related to the laboratory.

3.1.2. Responsibilities of the medical director include but are not limited to: a) policy development, b) quality control, c) fiscal administration, d) establishing criteria for granting privileges, e) reviewing applications for laboratory privileges, f) reviewing physician performance, g) making recommendations for re-credentialing, h) oversight of the nursing and technical supervisors and insuring appropriate CEU opportunities and i) organization of catheterization and M&M conferences.

3.2. A Technical Director or CCL supervisor (licensed technologist (RCIS) or registered nurse) with a minimum of 5 years' experience working in an invasive angiographic imaging laboratory.

3.3. A designated individual responsible for coordination of quality assurance and continuous quality improvement activities. This should be the Medical Director or their designee.

3.4. Physician privileges

For ACE accreditation CCLs must have:

3.4.1. Written criteria for the initial granting of privileges to work in the CCL based on prior formal training, clinical experience, and the recommendation of prior laboratory or fellowship directors.

3.4.2. Physicians working in the laboratory must be a fully accredited member of the hospital staff or for free-standing laboratories, a member of the hospital staff providing back-up support for the laboratory.

3.4.3. For adult laboratories, physicians must maintain ACLS certification and follow facility standards for radiation safety.

3.4.4. To maintain privileges, physicians must obtain 30 hours of Category 1 continuing medical education credits over a 2-year period in invasive or interventional cardiology.

3.4.5. A teaching attending physician must meet the same requirements as a non-teaching attending physician in a program instructing graduate physicians and fulfill all of the requirements established by the ACGME.

3.4.6. Procedure volume requirements for individual operators must be established by each facility. These requirements should be concordant with the most current ACCF/AHA/SCAI competency documents.(14)

3.4.6.1. No absolute operator volume requirement is recognized for diagnostic coronary angiograms, but each facility should establish a minimum number required for working in the CCL to maintain familiarity with the laboratory environment and emergency procedures.

3.4.6.2. PCI procedure volume requirements for individual operators must be established by each facility. These requirements should be concordant with the most current ACCF/AHA/SCAI competency document. (14) All facilities must establish their minimum recommended annual volume requirements for PCI operators to maintain proficiency and a minimum number of procedures at a particular facility to maintain familiarity with the laboratory environment and emergency procedures. Deviations from the ACCF/AHA/SCAI operator volume recommendations require special justification.

3.4.6.3. The performance of all operators must be assessed as part of ongoing QA efforts. If outliers are identified, appropriate fair and transparent action should be taken. It is expected that all operators actively participate in the cardiac catheterization laboratory educational and quality efforts. A 50% attendance is expected for these activities including M&M, cath conference, and quality assurance meetings. All operators must participate in ongoing random case review activities both as reviewers as well as by having cases reviewed.

3.4.6.4. For individual volume assessments, the preceding 24 month rolling data should be assessed and averaged to arrive at annual statistics.

3.4.7. Hospital privileges and state licensing should be maintained throughout the period of ACE certification for all operators. Any loss of either hospital privileges or state license shall be reported to ACE with an explanation from the Medical Director.

3.4.7.1. Board certification in cardiovascular disease and, if appropriate, interventional cardiology is strongly encouraged for all operators and it is strongly preferred that the Medical Director be board-certified in interventional cardiology. Exceptions to this requirement will only be made in unusual circumstances.

3.4.8. Other major program changes reported to ACE during annual review should include but are not limited to: 1) change of the Medical Director, 2) major changes to equipment or procedures performed, 3) addition/deletion of operators or 4) sentinel event as defined by the Joint Commission and 4) any other exceptional occurrences that the facility anticipates affecting accreditation status.

4. STANDARDS: Physician Extenders and Cardiology Fellows

For ACE accreditation non-physician healthcare providers (nurse practitioner or physician assistant):

4.1. 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. An attending must be administratively identified as the primary operator.

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

4.1.2. 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, d) emergency cardiac care, e) radiation safety, and f) the application of diagnostic data to the management of patients.

4.1.3. Specially trained nurses may function in the same role as non-physician providers but require increased supervision.

4.2. 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.

5. STANDARDS: Nursing Personnel

For ACE accreditation:

5.1. 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.

5.1.1. The nursing supervisor should be in charge of the pre and post procedure areas as well as the procedure laboratories.

5.1.2. 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.

5.1.3. 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.

5.1.4. The experience of catheterization laboratory registered nurses should preferably include 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.

5.1.5. Documentation of training of nursing personnel in the recognition and management of typical CCL complications is required.

5.1.6. Properly trained nursing assistants may also be used for some functions in laboratories.

5.1.7. 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. State requirements for performance and roles of personnel must be supplied and facilities will be reviewed for compliance based on these standards.

5.2. Conscious or deep sedation should only be performed following the standards established by The Joint Commission.

5.3. All Cath Lab staff, with direct patient care responsibilities, should be certified in ACLS.

6. STANDARDS: Technologists and Other Personnel

For ACE accreditation:

6.1. Each CCL should have at least one technologist. If not a certified radiological technologist there should be at least one RCIS 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.

6.1.1. State requirements that supersede the ACE requirements must be followed.

6.1.2. 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 where allowed by local/state policies.

6.1.2.1. Documentation of training, proficiency, and ongoing education of all lab personnel is required.

6.2. All technologists should be certified in ACLS. Other health care personnel with patient contact should be certified in BCLS.

7. STANDARDS: Reporting of Results

For ACE accreditation:

7.1. The reporting standards of The Joint Commission (TJC) for operative procedures must be followed. These include:

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

7.1.2. 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.

7.1.3. 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."

7.1.4. 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.

7.2. 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:

7.2.1. Patient demographics, primary operator and supporting staff present and procedures performed.

7.2.2. Indications for each component the procedure (e.g. right heart catheterization, renal angiography, etc ...)

7.2.3. Appropriate supporting history, physical findings, and laboratory findings.

7.2.4. The time course and procedural events with technical comments if helpful.

7.2.5. Access site information.

7.2.6. All catheters, sheaths, guide wires, and interventional equipment used should be reported in a procedural section.

7.2.7. 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.

7.2.8. Clear description of any complications or a positive statement that there were no apparent complications.

7.2.9. For diagnostic procedures a complete summary of hemodynamic findings (pressures, outputs, resistances, valve areas, etc.).

7.2.9.1. Hemodynamic recordings and other calculations should be reviewed by the physician in detail before data are accepted into the final procedure report. Simply inserting multiple computer-derived pressure recordings without oversight or review by the operator is unacceptable.

7.2.10. The minimum hemodynamic data reported from a left-heart catheterization should be the initial and ending aortic pressure, left ventricular systolic and end-diastolic pressure and a notation of presence or absence of gradient across the aortic valve.

7.2.11. The minimum hemodynamic data reported from a right-heart catheterization should be the right atrial, right ventricular, pulmonary artery, and pulmonary artery wedge pressures with mean pressures. Trans-valvular mean and peak pressure gradients and valve area determinations should be reported when appropriate with cardiac output and any shunt data if investigated.

7.2.12. If performed, the left ventriculogram description should include the regional wall motion abnormalities (hypokinesia, akinesia, dyskinesia) seen in the anterior, inferior, apical, posterior and lateral segments. Reporting quantitative methods of wall motion assessment are useful when available. A measured or estimated left ventricular ejection fraction should also be reported with the presence and severity of any valvular abnormalities (calcification, abnormal motion and regurgitation).

7.2.13. Minimum requirements for reporting the coronary angiogram are: 1) the presence or absence of the right and left coronary ostia and detailed descriptions of any abnormalities; 2) a description of the left main and each of the three main coronary arteries and their branches noting their size, extent of distribution and visual estimate of the degree of any narrowing. 3) dominance of the coronary vessels; 4) presence of collateral vessels with their origin and destination. A visual diagram of the coronary tree is helpful to communicate vascular anatomy and lesion location.

7.2.14. For interventional procedures a complete description of the procedure, equipment used, in lab results such as ACT measurements, complications occurring and outcome of the intervention. Technical comments are especially helpful should future interventions be necessary.

7.2.15. If performed, findings of intravascular ultrasound (IVUS) examinations and fractional flow reserve (FFR) measurements should be reported within the procedure report or as a separate document.

7.2.15.1. The minimum content of an IVUS report includes: a) appropriate patient demographic information and date with reference to the accompanying angiographic and/or interventional reports; b) indication for the procedure; c) brief description of the IVUS procedure, including the equipment used, the level of anticoagulation achieved, and the coronary arteries imaged; d) basic findings of the IVUS pullback, including any measurements that were performed such as minimum lumen diameter, minimum stent area, or plaque burden; e) any notable morphological plaque features such as dissection, calcium, or thrombus; f) changes in therapy that resulted from the information provided by IVUS; and g) IVUS-related complications and any consequent therapy. (5) A complete report would also include an analysis of three essential cross-sectional images—a distal reference segment, the most severe lesion site, and a proximal reference segment. Lumen and external elastic lamina areas, calculated plaque plus media area, plaque burden, and area stenosis can be reported. If a stent is present, minimum lumen area of the stent and a description of strut apposition can be included.

7.2.15.2. IVUS images must be archived for subsequent review.

7.2.15.3. The minimum content of a FFR report includes: 1) appropriate patient demographic information and date with reference to the accompanying angiographic and/or interventional reports; 2) indication for the procedure; 3) brief description of the FFR procedure, including the equipment used, documentation of anticoagulation given, drug used for vasodilation with amount and route of administration, the coronary arteries and specific lesions studied and 4) FFR result and interpretation regarding hemodynamic significance of the FFR.

7.2.15.4. Standardized reports for new imaging techniques (such as OCT) should be developed as needed and must include pertinent information similar to that described above for IVUS.

7.2.16. Summary of major findings or diagnoses.

7.2.17. Disposition of the patient as a result of the procedure and comments.

7.3. Procedural and hemodynamic records should be retrievable in their original form for at least 7 years and should be accessible within 24 hours. Angiographic images should be stored and available for a minimum of 7 years following the procedure. Appropriate back-up systems must be in place to protect all data from unexpected computer failures.

7.4. All information systems must be compliant with the 1996 Health insurance Portability and Accountability Act (HIPAA).

8. STANDARDS: Procedure Indications and Informed Consent

For ACE accreditation:

8.1. The indication for the proposed cardiac procedure must be documented.

8.1.1. The indication for the procedure should be consistent with published guidelines or appropriate use criteria (AUC).

8.1.1.1. There must be sufficient clinical information available in the procedure report and medical record to determine the indication for the procedure.

8.1.1.2. If the specific clinical scenario is not included in the AUC or if in the judgment of the physician the procedure is justified despite the AUC score, clear documentation of the reasoning should be included both in the medical record and in the catheterization report.

8.1.2. The appropriateness of diagnostic procedures must be assessed using the current Appropriate Use Criteria for Cardiac Catheterization. (14) Facilities are expected to document a rate of "appropriate" of ≥75% based on random case reviews. The goal is for the proportion of cases graded as appropriate, uncertain and inappropriate be similar to that reported in contemporaneous reports of the NCDR.

8.1.3. The appropriateness of PCI procedures must be assessed using the current Appropriate Use Criteria Coronary Artery Revascularization. (15) Facilities are expected to document a rate of "appropriate" of ≥75% based on random case reviews. The goal is for the proportion of cases graded as appropriate, uncertain and inappropriate be similar to that reported in contemporaneous reports of the NCDR CathPCI Registry.

8.1.3.1. Because of individual patient considerations not assessed within the current AUC and methodological limitations in the development and application of the AUC, some "appropriate" cases could be graded as "inappropriate" yet still represent good judgment on the part of the operator in the care of an individual patient. This number, however, should be small and thus CCLs must document that few if any PCI cases are judged inappropriate by current AUC standards.

8.1.3.1.1. "Inappropriate" cases and documentation by the operating physician as to the justification should be reviewed as part of the CCL quality review process and the outcome of those reviews should be documented as part of that process.

8.2. 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.

8.2.1. Each facility must have an approved consent form present in the medical record that includes risks, benefits, and alternatives to the procedure in terms the patient can understand. This should include the potential for ad hoc PCI and its risks/benefits, and alternatives when appropriate.

8.2.2. 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.

8.2.3. 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.

8.2.4. 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.

8.3. A recent (< 30 days) history and physical examination must be available in the catheterization laboratory at the time of the procedure.

8.3.1. If the history and physical were performed before the day of the procedure an attestation verifying no interval change must be included or pertinent changes documented.

8.4. Laboratory values and outside reports should be available and reviewed by the physician before the procedure.

8.4.1. Hemoglobin, platelet count, electrolyte panel, renal function testing and, in the anticoagulated 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. Women of child bearing potential should have a urine ß-HCG level or a serum ß-HCG checked within two weeks to exclude pregnancy.

8.4.2. Laboratory values should reflect current patient status. If interval changes or interventions have occurred, they should be repeated as clinically indicated.

9. STANDARDS: Procedure Preparation and Conduct

For ACE accreditation:

9.1. The anticipated procedure should be specified when the patient is scheduled so that necessary equipment and staff can be provided at the time of the procedure.

9.2. Facilities should have a written protocol or standardized order sets for the anticoagulated patient undergoing cardiac catheterization procedures and for various access site management including anticipated complications.

9.3. Facilities should have a written protocol or standardized order sets for the management of patients at high risk of contrast-induced nephropathy. This should include pre- and post-procedure hydration and follow-up. (4, 16)

9.4. Facilities should have a 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. (7)

9.5. Facilities must stock the standard medications used for sedation, reversal of sedation, pain relief, narcotic reversal, treatment of hypertension and hypotension, arrhythmias and allergic reactions plus selected antibiotics and have standard operating procedures regarding the use of these medications so all personnel evaluating patients or authorized to administer medications are familiar with the most commonly used.

9.6. Communication with the patient and family following the procedure should include plans for follow-up and other instructions provided in writing.

9.7. Operators should use appropriate hand washing or sterilization and wear a sterile gown and gloves. Personnel should wear hospital-based scrub attire.

9.8. All labs should have sterile/infection control protocols in place for access site prep, universal precautions, airflow, and other issues as outlined in the most recent Infection Control Guidelines (8)

9.8.1. Masks, eye shields, and protective caps are probably more important for keeping the patient's blood from splattering onto the operator than for protecting the patient from infection. There is wide variation in their use for routine cardiac catheterization procedures. Nevertheless, OSHA/SCAI guidelines suggest that masks, eye shields and caps be worn during invasive procedures.

9.8.2. Universal precautions should be followed with respect to sharp objects (e.g., never re-capping needles). Appropriate receptacles for sharp objects should be available.

10. STANDARDS: Patient Outcomes

For ACE accreditation:

10.1. Adverse in-hospital patient outcomes (complications) must be reviewed for diagnostic procedures.

10.1.1. Participation in the NCDR-CathPCI Registry fulfills the data collection requirements for diagnostic procedure complications. In the absence of participation in the NCDR-CathPCI Registry, the complications assessed must include:

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

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

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

10.1.2. 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.

10.2. Additional assessments for diagnostic and other CCL types should include:

10.2.1. Rate of coronary angiography with non-obstructive disease meeting the NCDR definition for inclusion in this metric without a ≥ 50% coronary diameter reduction by visual criteria or stenosis shown by another modality (eg. FFR, IVUS) to have functional significance by published criteria.

10.2.1.1. Any facility with a rate of non-obstructive coronary artery disease according to the NCDR definition of more than 2 standard deviations above the national benchmark as established by the NCDR in 2 consecutive individual quarters must conduct an internal audit and if the finding persists consider external review.

10.2.2. The diagnostic accuracy and adequacy of angiograms must be assessed as part of ongoing random case reviews representing 10% of cases by all operators.

10.2.2.1. The completeness and accuracy of diagnostic procedures should be assessed as part of the QA process. Inadequate or incomplete diagnostic procedures should not be > 5% for any operator.

10.2.2.1.1. Variables assess may include: a) adequate visualization of all coronaries in multiple views, b) complete study of all existing bypass grafts, c) left ventriculograms performed with adequate visualization, d) adequacy of pressure measurements in valve disease cases, e) others as defined by the laboratory.

10.3. In-hospital patient outcomes after PCI must be assessed.

10.3.1. Participation in a national database (NCDR-CathPCI Registry) fulfills all of the data collection requirements for interventional procedure outcomes and complications. Other state-wide registries may be acceptable for this purpose and will be considered.

10.3.2. 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 optimal, but not a requirement at this time.

10.4. Clinical performance metrics are now being tracked and reported publically in several sources (eg. www.hospitalcompare.hhs.gov). For ACE accreditation, the laboratory performance metrics that will be reviewed and performance level for accreditation are shown in the table below.

Performance Metrics

As part of the ACE application, performance metrics from the NCDR CathPCI Registry, NCDR ACTION Registry (if available) and the Hospital compare website will be reviewed. (www.hospitalcompare.hhs.gov) The specific performance metrics examined and their source are shown in the table below.

PCI Performance Metrics	Source	Line
PCI in-hospital risk adjusted mortality (all patients)	NCDR CathPCI	1
Composite: Discharge Medications in Eligible PCI Patients	NCDR CathPCI	38
PCI Process Metrics		
Proportion of elective PCIs with prior positive stress or imaging study	NCDR CathPCI	2
Median time to immediate PCI for STEMI patients (in minutes)	NCDR CathPCI	3
Proportion of STEMI patients receiving immediate PCI within 90 minutes	NCDR CathPCI	4
Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients (in minutes)	NCDR CathPCI	5
Median time from ED arrival at STEMI transferring facility to Immediate PCI at STEMI receiving facility among transferred patients (in minutes)	NCDR CathPCI	6
PCI Outcome Metrics		
Proportion of PCI patients with emergency CABG	NCDR CathPCI	12
Proportion of PCI procedures with post-procedure stroke	NCDR CathPCI	16
Composite :Proportion of PCI patients with death, emergency CABG stroke or repeat target lesion revascularization	NCDR CathPCI	17
PCI in-hospital risk adjusted mortality (patients with STEMI)	NCDR CathPCI	18
PCI in-hospital risk adjusted mortality (STEMI patients excluded)	NCDR CathPCI	19
Proportion of PCI procedures with transfusion of whole blood or RBCs post PCI*	NCDR CathPCI	25
PCI in-hospital risk adjusted rate of bleeding events (all patients)	NCDR CathPCI	37
PCI in hospital risk adjusted acute kidney injury (all patients)	NCDR CathPCI	39
PCI Appropriate Use Criteria (AUC)		
Proportion of PCI procedures not classifiable for AUC reporting	NCDR CathPCI	30
Proportion of evaluated PCI procedures that were appropriate (WITHOUT Acute Coronary Syndrome)	NCDR CathPCI	34
Proportion of evaluated PCI procedures that were of uncertain appropriateness (WITHOUT Acute Coronary Syndrome)	NCDR CathPCI	35
Proportion of evaluated PCI procedures that were inappropriate. (WITHOUT Acute Coronary Syndrome)	NCDR CathPCI	36

Patients WITH ACS Proportion of evaluated PCI procedures that were appropriate	NCDR CathPCI	31
Patients WITH ACS Proportion of evaluated PCI procedures that were uncertain	NCDR CathPCI	32
Patients WITH ACS Proportion of evaluated PCI procedures that were inappropriate	NCDR CathPCI	33
Diagnostic Cath Process & Outcome Metrics		
Incidence of non-obstructive disease (elective patients only) †	NCDR CathPCI	20
Proportion of Diagnostic Catheterization procedures with vascular access injury requiring treatment or major bleeding**	NCDR CathPCI	21
STEMI/NSTEMI Performance Measures		
Overall AMI performance composite	ACTION Registry	1
Overall defect free care	ACTION Registry	2
STEMI performance composite	ACTION Registry	3
NSTEMI performance composite	ACTION Registry	4
ACUTE AMI performance composite	ACTION Registry	5
Discharge AMI performance composite	ACTION Registry	6
Evaluation of LV systolic function	ACTION Registry	11
Time in minutes from ED arrival at STEMI referral facility to ED discharge from STEMI referral facility in patients transferred for PCI	ACTION Registry	18
Cardiac Rehabilitation patient referral from an inpatient setting	ACTION Registry	21
Medicare Hospital Compare Outcome Metrics		
Rate of unplanned readmission for heart attack patients. (ACC Pilot Readmission Measure)	Hospital Compare	
Heart attack patients given PCI within 90 minutes of arrival (Medicare patients)	Hospital Compare	
Average number of minutes before outpatients with chest pain or possible heart attack got an ECG (Medicare patients)	Hospital Compare	

*Patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Exclusions: Patients having CABG or other major surgery during the same admission.

**Vascular access site injury requiring treatment or major bleeding is defined as: 1) Bleeding at access site, hematoma at access site, or retroperitoneal bleed that occur within 72 hours of the procedure. To qualify, the event must be associated with a hemoglobin drop of >3 g/dL; transfusion of whole or packed red blood cells, or a procedural intervention/surgery at the bleeding site to reverse/stop or correct the bleeding. This excludes "GI", "GU" and "Other" bleeds. 2) Major access site related injury requiring treatment includes access site occlusion, peripheral embolization, dissection, pseudoaneurysm, AV fistula requiring treatment anytime from the procedure until discharge.

† Defined as patients with undergoing elective diagnostic cath and coronary angiography with all native coronary territories <50%. Exclusions: Patients with prior CABG, cardiac transplant evaluation; pre-op evaluation for non-cardiac surgery and diagnostic cath treatment recommendation of "other cardiac therapy without CABG or PCI".

11. STANDARDS: Quality Assurance

For ACE accreditation:

11.1. A cath lab specific quality assurance (QA) monitoring program must be present and integrated with the facility quality improvement (CQI) effort (9).

11.1.1. A QA program should include structural, process and outcome indicators.

11.1.1.1. Structural indicators may include: a) credentialing and re-credentialing criteria, b) licensure and board certification status, c) documentation of CME participation and d) other criteria.

11.1.1.2. Process indicators should include: a) quality of angiographic studies, b) completion of accurate and informative reports, c) emergency response times, d) total procedure and fluoroscopy times, e) contrast usage, f) radiation dose, and g) other criteria.

11.1.1.3 Outcome indicators assessed should be part of an overall quality assurance (QA) program.

11.1.2. The quality assurance program must include a peer-review process with randomly selected diagnostic and interventional procedures representing all operators performing cases in the CCL reviewed for their indications and complications and a periodic review of all major (MACCE) laboratory complication rates (11).

11.1.3. The QA program must include an assessment of: a) the rate of non-obstructive coronary artery disease based on the NCDR CathPCI registry definition b) an assessment of MACCE and vascular complication rates for all types of procedures performed, and c) an assessment of the diagnostic accuracy and adequacy of angiograms as defined in detail in section 10.2.2.

11.1.4. Major complications must be reviewed by the internal peer review process or by an independent expert.

11.1.5. Any operator with risk-adjusted procedure mortality or the need for same-day emergency CABG in the lowest quartile of performance (based on NCDR benchmark results) for 2 consecutive individual quarters must be reviewed.

11.2. A quality conference should occur on a regular basis (No less than quarterly) All operators must participate in a minimum of 50% of the quality review meetings.

12. STANDARDS: Radiation Safety

For ACE accreditation:

12.1. Each CCL should have a program to document the radiation exposure to patients and staff.

12.1.1. 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. (11) Documentation of personnel training in radiation safety must be provided.

12.1.2. 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.

12.1.3. This program should have the following mandated components: a) initial training or verification of prior training for all physicians and staff using fluoroscopy in the CCL; b) annual updates on radiation safety; c). hands on training for new operators in a facility and existing operators on newly purchased equipment.

12.2. Patient radiation dose needs to be monitored and recorded.

12.2.1. 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.

12.2.2. 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 >10Gy, and a mechanism for patient follow up of potential adverse effects from radiation.

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