2015

ACE Standards

for Pediatric and/or Congenital Cardiac Catheterization Laboratory Accreditation

Accreditation for Cardiovascular Excellence
Quality in Invasive Cardiovascular Care

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1. STANDARDS: Facility

A variety of catheter based cardiovascular procedures are now available for pediatric patients and adults with Congenital Heart Disease (CHD). Procedures in this population of patients should be performed in a Pediatric and / or Congenital Cardiac Catheterization Laboratory (PCCL). Procedures include, but are not limited to, hemodynamic evaluation, angiography, occlusion of intracardiac shunts, valvuloplasty, balloon dilation and /or stent dilation of stenotic vessels, flow redirection/vessel embolization, and valve implantation.

Because the majority of appropriate catheterization procedures in pediatric and adults patients with CHD will, or may, require an intervention, it is preferred all accredited labs be staffed and equipped to perform interventions. Each facility must document that they have the resources to safely perform the procedures offered in their laboratory. PCCL laboratories are defined as those offering a wide variety of diagnostic and interventional procedures on pediatric or adult patients with congenital heart disease (CHD). PCCL laboratories operate 24/7, 365 days/year.

For ACE accreditation:

1.1. PCCLs must document the on-campus 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 circulatory support devices and or ECMO are also required.

1.1.1. Limited-Service Facilities, who are performing diagnostic only and /or low risk interventions in the PCCL, operating in remote geographic areas, may be eligible for accreditation at the discretion of the ACE Board of Directors, with a focus on quality metrics and outcomes.

1.2. PCCLs 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. Accredited PCCL laboratories should perform a minimum of 150 catheterization procedures in pediatric or adults patients with CHD. At least 50 cases should be interventional procedures (excluding biopsies).

1.3. PCCLs must track, assess and report operator specific procedural volumes, procedural type, acute complications and failure rates. This data must be compared to a reported national data registry for benchmarking purposes semi-annually.

It is strongly encouraged the PCCL participates in the ACC-NCDR IMPACT Registry or another recognized national database, as they have become key sources of performance metrics and outcomes for congenital catheterization.

Adverse Event/Complications-Examples:

- mortality and major adverse event (MAE) rates as defined by current version of IMPACT.[21]
- rate of post procedure stroke, TIA or other neurological event within 72 hours or up to next procedure.
- rate of vascular complications requiring intervention- as defined by current version of IMPACT.
- bleeding requiring transfusion and or drop in Hgb greater than 3g/dl.
- rate of arrhythmia requiring treatment as defined by current version of IMPACT.
- rate of cardiac arrest in the cath lab.
- rate of new hemodynamic instability in the cath lab -as defined by current version of IMPACT.

1.3.1. Any PCCL facility whose risk adjusted procedural mortality or major adverse event rates are in the lowest quartile of performance for > 2 consecutive individual quarters must conduct and show evidence of a formal audit. The PCCL must show evidence of a meaningful internal review process to address findings/opportunities identified by this audit.

2. STANDARDS: Equipment

For ACE accreditation, all CCLs must demonstrate:

2.1. Digital fluoroscopy and angiography with multiple image intensifier sizes, adapted to use with pediatric and / or adult patients with CHD. Equipment should include radiation minimizing options 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. PCCL laboratories should have the capability to perform cardiac output and shunt measurements by the Fick method and thermodilution cardiac output in appropriate patients.

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

2.4. Facilities performing interventions must have a varied inventory of guiding catheters, guide wires, angioplasty balloons, stents, septal and vascular closure devices, and other treatment devices commensurate with the scope of services provided by the laboratory.

2.5. Emergency management equipment and systems are readily available in the PCCL. This includes resuscitation equipment, a biphasic pediatric equip defibrillator, vasoactive and antiarrhythmic drugs, endotracheal intubation, temporary transvenous pacemakers, intraaortic balloon pump, ECMO, (or other mechanical cardiorespiratory support), 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 and competencies.

3. STANDARDS: Leadership Structure

For ACE accreditation PCCLs must have:

3.1. A licensed, board-certified pediatric cardiologist or adult congenital heart disease cardiologist as a Medical Director who has successfully completed an advanced interventional fellowship-training program or completed training prior to 2000.

3.1.1. The medical director should have a minimum of 5 years experience in diagnostic catheterization and if an interventional lab, 5 years experience in pediatric interventional 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 /CME opportunities and i) organization of catheterization and M&M conferences.

3.2. A Technical Director or PCCL supervisor who is a licensed technologist (RCIS) and or Registered Nurse (RN), 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 PCCLs must have:

3.4.1. Written criteria for the initial granting of privileges to work in the PCCL 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 pediatric laboratories, physicians must maintain PALS certifications and other hospital requirements as appropriate.

3.4.4. All PCCL operators must follow facility standards for radiation safety.

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

3.4.6. 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.

3.4.7. 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.

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

3.4.7.2. Interventional procedure volume requirements for individual operators must be established by each facility. These requirements should be concordant with the most current competency document. All facilities must establish their minimum recommended annual procedural volume requirements for 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 operator volume recommendations require special justification.

3.4.7.3. 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.

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

3.4.8. 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.

3.4.8.1. Board certification in pediatric cardiology or ACHD is strongly encouraged for all operators and it is required that the Medical Director has completed advanced training in interventional cardiac catheterization for congenital heart disease. Exceptions to this requirement will only be made in unusual circumstances.

3.4.9. 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 5) 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 PCCL. 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 PCCL. The Nursing Supervisor is to have a dotted line reporting structure to the PCCL Medical Director.

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 pediatric critical care practice, knowledge of cardiovascular medications, ability to start peripheral IV lines 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 PCCL 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. or other accrediting organization.

5.3. All Cath Lab staff, with direct patient care responsibilities, should be certified in PALS (if only pediatric patients are cared for) and/or ACLS if adult patients with congenital heart disease are cared for exclusively or in addition to pediatric patients.

6. STANDARDS: Technologists and Other Personnel

For ACE accreditation:

6.1. Each PCCL should have at least one technologist. If not a certified radiological technologist there should be at least one RCIS certified cardiovascular 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 contrast 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 specialized equipment 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 PALS if the scope of practice is limited to pediatric patients and ACLS for an Adult Congenital Lab. 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 in addition to the ACC/AHA/SCAI 2014 Health Policy Statement on Structured Reporting for the Cardiac Catheterization Laboratory.

These include but are not limited to the following:

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."

7.2. All PCCL procedure reports should be standardized and structured to reflect: the ACC/AHA/SCAI 2014 Health Policy Statement on Structured Reporting for the Cardiac Catheterization Laboratory. "General Principles of structured reporting in cardiovascular imaging have been described in this published document. The key characteristics of a proper structured report are as follows: 1) it must be inclusive of all information relevant to both clinical care and operational administration; 2) it should be clear, concise, organized, and reproducible as well as straightforward to cognitively assimilate and comprehend, while being sufficiently flexible to accommodate evolutionary changes in procedures and documentation requirements; 3) it should contain all the required elements for documenting procedure indications and assessing appropriateness per local coverage determination rules and/or published[9-11]; 4) a consistent minimum data set should be included in the content of each report, anticipating clinical, operational, regulatory, and financial uses of appropriateness.

The PCCL report should include but is not limited to:

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

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, shunts calculations, 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 document a systemic ventricular systolic and end-diastolic pressure and either an arterial pressure measurement or a non-invasive B/P pressure and notation of presence or absence of gradient across the valve if felt to be significant.

7.2.11. The minimum hemodynamic data reported from a right-heart catheterization in a two ventricular system should be the right atrial, right ventricular, pulmonary artery, and or an estimate of pulmonary vein wedge pressures with mean pressures. For patients with single ventricular physiology, it is sufficient to report the single systemic ventricular (right/left) pressure.

7.2.12. If performed, the ventriculography description should include an estimate of ventricular function and the presence and severity of any valvular abnormalities, septal abnormalities and or out-flow obstructions.

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) dominance of the coronary vessels, 3) presence of collateral vessels with their origin and destination.

7.2.14. For interventional procedures a complete description of the procedure, equipment used, 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, the general findings of ultrasound (IVUS or ICE and TEE) examinations and measurements should be reported within the procedure report and described in sufficient detail to inform the rationale for the procedure and results as relevant even if a complete report of these findings can be found elsewhere within the medical record.

7.2.15.1. IVUS images must be archived for subsequent review.

7.2.15.2. Standardized reports for new imaging techniques (such as OCT) should be developed as needed and must include pertinent information.

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 or as defined by state /federal regulations. This record should be accessible within 24 hours. Angiographic images should be stored and available for a minimum of 7 years or as defined by state/federal regulations, 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 noted and described.

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. Indications for the intervention should be clearly stated.

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 and or the patient's family can understand.

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 procedural 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. A pre-procedure type and screen is optional. Women of child bearing potential should have a urine **β**-HCG level or a serum **β**-HCG checked to exclude pregnancy prior to the procedure.

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. It is desirable that the operator discusses in detail the planned procedure with all participating staff, including anesthesia.

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.

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. Operators must write a note on the chart of the patient briefly explaining the procedure performed and the immediate outcome, until the final report is available in the medical record.

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

9.8. Operators should use appropriate hand washing or sterilization and wear a sterile gown and gloves, hair cover, mask and protective eye wear. Personnel should wear hospital-based scrub attire.

9.9. 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]

9.9.1. 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.

9.9.2. 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: Outcomes & Performance Metrics

For ACE accreditation:

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

10.1.1. Participation in the ACC-NCDR IMPACT Registry or other nationally recognized registry fulfills the data collection requirements for PCCL procedure complications.

10.1.1.1. In the absence of participation in the ACC-NCDR-IMPACT Registry, facilities must have written definitions of the complications that are consistent with and allow comparisons to the most current ACC-NCDR IMPACT benchmarks.

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

10.2.1. Variables assessed may include: a) left ventriculogram performed with adequate visualization, b) adequacy of pressure measurements in valve disease cases, visualization of important anatomic features c) others as defined by the laboratory.

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

10.3.1. Participation in a national database fulfills all of the data collection requirements for interventional procedure outcomes and complications. Other statewide registries may be acceptable for this purpose and will be considered. See examples above in Section 1.3 for Adverse Events and Performance Metrics Examples on page 14.

Performance Metrics

As part of the ACE application, the most recent published performance metrics from the IMPACT Registry will be reviewed as benchmark comparison. Example performance metrics below are taken from IMPACT 2014.[21] Please see current examples from IMPACT.

Performance Metrics	Source	Line
Proportion of patients below 1 month of age that have DX Cath with MAE or death.	IMPACT	1
Proportion of patients over 1 month to 1 year of age that have DX Cath with MAE or death.	IMPACT	2
Proportion of patients over 1 year of age to 18 years of age that have DX Cath with MAE or death.	IMPACT	3
Proportion of patients over 18 years of age that have DX Cath with MAE or death.	IMPACT	4
Proportion of treated ASD closure defects leaving the PCCL with none to trivial shunt.	IMPACT	5
Proportion of patients that have a treated isolated ASD closure that have a device embolization (requiring device retrieval).	IMPACT	6
Proportion of patients that have an isolated PDA closure procedure leaving the PCCL with a none to trivial shunt.	IMPACT	7
Proportion of patients that have a treated isolated PDA closure procedure that have a device	IMPACT	8
Proportion of patients that had a coarctation repair by balloon angioplasty that have a post procedure coarctation peak systolic gradient of < 10mmHg.	IMPACT	9
Proportion of patients that had a coarctation repair with a stent that have a post procedure coarctation peak systolic gradient < 10 mmHg.	IMPACT	10
Proportion of patients that have an aortic valvuloplasty that have a post procedure aortic valve insufficiency increase of two or more grades.	IMPACT	11
Proportion of patients that have pulmonary valvuloplasty that have a post procedure systolic gradient < 30 mm Hg.	IMPACT	12

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 as defined and outlined in the SCAI Pediatric Tool Kit. (*http://www.scai.org/PEDQIT*).

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 (air kerma and DAP, 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 evidence of an ongoing peer-review process with randomly selected diagnostic and interventional procedures. The reviews should represent all operators performing cases in the PCCL, reviewing for documentation of indications, complications as well as periodic review of all major adverse laboratory complication rates (MAE).

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

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. (*http://www.scai.org/PEDQIT*)

12. STANDARDS: Radiation Safety

For ACE accreditation:

12.1. Each PCCL should have a program to document the radiation exposure to patients and staff. (Please see Radiation Safety Module in Pediatric SCAI Tool Kit - *http://www.scai.org/PEDQIT*)

12.1.1. Each PCCL 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 ($K_{a,r}$, Gy) and/or air kerma area product (PKA , $Gycm^2$). 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 ($K_{a,r}$) is 5 Gy or greater, P_{ka} of 500 $Gycm^2$, 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 $K_{a,r}$ >10Gy, and a mechanism for patient follow up of potential adverse effects from radiation. (Note: If using AP and lateral add the two together to come up with the total exposure.) SCAI Tool Kit - *http://www.scai.org/PEDQIT*

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Notes

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