

ACE Standards

for Peripheral Vascular Intervention (PVI) Accreditation



Accreditation for Cardiovascular Excellence
Quality in Invasive Cardiovascular Care

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1. STANDARDS: Facility Related

- 1.1. Each hospital department or section (cath lab, operating room, radiology suite, etc) performing Peripheral Angiography and Interventions (PVI) must document that they have the resources to perform the procedure in a safe manner.
- 1.2. Equipment
 - 1.2.1. Digital subtraction angiography(\geq 12-in image intensifier preferred) with on-line image storage and retrieval capabilities.
 - 1.2.2. Advanced physiologic monitoring with real-time and archived physiologic, hemodynamic and rhythm monitoring equipment with support staff capable of interpreting results and responding appropriately.
 - 1.2.3. Large inventory of disposable supplies for vascular access management, diagnostic angiography and peripheral vascular intervention.
 - 1.2.3.1. The inventory should include devices and drugs to assist in the management of emergent complications including allergic reactions, arterial thrombosis, thromboembolism or vessel rupture and dissection.
 - 1.2.3.2. All staff should be trained in the appropriate use of these devices.
 - 1.2.4. Emergency management equipment and systems must be readily available in the interventional suite. This includes resuscitation equipment, a defibrillator, vasoactive and antiarrhythmic drugs, endotracheal intubation, and personnel familiar with their indications and use.
 - 1.2.5. There must be a process documenting routine preventive maintenance and testing of laboratory equipment, including a comprehensive radiation safety program such as outlined by The Society for Cardiovascular Angiography and/or the American College of Radiology.

2. STANDARDS: Personnel Related

- 2.1. Each Department within the Institution (cath lab, radiology, and surgery) performing PVI must have:
 - 2.1.1. A licensed, board-certified physician in an appropriate specialty and/or sub-specialty as a Medical Director.
 - 2.1.2. A Technical Director (licensed technologist or registered nurse) with a minimum of 5 years experience working in an invasive angiographic imaging laboratory.
 - 2.1.3. A clearly delineated program for the initial granting of privileges with physician operators meeting the peer-reviewed national societal training standards appropriate for the individual's specialty. "The initial granting of privileges should be free of conflict of interest."
 - 2.1.4. A standard operating procedure for monitoring peri-procedural, in-hospital and 30-day outcomes.

2.2. Maintenance of physician privileges

- 2.2.1. Physicians must obtain 30 hours of Category 1 continuing medical education credits per year period with a minimum of 20 hours in the field of endovascular diagnosis and therapy of non-cardiac vascular diseases.
- 2.2.2. The institution must have a defined process for re-credentialing which should be based on volume, outcomes, fulfillment of CME requirements and other quality parameters and should be uniform for all operators irrespective of specialty. These may develop over time and be implemented in a later version of these standards.
- 2.2.3. Recertification criteria for individual practitioners should be decided by each institution but guidelines should include documentation for fulfillment of CME requirements as outlined in 2.2.1 and participation in at least 50% of Morbidity and Mortality and/or case review meetings.
- 2.2.4. An operator's complication rates should not exceed those defined in publications by professional societies or the following thresholds.
 - 2.2.4.1. Mortality $\leq 1\%$
 - 2.2.4.2. Stroke $\leq 1\%$
 - 2.2.4.3. Major complications: emergency surgery, transfusion, unplanned amputation, dialysis composite of $\leq 3\%$
 - 2.2.4.4. Minor complications: Hematoma, AV fistula $\leq 3\%$
- 2.2.5. Hospital privileges and state licensing should be maintained throughout the period of 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, CEO or CMO or institutional leader at the facility.
- 2.2.6. For adult laboratories, physicians must maintain ACLS certification and follow facility standards for radiation safety.

2.3. Other Health Care Professionals

- 2.3.1. Skilled allied health professionals in the laboratory (advanced practice clinicians, 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.
- 2.3.2. Documentation of training of nursing personnel in the recognition and management of acute cardiovascular syndromes and endovascular complications is required.
- 2.3.3. Documentation of training of support staff to interpret results from physiologic, hemodynamic and rhythm monitoring equipment.
- 2.3.4. All personnel with direct patient care responsibilities should be ACLS certified
- 2.3.5. 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 fellow in addition to providing all clinical decision making.

3. STANDARDS: Quality Assurance

- 3.1. A quality monitoring program must include a multidisciplinary peer-review conference with randomly selected PVI procedures reviewed for their indications, imaging quality, documentation, and complications. The quality oversight committee should also review outcomes and make privileging recommendations.
 - 3.1.1. All major complications should be reviewed.
- 3.2. A regularly scheduled quality monitoring conference must occur no less than quarterly. All operators must have documented participation in a minimum of 50% of the quality review meetings.
- 3.3. The quality oversight committee for this program should be representative of the individual specialties involved, and the Chair of the committee should rotate on a regular basis.
- 3.4. A cath lab/OR/endovascular specific quality assurance (QA) monitoring program must be present and integrated with the facility quality improvement program (CQI) effort.
 - 3.4.1. A QA program should include structural, process and outcomes indicators.
 - 3.4.2. Structural indicators may include: a) credentialing and re-credentialing criteria, b) completion of accurate and informative reports, c) documentation of CME participation.
 - 3.4.3. Process indicators may 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.
 - 3.4.4. Outcome indicators assessed should be part of an overall QA program.
- 3.5. The quality assurance program must include a peer-review process with randomly selected diagnostic and interventional procedures representing all operators performing cases. These should be reviewed for their indications and complications, and include a periodic review of all major laboratory/OR/endovascular complication rates.
- 3.6. The QA program must include an assessment of: a) the rate of non-obstructive peripheral disease, b) an assessment of overall and vascular complication rates for all types of procedures performed, and c) an assessment of the diagnostic accuracy and adequacy of angiograms.
- 3.7. The oversight committee should be empowered to identify the minimum case volume for primary operators to maintain privileges, as well as a threshold complication rate to trigger activation of measures for remediation or potential suspension of privileges.
- 3.8. Major events such as [30 day] Death, Major Stroke, and unplanned amputation rates should not exceed 1% of the patient volume, or established thresholds.

4. STANDARDS: Radiation Safety

- 4.1. There must be a procedure in place to document radiation exposure of the patients and staff. Patients with excessive radiation exposure or clinically evident radiation damage (skin burns, alopecia, etc.) will be counseled by the radiation safety office.
 - 4.1.1. The radiation safety program should be considered a component of the overall PVI facility quality assurance (QA) process with the Vascular Intervention program QA individual(s) actively involved with this process.
 - 4.1.2. Each PVI 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 this training must be provided. 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 peripheral intervention facility; b) annual updates on radiation safety; c) hands on training for new operators in a facility and existing operators on newly purchased equipment.
- 4.2. Patient radiation dose needs to be monitored and recorded.
 - 4.2.1. 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 should be included if technology permits its measurement.
 - 4.2.2. 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. Physician must wear radiation exposure badges, monthly dosages calculated, and yearly totals reviewed. The radiation safety officer is responsible for the monitoring of this process.

5. STANDARDS: Reporting of Results

- 5.1. The reporting standards of The Joint Commission (TJC) for operative procedures must be followed. These include:
 - 5.1.1. Preliminary procedure reports must be written or dictated immediately after the procedure. Final reports should be posted to the medical record within 72 hours.
 - 5.1.2. 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.

- 5.1.3. 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 the patient. Immediately after the procedure is defined as “upon completion of procedure, before the patient is transferred to the next level of care.”
- 5.1.4. 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.
- 5.2. All procedure reports at a facility should be individualized to the institution but be consistent with the HPS for structured reporting, standardized among operators and contain relevant content on each of the following topics:
 - 5.2.1. Patient demographics, primary and assisting operator(s) and supporting staff present and procedures performed.
 - 5.2.2. Indications for each component of the procedure (i.e. left femoral angiography, etc.)
 - 5.2.3. Appropriate supporting pertinent history, physical findings, and laboratory findings.
 - 5.2.4. The time frame and procedural events with technical comments for example, Interventional procedures performed and any issues of concern.
 - 5.2.5. Access site information and closure method.
 - 5.2.6. All catheters, sheaths, guide wires, and interventional equipment used should be reported in a procedural section.
 - 5.2.7. Drugs and doses given during the procedure, type and amount of radiographic contrast used, and estimation of radiation exposure should be included in the procedure report.
 - 5.2.8. A clear description of any complications or a positive statement that there were no apparent complications.
 - 5.2.9. Minimum requirements for reporting the peripheral diagnostic angiography are: 1) a description of the aorta and the vessels selected for arteriography, 2) a notation of the size, extent of distribution, tortuosity, and visual estimate of the degree of any narrowing, 3) patency of runoff vessels, 4) anatomic variations, 5) presence and severity of calcification, 6) presence and description of collaterals.
 - 5.2.10. For interventional procedures a complete description of the procedure, key equipment used, in lab results such as point-of-care ACT measurements, complications occurring and outcome of the intervention. Technical comments are helpful should future interventions be necessary.
 - 5.2.11. If performed, findings of intravascular ultrasound (IVUS) or OCT examinations and translesional pressure measurements or FFR should be reported within the procedure report.

- 5.2.11.1. 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 equipment used, the level of anticoagulation achieved and the peripheral vessels 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; g) IVUS related complications and any consequent subsequent.

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 diameter stenosis, lumen area of the stent and a description of strut apposition should be included.

- 5.2.11.2. If FFR and or pressure gradients are determined these must be documented.
- 5.2.11.3. IVUS images must be archived for subsequent review.
- 5.2.11.4. Standardized reports for new imaging techniques should be developed as needed and must include pertinent information similar to that described above for IVUS.

- 5.3. Summary of major findings or diagnosis.
- 5.4. Disposition of the patient as a result of the procedure and comments, including plans for follow-up care including medical therapy, imaging, and anticipated further interventions.

6. STANDARDS: Patient Indications

- 6.1. The indication for the peripheral vascular intervention must be documented according to accepted societal standards and be consistent with published guidelines, expert consensus documents, or appropriate use criteria (AUC) (15, 16, 17). Interventions for asymptomatic or non-threatening conditions are generally not warranted and must be fully supported by documented justification for performing the procedure.
 - 6.1.1. There must be sufficient clinical information available in the procedure report and medical record to determine the indication for the procedure.
 - 6.1.2. 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 procedure report.
 - 6.1.3. Elective patients with claudication should have failed or be intolerant of a trial of medical therapy (cilostazol) and exercise (preferably supervised).

6.2. Interventional indications based on Fontaine or Rutherford chronic limb ischemia criteria.

Rutherford Classification for Peripheral Arterial Disease

- Stage 0 – Asymptomatic
- Stage 1 – Mild claudication
- Stage 2 – Moderate claudication
- Stage 3 – Severe claudication
- Stage 4 – Rest pain
- Stage 5 – Ischemic ulceration not exceeding ulcer of the digits of the foot
- Stage 6 – Severe ischemic ulcers or frank gangrene

Fontaine Classification

- Stage 1 – Asymptomatic
- Stage 2A – Claudication pain walking more than two hundred meters
- Stage 2B – Claudication pain walking less than two hundred meters
- Stage 3 – Ischemic rest pain
- Stage 4 – Necrosis and/or gangrene of the limb.

6.3. Measurement and documentation of disease severity

6.3.1. Percent diameter stenosis:

- Severe = stenosis diameter > 70%
- Moderate = 50-69%
- Mild = < 50%

6.3.2. By ultrasound using the following criteria: 0-49%, 50-99%, Occluded

6.3.3. By ABI and TBI

6.3.4. By MRA/CTA by degree of stenosis

6.3.5. By Digital Subtraction Angiography (DSA)

- 6.3.5.1. The degree of peripheral stenosis shall be measured by duplex ultrasound or peripheral angiography and recorded in the patient's procedure report. If the degree of stenosis is measured prior to the procedure, then the degree of stenosis must be confirmed by angiography at the start of the procedure.

6.4. All patients shall have an angiogram clearly documenting pre and post lesion assessment.

6.5. > 90% of cases should meet these criteria for stenosis

6.6. All treated patients shall have a post procedure peripheral angiogram to evaluate flow and the occurrence of distal embolization

- 6.6.1. Pre-treatment peripheral anatomy may be evaluated by CTA, MRA, Ultrasound, or DSA but if so, documentation of these findings should be included as part of the pre-procedure evaluation. Otherwise, pre-procedure peripheral angiography should be performed as part of the initial angiographic lesions and anatomic assessment.

- 6.6.2. Residual stenosis should be < 30%. If not achieved, explanation such as severe calcification, etc should be included in the report.

7. STANDARDS: Patient Outcomes

7.1. Hospital-based outcomes, prior to discharge

7.1.1. Lesion success – adequate inflow and appropriate outflow are required to keep the revascularized segment functioning.

7.1.2. Procedural success rate should be > 90% of cases.

7.1.3. Complications

7.1.3.1. Access site complications

7.1.3.1.1. Requires re-intervention or surgical correction

7.1.3.1.2. Thromboembolism

7.1.3.1.3. Infection requiring antibiotics or drainage

7.1.3.1.4. Results in prolonged hospital stay

7.1.3.1.5. Requires any transfusion of PRBSs or platelets

7.1.3.2. Bleeding per Bleeding Academic Research Consortium (BARC) Criteria

Type 0 - No bleeding

Type 1 - Bleeding that is not actionable and does not cause the patient to seek treatment

Type 2 - Any clinically overt sign of hemorrhage that is actionable and requires diagnostic studies, hospitalization, or treatment by a health care professional

Type 3 - a. Overt bleeding plus Hgb drop of 3 to < 5 g/dL (provided the drop is related to bleed); transfusion with overt bleeding

b. Overt bleeding plus Hgb drop < 5 g/dL (provided the drop is related to bleed); cardiac tamponade; bleeding requiring surgical intervention for control; bleeding requiring IV vasoactive agents.

c. Intracranial hemorrhage confirmed by autopsy, imaging, or lumbar puncture; intraocular bleed compromising vision.

Type 4 - Surgery-related bleeding within 48 hours

Type 5 - a. Probable fatal bleeding

b. Definite fatal bleeding (overt, autopsy or imaging confirmation)

7.1.3.3. Target site complications: dissection, occlusion, extravasation

7.1.3.4. Renal failure (need for dialysis, doubling serum Cr, 25% increase from baseline or absolute increase of 0.5 mg/dl within 48 hours of contrast administration)

7.1.3.5. Access site complication not requiring intervention

7.1.3.5.1. Hematoma

7.1.3.5.2. Percutaneous repair (thrombin injection, ultrasound-guided compression) of pseudoaneurysm

7.1.3.5.3. AV fistula not requiring further treatment

- 7.1.3.6. Other procedure related complications, including cardiovascular or pulmonary compromise, radiation or other injury, and other events warranting clinical management or observation. Procedure related complications occur within 48 hours of the procedure or during the same hospitalization
- 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. Follow-up Outcomes to 30 days (3 to 6 weeks post-procedure)
 - 7.2.1. Symptomatic, functional, quality of life improvement
 - 7.2.2. Target lesion/vessel revascularization
 - 7.2.3. Wound healing
 - 7.2.4. 30 Day Adverse Event
 - 7.2.4.1. Death
 - 7.2.4.2. Myocardial Infarction
 - 7.2.4.3. Stroke
 - 7.2.4.4. All amputations, (planned and unplanned, reported separately)
 - 7.2.4.5. End-organ damage or renal failure
- 7.3. Follow-up Outcomes 180 days
 - 7.3.1. Symptomatic improvement
 - 7.3.2. Target lesion/vessel revascularization/Primary assisted patency/Secondary patency
 - 7.3.3. Wound healing
 - 7.3.4. 180 Day Adverse Event
 - 7.3.4.1. Death
 - 7.3.4.2. Myocardial Infarction
 - 7.3.4.3. Stroke
 - 7.3.4.4. All amputations, (planned and unplanned, reported separately)
 - 7.3.4.5. End-organ damage or renal failure

7.4. Follow-up Outcomes 360 days

7.4.1. Symptomatic improvement

7.4.2. Target lesion/vessel revascularization/Primary assisted patency/Secondary patency

7.4.3. Wound healing

7.4.4. 360 Day Adverse Event

7.4.4.1. Death

7.4.4.2. Myocardial Infarction

7.4.4.3. Stroke

7.4.4.4. All amputations, (planned and unplanned, reported separately)

7.4.4.5. End-organ damage or renal failure

8. Performance Metrics

As part of the ACE application, performance metrics from the NCDR PVI Registry Executive Summary will be reviewed. The specific performance metrics examined and their source are shown in the table below.

| Lower Extremity (LE) Process Metrics | Source | Line |
|---|-------------------|-------------|
| Measurement of ABI prior to procedure | NCDR PVI Registry | 27 |
| Smoking cessation intervention prior to discharge | NCDR PVI Registry | 28 |
| Antiplatelet therapy prescribed at discharge | NCDR PVI Registry | 29 |
| Statins prescribed at discharge | NCDR PVI Registry | 30 |
| LE Outcome Metrics | | |
| Angiographic success | NCDR PVI Registry | 31 |
| Incidence of bleeding or any vascular complications | NCDR PVI Registry | 32 |
| Incidence of any major adverse event | NCDR PVI Registry | 33 |

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