The IAC Standards for Carotid Stenting Accreditation
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Introduction

Introduction to IAC Standards for the Accreditation of Carotid Stenting Facilities

These standards list requirements and recommendations for Carotid Stenting facilities. All absolute requirements appear in bolded text. In addition to all standards listed in this document, the facility, including all medical and technical personnel, must comply at all times with all federal, state and local laws and regulations, including but not limited to laws relating to licensed scope of practice, facility operations, health, radiation and occupational safety.

The following documentation lists the requirements for facilities that apply for accreditation for cervical/extracranial carotid angioplasty and/or stenting through the IAC Carotid Stenting. This program is designed to accredit facilities that perform stenting of the extracranial carotid artery by ensuring that the facility meets benchmarks for quality based on resources, training and outcomes. Carotid stents may be appropriately placed for many indications (See Appendix), but the most common indication, and the indication for which outcome data is most widely available, is treatment of carotid bifurcation disease secondary either to atherosclerosis, post endarterectomy restenosis or radiation induced stenosis. Therefore the outcome benchmarks used in this program are intended to be applied only to cases treated for these indications. A facility that is able to meet the outcome benchmarks for these most common indications will most likely provide adequate outcomes for Carotid Stenting performed for less common indications (See Appendix).

A Carotid Stenting facility consists of at least one designated fluoroscopy system, a qualified physician, a nurse and an interventional technologist. Each facility must have a Medical Director and Technical/Administrative Director. The facility must meet the organizational requirements defined in this document. There may be additional physicians, interventional technologists and other professional and/or ancillary personnel. When more than one technical member is employed, a Technical/Administrative Director is responsible for supervision of the technical staff. If stenting is performed in more than one location within one facility, the facility is encouraged to apply for all locations within that facility under the overall direction of a Medical Director(s). All operators and all cases under the direction of the Medical Director(s) must be included in the application for accreditation.

The facility must be in compliance with all federal and state regulations and ensure compliance with all IAC Standards.
SECTION 1: Personnel and Supervision

STANDARD – Medical Director

1.1 The Medical Director must be a licensed physician.

1.1.1 Medical Director required training and experience:

1.1.1.1 Board certified in his/her relative specialty.

1.1.1.2 Have clinical expertise in the management of extracranial carotid occlusive disease, but need not personally perform cervical/extracranial carotid angioplasty and/or stenting.

1.1.2 Medical Director responsibilities:

The Medical Director is responsible for all cervical/extracranial carotid angioplasty and stenting services provided, including compliance, radiation safety, outcomes, quality control, quality of care and appropriateness of care provided. The responsibilities include, but are not limited to:

1.1.2.1 Compliance with all facility policies/procedures/protocols and will review and update all manuals periodically as necessary (minimum every three years) or as new policies are introduced. This review must be documented via signature (or initials) and date on the reviewed document or manual.

1.1.2.2 Active oversight of radiation safety within the facility as evidenced by membership on the institution’s radiation safety committee or periodic review of radiation safety issues and documentation. The radiation protection program content and implementation must be reviewed at least annually.

1.1.2.3 Delegation, when appropriate, of the supervision of radiation safety standards to the Technical/Administrative Director, radiation safety officer or health physics consultant. Records of radiation safety must be kept on file in accordance with local requirements and available for inspection.

1.1.2.4 The review and oversight of the clinical practice of cervical/extracranial carotid angioplasty and stenting services. This must include documentation of a comprehensive quality assurance program. Such a program should include a review of procedural indications, safety and complications as well as standardized and recognized clinical outcome measures.

Comment: The Medical Director may supervise the entire operation of the facility or delegate specific operations but is responsible for assuring compliance of medical and technical staff to the standards outlined in this document.
1.1.3 Continuing Medical Education requirements:

1.1.3.1 The Medical Director must obtain at least 15 hours of Category I continuing medical education (CME) credits, relevant to cerebrovascular disease that includes but is not limited to content that is directly related to the performance of cervical/extracranial carotid angioplasty and/or stenting and/or carotid atherosclerotic disease every three years.

If the Medical Director performs these procedures, he/she must meet the qualifications and maintenance of qualifications of the medical staff.

Comment: If the Medical Director has successfully attained one or more of the following within the three years prior to the application date, the CME requirement will be considered fulfilled:

A) Completion of an Accreditation Council for Graduate Medical Education (ACGME) approved (or similarly recognized) residency or fellowship.

OR

B) Attaining certification by an American Board of Medical Specialties (ABMS) recognized board.

1.1.3.2 Documentation of CME credits must be kept on file and available for inspection.

STANDARD – Medical Staff

1.2 All members of the medical staff must be licensed physicians.

1.2.1 Medical staff required training and experience:

1.2.1.1 The medical staff member(s) must meet one of the published national society training standards pertaining to cervical/extracranial carotid angioplasty and stenting and be credentialed by the health care facility to perform cervical/extracranial carotid angioplasty and stenting. The currently acceptable national society training standards are:

1.2.1.1.1 Training, Competency, and Credentialing Standards for Diagnostic CervicoCerebral Angiography, Carotid Stenting and Cerebrovascular Intervention: A Joint Statement from the American Academy of Neurology, American Association of Neurological Surgeons, American Society of Interventional and Therapeutic Neuroradiology, American Society of Neuroradiology, Congress of Neurological Surgeons AANS/CNS Section and Society of Interventional Radiology.5

1.2.1.1.2 Clinical Competence Statement on Carotid Stenting: Training and Credentialing for Carotid Stenting — Multispecialty Consensus Recommendations: A Report of the SCAI/SVMB/SVS Writing Committee to Develop a Clinical Competence Statement on Carotid Interventions.12

1.2.1.1.3 Qualification Requirements for Performing Neurointerventional Procedures: A Report of the Practice Guidelines Committee of the American Society of Neuroimaging and the Society of Vascular and Interventional Neurology.11
1.2.1.4 Other national society training standards may be considered appropriate subject to review and approval by the IAC Carotid Stenting Board of Directors.

1.2.1.2 All physicians (including the Medical Director, if applicable) performing cervical/extracranial carotid angioplasty and stenting must be privileged by clear and concise requirements as outlined by their hospital privileging committee that include periodic review and documentation of credentialed staff.

1.2.2 Continuing Medical Education requirements:

1.2.2.1 The medical staff members must obtain at least 20 hours of Category 1 CME credits, relevant to percutaneous therapeutic endovascular intervention and cerebrovascular disease every three years. Of these, 10 credit hours should be relevant to cervical/extracranial carotid angioplasty and stenting.

Comment: If the medical staff member has successfully attained one or more of the following within the three years prior to the application date, the CME requirement will be considered fulfilled:

A) Completion of an Accreditation Council for Graduate Medical Education (ACGME) approved (or similarly recognized) residency or fellowship.

OR

B) Attaining certification by an American Board of Medical Specialties (ABMS) recognized board.

1.2.2.2 Documentation of CME credits must be kept on file and available for inspection.

STANDARD – Technical/Administrative Director

1.3 The Technical/Administrative Director must be either an interventional technologist or nurse and meet the required training and experience qualifications as outlined in items 1.4 and 1.5 in this document.

1.3.1 The Technical/Administrative Director must have a reporting relationship with the Medical Director.

1.3.2 The Technical/Administrative Director responsibilities may include, but are not limited to:

1.3.2.1 The day-to-day operations of the facility.

1.3.2.2 The delegation, as necessary, of specific responsibilities to the technical and/or ancillary staff.

1.3.2.3 Verification/documentation of proper training and, at least annually, assessment of the competence of technical staff and/or any ancillary staff who report to the Technical /Administrative Director.
1.3.3 Continuing Education requirements:

1.3.3.1 The Technical/Administrative Director must obtain at least 15 hours of accredited continuing education (CE) in percutaneous interventional procedures or patient management every three years. All continuing education hours must be approved (i.e., Recognized Continuing Education Evaluation Mechanism (RECEEM), American Registry of Radiologic Technologists (ARRT)-Category A, American Society of Radiologic Technologists (ASRT), American Medical Association (AMA), American Nurses Credentialing Center (ANCC)-Category I).

Comment: If the Technical/Administrative Director has successfully attained an appropriate technical credential within the three years prior to the application date, the continuing education requirement hours will be considered fulfilled.

1.3.3.2 Documentation of CE credits must be kept on file and available for inspection.

STANDARD – Interventional Technologist(s)

1.4 Interventional technologist required training and experience:

1.4.1 The interventional technologist must meet ONE of the following criteria for required training and experience:

1.4.1.1 A registered radiologic technologist with the American Registry of Radiologic Technologists (ARRT) or the Canadian Association of Medical Radiation Technologists (CAMRT) with post primary certification in one of the following:

1.4.1.1.1 Cardiac-Interventional Radiography RT(CI)
1.4.1.1.2 Vascular-Interventional Radiography RT(VI)
1.4.1.1.3 Cardiovascular-Interventional Radiography RT(CV)

1.4.1.2 A registered radiologic technologist [RT(R)] with a minimum of one year of full-time equivalent experience as an interventional technologist under the direct supervision of personnel meeting pathway 1.4.1.1, as indicated above. A clinical rotation in interventional, cardiology, vascular or invasive procedures as part of their educational program may be counted for up to 6 months of clinical experience.

1.4.2 The interventional staff technologist must report to the Technical/Administrative Director.

1.4.3 The interventional technologist responsibilities may include, but are not limited to:

1.4.3.1 Reviewing and/or recording pertinent patient history and supporting clinical data.
1.4.3.2 Obtaining a record of anatomical, pathological and/or physiological data for interpretation by the physician.
1.4.3.3 Positioning of the patient, selection of radiation exposure parameters, imaging of the patient and archiving of the images.
1.4.3.4 Maintaining a high degree of awareness of all radiation and patient safety issues involved with any invasive procedure.

1.4.3.5 Demonstrating a thorough understanding and working knowledge of normal and abnormal anatomy, physiology, radiation safety, interventional supplies and equipment operation.

1.4.3.6 Recognizing and resolving equipment problems and discrepancies, anticipating patient needs and concerns and communicating the appropriate care needed.

1.4.3.7 Using professional judgment and critical thinking when performing procedures.

1.4.3.8 Scrubbing in and assisting the physician in the procedure when necessary.

1.4.3.9 Circulating within the procedure room and procuring equipment needed for any given procedure.

1.4.3.10 Performing other procedures and duties, as assigned.

1.4.4 Continuing Education requirements:

1.4.4.1 The interventional technologist staff must obtain at least 15 hours of accredited continuing education (CE) in percutaneous interventional procedures or patient management, every three years. All continuing education hours must be approved CE (i.e., RECEEM, ARRT-Category A, ASRT, AMA Category I).

Comment: If the interventional technologist staff member has successfully attained an appropriate technical credential within the three years prior to the application date, the CE requirement will be considered fulfilled.

1.4.4.2 Documentation of CE credits must be kept on file and available for inspection.

STANDARD – Interventional Nurse(s)

1.5 Interventional nurse(s) required training and experience:

1.5.1 The interventional nurse(s) must meet ONE of the following criteria for required training and experience:

1.5.1.1 Registered Nurse (RN)

1.5.1.2 Advanced health care degree or Bachelor of Science in Nursing (BSN) preferred.

1.5.1.3 Recommend certification in interventional nursing specialty such as Cardiac Vascular Nursing (CVRN), Cardiac Vascular Invasive Specialist (CVIS) or Certified Radiology Nurse (CRN).

1.5.2 Critical care or emergency room experience is required.

1.5.3 At least six months of critical care or emergency room nursing.
1.5.4 Basic Life Support (BLS) and Advanced Cardiac Life Support (ACLS) certification is required.

1.5.5 The interventional nurse responsibilities may include, but are not limited to:

1.5.5.1 Administering and monitoring moderate sedation.
1.5.5.2 Performing neurological assessment.
1.5.5.3 Knowing relevant radiation safety.
1.5.5.4 Monitoring and assessing clinical status of patient.
1.5.5.5 Cardiovascular and hemodynamic monitoring and management.
1.5.5.6 Advising patient care team and treating patient appropriately.

1.5.6 Continuing Education requirements:

1.5.6.1 The interventional nursing staff must obtain at least 15 hours of accredited continuing education (CE) in percutaneous interventional procedures, neurologic assessment and/or patient management, every three years. All continuing education (CE) hours must be American Nurses Credentialing Center (ANCC) approved. At least one contact hour in moderate sedation is required annually.

Comment: If the nursing staff member has successfully attained an appropriate specialty certification CVRN, CVIS or CRN within the three years prior to the application date, the CE requirement will be considered fulfilled.

1.5.6.2 Documentation of CE credits must be kept on file and available for inspection.

STANDARD – Neurological Assessment Examiner(s)

1.6 Neurological assessment examiner(s) required training and experience:

1.6.1 Independent neurologic assessments must be performed by a physician or physician extender as allowed by state law (i.e., physician assistant (PA) or nurse practitioner (NP) with neurological expertise). The independent examiner is defined as the person performing the assessment that is not the operator or any other person listed on the procedure documentation. Optimally, these examinations are performed by a neurologist.

1.6.2 The National Institutes of Health Stroke Scale (NIHSS) and Modified Rankin Scale (mRS) may be performed by physicians, nurses or other qualified health care professionals that have completed formal training and demonstrated competency in performing NIH Stroke and Modified Rankin scales. All examiners must have current NIHSS and Modified Rankin certification by a nationally recognized certification organization recognized by organizations such as the National Stroke Association or the American Stroke Association. Following initial certification, initial recertification is required at six months and then annually.

1.6.2.1 Documentation of current NIHSS and Modified Rankin certification must be kept on file and available for inspection.
STANDARD – Ancillary Personnel

1.7 The facility must ensure that adequately trained and experienced ancillary personnel are available to perform safe and effective patient care appropriate for the level of service as designated by the Medical or Technical/Administrative Director. The specific needs of a facility must be determined by an evaluation of the types and volumes of procedures as well as facility configuration.

1.7.1 Ancillary personnel may consist of, but are not limited to:

1.7.1.1 Anesthesia personnel
1.7.1.2 Technical assistants
1.7.1.3 Clerical and administrative assistants
1.7.1.4 Computer support staff
1.7.1.5 Equipment support staff (i.e., biomedical, x-ray service)

1.7.2 All ancillary personnel within the department must be supervised by the Medical Director or a qualified designee. The supervisor must document/verify proper training, at least annually and current competence of the ancillary personnel appropriate to the assigned duties.

STANDARD – Medical Physicist

1.8 A qualified medical physicist must be appointed for the facility.

1.8.1 Medical physicist required training and experience:

1.8.1.1 Board certification by the American Board of Radiology (ABR), the American Board of Medical Physics (ABMP), or the Canadian College of Medical Physics (CCMP) in a discipline that includes diagnostic imaging is recommended.

1.8.1.2 A physicist who has passed Part 2 of the ABR examination in a discipline of medical physics that includes diagnostic imaging is acceptable. Full certification by a recognized board as outlined above is required prior to the next accreditation cycle.

1.8.1.3 Licensed or certified in accordance with state and local regulations.

1.8.2 Medical physicist responsibilities:

1.8.2.1 Perform initial and annual surveys for equipment performance evaluation including:

1.8.2.1.1 Radiation output measurements
1.8.2.1.2 System quality control tests
1.8.2.1.3 Image quality performance measurements
1.8.2.1.4 Analyze all data with appropriate recommendations
1.8.2.2 Provide a written summary of all assessment and evaluations performed.

1.8.2.3 Provide guidance for any patient and/or staff dosimetry issues.

1.8.2.4 Provide radiation training for facility physicians and staff as required.

1.8.3 Other personnel, deemed by the medical physicist as competent to perform the assigned tasks, may assist the medical physicist in the collection of data under the direct supervision of the medical physicist. **The medical physicist must review and approve all such data.** The medical physicist remains personally responsible for the performance quality of the assigned tasks.

1.8.4 It is recommended that the physicist observe at least one (interventional) procedure per year.

1.8.5 Continuing Education requirements:

1.8.5.1 **The medical physicist must obtain at least 15 credits hours approved by the Commission on Accreditation of Medical Physics Education Program (CAMPEP) in diagnostic imaging including fluoroscopy, every three years.** The 15 hours should include the following categories: imaging, quality control/instrumentation and radiation safety.

Comment: If the medical physicist has successfully attained board certification within the three years prior to the application date, the continuing education requirement will be considered fulfilled.

1.8.5.2 **Documentation of CAMPEP credits must be kept on file and available for inspection.**
SECTION 2: Physical Facilities

STANDARD – Physical Space

2.1 Adequate facilities must be provided for all operations of the facility so that patient comfort, safety, dignity, and privacy are ensured as well as staff comfort and safety. Procedure areas must have sufficient space, be well maintained and clean. There should be adequate space for the interventional personnel to freely access the patient and for all staff to maintain the sterile field.

2.1.1 Physical space requirements include, but are not limited to:

2.1.1.1 Waiting, reception and patient/staff bathrooms

2.1.1.2 Patient education, consultation and examination areas

2.1.1.3 Readily accessible hand washing/sanitation for staff

2.1.1.4 Performance of pre-test/post procedures within appropriate proximity of the procedure area including adequate space for performing resuscitation in case of emergency.

2.1.1.5 There must be immediate access to computed tomography or magnetic resonance imaging to allow evaluation of possible complications.

2.1.1.6 Adequate space, facility configuration and doorways for the emergency transport of patients from patient care areas and for emergency exit of staff.

2.1.2 The procedure room/area must have or meet:

2.1.2.1 General anesthesia capability

2.1.2.2 Radiation shielded barriers that meet state and federal requirements

2.1.2.3 Interpretation areas

2.1.2.4 Patient records, reports and digital data storage areas. The storage must ensure confidentiality of data and should be safe from fire/flood.

2.1.2.5 Administration records and support areas

2.1.2.6 Equipment/supply storage areas

2.1.2.7 Patient post care areas

2.1.2.8 Room utilities: Adequate utilities based upon the types of procedures and workload. These utilities include water taps, lighting, electrical outlets, emergency power, telephones, heating/cooling and ventilation.

2.1.2.9 Room lighting: Overhead and task lighting must be adequate to perform carotid stent procedures and for clinical evaluation and treatment of the patient. The overhead lighting must be able to be dimmed during fluoroscopy. It is recommended that the overhead lighting be controlled by a foot pedal used by the operating physician.
2.1.2.10 Room power: The facility must have a plan that outlines the response to unexpected power loss or computer function, such as movement of the patient to another carotid stent capable procedure room in the immediate vicinity.

A) When normal power is not available, emergency power should be capable of providing a minimum of 10 minutes of fluoroscopy, and at least one hour of back up power for the computers, monitoring equipment and ancillary equipment.

B) For systems ordered after July 2011, there should be sufficient emergency power supply to run fluoroscopy for a duration of one hour and to run the remainder of the x-ray system components including lighting, for a minimum of 24 hours.

C) Utilization of emergency power must be visible by the operator at the normal working position.

D) X-ray equipment and computers should not require rebooting during transition between normal and emergency power or during power line instabilities.

STANDARD – Equipment and Instrumentation

2.2 Equipment and instrumentation used in the performance of carotid artery stenting must be appropriate, in good working condition and should substantially comply with the International Electrotechnical Commission (IEC) 60601-2-43 interventional standard.

2.2.1 All equipment and instrumentation must be routinely inspected for safety and proper functionality and records of the inspections kept on file. Equipment and instrumentation must include at a minimum the following:

2.2.1.1 A fixed (recommended) or portable, single or biplane (recommended) angiography system that must meet the following specifications:

A) Digital subtraction imaging of at least 3 frames per second, with the ability to do program change of rate during the image acquisition run

B) High quality, subtracted digital radiographs

C) Roadmapping with ability to refer back to an unsubtracted live image

D) Last image hold

E) Pulsed fluoroscopy

F) Dose measurement capability

G) Digital Imaging and Communications in Medicine (DICOM) compatible digital image storage with capability of storing uncompressed images on portable format without loss of image resolution

H) Ability to display and review prior relevant images during the procedure.
I) Minimum detector diameter of 9 inches
J) Minimum spatial resolution of matrix of 1000 x 1000
K) Minimum contrast resolution to see the 1.5 mm hole in a standard phantom (see Guidance Documents posted on www.intersocietal.org/carotid/main/sample_documents.htm.)
L) Image monitor performance using the Society of Motion Picture and Television Engineers (SMPTE) pattern
M) Ability to record fluoroscopy time and number of images, and least one of the following: cumulative dose or dose area product (DAP).7
N) Radiation use must be consistent with the “as low as reasonably achievable” principle or ALARA radiation safety guidelines.

2.2.1.2 Emergency equipment and supplies (response cart or kit) including but not limited to:
A) Oxygen/suction
B) Defibrillator/automated external defibrillator (AED)
C) External pacemaker equipment
D) Emergency drugs (including a master list with verification of expiration date)

2.2.1.3 Monitoring equipment must be available to perform:
A) Intravascular pressure
B) Noninvasive blood pressure
C) Pulse oximetry
D) Electrocardiogram (ECG)
E) Capnography (CO2) monitoring is recommended for use with moderate sedation

2.2.1.4 Low or iso osmolar contrast must be used for intravascular injections

2.2.1.5 Power or automated injectors (as applicable)

2.2.1.6 Adequate disposable supplies must be immediately available. These include U.S. Food and Drug Administration (FDA) approved catheters, wires, stents, balloons and embolic protection devices. Non-FDA approved devices may also be used as permitted by law.

2.2.1.7 Ancillary equipment as appropriate (e.g., monitoring equipment, blood coagulation testing equipment, workstations, picture archiving communication system (PACS), radiation protection for personnel (aprons and thyroid shields, portable shield either on wheels or suspended from ceiling)
STANDARD – Equipment and Instrumentation Quality Control

2.3 There must be a comprehensive quality assurance (QA) program to provide a standard of measurement for system performance and the documentation of any variance thereof.

2.4 A quality control committee should be appointed to provide oversight to the equipment and instrumentation quality control.

2.5 Fluoroscopic system quality control (QC) testing must include a comprehensive evaluation of the system components, image performance, and radiation output limits as outlined in the FDA Code of Federal Regulations (CFR) Title 21 subchapter J, Parts 1010 and 1020 and applicable FDA guidance documents.

2.6 Image quality requirements, radiation output limits, and other fluoroscopic performance requirements must also comply with the health-code regulations of the state in which the facility is located.

2.7 The site-appointed qualified medical physicist must complete the performance evaluations at equipment installation and annually, unless state regulations require more frequent testing. Equipment performance evaluations are recommended semi annually to include radiation output measurements, system quality control tests and image quality performance measurements.

2.8 The site-appointed medical physicist must perform a radiation safety survey to ensure that occupational workers and members of the public are shielded according to state regulation. This must be performed prior to installation of each new angiographic imaging system. A documented radiation safety survey of the interventional suite and adjacent areas that has been accepted by the State Radiation Program fulfills this requirement.

2.9 A radiation safety survey must be performed on all renovated or newly constructed interventional suites and adjacent areas. This must be performed prior to first patient use. This survey must confirm that the levels of radiation protection are in conformance with the State Radiation Program.

2.10 All spaces outside the procedure rooms should provide adequate protection for full time occupancy by nonradiation workers. This recommendation includes the control room.

2.11 Preventive maintenance (PM) service is recommended periodically per the manufacturers’ recommendations for each angiographic system at the facility.

2.12 Documentation of the physicists’ evaluation, preventative maintenance and quality control tests performed, and service records for all angiographic systems and ancillary equipment must be maintained at the facility and available for review. The reports must be signed and dated by the person(s) performing the tests.

2.13 Results of all QC tests must be documented, archived and stored on film, in digital format, or on other suitable media according to state requirements, if applicable.

2.14 Ancillary equipment (e.g., monitoring equipment, blood coagulation testing equipment, injectors, workstations, PACS, lead aprons, suction, oxygen lines, etc.) should also be included in a PM program.

2.15 The emergency response cart or kit must be checked at least monthly, with documentation to assure that all expected items are present and the supplies are not expired.

2.16 There must be a process to check inventory of disposable supplies (e.g., catheters, wires, balloons, stents, embolic protection devices, contrast, portable oxygen tank) on a regular basis to assure that these supplies are readily available during a procedure.
SECTION 3:
Volume of Clinical Procedures

STANDARD – Facility Volume

3.1. The procedure volume must be sufficient to maintain proficiency in procedure performance.

3.2. The facility must have specific privileging requirements for individual operators to perform both carotid/cerebral angiography and Carotid Stenting.

3.3. The facility must have performed at least 25 carotid stent procedures over the preceding three-year period for the facility to be considered eligible for accreditation.

   3.3.1. If the facility has performed fewer than 25 carotid stent procedures over the preceding three year period at least one operator must have performed 15 carotid stent cases (either in training or during post training experience as the primary operator) preferably with an embolic protection device in the past three years with adequate outcomes as defined in Quality Improvement Standards, items 5.3 and 5.4 in Section 5 of this document.

3.4. The facility quality assurance program must include all elective cases.

   3.4.1. Reporting of additional emergent cases which may involve additional intracranial or cervical advanced techniques should be given consideration.

Comment: The application review will recognize and take into consideration that a higher complication rate may be reported for the emergent cases.
SECTION 4:  
Process

STANDARD – Procedures and Protocols

4.1.  Carotid artery stent procedure overview

Carotid stenting is a procedure in evolution and the procedure overview described below is not intended to be a comprehensive list of requirements to perform a case, nor does it list every step necessary for every patient. It represents an overview of the general steps to perform a typical elective case in order to provide a context for the overall requirements of this accreditation program. Any item in bold text is required as part of the carotid stent procedure. A facility may find it helpful to use this description to create an institutional template to be used as a reference when analyzing outcomes.

4.1.1.  The facility must assure that appropriate staff with BLS and ACLS certification are present during the procedure.

4.1.2.  Appropriate staff must be available to assist the patient should an adverse event occur during the procedure and/or during recovery.

4.2.  Prior to performance of the procedure:

4.2.1.  An adequate supply of devices approved by the FDA for marketing or investigational use must be available. This includes, but is not limited to: interventional guide wires, diagnostic catheters, guiding catheters, angioplasty balloons, distal protection devices and carotid stents.

4.2.2.  Appropriate pharmacologic agents must be readily available for use during the procedure.

4.2.3.  Proper identification of the patient and planned procedure (e.g., target vessel) must be carried out prior to puncture according to national patient safety goals and the proper patient name or identification (ID) must be present on the imaging system.¹

4.2.4.  History and physical exam must be performed and should be in the chart and include documentation of relevant medications, allergies and bleeding disorders.

4.2.5.  Overall neurologic assessment, National Institutes of Health Stroke Scale (NIHSS) and modified Rankin Scale (mRS) scores are documented.

4.2.5.1.  Patients undergoing Carotid Stenting will undergo independent neurologic assessments prior to and following the procedure to document the functional performance status and neurological examination and evaluate for any adverse neurological events.

4.2.6.  Laboratory testing should be carried out including hemoglobin, hematocrit, platelet count, blood urea nitrogen (BUN), creatinine (within 30 days of the procedure) and pregnancy test (in women of childbearing age).

4.2.7.  Imaging assessment of the cerebral parenchyma must be performed for patients with recent symptoms (stroke or cerebral transient ischemic attack (TIA).
4.2.8. Imaging of the intra and extra cranial carotid and vertebral circulation should be performed for both symptomatic and asymptomatic patients using either catheter or noninvasive angiography.

4.2.9. The current standard treatment for antiplatelet agents/antithrombotic therapy should have been administered. At this time the current standard is a dual antiplatelet regimen consisting of aspirin and either clopidogrel or ticlopidine.

4.2.10. The facility must have a process to address intra-procedural complications, including development of a new neurological deficit during the procedure.

4.3. During the performance of the procedure:

4.3.1. Cardiac pacing supplies and equipment if necessary must be available.

4.3.2. Cardiovascular medications must be available.

4.3.3. Physiologic monitoring must include continuous ECG, blood pressure, and pulse oximetry. Capnography may be used, if appropriate.

4.3.4. Intravenous access for administration of fluids and medications must be in place.

4.3.5. Radiation should be monitored during the procedure.

4.3.6. The stent delivery sheath or guiding catheter should be connected to an airless flush system.

4.3.7. Baseline ipsilateral carotid and cerebral angiography must be performed.

4.3.8. Adequate anti-coagulation should be confirmed with activated clotting time (ACT) > 250 seconds prior to crossing the lesion.

4.3.9. Embolic protection device should be placed, if feasible.

4.3.10. Pre-dilation of lesion should be considered, if needed.

4.3.11. Deploy the stent.

4.3.12. Post-dilation should be considered, if needed.

4.3.13. Remove embolic protection following stent deployment.

4.3.14. Perform post stent deployment carotid and cerebral angiogram to check for stent patency, and to evaluate for distal emboli.

4.4. Following the performance of the procedure:

4.4.1. Perform and document post procedure basic neurologic evaluation to assess for new neurologic deficits prior to moving the patient off the table.

4.4.1.1. The facility must have a protocol in place to address post procedure neurologic deficits.

4.4.2. Assessment of blood pressure and the status of the puncture site.

4.4.2.1. Blood pressure must be controlled post procedure according to the facility protocol.
4.4.3. **A post procedure note in the patient’s chart must be generated summarizing the procedure and addressing any immediate complications and the patient’s status at the end of the procedure.**

4.4.3.1. **Radiation usage as recorded by the angiographic system (i.e., fluoro time, DAP, mGy) during the procedure must be documented in the final procedure report.**

4.4.4. **The patient must be moved to an appropriate setting such as a neuro critical care/ intensive care/step down unit with the equipment and trained personnel necessary to perform vascular, hemodynamic and neurological monitoring and stroke assessment.**

4.4.5. **Document post procedure independent neurologic assessment (including an NIHSS and modified Rankin score) within approximately 24 hours and also at approximately 30 days.**

4.4.5.1. **If there is any worsening from the pre procedure NIHSS (> 2 point change) or modified Rankin score or new neurological deficit, a neurologic consultation must be performed by a neurologist or if a neurologist is not available a physician with neurologic expertise.**

4.4.6. **Imaging of the stent must be performed at 30 days (+/- 10 days) for patency.** Duplex ultrasound is the recommended imaging study.
SECTION 5: Quality Improvement

STANDARD – Quality Improvement

5.1. Quality Assurance Program

5.1.1. The facility must have a quality assurance program and conduct internal quality assessment and improvement at regular intervals that are appropriate for the facility’s stated purpose and include carotid artery stenting (See Appendix). Typically, assessments are an ongoing process with monthly or quarterly review of results.

5.1.2. The Medical Director and appropriate staff must review and maintain minutes or reports of quality improvement evaluations and document, as applicable, corrective measures taken.

5.1.3. The performance of all medical, technical and ancillary staff must be assessed as part of the quality improvement program.

5.1.4. There must be a program in place to assess and evaluate patient and personnel radiation dose.

5.1.5. Adherence to National Patient Safety Goals must be documented.1

5.1.6. The program must show evidence of improvement activities or, if an assessment confirms acceptable quality of a measure, the program must demonstrate improvement by selecting a new or an additional area for assessment.

5.1.7. The program should have pre-defined indicators of quality and pre-defined thresholds that indicate the need for corrective action. Comparisons with external benchmarks are desirable.

5.1.8. The facility must have a mechanism in place to track each carotid stent procedure performed including but not limited to patient identification, date of birth, date of procedure, the clinical indication, pre and post procedure neurologic assessment including NIHSS and mRs, use of embolic protection device use, degree of stenosis improvement post procedure and any procedure complications that occur up to 30 days (+/- 10 days) after the procedure.

5.1.9. Documentation of a written process to contact all patients for the 30-day follow-up assessment (+/- 10 days) is required.

5.1.10. Participation in a national registry of carotid stent procedures is strongly recommended.

5.2. Quality Assessment Measures

5.2.1. For purposes of quality assessment and reporting of outcomes, the carotid stent procedure begins when the guide catheter or sheath for stent placement has been inserted into the patient. Deployment is considered successful if the stent has been placed across the target lesion per the instructions for use.

5.2.2. The quality improvement program must include clinical indications including risk category and outcome measures. Administrative quality components as outlined below in items 5.5, 5.6, 5.7 and 5.8, as appropriate should also be included.
5.2.3. **Outcome data is most widely available for treatment of carotid bifurcation disease secondary either to atherosclerosis, post endarterectomy restenosis, or radiation induced stenosis. Therefore the outcome benchmarks used in this program are intended to be applied only to cases treated for these indications.** However all cases should be included in outcome monitoring.

5.2.4. **Outcomes data must be consistent with national benchmarks and where there are no benchmarks the data must be used to internally improve processes and procedures.** For facilities not meeting the benchmarks described below in items 5.3 and 5.4, a plan for improvement must be submitted and documented improvement provided within 12 months before full accreditation will be considered.

5.2.5. **Reporting of outcomes**

5.2.5.1. **Initial accreditation:**

Many facilities may have low volumes of procedures when they apply for initial accreditation. This low volume makes statistical analysis of complication rates unreliable and may penalize a low volume facility that has a complication early in its experience. In addition, a new facility may not have performed any procedures (although at least one individual physician must have a minimum experience of 15 procedures in order to apply for accreditation). Similar to the technique used to evaluate the outcomes of vascular surgeons performing carotid endarterectomy, facilities applying for initial accreditation will be evaluated on a minimum of 100 patients (50 symptomatic and 50 asymptomatic) in the previous three years. If the facility has not performed 100 procedures in the three years prior to initial accreditation, the facility will be provided up to 50 complication-free hypothetical procedures in each indication category. For example, a facility with a low volume will be given up to 100 hypothetical procedures (50 symptomatic and 50 asymptomatic) without a death or stroke.

5.2.5.2. **Reaccreditation:**

After initial accreditation the facility will be evaluated only on cases performed since the initial accreditation. Each facility will be provided one time with 50 complication-free hypothetical procedures in each indication category. The facility will then create a running total of 50 procedures in each indication category. The outcomes must be tracked both by actual procedures as well as actual procedures plus hypothetical procedures. The overall combined analysis is what will be used to determine if a facility meets the benchmarks. However, complications and complication rates in actual procedures must be reviewed to prevent the hiding of an unacceptably high complication rate within the moving 50. For each actual procedure performed a hypothetical procedure will be dropped from the total until all hypothetic procedures are removed and outcomes are then based solely on actual procedures performed by the facility.

After the facility has performed 50 procedures in an indication category, analysis of outcomes for the facility for that category will be based on the total actual procedures performed since the initial accreditation, and the ability to use any hypothetical cases will be removed.

After a facility has performed 100 actual procedures in an indication category it will be evaluated on the running total of the most recent 100 procedures in that category.
5.3. Outcome measures: Benchmarks by indications for procedures

5.3.1. Elective Symptomatic Carotid Stenosis – defined as experiencing acute TIA symptoms or completed ischemic stroke within 6 months of the intervention, but neurologically stable for at least 24 hours.

5.3.1.1. Benchmark: < 6% all stroke and death within 30 days of the procedure. (See Appendix for definition of stroke)

Comment: In order to apply for accreditation, if the facility exceeds the benchmark of 6% but does not exceed 10%, a plan for improvement must be submitted and documented improvement provided within 12 months before full accreditation will be considered. Benchmarks must be met within three years.

5.3.2. Elective Asymptomatic Carotid Stenosis

5.3.2.1. Benchmark: < 3% all stroke and death within 30 days of the procedure. (See Appendix for definition of stroke)

Comment: In order to apply for accreditation, if the facility exceeds the benchmark of 3% but does not exceed 4%, a plan for improvement must be submitted and documented improvement provided within 12 months before full accreditation will be considered. Benchmarks must be met within three years.

5.4. Outcome measures: Technical

5.4.1. Peri/immediate post procedure

5.4.1.1. Successful stent deployment – Deployment is considered successful if the stent has been deployed across the target lesion per the instructions for use.

5.4.1.1.1. Benchmark = > 95% of the cases have successful stent deployment.

5.4.1.2. Improvement in degree of stenosis – post procedural % angiographic stenosis by NASCET methodology.4

5.4.1.2.1. Benchmark = > 95% of the cases have improvement in the degree of stenosis.

5.4.1.3. Measurement of neurological outcome by an independent examiner (defined as the person performing the assessment that is not the operator or any other person listed on the procedure documentation).

5.4.1.3.1. Modified Rankin Scale at 24 hours (or discharge)

5.4.1.3.2. NIHSS at 24 hours

5.4.1.3.3. Neurologic assessment – If there is any worsening from the pre procedure NIHSS (> 2 point change) or mRS or new neurological deficit, a neurologic consultation must be performed by a neurologist or if not available a physician with neurologic expertise.

5.4.1.3.3.1. Benchmark = 100% at 24 hours for pre and post procedure measurement of NIHSS and mRS.
5.4.1.4. Thirty-day follow-up

5.4.1.4.1. 80% of patients will have 30-day outcomes follow-up data

5.4.1.4.1.1. Imaging of stent must be performed at 30 days (+/-10 days) for patency. Duplex ultrasound is the recommended imaging study.

Comment: If stent occlusions occur in two or more patients at 30 days within a three-year review cycle then a process must be in place for review and reporting of causative factors and methods for improvement.

5.4.1.4.1.2. Measurement of neurological outcome

A) Modified Rankin scale
B) NIHSS
C) Neurologic assessment: If there is any worsening from the pre procedure NIHSS (> 2 point change) or Rankin or new neurological deficit, a neurologic consultation must be performed by a neurologist or if a neurologist is not available a physician with neurologic expertise.

5.5. Administrative Quality Assessment

5.5.1. The quality assurance program must be in place to assess and improve the administrative quality of the facility’s operation. Administrative areas that may be assessed include but are not limited to:

5.5.1.1. Patient education: On individual risk factors, smoking cessation, signs and symptoms of stroke and calling 911, importance of follow-up after discharge, review of discharge medications including importance of adherence to antithrombotic therapy.

5.5.1.2. Scheduling back logs

5.5.1.3. Patient wait times

5.5.1.4. Accuracy of patient information during scheduling

5.5.1.5. Completeness of documentation

5.5.1.6. Late reports

5.5.1.7. Time from completion of procedure to distribution of final report

5.5.1.8. Patient satisfaction

5.5.1.9. Referring physician satisfaction

5.6. Technical Quality Assessment

5.6.1. The quality assurance program must include assessment of the technical quality of the images and procedures being performed. Areas that may be assessed include but are not limited to:
5.6.1.1. Image quality
5.6.1.2. Image display/labeling
5.6.1.3. Documentation of adverse technical events such as equipment or device failure

5.7. Physician Performance Quality Assessment

5.7.1. The quality assurance program must include assessment of the performance of physicians regarding the quality of medical practice (such as report accuracy, appropriateness of care, effectiveness of performing the procedure) and physician behaviors (communication and professionalism). Areas that may be assessed include but are not limited to:

5.7.1.1. Peer review
5.7.1.2. Correlation of interpretation with other diagnostic studies, pathology/surgical results and/or patient outcomes
5.7.1.3. Time from completion of procedure to distribution of final report
5.7.1.4. Referring physician satisfaction
5.7.1.5. Patient satisfaction

5.8. Patient Radiation Dose Review/Evaluation

5.8.1. The quality assurance program must include an assessment of patient dose as compared to published guidelines. At a minimum the program must meet the criteria outlined in Guidelines for Patient Radiation Dose Management.\(^\text{13}\)

Comment: The radiation dose thresholds outlined in the reference are trigger values set at a prudently low value such that the possibility of an injury at the threshold level is highly unlikely. There is no implication that exceeding a threshold will always cause an injury.

5.8.1.1. When radiation dose thresholds are exceeded, the facility must have a process in place for patient monitoring and follow-up.
5.8.1.2. All steps in the evaluation and follow up process must be documented.

5.8.2. Other diagnostic angiographic procedures

5.8.2.1. Facility should have processes in place for monitoring cerebral diagnostic arteriography with complications not to exceed published guidelines.\(^\text{10}\)

5.9. Quality Assurance meetings

5.9.1. All relevant personnel assessed in the quality assurance program must participate in periodic facility meetings to review findings and determine actions for improvement of performance. At a minimum, these meetings must occur at least every six months.
5.9.2. Every stroke and death must be reviewed during these meetings.
5.9.3. All relevant personnel must be included in periodic facility meetings to provide in-service education containing relevant topics. Topics should include safety procedures, technical information and improvements to be made based on quality assessments and other information.
Selected Bibliography


Appendix

QUALITY ASSURANCE MEASURES: INDICATIONS AND ADVERSE EVENTS

I) INDICATIONS FOR CAROTID ANGIOPLASTY AND/OR STENTING

Definition: Symptomatic carotid stenosis is defined as a carotid stenosis associated with an ipsilateral cerebral or retinal TIA or infarction within the past 6 months.

Comment: Centers for Medicare and Medicaid Services (CMS) reimbursement policy requires patients to meet specific indications (www.cms.hhs.gov/Transmittals/Downloads/R98NCD.pdf - 2009-08-19). Currently, CMS policy requires that all patients are high surgical risk (see below) and have a pre-procedure mRS < 2. For symptomatic patients current CMS reimbursement policy requires > 70% angiographic diameter stenosis using NASCET criteria. For patients participating in an approved trial, the stenosis may be > 50%. For asymptomatic patients, current CMS reimbursement policy requires patients to be enrolled in an approved trial and have > 80% angiographic diameter stenosis using NASCET criteria.

High Risk Category as defined by CMS:

1. Congestive heart failure (CHF) class III/IV;
2. Left ventricular ejection fraction (LVEF) < 30%;
3. Unstable angina;
4. Contralateral carotid occlusion;
5. Recent myocardial infarction (MI);
6. Previous CEA with recurrent stenosis;
7. Prior radiation treatment to the neck; and
8. Other conditions that were used to determine patients at high risk for CEA in the prior carotid artery stenting trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.

IAC Carotid Stenting recognizes that not all patients fall into one of the above categories and CMS may alter reimbursement policy as more data are available. Other potential indications are listed below. However, the presence of one or more of these potential anatomic and medical conditions in a patient does not imply that carotid angioplasty and/or stenting is indicated for that patient. Appropriate therapy is determined by symptoms, severity of stenosis and an overall assessment of the risks and benefits of the procedure compared to alternative medical and interventional therapies.

1. Stenosis that is surgically difficult to access (e.g., high bifurcation requiring mandibular dislocation)

2. Stenosis in a patient with significant medical disease that would make the patient high risk for surgery

3. Stenosis and one of the following conditions:
   a. Significant tandem lesion that may require endovascular therapy
   b. Radiation-induced stenosis
   c. Restenosis following CEA
   d. Refusal to undergo CEA following proper informed consent
   e. Stenosis secondary to arterial dissection
   f. Stenosis secondary to fibromuscular dysplasia (stents rarely, if ever, indicated)
   g. Stenosis secondary to vasculitis (stents rarely, if ever, indicated)

4. Stenosis associated with contralateral carotid artery occlusion requiring treatment before undergoing cardiac surgery
5. Severe underlying carotid artery stenosis revealed after recanalization of carotid occlusion following thrombolysis for acute stroke (presumed to be the etiology of the treated occlusion) or to enable thrombolysis for acute stroke

6. Pseudoaneurysm

II) ADVERSE EVENTS

1. All stroke: For purposes of IAC Carotid Stenting quality assurance and comparing facility outcomes to national benchmarks, a stroke is defined as an ischemic or hemorrhagic brain injury causing a neurologic deficit that persists for more than 24 hours.
   a. Cerebral Infarction/ Ischemic Stroke
   b. Intracranial hemorrhage/ Hemorrhagic Stroke
   c. Unknown Type of Stroke (no imaging performed)

2. TIA (symptoms < 24 hours) with or without neuroimaging evidence of acute infarction is not considered a stroke for IAC Carotid Stenting quality assurance and comparison to national benchmarks, although it may be considered a stroke for research reporting purposes.

3. Other neurologic (edema/hyperperfusion syndrome)

4. All death

5. MI

6. Other cardiac event
   a. heart failure or pulmonary edema
   b. arrhythmia requiring cardioversion, pacemaker insertion, or ICD insertion
   c. hypotension requiring parenteral medications for > 24 hours post-procedure

7. Renal failure with new requirement for dialysis

8. Infection related to procedure requiring antibiotics

9. Angiographic complications
   a. Dissection requiring treatment
   b. Urgent surgery required for technical problems with stent deployment or placement.
   c. Intracranial embolization

10. Bleeding requiring blood transfusion

11. Arterial access
   a. Pseudoaneurysm requiring treatment with thrombin injection and/or compression during hospitalization
   b. Access site injury requiring open surgical repair

12. Vessel thrombosis, peripheral embolization, or ischemia of an extremity

13. Other
   a. Unexpected intubation or resuscitation
   b. Contrast reaction
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- Society of NeuroInterventional Surgery (www.snisonline.org/guest/guest.php)
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