

Current Training, Credentialing, and Facilities Guidelines for Carotid Stenting & National Carotid Outcomes Database: Rationale and Status Update

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Disclosures

Abbott

Bard

BSC

Cordis

Guidant

Medtronic

- *Research and training support*
- *Consultant/advisor*

Carotid Stenting

Unique programmatic issues

Why is this procedure different from all other procedures?

Organ system and Disease state

- Unique anatomy, pathol, access, response to intervention

Procedure

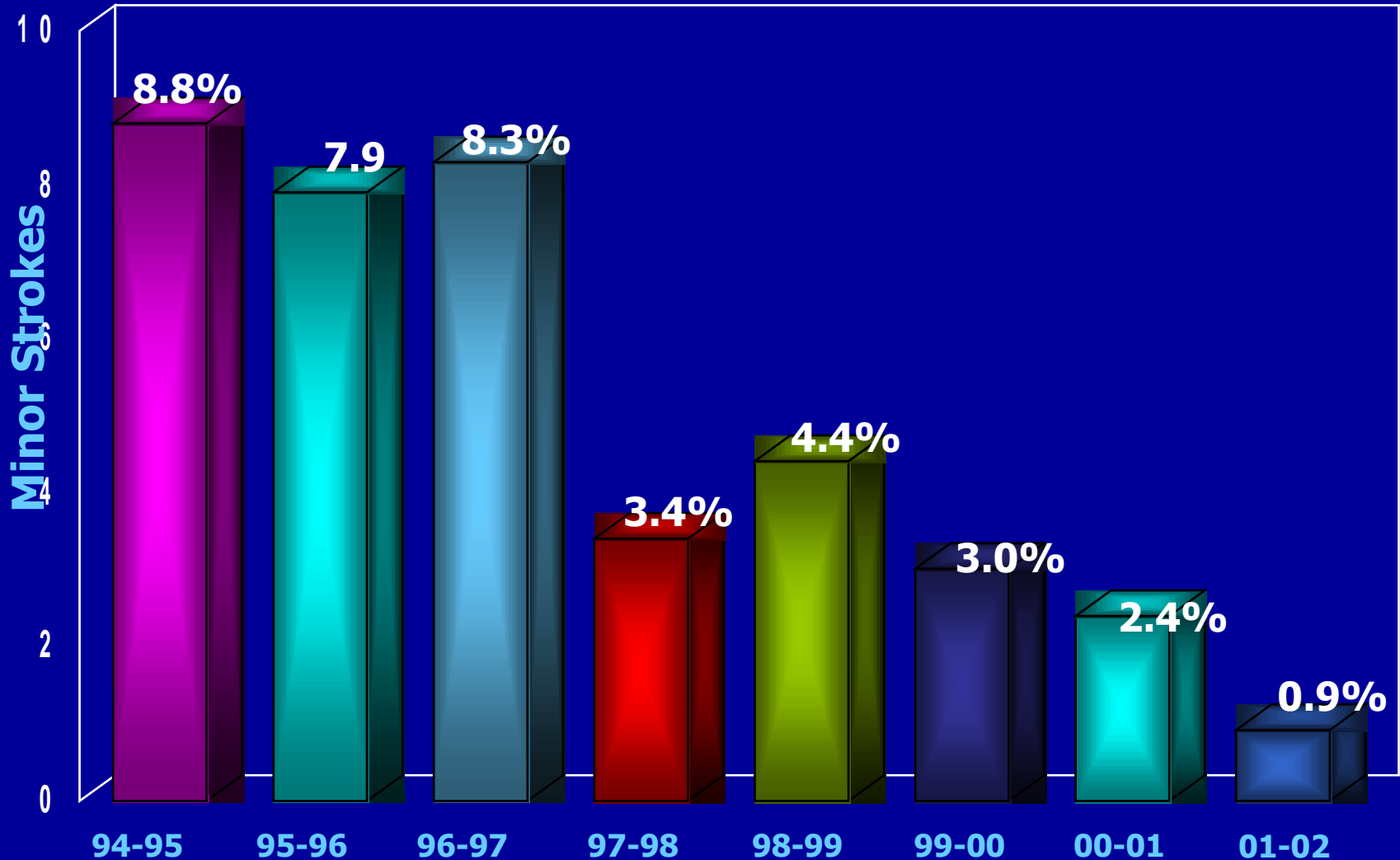
- New skill sets and different equipment
- Unique access considerations
- High risk; no room for error...*Little* errors cause a *lot* of hurt
- Must be “on” all the time...never let guard down...

Milieu

- Multidisciplinary disease
- many specialties traditionally involved and have “stake”
- unprecedented level of peer review and scrutiny
- unique opportunity to set quality standards and benchmarks which cross specialty lines

Declining Incidence of Strokes - Roubin, Iyer, Vitek, et al

Combined effects of learning curve, better devices and distal protection



Carotid Training & Credentialing Documents

Society	Subject	Date	Peripheral	Cerebral (Above the Arch)		Journal
				#Dx	#Rx	
ASITN/ SIR/ ASNR	Quality Improvement Guidelines Carotid Angioplasty and Stent Placement	2003	ACC/AHA Guidelines	200 or 100 + meet AHA PVD guidelines	10 cases or 4 w/16 hr training	JVIR 2003
ASITN/ SIR/ ASNR	Training, Competency, Credentialing for Angiography, Carotid Stenting, Cerebro-vasc Intervention	2004 2005	ACC/AHA Guidelines	200 or 100 + meet AHA PVD guidelines	10 cases or 4 w/16 hours training	AJNR 2004 JVIR 2004 Radiology 2005 Neurology 2005
ACC/ACP/SCAI/SVS/SVMB	Competency Document on PVD (section on carotid)	2004	ACC/AHA Guidelines	30 / 15	25 / 15	JACC 2004
SCAI/SVS/SVMB	Clinical Competency	2005	Peripheral credentials (ACC/AHA Guidelines)	30 / 15	25 / 15	CCI 2005 JACC 2005 JVR 2005 Vasc Med 2005

Training and Credentialing Documents

Society Recommendations

- **Neurovascular Coalition 2003**
- **ACC/ACP/SCAI/SVS/SVMB PVD 2004**
- **SCAI/SVS/SVMB Carotid 2005**
- **Neurovascular Coalition 2005**

Quality Improvement Guidelines for the Performance of Cervical Carotid Angioplasty and Stent Placement

Developed by a Collaborative Panel of the American Society of Interventional and Therapeutic Neuroradiology, the American Society of Neuroradiology, and the Society of Interventional Radiology

John D. Barr, MD, John J. Connors, III, MD, David Sacks, MD, Joan C. Wojak, MD, Gary J. Becker, MD, John F. Cardella, MD, Bohdan Chopko, MD, PhD, Jacques E. Dion, MD, Allan J. Fox, MD, Randall T. Higashida, MD, Robert W. Hurst, MD, Curtis A. Lewis, MD, MBA, Terence A.S. Matalon, MD, Gary M. Nesbit, MD, J. Arliss Pollock, MD, Eric J. Russell, MD, David J. Seidenwurm, MD, and Robert C. Wallace, MD, for the ASITN, ASNR, and SIR Standards of Practice Committees

J Vasc Interv Radiol 2003; 14:S321-S335

Abbreviations: ACAS = Asymptomatic Carotid Atherosclerosis Study, ACR = American College of Radiology, AHA = American Heart Association, ASITN = American Society of Interventional and Therapeutic Neuroradiology, ASNR = American Society of Neuroradiology, CAS = carotid angioplasty and stent placement, CEA = carotid endarterectomy, CREST = Carotid Revascularization: Endarterectomy vs. Stent Trial, NASCET = North American Symptomatic Carotid Endarterectomy Trial, NIHSS = National Institutes of Health Stroke Scale, SIR = Society of Interventional Radiology

Quality Improvement Performance of Cervical Carotid Stent Placement

Developed by a Collaborative
Interventional and Therapeutic
Society of Neuroradiology,
Radiology

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Robert C. Wallace, MD, for the ASITN, ASITN

J Vasc Interv Radiol 2003; 14:S321-S335

Abbreviations: ACAS = Asymptomatic Carotid Atherosclerosis; ASITN = American Society of Interventional and Therapeutic Neuroradiology; CAS = carotid angioplasty and stent placement; CEA = carotid endarterectomy; CREST = Carotid Revascularization Endarterectomy Trial; NIHSS = National Institutes of Health

J Vasc Interv Radiol 2003;14:S321-S335.

mize both patient and physician safety

2. The requirements for meeting the qualifications listed in (IV.B.1) may be met by obtaining the following training and experience. This training may be obtained through the appropriate ACGME-approved residency or fellowship (5,138) or through postgraduate experience that should include a, b, and c below. The postgraduate experiential training must be under the supervision of a qualified physician, defined as a physician who has already met the qualifications of section IV

OR

2. Ten consecutive CAS procedures as principal operator under the supervision of an on-site qualified physician on patients treated for appropriate indications documented by a log of cases performed and with acceptable success and complication rates according to the thresholds contained in this guideline and the ACR guideline for cervicocerebral angiography (4,78,86)

7. Recognition and treatment of cardiac arrhythmias associated with CAS
8. Technical aspects of performing CAS
9. Recognition of any cerebrovascular abnormality or complication related to the CAS procedure
10. Postprocedural patient management, particularly the recognition and initial management of procedure complications

Maintenance of competence requires continuing activity including

1. Regular performance of sufficient numbers of neurovascular procedures to maintain success and complication rates as outlined below
2. Participation in a quality improvement program that monitors these rates
3. Participation in courses that provide continuing education on advances in CAS
4. Continuing education should be in accordance with the ACR Standard for Continuing Education

V. SPECIFICATIONS OF THE PROCEDURE

A. Technical Requirements

There are several technical requirements that are necessary to ensure the safe and successful performance of CAS. These include adequate clinical facilities, angiographic and monitoring equipment, and support personnel. The minimal facility requirements are

1. An angiographic suite with sufficient space to allow positioning of patient-monitoring equipment and anesthesia equipment, while leaving adequate room for the circulating staff to move without contaminating the sterile field
2. A high-resolution image intensifier and imaging chain with the ability to acquire and store images digitally; imaging and recording must be consistent with the as low as reasonably achievable (ALARA) radiation safety guidelines

with no prior catheter experience (4,139), or at least 100 diagnostic cervicocerebral angiograms with documented acceptable indications and outcomes for physicians with experience sufficient to meet the AHA requirements for peripheral vascular interventions (124).

- b. Arterial stent experience as either:

1. 25 non-carotid stent complete procedures, plus attendance at and completion of a "hands-on" course in performance of CAS, plus performance and completion of at least four successful and uncomplicated CAS procedures as principal operator under the supervision of an on-site qualified physician; this must be a comprehensive course in which the attendees earn at least 16 hours of AMA category I continuing medical education credit

the following:

1. Indications and contraindications for CAS
2. Preprocedural assessment and intraprocedural physiologic, cerebrovascular, and neurologic monitoring of the patient
3. Appropriate use and operation of fluoroscopic and radiographic equipment and digital subtraction angiography systems
4. Principles of radiation protection, hazards of radiation exposure to the patient and to the radiologic personnel, and radiation monitoring requirements
5. Anatomy, physiology, and pathophysiology of the cerebrovascular system
6. Pharmacology of contrast agents and cardiac antiarrhythmia drugs and recognition and treatment of adverse reactions to these substances

2. The requirements for meeting the qualifications listed in IV.B.1 may be met by obtaining the following training and experience.

- a. Performance (under the supervision of a qualified physician and with at least 50% performed as the primary operator) of at least 200 diagnostic cervicocerebral angiograms with documented acceptable indications and outcomes for physicians with no prior catheter experience (4,139), or at least 100 diagnostic cervicocerebral angiograms with documented acceptable indications and outcomes for physicians with experience sufficient to meet the AHA requirements for peripheral vascular interventions (124).

mize both patient and physician safety

2. The requirements for the principal operator (IV) include the following:

The principal operator must have completed a training program in the supervision of a physician, defined as a physician who has all the qualifications of a principal operator and acceptable indications and outcomes.

- a. Performance (under the supervision of a qualified physician and with 50% performed as the primary operator) of at least 200 diagnostic cervicocerebral angiograms with documented acceptable indications and outcomes for physicians with no prior catheter experience (4,139), or at least 100 diagnostic cervicocerebral angiograms with documented acceptable indications and outcomes for physicians with experience sufficient to meet the AHA requirements for peripheral vascular interventions (124).

OR

2. Ten consecutive CAS procedures performed by the principal operator.

The principal operator must have completed a training program in the supervision of a physician, defined as a physician who has all the qualifications of a principal operator and acceptable indications and outcomes.

- 6) The principal operator must have completed a training program in the supervision of a physician, defined as a physician who has all the qualifications of a principal operator and acceptable indications and outcomes.

indications and outcomes for physicians with no prior catheter experience (4,139), or at least 100 diagnostic cervicocerebral angiograms with documented acceptable indications and outcomes for physicians with experience sufficient to meet the AHA requirements for peripheral vascular interventions (124).

5. An appropriate system for the monitoring of the patient's vital signs and oxygen saturation during the procedure.

6. Pharmacology of contrast agents and cardiac antiarrhythmia drugs and recognition and treatment of adverse reactions to these substances

7. Recognition and treatment of cardiac arrhythmias associated with CAS.

8. Treatment of neurovascular complications.

9. Recognition and treatment of cardiac arrhythmias associated with CAS.

Main components of a CAS program include:

1. Recognition and treatment of cardiac arrhythmias associated with CAS.
2. Treatment of neurovascular complications.
3. Recognition and treatment of cardiac arrhythmias associated with CAS.
4. Recognition and treatment of cardiac arrhythmias associated with CAS.

SPRINT PROGRAMS OF T

Technical requirements for the successful implementation of a CAS program include:

1. An appropriate system for the monitoring of the patient's vital signs and oxygen saturation during the procedure.
2. A high-resolution intensifier and imaging chain with the ability to acquire and store images digitally; imaging and recording must be consistent with the as low as reasonably achievable (ALARA) radiation safety guidelines

b. Arterial stent experience as either:

1. 25 non-carotid stent complete procedures, plus attendance at and completion of a "hands-on" course in performance of CAS, plus performance and completion of at least four successful and uncomplicated CAS procedures as principal operator under the supervision of an on-site qualified physician; this must be a comprehensive course in which the attendees earn at least 16 hours of AMA category I continuing medical education credit

mize both patient and physician safety

2. The requirements for meeting the qualifications listed in (IV.B.1) may be met by obtaining the following training and experience. This training may be obtained through the appropriate ACGME-approved residency or fellowship (5,138) or through postgraduate experience that should include a, b, and c below. The postgraduate experiential training must be under the supervision of a qualified physician, defined as a physician who has already met the qualifications of section IV with acceptable indications and outcomes.

- a. Performance (under the supervision of a qualified physician and with at least 50% performed as the primary operator) of at least 200 diagnostic cervicocerebral angiograms with documented acceptable indications and outcomes for at least 1 year with no prior carotid stent experience (4,139), or diagnostic angiograms documented acceptable indications and outcomes for physicians with sufficient to meet the requirements for Arterial Stent Placement either:
 1. 25 non-carotid stent complete procedures, plus attendance at and completion of a "hands-on" course in performance of CAS, plus performance and completion of at least four successful and uncomplicated CAS procedures as principal operator under the supervision of an on-site qualified physician; this must be a comprehensive course in which the attendees earn at least 16 hours of AMA category I continuing medical education credit

OR

2. Ten consecutive CAS

procedures as principal operator with a 50% division of patients with appropriate approval documentation

and outcomes for at least 1 year with no prior carotid stent experience (4,139), or diagnostic angiograms documented acceptable indications and outcomes for physicians with sufficient to meet the requirements for Arterial Stent Placement either:

1. Indications for CAS
2. Preprocedural preparation

7. Recognition and treatment of cardiac arrhythmias associated with CAS
8. Technical aspects of performing CAS
9. Recognition of any cerebrovascular abnormality or complication related to the CAS procedure
10. Postprocedural patient management, particularly the recognition and initial management of procedure complications

Maintenance of competence requiring continuing activity including regular performance of sufficient numbers of neurovascular procedures to maintain success and complication rates as outlined below
 Participation in a quality improvement program that monitors these rates
 Participation in courses that provide continuing education on advances in CAS
 Continuing education should be in accordance with the ACR Standard for Continuing Education

REQUIREMENTS OF THE

Requirements

Additional technical requirements necessary to ensure successful performance of CAS. These include technical facilities, angiographic monitoring equipment, support personnel. The following requirements are

An angiographic suite with sufficient space to allow positioning of patient-monitoring equipment and anesthesia equipment, while leaving adequate room for the circulating staff to move without contaminating the sterile field

A high-resolution image intensifier and imaging chain with the ability to acquire and store images digitally; imaging and recording must be consistent with the as low as reasonably achievable (ALARA) radiation safety guidelines

radiation protection, radiation exposure to the patient, radiologic and radiologic imaging requirements

5. Anatomy, and pathophysiology of the cerebral system

6. Pharmacology of contrast agents and cardiac antiarrhythmia drugs and recognition and treatment of adverse reactions to these substances

Neurovascular Coalition

American Academy of Neurology

American Association of Neurological Surgeons

Society of Interventional and Therapeutic Neuroradiology

American Society of Neuroradiology

Congress of Neurological Surgeons

AANS / CNS Cerebrovascular Section

Society of Interventional Radiology

Training, competency, and credentialing standards for diagnostic cervicocerebral angiography, carotid stenting, and cerebrovascular intervention

A Joint Statement from the American Academy of Neurology, the American Association of Neurological Surgeons, the American Society of Interventional and Therapeutic Neuroradiology, the American Society of Neuroradiology, the Congress of Neurological Surgeons, the AANS/CNS Cerebrovascular Section, and the Society of Interventional Radiology*

John J. Connors III, MD; David Sacks, MD; Anthony J. Furlan, MD; Warren R. Selman, MD;
Eric J. Russell, MD; Philip E. Stieg, PhD, MD; and Mark N. Hadley, MD;
for the NeuroVascular Coalition Writing Group†

Connors et al., Neurology (spring 2005)

Connors et al., Neurology (spring 2005)

4) All collaborating neuroscience societies recommend appropriately supervised cervicocerebral angiography training and resultant credentialing with an accumulated total of 100 diagnostic cervicocerebral angiograms before post-graduate training in cervicocerebral interventional procedures, including carotid stenting, as described herein.^{29,97}

5) All collaborating neuroscience societies endorse the principles of training and quality assurance espoused in the multisociety *Quality Improvement Guidelines for the Performance of Carotid Angioplasty and Stent Placement*,¹¹³ which include a defined training pathway for any qualified practitioner for carotid stent training.

200 angios
4 carotid stents

113: Barr et al JVIR 2003; 14:1079-97

Consensus of the collaborating neuroscience societies

- 1) All collaborating neuroscience societies are of the unanimous opinion that the safety of the patient is paramount.
- 2) Defined formal training and experience in **both** the cognitive **and** technical aspects of the neurosciences are essential for the performance and interpretation of diagnostic and therapeutic cervical and cerebrovascular procedures. Therefore, in addition to procedural technical experience requirements, a minimum of 6 months of formal cognitive neuroscience training is required in an approved program in radiology, neuroradiology, neurosurgery, neurology, and/or vascular neurology for any practitioner performing cervical carotid interventional therapy, including carotid stenting. This minimum neuroscience training recommendation applies to all practitioners, whether from specialties with or without dedicated training in the clinical neurosciences as part of their ACGME-approved residency programs.

“6 months of formal cognitive neuroscience training is required...”

Connors et al., Neurology (spring 2005)

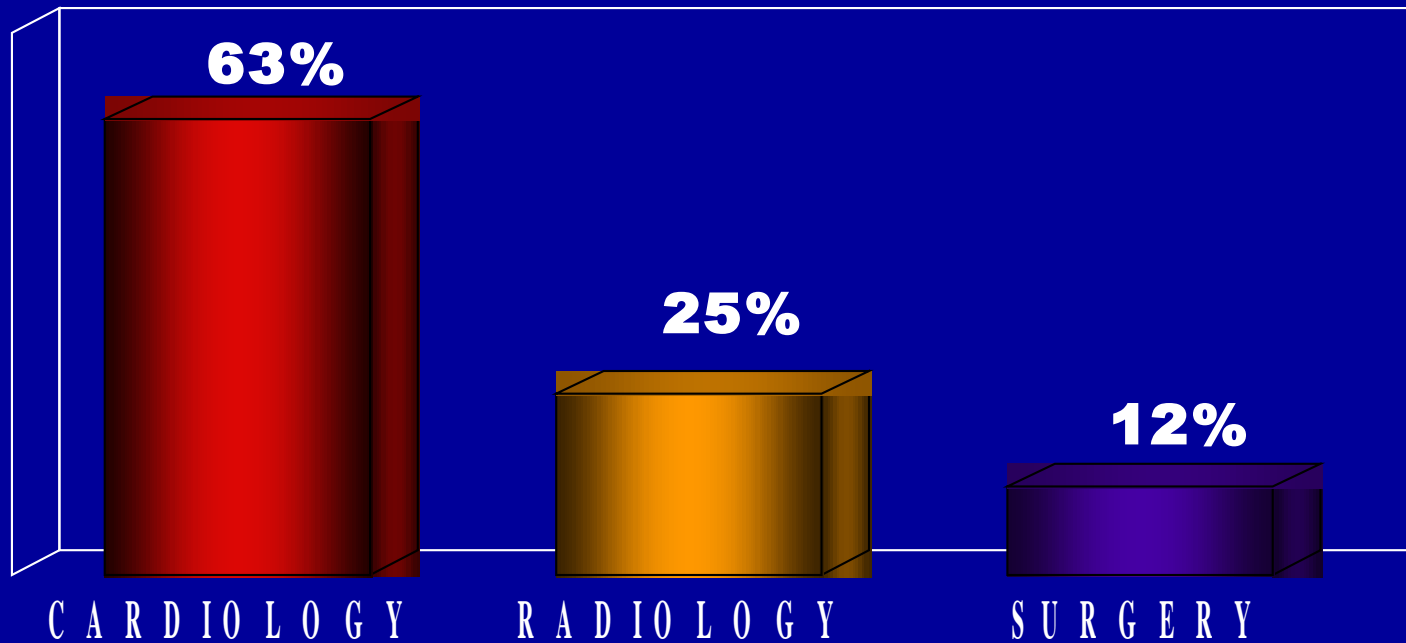
Credentialing for Carotid Stenting

Position of Neurovascular Coalition

- **100 diagnostic cervico-cerebral angiograms with appropriate indications**
- **6 month formal cognitive neuroscience training**
- **No mention in most recent documents of any need for experience with stents, distal protection, or carotid stent training**

Worldwide Registry

Carotid Stent by Physician Specialty



Who should do Carotid Intervention

Principles

- Individuals with...
 - Knowledge of disease state/natural history, therapeutic options, etc.
 - Appropriate skills (catheter and clinical)
 - Commitment to obtain appropriate training and credentials
 - Knowledge of limitations
- *Restrictions should not be Specialty-based*

ACC/ACP/SCAI/SVMB/SVS CLINICAL COMPETENCE STATEMENT

ACC/ACP/SCAI/SVMB/SVS Clinical Competence Statement on Vascular Medicine and Catheter-Based Peripheral Vascular Interventions

A Report of the American College of Cardiology/
American Heart Association/American College of Physicians
Task Force on Clinical Competence (ACC/ACP/SCAI/SVMB/SVS
Writing Committee to Develop a Clinical Competence Statement on
Peripheral Vascular Disease)

WRITING COMMITTEE MEMBERS

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CHRISTOPHER J. WHITE, MD, FACC, FSCAI

Physician seeking training for Carotid Stenting

- Multiple different clinical backgrounds
- Variable skill level in catheter-based techniques
- Variable familiarity with carotid/cerebral circulation
- Different cognitive knowledge base re: stroke and cerebrovascular disease

SCAI/SVMB/SVS CLINICAL COMPETENCE STATEMENT

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

WRITING COMMITTEE MEMBERS

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JACC, JVS, CCI
January, 2005

JVM
Feb, 2005

Skills Required for Carotid Intervention (Regardless of specialty)

- Cognitive
- Technical/Procedural
- Clinical

Cognitive Requirements

Table 1. Cognitive Requirements for Performance of Carotid Stenting*

Cognitive elements including the fund of knowledge regarding cardiovascular disease, its natural history, pathophysiology, diagnostic methods, and treatment alternatives.

- I) Pathophysiology of carotid artery disease and stroke.
 - a) Causes of Stroke
 - i. Embolization (cardiac, carotid, aortic, other)
 - ii. Vasculitis
 - iii. Arteriovenous malformation
 - iv. Intracranial bleeding (subdural, epidural)
 - v. Space-occupying lesion
 - b) Causes of carotid artery narrowing
 - i. Atherosclerosis
 - ii. Fibromuscular dysplasia
 - iii. Spontaneous dissection
 - iv. Other
 - c) Atherogenesis (pathogenesis and risk factors)
- II) Clinical manifestation of stroke
 - a) Knowledge of stroke syndromes (classic and atypical)
 - b) Distinction between anterior and posterior circulation events
- III) Natural history of carotid artery disease
- IV) Associated pathology (e.g., coronary and peripheral artery disease)
- V) Diagnosis of stroke and carotid artery disease
 - a) History and physical examination
 - i. Neurologic
 - ii. Non-neurologic (cardiac, other)
 - b) Non-invasive imaging and appropriate use thereof
 - i. Duplex ultrasound
 - ii. MRA
 - iii. CTA
- VI) Angiographic anatomy (nech, extracranial, intracranial, basal collateral circulation, common anatomic variants, and non-atherosclerotic pathologic processes)
- VII) Knowledge of alternative treatment options for carotid stenosis and their results (immediate success, risks, and long-term outcome)
 - a) Pharmacotherapy (e.g., anti-platelet agents, anticoagulation, lipid-lowering agents)
 - b) Carotid endarterectomy
 - i. Results from major trial (NASCET, ACAS, ECST, ACST)
 - ii. Results in patients with increased surgical risk
 - c) Stent revascularization
 - i. Results with and without distal embolic protection
- VIII) Case selection
 - a) Indications and contraindications for revascularization to prevent stroke
 - b) High risk criteria for carotid endarterectomy
 - c) High risk criteria for percutaneous intervention
- IX) Role of post-procedure follow up and surveillance

*In addition to baseline cognitive skills encompassed in the Competency documents (6).

Training in Carotid Intervention

Cognitive Component

- Knowledge of cerebrovascular disease, anatomy/pathophysiology of target organs, natural hx of disease
- Appropriate diagnostic testing, interpretation of results
- Therapeutic alternatives

“Cognitive knowledge base”

When is CAS relatively or absolutely contraindicated

- Large (pedunculated) Thrombus
- Complex lesion
- String sign or Total occlusion
- Heavy calcification
- Distal ICA severely tortuous or diffusely diseased
- Arch severely unfolded, making access impossible
- Arch severely diseased with friable plaque

Technical Skill

Table 2. Technical Requirements for Performance of Carotid Stenting*

Minimum numbers of procedures to achieve competence

- I) Diagnostic carotico-cerebral angiograms - 30 (≥ half as primary operator)†
- II) Carotid stent procedures - 25 (≥ half as primary operation)†

Technical elements for competence in both diagnostic angiography and interventional techniques

- I) High level of expertise with antiplatelet therapy and procedural anticoagulation
- II) Angiographic skills
 - a) Vascular access skills
 - b) Selection of guidewires and angiographic catheters
 - c) Appropriate manipulation of guidewires and catheters
 - d) Use of "closed system" manifold
 - e) Knowledge of normal angiographic anatomy and common variants
 - f) Knowledge of Circle of Willis and typical/atypical collateral pathways
 - g) Proper assessment of aortic arch configuration, as it affects carotid intervention
 - h) Familiarity with use of angulated views and appropriate movement of the X-ray gantry
- III) Interventional skills
 - a) Guide catheter/sheath placement
 - b) Deployment and retrieval of embolic protection devices
 - c) Pre- and post-dilation
 - d) Stent positioning and deployment
- IV) Recognition and management of intra-procedural complications
 - a) Cerebrovascular events
 - i. Stroke or cerebrovascular ischemia
 - ii. Embolization
 - iii. Hemorrhage
 - iv. Thrombosis
 - v. Dissection
 - vi. Seizure and loss of consciousness
 - b) Cardiovascular events
 - i. Arrhythmias
 - ii. Hypotension
 - iii. Hypertension
 - iv. Myocardial ischemia/infarction
 - c) Vascular access events
 - i. Bleeding
 - ii. Ischemia
 - iii. Thrombosis
- IV) Management of vascular access
 - a) Proper sheath removal and attainment of hemostasis
 - b) Closure device utilization

*In addition to technical skills encompassed in the Competency document (6). †Angiograms and stenting procedures may be performed in the same sitting (e.g., in the same patients), provided that one performs 15 angiograms as primary operator before performing the first stent as primary operator.

CEREBRAL ANGIOGRAPHY

- To achieve and ensure competency in the safe performance of cervico-cerebral angiography, interventionalists with proper credentials and demonstrated expertise in non-cerebrovascular vessels can achieve the required level of technical skill by performing **thirty (30) supervised angiograms, half as primary operator, in a supervised setting.**
- This recommendation acknowledges the transferable nature of basic and advanced catheter skills acquired in other vascular beds. **Prior to performance of these 30 angiograms, the trainee should have acquired extensive knowledge of neurovascular anatomy and pathology** through study of appropriate textbooks and case review of angiograms.

CAROTID STENTING

- Interventionalists training in carotid stenting must perform a **minimum of 25 patient procedures in a supervised setting, half as primary operator.**
 - “Supervision” implies that the mentor is scrubbed alongside the trainee; “primary operator” implies that, throughout the entire procedure, the trainee is personally directing the guidewires, placing the sheath, positioning and retrieving the distal protection device and balloons, and deploying the stent.
 - **Prior to functioning as a primary stent operator, the trainee must have performed at least 15 diagnostic cervico-cerebral angiograms as primary operator.**

Clinical Skills

Table 3. Clinical Requirements for Performance of Carotid Stenting*

Clinical elements, including the ability to manage inpatients and outpatient care

- I) Determine the patient's risk/benefit for the procedure
- II) Outpatient responsibilities
 - a. Adjust medications pre-procedure
 - b. Counsel patient and family
- III) Inpatient responsibilities
 - a. Admit patients (privileges required) and write orders
 - b. Obtain informed consent for procedures
 - c. Provide pre and post-procedure hospital care
 - i. Neurological evaluation pre and post-procedure
 - ii. Post-procedure pharmacotherapy
 - iii. Monitoring of hemodynamic and cardiac rhythm status
- IV) Coordinate post-stent surveillance and clinical outpatient follow-up

*In addition to clinical skills encompassed in the Competency document (6).

Training in Carotid Intervention

Clinical Component

General Skills

- Patient management, physical examination and evaluation of influence of disease on patient
- Inpatient admission, work-up and management, ability to evaluate and treat complications
- Interpretation of diagnostic tests
- Risk-benefit analysis

Clinical Skills for Carotid Stenting:

Complex hemodynamic management

- Hypertension
 - Rx vasodilators (avoiding bleed due to reperfusion hyperemia)
- Hypotension and bradycardia at time of balloon inflation, especially post-dilating stent
 - Rx Fluids and Atropine
- Persistent hypotension/bradycardia post procedure

Pathways to credentialing

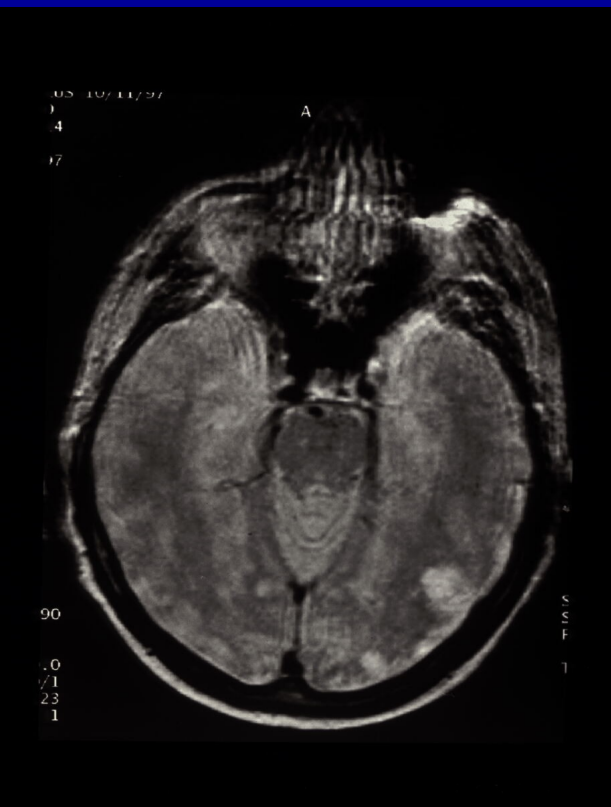
- Fellowship Programs (future)
- Didactic course work
 - THIS Course, SCAI live and web-based courses; VIVA
- Observation of cases
- Proctorship
- Partnering
- Industry FDA-mandated training
- SIMULATION Training

SIMULATOR TRAINING

- To assist physicians with differing backgrounds and skills to reach a common benchmark of proficiency, metric-based simulation may be incorporated into training.
- To provide skills acquisition in an objective manner, removing specialty biases from the training process.

“...the cost of a single tragic event can far exceed the cost of the simulation training that may have prevented it!”

-David Holmes, M.D.



STAFF TRAINING: *the team*



Role of Industry

- To ensure familiarization with specific equipment as required by the FDA, successful completion of an industry-sponsored certification course may be required.
- Industry-sponsored programs should assist the individual physician in completion of the requirements suggested above to achieve competency, **while not supplanting them.**
- The industry sponsored training may include didactic cognitive training, metric-based simulator training to proficiency, and proctoring.

Carotid Stent *Credentialing*

Credentialing is a process by which hospitals determine physician competency and establishes permission to perform particular procedures within that institution.

LOCAL ISSUE!

Facility Credentials

CMS: “High Quality Systems In Place”

- **High Resolution Imaging Equipment**
 - DSA
- **Advanced Hemodynamic Monitoring**
 - Real-time physiologic, hemodynamic and cardiac rhythm
- **Recovery Area**
 - Capable of access site management
- **Emergency Management**
 - Availability and skill in use of vasoactive drugs and resuscitation procedures
- **Skilled Allied Health Professionals**
 - Formal training and experience evaluating patients pre- and post-carotid artery revascularization
- **QA Systems Well-Defined and Operational**
 - Prospective collection of outcomes data for each carotid intervention
 - Thresholds for peer review and adjudication based on agreed upon national standards

Quality Assurance

- Independent assessment of carotid stent outcomes by a neurologist or other qualified NIH Stroke Scale certified individual is required.
- A systematic review of results from individual operators at standard intervals, i.e. after the initial 20 cases and quarterly thereafter.
- We support the creation of a mandatory national multi-specialty registry database for reporting of outcomes and assessment of ongoing institutional and individual operator competence.



VIVA

VASCULAR INTERVENTIONAL ADVANCES

THE NATIONAL EDUCATION COURSE FOR PERIPHERAL VASCULAR INTERVENTIONS



O5

SEPTEMBER 27-30, 2005

MANDALAY BAY RESORT, LAS VEGAS

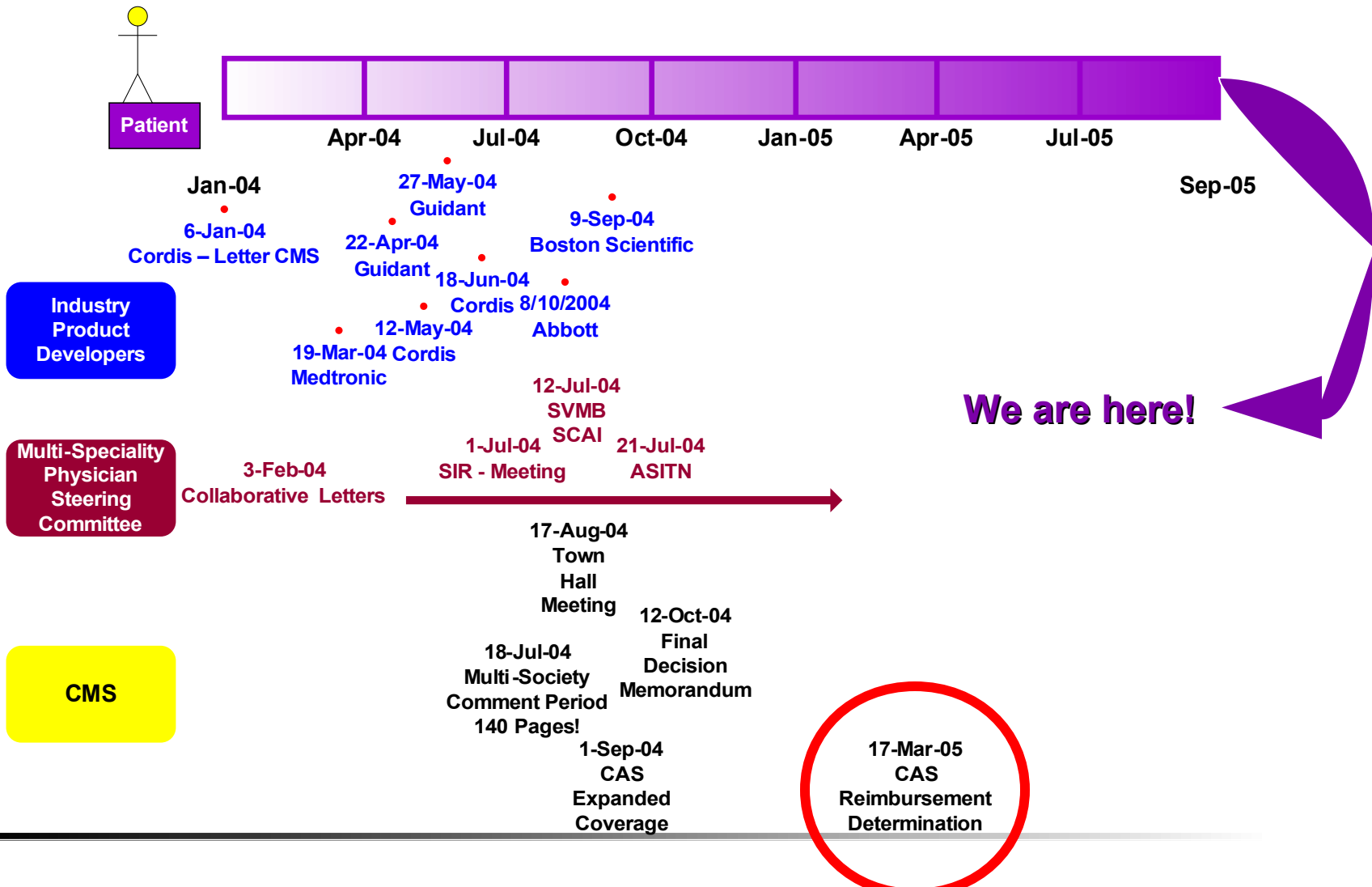
Implications of the CMS Coverage Decision on Your Clinical Practice

September 28, 2005

Ralph Brindis, MD, MPH
Chief Medical Officer, ACC-NCDR®

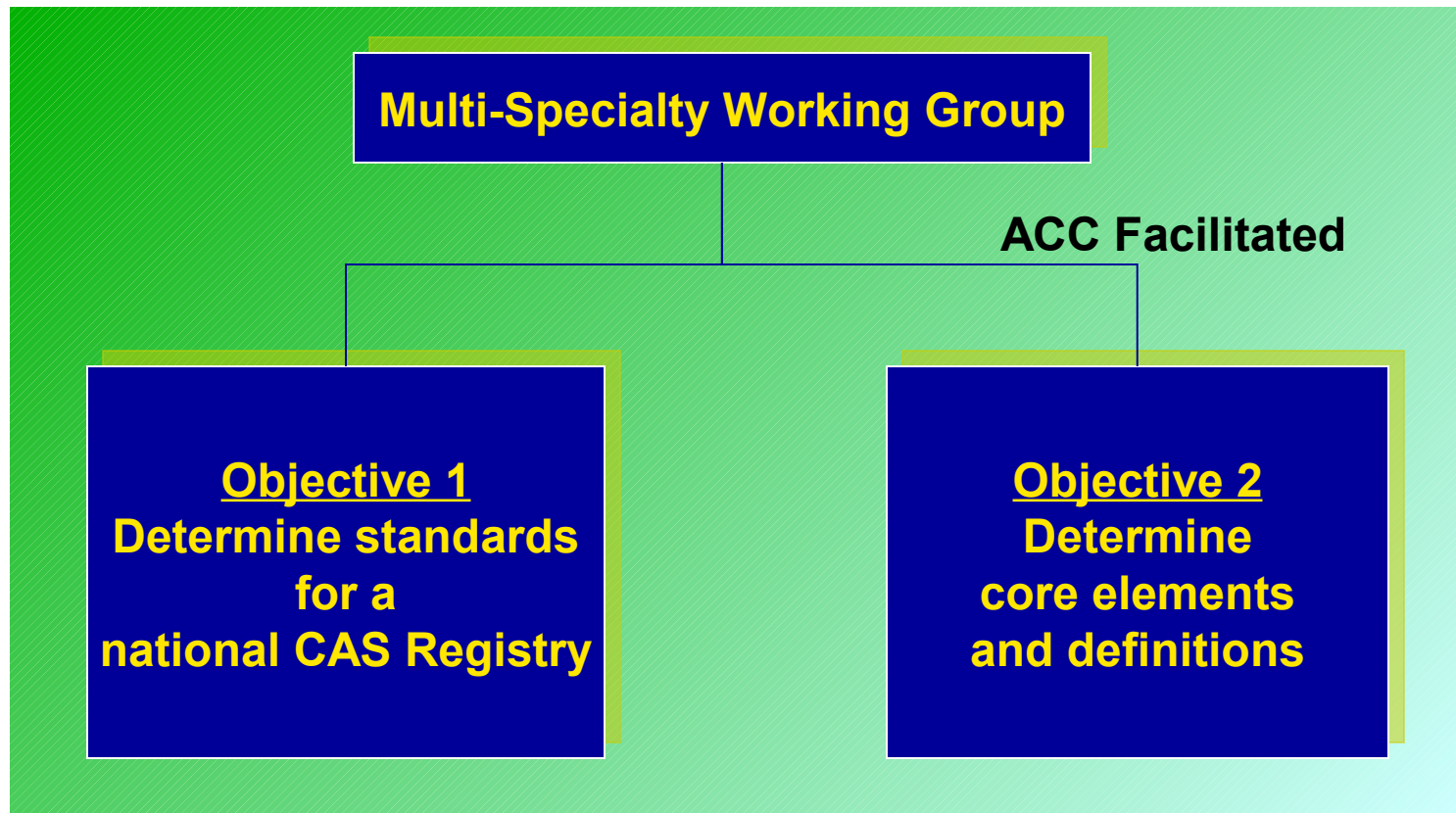


CMS Coverage Determination





Multi-Specialty Workgroup





Challenges at the Local Level

Data Collection

Burden on Facilities to Collect Data
Feasibility for Facilities to Fund Costs

Resource Constraints

Time Constraints

ACC-NCDR[®]

National Cardiovascular Data Registry



Carotid Stent Registry[™]



**Launch
VIVA September 2005 !!**

Fully Integrated Registries

Linked data elements to reduce redundant data collection



CathPCI Registry™



CathKIT™



ICD Registry™

In partnership with the



Heart Rhythm Society



Carotid Stent Registry™



ACC-NCDRØ Carotid Stent RegistryR v1.0 Data Collection Form

A. ADMINISTRATIVE:

Participant ID¹⁰⁰⁰: _____ Participant Name¹⁰¹⁰: _____

B. DEMOGRAPHICS:

Last Name²⁰⁰⁰: _____ First Name²⁰¹⁰: _____ Middle Name²⁰²⁰: _____
 SSN²⁰³⁰: _____ Unique Patient Id²⁰⁴⁰: _____ (automatic) Other ID²⁰⁴⁵: _____
 Date of Birth²⁰⁵⁰: ____/____/____ Gender²⁰⁶⁰: Male; Female
 Race²⁰⁷⁰: American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian; White; Other
 Hispanic Origin²⁰⁸⁰: No; Yes
 Auxilliary1²⁰⁹⁰: _____ Auxilliary2²¹⁰⁰: _____

C. ADMISSION:

Admission Date³⁰⁰⁰: ____/____/____ Date of Procedure³⁰¹⁰: ____/____/____
 Primary Insurance Payor³⁰²⁰: Government; Commercial; HMO; Non-U.S. Insurance; None
 → if Government, Type³⁰³⁰: Medicare; Medicaid; TriCare; VA Health Plan; Federal Employee Insurance
 Secondary Insurance Payor³⁰⁴⁰: Government; Commercial; HMO; Non-U.S. Insurance; None
 → if Government, Type³⁰⁵⁰: Medicare; Medicaid; TriCare; VA Health Plan; Federal Employee Insurance
 Auxilliary3³⁰⁶⁰: _____ Auxilliary4³⁰⁷⁰: _____

D. HISTORY AND RISK FACTORS:

General History & Risk Factors

Height⁴⁰⁰⁰: ____ (cm) Weight⁴⁰¹⁰: ____ (kg)
 History of Tobacco Use⁴⁰²⁰: Current; Former; Never
 Diabetes⁴⁰³⁰: No; Yes → if Yes, Diabetes Control⁴⁰⁴⁰ (Choose highest level only): None; Diet; Oral; Insulin
 Hypertension⁴⁰⁵⁰: No; Yes
 Creatinine Level Baseline Pre-CAS⁴⁰⁶⁰: ____ mg/dL
 Current Dialysis Dependent Renal Failure⁴⁰⁷⁰: No; Yes
 Hypercoaguable State⁴⁰⁸⁰: No; Yes
 Severe Lung Disease⁴⁰⁹⁰: No; Yes
 Home Oxygen Dependent⁴¹⁰⁰: No; Yes
 Peripheral Arterial Disease⁴¹¹⁰ (choose all that apply): No; Yes-Lower Extremity; Yes-Renal; Yes-AAA; Yes-Other Non-Cerebrovascular
 Dyslipidemia⁴¹²⁰: No; Yes

Cardiovascular History & Risk Factors

Coronary Artery Disease⁴¹³⁰: No; Yes
 Previous STEMI⁴¹⁴⁰: No; Yes → if Yes, Previous STEMI Date⁴¹⁶⁰: ____/____/____
 Previous NSTEMI: No; Yes → if Yes, Previous NSTEMI Date: ____/____/____
 Q Wave MI⁴¹⁵⁰: No; Yes
 Current Angina⁴¹⁷⁰: No; Yes
 Angina Type⁴¹⁸⁰: Stable Angina; Unstable Angina;
 Previous CABG⁴¹⁹⁰: No; Yes → if Yes, Date⁴²⁰⁰: ____/____/____
 Previous Percutaneous Coronary Intervention⁴²¹⁰: No; Yes → if Yes, Date⁴²²⁰: ____/____/____

Online Data Entry Tool

IT IT

- NCDR Maintenance
- Patient Management**
- View Incomplete
- Search Completed
- Admission
- Implant Information
- Adverse Events
- Discharge
- Medications
- Finalize Admission

Patient Management: Help

Patient: Admit: Disch: SSN: ID: OthID:

Last Name²⁰⁰⁰ : First Name²⁰¹⁰ : MI²⁰²⁰ :

Unique Patient ID²⁰⁴⁰ : Other ID :

*Autogenerated for Add new patient

SSN²⁰³⁰ : Date of Birth

Gender²⁰⁶⁰ : Race/Ethnicity

Auxillary 1²⁰⁸⁰ : Auxillary 2

- NCDR Maintenance**
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NCDR Maintenance: Help

Participant ID¹⁰⁰⁰ : 999999

Participant Name¹⁰¹⁰ : American College of Cardiology

Export Data:

Quarter 1 (Jan 1 to Mar 31)

Quarter 2 (Apr 1 to Jun 30)

Quarter 3 (Jul 1 to Sep 30)

Quarter 4 (Oct 1 to Dec 31)

Year :

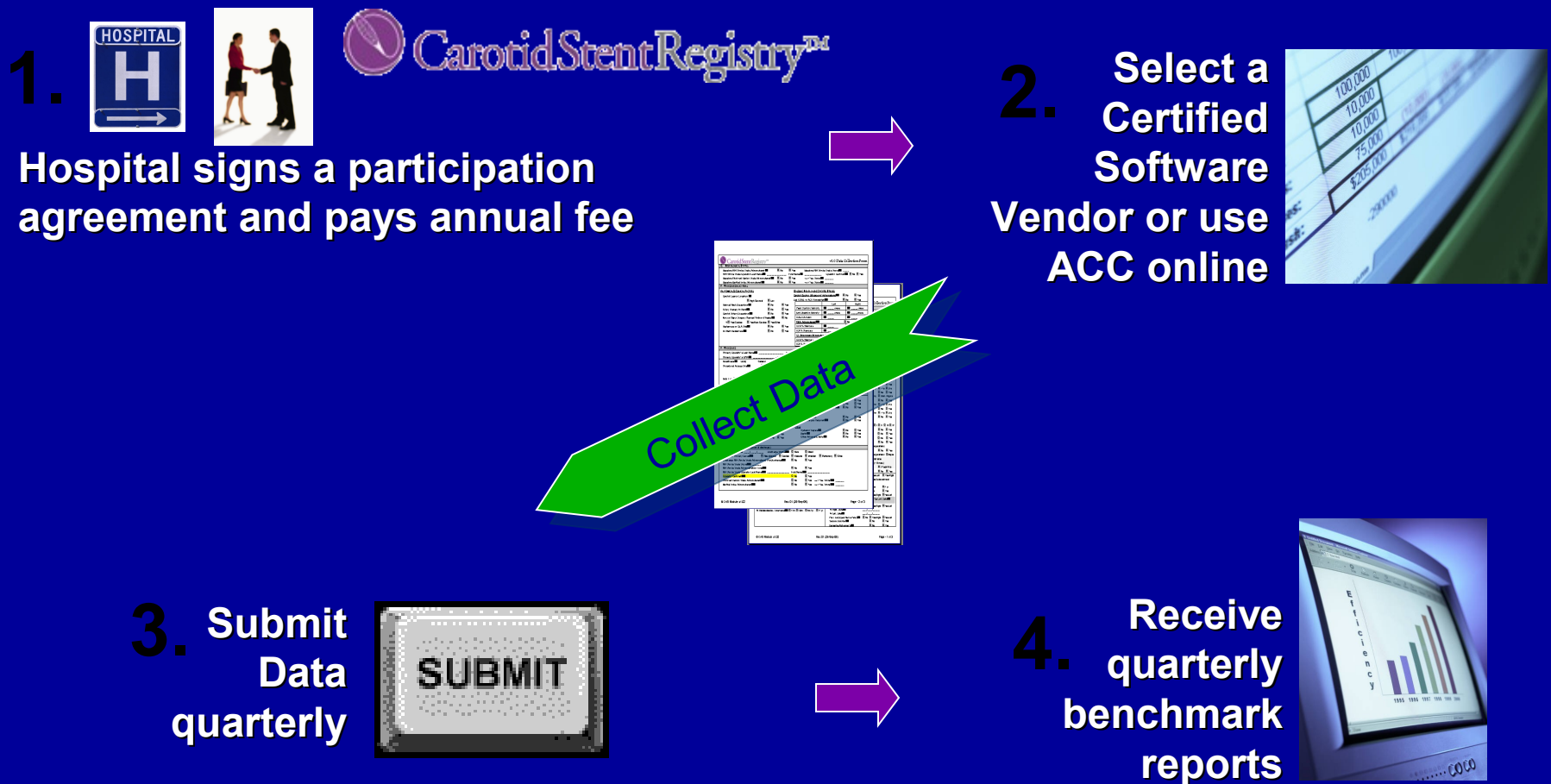
User Preference:

Drop down List View :

Education and Training Support

- Training Manuals
- Annual User Group Meetings
- Workshops
- Webcasts
- Online Help Tools

How the ACC-NCDR® Program Works

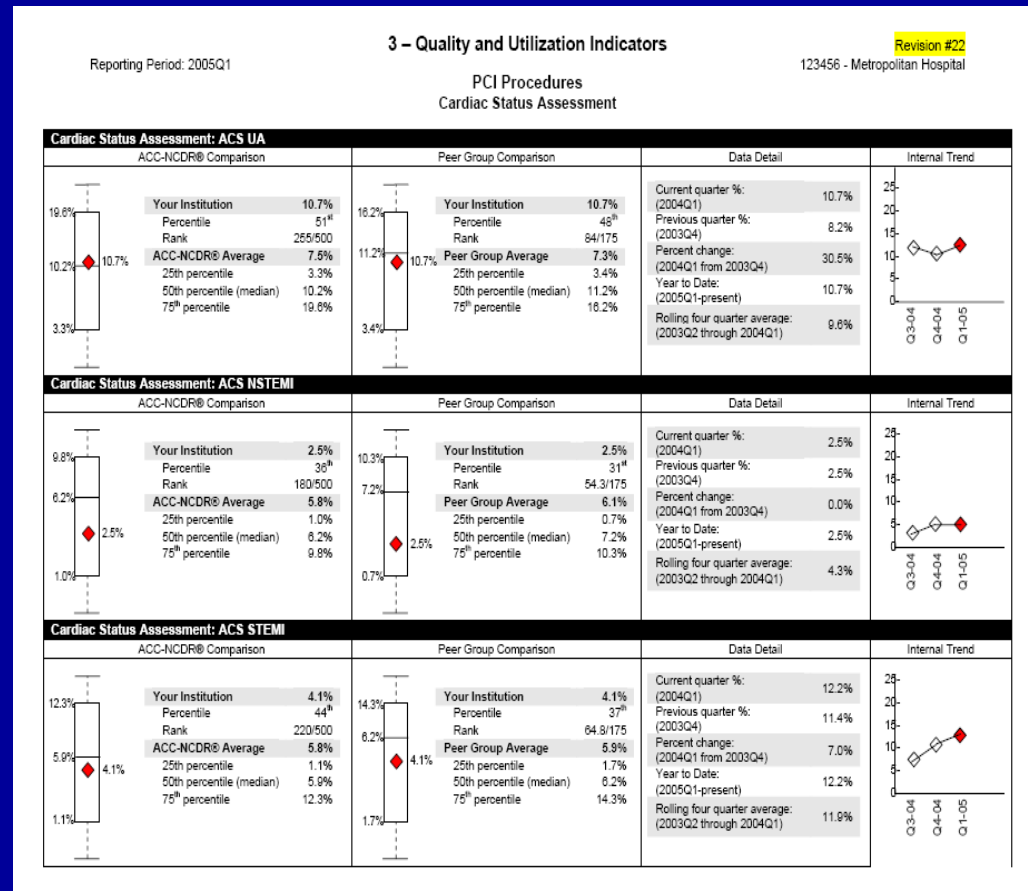


Monitor key measures of performance

with quarterly online benchmark reports

Divided into three main reporting sections

- Key Performance Measures
- Quality and Utilization Indicators
- Detail Section



Carotid Stenting

Multidisciplinary Team Approach

- Eliminates most politics and “turf battles”
- Pooling of complementary skills
- May shorten the learning curve
- Facilitates optimal patient care

A photograph of three surgeons in an operating room. They are wearing blue surgical gowns, light blue bouffant caps, and face masks. The surgeon on the left has a green mask and yellow gloves. The surgeon in the middle has a yellow mask and yellow gloves. The surgeon on the right has a green mask and yellow gloves. They are standing in front of a surgical light fixture and a cabinet. A blue speech bubble is overlaid on the top left of the image.

Stenting
Rocks!

Great benefit of integrated approach to management

Incorporating CAS into Your Practice

- **D**esignate 1-2 in practice who will do it
- **O**btain appropriate training and credentialing
- **I**dentify the team and install required facilities
- **T**rack results with proper QA program and database

JUST DO IT...

WELL!!!