



## **SCAI CAROTID STENTING FACILITY ACCREDITATION PROGRAM (SCAI-CAP)**

### **Executive Summary**

Carotid artery stenting (CAS) has emerged as a highly promising therapy for treatment of carotid artery stenosis. The March 2005 National Coverage Determination (NCD) issued by the Centers for Medicare and Medicaid Services (CMS) has served to accelerate dissemination of this new technology into broader clinical use. Concurrently, CMS published a list of criteria for facilities to use in demonstrating their ability to safely and effectively perform CAS.

CMS recognizes that facility self-certification is a temporary solution at best to assuring quality, and has encouraged third party organizations to undertake the important role of accrediting facilities to perform this procedure. This plan is consistent with the introduction of other new medical technologies, where non-governmental organizations (most notably the professional community itself) have designed and introduced accreditation programs.

In response to the CMS NCD, the Society for Cardiovascular Angiography and Interventions (SCAI) has created a CAS facility accreditation program, termed "SCAI-CAP" (SCAI Carotid Accreditation Program). This memorandum outlines SCAI's rationale for undertaking this endeavor, describes the approach being taken, and solicits input and partnership from other organizations involved with CAS.

### **SCAI-CAP Mission Statement**

The Mission of SCAI-CAP is to ensure high quality patient care in facilities where carotid stenting is performed, by providing a peer review mechanism and recognition of high quality care. This is being accomplished through an objective, cost-effective process of accreditation, focused on establishing requirements for accreditation and evaluation of applicants with respect to fulfillment of those requirements.

### **CMS National Coverage Decision**

On March 17, 2005, The Centers for Medicare & Medicaid Services (CMS) announced a National Coverage Determination (NCD) expanding Medicare coverage of carotid artery stenting (CAS) for patients at high risk for carotid surgery. In making that determination, CMS noted that "the coverage expansion reflects the latest evidence on the effective use of stenting, and includes support for development of better evidence in additional uses."

The NCD expanded coverage for CAS in high risk patients with symptomatic narrowing (>70%) of the carotid. CMS also stressed fostering efforts to evaluate and monitor provider and facility performance. CMS limited coverage of CAS to facilities and providers determined to be competent in performing patient evaluation, the procedure itself and follow-up care. Competency will be based on published CAS clinical guidelines for physician training and facilities.

The coverage decision is currently open and consideration is being entertained by CMS to expand the list of covered indications for carotid stenting and that the number of facilities providing these procedures will grow rapidly, further increasing the need for an independent third-party accreditation program.



### **CAS Facility Accreditation: Short-Term Approach**

For the short-term, facilities performing CAS are being permitted to self-certify in accordance with CMS' specified criteria, with the list of such facilities maintained on the CMS website. Although CMS received considerable input from all stakeholder organizations involved (industry, multiple professional societies and disciplines, trade associations, policy groups and quality assurance organizations), no long-term solution to accreditation has been achieved. CMS reported in its NCD that

*...many comments favored a national mechanism to monitor facilities and physicians for competency and expertise in performing carotid stenting procedures, [but] there was little comment on which organization would take the lead on such a task, nor definitive plans proposed for implementation.<sup>1</sup>*

Because no entity currently exists to accomplish this task, CMS developed a procedure that allows the agency to accredit facilities currently involved in CAS clinical trial protocols as well as those that submit affidavits to CMS attesting that the facilities have met the published requirements. These requirements reflect the proposed facility requirements presented in published training and competency documents such as the CAS clinical competency statement issued in March 2005 by SCAI in partnership with several other professional societies.<sup>2</sup>

### **CAS Facility Accreditation: the Need for a Permanent Solution**

All stakeholders understand the current self-accreditation process is a temporary solution. A long-term accreditation framework is needed through an objective, independent third party.

In the NCD, CMS noted that it "will continue to work with professional societies, industry and national quality assurance entities concerning appropriate standards".<sup>1</sup> In setting up this initial facility accreditation process, CMS indicated that the Federal Government has no plans to coordinate CAS accreditation efforts indefinitely. SCAI is therefore leading efforts in partnership with others to fulfill that need.

### **SCAI's Planned CAS Facility Accreditation Program**

SCAI has established an accreditation process – SCAI-CAP – that:

- Addresses the issues of multispecialty performance of CAS within a given institution;

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<sup>1</sup> CMS Decision Memorandum, Administrative File CAG # 00085R, Carotid Artery Stenting, March 17, 2005, p. 34.

<sup>2</sup> Rosenfield K, Cowley MJ, Jaff MR, Ouriel K, Gray W, Cates CU, Feldman T, Babb JD, Gallagher A, Green R, Kent KC, Roubin GS, Weiner BH, White CW. SCAI/SVMB/SVS 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. *Catheter Cardiovasc Interv*, 2005. 64(1):1-11.



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- Addresses the issues of multimodal performance, i.e., the same procedure performed in several locations (e.g., cath lab, radiology suite, operating room etc.) within a given institution; and
- Emphasizes the use of outcome measures to determine re-accreditation.

SCAI believes the fundamental goal of the accreditation process is to maximize the quality of the CAS procedure and outcomes. In addition to approval or rejection of accreditation, this process includes corrective action plans to address any deficiencies. The process is not punitive, but remediative whenever possible and always based on objective data. This takes the form of recommendations for systematic or operational changes as well as additional education for both operators and other members of the care team.

**SCAI Lab Survey Program: a framework for SCAI-CAP.** Since 1981, SCAI has operated a program with significant parallels to SCAI-CAP, the SCAI Cardiovascular Catheterization Laboratory Survey Program (“the Lab Survey”). Although the Lab Survey does not result in formal accreditation, the objective is very similar, i.e., fostering high quality cath lab care via independent review. The Lab Survey focuses on objective review of labs by an expert team of independent physicians, based on established criteria applied during site visits, interviews and chart/records review to improve quality. During many Lab Surveys conducted over the years, SCAI has found that this constructive, thorough and independent process contributes greatly to promoting quality care.

In many instances, the impetus for these surveys comes from within the health care institution itself, based on an internal commitment to continuous quality improvement. It is important to note, however, that at other times the impetus for these surveys is external, coming from state regulatory bodies responsible for monitoring and maintaining quality care within their jurisdictions. In the latter instance, reports from SCAI laboratory surveys are used by state agencies in decision-making regarding granting (or renewing) licenses for operation of cardiovascular catheterization laboratories.

Thus, through the Lab Survey, SCAI has developed deep experience with assessment and reviews of cardiac catheterization laboratories. These reviews have played an important role in decision-making regarding laboratory operations and licensing. The Lab Survey is sufficiently similar to demonstrate our understanding of the environment, our experience and our ability to accomplish this goal. (Note: the Appendix at the end of this document includes a description of the Lab Survey Program.)

SCAI-CAP shares the goal of promoting quality, and is configured to meet the current need for accreditation of facilities that wish to perform or continue to provide carotid artery stenting to Medicare beneficiaries.

**SCAI-CAP Overview.** SCAI-CAP is a program in which facilities conducting carotid stenting procedures are evaluated in terms of (a) compliance with the requirements of Medicare’s coverage decision on carotid stenting and (b) “best practices” as defined by existing guidelines and the SCAI-CAP Board.

The program seeks “deemed status” from CMS to show that all accredited facilities meet or exceed the standards set forth by CMS. The SCAI-CAP Standards have been created by a multi-specialty board of carotid artery stenting (CAS) physician experts, plus experts in the fields of



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peer review, hospital operations and data analysis. These experts are knowledgeable about development and evaluation of credentialing, medical/technical staff training, facilities planning, radiation safety and equipment. The standards include a review of process data submitted by the facilities, as well as outcomes data from the facilities submitted to SCAI-CAP or from registries such as the NCDR CARE Registry™ and the SVS VascularRegistry™

Highlights of the SCAI-CAP accreditation process can be summarized as follows (see remainder of this document for a detailed description of each step):

- Carotid stenting facilities initially are evaluated by a panel of trained reviewers based on written material as required in the SCAI-CAP Application. The application is designed to verify compliance to all of the standards for any carotid stenting facility. This includes site visits to validate all data submitted with initial reviews performed by trained nurse reviewers.
- Two independent physician reviewers review each application and data and render an independent opinion. The reviewers recommend to the Board either “accreditation,” “delay” until specific improvements have been put in place, or “denial”.
- For facilities that are being denied, a physician site visit may be performed at the institution’s request
- The Board of Directors then renders a final decision.
- A written procedure for appeal of a decision specifies the process for submission and adjudication of appeals. Initially all reviewers are those who were intimately involved with the development of the CAS Standards. As warranted, additional reviewers will attend appropriate training to serve as a reviewer. All stakeholder specialties and subspecialties are included in the reviewer pool.
- Application for re-accreditation and data from all procedures performed within 24 months the facility’s effective date of certification must be submitted to SCAI-CAP no later than 27 months after the effective date of certification.

**Intersocietal emphasis.** SCAI has prepared this document (based on many discussions with other stakeholder organizations and other organizations performing accreditation in other clinical specialties), since interventional cardiologists perform the majority of CAS procedures. SCAI is committed to working closely with all other interested groups. The intersocietal approach to accreditation has been proven in diagnostic modalities including noninvasive vascular testing, echocardiography, nuclear cardiology and nuclear medicine.

SCAI-CAP is an inclusive undertaking, involving multiple stakeholder organizations as partners. To that end, SCAI has had positive discussions with several other professional societies: the Society of Interventional Radiology (SIR), the Society for Vascular Surgery (SVS), the American Academy of Neurology (AAN) and affiliated subspecialty societies, the American College of Cardiology (ACC) among them. Individuals from each of these specialties are engaged in the accreditation process.

**Timeliness of this initiative.** The CMS mandate that carotid stenting facilities meet specific accreditation criteria -- and the agency’s explicit request for alternatives to the current self-accreditation option – is in recognition that CMS is encouraging development of one or more independent CAS accreditation programs to improve patient outcomes. The multidisciplinary nature of this area further supports the need for an unbiased and consistent approach to the review of facilities.

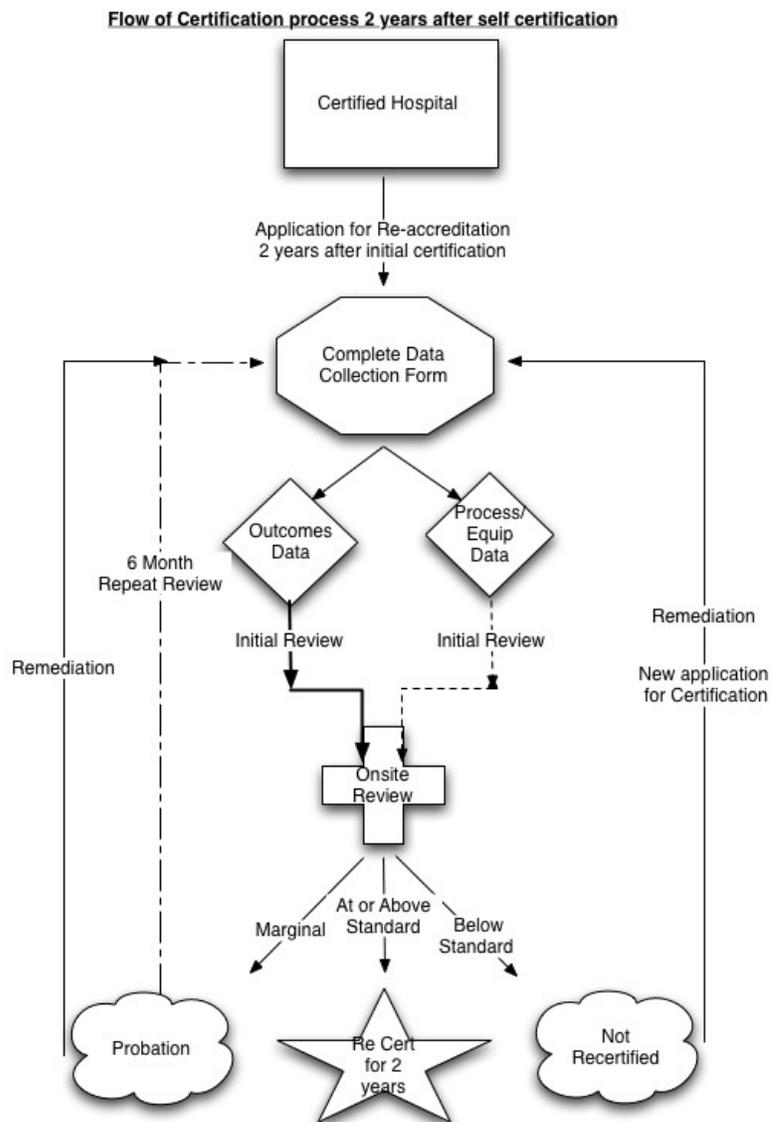


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Because there are no alternative accrediting bodies and because CMS involvement in this area may not continue indefinitely, the need is especially pressing to offer this alternative to the more than 1000 carotid stenting facilities currently registered with CMS. In addition, due to the significant emphasis on the outcome component of the SCAI-CAP accreditation program, many facilities likely will opt for the more comprehensive SCAI-CAP accreditation, and promote its achievement as an indicator of excellence.

**The SCAI-CAP Process**

Exhibit I provides an overview of the SCAI-CAP process.



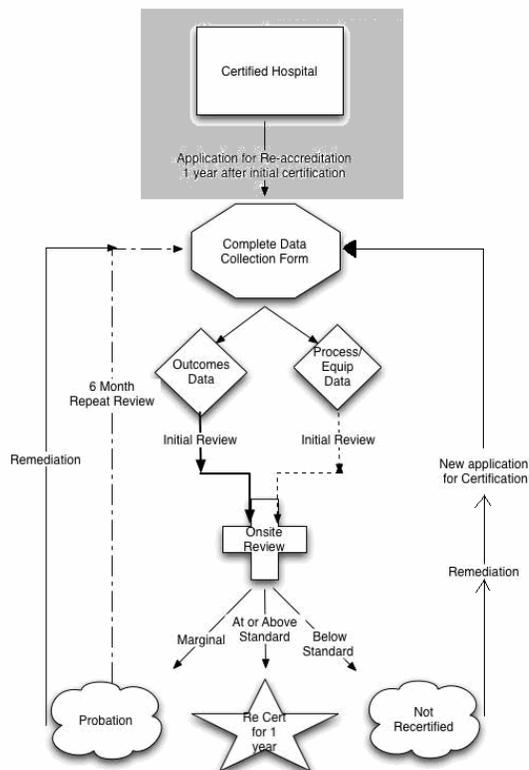


## SCAI-CAP

As the exhibit illustrates, there are five significant steps to the SCAI-CAP process. The following sections discuss each in terms of rationale, processes and efforts performed to date.

### Step 1: Certified Hospitals

Step #1 in the SCAI-CAP process (see exhibit below) is that of determining which facilities are eligible for certification and re-certification. More than 1000 facilities have self-certified to perform carotid artery stenting on CMS beneficiaries. Currently, self-certification per the CMS procedures is the sole means to provide accreditation of facilities for carotid stenting. The CMS limited coverage decision for carotid artery stenting, requires all facilities to collect data on carotid stenting at their institutions. In addition, these self-accredited facilities are required to report these data to CMS biannually if requested.



At present, it is likely that most facilities that offer (or intend to offer) carotid stenting in the near-term have already registered with CMS through this self-certification process. It is unlikely that the number of facilities will significantly grow so long as the current Medicare coverage restrictions (only high risk, symptomatic patients with > 70% stenosis) remain in effect.

The number of facilities offering CAS services may accelerate if CMS broadens the coverage decision, although at present that is a hypothetical situation. Thus this proposal is based on current realities and addresses several types of facilities, each having unique situations and requirements, it would however be expanded to meet the needs of new accreditations should the opportunity arise:



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1. For facilities applying for initial accreditation (i.e., having not self-certified under the CMS procedures), little or no consistent performance or outcomes data is generally available. As a consequence, the SCAI-CAP application and data reporting requirements are focused on the processes in place, equipment, and credentialing of operators.
2. For facilities applying for re-accreditation via SCAI-CAP (having previously self-certified under the CMS procedures), two subcategories of facilities are encountered:
  - 2A. Facilities that have had their self-accreditation for more than 2 s but have relatively limited experience because of the volume of symptomatic patients treated; these facilities represent the largest group.
  - 2B. Facilities with substantial experience with carotid stenting extending over a number of years (3-5 years or more) or those with high volumes (as defined by the SCAI-CAP steering committee) that apply for re-accreditation.

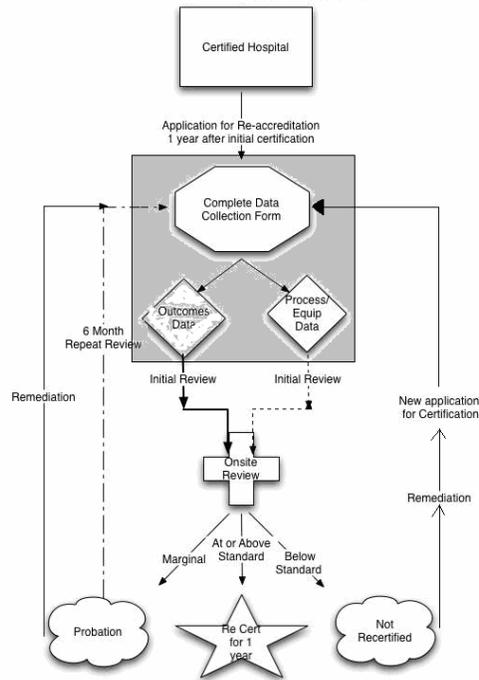
Differences in emphasis are necessary for each of these groups, as described below however are held to the same outcome standards as described below.

Accreditation applications are accepted from facilities where cardiologists, radiologists, vascular surgeons and others practice. Based on Medicare billing data, we assume that the proportions over the long-term will be 54%, 18%, 15% and 13% respectively. One application per facility is accepted and this encompasses carotid stenting procedures performed throughout the applicant institution.

The program is anticipated to be self-sustaining by the end of the second year given the current interest in accreditation by multiple medical specialties including the American College of Cardiology (ACC), the Society for Interventional Radiology (SIR) and the Society for Vascular Surgery (SVS) and other organizations.

#### **Step 2: Data Collection**

Applicants for initial accreditation. Hospitals applying for initial accreditation are required to meet the criteria specified in the national coverage decision document The accreditation process at such facilities focuses on the equipment, policies and procedures of the institution as they apply to carotid artery stenting and compliance with CMS guidelines. Little or no data is generally available for these institutions and outcome data will therefore be reviewed when they applied for re-accreditation although experience of the operators applying for credentials are reviewed to determine if they meet subspecialty guidelines for training and competency.



As illustrated by the exhibit above, both outcomes and process data are collected. In the case of initial accreditation, the facility is required to complete a data sheet and submit it for review. The key areas of data collected are shown on the following table:

### SCAI-CAP Evaluation and Accreditation Criteria

1. Policies and procedures	a. Patient selection b. Quality assurance c. Data acquisition and reporting
2. Operator credentialing criteria and review	a. Criteria used b. Past experience c. Radiation safety training
3. Support staff	a. Nurses i. Licensure ii. Experience b. Technicians i. Certifications ii. Experience
4. X-ray equipment	a. Vendor b. Model c. Archiving technology d. Image quality measures
5. Physiologic monitoring	a. Vendor b. Model c. Real-time acquisition d. Archive technology
6. Other equipment	a. ACT monitoring



	<ul style="list-style-type: none"> <li>b. Catheter and device inventory</li> <li>c. Emergency equipment &amp; resources               <ul style="list-style-type: none"> <li>i. Defibrillator</li> <li>ii. Intubation supplies</li> <li>iii. Anesthesia support</li> <li>iv. Medications                   <ul style="list-style-type: none"> <li>a. Pressors</li> <li>b. Vasodilators</li> </ul> </li> </ul> </li> <li>d. Medications</li> </ul>
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In many institutions carotid stent procedures are performed in a variety of locations (cath lab, radiology suite, operating room). Therefore for each location, the equipment, policies and procedures (if site specific) and system/operational differences are reported for review.

The majority of facilities obtained their initial accreditation without onsite review. Site visits to a by trained nurse reviewers validate the reliability of the data. These data and reports are then reviewed by two independent physician reviewers for final recommendation to the SCAI-CAP Board for final accreditation.

In order to operationalize the broad criteria presented in the above table, the standards presented in the multispecialty clinical competency statement are especially valuable. Those standards are detailed in the following table.

#### SCAI-CAP Accreditation Criteria

<i>Carotid intervention should be performed in facilities that have the necessary imaging equipment, device inventory, staffing, and infrastructure to support a dedicated carotid stent program. Specific minimum requirements are as follows:<sup>3</sup></i>	
STANDARDS AREA	REQUIREMENTS/STANDARDS DETAIL
<b>Imaging equipment and quality</b>	First, high-quality X-ray imaging equipment is a critical component of any carotid interventional suite. High-resolution digital imaging systems with the capability of subtraction, magnification, road mapping, and orthogonal angulation are necessary. Image storage, retrieval, and archiving capability are required. Carotid intervention has been performed effectively with image intensifiers of a variety of field sizes, ranging from 9 to 16, and with both fixed and advanced mobile units. The quality of the image is more important than size of the field.
<b>Physiologic monitoring Equipment and staffing</b>	Second, advanced physiologic monitoring must be available in the interventional suite. This includes real-time and archived physiologic, hemodynamic, and cardiac rhythm monitoring equipment, as well as support staff who are capable of interpreting the findings and responding appropriately. The ability to measure activated clotting time on-site is highly desirable.



<p><b>Proper and sufficient disposable supplies</b></p>	<p>Third, a large and diverse inventory of disposable supplies is critical to a successful carotid stent program. This includes, but is not limited to, items such as guidewires (0.035”, 0.018”, and 0.014”); balloon dilation catheters (coronary and noncoronary balloons in diameters ranging from 2 to 14 mm; balloon lengths from 10 to 40 mm with sufficient useable catheter length); self-expanding (4-10 mm diameter, 20-60 mm length) and balloon-expandable (2-12 mm diameter) stents with sufficient useable catheter length; coronary guide catheters (6-9 Fr) and long arterial sheaths ranging from 6 to 8 Fr in size and at least 85 cm in length; temporary pacemakers; and emboli protection devices. Covered stents, coils, snares, and vascular access closure devices should also be available.</p>
<p><b>Emergency management equipment and procedures</b></p>	<p>Fourth, emergency management equipment and systems must be readily available in the interventional suite. Specifically, these include resuscitation equipment, a defibrillator, vasoactive and antiarrhythmic drugs, endotracheal intubation capability, and anesthesia support. The procedure staff should be familiar with rapid response to hemodynamic and rhythm instability.</p>
<p><b>Pre- and post-procedure training &amp; experience (allied health professionals)</b></p>	<p>Skilled allied health professionals in the laboratory (nurses and technicians) must be trained and experienced in evaluating patients before and after catheter-based interventional procedures. Training in the recognition and management of acute neurological syndromes is required.</p>
<p><b>Privileging and quality policies</b></p>	<p>Each institution must have a clearly delineated program for granting carotid stent privileges and for monitoring the quality of the individual interventionalists and the program as a whole. The oversight committee for this program must be empowered to identify the minimum case volume for an operator to maintain privileges, as well as the (risk-adjusted) threshold for complications that the institution will allow before suspending privileges or instituting measures for remediation.</p>

These criteria will be expanded and modified as scientific developments and experience warrant.

In the case of re-accreditation for those facilities whose most recent accreditation was through SCAI-CAP, data are submitted for review to verify no significant operational changes in the facility. More importantly, patient data acquired and reported during the interval between accreditation and application for re-accreditation is reviewed by the SCAI-CAP review team in a HIPAA-compliant manner. SCAI encourages participating facilities to report these data through reporting to a registry with data elements including outcomes consistent with one of the data registries. This facilitates broad-based benchmarking and ongoing analysis.

Both the Society of Vascular Surgery (SVS) and the National Cardiovascular Data Registry (NCDR) have operational data engines for reporting these data. ACR is also developing a registry. It is critical that data from these repositories adhere to consistent data definitions and standards. SCAI is actively working with those organizations to ensure that all such registry efforts collect data in a consistent manner, to facilitate meaningful analysis regardless of source.

Benchmark data (indications, patient characteristics, procedural outcomes and predictors of these outcomes) will be available either from these sources or from the post market industry studies (or both) prior to any facility being eligible for re-accreditation. Individual facility data will then be compared to benchmark values.

Both the NCDR and SVS registry structures include data validation procedures. The nature of these validation processes vary. Consistency of validation in those elements that are most highly



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related to outcomes is critical and forms the rationale behind site visits for data validation and verification.

Application Process for Initial SCAI-CAP Re-accreditation (limited experience). Facilities with relatively recent carotid programs or with limited experience, which require re-accreditation, have carotid stent outcomes data available within their institutions. To apply for SCAI-CAP re-accreditation, those institutions must submit such data for review and analysis. These facilities also are expected to meet pre-established quality standards. Criteria from the Capture trial and other relevant post market surveillance trials have been helpful in preparing those standards.

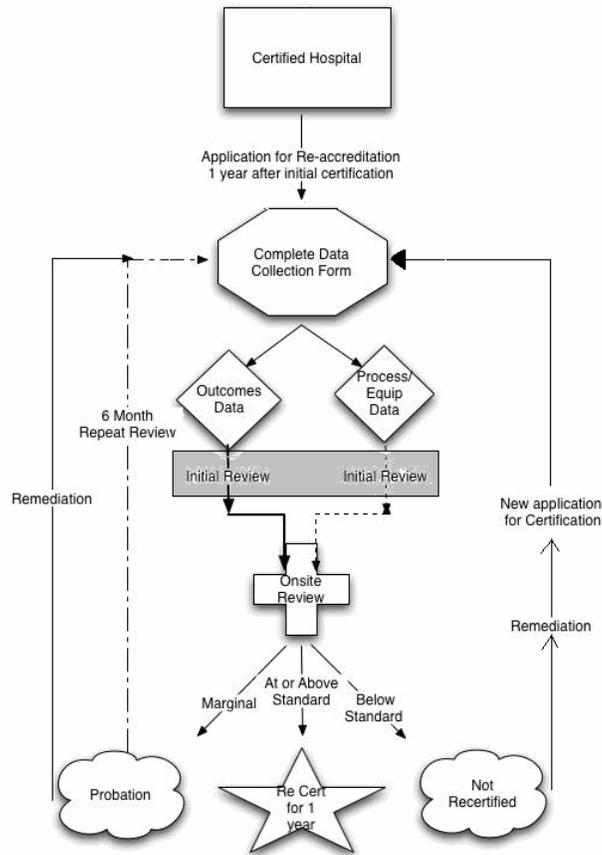
Since those facilities were, by definition, initially self-accredited, the re-accreditation process provides an opportunity for independent review of equipment, policies and procedures to confirm the facility's compliance with CMS guidelines including appropriateness and inclusion criteria. Quality outcomes are the focus of this review process, but verification of self-reported information is important and necessary for validation of data integrity. Because of the relatively low volume of procedures in this group, statistical comparison to the benchmarks can be difficult because of broad confidence intervals and therefore these facilities require more frequent evaluation to be confident that deterioration of outcomes are not occurring.

Application Process for Initial SCAI-CAP Re-accreditation (substantial experience). Facilities with a substantial carotid stent experience extending over a number of years: this group requires a less detailed review of equipment, policy, and procedures. This is only to the extent that no undesirable changes have occurred in the interval since prior accreditation. The focus of this review is on quality and outcomes assessment. The standard to be met is that set by CMS but reflecting all data available at the time of the review relative to optimal outcomes of carotid artery stenting in the target populations.

### **Step 3: Initial Review**

Based upon the required completed application forms and data, the SCAI-CAP review staff conducts an initial review of each facility applying for certifications. Following completion of the initial application documents, a site visit is schedule and performed by trained nurse reviewers.

The SCAI-CAP review committee provides ongoing support and education to the staff performing these reviews. Independent physician reviewers evaluates all recommendations from the review staff before making a recommendation to the SCAI-CAP Board for accreditation.



#### **Step 4: Onsite Review**

The SCAI-CAP staff assigns a team of experienced, trained, objective nurse reviewers to conduct the review. In offering its Catheterization Laboratory Survey for many years, SCAI has become highly experienced in developing the procedures for training individuals and conducting the onsite reviews in a professional, thorough manner.

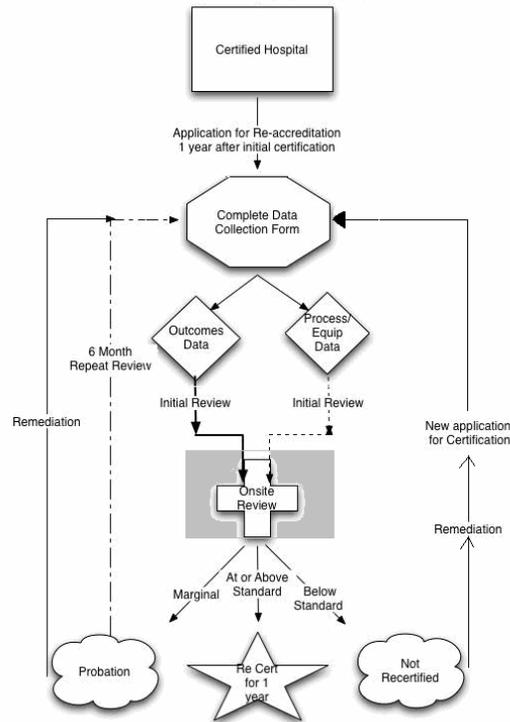
These reviewers submit a report detailing their findings to the assigned physician reviewers. These individuals are determined from a pool of experience carotid stent and neurologic clinicians who review the specific data as well as the summary report from the nurse reviewers. They independently recommend accreditation to the SCAI-CAP board. In the case of a disagreement between the physician reviewers, the Board may either review the application as a whole or assign an additional physician reviewer to assist in consensus building with the initial reviewers.

A corrective action plan is developed for facilities not meeting performance standards that includes a probationary period pending repeat review. Depending on the specific problems, additional training can be recommended by enrollment in an appropriate training program. Based



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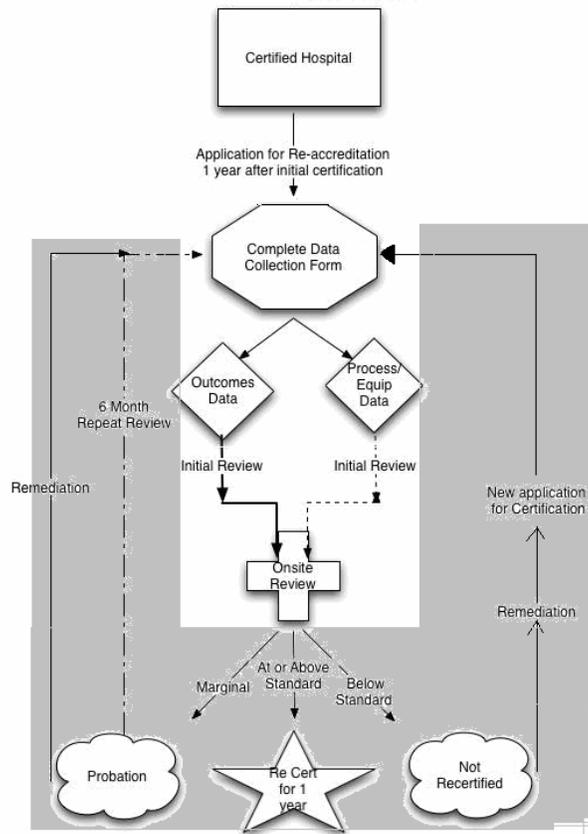
on the corrective plan provided to a particular institution, SCAI may recommend to CMS that the institution continue to perform CAS under certain circumstances or that the program be suspended until remediation as recommended is achieved and approved by CMS or SCAI-CAP.



### **Step 5: Analysis and Findings**

As the final accreditor, that entity has the ultimate responsibility for thorough review and making those decisions in an impartial, objective manner. An inclusive Board including all relevant stakeholder organizations performs this function. This includes representatives from the following organizations:

- SIR, whose members frequently perform CAS;
- SVS, whose members also perform CAS and contribute to the Society’s CAS Registry;
- The Neurovascular coalition, representing several professional societies committed to quality of care in this emerging technology; and
- The CARE Registry, a major CAS data registry developed by the ACC in partnership with SCAI.
- The American Hospital Association



In developing an approach for conducting this analysis and rendering fair, impartial decisions, the multispecialty society clinical competency statement for CAS referenced earlier<sup>3</sup> provides a useful framework, particularly regarding facilities, equipment and allied personnel for performing CAS:

In addition to the studies that resulted in FDA approval of devices for carotid stenting with distal protection as well as CMS’s national coverage decision, more recent results from post-market approval studies are now available and formed the basis for the reopening of the coverage decision. These data allow for more real-time assessment of the characteristics of patients being treated as well as the changing outcomes for the procedure.

In order to provide more valid criteria for re-accreditation, newer, more contemporary outcomes data from clinical trials, post-market surveillance studies, and other registries for the benchmark criteria for outcomes quality assessment will continuously be incorporated as they become available. In light of the current coverage guidelines, it will also be important to evaluate appropriateness criteria for case selection, and to confirm (by the on-site review process described

<sup>3</sup> Rosenfield K, Cowley MJ, Jaff MR, Ouriel K, Gray W, Cates CU, Feldman T, Babb JD, Gallagher A, Green R, Kent KC, Roubin GS, Weiner BH, White CW. SCAI/SVMB/SVS 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. *Catheter Cardiovasc Interv*, 2005. 64(1):1-11.



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above) the documentation regarding patient inclusion criteria in order appropriately evaluate the outcome data.

**The CAPTURE** study. The CAPTURE post-market surveillance study provides the most current information on outcomes and practice patterns. This information has been critical for development of the standards necessary for implementation of the accreditation process described above. CAPTURE identified a significant shift in the baseline characteristics, compared to ArCher. Specifically in Archer, the patients were younger and more likely to be symptomatic (23.8% versus 9.7%) compared to CAPTURE. The CAPTURE population also included a higher proportion of women (40% versus 32.9%) and fewer patients with congestive heart failure (13.7% versus 33.6%).

CAPTURE reported an overall composite endpoint rate of 5.1% (95% confidence interval 4.1-6.3%) for patients in the study. Based on these data, and in the absence of any more recent results, a composite endpoint rate of 6.3% (the upper value of the 95% confidence interval) can be considered to represent an appropriate overall benchmark upper limit value for outcomes for the re-accreditation process.

It should be noted that adjustments may be necessary for certain baseline characteristics which influence risk. For example, outcomes in CAPTURE were different by patient age, with a composite endpoint (death, stroke, and MI) rate of 4.3% in patients under 80 years of age compared with a rate of 7.7% in patients 80 years of age or older.

In addition, the most patients enrolled in the CAPTURE registry were asymptomatic, so the adverse events endpoint rates in CAPTURE may not reflect the expected rates in a predominantly symptomatic group of patients, who, in general, would have higher event rates with treatment. While these event rates may be lower than would be encountered in a symptomatic population, participants in these studies were required to have independent neurological evaluation for assessment of peri-procedural stroke. Individual facilities, outside of the post-market surveillance trials, are not required to have independent neurological assessment, so the actual rate of stroke may be under-reported in this setting. This may be mostly related to minor stroke and transient neurologic events so the incidence of Major stroke may be more accurately reported.

Stroke/death alone and major stroke/death were similar in CAPTURE with rates of 5.2% and 2.5% respectively. In the symptomatic patients, the rates of stroke/death alone and major stroke/death were 10.6% and 5.3% for CAPTURE. For the asymptomatic group, the rates of stroke/death alone and major stroke/death were 4.6% and 2.2%. These rates are comparable to those reported in ArCher.

Symptomatic patients represented less than 10% of the study population in the CAPTURE study, but the composite event rate was comparable to that seen in ArCher Registry (14.1% vs. 13%), suggesting similar outcomes as usage expanded to a broader range of institutions and less experienced operators. Therefore, until there is a change in the current coverage decision, this value (upper value of 95% confidence interval) may be an appropriate benchmark value for re-accreditation purposes.

The potential confounder, and the reason that these data appear different than those reported in the earlier trials, is that self-reporting of neurologic events is generally associated with lower reported event rates than in studies in which event adjudication is performed by an independent



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reviewer. This phenomenon has been previously documented with carotid endarterectomy surgery studies (Rothwell & Warlow, Stroke 1996; 27: 260-265). It therefore may be preferable to utilize an endpoint of death and major stroke for the primary benchmark outcome analysis, rather than an endpoint of death/stroke/MI, since inclusion of minor stroke (or MI) may result in significant variations in incidence among different institutions depending on whether rigorous neurological assessment is done at these facilities. The use of hard endpoints which are easier to verify should provide a more consistent evaluation and also not penalize sites which have a more rigorous post procedure evaluation.

**Implications for analysis and accreditation decisions.** Analysis of results from the CAPTURE data has identified factors which are associated with an increased incidence of adverse outcomes. These predictors include increasing age, symptomatic carotid artery disease, congestive heart failure, and severity of carotid stenosis. Adjustment of benchmark data to reflect significant predictors of outcome allows more standardized analysis of outcomes. In addition, as further data becomes available, incorporation of new variables or re-weighting of established variables may be important in developing a risk stratification model that can further refine the benchmark standards.

Facilities that exceed an acceptable event rate (as approved by CMS for the re-accreditation process benchmark) for death/stroke are recommended for probationary status. The review team assists the site in developing a corrective action plan. These facilities will be re-reviewed on an accelerated schedule (6-12 months) as opposed to the CMS mandated initial 2-year interval. Once the backlog of reaccreditation is completed, this interval will become yearly. Facilities that remained significantly above the target benchmark level (beyond 2 SD above this level) will not be re-accredited. These sites may subsequently reapply for accreditation after they have implemented the necessary steps to correct the deficiencies identified during the review process.

Some institutions undergoing re-accreditation review may have carotid artery stenting procedure volumes which are insufficient to allow valid statistical analysis of outcomes results due to the wide confidence intervals associated with low procedure volume. In these situations, re-accreditation may be granted either for a shorten approval duration, or may be granted on a conditional basis with a requirement for greater institutional oversight of results or for more frequent analysis and reporting of outcomes data (with a focus on occurrence of major complications).

Given that additional data will continue to become available and the population of CMS beneficiaries may change over time, the SCAI as an accrediting body will continue to adjust the benchmark values (in collaboration with CMS) to reflect the more recently outcomes data (as appropriate) and will communicate any changes to all participating facilities on a regular basis in order to maintain fairness and equality in the process.

### **Rationale for SCAI's Involvement**

SCAI has taken the leadership role in CAS facility accreditation, in close partnership with the other stakeholder organizations noted above. SCAI has significant experience in similar undertakings to assure quality care in invasive and interventional cardiology. Concurrently, the Society has been closely involved with CAS in multiple ways since the technology was first proposed, often partnering with other stakeholder organizations.



#### SCAI-CAP

SCAI is the primary professional association for invasive and interventional cardiologists. Founded in 1978, the Society is a 501(c) (3) nonprofit educational association, headquartered in Washington, DC. SCAI currently has 3,700 members (all physicians), approximately 88% of them residing in the U.S. SCAI's mission is to promote excellence in invasive and interventional cardiovascular medicine through physician education and representation, and the advancement of quality standards to enhance patient care. SCAI pursues its mission through standing committees plus ad hoc task forces as needed.

SCAI has a long-standing tradition of dedicated physician volunteers willing to advance quality care. Focus areas for SCAI include establishing standards and guidelines for cardiovascular catheterization, angiography and intervention, as well as training, credentialing, safety and quality assurance.

As a result, SCAI has a long, active history of efforts to promote quality in the catheterization laboratory. SCAI is committed to taking on the role of accreditation body for facilities performing CAS, as a responsibility directly derived from its mission statement.<sup>4</sup>

SCAI has taken on this role after careful analysis of the following factors:

- CAS clinical competencies and facility resources. During 2003-2004 SCAI led a multispecialty society effort to prepare a definitive guideline specifying competencies clinicians need to safely perform CAS.<sup>2</sup> The statement also presented guidelines as to the resources facilities need to properly support CAS. This guideline has been widely adopted in the U.S. and abroad.
- Mission statement. CAS facility accreditation is consistent with SCAI's mission.
- CAS practitioners. The great majority of CAS procedures in recent clinical trials were performed by interventional cardiologists, a trend that has continued subsequent to CMS' coverage decision.
- Experience with facility quality assurance. Since 1981, SCAI has offered its Lab Survey program, as described above and in the Appendix, a comprehensive service dedicated to catheterization laboratory review, inspection and quality improvement.
- Experience with clinical data registries. SCAI developed the first large-scale data registry for cardiac catheterization and coronary angiography. This was subsequently expanded to include the first large-scale societal-based registry of coronary intervention. The SCAI Registry was the most comprehensive of its type, and served as an excellent quality assurance system for participating laboratories. It also led to numerous publications that established original benchmark data for cardiac catheterization and interventions.

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<sup>4</sup> Note that SCAI is limiting its facility accreditation efforts to the area of CAS (not other procedures) in cath labs; note also that these efforts will focus on facility accreditation, not certification of physicians performing CAS.



#### SCAI-CAP

- Partnerships. During many of the above efforts, SCAI made concerted efforts to partner with the spectrum of other organizations involved, including other societies, research organizations, government, health providers and industry.
- AHRO grant. SCAI has partnered with the National Center for Quality Assurance (NCQA) to plan and conduct a conference this December on CAS quality measurement efforts, bringing together all stakeholders to identify approaches to collect, analyze and use data toward excellence in CAS care.
- Committee leadership and staff. SCAI's Board of Trustees, Committee Chairs and other leaders are enthusiastic about successfully pursuing this effort, and have a long-standing commitment to supporting their professional society to that end. SCAI's staff similarly is experienced in the issues and activities to be involved.

In sum, SCAI has a long tradition and experience with quality assessment and review of cardiac catheterization laboratories, involving virtually all of the activities and skills necessary for the planned CAS accreditation process. This experience has been adapted to the current environment of accrediting facilities that wish to perform or continue to perform carotid artery stenting procedures on Medicare beneficiaries.

#### Summary

SCAI has made the commitment to become an accrediting agency for facilities wishing to perform carotid stenting procedures on Medicare beneficiaries. As part of this process, we have outlined the process we are following to accomplish this goal. As we have done to date, SCAI intends to continue working closely with our membership and other stakeholders (such as other physician groups, healthcare systems, third-party payors and others) to implement SCAI-CAP in an impartial, professional manner toward the best possible patient care.



## **Appendix: Description of the SCAI Cardiovascular Catheterization Laboratory Survey Program**

*(Note: this is the description provided to facilities inquiring about the Program)*

### **What is the SCAI Cardiovascular Catheterization Laboratory Survey Program?**

SCAI's Laboratory Survey Program is a resource for physicians and laboratory administrators seeking comprehensive, independent outside review of their cardiovascular catheterization laboratories. The program was the brainchild of several pioneers in invasive and interventional cardiology. In 1981, not long after SCAI was established, they found themselves overwhelmed by requests from physicians seeking expert input on how to run safe and successful laboratories. After several site visits demonstrated that many cardiovascular catheterization laboratories could be improved through constructive review, the program was formalized. Since then, numerous physicians and administrators have turned to SCAI for assistance in identifying their labs' strengths and deficiencies and developing plans for improvement.

### **How Does the SCAI Cardiovascular Catheterization Laboratory Survey Program Work?**

A lab survey is initiated at the institution's request. SCAI selects two senior Fellows with extensive experience in catheterization laboratories. In many cases, they are or have been directors of major laboratories. Whenever possible, the survey team includes one member from an academic setting and another from private practice. SCAI ensures that both reviewers are always from geographic areas far from the lab to be surveyed.

The team spends one to two days onsite, reviewing all aspects of lab functioning. The facilities are toured, equipment is examined, records are reviewed, and statistics are analyzed. The team reviews cases at random, considering patient selection, imaging quality and accuracy of the catheterization reports. At the end of the site visit, the reviewers provide preliminary, face-to-face feedback, enabling lab management to ask questions and start developing ways to improve the lab. In a few weeks, a comprehensive written report is provided with recommendations for enhancing lab performance and, of course, delivering better patient care.

### **Who Sees the Report on My Lab?**

You. No one else, unless you choose to share it with others. The report is prepared by the survey team and delivered to you. All findings and recommendations are kept in the strictest confidence and covered by peer review confidentiality.

### **Why Have Other Labs Requested Reviews?**

Today's cardiovascular catheterization laboratories are facing difficult and often conflicting priorities. They are being challenged to curtail costs, incorporate new technologies into their care protocols, ensure quality, and document outcomes improvement. With all of these pressures, as well as increased scrutiny from regulatory agencies, many labs are looking for an unbiased assessment of their performance and insights into their problems.

### **How Do I Initiate a Review of My Lab?**

Any hospital or cardiovascular catheterization laboratory may request a review of its program. Call 1-800-992-7224 or send a letter of request to:  
The Society for Cardiovascular Angiography and Interventions  
Attn: Lab Survey Committee  
2400 N Street NW  
Washington, DC 20037-1153