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CARE Registry[®]

Program Overview
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1. Background

Stroke is the third leading cause of death in the United States, affecting over half a million people per year, following coronary artery disease (CAD) and cancer (AHA, 2006). A stroke occurs when the blood supply to part of the brain is transiently or permanently interrupted (ischemia) or when a blood vessel in the brain bursts (hemorrhage), spilling blood into the spaces surrounding brain cells (Topol, 2002). Brain cells die when they no longer receive oxygen and nutrients from the blood, or when there is sudden bleeding into or around the brain.

The National Institute of Neurological Disorders and Stroke warns of the symptoms of stroke:

- Sudden numbness or weakness of face, arm or leg – especially on one side of the body
- Sudden confusion, trouble speaking or understanding speech
- Sudden trouble seeing in one or both eyes
- Sudden trouble walking, dizziness, loss of balance or coordination
- Sudden severe headache with no known cause

Despite a decline in the number of deaths due to stroke from 1993 to 2003, each year about 700,000 people in the United States experience a new or recurrent stroke. About 500,000 of these are first attacks and 200,000 are recurrent attacks (AHA, 2006; Faxon, 2004).

Many factors influence stroke risk; some are modifiable and others are not. As with coronary arteries, occlusive atherosclerotic stenosis is a modifiable risk factor that purportedly accounts for approximately 20% of all strokes (Faxon et al, 2004; Sacco et al 1989). Over time, the arteries may become blocked or occluded due to tobacco use, high blood pressure, high cholesterol, or other factors. As a result of these risk factors, calcium, fatty substances, cholesterol, and other substances may accumulate in the carotid arteries (Higadisha, 2004; Zarins, 1996). This build-up, or plaque, results in a blockage of the blood flow within the artery, and a blood clot may form at the site of the blockage. The danger lies in the potential for the clot, or a piece of the blockage, to break off and travel to the brain, which may trigger a stroke or transient ischemic attack (TIA), a type of “mini-stroke” that lasts for less than 24 hours. Long-term effects of carotid artery stenosis may contribute to increased risk of coronary events such as myocardial infarction.

Stenosis of the carotid arteries may be treated through medical therapy, surgical carotid endarterectomy (CEA), or carotid artery stenting (CAS). Since the 1950s, CEA has been performed to excise plaque from the artery, and has been considered the standard of care based on randomized controlled trials demonstrating its efficacy: notably the North American Symptomatic Carotid Endarterectomy Trial (NASCET), European Carotid Surgery Trialists (ECST), Asymptomatic Internal Carotid Atherosclerosis Study (ACAS) and European ACAS, comparing CEA to medical management (Das, 2005).

Over 117,000 carotid endarterectomies were performed in 2003, making it the most widely used form of treatment in preventing stroke (AHA, 2006) – however, CEA is not free of complications. In the NASCET study, 5.8% of patients suffered from perioperative stroke and death, and it was also reported that subgroups of patients at high risk had mortality and morbidity at a rate up to 18% (Barnett, 1998). Patients who are generally healthier tend to tolerate endarterectomy very well. However, patients with physiologic or anatomic risk factors, such as end-stage renal disease or prior radical neck dissection, tend to have less favorable outcomes with a surgical intervention, carrying a higher risk of complications (Ouriel, 2003).

Carotid artery stenting (CAS), a less invasive procedure that is similar in principle and mechanics to angioplasty and stenting of the coronary and peripheral blood vessels, has emerged as an alternative to CEA in high-risk patients. The first procedure, involving angioplasty with the insertion of a stent, occurred over 20 years ago (Levy 2005). Early trials

comparing CAS with CEA were closed because cerebro thromboemboli and periprocedural complications were found to be more common in the CAS arm.

At least 12 randomized trials have been launched since 1998 to compare CEA and CAS, with most now incorporating the use of embolic protection devices (Goodney et al, 2006). Additionally, there are many non-randomized, single-arm studies of CAS only. Most of these studies are typically designed like registries and are carried out through single centers or industry sponsors, such as the BEACH trial from Boston Scientific (Ouriel et al, 2003). In reviewing the results from a multitude of clinical trials, it is important to note the challenge in comparing results. One of the difficulties has been the inconsistency in reporting of results, mainly due to differences in patient populations, operational definitions, study design, and outcome measurement. This has made it difficult to draw definitive conclusions and make standardized comparisons across studies (Goodney et al, 2006).

With the introduction of new advances in technology, such as embolic protection devices, the complication rates have decreased and outcomes have reached equivalence with endarterectomy for high-risk surgical patients (Levy, 2005). The SAPPHIRE trial (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy) examined stenting with embolic protection and endarterectomy in patients at high risk for surgery. In this pivotal study, CAS and CEA were found to be statistically similar in terms of outcomes. After accounting for the use of embolic protection devices, there were fewer post-procedural risks when compared to CEA. More specifically, for myocardial infarction, cranial nerve palsy, need for revascularization, and length of hospital stay, carotid stenting was superior to endarterectomy. The incidence of ipsilateral stroke and death, however, was equivalent in both groups (Yadav, 2004).

In sum, it appears that carotid stenting offers a less invasive alternative for the highest risk group of patients. Additionally, the risk of perioperative myocardial infarction is less, and there is no risk of laryngeal nerve paralysis. Stent placement is performed without general anesthesia, with a shorter hospital stay, and with lower costs. Carotid stenting is particularly attractive for patients shown to be at high risk for surgery.

As a result of these latest clinical trials, in August of 2004, the Food and Drug Administration (FDA) approved the use of a carotid artery stent system in the treatment of patients with carotid occlusive disease. At that time, there were only two embolic device and stent systems approved for use by the FDA: the Guidant Acculink/Accunet system and the Abbott Xact/Emboshield system. It has been estimated that, since approval of the device in 2004, over 10,000 patients have undergone the procedure (Feder, 2005).

Several weeks after the approval of carotid stent procedures, the Centers for Medicare and Medicaid Services (CMS) approved "the expansion of coverage for percutaneous transluminal angioplasty of the carotid artery with stenting to Medicare-eligible patients in the post-approval studies for this stent." In 2005, CMS further broadened its coverage by providing reimbursement of carotid stent procedures for select high-risk patients. Then, in April 2007, coverage was expanded for those patients who are at high risk of CEA and with symptomatic stenosis $\geq 70\%$. In these patients, an FDA-approved stent and embolic protection device are required. Additionally, coverage was afforded to patients with symptomatic stenosis between 50%-69% who are participating in approved clinical trials, as well as in asymptomatic patients with stenosis $\geq 80\%$. This is particularly important as stroke affects over 70% of American adults in Medicare's target population. As a condition for coverage, CMS requires that facilities must be certified to perform carotid stenting and that they must collect data on all CAS procedures. In addition, an internal analysis of these data should occur no less than every 6 months and be made available as a part of recertification. At this time, CMS does not recommend a specific method or database to be used for data collection.

2. CARE Registry Description

The CARE Registry (Carotid Artery Revascularization and Endarterectomy) is a national, outcomes-based quality improvement program. It is one of a suite of cardiovascular registries under the auspices of NCDR[®] (National Cardiovascular Data Registry), whose goal is to be the largest, most comprehensive national cardiovascular patient data repository ever developed. The CARE Registry measures outcomes of carotid artery stenting and endarterectomy procedures, including those patients enrolled in post-market surveillance and Investigational Device Exemptions (IDE) trials. By participating in the CARE Registry, enrolled hospitals can measure their performance through broad-based benchmarking with hospitals in similar and national comparison groups.

The CARE Registry data elements were developed to align with the CMS coverage determination statement, so participation in the CARE Registry meets CMS data collection requirements. Undoubtedly, the analysis of CARE Registry data will provide insight into practice patterns, the prevalence and use of the devices, the patient population in which the stents are being used, adverse events associated with the use of carotid artery stents, and subsequent long-term outcomes. The data provided by the CARE Registry will be a quality resource that improves upon previous industry and government data collection efforts.

The purpose, objectives, audience, and scope of the CARE Registry are far-reaching.

3. Purpose of the CARE Registry

- Create a national surveillance system to assess the characteristics, treatments, and outcomes of patients with carotid artery disease (CAD) who undergo stenting and endarterectomy procedures
- Facilitate efforts to improve the quality and safety of CAD patient care, and investigate novel quality improvement methods
- Meet CMS requirements for data collection and reporting

4. Objectives of the CARE Registry

- Monitor the characteristics, treatments, and outcomes of patients with carotid artery disease who undergo procedures in cardiac catheterization laboratories, radiology suites, and operating rooms
- Explore the association between evidence-based acute treatment strategies and risk-adjusted clinical outcomes
- Assess utilization of diagnostic non-invasive testing procedures and track hospital length of stay data
- Assess utilization of evidence-based medications at hospital discharge, and risk-factor modification interventions
- Provide a useful tool for hospitals to analyze, report, and improve quality of patient care at a local level

Sample questions the CARE Registry can answer:

- What are the characteristics of the patient?
- What are the characteristics/competencies of the individual implanting the carotid stent?
- What are the indications for the carotid stent?
- What are the in-hospital, procedure-related complications?
- What are the relative outcomes within the registry population?
- What are the procedures that are being used based on history and risk factors, and how do they relate to outcomes?
- What carotid artery devices are being used and how do they relate to outcomes?

5. CARE Registry Audience

Clinicians (cardiologists, surgeons, radiologists, neuroradiologists, neurologists, neurosurgeons, vascular surgeons, emergency medicine physicians, primary care physicians, nurses, physician assistants, nurse practitioners, and technologists), pharmacists, case managers, allied health care personnel, hospital quality improvement personnel and administrators, professional organizations, accrediting organizations, regulatory agencies, payers, pharmaceutical and device industries, and clinical research organizations.

6. How to Participate in the CARE Registry

First steps include registering at the NCDR CARE Registry Website, www.ncdr.com. A CARE Registry Support Specialist will contact you after registration with the forms you'll need to complete your enrollment, including the Business Associate Agreement.

7. CARE Registry Case Inclusion/Exclusion Criteria

Adult patients who have attained the age of 18, based on admission date to the hospital, and who undergo carotid artery stenting (the insertion of an interventional guidewire and/or embolic protection device [EPD] into the carotid artery with the intent of performing carotid revascularization) or carotid endarterectomy (a surgical revascularization of the carotid artery, including, but not limited to, carotid endarterectomy, patch angioplasty, grafting, or other operative technique aimed at revascularization of the carotid artery) procedure during their episode of care.

8. CARE Registry Data Collection

NCDR registry products, including the CARE Registry, are created under the leadership of clinical experts with critical input from NCDR participants regarding the feasibility of implementation and the burden of data collection. The CARE Registry collects data on multiple variables, including the usage of balloons, stents, and embolic protection devices; history and risk factors; in-hospital procedure information; medications; and neurological assessments before, immediately after, and at 30 days post-procedure. Data are collected, validated, and submitted under the responsibility of a designated Registry Site Manager at each participating institution.

8.1 *Web-Based Data Capture*

Information collected on Data Collection Forms (DCFs) may be entered by participating facilities via a secure, password-protected Website managed by NCDR. Participation in the CARE Registry is required to be able to enter and access data.

8.2 *Vendor-Based Data Capture*

In 2008, NCDR will provide CARE Registry software specifications to interested vendors who wish to develop a registry software package product. With this data collection method, data are submitted via a secure Website in an encrypted, password-protected file.

9. Collection of Existing Recorded Data, Privacy, and Ethical Considerations

The American College of Cardiology Foundation (ACCF) does not require Institution Review Board review and approval as a condition of participation in NCDR. However, the ACCF does require that all participating facilities abide by the policies and procedures of their facility. Please consult with your facility for guidance in participation in quality improvement activities. This program summary for the registry may be used for presentation to your IRB if required by your facility policies.

Registry data is collected based on the registry specific inclusion criteria. Data collected in the registry are collected using existing medical record data. The registry does not require participating facilities to contact individual patients.

The ACCF takes reasonable safeguards to protect the data collected through the registry including physical, technical and administration safeguards required of a Business Associate under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as amended by the HITECH ACT. All facilities participating in the registry are required to sign a Business Associate Agreement with the ACCF which stipulates permitted and restricted data uses.

The registry requires collection of direct identifiers allowing data captured in multiple registries to be interoperable, hence reducing the data collection burden of participating facilities. The Business Associate Agreement also stipulates permitted disclosures and secondary uses of registry data. Please note that the ACCF is only permitted to disclose a Limited Data Set to third parties for very restrictive purposes. The only permitted disclosure of direct identifiers is to entities who actively act as sub-contractors of the ACCF. Such sub-contractors are bound by contract under the same requirements stipulated in the Business Associate Agreement as required by HIPAA. Additionally, ACCF may release data to entities where a Participant has authorized the release of such information.

10. CARE Registry Data Quality

The NCDR Data Quality Program (DQP) is designed to meet the requirements needed for a comprehensive health information management system. The Onsite Data Audit Program is a component of this effort. The overall purpose of the DQP is to ensure that data submitted to NCDR are complete, consistent, and accurate - ultimately improving the overall quality of the CARE Registry.

10.1 Data Completeness

In keeping with established NCDR data quality procedures, participant data submissions are reviewed to establish overall completeness prior to analyzing and developing reports for any given quarter. The Data Quality Report (DQR) process assesses the overall completeness of a participant's data submission, and provides feedback to the participating hospitals. The DQR provides participants with a confidential analysis of their data completeness, and is used by the participant to help prioritize data "cleaning" efforts.

10.2 Data Consistency and Accuracy

Each year, participating sites will be randomly selected to be audited. Trained nurse abstractors will conduct medical record reviews and blind data abstraction of randomly selected patient medical records at each site. Audit results will be analyzed for overall accuracy by comparing audit findings against data originally submitted from each site. The participants that are selected for audit will receive a confidential report which will display their audit score and individual accuracy for each data element.

11. CARE Registry Reporting and Data Analysis

CARE Registry participants receive access to comprehensive, timely information about measuring quality of care for their CAD patients in the form of quarterly and annual comparative benchmark reports. These institution-specific reports are comprised of evidence-based elements that correspond to the CARE Registry data elements, facilitating continuous monitoring of quality improvement efforts and enabling facilities to compare, on a blinded basis, their institution's practice patterns to national averages and volume-based peer comparison groups. Participants can use this information for reducing complications in CAS and CEA procedures, improving patient care, supporting local quality-improvement programs, and communicating with regulatory and contracting organizations.

As a result, the CARE Registry provides a potent research tool that permits focused analysis of clinical treatment, procedures, and outcomes of patients with occlusive cerebral vascular disease treated with a carotid artery stenting or carotid endarterectomy procedure. Data collected through the CARE Registry can be analyzed to assess determinants of practice guideline implementation, to assist in medical decision-making, and to provide clinical evidence to help support the Centers for Medicare and Medicaid Services (CMS) in their National Coverage Decision (NCD), *Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting*.

12. Using CARE Registry Data to Meet Physician Board Maintenance of Certification (MOC) Requirements

All physicians who are board-certified and have a time-limited certification must complete a Maintenance of Certification (MOC) process to renew their certification. For example, ABIM-certified physicians have 10 years to complete the process, which includes self evaluation of practice performance. NCDR CARE Registry data can be used to earn up to 80 points out of the 100-point total required by ABIM. This practice performance requirement is referred to as MOC Part IV. Visit www.cardiosource.com/moc for more information.

There are several Web-based tools offered by ABIM to complete MOC Part IV called Practice Improvement Modules (PIMs). The ABIM self-directed PIM allows physicians to use ABIM-approved data sources to complete the module. The NCDR is an approved data source for completing the ABIM self-directed PIM for physicians whose patient records are submitted to the CARE Registry. Completion of the ABIM self-directed PIM is also recognized by a number of insurance companies and Pay for Performance programs. For more information, visit <http://www.abim.org/moc/healthcare/healthplans/default.aspx>.

Physicians certified by medical specialty boards other than ABIM, such as vascular surgeons, radiologists, neurologists, or neurosurgeons who have their patient records submitted to the CARE Registry, should consult their individual boards to see how their facility's CARE Registry data can be used to meet MOC Part IV requirements.

13. Ongoing CARE Registry Participant Support

The CARE Registry provides "help desk" support to all participants from 9 am to 5 pm (ET) on regular business weekdays. This includes telephone and email support for participants who have questions or need assistance with any facet of the registry operations.

13.1 Participant Training and Orientation

Training and orientation are critical functions to ensure data quality and, ultimately, a high-quality registry. In addition to the "help desk" functions described above, training and orientation also include:

- **Introductory Calls and Webcasts**

CARE Registry participants are invited on a routine basis to join calls and/or Webcasts where registry staff provide an overview to the CARE Registry program and answer questions.

13.2 Regional Group Meetings

NCDR registry participants, in many cases, have organized themselves into regional training and networking groups. Educational meetings and/or teleconferences may include presentations regarding recent findings from CARE Registry data analyses, strategies for ensuring successful collaboration between various hospital specialties and departments in support of the quality improvement process, question and answer sessions or case studies, and other topics of interest.

14. CARE Registry Governance

The mission of NCDR is to improve the quality of cardiovascular patient care by providing information, knowledge, and tools; implementing quality initiatives; and supporting research that improves patient care and outcomes. Oversight of NCDR is provided by the NCDR Management Board.

14.1 CARE Registry Steering Committee

The CARE Registry Steering Committee reports to the NCDR Management Board. The Steering Committee provides strategic direction for the CARE Registry and monitors research and clinical activities to include the following:

- Sets a high level agenda for the strategic direction of the CARE Registry
- Advocates, promotes and influences key groups regarding CARE Registry activities
- Assures activities conducted by the CARE Registry Research and Publications Committee and Clinical Support Team are congruent with NCDR methodologies and policies
- Identifies new opportunities and strategies to further promote utilization of the CARE Registry
- Establishes working groups as needed to support specific projects.

The committee consists of nine members and includes:

- A Chair (appointed with collaborative approval by the partnering societies and the Chair of the NCDR Management Board)
- At least three SCAI members
- At least three ACC members
- One member from the neuroscience community
- One member from the radiology community
- The NCDR Chief Medical Officer or an NCDR Board member designee

14.2 CARE Registry Research and Publications Subcommittee

This committee oversees all activities related to research and publications for the CARE Registry including:

- Oversees all research activities, including the evaluation, improvement, approval, and prioritization of investigational, industry and government research proposals
- Oversees the production of analytical and/or descriptive abstracts, poster presentations, and manuscripts
- Selects secondary reviewers for abstract and manuscript development
- Participates in open sessions of the Data Monitoring Board and reviews reports from closed sessions.

14.3 CARE Registry Clinical Support Team

The CARE Registry Clinical Support Team provides ad hoc clinical expertise as needed to respond to questions from participating hospitals regarding data elements and data collection. The team consists of clinical experts on the CARE Registry patient population.

15. CARE Registry Operations Oversight

NCDR oversees all activities associated with the CARE Registry, including the NCDR Information Technology and Research and Innovation departments that provide all technology management, data coordinating, report generation, and statistical functions for the CARE Registry.

16. CARE Registry Sponsorship

There is no outside funding for the CARE Registry.

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