CAS Training Issues

Questions remain regarding device training and credentialing.

BY TAKAO OHKI, MD, PHD

The introduction of the first FDA-approved carotid stent and embolic protection system more than a year ago was a breakthrough in treating high-risk patients at risk of stroke. The delicate nature of the procedure and potential for adverse outcomes, however, demands that only highly skilled and trained specialists perform carotid artery stenting (CAS). An ongoing debate among endovascular specialties, professional societies, and industry continues regarding the level of experience that should be required, as well as the role of industry in training physicians.

Guidant (Indianapolis, IN) remains the only company with FDA approval for its RX Acculink/RX Accunet carotid stent system. A requirement of Guidant's August 30, 2004 FDA approval was the implementation of an FDA-mandated, company-provided physician training program, which was reviewed and approved by the FDA in May 2004. To date, more than 1,000 physicians have gone through the company's training program and are performing CAS as part of their practices.

Some physicians have raised concerns regarding the entry criteria into the program, the intensity of the program, and the fact that physician proctoring is not required. Also, there is some confusion regarding the difference between device training and credentialing. This article reviews the industry-sponsored training programs and the societal guidelines in an attempt to clarify some of these issues.

SOCIETAL GUIDELINES

Endovascular Today's November 2004 issue reviewed training programs and the topic of accreditation.[1] In December 2004, a multispecialty consensus document on credentialing requirements for physician training was published by a collaboration of cardiologists, represented by the Society of Cardiovascular Angiography and Intervention (SCAI) and the American College of Cardiology (ACC); vascular internists, represented by the Society of Vascular Medicine and Biology (SVMB); and vascular surgeons, represented by the Society of Vascular Surgery.[2]

> "An ongoing debate . . . continues regarding the level of experience that should be required, as well as the role of industry in training physicians."

This clinical competence statement notes that training and credentialing requirements must "recognize this diversity, acknowledge the relevant background experience of individuals from each specialty, and be tailored to the particular needs of the individual seeking training."[2] It also recommends that, in addition to fully understanding cerebrovascular disease, its natural history, pathophysiology, diagnostic methods, and treatment alternatives, physicians seeking credentials for carotid stenting should be competent in both diagnostic angiography and interventional techniques. The coalition requires a minimum of 30 carotid angiograms and 25 carotid stent procedures, with half of those procedures performed as the primary operator. The recommendations recognize that the "excellent results of carotid stenting in clinical trials indicate that cardiologists, surgeons, radiologists, and other interventionists possessing peripheral vascular interventional skills …

TABLE 1. GUIDANT AND CORDIS TRAINING OVERVIEW

Training Activity	Guidant	Cordis
Didactic/didactic review	9 hours	10 hours
Carotid stent cases review	3 hours	4 hours
Simulation and product training	4 hours	6 hours
Proctoring	8 hours (upon request)	8 hours
Staff in-service	4 hours	6 hours
Sales support	First three cases	First three cases
Total	28 hours	34 hours

can perform carotid stenting safely." The consensus document therefore recommends that physicians should be required to first obtain privileges for peripheral vascular intervention in their hospitals prior to performing carotid stenting procedures. This is deemed necessary because the equipment used in carotid stenting is quite different than that used in coronary intervention or open surgery.

INDUSTRY-SPONSORED TRAINING PROGRAM

The Guidant and proposed Cordis (a Johnson & Johnson company, Miami, FL) training programs both involve regional training courses, in-hospital proctoring, and staff training totaling approximately 30 hours (Table 1). (A detailed comparison of the companies' programs can be found in the November/December 2004 issue of *Endovascular Today*.) The training programs' recommendations are similar to those of the consensus document, but do not require the physicians to first obtain privileges for peripheral vascular intervention in their hospitals.

Both the Guidant and the Cordis training programs place physicians into one of three different levels of product training based on their previous experience in the field of carotid stenting (Table 2). For the Guidant program, level I physicians are Guidant carotid clinical trial investigators with at least five carotid stent cases using the RX Acculink/RX Accunet device systems as primary operator. Level II physicians are those who have performed at least 10 successful carotid stent cases as primary operator or have attended another manufacturer's CAS training program and performed at least five successful carotid stent cases as primary operator. Level III physicians attend a 2-day training program after they have performed 25 selective carotid angiograms, 10 peripheral self-expanding stent cases, and 10 procedures using .014-inch monorail systems, all as primary operator. Entry criteria for the Cordis program is also listed (Table 2).

CONFUSION ABOUT AND CRITIQUE OF THE GUIDANT PROGRAM

Why did Guidant develop a training program that is inconsistent with the societal guidelines?

The implementation of a company-provided physician training program was a requirement of the August 30, 2004 FDA approval. Therefore, Guidant's training program was designed 8 months prior to publication of the consensus recommendations. At that time, no societal guidelines existed, therefore, this training program was created based on input from experts in the field. Moreover, the guidelines outlined the requirements for hospital credentialing, whereas Guidant's requirement is simply for device training and, therefore, inconsistency is not a problem.

Many physicians have raised concerns regarding the low entry criteria into the training program compared to the guidelines. What are the requirement differences?

In fact, some of its requirements are more stringent than those of the consensus document. For example, the guidelines requires 30 angiograms, with 15 as primary operator, whereas Guidant's training requires 25 angiograms, all as primary operator. This author believes that this is a stringent enough requirement for one to enter into a training program.

Why didn't Guidant revise its guidelines to match those put forth in the societal recommendation, in effect requiring participants to be fully credentialed by their hospitals prior to receiving training on the product?

During the development of Guidant's training programs, which preceded the publication of the guidelines, the majority of physicians consulting the company advised that it was the role of the societies and hospitals to establish guidelines for credentialing individual doctors, and that it was the role of each company to train physicians on a particular product. These advisors believed that credentialing should not be "mixed" with industry's role of product training. At the same time, these clinicians proposed a set of hur-

TABLE 2. PRODUCT TRAINING BASED ON PHYSICIAN EXPERIENCE

	Guidant	Cordis
Training levels	Level 1: Trial Level 2: 10 CAS Level 3: 25 angiograms, 10 Sx, 10 Rx	Level 1: Trial Level 2: 25 CAS Level 3: Credentiable
Training design	Didactic Observation + Simulator Sales rep proctor online didactic	Online didactic Observation + Simulator MD proctor Objective testing

Sx = Self-expanding stents; Rx = Rapid exchange catheters.

dles to define multiple levels of experience, and therefore training content, for clinicians with varying degrees of experience in this field. The requirement of 25 carotid angiograms as primary operator and the signature of the department chairperson was believed to be a key hurdle for those clinicians who had performed fewer than 10 carotid stenting procedures. Guidant discussed its approach for three levels of training content with the FDA and then submitted that plan in May 2004. The FDA approved that plan with the PMA in late August. The company has said that postmarket data contained in the CAPTURE study will provide important feedback to the approach it took in early 2004 based on the contributions of physicians from multiple societies. Those data will be available later this year.

Concerns have been raised that Guidant does not have enough authority to audit or regulate physician practice. In other words, how can one believe whether one has done 10 CAS (level 2) or 25 angiograms (level 3)?

This is true, although it is also true that the company requires the physician's department chairperson to verify the physician's clinical experience with signed documentation. I believe that this is as stringent as it can get. I know of several instances in which a physician artificially increased the numbers (of either CAS or angiogram) and the chairperson rightfully refused to sign off. I have to believe that this system is working. Moreover, what more can one do?

What is the difference between credentialing and an industry-sponsored device training program?

I believe that through the approval process, the FDA has defined the role companies play in the introduction of a new therapy—providing the training to use the device. On the other hand, it is the role of the medical societies to define competencies needed once the physician has been properly trained. Guidant notes that its training programs teach physicians how to use the device, but are not a license for a physician to perform a carotid stent procedure. In the absence of a national standard or credentialing body, each hospital's medical staff or administration makes decisions about individual physicians' ability to perform the procedure. Although Guidant does have strict criteria for admission to its training programs, the company believes that ultimately it is not the manufacturer's role to dictate which physicians have access to its products. During its training program, the company does refer participants to the societies' recommendations and clearly states that each trainee must be credentialed by his or her hospital.

In *Endovascular Today*'s November 2004 issue, Barry T. Katzen, MD, weighed in on the issue. "Credentialing is the responsibility of medical staffs and hospital administration, not medical device companies," said Dr. Katzen. "Particularly with respect to carotid artery stenting, credentialing must entail more than device training and certification. The medical societies have a number of documents pertaining to carotid artery stenting credentialing in the works right now, but what is missing is a unified statement on carotid accreditation that applies to all specialties. This is unfortunate because it will become a source of confusion for hospitals attempting to resolve this issue." Indeed, despite the "unified statement" proposed by the multispecialty coalition, Dr. Katzen's words have proven prophetic. ■

1. McChesney C. CAS training programs. Endovasc Today. November/December 2004:20-22.
2. Clinical competence statement on carotid stenting: Training and credentialing for carotid stenting—multispecialty consensus recommendations. A Report of the SCAI/SVMB/SVS Writing Committee to Develop Clinical Competence Statement on Carotid Interventions. J Vasc Surg. 2005;41:160-168.

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