# Performance and training standards for endovascular acute ischemic stroke treatment

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## ABSTRACT

Stroke is the third leading cause of death in the United States, Canada, Europe, and Japan. According to the American Heart Association and the American Stroke Association, there are now 750,000 new strokes that occur each year, resulting in 200,000 deaths, or 1 of every 16 deaths, per year in the United States alone. Endovascular therapy for patients with acute ischemic stroke is an area of intense investigation. The American Stroke Association has given a qualified endorsement of intra-arterial thrombolysis in selected patients. Intra-arterial thrombolysis has been studied in 2 randomized trials and numerous case series. Although 2 devices have been granted FDA phase 3 approval with an indication for mechanical stroke thrombectomy, none of these thrombectomy devices has demonstrated efficacy for the improvement of patient outcomes. The purpose of the present document is to define what constitutes adequate training to perform neuroendovascular procedures in patients with acute ischemic stroke and what performance standards should be adopted to assess outcomes. These guidelines have been written and approved by multiple neuroscience societies that historically have been directly involved in the medical, surgical and endovascular care of patients with acute stroke. These organizations include the Neurovascular Coalition and its participating societies, including the Society of NeuroInterventional Surgery (SNIS), American Academy of Neurology (AAN), American Association of Neurological Surgeons/Cerebrovascular Section (AANS/CNS), and Society of Vascular & Interventional Neurology (SVIN). ***Neurology*® 2012;79 (Suppl 1):S234–S238**

## GLOSSARY

**ABMS** = American Board of Medical Specialties; **ACGME** = Accreditation Council for Graduate Medical Education; **FDA** = US Food and Drug Administration; **IA** = intra-arterial.

Stroke is the third leading cause of death in the United States, Canada, Europe, and Japan. According to the American Heart Association and the American Stroke Association, there are now 750,000 new strokes that occur each year, resulting in 200,000 deaths, or 1 of every 16 deaths, per year in the United States alone.[1] Ischemic stroke accounts more than 80% of the total, while hemorrhagic stroke accounts for the remainder. Stroke is the leading cause of adult disability in North America[2] and the primary cause for inpatient Medicare reimbursement for long-term adult care.[3,4] The NIH estimates that stroke costs now exceed $62 billion in US health care dollars per year.[1]

At present, the only therapy demonstrated to improve clinical outcomes from acute ischemic stroke is thrombolysis of the clot responsible for the ischemic event.[5] Specifically, the only US Food and Drug Administration–approved stroke therapy is IV tissue plasminogen activator within 3



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hours of stroke onset.[5] Endovascular therapy for patients with acute ischemic stroke is an area of intense investigation. The American Stroke Association has given a qualified endorsement of intra-arterial (IA) thrombolysis in selected patients. IA thrombolysis has been studied in 2 randomized trials[6,7] and numerous case series showing clinical efficacy for the IA prourokinase in proximal middle cerebral artery occlusion.[7] Although 2 devices have been granted FDA approval with an indication for mechanical stroke thrombectomy,[8] neither of these thrombectomy devices has demonstrated efficacy for the improvement of patient outcomes in spite of high rate of recanalization awaiting randomized trials.

The purpose of the present document is to define what constitutes adequate training to perform neuroendovascular procedures in patients with acute ischemic stroke and what performance standards should be adopted to assess outcomes. Neuroendovascular procedures are technically challenging and not directly transferable from other vascular systems, involve an organ with unique physiology and anatomy, and require careful patient selection because of the risk of potentially fatal brain hemorrhage. It has become abundantly clear over the past 20 years that inadequate physician training and experience can adversely affect clinical outcomes in studies of emerging technologies.[9,10] Overexuberance both on the part of physicians and industry has led unqualified physicians to perform endovascular carotid revascularization procedures yielding inferior results.[9,10] Therefore, it is especially important that the involved physicians strictly adhere to appropriate standards when performing high-risk procedures such as endovascular stroke treatment. Standardization of training requirements is of critical importance as the interest in and utilization of endovascular methods increases among various specialties. These guidelines are modeled after prior standards documents such as the training, competency, and credentialing standards for diagnostic cerebral angiography, carotid stenting, and treatment of acute stroke, written and endorsed by multispecialty groups[11–13]; and training standards for the performance of uterine artery embolization written by the Society of Interventional Radiology.[14] These guidelines also parallel the training standards of successful subspecialty training programs such as Interventional Cardiology and the credentialing standards for the performance of acute coronary intervention.[15] These guidelines have been written and approved by multiple neuroscience societies that historically have been directly involved in the medical, surgical, and endovascular care of patients with acute stroke and are considered experts in the field of endovascular stroke therapy. These organizations include the Society of NeuroInterventional Surgery (SNIS), American Academy of Neurology (AAN), American Association of Neurological Surgeons/Cerebrovascular Section (AANS/CNS), and Society of Vascular & Interventional Neurology (SVIN).

**Minimum training requirement for acute stroke interventions.** Cognitive training and qualifications:

1. Accreditation Council for Graduate Medical Education (ACGME)–approved residency training including documented cerebrovascular training including the diagnosis and management of acute stroke and the interpretation of cerebral arteriography and brain imaging under the supervision of a board-certified neurologist, neurosurgeon, or neuroradiologist with subsequent American Board of Medical Specialties (ABMS) eligibility or certification. A minimum of 6 months during a 4-year residency is suggested.
2. One year of graduate medical education in endovascular surgical neuroradiology. An ACGME-approved program is preferred but not required.

Technical training and qualifications:

1. Documented prior training and experience in catheter arteriography, including 100 cerebral arteriograms. Clinical outcomes must meet or exceed American College of Radiology benchmarks for technical success and complications.[11,16]
2. Documented prior training and experience in intracranial microcatheter (≤3 French) and microguidewire (≤0.014 in) navigation under the supervision of fellowship-trained and credentialed neurointerventionalist(s).
3. Documented prior experience in assessment and performance of endovascular stroke interventional procedures as the primary operator in 10 patients under the supervision of fellowship-trained and credentialed neurointerventionalist(s).
4. Previously credentialed physicians who perform IA catheter-directed stroke procedures at their local institutions should have documented procedural and clinical outcomes that meet national standards and published evidence-based guidelines.[12,13]

During the next 2–3 years as the nation progresses to regional stroke care with comprehensive stroke centers it is conceivable that selective hospitals may choose to credential individuals for IA stroke therapy who have not had a full year of neurointerventional fellowship training. While this is not endorsed as best clinical practice, if such local situations occur and if hospitals choose to credential individuals who have not had a full year of neurointerventional training, it is recommended that at a minimum these individuals should have had adequate neuroscience cognitive training (including a minimum of 6 months documented neuroscience training in an ACGME-approved postgraduate training program); adequate technical and interpretive cerebral angiography training (including a minimum primary operator experience of 100 appropriately supervised cerebral angiograms, which is the minimum prerequisite for neurointerventional training); adequate cerebral microcatheter experience (including a minimum of 30 cases as primary operator in the intracranial internal carotid artery/vertebral basilar circulation) mentored by a credentialed, fellowship-trained neurointerventionalist); and mentored experience in IA stroke therapy (including a minimum of 10 cases mentored by a fellowship-trained neurointerventionalist credentialed in IA stroke therapy) prior to being credentialed to perform IA therapy. It is anticipated that by the end of 2012 stroke centers that are providing IA stroke therapy will be staffed with exclusively fellowship-trained neurointerventionalists and/or practitioners who have met the above prerequisite guidelines and have demonstrated credentialed experience in IA therapy with adequate outcomes. Further, it is anticipated that after 2012 additional manpower for providing IA stroke therapy in stroke centers will come exclusively from fellowship-trained neurointerventionalists.

**Training in endovascular surgical neuroradiology.** In the United States, Canada, Europe, and Japan, educational programs are specifically designed to train neuroscience physicians to treat acute hemorrhagic and ischemic stroke. This training represents the "gold standard" for performance of endovascular cerebrovascular procedures, including the endovascular treatment of acute stroke.

Since the year 2000, program requirements have been formally established and published in North America to ensure uniform training in endovascular surgical neuroradiology, a field specializing in the endovascular treatment of acute stroke.[17] "Endovascular Surgical Neuroradiology" is the title or moniker used to describe the training pathway that is recognized by the ACGME.[17,18]

Mechanical revascularization (thrombectomy/embolectomy) devices have not yet been proven to improve patient outcomes. In addition, it is not possible to define general training requirements when there is currently significant clinical experience with only one mechanical revascularization clot retrieval device and it is unknown what the necessary interventional skills would be for newer generations of clot retrieval devices. There is consensus that the skills needed and risks associated with use of these devices are greater than the skills needed and risks associated with use of catheter-based pharmacologic lysis, but it is not possible to make specific training recommendations at this time. However, at a minimum, the physician must meet the training criteria described herein for pharmacologic lysis for emergency stroke therapy and have successfully completed a training course for use of any specific device. Furthermore, procedural complication rates, including intracerebral hemorrhage, should conform to evidence-based national guidelines.

**Maintenance of physician and facility qualifications.** The physician should have ongoing stroke specific continuing medical education of at least 15 hours/2 years. The physician should have procedure outcomes that conform to national standards and institutional requirements.

Neuroendovascular acute ischemic stroke procedures should be performed only at Joint Commission or state-certified primary or comprehensive stroke centers.[19] Outlying and community hospitals should develop access via telemedicine or other means to endovascular acute stroke therapy through the development of stroke systems of care if comprehensive stroke center capabilities are not available.[20] The interventionalist must have 24/7 access to neurologists and neurosurgeons knowledgeable in patient selection and in the pre- and postneurologic critical care of endovascularly treated stroke patients. There must be 24/7 neurology and neurosurgical availability to treat possible complications of stroke therapy. There must be an active quality assurance program for stroke therapy to monitor outcomes both in the periprocedural period and at 90 days. All emergency interventional stroke therapy patients must be reviewed by the quality assurance program. Outcomes should be tracked and recorded. All centers should participate in and enroll all stroke patients in available national stroke registries or multicenter stroke trials.

**CONCLUSIONS** Medical disciplines with ACGME-approved training in neurosciences and the care of stroke patients agree on the importance of safety and quality of care for stroke patients. Due to the grave consequences of inadequate or deficient training, stringent credentialing criteria with formal neuroscience training as specified herein and by peer-reviewed published standards should be mandated

for emergency endovascular stroke therapy,[17,21] analogous to vascular interventions for acute myocardial infarction or other high morbidity and mortality conditions.[22–30] Credentialing committees at each health care facility are empowered to enforce training and practice standards and thus have an obligation to maintain recognized accreditation standards and to be aware of recommendations endorsed by the national organizations most directly involved in the diagnosis and management of acute stroke. Physician credentials, maintenance of certification, and quality improvement programs must be consistent with mandated and accepted standards defined by the ACGME, American Medical Association, ABMS, and state licensing boards.

## AUTHOR CONTRIBUTIONS

All the authors participated in the writing and editing of the final manuscript.

## DISCLOSURE

The authors report no disclosures relevant to the manuscript. **Go to Neurology.org for full disclosures.**

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