Recommendations for the Establishment of Primary Stroke Centers

Mark J. Alberts, MD
George Hademenos, PhD
Richard E. Latchaw, MD
Andrew Jagoda, MD
John R. Marler, MD
Marc R. Mayberg, MD
Rodman D. Starke, MD
Harold W. Todd
Kenneth M. Viste, MD
Meighan Girgus
Tim Shephard, RN
Patti Shwayder, MPA
Michael D. Walker, MD
for the Brain Attack Coalition

Despite significant advances in its diagnosis, treatment, and prevention, stroke remains a common disorder. An estimated 700,000 to 750,000 new and recurrent strokes occur each year in the United States, and as the population ages, the number of patients with stroke may increase. The lifetime costs of stroke exceed $90,000 per patient for ischemic stroke and more than $225,000 for subarachnoid hemorrhage. The extreme sensitivity of neuronal tissue to even brief periods of ischemia mandates that stroke be treated as a medical emergency.

However, many hospitals do not have the necessary infrastructure (personnel and equipment) and organization required to triage and treat patients with stroke rapidly and efficiently. In one recent study, 66% of hospitals surveyed did not have stroke protocols, and 82% did not have rapid identification for patients experiencing acute stroke. This shortcoming is further demonstrated by the experience with tissue-type plasminogen activator (tPA) as a stroke therapy. The approval of intravenous tPA as the first treatment for acute ischemic stroke was a landmark event, yet a recent study in the Cleveland, Ohio, area found that only 1.8% of patients with ischemic stroke received this agent.

Objective To develop recommendations for the establishment and operation of primary stroke centers as an approach to improve the medical care of patients with stroke.

Participants Members of the Brain Attack Coalition (BAC), a multidisciplinary group of representatives from major professional organizations involved with delivering stroke care. Supplemental input was obtained from other experts involved in acute stroke care.

Evidence A review of literature published from 1966 to March 2000 was performed using MEDLINE. More than 600 English-language articles that had evidence from randomized clinical trials, meta-analyses, care guidelines, or other appropriate methods supporting specific care recommendations for patients with acute stroke that could be incorporated into a stroke center model were selected.

Consensus Process Articles were reviewed initially by 1 author (M.J.A.). Members of the BAC reviewed each recommendation in the context of current practice parameters, with special attention to improving the delivery of care to patients with acute stroke, cost-effectiveness, and logistical issues related to the establishment of primary stroke centers. Consensus was reached among all BAC participants before an element was added to the list of recommendations.

Conclusions Randomized clinical trials and observational studies suggest that several elements of a stroke center would improve patient care and outcomes. Key elements of primary stroke centers include acute stroke teams, stroke units, written care protocols, and an integrated emergency response system. Important support services include availability and interpretation of computed tomography scans 24 hours everyday and rapid laboratory testing. Administrative support, strong leadership, and continuing education are also important elements for stroke centers. Adoption of these recommendations may increase the use of appropriate diagnostic and therapeutic modalities and reduce peristroke complications. The establishment of primary stroke centers has the potential to improve the care of patients with stroke.

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experience of trauma centers, which were organized to provide care for patients with acute trauma. Trauma centers were established after studies found that many lives were being lost due to the frequent lack of necessary medical infrastructure needed to stabilize and treat patients with severe trauma.\textsuperscript{13-15} The trauma center concept has been extremely successful in organizing effective acute trauma care as reflected in improved survival rates after major trauma.\textsuperscript{14,16} The trauma center concept appears to be effective in both urban and rural settings.\textsuperscript{19,17-19} Based on this experience, combined with studies showing the need for rapid diagnosis and treatment of patients with stroke, we believe that it is reasonable to explore the center concept for acute stroke.

To establish guidance about the formation and operation of stroke centers, the Brain Attack Coalition (BAC) formed a working group to study this issue. The BAC is a multidisciplinary organization that includes most major medical organizations involved with stroke care.

BAC members determined that 2 levels of stroke centers should be established: a primary stroke center and a comprehensive stroke center. A primary stroke center would stabilize and provide emergency care for patients with acute stroke. Such centers would then either transfer the patient to a comprehensive stroke center or could admit the patient and provide further care depending on the patient's needs and the center's capabilities. A comprehensive stroke center would provide complete care to patients experiencing the most complex strokes that require specialized testing and other interventions. Such comprehensive stroke centers typically would include tertiary care medical centers and hospitals with the infrastructure and personnel necessary to perform highly technical procedures and provide all needed levels of care.

Because most patients with stroke are initially evaluated and treated in hospital settings that are most conducive for establishing a primary stroke center, we decided to focus this article on recommendations for such facilities. We anticipate that this approach will benefit the largest number of patients with stroke.

\textbf{METHODS}

We conducted a comprehensive review of the English-language literature to identify articles dealing with the formation, function, and outcomes of centers for various medical conditions, with a focus on stroke centers and trauma centers. We searched MEDLINE from 1966 through March 2000. This review was also used to identify evidence-based interventions shown to be efficacious for treatment of patients with acute stroke and that would require a specialized infrastructure for implementation. Publications of randomized clinical trials, care guidelines, or appropriate observational studies were selected and reviewed. In reviewing the literature, we paid particular attention to issues such as outcomes, the economic impact on the health care system, patient comfort, and logistical aspects of patient care. These publications were reviewed initially by 1 of the authors (M.J.A.). These data and subsequent recommendations were then reviewed and analyzed by BAC members to help develop recommendations for key elements of a primary stroke center. Based on the membership of the BAC, each element was thoroughly reviewed, assessed, and modified (as needed) from a multidisciplinary perspective before being included. In all cases a consensus was reached among all BAC participants before an element was added to the list of recommendations.

\textbf{RESULTS}

The literature review included more than 600 articles, some of which provided evidence for some but not all of the elements of a primary stroke center. A consensus of the BAC membership and those with expertise in stroke was used to supplement or develop other areas not fully addressed in the literature. These recommendations for primary stroke centers are organized around 11 major aspects of stroke care. The focus is clearly on acute aspects of stroke care, because such acute care can often significantly influence aspects of subsequent care and outcome. For each specific area, we have included one or more methods by which the recommendation can be met or documented. The recommendations have been grouped into direct patient care areas and support areas (Table 1).

\textbf{Acute Stroke Teams}

The formation of an acute stroke team is an important step for organizing and delivering care to patients with acute stroke. Literature supporting the formation and use of such teams is increasing.\textsuperscript{20-22} The team may be staffed by a variety of health care professionals depending on the resources available at a particular facility. Different members may alternate serving on the team depending on staffing levels and patient needs. Although the acute stroke team does not have to be led by or include a neurologist or neurosurgeon, it is recommended that the team include personnel with experience and expertise in diagnosing and treating patients who have cerebrovascular disease. At a minimum, the team should include a physician and another health care professional (ie, nurse, physician’s assistant, nurse practitioner) who are available 24 hours everyday. It is recommended that the team respond to

\begin{table}[h]
\centering
\caption{Major Elements of a Primary Stroke Center}
\begin{tabular}{|l|}
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Patient care areas \\ Acute stroke teams \\ Written care protocols \\ Emergency medical services \\ Emergency department \\ Stroke unit* \\ Neurosurgical services \\ Support services \\ Commitment and support of medical organization; a stroke center director \\ Neuroimaging services \\ Laboratory services \\ Outcome and quality improvement activities \\ Continuing medical education \\
\hline
* A stroke unit is only required for those primary stroke centers that will provide ongoing in-hospital care for patients with stroke.
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patients with acute stroke in the emergency department (ED), in other hospital wards, or in a clinic within or adjacent to the hospital. There must be a specific and well-organized system for rapidly notifying and activating the team to evaluate patients presenting with symptoms suggestive of an acute stroke. A member of the team should be at the patients’ bedside within 15 minutes of being called.23 The precise organization of the team would vary by institution but should include these key elements.

Health care personnel who staff the acute stroke team typically would have other daily duties, perhaps carry a beeper on an alternating basis, and may receive a salary supplement. In one study the average annual cost for an acute stroke team ranged from $5000 to $10 000.21 The existence and operations of the team should be supported by a written document that provides information about administrative support, staffing, notification plans, response times, and the number of patients seen. A log should be kept that documents call times, response times, patient diagnoses, treatments, and outcomes. This log could be kept by the team leader or a designee and be used for quality improvement monitoring.

**Written Care Protocols**

The use of written care protocols has expanded greatly in the past few years for all aspects of medical care. The availability of such protocols for the use of tPA in acute stroke has been shown to be a key step in reducing tPA-related complications.8,24,25 Several studies have shown the efficacy of written care protocols for stroke patients in general.26-28 Such protocols can be implemented across a multihospital system to reflect individual diagnostic capabilities and treatment preferences.29 For a primary stroke center, such protocols should include the emergency care of patients with ischemic stroke and hemorrhagic stroke, including stabilization of vital functions, initial diagnostic tests, and use of medications (including but not limited to intravenous tPA treatment). These protocols could be based on previously published guidelines or could be developed by a multidisciplinary team organized by the stroke center.

Documentation should include written care protocols for acute stroke that are available in the ED and other areas likely to evaluate and treat patients with stroke. These protocols should be reviewed and updated at least once a year. It is understood that individual physicians and patients may not follow a particular protocol due to variations in the clinical situation and preferences of the patient, physician, or both. Adherence to the stroke protocol could be a component of quality improvement.

**Emergency Medical Services**

Substantial evidence supports the key role of emergency medical services (EMS) personnel in providing timely care to patients with stroke.8,24,30,32 Because EMS has such a vital role in the chain of survival for patients with stroke, it must be an integral component of a primary stroke center. For example, a call for a possible stroke should be assigned a high priority to ensure rapid evaluation and transport. A significant challenge is that the EMS system in the United States is not nationally regulated, which makes it difficult to design and mandate specific educational programs and care protocols. This also leads to considerable variability in organization and training in each city and region.33,34

Although rapid EMS transportation may be easily achievable in urban settings, it is unclear whether expectations for similar transport times hold for patients with stroke in a rural setting. Prior studies of stroke presentation times have failed to identify whether a rural setting is an independent predictor of a delayed hospital presentation.35 Studies of EMS transportation practices for trauma patients have been conducted in rural settings, and all have shown that rapid access to EMS is both possible and beneficial.18,36 Although use of EMS for the rapid transportation of patients with acute stroke in a rural setting may present some logistical challenges, the experience with trauma patients suggests that these obstacles can be overcome.

It is vital that the EMS system be integrated with the stroke center. The stroke center should be able to communicate effectively with EMS personnel in the out-of-hospital setting during transportation of a patient experiencing an acute stroke. The ED should be able to efficiently receive and triage patients with stroke arriving via EMS. The stroke center staff should support and participate in educational activities involving EMS personnel. The integration of an EMS system with a stroke center should be documented by a written plan for transporting and receiving patients with stroke via EMS, a letter of cooperation between the stroke center and the EMS system, and evidence of cooperative educational activities at least twice a year.12

An important issue is whether EMS personnel should transport patients with acute stroke only to facilities with a stroke center. Different jurisdictions and regions have a variety of policies and laws that govern or regulate patient transportation.37 However, we anticipate that once the stroke center concept is fully implemented, EMS officials will recognize the benefit of triaging patients with acute stroke to such centers and appropriate policies will be developed.32 Regional health care systems also may assist in directing patients with acute stroke to designated facilities, since this may improve patient care and outcome.

**Emergency Department**

The ED is a key part of the stroke center because it is usually the point of first contact between the patient and the medical facility.34 Emergency department personnel should be trained in diagnosing and treating all types of acute stroke. The ED should have well-established lines of communication with EMS personnel and be able to prepare for the arrival of patients with strokes from the EMS system. Emergency department personnel should be
familiar with the acute stroke team, how it is activated and how it functions. Some ED personnel, most likely, will be members of the team. The ED staff should have written protocols for triage and treatment of patients experiencing an acute stroke (ie, use of thrombolytic therapy, management of increased intracranial pressure and blood pressure).

For instance, increasing the appropriate use of tPA in acute ischemic stroke can result in an additional 11% to 13% of patients having an excellent neurologic outcome at 90 days. In addition, patients with stroke treated with tPA have a 48% likelihood of being discharged to home compared with 36% of patients not receiving tPA.

Emergency department personnel, including physicians and nurses, should participate in educational activities related to stroke diagnosis and treatment at least twice a year. Written documents that detail the ED procedures for managing patients with acute stroke should be provided. Such documentation should include policies and statements about how the ED is integrated with the entire stroke center, along with treatment algorithms and flow charts.

**Stroke Unit**

Evidence from individual studies and from meta-analyses support the efficacy of stroke units in the care of patients with acute stroke. Compared with patients with stroke who receive care in general medical wards, patients who receive care in stroke units had a 17% reduction in death, a 7% increase in being able to live at home compared with 36% of patients not receiving tPA.

For the purposes of a primary stroke center, neurosurgical care for the patient should be available within 2 hours of when it is deemed clinically necessary. This recommendation is based on a consensus from a national symposium on stroke and is also endorsed by the BAC. This means that either the patient could be transferred to another facility with a neurosurgeon or the neurosurgeon could be on-call at the initial hospital and able to see the patient within 2 hours.

Hospitals providing neurosurgical care must have an operating room staffed 24 hours every day with the necessary equipment and support personnel (ie, anesthesiology, radiology, pharmacy) to perform neurosurgical procedures that patients experiencing a stroke might require urgently. Neurosurgical coverage should be documented in a written plan approved by the covering neurosurgeon, stroke center leaders, and involved facilities. A call schedule should be readily available in the ED and to stroke center personnel. A written transfer plan and protocol should be developed, reviewed, readily available, and agreed on in advance by the transferring and receiving facilities.

**Neurosurgical Services**

Some patients with acute stroke will require a neurosurgical procedure or evaluation during their illness. However, due to the limited supply of neurosurgeons, many hospitals may not have ready access to a neurosurgeon. The delivery of high-quality and efficient care for patients with acute stroke is highly dependent on the degree of commitment of the facility, its administration, and personnel. Without such commitment from the administration and personnel, it is unlikely that the necessary training, organization, infrastructure, and funding will be available. Also, a primary stroke center should have a designated medical director who has training and expertise in cerebrovascular disease. The director does not have
to be neurologist but should have sufficient knowledge of cerebrovascular disease to provide leadership and guidance to the program. Examples of such knowledge might include 2 or more of the following criteria: (1) completion of a stroke fellowship, (2) participation (as an attendee or faculty) in at least 2 regional, national, or international stroke courses or conferences each year, (3) 5 or more peer-reviewed publications on stroke, (4) 8 or more continuing medical education (CME) credits each year in the area of cerebrovascular disease, and (5) other criteria agreed on by local physicians and hospital administrators.

Physician staffing for a primary stroke center should include clinicians with training and expertise in treating patients with cerebrovascular disease. Evidence of such training could include one or more of the criteria listed above. The importance of having neurologic expertise in caring for patients with stroke is supported by prior studies. For example, a study of more than 38,000 Medicare patients with stroke found the 90-day mortality rates were 16% for patients treated by a neurologist, 23% for those treated by an internist, and 25% for those treated by a family practitioner. These differences were statistically significant after controlling for differences in severity of illness and other comorbid conditions.

Administrative support for a stroke center would be enhanced if the center is shown to be cost-effective. Several key elements of stroke centers have been shown to be cost-effective, including the proper use of tPA to treat ischemic stroke, the use of stroke units, and aggressive measures to prevent subsequent strokes, particularly in high-risk patients. To the extent that these interventions and infrastructure elements improve patient outcomes and reduce costs, it is anticipated that hospital administrators and health system leaders would support them as part of a stroke center.

Evidence of administrative support can be provided by written documents that include a statement of support from the administration, an organizational chart, a listing of available infrastructure for the stroke center, and a budget. The curricula vitae of key personnel should be provided to demonstrate their training and expertise in cerebrovascular disease.

**Neuroimaging**

The ability to perform brain imaging studies for patients with acute stroke is vital for rapidly establishing an accurate diagnosis. Such studies also can provide information about the vascular abnormality that has caused the acute event. Primary stroke centers must have the capability of performing either a cranial computed tomographic scan or a brain magnetic resonance imaging scan within 25 minutes of the order being written. These imaging capabilities must be available 24 hours everyday.

Also, physicians experienced in interpreting computed tomographic and magnetic resonance imaging studies must be available to read these scans within 20 minutes of their completion. These physicians may include radiologists with experience interpreting cranial computed tomographic or magnetic resonance imaging films, as well as neurologists and others with expertise and experience with these techniques. Such persons can be available in the hospital or by remote access (ie, teleradiology). Teleradiology could be linked to radiologists (or other physicians) at home or at a remote site such as a comprehensive stroke center. There should be written documentation that such scans were performed and read within the specified times and that such scans can be performed 24 hours everyday. A log book that documents such scans with time parameters and interpretation is one way to document and monitor this capability.

**Laboratory Services**

Efficient diagnosis and treatment of patients with stroke requires the availability of standard laboratory services 24 hours everyday. These include the ability to perform and report complete blood cell counts, blood chemistries, and coagulation studies rapidly. Also, a primary stroke center should be able to complete an electrocardiogram and chest radiograph rapidly. It is recommended at primary stroke centers that these laboratory results be completed within 45 minutes of their being ordered. A letter of support from the laboratory director, along with written documentation that the necessary laboratories and services can complete the examinations within the recommended time, should be provided.

**Outcomes and Quality Improvement**

Stroke centers should have a database or registry for tracking the following: number of patients and type of stroke each patient experienced, type of treatments provided, time lines for providing treatments, and measurement of outcomes. A written system should be in place so that such data can be systematically collected, reviewed, and acted on. Specific benchmarks for comparisons should be established. For example, published guidelines recommend that the door-to-needle time for the use of intravenous tPA treatment in patients with stroke should be no more than 60 minutes.

Studies have documented the usefulness of quality improvement programs for the care of patients with stroke. The stroke center should select at least 2 relevant patient-care issues to serve as benchmarks each year. Prespecified committees should meet, review, and modify practice patterns (if needed) at least 3 times a year. Documentation should be provided about specific benchmarks, quality improvement areas, and minutes from at least biannual meetings of the appropriate committee(s).

**Educational Programs**

Due to the rapidly changing nature of diagnosis and management of cerebrovascular disease, it is recommended that the stroke center’s professional staff (including staff working in a stroke unit) receive at least 8 hours a year of CME credit (or an equivalent amount of nursing educational credit) in areas...
related to cerebrovascular disease. Although this educational requirement is somewhat less than that recommended for trauma center personnel, BAC members believe this is appropriate considering the scope of cerebrovascular disease. Several studies have shown public about prevention and recognition of stroke and the availability of acute therapies. Several studies have shown the effectiveness of such public educational programs for improving stroke recognition and reducing time delays of presentation. Even though such educational programs that target the public are labor intensive and may have to be repeated to be effective, they are a key component and key mission of a stroke center and an important aspect of public health policy.

Documentation of educational programs can be achieved through CME credits for the professional staff. Evaluation questionnaires for the public educational programs should be reviewed and saved to document such programs. The estimated annual costs for such staff and public educational activities would range from $3000 to $15 000 depending on the size of the program and the number of staff who participate.

**COMMENT**

Two major goals in our development of stroke center recommendations are to improve the level of care and to standardize some aspects of acute care for patients with stroke (Table 2). This effort was further motivated by several factors, including (1) the large number of patients with strokes in the United States; (2) the realization that many patients with stroke do not receive optimal care as defined by groups such as the American Heart Association and the National Stroke Association; and (3) the importance of making new therapies available to patients with strokes efficiently and safely.

A recent study of hospitals in the Cleveland area demonstrates the importance of following care protocols when treating patients with ischemic stroke with tPA. The study found that the rate of symptomatic intracranial hemorrhage following tPA administration was 15.7%, but for 50% of treated patients, national treatment protocol criteria were violated. In another multicenter study, the rate of intracranial hemorrhage following tPA administration was 3.3%, with only 15% of treated patients having violations of treatment protocols. These disparate results may support the need for regional stroke centers that have expertise and experience in treating patients with stroke and can closely follow detailed clinical protocols.

It is unlikely that every primary stroke center would have a neurologist with expertise in vascular disease on its attending staff. However, it is anticipated that a stroke center will facilitate an environment in which the expertise of a neurologist can be developed in facilities lacking a neurologist with expertise in stroke, thereby, resulting in improved care and outcomes. For example, some trauma centers (ie, level II) are not required to have a trauma surgeon on staff, although a surgeon must be available. For primary stroke centers, another option is to have a neurologist with expertise in cerebrovascular disease assist in the planning and operations of a stroke center, even if that neurologist is not part of the attending staff.

In the setting of managed care and specified networks of care facilities, it is important that patients receive the proper care for their medical conditions. When patients with acute stroke can be taken to a number of hospitals within a specific network, we hope that they would be taken to a designated stroke center, because we believe doing so would optimize their care and may result in cost savings. For example, if the stroke center designation increased the appropriate use of tPA, there could be substantial cost savings for a managed care system. One study estimated that for every 1000 patients with stroke treated with tPA, there is an overall savings of almost $5 million. Such designs also could aid managed care plans in hospital selection in that they could make an effort to include a certain number of hospitals with stroke centers as part of their care network.

It is difficult to determine accurately the costs for a primary stroke center because of the paucity of published data on most aspects of these specific costs. It is likely that the start-up costs would be higher than for annual operations once the infrastructure was in place. The estimated annual operational costs may range from $8000 to more than $20 000 (Table 3) depending on current staffing levels, the need for salary supplements, and the presence of various programs and infrastructure. In general, these expenditures are relatively small compared with the annual budget for most hospitals. It is possible that most costs
could be recouped by shortening the length of stay for patients with stroke by just 1 day or by preventing several recurrent strokes in the course of a year.58 By reducing complications and improving patient status at discharge, the savings to the health care system could be substantial.26,42,43

Some hospitals may be located too far away from a primary stroke center to permit easy or rapid transfer of patients with acute stroke. In such circumstances, strategies such as communication and telemedicine links to a stroke center may be a viable alternative. Preliminary studies have demonstrated that telemedicine systems are technically feasible for computed tomographic scan interpretation and patient evaluation for patients with acute stroke.45 Triage and transportation of acutely injured patients has worked well for the trauma system, and this expertise and knowledge could be applied to acute stroke care.46(p1150-22)

These proposed recommendations are not formal guidelines and are not intended to be used as credentialing criteria. Since there has not been a formal definition of a stroke center, data about the efficacy of stroke centers have not yet been generated. However, there are data about the efficacy of some of the key components of a stroke center, such as stroke units, care by a neurologist, and the use of tPA.39-40,42 As the stroke center concept evolves, outcomes-based research must be performed to determine the efficacy of this approach. We hope that these recommendations will begin a process by which the stroke center concept will evolve and grow. If the stroke center concept is accepted by the medical community, there may be a future need for the more formal process of credentialing or validating such centers.

An important element of stroke care that has not been addressed in this article is rehabilitation. Although our focus has been on acute care, initiation of early rehabilitation can hasten recovery following stroke.29 However, most of this rehabilitation occurs after the acute hospitalization and often in facilities remote from the acute care hospital. Stroke prevention is another area of importance.60 Many preventive therapies, such as antiplatelet agents or warfarin sodium, are highly effective, may be started during the acute hospitalization, and typically continue for many months or years.61,62

We have attempted to draw several analogies between stroke centers and trauma centers. The trauma center concept grew in part due to the high number of avoidable deaths in patients who experience trauma.63-66 A similar situation may be present in patients with acute stroke, in that many patients do not receive effective treatments for a variety of reasons.6,8,10 Both stroke and trauma occur acutely and both require an organized and multidisciplinary approach to optimize therapy and outcomes.10,67 In both cases, time to definitive therapy appears to be a key determinant in improving outcomes.39,40 Although we are hopeful that the center concept used in trauma can be modified for stroke, there are important differences between patients with trauma and patients with stroke. For example, most patients with trauma are younger than most patients with stroke, and they often receive medical and surgical therapy in a more rapid manner due to a higher transportation and triage priority.46(p1150-17,49,60) Despite these differences, the BAC believes strongly that the trauma center model has important elements that are applicable to stroke centers.

The BAC members have developed recommendations for the formation and operation of primary stroke centers. We also intend that these recommendations be used to assist hospitals and health care programs in the development of the infrastructure and programs to provide optimal care to patients with acute stroke. We anticipate that if hospitals adopt and follow these recommendations, patients and health care professionals may be aided in selecting facilities for acute stroke care. Considering the high incidence of stroke and the high costs of this disease, more efficient and effective care will be beneficial for patients with stroke.

Author Affiliations: Division of Neurology, Duke University Medical Center, Durham, N.C. (Dr Alberts); American Heart Association, Dallas, Tex (Drs Hademenos and Starke and Ms Girgus); Department of Radiology, University of Miami School of Medicine, Miami, Fla (Dr Latchaw); Deparment of Emergency Medicine, Mount Sinai Medical Center, New York, NY (Dr Jagoda); National Institute of Neurological Disorders and Stroke, National Institutes of Health, Rockville, Md (Drs Marler and Walker and Ms Emr); Department of Neurology, the Cleveland Clinic Foundation, Cleveland, Ohio (Dr Mayberg); National Stroke Association, Englewood, Colo (Mr Todd and Ms Shwayder); Lake Erie Neuroscience, Ochkoosh, Wis (Dr Viste); and Medical College of Virginia Hospitals and Virginia Commonwealth University Neurosciences Center, Richmond (Mr Shephard).

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