Special Report

Revised and Updated Recommendations for the Establishment of Primary Stroke Centers
A Summary Statement From the Brain Attack Coalition

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Background and Purpose—The formation and certification of Primary Stroke Centers has progressed rapidly since the Brain Attack Coalition’s original recommendations in 2000. The purpose of this article is to revise and update our recommendations for Primary Stroke Centers to reflect the latest data and experience.

Methods—We conducted a literature review using MEDLINE and PubMed from March 2000 to January 2011. The review focused on studies that were relevant for acute stroke diagnosis, treatment, and care. Original references as well as meta-analyses and other care guidelines were also reviewed and included if found to be valid and relevant. Levels of evidence were added to reflect current guideline development practices.

Results—Based on the literature review and experience at Primary Stroke Centers, the importance of some elements has been further strengthened, and several new areas have been added. These include (1) the importance of acute stroke teams; (2) the importance of Stroke Units with telemetry monitoring; (3) performance of brain imaging with MRI and diffusion-weighted sequences; (4) assessment of cerebral vasculature with MR angiography or CT angiography; (5) cardiac imaging; (6) early initiation of rehabilitation therapies; and (7) certification by an independent body, including a site visit and disease performance measures.

Conclusions—Based on the evidence, several elements of Primary Stroke Centers are particularly important for improving the care of patients with an acute stroke. Additional elements focus on imaging of the brain, the cerebral vasculature, and the heart. These new elements may improve the care and outcomes for patients with stroke cared for at a Primary Stroke Center. (Stroke. 2011;42:2651-2665.)

Key Words: cerebrovascular disease ■ disease management ■ stroke centers ■ stroke units

Stroke is a common and serious disorder. Each year in the United States, approximately 795,000 people will have a new or recurrent stroke.1 It is the fourth leading cause of death in the United States and a major cause of adult disability.2 Stroke is also a costly disease with lifetime costs in excess of $140,000 for ischemic stroke and $225,000 for subarachnoid hemorrhage.3,4 Annual costs for stroke in the United States exceed $73 billion.1 Improved care of patients with an acute stroke may reduce the high morbidity and mortality from this disorder and have significant public health and financial implications.

Prior studies have shown that many patients with stroke are not treated according to contemporary guidelines.5,6 One approach to improving stroke care is the development of Stroke Centers.7,8 These hospitals would act as focal points for the care of patients with an acute stroke. The fact that 77% of US counties lack a hospital with neurological services further highlights the need for more organized and centralized stroke care.1 Two levels of Stroke Centers have been delineated in the literature: (1) a Primary Stroke Center (PSC); and (2) a Comprehensive Stroke Center (CSC).10 A PSC would provide acute care to most patients with stroke, be able to use some acute therapies, and admit the patient if it had a Stroke Unit.9 A CSC would provide care to those patients with large or complex strokes, hemorrhagic strokes, patients who required specialized treatments (endovascular, surgery),
or those with multisystem involvement.10 A third type of facility, the Acute Stroke Ready Hospital, is currently under development. The Acute Stroke Ready Hospital would have fewer capabilities than a PSC but be able to diagnose, stabilize, treat, and transfer most patients with stroke. An Acute Stroke Ready Hospital would typically be a smaller facility in a small community or rural setting with limited resources.

Since The Joint Commission (TJC) and other entities/organizations (ie, state health departments, the Healthcare Facilities Accreditation Program) have begun to formally certify and recognize certain hospitals as PSCs, the number of such hospitals has increased dramatically.11 To date, there are >800 PSCs certified by TJC and perhaps another 200 to 250 certified by various state-based agencies, the Healthcare Facilities Accreditation Program, and other organizations. On average a typical PSC admits approximately 400 to 440 patients with stroke per year, has an average of 400 beds, and is in an urban area. Most are not major teaching hospitals.12

Since the initial publication of the PSC recommendations in 2000, there have been substantive modifications and changes in how patients with stroke are diagnosed and treated.13–16 These relate to the efficacy and importance of stroke teams, Stroke Units, the use of intravenous tissue plasminogen activator (tPA), and imaging advances, among others. Some other important advances such as endovascular therapies and acute surgery are more germane to a CSC and are not reviewed here. This revision will re-examine the key elements for a PSC, performance measures, and options for certification in an effort to update them and provide levels of evidence.

Methods

A comprehensive review of the English language literature using MEDLINE and PubMed was conducted to identify articles dealing with the formation, function, and outcomes of Stroke Centers; the use of acute imaging techniques; and related treatments and outcomes related to acute stroke care. Key words and terms used included Stroke Centers, stroke teams, Stroke Units, stroke guidelines, brain imaging, acute treatment, and other specific terms that might reflect care elements at a PSC. These publications deal with the diagnosis and treatment of all types of strokes (ischemic and hemorrhagic). We focused on articles published between March 2000 and January 2011, but also cited older literature if it contained relevant information. We reviewed randomized clinical trials as well as large case series, care guidelines, consensus publications, and appropriate observational studies. These data and subsequent recommendations were then reviewed and analyzed by the members of the Brain Attack Coalition (BAC) to help develop recommendations for this revision of the PSC recommendations.

Most recommendations were graded using a slightly modified form of the American Heart Association evidence-based grading system.17 Other grading criteria relevant to therapies and diagnostic imaging were used as appropriate.18 A summary of these criteria is in Table 1. The modifications were made to accommodate the diverse care aspects that are integral parts of a PSC. In some cases, recommendations from other care guidelines and scientific statements from organizations such as the American Heart Association and the American Academy of Neurology were reviewed and included or modified based on a review by the BAC (and were referenced as appropriate). The inclusion of specific grading criteria is an improvement over the prior recommendations, because levels of evidence were not included in that publication.19 Individual articles were graded based on their study design, methodology, number of

Table 1. Grading Criteria Used for Recommendations*

<table>
<thead>
<tr>
<th>Class of recommendation</th>
<th>Explanation</th>
<th>Comment</th>
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<tbody>
<tr>
<td>I</td>
<td>Benefits of treatment, test, intervention, or personnel clearly outweigh any risks</td>
<td>This treatment, test, intervention, or personnel should be used</td>
</tr>
<tr>
<td>IIa</td>
<td>Benefits of treatment, test, intervention, or personnel likely outweigh any risks</td>
<td>It is reasonable to use treatment, test, intervention, or personnel</td>
</tr>
<tr>
<td>IIb</td>
<td>Benefits of treatment, test, intervention, or personnel is possibly greater than the risks</td>
<td>It is reasonable to consider this treatment, test, intervention, or personnel in some cases</td>
</tr>
<tr>
<td>III</td>
<td>Risks may be equal to or greater than any benefits</td>
<td>Treatment, test, intervention, or personnel should not be used</td>
</tr>
</tbody>
</table>

Level of evidence

A Treatment or test validated in multiple studies/populations, meta-analyses, or circumstances | Very consistent treatment effects or test sensitivity and specificity |
B Treatment or test studied in studies/populations or circumstances with some limitations | Treatment effects promising but somewhat limited; testing results less robust |
C Treatment or test examined in few or very limited studies/populations or clinical circumstances; case series, expert opinion | Treatment or test recommendation based largely on expert opinion or is standard of care; may be a need for further studies/data |

*This grading system has been adapted and modified from other publications (see references 14–18) to reflect the unique components of Primary Stroke Centers.

patients, and general applicability of the results to a broad stroke population. The BAC also considered other aspects of its recommendations such as logistical issues, feasibility, applicability, and costs. In cases of disagreement about the inclusion about a specific care element or recommendation, the BAC membership would vote on its inclusion or modification, with a two thirds majority needed for final approval and inclusion.

Results

A thorough literature review provided high levels of support for many of the initial key elements of a PSC. In addition, there was support for several additional elements of a PSC, mostly dealing with imaging of the brain, the cerebral vasculature, and the heart (Table 2). These recommendations are organized around 13 major aspects of stroke care. The focus is clearly on acute aspects of stroke care, because this is the logical place to begin and such acute care can often
Element Service/Center Recommendations

hemorrhage may be cared for at a CSC,10 some may also patients with intracerebral hemorrhage and subarachnoid lying etiology. Although we recognize that some or most [ICH], subarachnoid hemorrhage [SAH]) regardless of under-
types of acute strokes (ischemic, intracerebral hemorrhage
met or documented. These elements apply to patients with all
included
summarized in Table 3. For each specific area, we have
significantly influence subsequent care decisions and out-
comes. Early rehabilitation is also included as an important
aspect of care at a PSC. Important revisions and additions are
summarized in Table 3. For each specific area, we have
included ≥2 methods by which the recommendation can be
met or documented. These elements apply to patients with all
types of acute strokes (ischemic, intracerebral hemorrhage
[ICH], subarachnoid hemorrhage [SAH]) regardless of under-
lying etiology. Although we recognize that some or most patients with intracerebral hemorrhage and subarachnoid hemorrhage may be cared for at a CSC,10 some may also receive care at a PSC; therefore, they are included in our recommendations.

Patient Care Areas

Acute Stroke Teams

The formation of an acute stroke team (AST) is an important step for organizing and delivering emergent stroke care. As used in this setting, the AST is responsible for responding to patients with an acute stroke and initiating diagnostic testing and immediate care (not ongoing in-hospital care). There is a growing literature supporting the formation and use of such teams.19,20 Recent studies have shown that the AST is a key element in the screening and delivery of acute therapies (such as intravenous tPA) to patients with acute stroke.21–23 Such teams also improve overall outcomes for patients with stroke.24–26 The AST may be staffed by a variety of healthcare personnel depending on the resources available at a particular facility. Different members may rotate on the team depending on staffing levels and patient needs. Although the AST does not have to be led by or include a neurologist or neurosurgeon, it is recommended that the AST include personnel with experience and expertise dealing with cerebrovascular disease. At a minimum, the AST should include 1 physician and 1 other healthcare provider (ie, nurse, physician’s assistant, nurse practitioner) who are available on a 2-hours/day, 7 days/week (24/7) basis. A member of the AST should be at the patient’s bedside within 15 minutes of being called.9,26,27 Although it is preferred that members of the AST be in-house on a continual basis, a rapid response from outside the hospital may be reasonable in specific situations as long as the response time remains ≤15 minutes.

It is recommended that the AST respond to patients with acute stroke in the emergency department (ED), in other hospital wards, or in a clinic within or immediately adjacent to the hospital (if logistically feasible and legally allowable). There must be a specific and well-organized system for rapidly notifying and activating the AST to evaluate patients presenting with symptoms suggestive of an acute stroke (ie, pager, cell phone, overhead calling). The precise organization of the AST will vary by institution but should include the key elements outlined here.

In some cases, members of the AST will assist and advise personnel at outside hospitals about acute measures than can be used to stabilize and treat patients before transfer to the PSC. Examples might include beginning intravenous tPA therapy (drip and ship method), reversal of anticoagulation, stabilization of vital signs, etc. There is abundant literature supporting the safety and efficacy of “drip and ship” protocols for the use of intravenous tPA.28–31 Members of the AST must have familiarity and expertise with the recognition, diagnosis, stabilization, and acute care of all types of patients with stroke. Evidence-based protocols should be used by the AST members to guide acute care and determine which patients should be transferred to other facilities. The protocols should apply to all major stroke types.

The existence and operations of the AST should be supported by a written document that provides information about administrative support, staffing, notification plans, and care protocols. A log should be kept that documents call
times, response times, patient diagnoses, treatments, and outcomes. This log could be kept by the AST leader or a designee and be used for quality improvement projects.

The AST is supported by a Class I, Level A recommendation. Although the inclusion of the AST as a key element in a PSC has not changed since the original publication, its specific elements and operations have been better defined to reflect current experience and knowledge about the importance of the AST to improve the rapid diagnosis and treatment of patients with stroke at a PSC.

Written Care Protocols
The use of written care protocols has expanded greatly in the past 10 years for all aspects of medical care. The availability of such protocols for the use of intravenous tPA in acute stroke has been shown to be a key step in enhancing the administration and reducing complications of this therapy. Numerous studies have shown the efficacy of written care protocols for general patients with stroke. Such protocols can be implemented across a multihospital system to reflect individual diagnostic capabilities and treatment preferences. For a PSC, such protocols should include the emergent care of patients with ischemic and hemorrhagic strokes, including stabilization of vital functions, initial diagnostic tests, and the use of various medications. These protocols could be based on previously published ones or could be developed by a multidisciplinary team organized by the Stroke Center. For hospitals using electronic medical records, these protocols should be included in admission orders to ensure their consistent use. The use of electronic medical records also enhances the ability of such care protocols to include certain orders (eg, prohibition of anticoagulants immediately after intravenous tPA administration) or mandate certain activities (eg, a swallow evaluation before feeding, deep vein thrombosis prophylaxis) that affect care and outcomes.

Documentation should include written care protocols for acute stroke that are available in the ED and other areas likely to treat such patients. These protocols should be reviewed and updated at least once per year by a multidisciplinary team using evidence-based medical guidelines. 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 and/or physician. Adherence to ≥1 components of a stroke protocol could be one component of a quality improvement project. Examples of such protocols can be found at the following web sites: www2.massgeneral.org/stopstroke/treatmentProtocols.aspx, www.stroke-site.org/pathways/pathways.html, and www.innovations.ahrq.gov/content.aspx?id=2782.

The use of written care protocols is supported by a Class I, Level A recommendation.

Emergency Medical Services
There is abundant evidence supporting the key role of the emergency medical services (EMS) in providing timely identification, care, and transportation for patients with acute stroke. Patients with stroke who activate the EMS system by calling 911 and are transported by EMS clearly demonstrate shorter delay times and more rapid assessment and treatment. Notification of EMS of a call for a patient with a possible stroke should be assigned a high priority to ensure rapid transportation. A significant challenge is that the EMS system is not nationally regulated in the United States, 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, state, and region.

It is recommended that each EMS system demonstrate proficiency in basic emergency stroke care, including (1) the recognition of patients with acute stroke; (2) their assessment using a validated scale (ie, Los Angeles Prehospital Stroke Screen, Cincinnati Prehospital Stroke Scale); (3) stabilization and treatment of such patients onsite and during transportation; (4) assistance with establishing time of onset; (5) transporting a patient’s medications with them to the hospital; and (6) effective and accurate communications with the receiving facility.

Although rapid EMS transportation may be easily achievable in urban settings, can similar expectations hold for patients with stroke in a rural setting? Prior studies of stroke presentation times have failed to identify living in a rural setting as an independent predictor of a delayed hospital presentation. Numerous studies of transportation practices of trauma patients have been conducted in rural settings, and all have shown that rapid access to EMS is both possible and beneficial. Although we appreciate that the 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. A recent study showed using a “pay-for-performance” system could improve EMS responses to several medical emergencies, including stroke. A geographic information system can also reduce response times.

The PSC staff should support and participate in educational activities involving EMS personnel. Prior studies have shown that such programs can improve response times and patient care. The cooperation between EMS and the PSC should be documented by written protocols for transporting patients with stroke by EMS to the PSC, a letter of cooperation between the PSC and EMS, and evidence of cooperative educational activities at least twice per year.

The issue of whether EMS personnel should take patients with acute stroke only to facilities with a Stroke Center has been addressed in recent guidelines. It is now a Class I, Level B recommendation that patients with acute strokes be transported initially to the nearest facility that can operate as a PSC. This should be the case unless there is another concomitant imminent life-threatening condition (cardiac arrest, severe hypotension) that would necessitate EMS transporting the patient to the nearest appropriate ED. Regional healthcare systems may also assist in directing patients with acute stroke to designated facilities, because this may improve their care and outcome. In areas with laws or regulations that mandate the preferential transportation of patients with acute stroke to the nearest PSC, the EMS care providers should develop and implement such protocols.
within 6 to 9 months of when the law was passed or the regulation was approved (Class 1, Level B).14,23,34

The use of telemedicine and air ambulances may be efficacious for treating and transporting patients in a rural setting remote from a PSC, thus allowing the expertise of the PSC to be “exported” to a remote facility and expediting transfer of the patient to a PSC.60,61 There are numerous reports and growing experience with telemedicine/telestroke being used successfully in many different healthcare settings (mostly hospital to hospital and physician to hospital links) to reduce time delays and increase the use of acute therapies in a timely manner.60,62–74 The ability to use an air ambulance transportation system may vary depending on local factors (ie, ability to land a helicopter). The use of telemedicine as a direct part of EMS transportation (ie, a link in the ambulance) is an emerging area with some technical and logistical challenges. At present, there are insufficient data for the BAC to make a recommendation about the usefulness of these technologies as part of acute EMS care (not care in the ED).74

In some settings, a PSC might use telemedicine within its own facility to deal with acute stroke assessment and treatment for patients in the ED. However, this would not be a substitute for in-house neurological expertise or ongoing care beyond an emergency setting. More extensive use of telemedicine/telestroke and related technologies will be discussed in the Acute Stroke Ready Hospital guidelines as it relates to emergent care in the ED. There are some data to support the use of helicopter transportation/air ambulances in improving the care of patients with acute stroke and reducing transportation times.62,63,75–78

The importance of including EMS in a PSC is supported by a Class I, Level A recommendation. The BAC supports the emergent triage of patients with stroke to the nearest Stroke Center that can provide appropriate care unless there is another life-threatening emergency that would necessitate taking the patient to the closest facility (Class I, Level B; new recommendation). The inclusion of air ambulances is a Class IIa, Level B recommendation (new recommendation). The use of technologies such as telemedicine/telestroke/teleradiology, although more ger- mane to Acute Stroke Ready Hospitals, are useful components for PSCs that may serve as support hospitals for other facilities in need of such support (Class I, Level A; new recommendation).

Emergency Department
The ED is a key part of the PSC, because it is the point of first contact (in most cases) between the patient and the medical facility.79 The ED should have well-established lines of communications with EMS personnel and be able to receive patients with stroke from the EMS system. ED personnel should be trained in the diagnosis and treatment of all types of acute stroke, including the use of intravenous tPA in acute ischemic stroke.80 ED personnel should be familiar with the AST, how it is activated, and its functions.34 It is possible that some ED personnel also will be members of the AST. It is recommended that a door-to-physician assessment time for patients with suspected stroke be no more than 15 minutes.

The ED staff should have written protocols for stroke triage and treatment, including the use of intravenous tPA as well as other acute therapies (ie, management of increased intracranial pressure, blood pressure management, reversal of coagulopathies).70,81,82 Such protocols should also delineate areas of responsibility between ED physicians/staff and other medical staff such as the AST, among others. The ED medical staff should have a clear protocol for monitoring patients with an acute stroke that includes frequent assessment of vital signs and neurological function.27 The use of acute therapies in an ED setting should be supported by other personnel, including but not limited to neurologists, neurosurgeons, radiologists, and others. Proper monitoring protocols for the use of intravenous tPA and other acute therapies should be developed and in place with adequate in-service training of key personnel.55,83

Key ED personnel should participate in educational activities related to stroke diagnosis and treatment at least 2 times per year.9 Written documents that detail the ED operations for managing patients with acute stroke should be provided. Such documentation should include clear statements about how the ED is integrated into the entire Stroke Center along with treatment protocols. A log of patients with stroke and a record of door-to-physician times should be maintained.

The existence of a well-trained and staffed ED is a Class I, Level B recommendation. The specific inclusion of monitoring protocols is seen as an enhancement of the overall ED function and not a separate recommendation.

Stroke Unit
There is abundant evidence from individual studies as well as several new and updated meta-analyses that support the efficacy of Stroke Units in the care of patients with acute stroke. Although the definition of a “Stroke Unit” can vary in different regions of the world, in this setting, we are referring to (typically) a defined group of beds, staff, and protocols that are used for the acute care of patients with a stroke. Compared with general medical wards, patients cared for in Stroke Units had a 17% to 28% reduction in death, a 7% increase in being able to live at home, and an 8% reduction in length of stay.84,85 Recent studies have further affirmed the importance of a Stroke Unit in improving outcomes with a 19% increase in good outcomes and a reduction in mortality.86 PSCs that intend to provide care beyond the very acute period (ie, longer than an ED evaluation) should provide such care in a Stroke Unit setting. Stroke centers that do not intend to provide care beyond that very acute period do not require Stroke Units. An example would be a hospital that treats patients with stroke with intravenous tPA in the ED and then transfers the patients to another facility.

Although Stroke Units do not have to be geographically distinct hospital wards or units, in most settings they are distinct and operate better using this paradigm. In all cases, they should be staffed and directed by personnel (ie, nurses, physicians, speech therapists, physical therapists) with training and expertise in caring for patients with cerebrovascular disease.9 In general, most Stroke Units operate as a “step-down” unit and have nurse-to-patient ratios of approximately 1:3. It is now recommended that a Stroke Unit include...
The importance of such telemetry in detecting important rhythm disturbances and other changes in vital signs that might have significant clinical implications.87–90

Other aspects of a Stroke Unit such as written care protocols are also key components.27 Nurses in the Stroke Unit should have experience and expertise in performing serial neurological assessments using the National Institutes of Health Stroke Scale or a similar validated tool.91 There should be a written protocol that details how changes in a patient’s status are detected, how they are documented, and how medical staff are notified of such changes.92 For example, a standard protocol might include vital signs every 1 to 2 hours for 24 hours after admission and neurological checks (using the National Institutes of Health Stroke Scale or similar assessments) every 2 to 4 hours. These would vary depending on the patient’s clinical status, but some minimum standard should be defined. Notification of the medical staff of any changes or worsening in vital signs and/or neurological status might include a protocol that defines who gets called initially (house officer, advanced practice nurse, attending) and when and how additional personnel are notified as well as expected response times.

In some cases, a Stroke Unit may have the capability to use arterial catheters and administer some vasoactive agents (ie, low-dose dopamine, intravenous nicardipine), although these interventions are typically performed in an intensive care unit (ICU). Stroke Units do not have to include all of the features of an ICU, although there may be some overlap. In some hospitals, the Stroke Unit could be a part of an established ICU. If this is the case, the ICU nurses should receive specific training about the care of patients with stroke (see previous details). The physicians caring for patients with stroke in an ICU should be intensivists and preferably neurointensivists, who can improve overall outcomes.93 However, the vast majority of patients with stroke do not require the services of a typical ICU. The monitoring of stroke patients after treatment with intravenous tPA can be performed in a Stroke Unit or an ICU, depending on the staffing levels, nursing protocols, expertise, and telemetry available in that unit.

For PSCs with a Stroke Unit, documentation should be provided about the staffing and operations of the unit, including admission and discharge criteria, care protocols, patient census, and outcome data. All physicians, physician assistants, advanced practice nurses, and nurses on the Stroke Unit staff who provide direct patient care or supervise such care must receive at least 8 hours per year of medical education (continuing medical education or other types of education) related to cerebrovascular disease. This amount of education is 50% of the 16 hours per year recommended for healthcare professionals at Level I and Level II trauma centers.94 These educational requirements can be met through a variety of means, including lectures, online courses, webcasts, journal continuing medical education activities, etc.

The ability to perform brain and vascular imaging studies on patients with acute stroke is vital for determining an accurate and timely diagnosis. Such studies can also provide information about the vascular abnormality and mechanism that has caused the stroke. PSCs must have the capability to perform a head CT within 25 minutes of the order being written.97 This implies that such capabilities are available on a 24/7 basis. Also, physicians experienced in interpreting such images must be readily available so that the scans can be read within 20 minutes of their completion.97 These physicians may include radiologists (or neuroradiologists) with experience interpreting head CTs as well as neurologists, neurosurgeons, and others with expertise and experience with these techniques. Such availability may be through remote access

Neurosurgical Services
Some patients with acute stroke will require a neurosurgical procedure or evaluation during their illness. Examples of such interventions include insertion of a ventricular drainage catheter, evacuation of a hematoma, and decompressive hemicraniectomy in cases of massive hemispheric infarction.14,82,95 There are compelling data about the improved survival and outcomes seen with decompressive hemicraniectomy in patients with large ischemic strokes and early signs of swelling who undergo early surgery.95,96 However, due to the limited number of neurosurgeons, it is appreciated that many hospitals do not have ready access to a neurosurgeon.

For the purposes of a PSC, it is suggested that neurosurgical care for the patient be available within 2 hours of the time 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.97 This means that either the patient could be transferred to another facility with a neurosurgeon or the neurosurgeon could be on-call and able to see the patient within 2 hours. If the hospital will be providing such care, it must have an operating room staffed on a 24/7 basis with the necessary equipment and support personnel (ie, anesthesiology, radiology, pharmacy) to perform neurosurgical procedures that a patient with stroke might require on an urgent basis. These procedures, which may be life-saving in some circumstances, can typically only be performed by a neurosurgeon. (Treatment of patients with large intracerebral hemorrhages, subarachnoid hemorrhages, and those needing advanced neurovascular surgeries is discussed in more detail in the CSC recommendations.)10

Neurosurgical coverage should be documented in a written plan that is approved by the covering neurosurgeon(s), Stroke Center leaders, and involved facilities. A call schedule should be readily available in the ED and to PSC personnel. In cases in which such patients will be transferred to another facility for neurosurgical care, a written transfer agreement, plan, and protocol should be developed and readily available.

The availability of neurological services is a Class 1, Level A recommendation.

Cerebral and Cerebrovascular Imaging
The ability to perform brain and vascular imaging studies on patients with acute stroke is vital for determining an accurate and timely diagnosis. Such studies can also provide information about the vascular abnormality and mechanism that has caused the stroke. PSCs must have the capability to perform a head CT within 25 minutes of the order being written.97 This implies that such capabilities are available on a 24/7 basis. Also, physicians experienced in interpreting such images must be readily available so that the scans can be read within 20 minutes of their completion.97 These physicians may include radiologists (or neuroradiologists) with experience interpreting head CTs as well as neurologists, neurosurgeons, and others with expertise and experience with these techniques. Such availability may be through remote access
Brain MRI may be performed acutely, in lieu of a head CT, if the same time parameters can be met in the acute setting. Teleradiology links could be to radiologists (or other physicians) at home or to a remote site such as a CSC. Remote viewing sites and services must have the equipment and infrastructure to ensure that the quality of reviewed images meets appropriate standards. There should be written documentation that such scans were performed and read within the specified times and that such scans can be performed on a 24/7 basis. A log book that records such scans with time parameters and interpretation is 1 way to document this capability.

The timely performance of a head CT scan or brain MRI and its rapid interpretation is a Class I, Level A recommendation. The inclusion of MRI is a new recommendation.

It is well established in the literature and in recent guidelines that brain MRI is more sensitive than head CT for detecting small strokes, acute strokes, and many lesions and processes that could produce stroke-like symptoms (ie, demyelinating plaques, small tumors, areas of infection or inflammation). In many cases, the detection of such lesions could change significantly the evaluation and therapy for such patients. MRI is now widely available in the vast majority of US hospitals, particularly those that are currently PSCs. Although an MRI examination may not be needed for every patient with stroke, it should be available at a PSC for those patients who are admitted and might benefit from such testing. MRI does not have to be performed in the hyperacute setting, but if needed (as judged by the treatment team), it should be available at the PSC as part of the evaluation for admitted patients.

Imaging of the extracranial and intracranial vasculature is an important component of the assessment for admitted patients with a stroke. Two widely used techniques are MR angiography (MRA, often performed with contrast enhancement) and CT angiography (CTA, which must be done with contrast). MRA and CTA are capable of detecting abnormalities that can be missed by routine carotid Doppler such as stenotic lesions of the origins of the great vessels, intracranial stenoses, aneurysms, vasculitis, and some dissections. The detection of such lesions might alter patient management for acute care as well as secondary prevention. The inclusion of MRA and/or CTA reflects current standard imaging techniques widely available in the United States and is supported by numerous studies as well as imaging guidelines. They should be available at a PSC, although their performance on a hyperacute basis is not recommended at this time. Like with MRI, these techniques may not be needed or clinically indicated in some patients (ie, patients who have a terminal condition or would not benefit from further evaluation or therapies). These imaging tests (MRI, MRA, CTA) should be performed at a PSC within 6 hours of being ordered and they should be interpreted within 2 hours of test completion (during normal working hours) if they are thought to be needed to determine or guide treatment decisions.

The inclusion of brain MRI for admitted patients (Class I, Level A) and vascular imaging with an MRA or CTA are new recommendations (Class I, Level B). Such imaging is not required for all patients and is not meant to be performed in the hyperacute setting but should be available at a PSC for those patients who might benefit from such testing.

Cardiac Imaging
A significant percentage of ischemic strokes are due to cardioembolic disease. Atrial fibrillation, myocardial infarction, valvular disease, aortic arch plaques, and other disorders are well-recognized etiologies for ischemic strokes. Cardiac imaging using transthoracic echocardiography, transesophageal echocardiography, or cardiac MRI often provides important information about underlying cardiac and aortic pathologies that may provide an etiology for a stroke and provide important information about future therapies. Due to the importance of cardiac imaging, it is recommended that a PSC have at least 1 modality (and preferably both transthoracic echocardiography and transesophageal echocardiography) to image the heart for all admitted patients with stroke. One or more of these imaging modalities are widely available at most acute care hospitals. Adequately trained echocardiography technicians or cardiac MRI technologists as well as physicians to interpret such images are also recommended.

The inclusion of transthoracic echocardiography, transesophageal echocardiography, or cardiac MRI is a new recommendation for a PSC (Class I, Level A for transthoracic echocardiography and transesophageal echocardiography; Class IIb, Level C for cardiac MRI).

Laboratory Services
The efficient diagnosis and treatment of patients with stroke requires the availability of standard laboratory services on a 24/7 basis. These include the ability to rapidly perform and report complete blood counts, blood chemistries, coagulation studies, and a pregnancy test (as appropriate). Also, a PSC should be able to rapidly complete an electrocardiogram and chest x-ray. This is based on the high prevalence of cardiac disease in a typical stroke population as well as the high risk of lung and thoracic disease in these patients. It is recommended that the studies cited be completed within 45 minutes of being ordered.

Guidelines from the Centers for Disease Control and Prevention recommend that an HIV test be performed on most adults admitted to the hospital. We support HIV testing in accordance with the Centers for Disease Control and Prevention guidelines based on the high prevalence of HIV, its importance as a public health matter, and the relationship between HIV and cerebrovascular disease. A blood or urine test for drug toxicology is also suggested based on the high prevalence of drug abuse and the association between illicit drug use and stroke. A letter of support from the laboratory director(s) should be provided along with written documentation that the testing noted can be completed within the recommended time period.

The performance of laboratory tests in a timely fashion is a Class I, Level A recommendation. The addition of an electrocardiogram, chest x-ray, HIV, pregnancy test, and drug toxicology test are new since the original publication.
for HIV; Class IIa, level C for drug toxicology, chest x-ray, and pregnancy test).

Rehabilitation Services
The initiation of rehabilitation activities such as speech therapy, physical therapy, and occupational therapy can improve poststroke recovery and overall functional outcomes.\(^1\) The Joint Commission has now included rehabilitation consideration as a disease performance measure for PSCs. Various elements of rehabilitation are supported by recent guidelines, but the strength of the supporting evidence varies based on the type of rehabilitation service (ie, speech, physical therapy, occupational therapy).\(^1\) For patients admitted to a PSC, the early assessment of rehabilitation needs and initiation of rehabilitation therapy such as basic speech therapy and physical therapy/occupational therapy should be readily available for patients in need of such services. It is recognized that many PSCs may not have extensive inpatient rehabilitation services onsite nor is this the intended purpose of our recommendation. However, an assessment for rehabilitation potential and the early initiation of basic rehabilitation activities should be part of a PSC that admits patients with acute stroke.

The recommendation for rehabilitation assessment and early initiation of basic rehabilitation services is supported by multiple studies with different classes of evidence depending on the specific aspect of rehabilitation that is being considered.\(^1\) In general, most of the elements are supported by Class I to Class IIa, Level B to C evidence depending on the specific service (see previously). This is a new recommendation.

Support and Administrative Services
Commitment and Support of the Medical Organization
The delivery of high-quality and efficient care to patients with acute stroke is highly dependent on the degree of commitment of the facility, its administration, and personnel. Without such commitment, it is unlikely that the necessary training, organization, infrastructure, and funding will be available. Also, a PSC should have a designated director who has training and expertise in cerebrovascular disease. The director does not have to be a neurologist or neurosurgeon but should have sufficient knowledge of cerebrovascular disease to provide administrative leadership and clinical guidance and input to the program. Examples of such knowledge might include \(\geq 2\) of the following: (1) completion of a vascular neurology fellowship or board certification in vascular neurology; (2) participation (as an attendee or faculty) in at least 2 regional, national, or international stroke courses or conferences in the past 2 years; (3) \(\geq 5\) peer-reviewed publications in the area of clinical cerebrovascular disease; (4) \(\geq 8\) continuing medical education credits (or equivalent educational extension) each year in the area of cerebrovascular disease; and (5) other criteria agreed on by local physicians and hospital administrators. Other physician staffing for a PSC should include staff with some training and expertise in cerebrovascular disease. Evidence of such training could include \(\geq 1\) of the criteria cited above.

The importance of having neurological expertise in caring for patients with stroke is supported by several studies. For example, a study of \(\geq 38,000\) Medicare patients with strokes found that patients cared for by a neurologist had a 90-day mortality rate of 16% compared with 23% for internists and 25% for family practitioners.\(^1\) Hospitals with neurologists or vascular neurologists had a \(\geq 50\)% reduction in mortality in a study of patients with ischemic strokes admitted to academic medical centers and Veterans Affairs hospitals.\(^3\) Similar findings were found for Stroke Units staffed by physicians and staff with neurological expertise.\(^4\) These differences were statistically significant after controlling for differences in illness severity and other comorbid conditions.

Administrative support for a PSC might be enhanced if the center is shown to improve patient outcomes and be cost-effective. Several key elements of Stroke Centers have been shown to be cost-effective. These include 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.\(^5,6\) Patients at a PSC will have fewer peristroke complications and a reduced length of stay.\(^7,8\) A recent study from Finland found that patients cared for at a PSC had reduced mortality and improved outcomes when compared with patients at a general hospital.\(^9\)

Based on these data, it is anticipated that many hospitals would benefit from becoming a PSC, particularly if they admit several hundred patients with stroke each year. However, even smaller hospitals can become PSCs and perhaps achieve improved patient outcomes.\(^10\) Becoming a PSC might increase hospital admissions and increase stroke volumes, thereby improving the efficiency of overall care.\(^11\) Hospitals with an active cardiac program might consider becoming a PSC, because both diseases often coexist and share risk factors.

The issue of “call pay” for taking stroke call is one of growing importance in the United States. In some cases neurologists, neurosurgeons, and others are receiving extra compensation to take stroke call, which includes being available (during nights and weekends) by telephone for emergency consultation and being willing to come to the hospital to direct therapy in urgent situations. Such call pay might range from \(\geq 500\) for a 24-hour period and up to \(\$1500\) for weekend or holiday coverage (based on an informal survey of neurologists in various care settings throughout the United States).

In some areas of the United States, neurologists are reluctant to leave their office-based practices to care for hospitalized patients. To address this issue, hospitals are employing neurohospitalists to provide coverage for hospitalized patients with various types of neurological conditions, including acute stroke.\(^12\) Neurohospitalists are typically neurologists who specialize in the care of in-hospital patients with a variety of neurological conditions (including stroke) and provide neurology consultations to other admitted patients.

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.
Budgetary support for the PSC medical director, other key personnel, and call pay would also be evidence of administrative support. The curriculum vitae of key personnel should be provided to demonstrate their training and expertise in cerebrovascular disease.

Anecdotal data suggest that administrative support is a key factor in establishing and operating a PSC. Medical staff with neurological expertise improves outcomes and is an important element of a PSC (Class I, Level B). Having a PSC director with training and expertise in the area of cerebrovascular disease is also a key element for a PSC (Class IIa, Level C). The concepts of call pay and neurohospitalists are new and require further data before formal recommendations can be made.

Outcomes and Quality Improvement
Stroke Centers should have a database or registry for tracking the number and type of patients with stroke seen, their treatments, timelines for receiving treatments, and some measurement of their outcomes. The inclusion of such resources is a key component and mission of a PSC and public health. The concepts of call pay and neurohospitalists are new and require further data before formal recommendations can be made.

The PSC should select at least 2 relevant patient-care parameters for benchmarking each year. Prespecified committees should meet, review, and alter practice patterns (if needed) at least 2 times per year. Documentation should be provided about specific benchmarks, quality improvement areas, and minutes from at least biannual meetings of the appropriate committee(s).

The inclusion of a stroke registry, database, or similar monitoring program such as Get With the Guidelines–Stroke and Paul Coverdell National Acute Stroke Registry for quality improvement was not specifically addressed in the initial publication but in most cases is a key component for several types of quality improvement programs and is often used for PSC certification by TJC and other bodies. The inclusion of such resources is a new Class I, Level A recommendation. The inclusion of 2 relevant quality improvement projects is a new Class I, Level A recommendation.

Educational Programs
Due to the rapidly changing field of medicine, particularly as it relates to cerebrovascular disease, it is recommended that the professional staff of the Stroke Center receive at least 8 hours/year of educational credit (or an equivalent amount of nursing and allied health educational credits) in areas related to cerebrovascular disease. This is less than is recommended for trauma centers, but the BAC believes this is appropriate considering the scope of cerebrovascular disease. Prior studies have shown the importance of such educational activities for improving the care of patients with stroke. This will provide one mechanism to ensure that the Stroke Center staff is aware of new knowledge in this area.

There has been some confusion about which professional staff are required to meet the educational goals outlined above. The BAC recommends that all physicians, nurses, and advanced practice nurses involved in direct care of patients with stroke meet the educational goals. Although it would be optimal if all nurses and therapists also met these goals, we realize that this might not be feasible or practical in many cases because staffs rotate among many different patient populations. We also recommend that nurses in leadership roles (ie, nurse managers, head nurses, charge nurses) as well as program directors for allied health services attain the educational goals cited here. It is also suggested that the PSC staff engage in professional education of their peers and colleagues in an effort to raise the overall knowledge about the care of patients with stroke.

In addition to professional education, the PSC should have at least 2 annual programs to educate the public about stroke prevention, diagnosis, and/or the availability of acute therapies. Past studies have shown that much of the population lacks basic information about stroke, its risk factors, and treatments. Various public education programs have shown a positive effect in improving stroke recognition and reducing time delays of presentation. Although 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 mission of a PSC and public health policy.

Documentation of educational programs can be done by monitoring educational credit and attendance for the professional staff. The date, title, speaker, and duration of each talk should be recorded and filed. Evaluation questionnaires for the public educational programs should be reviewed and saved to document such programs. The estimated annual costs for such educational activities for the staff might be $5000 to $10 000 depending on the size of the program and the number of staff who participate. The costs for public educational programs might range from $2500 to $5000 per program depending on its size, content, and complexity.

The requirement for professional and public education has not changed from the original publication (Class I, Level B).

Stroke Center Certification
The original PSC recommendations did not address the issue of certification because it was unclear in 2000 if any group or
organization would certify PSCs nor was it clear if any hospitals would opt for a certification program. During the past 10 years, several groups have begun successful programs to certify PSCs; these include TJC, Healthcare Facilities Accreditation Program, and various state health departments and other organizations. The BAC strongly supports and endorses such certification programs as a means to (1) independently verify the components, protocols, level of care, and outcomes of a PSC; (2) provide patients and the public with assurances that a PSC provides the intended quality of care on an ongoing basis; and (3) ensure proper recognition of such facilities.8,11,15

Any PSC certification program should fulfill several criteria to ensure the accuracy and rigor of such programs; these include (1) the certifying body should be administratively and financially independent of the hospital; (2) the program should include an assessment of infrastructure, personnel, protocols, and programs; (3) a site visit should be performed at least every 2 years; and (4) well-defined and quantifiable disease performance measures should be developed and assessed on a regular basis.15 Self-certification programs are discouraged based on prior studies showing that such efforts often produce unreliable results.149

The inclusion of specific recommendations for certification is new and is supported by Class I, Level B evidence.

Acute Stroke Ready Hospitals

In some states and regions, there has been a recent effort to define another level of Stroke Center, often referred to as “acute stroke-capable” or an “acute stroke-ready” facility. Such hospitals do not meet the definition of a PSC. The purpose would be to define a group of facilities that provide more complete acute stroke care than other surrounding hospitals and to help EMS route such patients in rural areas with significant distances between hospitals and with no nearby PSCs. The BAC supports any effort to provide improved care to patients with an acute stroke. However, the lack of data about the function of such facilities, outcomes, and how they would operate in a stroke system of care makes us cautious about making a recommendation until more data are available. We urge any such programs to collect performance and outcomes data on the “stroke-ready” hospitals. The BAC is developing formal criteria for such “acute stroke-ready” hospitals.

The possible designation of an “acute stroke-ready” hospital is a potentially important addition to a Stroke System of Care and might be a viable alternative in some areas of the country. However, the lack of data about the function, outcomes, and certification of such facilities precludes us from making any recommendations at this time.

Discussion

Since our original publication of recommendations for PSCs, the concept of using the Stroke Centers to improve care has been validated by several studies showing improved outcomes as well as surveys and expert opinion from stroke leaders throughout the world.129,150–152 There are now >800 PSCs certified by TJC and several hundred more recognized by other organizations in the United States (www.jointcommission.org). Other nations have also adopted and promoted the Stroke Center concept.6 Preferential triage of patients with acute stroke occurs routinely in some major metropolitan areas and a growing number of cities and states. Protocols for the care of patients with an acute stroke combined with well-formulated disease performance measures are now commonplace in many hospitals, even if they are not a formally designated Stroke Center.152,153 All of these developments have improved the overall care for these patients with stroke throughout the United States and in many other countries.

As we have gained experience with organized stroke care, medical science has developed new tools to better diagnose and treat stroke. Some have been included in these revised guidelines to ensure that all patients cared for at a PSC receive optimal care. From all available data, it is clear that better imaging of the brain, cerebral vasculature, and the heart will lead to a better understanding of stroke etiology, mechanism, acute care, and secondary prevention. For example, a patient with an MRI that shows a shower of small infarcts in multiple vascular territories might lead to a search for a source of cardiac embolism, a central nervous system vasculitis, or a hypercoagulable state. These entities might require different therapies compared with an isolated ischemic stroke presumed to be caused by small-vessel atherosclerosis.

The addition of MRI and either MRA or CTA might incur additional costs for some hospitals. However, the vast majority of US hospitals have head CT and brain MRI readily available, and the addition of MRA or CTA accrues only modest additional costs for equipment and software. Therefore, almost all hospitals that are currently PSCs or might desire to become a PSC should not incur significant additional capital expenses due to these recommendations. There might be modest additional costs related to technical support, staffing, and training. These costs might be partially offset by changing billing practices.

Physician staffing at a PSC, particularly neurologists and neurosurgeons willing to take emergency call, has often been mentioned as a challenge for some hospitals and in some areas of the country. The use of call-pay and neurohospitalists are 2 important trends that may address some of these issues.154 It will be important for hospital systems and national organizations to monitor these trends to see if coverage and response times improve. As healthcare reform is implemented, it will be interesting to track hospital and physician reimbursement and correlate such changes with specific patient outcomes and PSC performance measures.

As the number of PSCs has increased, some have asked if overall outcomes are improved. Doing rigorous pre- and postcomparisons is problematic now because some non-PSC facilities may have adopted protocols that improve patient outcomes and reduce peristroke complications (eg, dysphagia screening, deep vein thrombosis prophylaxis). Available published data have shown that care at a PSC does positively affect several key measures of stroke care such as the use of intravenous tPA, a decline in tPA protocol violations, reduced time delays in emergent evaluation, and an increase in the number of patients admitted to a Stroke Unit.27,127 Data from quality improvement programs such as Get With the Guidelines have also shown that a PSC is associated with improved
compliance with and achievement of many disease performance measures.  

A large national study from Finland has shown that patients cared for at a PSC or CSC have reduced mortality and improved outcomes.  

A similar study in New York state also found significantly reduced mortality for patients cared for in a PSC compared with a non-PSC facility. This effect was specific for stroke care, because outcomes for gastrointestinal hemorrhage and myocardial infarction were not improved. Thus, there are convincing data from many parts of the world that a PSC does improve a number of patient outcomes.

Several recent studies have shown that patient volume is an important factor in stroke outcomes in that hospitals with more patients with stroke tend to have improved outcomes, particularly stroke mortality, even if they are not Stroke Centers. Other studies cited have clearly shown that designated PSCs have improved outcomes also. These data support the concept of having patients with acute stroke concentrated at larger facilities with higher numbers of patients with stroke. However, there are some cases of smaller hospitals achieving PSC status and having excellent outcomes. The local and regional distribution of hospitals and patients are key factors in making these decisions.

The issue of PSC certification has always been a challenge due to diverse opinions and options for certification programs. TJC launched a PSC certification program in 2004 that includes several important components such as a review of the PSC staff, facilities, processes of care, and disease performance measures. These are accomplished by data analysis as well as a 1-day site visit every other year. Some states use government entities such as health departments to conduct a similar type of review and certification process. In some cases, a hospital can ‘attest’ to meeting the criteria for being a PSC, although an external independent review and site visit are not mandated. Prior studies have shown that an independent external review is more rigorous and accurate than self-certification; hence, the BAC strongly endorses such independent certification programs.

As has been noted in other publications, a PSC is one component of a large stroke system of care. Such systems include EMS, local/regional governments and agencies, PSCs, CSCs, and other healthcare facilities. All resources should be integrated and communicate at a citywide or regional level to ensure the most efficient care for patients with all types of stroke. Newer technologies such as telemedicine, teleradiology, telestroke, and robotic care should be used as appropriate to build a functional network of care for all patients with an acute stroke. The staff and expertise at a PSC should serve as a resource to other facilities and healthcare providers for acute and ongoing care of patients with cerebrovascular disease.

Clinical research studies involving patients with acute stroke have often experienced very slow rates of patient enrollment due to a variety of reasons. The current network of >800 PSCs provides an excellent resource for such clinical trials, because these facilities will have the personnel, infrastructure, protocols, and expertise to efficiently identify, enroll, and treat patients with acute stroke.

In summary, the BAC has updated and modified our recommendations for the formation and operation of PSCs based on the past 10 years of experience and advances in medical care and technology. We anticipate the updated disease performance measures that mirror these recommendations will result in improved care for patients at a PSC. It is anticipated that if hospitals adopt and follow these recommendations, patients will achieve more accurate diagnoses, more timely therapies, and improved overall outcomes. Updated PSCs will be an important addition in any stroke system of care.

Appendix

The Brain Attack Coalition includes representatives from the following organizations. The authors listed have reviewed the content of the article and approved its publication (exceptions noted with an asterisk): National Institute of Neurological Disorders and Stroke, Michael D. Walker, MD (BAC Chair), Marian Emr, Margo Warren; American Academy of Neurology, Lawerence R. Wechsler, MD; American Association of Neurological Surgeons, E. Sander Connelly, Jr, MD; American Association of Neuroscience Nurses, Barbara Mancini, RN; American College of Emergency Physicians, Andy Jagoda, MD; American Society of Neuroradiology, Richard E. Latchaw, MD; American Stroke Association, Stephen Prudhomme; Centers for Disease Control and Prevention, Mary G. George, MD; MSHSP; Congress of Neurological Surgeons, LTC Rocco A. Armonda, MD; Department of Veterans Affairs, Robert Ruff, MD; National Association of Chronic Disease Directors, Kathy Foell, MS, RD; National Association of EMS Physicians, Todd J. Crocco, MD; National Association of State EMS Officials, Robert R. Bass, MD; National Stroke Association, James Baranski; Neurocritical Care Society, Daryl R. Gress, MD; Society of NeuroInterventional Surgery, Mary E. (Lee) Jensen, MD; and Stroke Belt Consortium, Mark J. Alberts, MD. *This manuscript represents the opinion of the authors and may not necessarily represent the official position of the American College of Emergency Physicians, the Centers for Disease Control and Prevention, and the National Institute of Neurological Disorders and Stroke.

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Disclosures

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Establishment of Primary Stroke Centers

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Revised and Updated Recommendations for the Establishment of Primary Stroke Centers: A Summary Statement From the Brain Attack Coalition

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