Endovascular comprehensive stroke center designation parameters

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The approval of IV tissue plasminogen activator (IV tPA),¹ the first stroke revascularization therapy, limiting ischemia in progress, led to the establishment of criteria to define primary stroke centers (PSCs),² capable of delivering this treatment. Corollary to PSC designation, the establishment of stroke units, comprising nursing and physician personnel trained in the care of stroke patients, improves outcome for stroke patients.^{3–7} The market approval of various novel devices aimed at removing thrombus from occluded blood vessels in the setting of acute ischemic stroke (AIS)^{8,9} and the recognition of these as a potential treatment option for certain patients has helped spur the development of recommendations and metric standards for comprehensive stroke centers (CSCs) by the Brain Attack Coalition (BAC), and endorsement by the Society of Vascular and Interventional Neurology (SVIN).^{10,11} Additionally, the evolution of the neurocritical care discipline over the past 2 decades, with specialized care for AIS and hemorrhagic stroke, including subarachnoid and intracranial hemorrhage, is considered as an optional component in the proposed metrics criteria for CSCs (table).

Many proposed components of CSCs include infrastructure also necessary for PSC function: “acute stroke teams, written care protocols ... [and an] integrated emergency response system.” In addition, basic services required for care of stroke patients remain core requirements for both PSCs and CSCs: “availability and interpretation of CT scans 24 hours ... and rapid laboratory testing, administrative support, strong leadership, and continuing education.”¹² Beyond these elements, CSCs may be further distinguished by the availability of “vascular neurosurgery and neurology; advanced neuroimaging capabilities such as MRI and various types of cerebral angiography; surgical and endovascular techniques, including clipping and coiling of intracranial aneurysms, carotid endarterectomy, and intra-arterial thrombolytic therapy.”¹⁰ Optional components for CSCs include

neuroscience intensive care units (neuro-ICUs), perfusion imaging techniques, and other (laboratory and research) personnel.

The designation of PSCs creates an infrastructure for the improved delivery of hyperacute therapy. In addition, it aids emergency medical services (EMS) in identifying appropriate acute stroke facilities for patient transport and improves dialogue and collaborations between EMS and hospitals. PSC-designated facilities must also hold at least biannual community education events, thereby having direct public impact.² Quality review processes to assess ongoing performance, also required for designated CSCs, further enhance centers’ ability to continually reassess their delivery of stroke care at a high standard. Success of the system is manifested in increased rates of IV tPA utilization in the United States; for example, in Michigan the rate increased by 50% (to 4.6%, from 3%),¹² and in New York the rate doubled (to 5.2%, from 2.4%)¹³ after the certification process began for PSCs. Also, 33% of patients were evaluated by a stroke or rapid response team at certified centers, vs 0.4% at noncertified centers.¹² Furthermore, whereas many stroke treatments have failed to demonstrate improvements in mortality rates,¹ care of patients in stroke centers has.¹⁴

Ideally, the formation of CSCs would have the same effect on the delivery of endovascular recanalization therapy (ERT), by improving institutional support for endovascular services and aiding implementation of a systems-based approach to stroke care with regional transport protocols.

There are important practical issues involved in patient transport to CSCs, and these create considerable debate among stakeholders in the CSC certification process. These issues may relate to loss of reimbursement and revenues for hospitals that may be capable of providing PSC level care but not ERT. More important, the greater distance between the patient’s origin and final hospital increases the time to arrival at the tertiary stroke hospital, which could de-

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Table Primary vs comprehensive stroke center requirements^a and optional elements

Element	PSC	CSC
Neurologic availability	Optional	Required
Neurosurgical availability	Required ^b	Required
Vascular surgery	ND	Required
Stroke team	Required	Required
Neurointerventional capabilities	ND	Required
Advanced practice nurse	ND	Required
Written care protocols	Required	Required
Emergency department	Required	ND
Intensive care unit		
Stroke unit	Optional ^c	Required
Neurocritical care unit	Optional	Optional
Neuroimaging ^d	Required	Required
Perfusion imaging	ND	Optional
Rehabilitation therapy	ND	Required
Speech/swallow assessment	ND	Required

Abbreviations: CSC = comprehensive stroke center; ND = not discussed in recommendations for PSCs or CSCs; PSC = primary stroke center.

^a Some requirements of PSCs and CSCs, as proposed by Alberts et al.^{2,10} (see text also).

^b On-site neurosurgical service not required, but neurosurgical services should be available to patients within 2 hours either on-site or by transfer to another hospital.

^c Required only for those hospitals providing ongoing stroke care after initial emergency department treatment.

^d Cranial CT or MRI available within 25 minutes for acute stroke patients, 24 hours/day.

lay the initiation of therapy. This expends sometimes limited EMS resources and also places burdens on families who must accompany patients to distant hospitals for extended periods of time. Currently, there is Class I, Level B evidence for consideration of endovascular treatment for ruptured intracranial aneurysms and intra-arterial thrombolysis for select patients.^{15,16} Additional studies would likely increase the acceptance of ERT for AIS. Although there is understanding among the neurovascular and neurointerventional community that additional data on ERT are needed, even IV tPA, the current standard of care, has not demonstrated lower mortality, an important outcome.¹ Despite limited data for ERT in AIS, IV tPA may be less effective in recanalizing large artery occlusion (LAO).^{17,18} Furthermore, even though designation of PSCs has helped increase utilization of IV tPA, its administration is still limited to a minority of the population,^{12,13} thus limiting its overall impact on stroke morbidity. ERT may potentially have additional effect on this. In patients with suspected LAO transferred for ERT, delays in transfer reduce the number of patients ultimately offered catheter-based intervention.¹⁹

Other optional proposed CSC components may be difficult to achieve for even tertiary centers. The nationwide shortage of neurointensivists, who may have a positive impact on discharge disposition and outcome of critically ill patients with ischemic stroke,^{20,21} is demonstrated by the fact that many hospitals lack dedicated neuro-ICUs (which have been linked to higher rates of aneurysm-specific treatment and discharge to home among subarachnoid hemorrhage patients²²), though they are fully capable of providing round-the-clock endovascular ischemic or hemorrhagic stroke treatment. This may create a need for additional interfacility arrangements such as “drip-and-ship” or “clip-and-ship” to a hospital where a dedicated neuro-ICU, certified neurointensivists, certified vascular neurologists, and neurosurgeons are available. And just as delayed transfer of patients with stroke negatively impacts possible endovascular treatment, stays in emergency departments for longer than 5 hours for neuro-ICU-bound patients have been linked to poor outcome in retrospective studies.²³

Various stakeholders directly or indirectly further the advancement of stroke center designation. Professional societies, as mentioned above, evaluate the data and literature and provide guidelines for stroke centers. Industries that manufacture medications and devices used in the treatment of patients with stroke often partner with hospitals, physicians, scientists, and granting agencies to provide community education and support registries to collect data on treatments for stroke.^{24–27} Ultimately, the judicious evaluation of such data must be performed by non-partisan experts within the context of randomized clinical trials, with operator-independent adjudication of outcome measures. Professional organizations, such as SVIN, the American Academy of Neurology, and American Heart/American Stroke Association, must partner with the NIH/National Institute for Neurological Disorders and Stroke, private industry, and the US Food and Drug Administration to rigorously evaluate new therapies.

If future studies establish firm benefit of ERT for patients with AIS, then the implementation of CSCs will be indispensable to optimize its use in acute stroke management. The CSC certification process would aid EMS in the identification of facilities capable of performing ERT, as well as aid neurologists, emergency physicians, primary care physicians, and the community at large in identifying comprehensive stroke centers of excellence. Emergency medical services will then be charged with the task of transporting stroke victims to the most appropriate nearest facility. Additionally, CSCs should help shape and organize regional approaches to the transport of patients with acute stroke. Streamlined hospital-to-hospital transfer protocols should be developed and

continually refined to minimize delays. When patients arrive at a CSC, treatment protocols and algorithms can make acute stroke care expedient, with increased quality of services provided. Complete or limited telestroke consultation, with online access to imaging studies, electrocardiographs, and laboratory studies from the referring hospital, can help the stroke and endovascular teams at the recipient hospital assess baseline neuroimaging studies and become more efficient in their evaluation of the patient.

The development of CSC certification represents a powerful opportunity to increase the availability of ERT for patients with acute stroke and create expeditious arrangements between hospitals to facilitate sharing of limited resources, to the benefit of the public. The process will raise important policy and monetary issues. The initial metric paper of the BAC provides a framework for CSCs. However, greater and more detailed standards, such as “times to groin,” for ERT, analogous to “times to needle” for IV tPA, must be established (see companion article in this supplement, p. S243).

The collective societies representing vascular neurologists, neurointensivists, neurointerventionalists, and neurosurgeons must be ready to actively engage in these important discussions.

AUTHOR CONTRIBUTIONS

Dr. Janjua: drafting/revising the manuscript, study concept or design. Dr. Katzan: drafting/revising the manuscript. Dr. Badruddin: drafting/revising the manuscript. Dr. Nguyen: drafting/revising the manuscript. Dr. Abou-Chebl: drafting/revising the manuscript. Dr. Zaidat: drafting/revising the manuscript, study concept or design, analysis or interpretation of data, study supervision.

DISCLOSURE

Dr. Janjua was reimbursed for airfare and hotel expense to attend the roundtable SVIN Summit and performs intra-arterial stroke procedures. Dr. Katzan has served as a consultant for Genentech, Inc., for the development of an EMS education tool for acute stroke, receives research support from Ohio Department of Health, and is lead physician for the Ohio Paul Coverdell Stroke Registry. Dr. Badruddin reports no disclosures. Dr. Nguyen has served as an Associate Editor of *Frontiers of Vascular and Interventional Neurology* and Editor of *SVIN Newsletter*. Dr. Nguyen performs intra-arterial stroke procedures. Dr. Abou-Chebl serves on the advisory boards for Focal Cool Inc. and Arterain Medical Inc.; has served on the editorial advisory board for *Stroke* and *Frontiers in Neurology*; served on the speakers bureau for BMS/Sanofi Partnership; performs cerebral angiography and intra-arterial thrombolysis procedures; and holds stock options in Focal Cool Inc. and Arterain Medical Inc. Dr. Zaidat serves on the scientific advisory board for Talecris; served on the adjudication committee for Stryker; received speaker honoraria from Stryker; served on the editorial board of *Frontiers in Neurology* (Endovascular & Interventional Neurology Section); serves as Editor of *The Journal of Neurointerventional Surgery*; and serves as Associate Editor and is a member of the editorial board of *Journal of Stroke & Cerebrovascular Diseases*; served as a consultant for Stryker Neurovascular–Commercial, Codman Neurovascular–Commercial, and Microvention Inc.–Commercial; and has received research support from a Society of Vascular & Interventional Neurology (SVIN) grant for this educational activity. **Go to Neurology.org for full disclosures.**

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