

Stroke patients can't ask for a second opinion: a multi-specialty response to The Joint Commission's recent suspension of individual stroke surgeon training and volume standards

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If you were considering surgery on your brain to stave off a devastating stroke, you might ask about the training of the surgeon. You might ask how many times they had done the procedure. Unfortunately, patients with emergent large vessel occlusion strokes (ELVO) often cannot ask these important questions. Even if they could, they lack the time to consider their options. They depend on the healthcare system to bring them to a surgeon who gives them the best chance.

On September 17 2018, The Joint Commission (TJC) announced the suspension of individual physician training and volume requirements for acute ischemic stroke thrombectomy at hospitals certified as Comprehensive Stroke Centers (CSC) and Thrombectomy-Capable Stroke Centers (TCC). TJC decided to remove

its previously established requirement for both an individual thrombectomy volume minimum and for physician-specific certification to perform acute stroke thrombectomy. These requirements were established based on multiple discussions of TJC's own technical advisory panel (TAP). No discussion was held with the TAP before the suspension of training and volume requirements for individual physicians.

WHY HAVE INDIVIDUAL REQUIREMENTS?

Initial evidence to support these requirements can be found in the multi-specialty recommendations for training by the Committee for Advanced Subspecialty Training (CAST).¹ These recommendations emphasize the importance of training and experience for achieving optimal outcomes. As essential elements, the CAST recommendations include: cognitive training in the clinical neurosciences; critical procedural neuroendovascular training; and annual performance of a minimum of thrombectomies and other neuroendovascular procedures. These recommendations are based on a large body of evidence published in peer-reviewed literature consistently demonstrating that standards of training and case volumes for both physician operators and treating medical centers significantly influence procedural outcomes and should be requirements to ensure high-quality care for patients.²⁻⁶ The physician volume requirement is further supported by the same 2016 Centers for Medicare and Medicaid Services (CMS) Physician Supplier and Provider Services (PSPS) files and Provider Utilization File (PUF) cited by TJC in their suspension of volume requirement justification. The cited median volume of 15 thrombectomies

for the physician cohort with >10 thrombectomies does not take into account that Medicare represented only 59% of thrombectomy patients.⁷ Simply adjusting for this differential raises the median to 25 thrombectomies. Additionally, the cited data do not account for the 30% increase in CMS thrombectomy claims from 2016 to 2017 (2016=5905 versus 2017=7649). This would suggest the median total volume for those same physicians would approximate to 35 in 2017. While 2018 data are not yet available, it is hard to imagine that these thrombectomy numbers have declined. By suspending physician training and volume requirements, TJC has adopted a position that lacks evidentiary foundation and is detrimental to patients.

THROMBECTOMY IS EFFECTIVE... WHEN PERFORMED BY HIGH-VOLUME PHYSICIANS WHO HAVE UNDERGONE ADVANCED SUBSPECIALTY TRAINING

Level 1A evidence gathered from 10 randomized, controlled clinical stroke trials has unequivocally proven thrombectomy superior to medical management for acute ischemic stroke secondary to large vessel occlusion.⁸⁻¹⁷ It is essential to realize that these studies required experienced neuroendovascular physicians with established neurovascular clinical expertise. Translation of the beneficial outcomes from such trials into community practice without specialized physicians cannot be assumed. The importance of specialty expertise and volume was so important to these trials that, shortly after the trials' publications, many of the principal investigators came together in 2015 to write an editorial emphasizing this critical aspect of their studies.¹⁸ In this editorial, the authors emphasized, 'These data strongly suggest that high-volume centers that frequently treat stroke patients achieve better outcomes than low-volume hospitals that care for stroke patients infrequently. The recently published trials all enrolled the vast majority of their patients at such centers. As a result, it is reasonable to assume that similar outcomes may not be obtained from lower volume, less specialized hospitals.' They further state that, 'neurointerventionalists with appropriate expertise... are... critical components' to thrombectomy care, and that 'inexperienced or low-volume stroke hospitals will potentially jeopardize patient care and could lead to worse outcomes.' These authors, many of whom ran the definitive trials providing evidence for thrombectomy, then concluded, 'To ensure attainment of trial results in actual

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practice, patients should receive treatment at facilities certified as having the resources, personnel, organization, and continuous quality improvement processes characteristic of trial centers.' The concept that low-volume, non-credentialed practitioners can suffice to garner TCC or CSC certification is as unrealistic now as it was in 2015.

The assumption that the benefit of acute stroke thrombectomy performed by expert physicians persists for physicians who lack neuroscience, cognitive, and procedural training, or who are operating with low case volumes is flawed. Furthermore, this assumption is not substantiated by published evidence and, if applied for certification or credentialing purposes, almost certainly will result in substandard patient outcomes.

THE CRISIS FOR STROKE PATIENTS

Due to the critically time-sensitive nature of reperfusion therapy for cerebral ischemia, ELVO patients are some of the *most vulnerable* patients in existence. They are in immediate jeopardy of death or disability if they do not receive prompt and appropriate intervention by an expert physician practicing at a properly equipped institution. They are at the mercy of where the pre-hospital system of care delivers them. They have no time to seek a second opinion. They have little or no ability to choose the hospital or doctor who cares for them. They are absolutely reliant on the system to function properly so that they are delivered to a hospital that can give them the best chance for survival and recovery. This includes, depending on certain circumstances, preferential transport directly to an endovascular center. In fact, an analysis of data from 984 patients enrolled in the Systematic Evaluation of Patients Treated with Stroke Devices for Acute Ischemic Stroke (STRATIS) Registry showed that development of an appropriate triage model with a 20-mile radius for direct to endovascular center care would delay IV tPA administration by only an average of 7 min, but would improve thrombectomy delivery by 94 min.¹⁹ This has been demonstrated in multiple other studies, both within and outside the United States.²⁰ Stroke patients would likely be better served if stroke systems aligned more closely with the trauma model, designating regionalized centers of excellence, as was well reviewed in a recent paper in the journal *Stroke*.²¹ Stroke patients need maximized center expertise and efficiency, not a proliferation of low-volume centers that lack adequate expertise.

Unfortunately, the widely recognized need to ensure patients have timely access to thrombectomy has spurred an explosion of hospitals claiming to offer such care. However, anecdotal reports suggest that many centers are not equipped or staffed to handle the complexity of care ELVO patients require. There is no better evidence for this than TJC's own statement that "One (anonymous) healthcare system said they had no physician in their system that met the training requirement... Analyses conducted by the healthcare system mentioned previously showed that only three of the eight interventional radiologists in their system were at or near this [15 annual case volume] benchmark."²² This unknown health system continues to maintain an eight-person call pool for thrombectomy, despite not a single physician having undergone specialized training and no more than one or two of the physicians meeting the reasonable proposed minimum. Rather than this being a justification to lower standards, this statement should be a wake-up call.

We recognize that these requirements create an inherent challenge for hospital systems. Stroke is seen as a 'growth industry' and there may be natural pressure for a given hospital to retain these patients. Certainly, we do not mean to suggest nefarious intentions. Rather, we highlight that there are inherent potential biases that must be consciously acknowledged. Once this potential bias is acknowledged, TJC decision to lower standards becomes an even more concerning event.

Currently, across most of the United States, there is no way to ensure that inappropriately staffed hospitals do not declare themselves a 'thrombectomy center'. This is particularly troubling when hospitals offering substandard thrombectomy services are located in geographic proximity to centers that have the proper neuroendovascular specialists to provide high-quality care. Our current system essentially ensures that, without appropriate standards, stroke patients will be hurt by a proliferation of poor quality 'thrombectomy centers'.

THE NEED FOR EVIDENCE-BASED CERTIFICATION

An evidence-driven certification process represents stroke patients' best hope. It should be designed to protect them from inherent political or financial considerations that may otherwise affect delivery of ELVO patients to suboptimal facilities. In the absence of appropriate certification pathways, such as those addressing delivery of trauma care, we must strive

for:¹ transparent, accountable, and evidence-based certification for stroke hospitals as CSC/TCC; and² recognition of those certifications by Emergency Medical Services (EMS) systems to direct the transport of severe stroke patients directly to certified centers. The evidence is clear that:¹ the data to support the performance of thrombectomy for ELVO patients were overwhelmingly generated by specialized high-volume neuro-interventionalists;² there are no data to confirm that these results are applicable to low-volume non-neurointerventionalists;³ stroke center volume is strongly associated with outcome quality;⁴ practitioner experience with thrombectomy, as well as essentially all surgical procedures, is correlated with outcome quality;⁵ all three neurointerventional societies, whether the parent organization represents radiologists, neurologists, or neurosurgeons, have agreed on a common credentialing standard for physicians who wish to perform thrombectomy;⁶ the 2016 CMS, PSPS, and PUF data cited by TJC does not refute the suggested minimums but instead supports them; and⁷ TJC remains the broadest and most influential organization empowered to protect stroke patients from the proliferation of substandard care. For these reasons, TJC's decision to suspend individual physician training and volume requirements represents a substantial backward step in stroke patients' care.

PATIENT ACCESS

We need to develop systems of stroke care that account for widely variable geographies, populations, and resources to ensure adequate and timely access to thrombectomy, while also ensuring that patients are not put at increased risk through procedures performed by inadequately trained and/or inexperienced operators at low-volume centers. Striking the right balance between addressing needs in underserved areas and ensuring proper endovascular credentialing and certification can be successfully accomplished with collaboration and access/needs testing. It is worth noting that, in a 2014 analysis, 85% of the US population was identified as being within 1 hour of access to an endovascular stroke center.²³ While underserved areas doubtless exist, the primary issue is not availability of services, but rather getting patients to the correct centers to provide those services. Several states have already made great progress in this effort.

THE WAY FORWARD

Minimum training and volume requirements for physicians performing thrombectomy should not be a point for debate. Additionally, all practitioners who meet these requirements should be welcomed into the multidisciplinary teams necessary to obtain high-quality outcomes in this most complex and vulnerable category of acute stroke patients.

ELVO stroke patients often lack the time and ability to ask for a second opinion. We owe it to them to ensure that their best interests are the first and foremost consideration in our effort to deliver the quality care they so desperately need.

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