Whereas, The government is moving to credential hospitals as different level stroke centers and would then direct ambulances to divert patients to these hospitals; and

Whereas, Much of the focus for such diversion would be a hospital’s ability to provide mechanical thrombectomy service; and

Whereas, Mechanical thrombectomy is a relatively straightforward endovascular procedure that is infrequently performed as part of successful stroke management—for example a hospital that sees 1000 patients per year as a “rule out stroke” might actually only have 500 stroke patients, and only 20 patients who qualify for mechanical thrombectomy, of which only 10 will potentially do well after the thrombectomy; and

Whereas, Some of the planned requirements for these stroke center designations, such as from The Joint Commission, are arbitrary, and unduly burdensome, and not based on sound scientific evidence such as:

(a) Doctors who perform fewer than 15 thrombectomies per year would no longer be eligible to cover call

(b) Doctors covering endovascular services could only cover one hospital at a given time; and

Whereas, There are no studies available that establish a distinct threshold for a volume – outcome relationship in regards to mechanical thrombectomy; and

Whereas, These stringent requirements will unnecessarily disqualify most endovascular proceduralists – endovascular neurosurgeons, endovascular neurologists, and endovascular neuro-radiologists – from continuing to work, as they will not be able to perform 15 thrombectomies per year; and

Whereas, The Society for Interventional Radiology sponsored an independent analysis of the Centers for Medicare and Medicaid Services’ thrombectomy data from 2016 that showed that 85% of physicians who billed this code, billed it 10 times or fewer, and of the 15% of physicians who performed the procedure more than 10 times that year, the median number was 15; that is to say, most physicians who were performing the procedure, would not meet the stringent volume requirement; and
Whereas, There is no reason that a doctor could not cover more than one hospital at a time for
a procedure that is straightforward, brief, and will likely be performed at even a busy hospital no
more than once per week; and

Whereas, These unusually stringent requirements will actually prevent most hospitals from
achieving appropriate stroke center designations, and will thus lead to having all neurological
volume diverted away from their ER’s, leading paradoxically to potential stroke patients being
diverted long distances for care when such care was readily available nearby; therefore be it

RESOLVED, That our American Medical Association advocate for changing the following two
provisions from The Joint Commission Stroke Center Requirements:

1) Stroke procedurists should not be required to perform 15 mechanical thrombectomies per
year to qualify for taking endovascular call at designated stroke hospitals; and

2) Stroke procedurists should be able to take call at more than one hospital at a time.
(Directive to Take Action)

Fiscal Note: Not yet determined

Received: 04/25/19
The Argument against stringent stroke center requirements, and in particular, the argument against individual stroke surgeon volume requirements.

A Position Statement from The New York State Neurosurgical Society

The ramifications of stroke center designation are enormous. Our knowledge of current stroke management is new and rapidly evolving. The Joint Commission just changed its requirements for stroke center designation. As such, we would strongly encourage reconsideration of some of the points currently under consideration.

Stroke is a common and devastating disease. Much progress has been made in the management of stroke in recent years. Major advances have come with the ready availability of CT scans, MRI’s, tPA, mechanical thrombectomy, surgery, wider availability of specialists, and, specifically, improvement of care in the community near where the stroke is likely to occur. 20 years ago, advanced cerebrovascular care was available only at a few quaternary centers in major cities. Now this care is readily available throughout New York State and the nation.

The intent of “stroke center” designation is presumably to improve the care of patients with stroke or potential stroke. However, part and parcel of that plan will be to divert ambulances greater distances to those centers that might be more appropriate. As such, requirements of stroke center designation must be evaluated as public policy in terms of the effects of those ambulance diversions.

It is our contention, that modern stroke care is, in many ways, new and rapidly evolving. What does seem to be agreed to by everyone is that “time is brain” and that getting patients evaluated as promptly as possible by competent physicians and hospitals is very important. As such, there should be a fairly high burden selected for diverting such patients longer distances.

Rigid requirements, especially for procedure volume for mechanical thrombectomy is completely inappropriate, and should not serve as a determinant of what level stroke center a facility can achieve. The Joint Commission, as recently as October of 2018 [1] got this point exactly right when it suspended all additional training and volume requirements for individual physicians in stroke certification. To be clear, everyone agrees that rigorous training and continued medical activity are important in stroke care and all medical care. People would agree that these doctors should have gone to medical school, and then done an internship, and then a residency, and then an extensive fellowship in neuro-endovascular care. People would agree these doctors must be in good standing with the hospitals and must participate in ongoing medical activity and education. But there is no evidence that additional requirements that had been imposed by the Joint Commission in the past (such as CAST certification or requirements of performing 15 thrombectomies per year) would improve public health over the
requirements that the hospitals themselves would require of these doctors, and for this reason, these onerous requirements were suspended.

The numerous reasons that The Joint Commission cited remain completely valid today, just months later. These include the following:

1) CAST requirements, which are difficult for many physicians to meet because of the differences in their training and ongoing activity (such as requirements of treating aneurysms and arteriovenous malformations) are not necessarily indicative of competence or lack thereof for mechanical thrombectomy.

2) There are many individual physicians who have been successfully performing thrombectomy and other endovascular procedures for years, but would be precluded because they would not satisfy the CAST or thrombectomy volume requirements.

3) Limiting stroke center eligibility because of failure to meet these guidelines will adversely harm patients who will have to travel much longer distances to giant hospitals that can meet these requirements.

4) One health system, for example, showed they had 8 interventional radiologists, none of whom met the stringent training and volume requirements, but all of whom had documented results comparable to those reported in the clinical trials.

5) There are no studies available that establish a distinct threshold for a volume-outcome relationship.

6) The Society for Interventional Radiology sponsored an independent analysis of CMS thrombectomy data from 2016 that showed that 85% of physicians who billed this code billed it 10 times or fewer, and of the 15% of physicians who performed the procedure more than 10 times that year, the median number was 15. That is to say, most physicians who were performing this procedure, would not meet the stringent volume requirement.

Other national stroke center accrediting companies, such as DNV Healthcare (which also accredits stroke centers in New York), also have no volume requirements for the stroke procedurists.

Unfortunately, subsequent to this recent decision by The Joint Commission, there were some people who objected, and their objections seemed to have held sway, for now, and The Joint Commission completely reversed its position. One editorial, for example [2] -- written by 12 doctors, neurosurgeons,
neurologists, and radiologists—tried to lay out the argument, in detail, for why the Joint Commission should reinstate its strict requirements, and we would like to clarify why this “editorial” is not correct.

1) First and foremost in the evaluation of this editorial and other “scientific” endeavors is a disclosure of personal conflict and personal stake in the matter at hand. These authors and many other purportedly “disinterested” parties have a great deal at stake personally, in this issue, and they are not really fully disclosing this fact. The advocates of the “stringent criteria” for physicians and hospitals are overwhelmingly physicians at quaternary hospitals who will meet these criteria, and who would likely see much more business in the future if competitor smaller tertiary and medium sized hospitals somehow cannot meet the criteria and ambulances must be diverted long distances to bring patients to them.

2) Over the past 20 years, amazing progress has occurred as small and medium sized community hospitals have developed the ability to care for patients with cerebrovascular disease. Many hospitals now have CT Scans, MRI’s, tPA capability, neuro ICU’s, and many neuro-endovascular experts who can deliver excellent and prompt care. These hospitals have several advantages over the quaternary hospitals. First, they are much closer to the patients. Second, they generally use attending physicians exclusively to provide care, instead of relying on less experienced residents. Third, these hospitals generally provide care at much lower cost than quaternary hospitals. Doctors at quaternary centers who would seek to impose stringent volume criteria on stroke centers, would, conveniently, block most other hospitals from gaining higher level stroke center designation, and undo the progress of the last 20 years, and, paradoxically, divert patients to hospitals that are the furthest away.

3) Two major categories of “scientific evidence” are cited by these authors, and other others, neither of which is relevant. The first set of articles confirms that there are studies, such as the DAWN study [3] and the DEFUSE study [4] that show some benefit for appropriate patients who receive mechanical thrombectomy. But this point is not in dispute, and doesn’t argue one way or the other for imposing stringent training or volume requirements on doctors who work in stroke centers. The other set of studies support the notion that a certain amount of experience is needed to become good at something, including a medical procedure. In summary, “practice makes perfect”. But this point isn’t contested. Everyone agrees that a rigorous and lengthy training and regular continued medical activity is appropriate for stroke doctors. The only issue is whether stroke certifiers should impose additional requirements for training and volume for mechanical thrombectomy above what the hospital would require, and these studies do not prove this at all. To the contrary, imposing strict criteria will concentrate cerebrovascular disease back in the hands of the few quaternary practitioners, and as ambulances are diverted away from most hospitals, most doctors who had proficiency in stroke care will lose it.

It is worth, at this point, reviewing some of the actual articles that are being used as supposed evidence for the training and volume requirements.
Several of the studies that have been cited as evidence are just other opinion pieces and review articles [6,7,8].

One study from 2011 that was felt to be relevant [9] showed that 30 day mortality was less after placement of carotid stents by providers who placed 24 or more stents per year, as compared with providers who placed 5 or fewer stents per year, a difference of 2.5% versus 1.4%. There is no mention that there was any difference in the rate of good outcomes, and of interest, there is no difference even in the 30 day mortality in the “high operator volume” (24 or more cases per year) versus the “low operator volume” group (6-11 cases per year). There is no evidence that carotid stenting is comparable to mechanical thrombectomy, and, if anything, this study would seem to suggest that as many as 6 cases per year would be just as good as any other higher number.

Another study quoted [10], also from 2011, summarizes trends in hospital volumes and operative mortality for “high-risk” surgery. It noted that many complex procedures were performed more over the period of 1999-2008, and that there was a trend towards lower operative mortality. This was, however, not the case with all procedures, and the cause was felt to be multifactorial. Mechanical thrombectomy is certainly not the most high risk cerebrovascular surgery that is performed, or even the most complex neuro-endovascular procedure that is performed. This study really provides no evidence for the specific stroke center requirements suggested.

Another article quoted as evidence [11] is a 2013 committee report expressing general opinions on establishing competence for performing coronary artery interventional procedures. Again, the fact that articles are being cited that are so far removed from the topic at hand should itself suggest that there is no real compelling evidence for the specific claims being made for stroke volume.

Another study quoted [12], from 2011, (on data collected from 2009-2011) found better clinical outcomes at 3-4 months for stroke patients treated with mechanical thrombectomy at “higher” vs. “lower” volume hospitals. Determination of “higher” and “lower” was completely arbitrary, based on the median volume figure of this particular study. The study did not look at volumes of doctors performing the procedures at all, and one could argue that stroke centers and stroke doctors have all become much more experienced in the last 10 years since this study began.

Another relevant study done in 2012 [13] showed a decreased hospital mortality rate for high volume hospital centers versus low volume centers. This study considered a high volume center to be a hospital with 10 or more thrombectomies per year. The reduction in mortality rates was small but statistically significant (24% vs 28.3%) While no data was collected on the doctors’ volumes, one could presume, that many of the doctors at the “higher volume centers”
weren’t doing 15 cases per year, as their entire hospital didn’t necessarily do that many cases. Also, while this study looked at inpatient mortality, it did not note whether there was any difference in the rate of good outcomes, which is what matters most.

Another study referenced [14] that compared the results for stroke patients who had thrombectomy at the hospital they were first admitted to, versus patients who had a thrombectomy at a hospital they were transferred to, showed a slight but statistically significant improvement in functional outcomes for patients admitted initially to the hospital where they received their thrombectomy (60% achieving functional independence vs 52%). Presumably this was because of the delay in time during hospital to hospital transfer. Of note, this study did not subdivide patients by hospital or physician volume. If anything, one would conclude from this study, that a stroke patient who needed a thrombectomy should be brought to the nearest hospital that can perform a thrombectomy, regardless of hospital or physician volume.

Another study sometimes referenced from 2017 [15] involved a retrospective search of a national database of stroke outcomes after mechanical thrombectomy. Based on data that was collected, the hospitals were subsequently divided into low, medium and high volume thrombectomy hospitals. This study compared the mortality rates and outcome rates (as measured by rate of discharge to home and rate of discharge to a skilled nursing facility) between patients who were directly admitted to the hospital where they received their thrombectomy versus patients who received their mechanical thrombectomy at a hospital after transfer from another hospital. The study found that there was a slight, but statistically significant reduction in mortality for patients who were admitted directly (14.9% vs. 18.6%), but in regards to outcomes (rate of discharge to home and rate of discharge to a skilled nursing facility) there was no statistical difference. The study also looked at mortality and outcomes at what they classified as low, medium, and high volume thrombectomy hospitals. They again found a statistically significant difference in mortality rates between the low, medium and high volume hospitals (low 19.7%, medium 14.9%, and high 9.8%), but no statistically significant difference in the overall outcomes as determined by the number of patients discharged to home and discharged to a skilled nursing facility, though the percent of patients who were discharged to home was much higher for the low volume hospitals (low 11.5% vs medium 6.5% vs high 6.7%).

Another study on the matter [16], published in 2016, not often quoted for this purpose, but one of the only studies in the Neurosurgery literature on the matter, assessed the rate of in-hospital mortality for stroke patients treated with mechanical thrombectomy at “low volume centers” (under 10 cases per year) versus “high volume centers” (10 or more cases per year). Over 13,000 procedures were analyzed. This study found that risk adjusted in-hospital mortality and complication rate was no different at the high versus low volume centers.
The summary of the “scientific” evidence for training requirements or volume requirements for stroke doctors or volume requirements for stroke centers is that there is none.

There are many other issues that have not been considered.

The issue with stroke center designation is “ambulance diversion” not simply the results of mechanical thrombectomy, which are a very small component of the relevant patient population. Consider that most patients brought to a hospital emergency room as a “rule out stroke” do not in fact have a stroke. For arguments sake, let’s say that 50% will actually have a stroke. Only a small percent of the stroke patients have, at least thusfar, been candidates for mechanical thrombectomy, in the range of 3-5%. Of mechanical thrombectomy patients, even in the best of studies, with the best of results, about half of these patients likely have a chance of a good outcome. So just to put some sample numbers in place: A pretty busy hospital could have 2000 patient visits per year to the ER with a diagnosis of “rule out stroke”. Of those, about 1000 might actually have a stroke. Of those, about 40 will be candidates for thrombectomy, and of those, about 20, under the best of circumstances may have a “good outcome”.

Unfortunately, it is not clear, which those 20 patients are prior to arriving in the hospital, so, to alter the “immediate” management of these 20 patients, necessarily requires diverting all 2000 patients. The studies that have been done, don’t address this issue at all. In other words, what really matters, from a public policy viewpoint, is “what is the effect of diverting 2000 patients with possible stroke from the closest hospital?” Even if there were strong evidence that stroke doctors with a certain thrombectomy training or annual thrombectomy volume or hospitals with a certain thrombectomy volume had a significant improvement in good outcomes, say 25%, such that there were 20 good outcomes in one scenario versus 16 in the other – and there is no such evidence at all – that would still just represent a difference of 4 patients of a total of 2000, or 0.2% of the total. The studies that exist completely ignore the other 99.8% of the patients, but this is exactly the consideration that a public policy change to divert ambulances must consider. What happens to the other 99.8% of the patients, who are suspected of having a stroke who are diverted by the ambulance away from the nearest hospital? We have no idea, but there’s certainly no evidence that the results are improved.

Consider the now onerous call schedule under the new proposed guidelines. This hospital could have had 4-5 endovascular doctors working there, taking every fourth or fifth day of call. Each doctor could have been doing 150 other endovascular cases per year. All would be completely competent to perform the clot extraction. Under the new guidelines, only 2 doctors could get credentialed, because there is only enough volume for 2 doctors to perform at least 15 cases.
Consider that this will mean that the other 2-3 doctors will need to leave that hospital.

Consider that the two remaining doctors will have to take primary call every other day, and provide back up for the other one (for when they perform other procedures) the other 15 days a month. That is fairly onerous, particularly when there is no established benefit for this. Which doctors will want to take call every night (15 days a month primary, and 15 days a month back-up)?

Consider that many good people will no longer want to train to be endovascular doctors. The nature of the work is already challenging because of the frequency of emergencies, but this will make things much more unpleasant.

Consider that many doctors will have to stop performing these procedures so that the “lucky” few will be able to continue doing the needed volume.

Consider that many hospitals and doctors will also start to perform clot extraction on patients whom they would have advised against doing the procedure in the past, so as to reach the arbitrary and difficult threshold volume requirements.

Consider that almost every other major neurosurgical procedure has no volume requirements, and that thrombectomy is one of the lowest risk and least technically challenging of all neurovascular procedures. Why would we want an ambulance to bypass a hospital with a doctor who has done thousands of endovascular procedures, and many endovascular procedures each year that are more difficult than thrombectomy but only does 10 thrombectomies per year, just to travel a greater distance to get to a hospital with a doctor who may have much less experience each year and over time, but does 15 thrombectomies per year?

Consider what will happen if something happens to one of the two doctors who remain at that busy hospital? Will the hospital lose its entire stroke program? It can take a long time to find a replacement, particularly someone who wants to be on call every day.

Consider that it will become impossible for anyone in practice who is not currently doing 15 thrombectomies per year to work again. Someone doing 12 cases per year will not be able to take call any more. As such, they will do no thrombectomies going forward (all thrombectomies going forward will presumably be done by doctors at level 2 or 3 stroke centers). There will quickly become few people with any thrombectomy experience. All of neuro-endovascular care will revolve around this one straightforward yet uncommon procedure.

Consider a hospital with 1000 ER visits per year for possible stroke. That hospital might see 500 actual strokes, and perform 20 thrombectomies per year, still not an insignificant volume. Under the new requirements, they would only have enough volume to have one endovascular procedurist. That doctor would have to be on call 24 hours a day, 7 days a week, all year round.
Who will want to take that job? Most hospitals will probably not be able to even recruit such a person. That entire community will now have to go without thrombectomy services, as would all hospitals with volumes at or below this number.

Consider also the burden and consequences of the stroke procedure doctor not being able to cover call at multiple hospitals. Doctors in general, and neurosurgeons in particular, routinely cover call at multiple hospitals at once. It is more economical and efficient. Often, there is no need for emergency neurosurgery at any one of several hospitals on a given night. Similarly, thrombectomy is an infrequently performed procedure. A hospital performing 52 thrombectomies a year, is only doing, on average, one for an entire week. There is no reason that one stroke doctor couldn’t easily cover more than one hospital at a given time. To require 3 doctors, for example, to cover 3 separate stroke hospitals each night is a severe burden and totally unnecessary. It means hiring many more doctors than are needed at great added cost, and having doctors cover many more nights of call than are necessary.

Consider than overly stringent requirements will cause fewer hospitals to get certified, which will lead ambulances away, and lead to even lower volumes and less experience and expertise. A vicious cycle will be created.

Consider that other programs are dependent on the stroke program. Losing those 1000 or 2000 patients per year may affect the hospital’s seizure program or brain tumor program, as sometimes patients with seizures or brain tumors can present with stroke-like symptoms.

Consider that the loss of business to the hospital may cause loss of revenues that affect the hospital’s ability to deliver on other needed services to the community. Often hospital operating margins are razor thin. What if the loss of ER volume led the hospital to financial distress and to close? What would the health effects to that community be?

Consider that the very people arguing for high volume requirements for stroke doctors are the same people who rely heavily on residents, doctors in training, to deliver most of the patient care. Is it not possible that there are some downsides to the heavy involvement of doctors in training that might offset some of the alleged benefits of doctors with higher thrombectomy volumes? If vast experience is so critical for caring for stroke patients, one could just as well argue that stroke patients should only go to hospitals where attendings themselves provide the care.

Consider that, paradoxically, most of the strict credentialing requirements will work against the basic concepts of getting stroke patients to a capable nearby hospital as quickly as possible.

Consider that much more important than trying to treat a stroke once it has happened, is trying to prevent a stroke from happening in the first place. Perhaps stroke centers should
focus also on preventing strokes – decreasing smoking, decreasing vaping (which frequently leads to smoking), decreasing obesity, decreasing high blood pressure, controlling diabetes, and optimally managing carotid stenosis, cerebral hemorrhage, cardiac arrhythmias, and blood clotting disorders.

Consider that our current understanding and management of stroke is very new and rapidly evolving. As such, there is little scientific study and much we still don’t know, and, as such, we should encourage as many doctors and hospitals to excel at stroke care as possible. Harsh guidelines that will block most doctors and hospitals from stroke care, and that will make the care onerous and expensive for those doctors and hospitals that do want to participate, should be reconsidered. Also, with new technology and new paradigms, we need more centers educated and providing such care, not fewer. Furthermore, as the population ages there will be more need for stroke care, again suggesting more lenient and inclusive public programs.

Consider that hospitals will naturally, without any added requirements, tend to select appropriate level stroke centers for themselves. Because there is significant cost associated with the equipment and personnel and build-out required for different programs, hospitals will likely only pursue different levels of stroke capability (aneurysm and neurosurgery, thrombectomy, or tpa only) based on appropriate or projected volumes of such activity.
Recommendations

1) Stroke centers should, among other goals, pursue the highest level of care for PREVENTING strokes from happening in the first place.

2) Evaluation of stroke center function as well as consideration for ambulance diversion, should consider the outcomes of ALL patients who come to that hospital with the diagnosis of “rule out stroke”. Ambulance diversion plans should consider also the overall effects on the hospitals and communities of such plan. Furthermore, prior to diverting potential stroke patients from a nearby hospital, there should be very strong evidence for doing so.

3) There should be no training or volume requirements on stroke proceduralists beyond what the hospitals themselves require (just as is the case with almost every other medical procedure).

4) Stroke proceduralists should be able to take call at more than one hospital at a time (just as is the case with almost all other neurosurgery call).

5) There should be no volume requirements for hospitals to achieve various stroke center designations. Hospitals will naturally invest in “thrombectomy capable / level 2” or “brain aneurysm / neurosurgery capable / level 3” centers based on existing or projected volume of such activity.

6) Mechanical Thrombectomy, while important, will at best help a small fraction of patients who come to the hospital ER as a “rule out stroke”, and, as such, it should not be the only consideration or even the most important consideration in determining stroke center designation. A hospital that can usually provide thrombectomy, but needs to rarely transfer a patient out, should still be eligible for “Thrombectomy capable / level 2” status. Similarly, a hospital that can usually provide brain aneurysm / neurosurgery care, but needs to rarely transfer a patient out, should still be eligible for “brain aneurysm / neurosurgery / level 3” designation.
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